

**Human tissue legislation in the United Kingdom 1952-
2006: a history and comparative analysis of policy
development.**

A Thesis submitted for the degree of PhD

By

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To

Queen Mary, University of London.

**To my dearest wife, Joan, for all her support in this endeavour, and
for much more,
this Thesis is affectionately dedicated.**

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Mrs Jean Robinson, Mr David Tysell, Ms Wendy Trevis Smith, Lord Walton of
Detchant, Mrs Gina Williams.

DECLARATION.

I declare that the work presented in this Thesis is my own.

Alexander S McNeish.

ABSTRACT.

This is a study of the genesis of the Corneal (Grafting) Act 1952, the Human Tissue Act 1961, the Human Tissue Act 2004, and the Human Tissue (Scotland) Act 2006. The aim has been to understand why so much had apparently changed between 1952-61 and 2004-06, both in society and in medical practice, as an explanation of why the earlier Acts were essentially 'enabling/permissive', whereas the later Acts were 'regulatory/restraining'. A comparison between the Human Tissue Act 2004 and the separate Human Tissue (Scotland) Act 2006 (both Acts concerned with 'human tissue' and with origins in 'retention of organs without consent', but with significant differences in their respective provisions), has allowed a finer dissection and comparative analysis of the possible factors involved.

The Thesis focuses on the 'inspiration', 'deliberation/ formulation' and 'legitimation' phases of the legislative process (using the terminology of Drewry)- that is, the genesis of the various Acts- and has not sought to study the later (Drewry) phases of 'implementation' of the law nor subsequent 'feedback'.

The methodology has been to 'interrogate the sources' through in depth study of archived records, using publicly available documents, certain confidential papers made available by the Royal College of Pathologists and the Royal College of Physicians (London), papers released under Freedom of Information Acts, and analysis of the scholarly literature. The findings suggest that a complexity of factors contributed to shaping the 2004 and 2006 legislation, in addition to the proximate 'organ scandals'.

The study may contribute specifically to any wish of Government and the medical/scientific professions to review their processes of consultation and negotiation prior to developing new legislation with an impact on research; and more generally to the case for more regular use of pre-legislative scrutiny of Bills.

CONTENTS

Acknowledgments. 3

Declaration. 5

Abstract. 6

Chapter contents in detail. 8

Introduction. 19

Chapter One: The development of human tissue legislation in the mid-20th century. 39

Chapter Two : Human Tissue Act 1961: execution, application and feedback. 81

Chapter Three: A profession under pressure? Or sailing unconcernedly towards the rocks? 132

Chapter Four: ‘Five tumultuous years’: which culminated in the Human Tissue Act 2004. 186

Chapter Five: Tissue legislation in Scotland: ‘a more proportionate response’? 244

Chapter Six: Further analysis, conclusions and recommendations. 293

Table of legal authorities cited. 332

Sources and bibliography. 335

Glossary. 366

CHAPTER CONTENTS IN DETAIL.

INTRODUCTION. 19

1 Preamble. 19

1.1 The origins of this Thesis. 19

1.1.1 My core questions. 19

1.2 A brief overview of the scholarly literature. 21

1.2.1 Content. 21

1.2.2 A gap to be filled. 26

3 Aim of the Thesis. 27

4. Methodology. 27

4.1 Analysing public policy in terms of a process framework. 28

4.2 Application to law-making processes. 30

5. Scope and structure of the Thesis. 35

CHAPTER ONE. 39

1. Medical (including transplantation) research in the 1950s. 39

2. The Corneal Grafting Act 1952 ('1952 Act'). 41

2.1 The legislative process. 41

2.2 Unintended consequences of the 1952 Act. 44

2.2.1 Experimental grafting of other tissues. 44

2.2.2 Researchers 'go public'. 45

3. The response of the Ministry of Health. 48

3.1 Inspiration for new legislation. 48

3.2 Further deliberation, and formulation of a Bill. 51

3.3 Instructions to Parliamentary Counsel. 56

3.3.1 Whatever happened, in drafting the Bill, to 'retention' and 'consent'? 59

4. The Human Tissue Act 1961 ('1961 Act'). 63

4.1 'Legitimation': passage of the 1960-61 Human Tissue Bill. 63

4.2 Further consideration of aspects of the 1961 Act. 68

4.2.1 Retention of organs and tissues. 68

4.2.2 'No objection'. 69

4.2.3 Expressions of concern from members of the public. 71

4.2.4 'The person in lawful possession'. 72

4.2.4.1 Identity. 72

4.2.4.2 Does the person in lawful possession have discretion? 73

5. Summary. 73

CHAPTER TWO. 81

1. Preamble: the desirability of post- legislative scrutiny. 81

2. The 1961 Act: execution and application in relation to developments in transplantation. 83

2.1 Clinical developments. 83

2.2 Uncertainties about the 1961 Act revealed. 84

2.2.1 The power to donate a body for medical purposes. 84

2.2.2 The identity of 'the person in lawful possession of the body'. 86

2.2.3 The meaning of 'such reasonable inquiry as may be practicable'. 88

2.3 Pressures to amend legislation with regard to transplantation, 1968-73. 90

2.3.1 The efforts of Parliamentarians. 90

2.3.2 The 1968 Conferences and immediate aftermath. 92

2.3.3 Advisory Group on Transplantation Problems and its outcome. 94

2.3.4 A miscellany of other factors. 96

2.3.4.1 The further efforts of Parliamentarians. 96

2.3.4.2 The Report of the Committee on death certification and coroners (Broderick Report). 98

2.3.4.3 Report of the Advisory Group on the use of fetuses and fetal tissue for research (Peel Report). 99

3. Contraventions of the 1961 Act. 99

3.1 Clinical cases. 99

3.1.1 The 'Couve de Murville' case. 100

3.1.2 Mrs AH Howard, deceased. 101

3.1.3 Patrick Joseph O'Sullivan, deceased. 101

3.1.4 Nigel Peter Ford, deceased. 102

3.1.5 Michael McEldowney, deceased. 103

3.2 The Human Pituitary Collection. 103

3.3 Continued ignorance of, and non-compliance with, the law. 105

3.3.1 Evidence that the problem was widespread. 105

3.3.2 Royal College of Pathologists: the Bernard Knight review paper. 107

3.4 Radiation studies. 109

3.4.1 Strontium 90 research. 110

3.4.2 Workers in the nuclear industry. 112

3.4.2.1 The Redfern Inquiry 2010. 114

4. Coroners' 'fiefdoms'. 116

5. Continued work by officials to prepare for amending legislation. 119

5.1 Work with the Joint Consultants Committee and others. 119

5.2 Any amending legislation should be broadly drawn. 122

5.2.1 Post mortem examinations. 123

6. Summary. 125

CHAPTER THREE. 132

Preamble. 132

1. Attitudes towards the medical profession in the UK. 133

1.1 Relations between the state and medicine. 133

1.1.1 Influential critiques. 133

1.1.2 National policy and medical decisions. 138

1.2 Doctor-patient relationships. 145

1.2.1 The rise of the articulate consumer. 145

1.2.2 The particular contribution of Ian Kennedy to the debate. 146

1.2.3 'A good doctor'. 147

1.2.4 Has there been a decline in trust? 147

1.2.5 The role and performance of the General Medical Council. 155

1.2.6 Summary and interim conclusions. 157

2. Attitudes to medicine and doctors in the USA. 159

2.1 'A golden age'? 159

2.2 The end of the golden age in the USA. 161

2.3 Summary and interim conclusions. 164

3. Societal trends. 165

3.1 Inglehart on post-materialism and cultural shift. 166

3.2 Beer: in search of a new public philosophy. 168

3.3 Giddens on modernity and self identity. 170

3.4 Summary and interim conclusions. 173

4. Professionalism. 178

4.1 The response of the medical establishment in the mid 1990s. 178

4.2 Has there been an erosion of the professional status of medicine? 180

4.3 Deprofessionalisation. 182

5. Overall conclusion. 185

CHAPTER FOUR. 186

Preamble. 186

1 'Inspiration'. 186

1.1 Inquiries. 186

1.1.1 Bristol Royal Infirmary Inquiry ('*Bristol*'). 186

1.1.1.1 *Bristol* Interim Report: Removal and retention of human material. 188

1.1.2 The Royal Liverpool Children's [Hospital] Inquiry ('Alder Hey'; 'Redfern').	189
1.1.2.1 Findings of the <i>Redfern</i> Inquiry.	190
1.1.3 The 'Isaacs' Report.	192
1.1.3.1 Background.	192
1.1.3.2 Findings.	192
1.1.4 Commonality of features in <i>Bristol</i> , <i>Redfern</i> and <i>Isaacs</i> .	193
1.2 Further 'inspiration' factors which influenced the climate in which new human tissue legislation was brought forward.	195
1.2.1 <i>Bristol</i> Interim Report, Annex B.	195
1.2.2 A commitment to parents: the Chief Medical Officer's 'Summit' meeting on organ retention.	196
1.2.3 Public opinion and the Press.	198
1.2.4 The response of the Secretary of State to <i>Redfern</i> .	200
1.2.5 The Chief Medical Officer's Report of the census of retained organs and tissues conducted throughout England during 2000. ('CMO's Census').	201
1.2.6 The Chief Medical Officer's Advice on the removal, retention and use of human organs and tissue from post-mortem examination ('CMO's Advice').	201
1.2.7 A postscript about the medical profession at the end of the 'inspiration' phase.	203
1.2.7.1 Royal Colleges and individual doctors.	203
1.2.7.2 The response of the medical press to the Inquiries.	205
2. 'Deliberation and formulation'.	206
2.1 Retained Organs Commission (ROC).	206
2.2 A 'fundamental and broad review' of the law (Recommendation 6, CMO's Advice).	208
2.2.1 The primacy of consent.	208
2.2.2 The origins of the decision to include 'tissues from the living' within new legislation.	209
2.2.3 Possible influence of the 'in tray'.	211
2.2.4 Litigation on behalf of parents.	213

2.3 Consultation: ‘Human Bodies, human choices’.	214
2.4 An absence of pre-legislative scrutiny.	218
3 ‘Legitimation’: passage of the Human Tissue Bill 2003-4.	219
3.1 Purpose of the Bill.	219
3.2 Support from the National Committee relating to Organ Retention.	220
3.3 Support at Second Reading House of Commons (HC): with three areas of concern identified.	221
3.3.1 Complex and unclear drafting.	221
3.3.2 Lack of pre-legislative scrutiny.	221
3.3.3 An adverse effect on research and education?	222
3.4 Subsequent passage of the Bill: themes and chronology.	222
3.4.1 Introduction to a ‘tug of war’.	222
3.4.2 Structure of the Bill (as introduced).	223
3.4.2.1 Why was the Bill so drafted?	224
3.4.3 ‘The foundation of the Bill’.	225
3.4.4 Committee Stage (HC).	226
3.4.4.1 Concerns of the biomedical community.	226
3.4.4.2 Unsuccessful attempts to modify Part 1, Schedule 1.	227
3.4.4.3 The proposed Human Tissue Authority.	228
3.4.5 Activities during the gap between Committee stage and Report/Third Reading (HC).	229
3.4.6 Report/Third Reading (HC).	231
3.4.6.1 Agreement to research on residual tissue without consent, with safeguards.	231
3.4.6.2 Concerns about non consensual analysis of DNA resolved.	231
3.4.6.3 Education and training in research remained problematic.	232
3.4.6.4 Two further amendments (a) DNA and mental handicap b) payments by the pharmaceutical industry).	233
3.4.6.5 Progress made, but unfinished business remained.	233
3.4.7 Second Reading, House of Lords (HL).	233

3.4.7.1 Further briefing from the research community.	233
3.4.7.2 Identification of issues requiring further resolution.	234
3.4.8 Grand Committee (HL).	235
3.4.8.1 Continuing Government 'caution'.	235
3.4.9 Report (HL).	236
3.4.9.1 Use of tissue for education in research techniques.	237
3.4.10 Third Reading (HL).	237
3.4.10.1 Further amendments resisted.	237
3.4.11 The last lap.	238
3.5 Commentaries on the 2004 Act.	238
3.6 Conclusion.	243

CHAPTER FIVE. 244

1. Background. 244

2 Response of Scottish Executive. 244

2.1 Independent Review Group on Organ Retention ('IRG'). 244

2.1.1 The work of IRG: crucial to 'inspiration', 'deliberation' and 'formulation'. 245

2.1.1.1 Phase 1: methodology and findings. 246

2.1.1.2 Phase 1: recommendations. 248

2.1.1.3 The early response of the Scottish Executive. 250

2.1.1.4 Phase 2: method of working. 251

2.1.1.5 Recommendations in 'Final Report' of Phase 2. 252

2.1.1.5.1 New legislation needed for Scotland. 252

2.1.1.5.2 Authorisation. 252

2.1.1.5.3 Tissue blocks and slides. 256

2.1.1.5.4 Medical education and research. 257

2.1.1.5.5 Organ donation. 257

2.2 Response of Scottish Executive to the Final Report. 258

2.2.1 Consultations.	258
2.2.2 Compensation made to parents.	259
3. 'Legitimation': the Human Tissue (Scotland) Bill.	260
3.1 Scottish legislative process: passage of a Public Bill.	260
3.2 Policy Memorandum regarding the Human Tissue (Scotland) Bill.	262
3.2.1 Overall policy intentions.	262
3.2.2 Transplantation.	263
3.2.3 PM examinations.	264
3.2.4 An absence of provision regarding tissue from the living.	265
3.2.5 Penalties.	265
3.2.6 Inspection and regulation.	266
3.2.7 Examinations instructed by the Procurator Fiscal.	266
3.2.8 Anatomical examination.	267
3.2.9 Miscellaneous provisions.	267
3.2.10 Arrangements by Scottish Ministers for assistance.	268
3.3 The Health Committee (see also 3.5.2).	268
3.4 Parliamentary stages of the Human Tissue (Scotland) Bill.	269
3.5. Further scrutiny of aspects of the 2006 Act.	272
3.5.1 Why separate legislation for Scotland?	272
3.5.2 The role of Committees within the Scottish Parliament.	274
3.5.3 The wider consultative process.	275
3.5.4 Authorisation.	276
3.5.5 Age of legal capacity, and consent/authorisation.	278
3.5.6 Post-mortem examination as part of a continuum of care: ramifications for standards of practice.	279
3.5.6.1 Hospital post-mortems.	279
3.5.6.2 Fiscal post-mortems.	282
3.5.7 Tissue from the living.	285

- 3.5.7.1 Sources of prior advice? 287
- 3.5.8 Awareness of parental sensitivities. 288

4. Summary and overall conclusions. 290

CHAPTER SIX. 293

1. Recapitulation. 293

2 Further analysis. 293

2.1 Factors operating on both sides of the English- Scottish border as ‘inspiration’ for new legislation. 294

2.1.1 ‘Normal’ post-mortem practice, including organ ‘collections’, combined with misunderstanding of an ‘uncertain’ law. 294

2.1.2 Issues of communication and consent. 296

2.1.3 The collective pressure exerted by parents and relatives. 297

2.1.4 The Press. 298

2.1.5 A desecration of the dead, as a factor? 300

2.1.6 Medical science and society. 301

2.1.7 A wish for recompense and retribution? 301

2.2 Cross-border differences acting within the ‘inspiration’ phase for new legislation. 302

2.2.1 The ‘in-tray’. 302

2.2.2 The Reports, and early government response. 303

2.2.3 The Human Tissue Act 1961 was not listed in Schedule 5 to the Scotland Act 1988. 305

2.3 Factors important in ‘deliberation and formulation’. 306

2.3.1 The role, and perceived status, of the medical profession. 306

2.3.2 The scope and method of consultation. 308

2.3.3 Role of ROC and IRG. 310

2.3.4 The contribution of parents to deliberation and formulation. 311

2.3.6 The role of officials. 313

2.3.7 Pre-legislative scrutiny. 315

2.4 Legitimation, in theory and practice. 317

2.4.1 Overview of the legitimation process: 1961, 2004 and 2006 Acts. 317

2.4.2 A comparison of the structure of the 2003-4 and the 2005-6 Bills. 319

2.4.3 Legitimation in respect of certain provisions: a comparison between 2004 and 2006 Acts. 320

2.4.3.1 The need for broad congruence throughout the UK. 320

2.4.3.2 Tissues from the living. 320

2.4.3.3 Retention of tissue blocks and slides. 321

2.4.3.3.1 Scotland. 321

2.4.3.3.2 Remainder of UK. 323

2.4.3.3.3 Implications for Sudden Infant Death Syndrome. 325

3. Overall conclusions. 326

4. Recommendations. 330

***'Although the parliament has a right to legislate for the people of this country while living, yet every man in the country has a right to Christian burial when dead, and parliament has no right to pursue people beyond the limits of the grave.'* (The Earl of Harewood, House of Lords, June 1829.)¹**

***'Records, like the little children of long ago, only speak when they are spoken to, and they will not speak to strangers.'* (CR Cheney (1906-1987).)²**

¹ (1829) 21 Parl. Deb. (Hansard, 2nd series), HL 1748.

² Oxford Dictionary of National Biography. Volume 11. Oxford. Oxford University Press, 2004, p303.

INTRODUCTION

1 Preamble.

This Thesis concerns the genesis of the Corneal Grafting Act 1952 ('the 1952 Act')³, the Human Tissue Act 1961 ('the 1961 Act')⁴, the Human Tissue Act 2004 ('the 2004 Act')⁵ and the Human Tissue (Scotland) Act 2006 ('The 2006 Act')⁶.

1.1 The origins of this Thesis.

My original choice of topic for a PhD thesis would have concerned an aspect of international research. I judged that the first chapter of the putative thesis should contain a brief review of human tissue legislation in the UK as relevant background. I soon came to realise that the picture was more complicated than I had thought. From my early reading a number of questions arose which I realised would require more than one chapter to try to resolve. International research was set aside. Four years later, I present this Thesis as an attempt to answer those early questions.

1.1.1 My core questions.

First, it appeared that earlier UK Acts, specifically the 1952 Act and the 1961 Act, had been essentially *enabling*, in the sense that they would allow doctors and scientists, within the law, to continue to develop the then new science and practice of transplantation. In contrast, legislation in the early 21st century, specifically the 2004 Act and the 2006 Act, appeared to include a purpose of *regulating*, (perhaps with overtones of *restraining*), doctors and scientists in certain activities, and to

³ *Corneal Grafting Act 1952*. (1952, c. 28.)

⁴ *Human Tissue Act 1961*. (1961, c. 54.)

⁵ *Human Tissue Act 2004*. (2004, c.30.)

⁶ *Human Tissue (Scotland) Act 2006*. (2006 asp 4.)

impose sanctions for transgressions. **What had happened between 1950 and 2000 to bring about this change in approach within the law?**

Second, in the House of Commons just before the 2004 Act was passed, the Minister had said that, in her view, the Bill had achieved the necessary ‘balance’ between ‘the regulation that all society wanted us to introduce’, accompanied by ‘reassurance that the Bill would be based on the principles of consent’, and ‘the need to convince the research and medical community that we were not trying to stifle some of the excellent work being done’.⁷ **How and why had ‘all society’ come to express a wish for regulation? Why was ‘reassurance’ needed about ‘consent’? How had the research community come to feel potentially stifled?**

Third, when I began work in early 2007, I believed, in common with others^{8 9}, that the then recent legislation had been the outcome of events in Bristol¹⁰ and Liverpool (Alder Hey)¹¹ a few years earlier. Yet there appeared to have been *two* distinct legislative outcomes, as between England and Scotland, from, apparently, a common starting point. Further, it was said by some that the Scottish legislation in 2006 was a more proportionate response to the problems of organ retention revealed at Bristol and Alder Hey than was the 2004 Act.^{12 13} In 2006-07 this view had been endorsed by the Joint Committee on the Human Tissue and Embryos

⁷ (2004) 426 Parl. Deb. (Hansard, 6th series), HC 896.

⁸ Liddell K, Hall A. *Beyond Bristol and Alder Hey: the future regulation of human tissue*. Med L Rev 2005; 13(2): 170-223.

⁹ Price D. *The Human Tissue Act 2004*. MLR 2005; 68(5): 798-821.

¹⁰ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*, May 2000.

¹¹ The Royal Liverpool Children’s Inquiry Report. Printed by order of the House of Commons, January 30 2001.

¹² Furness P. Editorial. *The Human Tissue Act: reassurance for relatives, at a price*. BMJ 2006; 333(7567): 512.

¹³ Underwood JCE. *Human Tissue Legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-202, at p 202.

(Draft) Bill in a recommendation to Government to amend the 2004 Act.¹⁴ **In what ways did the 2004 and 2006 Acts differ? How did these differences arise?**

Fourth, the areas of legislation which the Joint Committee recommended for amendment concerned aspects of medical (diagnostic) and research practice, and gave as examples provisions relating to tissues from the living and retention of post-mortem specimens after sudden infant death. This led me not only to questions but also to a decision. **My Thesis will focus particularly on those aspects of legislation which related to diagnostic and research practice.**

Having identified questions which I judged important, were answers already available?

1.2 A brief overview of the scholarly literature.

The purpose of this overview is to try to place the starting point for this Thesis within a larger body of work. Selected references are discussed in detail as appropriate within the text of each chapter.

1.2.1 Content.

The scholarly literature concerning the four Acts varies considerably in volume and content. Publications about the 1952 Act in the years following its enactment were relatively few, and were mainly to be found in specialist medical journals. Their purposes included acquainting a general medical readership with the [then recent] availability of corneal grafting¹⁵, making a plea for an increase in the number of donors¹⁶, describing for the specialist surgeon details of technical advances¹⁷, giving

¹⁴ Joint Committee on the Human Tissues and Embryos (Draft) Bill (Session 2006-07). Volume 1: Report. The Stationery Office, 2007.

¹⁵ Rycroft BW. *The corneal graft*. Postgrad Med J 1955; 31: 135-139.

¹⁶ Rycroft BW. *The Corneal Grafting Act 1952*. BMJ 1955; 1(4905): 105.

¹⁷ Sourdille GP. *Special methods*. In: Rycroft BW (ed.) *Corneal Grafts*. London, Butterworth & Co. (Publishers) Ltd., 1955, pp 157-168.

guidance about how to set up and organise 'eye banks'¹⁸, and identifying the biological obstacles yet to be overcome¹⁹.

The passing of the 1961 Act appears to have attracted relatively little attention within the medical literature except from transplant surgeons highlighting the clinical problems that were arising from a scarcity of [especially kidney] donors²⁰, and uncertainties in interpreting the provisions of the 1961 Act²¹ (which had included some well published clashes between coroners and surgeons²²). Instead, from the mid 1960s the statute attracted critical comment from predominantly legal scholars.^{23 24} Dworkin, in a magisterial review in 1970 of the law relating to organ transplantation in England, noted that 'as one would expect' there were several aspects of the law which were uncertain and obscure, as a result of which 'the legal literature was growing'.²⁵ Skegg was a prominent interpreter of the 1961 Act throughout the period²⁶, concentrating particularly on the authorised and unauthorised use of corpses for medical education and research^{27 28}, and liability

¹⁸ Archer DB, Trevor-Roper PD. *Organization and administration of the Westminster-Moorfields eye-bank*. Brit J Ophthal 1967; 51(1): 1-12.

¹⁹ Billingham RE, Brent L, Medawar PB. 'Actively acquired tolerance' of foreign cells. Nature 1953; 172 (4379): 603-606.

²⁰ Calne R Y. *Supply and preservation of kidneys*. Brit Med Bull 1965; 21(2): 166-170.

²¹ Editorial. *Kidney donation and the law*. BMJ 1973; 3(5875):360-362.

²² Editorial. *Coroners and transplants*. BMJ 1977; 1(6073): 1418.

²³ Kennedy I. *Treat me right: essays in medical law and ethics*. Chapter 11: *Further thoughts on liability for non observance of the provisions of the Human Tissue Act 1961*. Oxford. Clarendon Press, 1988, p225.

²⁴ Lanham D. *Transplants and the Human Tissue Act 1961*. Med Sci Law 1971; 11(1): 16-23.

²⁵ Dworkin G. *The law relating to organ transplantation in England*. MLR 1970; 33(4): 353-377, at p353.

²⁶ Skegg PDG. *Interpretation of the Human Tissue Act 1961*. Med Sci Law 1976; 16(3): 193-199.

²⁷ Skegg PDG. *The use of corpses for medical education and research: the legal requirements*. Med Sci Law 1991; 31(4): 345-354.

²⁸ Skegg PDG. *Criminal liability for the unauthorised use of corpses for medical education and research*. Med Sci Law 1992; 32(1): 51-54.

for unauthorised removal of cadaveric transplant material²⁹. Calls for reform of the Act centred on the need for clarity in the authorisation procedures prior to transplantation³⁰ and for sanctions against doctors acting ‘in defiance’ of the provisions of the Act.³¹ By the beginning of the 1990s, and stimulated by technical advances involving the ‘use’ of tissues, a literature began to develop around ‘rights in the body and its parts’^{32 33}.

The 2004 Act had a long and complex history, as Chapters Two and Four will show, and it reached the statute book only after ‘five tumultuous years of negotiation’³⁴. Not surprisingly, a sizeable literature has been generated which, from my reading, may be assembled approximately into four groupings. The largest arose from consideration of the position of the families involved, and explored, for example, the nature of and requirements for consent^{35 36 37 38 39}, the law and ethics underpinning the use of human tissue^{40 41 42 43 44}, and societal attitudes to dying

²⁹ Skegg PDG. *Liability for the unauthorised removal of cadaveric transplant material*. Med Sci Law 1974; 14(1): 53-57.

³⁰ Report of the Special Committee on organ transplantation. BMJ 1970; 1(5698): 750-751.

³¹ Kennedy IM. *Further thoughts on liability for non observance of the provisions of the Human Tissue Act 1961*. Med Sci Law 1976; (16(1): 49-55.

³² Dworkin G, Kennedy I. *Human tissue: rights in the body and its parts*. Med Law Rev 1993; 1(3): 291-319.

³³ Grubb A. ‘I, me, mine’: *bodies, parts and property*. Medical Law International 1998; 3(4): 299-317.

³⁴ Editorial. *Effective implementation of the Human Tissue Act*. Lancet 2006; 368(9739):891.

³⁵ O’Neill O. *Some limits of informed consent*. J Med Ethics 2003; 29(1): 4-7.

³⁶ Brownsword R. *The cult of consent: fixation and fallacy*. KCLJ 2004; 15:223-251.

³⁷ Marks P. *The enigma of consent*. Clinical Medicine 2001; 1(2): 118-120.

³⁸ Grimley Evans J, Beck P. *Informed consent in medical research*. Clinical Medicine 2002; 2(3): 267-272.

³⁹ Brazier M. *Organ retention and return: problems of consent*. J Med Ethics 2003; 29(1): 30-33.

⁴⁰ Harris J. *Law and regulation of retained organs: the ethical issues*. Legal Stud 2002; 22(4): 527-549.

⁴¹ Brazier M. *Retained organs: ethics and humanity*. Legal Stud 2002; 22(4): 550-569.

and bereavement^{45 46 47}. Second, papers from the medical profession offered a defence⁴⁸, apologies⁴⁹, or a way forward⁵⁰: some warned of the damages to pathology services of the scandals⁵¹, and of the (restricting) consequences of the new legislation on specific clinical specialties^{52 53 54}. Third were papers written during the legislative process itself, some of which could be seen as adjuncts to a lobbying campaign from the scientific community^{55 56 57}. Fourth were papers

⁴² Womack C. *Ethical issues relating to supply of human tissue to the commercial biomedical sector*. Cell and Tissue Banking 2002; 3: 2002.

⁴³ Giordano S. *Is the body a republic?* J Med Ethics 2005; 31(8): 470-475.

⁴⁴ Arcus KD, Kessel AS. *Are ethical principles relative to time and place? A Star Wars perspective on the Alder Hey affair*. BMJ 2002; 325(7378): 1493-1495.

⁴⁵ Black D. *Coping with loss: the dying child*. BMJ 1998; 316(7141): 1376-1378.

⁴⁶ Savulescu J. *Death, us and our bodies: personal reflections*. J Med Ethics 2003; 29(3): 127-130.

⁴⁷ Callahan D. *Death, mourning and medical progress*. Perspect Biol Med 2009; 52(1): 103-115.

⁴⁸ Bennett J. *The organ retention furore: the need for consent*. Clinical Medicine 2001; 1(3): 167-171.

⁴⁹ Hall D. *Reflecting on Redfern: what can we learn from the Alder Hey story?* Arch Dis Childh 2001; 84(6): 455-456.

⁵⁰ Bauchner H, Vinci R. *What have we learned from the Alder Hey affair?* BMJ 2001; 322(7282): 309-310.

⁵¹ Cox P, Scott R. *Perinatal pathology in 2001*. Arch Dis Childh 2001; 84(6): 457-458.

⁵² Laker MF. *The Human Tissue Act: implications for clinical biochemistry*. Ann Clin Biochem 2006; 43(6): 427-430.

⁵³ Lucassen A, Kaye J. *Genetic testing without consent: the implications of the new Human Tissue Act*. J Med Ethics 2006; 32(12): 690-692.

⁵⁴ Underwood JCE. *The impact on histopathology practice of the new human tissue legislation in the UK*. Histopathology 2006; 49(3): 221-228.

⁵⁵ Furness P, Sullivan R. *The human tissue bill: criminal sanctions linked to opaque legislation threaten research*. BMJ 2004; 328(7439):333-334.

⁵⁶ Parry B. *The new Human Tissue Bill: categorization and definitional issues and their implications*. Genomics Society and Policy 2005; 1(1): 74-85.

⁵⁷ Price D. *From Cosmos and Damian to van Velzen: the human tissue saga continues*. Med LR 2003; 11(1): 1-47.

describing and commenting on the content of the Act itself.^{58 59 60 61 62 63 64}. [There is a fifth group of publications which have considered in various ways the 2004 Act 'in action'.⁶⁵ These are largely beyond the scope of this Thesis- see section 3, below] In contrast, the 2006 Act has not (yet) attracted a substantial literature, but has been discussed to make points of comparison with the provisions of the 2004 Act.^{66 67}

Of those papers which commented on the 2004 Act, two in particular, by their differing use of the concept of 'consensus', touched on matters of direct relevance to the questions I had formulated. Price wrote that the passage of the Bill had been remarkable for a high level of consensus and all party support. He conceded that lack of pre-legislative scrutiny had contributed to 'initial drafting problems, a hiatus of four and half months between Committee and Report stages in the House of Commons, and steady revisions up until the very culmination of Parliamentary deliberations'⁶⁸. This suggested to me that his identification of a 'consensus' had

⁵⁸ Editorial. *Effective implementation of the Human Tissue Act*. Lancet 2006; 368(9539): 891.

⁵⁹ Furness P. *The Human Tissue Act: reassurance for relatives, at a price*. BMJ 2006; 333(7567): 512.

⁶⁰ Liddell K, Hall A. *Beyond Bristol and Alder Hey: the future regulation of human tissue*. Med L Rev 2005; 13(2): 170-223, op.cit.

⁶¹ Price D. *The Human Tissue Act 2004*. MLR 2005; 68(5): 798-821, op.cit.

⁶² Brazier M, Fovargue S. *A brief guide to the Human Tissue Act 2004*. Clinical Ethics 2006; 1(1): 26-32.

⁶³ Bell MDD. *The UK Human Tissue Act and consent: surrendering a fundamental principle to transplantation needs?* J Med Ethics 2006; 32(5): 283-296.

⁶⁴ McHale J. *The Human Tissue Act 2004: innovative legislation-fundamentally flawed or missed opportunity?* Liverpool Law Review 2005; 26: 169-188.

⁶⁵ McLean SAM, Campbell A, Gutridge K, Harper H. *Human tissue legislation and medical practice: a benefit or a burden?* Medical Law International 2006; 8(1): 1-21.

⁶⁶ Joint Committee on the Human Tissues and Embryos (Draft) Bill (Session 2006-07). Volume 1: Report. The Stationery Office, 2007, op.cit.

⁶⁷ Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-203.

⁶⁸ Price D. *The Human Tissue Act 2004*. MLR 2005; 68(5): 798-82, op.cit., at p 799.

been somewhat overdrawn. Within a major paper which explored the ramification of the 2004 Act for the future regulation of human tissue samples, Liddell and Hall analysed the amendments which were made during the passage of the Bill against a proposition that legal policy on ethically controversial issues should be based on norms which represented 'an overlapping consensus' amongst competing ethical positions.⁶⁹ The authors concluded that the 'much criticised first version of the Bill suggested that the Government had misjudged the nature and difficulty of the task.' Further 'it had erroneously assumed that reasonable citizens agreed that specific consent should be required in every field of tissue based medical research and research training, and that this was a practical policy to implement'.⁷⁰

1.2.2 A gap to be filled.

In summary, many of the published papers had dealt with aspects of the Acts as they were, and/or with implications for the law in action. Papers which discussed antecedents to the Acts had tended to concentrate on the passage of the Bill in Parliament itself, or had considered broad moral and ethical underpinnings from a theoretical point of view. With the exception of Kennedy (as lawyer, academic, activist), Skegg, and a few others, I was unable to establish that lawyers as a cadre had taken much interest in reform of human tissue regulation for much of the later 20th century (until perhaps the rise of interest in 'rights' and 'ownership' in the 1990s). Even taken together, the literature failed to explain adequately to me why the recent legislation in England and Wales was seen as controversial (as between those who thought it had not gone far enough⁷¹ and those who thought its provisions attempted too much⁷²), or why the Scots had taken their own line (with an outcome that was later approved as having 'achieved a far better result' by a

⁶⁹ Liddell K, Hall A. *Beyond Bristol and Alder Hey: the future regulation of human tissue*. Med L Rev 2005; 13(2): 170-223, op.cit., p 173.

⁷⁰ Ibid., p 220.

⁷¹ McHale J. *The Human Tissue Act 2004: innovative legislation-fundamentally flawed or missed opportunity?* Liverpool Law Review 2005;26: 169-188, op.cit.

⁷² Brazier M, Fovargue S. *A brief guide to the Human Tissue Act 2004*. Clinical Ethics 2006;1(1): 26-32, op.cit., p31.

Parliamentary Joint Committee⁷³). In short, my core questions had not been answered.

Law making is complex. My hypothesis was that answers might lie within a greater understanding of the *processes* by which new legislation had occurred, the *climate* of the time and the *institutions* and even *individuals* who had been involved, within an essentially narrative account: and that much might be revealed by a study of available records.

3. Aim of the Thesis.

I hope to understand, through analysis of the contribution of forces, interests, issues, organisations and individuals, how the specific pieces of legislation came into being, in two planes: vertically across time between 1952 and 2006, and horizontally as between England and Scotland in the early 21st century. More speculatively, I hope to place the findings within an (inevitably partial) analysis of changing relations between medicine, the public and the state.

Specifically, this Thesis concentrates on the processes of planning, consultation and negotiation prior to developing new legislation with an impact on research. It does not provide an analysis of the Acts in detail, nor does it cover all issues regulated by the [recent] Acts. It is concerned with the genesis of the legislation. Consideration of the implementation phase, and of the institutions which had to operate within the law, is confined to the 1952 and 1961 Acts, and only to the extent that they might have influenced the genesis of the 2004 and 2006 Acts. Consideration of the implementation phase of the latter Acts (including, in the case of the 2004 Act, the establishing and subsequent activities of the Human Tissue Authority), is beyond the scope of this Thesis.

4. Methodology.

The methodology has been essentially two-fold. First, I have ‘interrogated the sources’ through in depth study of: archived records: publicly available documents;

⁷³ Joint Committee on the Human Tissues and Embryos (Draft) Bill (Session 2006-07). Volume 1: Report. The Stationery Office, 2007, op.cit., p36, para 114.

certain confidential papers made available by the Royal College of Pathologists, the Royal College of Physicians (London), and the Wellcome Trust; papers released under the Freedom of Information Act⁷⁴ and the Freedom of Information (Scotland) Act⁷⁵; and analysis of the scholarly literature. I have been guided in my searches by informal discussions with a number of colleagues, but no formal or structured interviews took place. Second, with regard to analysis of the findings, I judged that ‘analysing public policy in terms of a process framework’ might usefully be applied to the task in hand.

4.1 Analysing public policy in terms of a process framework.⁷⁶

The main methodological innovations in this field were led by the work of Riggs⁷⁷, and Almond and Coleman⁷⁸, who developed ‘structural-functional’ and ‘systems’ approaches, which owed much to the field of anthropology, and to the work of sociologists such as the Canadian social scientist David Easton.^{79 80 81}

According to Hogwood and Dunn, the advantages of using a process framework in analysis are: first, that it is *dynamic*, in that both forward movement can be measured and, via feedback, modifications can be made at many points in the process; second, process frameworks can aid the identification and study of

⁷⁴ *Freedom of Information Act 2000*. (2000, c.36.)

⁷⁵ *Freedom of Information (Scotland) Act 2002*. (2002, asp 13.)

⁷⁶ Hogwood BW, Gunn LA. *Policy analysis for the real world*. Oxford. OUP, 1984, pp 24-26, and chapter 4.

⁷⁷ Riggs FW. *Agraria and Industria: towards a typology of comparative administration*. In Siffin WJ (ed.) *Towards the comparative study of public administration*. Bloomington, IA. Indiana University Press, 1957.

⁷⁸ Almond G, Coleman I (eds.) *The politics of developing areas*. Princeton. Princeton University Press, 1960.

⁷⁹ Easton D. *An approach to the analysis of political systems*. *World Politics* 1957; 9(3): 383-400.

⁸⁰ Easton D. *A framework for political analysis*. Englewood Cliffs, NJ. Prentice-Hall Inc., 1965; especially: *Chapter Two: Political life as a system of behaviour*, pp 23-34.

⁸¹ Easton D. *A systematic analysis of political life*. New York. John Wiley and Sons, 1965; especially: *A flow model of the political system*, pp29-33.

interactions, not only among the various stages in the process but also among various participating organisations and between organisations and the larger social and economic environment; third, the approach is *flexible* in that it allows existing knowledge to be systematised without precluding the integrating of future insights (for example, about stages, influences, or interactions) to the framework.⁸²

Easton's model (derived from cybernetics, and outlined here in a simplified form⁸³) depicted a political system as a 'box', with precisely defined boundaries, in which decision making involved a series of steps. First, there are various 'demands' for 'outputs' in the form of policies or resource distribution, 'supported' by various individual and group actors. Second, these competing groups and their demands are processed by the system and converted into authoritatively binding decisions- 'outputs'. Third, these policy outputs interact with the wider 'environment', including political culture, social structure, prevailing economic conditions, level of national security, international law, and opinion, to generate, fourth, a new set of demands and supports through, fifth, a 'feedback' mechanism. At which point the cycle begins anew.

There are also some general limitations and potential dangers within this approach.

⁸⁴ Care must be taken to avoid imposing an explanatory scheme derived from past research upon future events, when it would be inappropriate or constricting to do so. There is an associated danger that the use of a model with clearly defined stages may lead to false rationalisation or justification of past events, in that, instead of the neat cycle which the model comprises, in practice 'policy is often a seamless web involving a bewildering mesh of interactions and ramifications'⁸⁵. There have been further criticisms of a 'systems' approach, and variants of it, on a number of counts (for example, it could not be shown to be unfalsifiable; its claims of universality notwithstanding, it less easily accommodated non-democratic

⁸² Hogwood BW, Gunn LA. *Policy analysis for the real world*. Oxford. OUP, 1984, op.cit., pp 24-26.

⁸³ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, p103.

⁸⁴ Hogwood BW, Gunn LA. *Policy analysis for the real world*. Oxford. OUP, 1984, op.cit., pp25-26.

⁸⁵ Ibid., p26.

authoritarian systems; it laid too much stress on stability, and was therefore of limited use in analysing circumstances of conflict and systems failure).⁸⁶

Nevertheless, the systems approach is thought to have enduring value as a means of describing political processes and arrangements.⁸⁷

4.2 Application to law-making processes.

Drewry proposed that the 'systems' or 'framework' approach may be useful in describing and comparing law making processes which generate and consolidate those 'authoritative policy decisions' to be found at the centre of Easton's systems model and which involve many kinds of actor apart from elected 'legislators'.⁸⁸ Easton depicted decision making in a political system as a series of sequential steps. Drewry modified the approach for the specific purpose of describing the law making process. In his approach there are five steps or stages (he described 'four' by linking 'application' and 'feedback'). Each could be considered to be a 'process' in its own right, as follows: 1) 'Inspiration'; 2) 'Deliberation and formulation'; 3) 'Legitimation'; 4) 'Execution and application'; 5) 'Feedback'.⁸⁹

The first step is the initial idea for a policy or new law; the second is the firming up of the idea into a formal legislative or policy proposal; the third is the process by which the proposal is converted into an authoritative decision, that is, a law recognised as binding and accepted as such by the courts and by those responsible for putting it into effect; the fourth stage encompasses the means by which the law or the policy is made to work in practice; and the fifth is the process of feedback whereby the whole system can learn from the successes or failures, not only of the ultimate output (law or policy in practice), but of the antecedent steps as well.⁹⁰

⁸⁶ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, op.cit., p104.

⁸⁷ Ibid.

⁸⁸ Ibid.

⁸⁹ Drewry G. *Legislation*. In Ryle M, Richards PG (eds.) *The Commons under scrutiny*. Third edition. London, Routledge, 1988, pps 120- 140.

⁹⁰ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, op.cit.

Who are the stakeholders in the law making process in the UK? According to Walkland:

The legislative process is now complex: it comprises deliberative, parliamentary and administrative stages, over all of which executive influence is predominant. Legislation is now an almost exclusively executive function, modified, sometimes heavily, by practices of group and Parliamentary consultations.⁹¹

Drewry has drawn up a more detailed list, and has considered the actors under the following categories:

- Ministers, politicians and civil servants, who have a direct professional stake in policy making and legislation;
- Citizens (voters and taxpayers). At an individual level, most are ill informed, and not much concerned about political issues: but collective opinion, as expressed through political parties and pressure groups, can exert serious influence.
- 'Public opinion'- an elusive phenomenon, gauged by opinion polls and sometimes through processes of official consultation- can make an impact on politicians, and which increases in the run up to elections.
- The mass media claim to reflect public opinion, and ministers are sensitive, perhaps over sensitive, to the views of the mass circulation tabloid press. At the same time, serious media coverage of policy issues can have an important informative and educational role to play in the legislative process.
- Pressure groups (sometimes distinguishable as between 'cause groups' and 'interest groups', and as between 'outsider' and 'insider' groups). More recently, there has been a growing tendency to depict policy making as involving 'policy networks' and 'policy communities', containing both

⁹¹ Walkland SA. *The legislative process in Great Britain*. London, Allen & Unwin, 1968, at p 20.

governmental and non- governmental actors, and constituted differently for each policy sector.⁹²

- Political parties have the function of aggregating individual and group interests into the policy programmes which form the basis of electoral competition;
- Non-Governmental Organisations (NGOs) and parastatal bodies, which, in some contexts, overlap in their roles with those of 'insider' pressure groups, and are allowed privileged access to the corridors of government power.⁹³
- [In recent times, the relevant arms length body or regulator could be added to the list of 'actors' (for example, the Human Fertilisation and Embryology Authority was a principal adviser to the Department of Health⁹⁴ during the revision of the Human Fertilisation and Embryology Act 1990⁹⁵ by the amending Human Fertilisation and Embryology Act 2008⁹⁶].

How do these *dramatis personae* perform in the play in five acts that is the UK legislative process as described by Drewry?

'Inspiration'.

Inspiration for legislation can come from many sources, inside or outside government. These include political parties (through pressure groups, conference resolutions, manifesto pamphlets and the like), sometimes involving interest groups en route. Government departments are often the apparent source of the 'idea', but they in turn may be responding to a Commission, a Committee of Inquiry, or

⁹² Heywood A. *Politics*. Third edition. Basingstoke. Palgrave Macmillan, 2007, pp 294-297.

⁹³ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008: 29(2); 100-110, op.cit., at pp 106-7.

⁹⁴ Human Fertilisation and Embryology Authority. *Advice to the Department of Health on the proposed approach of not defining an embryo in any new legislation*. October 2006.

⁹⁵ *Human Fertilisation and Embryology Act 1990*. (1990, c.37.)

⁹⁶ *Human Fertilisation and Embryology Act 2008*. (2008, c.22.)

another government institution (including the EU). Private members' Bills may have their origin in the inspiration of individual MPs, but many will have been prepared by pressure groups, and some are Government Bills in disguise. There may have been feedback from the judicial or administrative processes. In addition, the perceived need for legislation may arise from what Drewry styled 'an emergency'- usually resulting in early involvement of the relevant Ministry.⁹⁷ It should also be noted that calls for legislative reform can also fall on deaf ears, as for example in the aftermath of *Airedale NHS Trust v Bland*⁹⁸.

'Deliberation and formulation'.

According to Walkland, writing in the late 1960s, in so far as there was a deliberative stage in the legislative process, this was to be found much earlier than the Parliamentary stages than in previous generations, in the interplay between political parties, pressure groups, Departments and the Cabinet, which together formed a complex decision making structure, involving a variety of social and political forces.⁹⁹

In the Westminster Parliament, once an idea has been accepted as a basis for action, and there is thought to be Parliamentary time (in the case of proposed new statute law, this will require the approval of the appropriate Cabinet Committee), the lead ministry will have the responsibility for expanding the idea into a formal policy document and/or a draft law. The ministry will usually set up a committee (ministers plus civil servants) in order to draft instructions for Parliamentary Counsel (who are the specialist drafters). Consultation documents may be issued widely. It is also at this early stage that non-governmental organisations make their contribution. The cooperation, expertise and input of the most influential and relevant 'insider' pressure groups may be sought, in order to ensure their feeling of involvement in, and if possible commitment to, the final proposals. Parliamentary

⁹⁷ Drewry G. *Legislation*. In Ryle M, Richards PG (eds.) *The Commons under scrutiny*. Third edition. London. Routledge, 1988, at p124.

⁹⁸ [1993] 1 All ER 821.

⁹⁹ Walkland SA. *The legislative process in Great Britain*. London. Allen & Unwin, 1968, at p71.

select committees may sometimes conduct their own inquiries into proposals. If the Government publishes a draft Bill, this can give a valuable opportunity for pre-legislative scrutiny by Parliament and its committees.^{100 101}

There are significant differences in the detail of procedures in the Scottish Parliament which will be discussed in Chapter Five. Evidence will be presented that the differences in procedure played a pivotal role in ensuring that the *content* of the legislation was different.

'Legitimation'.

The process of turning a Bill into a legally authoritative and binding Act is a major function of any legislature: in the UK it is the major function of the Parliament at Westminster. By the time a Bill reaches Parliament, it will already have been subject to much discussion and negotiation, with the result that ministers are usually reluctant to concede new amendments, either in debates, or in the clause by clause analysis which take place in the standing committees. It is here that the opposition parties, often informed by ideas and concerns of 'outsider' pressure groups, will try to influence the detailed content of the proposed legislation, but often, it has been said, without much effect.¹⁰²

'Execution and application'.

An Act of Parliament must *work*, and be *seen* to work. Well planned legislation and policy will have made proper allowance for how it is to be made effective, including the provision of sufficient manpower and resources. Parliament and its committees nowadays are taking an increasing interest in post-legislative scrutiny, an area of activity which has been reviewed by the House of Lords Select Committee on the

¹⁰⁰ First Report of the House of Commons Select Committee on Modernization 2007-8. *Scrutiny of the draft legislative programme*. HC 81.

¹⁰¹ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110 op.cit., p108.

¹⁰² Ibid., p109.

Constitution¹⁰³ and the Law Commission¹⁰⁴, and accepted in principle by Government¹⁰⁵.

'Feedback'.

The experiences of those professionally involved in implementing or interpreting the legislation, and the findings of post- legislative scrutiny by select committees, form important components of a feedback loop into the early stages of the legislative process- as does the response of the public to the legislation or policy as experienced 'on the street'. The activities of the mass media in interpreting or influencing public opinion can also have a major impact on ministers.¹⁰⁶ An essential feature of efficient 'closed loop' systems as described by Easton is that the data in the feedback arm are analysed *systematically* and the results used to modify the subsequent output from the system.^{107 108 109} Evidence is presented in Chapter Two which indicated that, as recently as 2006, 'feedback' was far from being systematic in the Westminster Parliamentary system.

5. Scope and structure of the Thesis.

It is on the first three of the five components of Drewry's framework that the account in this Thesis will mainly concentrate, namely 'inspiration', 'deliberation and formulation', and 'legitimation'. The processes of 'execution and application'

¹⁰³ House of Lords. Select Committee on the Constitution. 14th Report of Session 2003-4. *Parliament and the legislative process*. HL 173-1.

¹⁰⁴ The Law Commission (Law Com No.302). *Post-legislative scrutiny*. Cm 6945, October 2006.

¹⁰⁵ House of Lords. Select Committee on the Constitution. 6th Report of Session 2004-5. *Parliament and the legislative process: the Government's response*. HL114. Report. Appendix 1, p11, para 47.

¹⁰⁶ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, p106.

¹⁰⁷ Easton D. *An approach to the analysis of political systems*. World Politics 1957; 9(3): 383-400.

¹⁰⁸ Easton D. *A framework for political analysis*. Englewood Cliffs, NJ. Prentice-Hall Inc., 1965; especially: *Chapter Two: Political life as a system of behaviour*, pp 23-34, op.cit.

¹⁰⁹ Easton D. *A systematic analysis of political life*. New York. John Wiley and Sons, 1965; especially: *A flow model of the political system*, pp29-33, op.cit.

and ‘feedback’ are considered with respect to the 1952 and 1961 Acts, but only in as far as they appeared to play a role in the prelude to the 2004 (and 2006) Acts.

Chapter One considers the background to, and the passing of, the 1952 and 1961 Acts, and relies especially on an in depth study of files in the National Archives. In the process some new insights on that legislative process have emerged, including findings that I have already published elsewhere.¹¹⁰

Chapter Two examines the 1961 Act ‘in action’ up to the millennium. There was no systematic post-legislative scrutiny. Evidence is presented, which I have characterised as accumulations in an ‘in-tray’, of: pressures by politicians and clinicians to change the law relating to organ transplantation; recognition by officials as early as 1970 of a need for amending legislation in regard to retaining tissues from post mortems; pathologists’ ignorance of the law; contraventions of the 1961 Act both by doctors and government agencies; and a dawning awareness in official circles of the voice of the public.

Chapter Three steps outside the chronological narrative to consider changing relationships between medicine, the public and the state, particularly: changing attitudes to doctors in the UK (and for comparison in the USA); consideration of wider societal changes outside the health field (relying in particular on the survey data of Inglehart, the analysis of ‘a new public philosophy’ of Beer; and the seminal studies of Giddens, with their emphasis on reflexivity and active trust). The threat of deprofessionalisation of the medical profession, and their steps to avoid it, are also considered.

Chapter Four takes the narrative from organ retention ‘scandals’, through ‘five tumultuous years’, to the passing of the 2004 Act. A commonality of features is identified, involving families and their beliefs, medical practice, coronial ‘fiefdoms’, and the role of the press, on the background of an uncertain law. The inspiration, formulation, and deliberation phases are examined in detail, and a lack of pre-

¹¹⁰ McNeish AS. *Anticipating the Redfern inquiry: a historical note about tissue retention and consent*. J Clin Pathol 2009;62: 958-959.

legislative scrutiny noted, to try to explain why the scope of the 2003-4 Bill was more broadly drawn than might have been expected as a response to irregularities in post-mortem practices. Aspects of the legitimisation process are seen as a struggle between a government which had made a prior and overriding commitment to families, and which was very influenced by the Bristol Interim Report and perhaps by 'past history', and a medical and scientific community which, initially demoralised and sidelined, eventually formed an effective lobby. At several stages in the narrative a pivotal role is identified for certain individuals (including Professor (now Sir) Ian Kennedy, Rt Hon Alan Milburn MP, and Mrs Michaela Willis).

Chapter Five moves to Scotland, and considers the 2006 Act. Organ retention, parental outcry and press coverage led to the setting up by the Scottish Executive of an Independent Review Group. The influence of this Group, and of the multiple layers of consultation (including pre-legislative scrutiny) which followed are analysed in an attempt to explain the narrower focus and the wide acceptance of the new legislation. The importance of parallel involvement of NHS quality assurance bodies, and of the Crown Office and Procurator Fiscal Service, is also discussed.

Chapter Six attempts to synthesise the analysis of processes, climate, institutions and individuals in earlier Chapters to explain the changes over time, and to understand how alternative 'solutions' to the 'same' problem were possible at other times and places. It is concluded that the outcomes can be understood as having been contingent on the influence of all four factors, with differences in 'climate' being most important in the vertical axis between approximately 1950 and 2000, and in 'process' between the 2004 and 2006 Acts. The findings may have relevance for any future negotiations between government and researchers. Pointers towards the more general worth of pre-legislative scrutiny of Parliamentary Bills have emerged.

The starting point for the present study took account of Drewry's warning that:

When we try to discover the source of the original idea that led to a new policy or a new piece of legislation, we usually find a tangled tale that offers a confusing mixture of different possibilities- and indeed, with most legislation, there is seldom a single inspirational source. Finding the true origin is not helped by the fact that, if the policy turns out to be popular and successful, then everyone wants to claim some of the credit; and, conversely, if it fails, then everyone will want to deny responsibility.¹¹¹

¹¹¹ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, op.cit., p108.

CHAPTER ONE.

The development of human tissue legislation in the mid-20th century.

This account of the sometimes turbulent history of human tissue legislation in the United Kingdom between 1952 and 2006 begins with events leading to the Corneal Grafting Act 1952. At first reading, it is difficult to see a smooth connection between, on the one hand, the Corneal Grafting Act 1952 ('the 1952 Act') and the Human Tissue Act 1961 ('the 1961 Act'), whose associated Bills were introduced in the House of Commons as follows, respectively:

Surgical science is doing its job and now it is asking the legislators to help it to carry on further.¹ (Corneal Grafting Bill 1952), and
[one which is] mainly concerned with the removal of doubt, but [which] may nevertheless be described as wholly beneficial and in some cases a life-saving measure.² (Human Tissue Bill 1960);

and its successor, the Human Tissue Act 2004 ('the 2004 Act'), whose associated Bill was described at Second Reading in the Commons in these terms:

The background to this Bill is scandal...A practice that resulted in such tragedy for so many families may once have had its place, but it certainly has no place in today's health service.³

The story began much earlier.

1. Medical (including transplantation) research in the 1950s.

The 1950s were years during which the activities of medical science, internationally, began to rise exponentially, and received the increasing support of Government. In the USA, medical research expenditure by the National Institutes of Health increased from \$0.706m in 1945, to \$36.06m in 1955, and by 1965 had reached

¹ (1952) 500 Parl. Deb. (Hansard, 5th series), HC 1446.

² (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1231.

³ (2004) 416 Parl. Deb. (Hansard, 6th series), HC 1041.

\$436.6m.⁴ Expenditure in the UK showed a similar trend, albeit on a more modest scale: Government grant- in aid to the Medical Research Council increased from £295,000 in 1945⁵, to £2.33m in 1955⁶, and to £9.05m by 1965⁷.

Transplantation was one of the many fields in which progress was made during these years. At a clinical level, by the mid 1950s transplantation of homografts (human to human) was ordinarily limited to: cornea and cartilage, which could persist for a prolonged periods because they were avascular; skin, which was of temporary value in severely burned patients; and bone, and segments of blood vessels, which provided scaffolding for regenerating tissues in the recipient.^{8 9}

These human grafts were taken by a postmortem procedure from the recently deceased, for undoubted reasons of beneficence, but in circumstances of questionable legality in the UK, under the Anatomy Act 1832¹⁰ ('the 1832 Act'). This Act had had as its main purpose the expansion of the legal supply of cadavers for anatomical examination by dissection in support of education and research. Section 15 of the 1832 Act made a saving for postmortem examinations 'required or directed to be made by any competent legal authority'.¹¹ The Act gave no consideration to the retention of parts of a body following anatomical examination.

⁴ Quoted by Beecher HK. *Ethics and clinical research*. New Engl J Med 1966; 274: 1354-60 at p 1355.

⁵ Report of the Medical Research Council 1939-45. *Medical research in war*. Cmnd. 7335. Presented in Parliament December 1947.

⁶ Annual Report of the Medical Research Council 1955-6. Cmnd 180. Command papers 1956-7.

⁷ Annual Report of Medical Research Council October 1963- March 1965. Cmnd 2787. Command papers 1964-5.

⁸ Hutchison J. *The fate of experimental bone autografts and homografts*. Brit J Surg 1952; 39(158): 552-561.

⁹ Longmire WP, Smith SW. *Homologous transplantation of tissues: a review of the literature*. AMA Arch Surg 1951; 62(3): 443-454.

¹⁰ *Anatomy Act 1832*. (1832, c.75).

¹¹ *Ibid.*, s.15.

Doubt had existed about whether the provisions of the 1832 Act prohibited all post-mortem examinations ('PMs'; 'autopsies'), other than those required or directed to be made by a competent legal authority, or whether the provisions of that Act was limited to anatomical examinations carried out in schools of anatomy. Certainly by 1953, experts had been expressing the need for clarification of the law as it related to PMs. According to Coulson and colleagues, who were experienced pathologists, it had not been suggested that any of the many thousands of examinations had been made from other than laudable motives. Their probable illegality had not been appreciated even by the employing authorities, who not infrequently had used experience of PMs as a necessary criterion for appointment to a post of consultant pathologist in the NHS. As put by Coulson and colleagues:

These unofficial and apparently unlawful examinations have become an accepted practice. There appears to be no instance of any prosecution having been instituted, or any civil cause decided, because of their performance. The situation, however, is unsatisfactory and should be regulated by suitable amendment of the Anatomy Acts or by entirely fresh legislation.¹²

2. The Corneal Grafting Act 1952 ('1952 Act').¹³

2.1 The legislative process.

The international nature of medicine, and of medical research, imposes pressures which are not confined to one legislature. By the early 1950s, remedial legislation to permit corneal grafting had been passed, or was in the process of being passed, in several countries, including the Union of South Africa, France, Tunis, Morocco, Syria, Spain, and the Territory of Alaska.¹⁴ France had been the pioneer: a 1947 law removed an earlier requirement for a 24 hour delay before removal of tissue from a cadaver. It authorised prompt excision of eyes from the dead in certain specified hospitals, even in the absence of permission from the family, whenever, in the

¹² Coulson CJ, Brittain RP, Marshall TK. *The disposal of the dead*. London. English Universities Press, 1953, pps28-9.

¹³ *Corneal Grafting Act, 1952* (1952, c. 28.)

¹⁴ Townley Paton R. *Donor material and the law*. In: Rycroft BW (ed.) *Corneal Grafts*. London, Butterworth & Co. (Publishers) Ltd., 1955, at p 217.

opinion of the medical director, a scientific or therapeutic purpose was to be served.¹⁵ It was recorded that, prior to 1947, eye surgeons in France had been 'compelled (sic) to perform their grafts outside the law'¹⁶.

The legal uncertainties and practical difficulties in regard to corneal grafting in the United Kingdom were first confronted in Parliament in 1952. For some time previously there had apparently been a climate of 'the less said, the better'.

Kenneth Robinson MP recalled a time when, as a young Member of Parliament, he was contacted by certain members of the medical profession about the difficulties of getting sufficient corneas for grafting. He had approached the then Minister of Health and asked if there was anything that he, Robinson, could do by way of publicity and Parliamentary Questions. The Minister had returned, having seen his advisers, and said: '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'.¹⁷

Similar reservations had also been expressed to other Members of Parliament, notably Dr Horace King MP and Gerald Williams MP, who were also interested to promote the cause of corneal grafting. Happily for blind patients with corneal disease, these MPs pressed ahead nonetheless. Their fears of opposition turned out to be unfounded, probably due in no small measure to the prior lobbying of fellow MPs that they themselves undertook.¹⁸ When the Corneal Grafting Bill itself was presented as a Private Members' Bill under The Ten Minutes' Rule on May 14 1952 by Gerald Williams MP, he spoke for six minutes only, and the House gave leave to introduce the Bill.¹⁹ A week later, it passed through its Second Reading, its Committee Stage, and its Third Reading, all in the space of thirty seconds, 'on the

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1235.

¹⁸ Ibid., 1240.

¹⁹ (1952) 500 Parl. Deb. (Hansard, 5th series), HC 1445.

nod', without a single word being spoken on either side of the House.²⁰ The House of Lords was equally welcoming. At Second Reading, there was unanimous support for the Bill.²¹ Committee Stage produced no amendments.²² The Bill was reported and passed two days later.²³ The Corneal Grafting Act 1952 received Royal Assent on June 26, 1952.²⁴

The provisions of the Corneal Grafting Act 1952 were simple and direct. The person in lawful possession of the body after death may authorise the removal of eyes after death by a registered medical practitioner: if the person, either in writing at any time, or orally in the presence of two or more witnesses during his last illness, expressed a request that his eyes be used for therapeutic purposes²⁵; or, to the knowledge of the person in lawful possession, the deceased had never expressed an objection to such use; provided in the latter case that the surviving spouse or any surviving relative had no objection to their being so used.²⁶ It is of note that the Act did not require an enquiry in regard to objections to be made.

Of the greatest practical significance was the lifting of the 48h embargo. If it were the case that the work of transplant surgeons fell within the scope of the 1832 Act, a crucial restriction imposed by that Act inhibited the likelihood of a successful operation. The 1832 Act required that 48h should elapse after death before the body 'shall be moved for anatomical examination'; and this after at least 24h following notification to the authorities of intent to proceed; and after receipt of a death certificate from a physician, surgeon or apothecary²⁷. Such delays inevitably

²⁰ (1952) 501 Parl. Deb. (Hansard, 5th series), HC 624.

²¹ (1952) 176 Parl. Deb. (Hansard, 5th series) HL 1465.

²² (1952) 177 Parl. Deb. (Hansard, 5th series) HL 10.

²³ Ibid., at c.120.

²⁴ *Corneal Grafting Act, 1952* (1952, c. 28.)

²⁵ Ibid., s. 1(1).

²⁶ Ibid., s. 1(2).

²⁷ Ibid., s.9.

altered the chemical and physical composition of cadaveric tissues such as would have limited their usefulness as grafts. With the passage of the 1952 Act it became legal for eyes to be removed by a medical practitioner as soon as he was satisfied, after examination, that life was extinct²⁸, and that the necessary authorisation had been given.

The years that followed allowed corneal surgery to be further developed, in support of which most of the leading eye hospitals developed 'eye banks' in which cadaveric corneas were stored awaiting use.

2.2 Unintended consequences of the 1952 Act.

2.2.1 Experimental grafting of other tissues.

One of the unintended consequences of the 1952 Act was to add doubt about the legality of using other parts of a dead body during a decade in which further progress was made in understanding, for example, the immunological basis of tissue rejection following experimental transplantation, and how it might be ameliorated. Despite concern about the legality of transplanting non-corneal tissues, clinicians and experimentalists continued to explore the possibility of grafting other organs and tissues through the 1950s, many probably in complete ignorance of the law.

It is beyond doubt that these activities were known at high levels by the latter years of that decade, and that blind eyes were turned in a manner akin to that experienced earlier by Kenneth Robinson MP with regard to corneal grafting in the early 1950s. In 1958 at a meeting of the Presidents of the several Royal Colleges, Sir James Paterson Ross (PRCS (Engl.)) and Professor John Bruce (PRCS (Ed.)) were asked to approach the Lord Chancellor and the Lord President of the Court of Session respectively about the legal position with regard to homografts. The matter was subsequently discussed by Dr George Godber, Deputy Chief Medical Officer (DCMO), with Sir James Paterson Ross in his capacity as the Consultant Adviser in Surgery to the Ministry of Health. While it was agreed that sooner or

²⁸ Ibid., s.1(3).

later something would need to be done it was thought that the time was not right for legislation and that any action in that direction might cause some curtailment of the work already being done.²⁹ In January 1960, the DCMO wrote to the Under Secretary at the Ministry of Health, following a meeting of Senior Administrative Medical Officers (the senior representatives of the Chief Medical Officer in each Health Region in England and Wales, referred to as 'SAMOs'):

It was clear from what we were told yesterday that the practice of preserving tissues taken at autopsy is widespread and increasing. The taking of tissues is clearly regarded as of uncertain legality, although in many cases Coroners know what is going on and do not object. If an autopsy is to be performed on the Coroner's instructions removal of artery or bones is unlikely to cause any comment because it may not be known.³⁰

There were (and are) two types of post mortem examination- those requested or directed by a coroner to be performed ('CPM'), and those performed in hospital as part of hospital practice ('HPM'). The coroner would have known (and, according to the DCMO, had not objected to) 'what was going on' only in those PMs under his jurisdiction. An internal memorandum within the Ministry of Health in June 1960 went further in allocating a role for coroners by recognising that 'much of the success of the present arrangements is due to the cooperation of the coroners'.³¹ However, not all the 'success' could be attributable to the action or inaction of coroners. Coroners would not have known, and would not have needed to know, what had been the practice in relation to HPMs. If, as seems likely, HPMs had also been a source for obtaining experimental grafting material, presumably it was the cooperation of the hospital pathologists that would have been essential in those cases.

2.2.2 Researchers 'go public'.

²⁹ The National Archives. Ref. MH58/497. *Grafting of human tissues: notes for Minister*, July 1960.

³⁰ Ibid. Letter from GE Godber to JE Pater, January 29 1960.

³¹ Ibid. Memorandum from SI Smith to D Emery, [?28] June, 1960.

The meeting of SAMOs had been called to discuss recent correspondence between the Medical Research Council (MRC) and the Ministry of Health about the use of freeze dried cadaveric human bone as grafting material. It was this activity that arguably was the trigger for the legislative process concerning tissue transplantation to begin.

In late October 1959, Dr HA Sissons of the Institute of Orthopaedics wrote to the MRC about the promising results he and colleagues had obtained from the experimental use of freeze dried human bone sterilised by gamma irradiation as bone grafting material- work which the MRC had supported through a research grant. Dr Sissons proposed that a small number of centres should be established to prepare supplies (banks) of freeze dried irradiated bone for clinical use. He suggested that the MRC should consider endorsing and underwriting the scheme.³²

A copy of this letter was sent from the MRC to the DCMO who, in welcoming a meeting to discuss the subject further, indicated that:

If cadaver bone is to be used here, we are up against the old (sic) problem of the legality of taking human tissue. The legal position is only clear for corneal grafting, and we are beginning to think that we may have to get a clarification of the law on the taking and storing of other tissues³³.

A meeting over lunch at the Athenaeum had already been arranged on November 16, 1959, between Sir Harold Himsworth (Secretary, MRC), Mr FJC Herrald (MRC), Dr Godber (DCMO) and Dr HJ Seddon, Director of the Institute of Orthopaedics, to discuss artificial limbs. It was agreed to add the issue of bone grafting to the discussion points. This was not the first or the last time that the Coffee Room [dining room] of 'the Club', as Himsworth described it, would be used for gentle lobbying and exchange of information. After discussion, it was agreed that no action should be taken on the matter that had been raised in Sisson's letter until an

³² The National Archives. Ref. FD23/2008. Letter from HA Sissons to PO Williams (MRC) [?date] October 1959.

³³ Ibid. Letter from G Godber to FJC Herrald (MRC), November 5, 1959.

already scheduled meeting in the Ministry of Health to discuss legal aspects of grafting had taken place.³⁴

Over the following months there were further exchanges of letters, the researchers expressing frustration at 'lack of action', and the Ministry insisting that it was still 'involved in a re-examination of the legal position'.³⁵ On April 1 1960, Dr HJ Seddon vented his impatience in a letter to the MRC, saying:

Banked bone of some kind or another has been used in this and other countries for ten years or so. And now, just when we are ready to put the thing on a proper footing, this legal question crops up...if the MRC and the Ministry of Health do not move soon then I think we shall have to consider taking independent action [unspecified] and damning the consequences.³⁶

Seddon's next independent action was to write a letter to the *Lancet* about '[being] compelled to mark time', and finding it 'regrettable that, apart from corneal grafting, we are six years behind New Zealand'. The letter concluded 'it is in the interest of many patients that legislation to permit the removal of various tissues from the cadaver for surgical use should be permitted without delay'.³⁷ This provoked an internal memorandum to the Secretary of the MRC: 'I am doubtful whether he [Seddon] is advancing his cause by bringing the matter to public notice in this way ...he has effectively prevented the Council from taking any active steps in promoting work on this problem until the legal position has been officially determined'.^{38 39}

³⁴ The National Archives. Ref FD9/4607 . Memorandum (S.479/3) by FJC Herrald (MRC), November 19, 1959.

³⁵ Ibid. Letter from GE Godber to FJC Herrald, February 23, 1960.

³⁶ Ibid. Letter from HJ Seddon to FJC Herrald, April 1 1960.

³⁷ Seddon HJ. *Legal aspects of homografting*. *Lancet* 1960; 275(7131): 974.

³⁸ It is of interest that no mention was made of any possible 'interests' of the deceased person- or cadaver, as Seddon had it.

³⁹ The National Archives. Ref. FD23/2008. Memorandum from FJC Herrald to H Himsworth (MRC), May 12, 1960.

Seddon's letter was not the only communication to the medical press around that time about the legal difficulties posed by homografting. Two weeks previously, Professor MFA Woodruff had written to the *Lancet*, highlighting recent developments in the potential for kidney transplantation, and drawing attention to the Medical Amendment Act 1954 of New Zealand, which, subject to appropriate conditions, regularised the removal of all tissues and organs for therapeutic purposes and for education and research⁴⁰. Woodruff described this as 'a shining example of enlightened legislation [but of] no help to patients in the United Kingdom'. He thought it 'clearly desirable' that both doctors and laymen should have a proper appreciation of the situation, and recommended that a working party should be set up to advise the Government on appropriate legal action.⁴¹

The content of Woodruff's letter was the subject of an editorial article in the Scottish medical press which could not find 'any valid reason' for delay in introducing legislation akin to that in New Zealand, legislation which was 'urgently required'.⁴² The contents of this editorial were relayed to the wider public in *The Scotsman* under the headlines 'Working party needed. Grafting operations raise problems. Legislation needed.'⁴³

3. The response of the Ministry of Health

3.1 Inspiration for new legislation.

Archival resources have revealed that the thinking in the Ministry of Health moved from 'we are beginning to think that we may have to get a clarification of the law' (November 1959)⁴⁴, through 'the difficulty [associated with] homograft material... has been included in a list of possible subjects for legislation, [but with] no

⁴⁰ New Zealand Statutes. *The Medical Amendment Act 1954*, 1954, No.40.

⁴¹ Woodruff MFA *Legal aspects of homografting*. *Lancet* 1960;275(7129):874.

⁴² Editorial. *Problems of homografts*. *Scot. Med J.* 1960; 5:460-1.

⁴³ *The Scotsman*, November 1 1960.

⁴⁴ The National Archives. Ref. FD23/2008 Letter from GE Godber to FJC Herral (MRC), November 5, 1959, op.cit.

assurance of time' (April 1960)⁴⁵, to 'if it is accepted that the legal position ought to be clarified...there does not seem to be anything to be gained by delay' (July 1960: Briefing for Minister of Health)⁴⁶.

It is difficult to be certain of all the factors which contributed to this stage of 'inspiration' for new legislation. The inexorable march of scientific progress, led by sometimes impatient scientists; an anxiety about being able to continue to turn a blind eye (for example, SAMOs who 'were aware of various attempts to maintain tissue banks, but were avoiding learning too much because they were really uncertain of the legal position'⁴⁷, and 'coroners who were aware of what was going on'⁴⁸); a sincere wish, on behalf of both clinicians and civil servants, to ensure clinical advances for the benefit of patients (the briefing for the Minister in July 1960 spoke of 'a practice which is already of importance in saving or prolonging life, and which is likely to develop further and increase in importance'); all are likely to have been influential in perceiving the need for legislation. Articles in the medical and lay press may also have played a role.⁴⁹

It was at this time that advice was sought from the Department of Health in New Zealand.⁵⁰ A letter from a Ministry of Health official indicated to his counterpart in New Zealand that 'we contemplate something very much on the lines of your Act'⁵¹. It is of interest that nearly two years previously, officials in the Scottish Office had separately sought information about the background to, and provisions of, the New

⁴⁵ The National Archives. Ref. MH58/497. Letter from GE Godber to JE Pater, April 26, 1960.

⁴⁶ The National Archives. Ref. MH58/497. *Grafting of human tissues: note for Minister*, July 1960.

⁴⁷ The National Archives. Ref. FD23/2000. Letter from GE Godber to FJC Herrald, Feb 23 1960, op.cit.

⁴⁸ The National Archives. Ref. MH 58/497. Letter from GE Godber to JE Pater, January 29 1960, op.cit.

⁴⁹ The National Archives. Ref. MH58/497. *Grafting of human tissues: note for Minister*, July 1960, op.cit.

⁵⁰ The National Archives. Ref. MH58/497. Letter from NM Goodman to Director General for Health, New Zealand, (for attention of DP Kennedy), June 23, 1960.

⁵¹ Ibid.

Zealand legislation on human tissues⁵², and had received a bundle of papers in response, which included a summary of Explanatory Notes prepared for Parliamentary use in New Zealand.⁵³ It would appear that they had omitted to share this with colleagues in England.

In New Zealand, the Medical Act 1908⁵⁴, through the Medical Amendment Act 1954⁵⁵, came to permit *inter alia*: first, the removal of healthy tissue (eyes or any other part of the body) after death for therapeutic purposes, if either the person had expressed such a request during his last illness (and was not known to have withdrawn it), or the person in lawful possession of the body authorised the removal of healthy tissue, provided that person had no reason to believe that the deceased had expressed a prior objection, or that the surviving spouse or any known relative required that the body be buried or cremated without such removal⁵⁶; second, a post mortem examination for the purposes of medical research or the teaching of pathology to be carried out, with similar provisos to be satisfied as were to be operative in the removal of tissue for therapeutic purposes- with the important requirement that ‘the surviving husband or wife, or if there is no husband or wife known to be surviving and there is known to be a relative, any such relative, *consents (my emphasis)* to a post mortem examination⁵⁷.

It is difficult to believe that the publicity in the professional and lay press in the UK did not play a role in determining the timetable. The civil servant who drafted the Ministerial Memorandum for the Cabinet Home Affairs Committee noted to a colleague that ‘it is noticeable [from the files] that since early 1959 there has been

⁵² The National Archives for Scotland. Ref. HH101/2183. Letter from J Hogarth to the High Commissioner for New Zealand, December 16, 1958.

⁵³ The National Archives for Scotland. Ref. HH101/2183. *Medical Amendment Act 1954*. Memorandum 1954/260 to all Medical Officers of Health from the Director-General of Health, New Zealand. October 13, 1954.

⁵⁴ New Zealand Statutes. *The Medical Act 1908*, 1908, No.116.

⁵⁵ New Zealand Statutes. *The Medical Amendment Act 1954*, 1954, No. 40.

⁵⁶ *Ibid.*, s.2(1) (inserts s.24A into *The Medical Act 1908*).

⁵⁷ *Ibid.*, s.2(2) (inserts s.24B into *The Medical Act 1908*).

some change in the view of our medical colleagues on the desirability for introducing new legislation, partly because the practice is increasing and partly because the interest in the subject indicated by recent articles in the medical and lay press make it not impossible that we may be challenged...it seems to me that there is considerable risk in allowing matters to go on as they are doing at present and that there is everything to be gained by introducing legislation at a time chosen by us rather than being forced into an embarrassing cover up'.⁵⁸

3.2 Further deliberation, and formulation of a Bill.

In Drewry's terms, the stage of 'deliberation and formulation' of new legislation was now well underway to the extent that the skeleton of the future Bill could already be found in the memorandum which had been prepared for the Cabinet Home Affairs Committee ('HAC'; 'the Committee') in July 1960⁵⁹, and in the accompanying briefing notes for the Minister of Health, the Rt Hon J Enoch Powell MP⁶⁰.

The need for a new Bill was explained in the memorandum in these terms:

It is uncertain whether the removal of tissue from a dead body is lawful, even when consent is given: and, further, if retention with consent is lawful, whose consent is required. It is doubtful whether there is property in a dead body, and the precise legal effect of the bequest of one's body is not certain. The Corneal Grafting Act, 1952, was introduced in order to remove these doubts in respect of the corneas of the eyes. That Act authorises the corneas of deceased persons to be used for therapeutic purposes- (i) if they have so expressed an objection or that his surviving relatives might object.⁶¹

⁵⁸ The National Archives. Ref. MH58/497. Memorandum from SI Smith to D Emery, undated [?June 1960].

⁵⁹ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105.

⁶⁰ The National Archives. Ref. MH58/497. *Grafting of human tissue: notes for Minister*, July 1960, op.cit.

⁶¹ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

The memorandum, having highlighted the then recent advances in surgery and the preservation of tissues, predicted the likelihood that whole organ transplantation into gravely ill patients would become feasible in the near future. It drew attention to the legal uncertainty and to related 'comment in the national and medical Press', which might make the then present activities, taking place in an increasing number of hospitals, difficult to justify if legally challenged. Such an eventuality would jeopardise the great progress being made in this field of surgery. It was anticipated that a Bill which attended to the issues 'would be generally welcomed by the medical profession and well received by Parliament and by informed public opinion'. The memorandum noted that there had been no opposition in Parliament to the Corneal Grafting Bill, but recognised that there could be opposition from certain religious denominations such as Orthodox Jews. However, it was anticipated that the safeguards contemplated should be sufficient to meet any objection on that score.⁶² It is worth noting in passing that, in 1953, the Presiding Rabbi of the Union of Orthodox Hebrew Congregations had written to the Home Secretary about their concern about post-mortem examinations. He had asked for an interview to consider protection for the bodies of deceased strictly orthodox Jews. During 1960, officials in the Ministry of Health were unable to find evidence that this had been followed up.⁶³ ⁶⁴ There is no evidence in the HAC papers that there had been specific discussion about 'consent'. The Minister had been briefed on provisions relating to consent in these terms:

Shortly before the Corneal Grafting Act came into force the Ministry advised that hospitals should not take advantage of the power given by that Act to remove a dead person's eyes in the absence of any known or presumed objection from himself or his relatives, and that wherever relatives were available their consent should be obtained. In a letter to Secretaries of Hospital Boards and Management Committees it was said that if relatives were known to exist but

⁶² Ibid.

⁶³ The National Archives. Ref. MH58/497. Memorandum to SI Smith from ASJ (sic), June 23, 1960.

⁶⁴ This omission may have contributed, in the long term, to the circumstances of the *Isaacs* case discussed in Chapter Four.

were unavailable to give consent the eyes should not be removed.⁶⁵ It was realised that it might be difficult and embarrassing to seek consent so soon after death but this was thought to be better than the alternative of relying on absence of objection. This advice (which is disliked by the Faculty of Ophthalmologists, who have been pressing the Ministry to 'apply the Act') was given because it was felt that at that time public opinion was not sufficiently advanced to accept the full application of the Act. Consideration has been given to so as to require consent to be sought in every case, since as matters stand, the been felt, however, that this would be a retrograde step and that the Act should be left in its present form, in the hope that public opinion will eventually become sufficiently enlightened to permit the full powers of the Act. In the same way it is considered that any Bill introduced now should contain consent provisions on the lines of those in the Corneal Grafting Act.⁶⁶

I have no evidence about whether or not the Minister of Health shared these hopes for the coming of more enlightened times, but there is evidence from the Parliamentary debates on the Human Tissue Bill, which will be discussed below, that he understood at least some of the sensitivities which surrounded 'consent' and 'an absence of objection'.⁶⁷

The driving force for proposed legislation was the progress being made in transplantation. Because it was recognised in the memorandum that the best source of human tissue for therapeutic purposes was from the young who had been involved in fatal road traffic accidents, officials had thought it desirable, subject to the views and agreement of representatives of coroners, to legalise the removal of tissue in such circumstances, recognising that the permission of the Coroner (Procurator Fiscal in Scotland) would be required in each case.

⁶⁵ The National Archives. Ref. MH58/502. *Corneal Grafting Act*. NHS Memorandum RHB(52)77,HMC(52)70,BG(52)74. June 26, 1952, para 10.

⁶⁶ The National Archives. Ref. MH58/497. *Grafting of human tissue: notes for Minister*, July 1960, op.cit.

⁶⁷ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1256.

On July 22, 1960, HAC, in discussion, 'showed general agreement with the proposals; and approved the proposal in [the Ministerial memorandum⁶⁸] for a Tissue Grafting Bill' to be handed to a private member in the Session of 1960/61'⁶⁹.

There is archival evidence that provisions regarding post mortems were not included in the Bill until late in the process of 'formulation'. At a meeting in the Minister's room on November 29, 1960 to discuss the draft of the Bill, on the very morning of a meeting of the Cabinet Home Affairs Committee, there was some discussion about the legality of post-mortems as such. The minute read:

The view hitherto of all concerned had been that post mortems carried out in hospitals to establish the reasons for the death of a particular patient were legal and were not affected by the Anatomy Acts; it was, therefore, unnecessary to make specific provision in the present Bill to establish their legality. The Minister however was having increasing doubts about this, in view of a recent case in a Nottingham mortuary where a dead body had been the subject of an assault by a mortuary attendant. Apparently the position was that there was no law governing what might or might not be done to a dead bodies (provided there was no offence to public decency) and he thought that there might be Parliamentary pressure for some more specific legal control about what might be done to dead bodies. It was agreed that Parliamentary Counsel might be asked to produce a draft clause establishing the legality of post mortem examinations in case, on further consideration, it was thought necessary to incorporate this in the Bill.⁷⁰

This explains why the memorandum to HAC also recommended, under 'related provisions', that the new legislation should deal with certain shortcomings of the Anatomy Act, 1832:

Doubts had been felt in some quarters' about the legality of post-mortem examinations for the purpose of medical research and teaching of pathology, outside the provisions of the Anatomy Acts 1832 and 1871. This doubt had arisen because Section 15 of the Anatomy Act, 1832, had made a saving only in respect of

⁶⁸ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

⁶⁹ The National Archives. Ref. CAB 134/80. Minutes of the Cabinet Home Affairs Committee. H.A. 105, 17 (4).

⁷⁰ The National Archives for Scotland. Ref. HH61/1055. Document 52: *Human Tissue Bill*. Memorandum by JB Hume, November 29, 1960.

post mortem examinations 'required or directed to be made by any competent legal authority'.⁷¹

It was pointed out to the HAC that it was the regular practice in many hospitals, with the consent of the relatives, to have a routine PM of a patient who had died in hospital, even where the cause of death may be certain, in order to study the effect of disease on the body. Tissues required for grafting were often removed in the process of such examination, and it was considered essential to remove any doubt about the legality of these activities, including the removal of tissues, where there was no objection. The memorandum also commended taking the opportunity to cover the *retention, with consent (my emphasis)*, of anatomical specimens removed for purposes of teaching and research during post mortem examinations carried out outside the Anatomy Act, as well as during anatomical dissection.⁷²

The minutes of the two meetings of HAC which considered the proposal to introduce new legislation appeared to reflect a quickening pace. At the meeting on November 24, 1960, the supporting papers from the Minister of Health and the Secretary of State for Scotland warned that the need to introduce the Bill urgently may arise either because the Medical Research Council may be pressed to develop new facilities for storing tissues taken from dead bodies, or the legality of current practices may be challenged, directly or indirectly, in a court.⁷³ The Minister was also mindful of the 'Nottingham case', as described above, although no specific mention was made of it either in his memorandum to HAC in November 1960, or in the minutes of the HAC meeting. HAC minuted that 'in view of the rapid development of the practices, now of doubtful legality, which the Bill would legalise, its introduction might at any time become a matter of urgency'. HAC changed its previous decision that the Bill would be suitable for introduction by a Private Member and approved instead that it should be introduced by the

⁷¹ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

⁷² Ibid.

⁷³ The National Archives. Ref. CAB134/83. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 163.

Government.⁷⁴ The Chairman of HAC (Rt Hon. RA Butler MP, Home Secretary) agreed in his capacity as Chairman of the Future Legislation Committee that a Bill should be drafted.⁷⁵ The path was clear to instruct Parliamentary Counsel.

3.3 Instructions to Parliamentary Counsel.

Parliamentary Counsel was requested to prepare a Bill:

to authorise the removal and retention of human tissues from dead bodies for therapeutic purposes or use in connection with medical and pathological research and education;

to clarify the law so as to ensure that post-mortems can be conducted, whether to ascertain the cause of death in a particular case or for the purposes of medical and pathological research and education, although not exempted from the provisions of the Anatomy Act, 1832, by section 15 of that Act; and

to amend Section 13 of the Anatomy Act, 1832, so as to enable bodies which have been the subject of anatomy under that Act to be cremated as an alternative to burial and to enable tissue obtained from such bodies to be retained for such period as may be required.⁷⁶

In the explanatory paragraphs that followed, attention was drawn to the Medical Amendment Act 1954 of New Zealand, which ‘followed to some extent the [UK] Corneal Grafting Act 1952’ but which was made to extend to removal of tissue from all parts of the body. Counsel was asked to consider whether the object of the Bill would be best achieved by amending the 1952 Act, or by repealing it and incorporating its provisions into the forthcoming Bill. The need to authorise the removal and retention of tissue for research and education, as well as for therapeutic purposes, was emphasized, as was the need for the cooperation of the coroner in allowing tissue removal for therapeutic cases in certain circumstances (for example, road traffic deaths) where an inquest was mandatory.

⁷⁴ The National Archives. Ref. CAB 134/80. Minutes of the Cabinet Home Affairs Committee. H.A. 163, 23 (7).

⁷⁵ The National Archives. Ref. CAB 134/80. Minutes of the Cabinet Home Affairs Committee. H.A. 105, 17 (4), op.cit.

⁷⁶ The National Archives. Ref. MH 58/497. *Human Tissue grafting Bill: instructions to Parliamentary Counsel*. Ministry of Health.

With regard to PMs, the Instructions pointed out the doubt which existed about whether the provisions of the Anatomy Acts of 1832 and 1871 prohibited PMs, other than those required or directed to be made by a competent legal authority, or whether the provisions of these Acts were limited to anatomical examinations carried out in schools of anatomy. The Instructions described the regular practice in many hospitals over many years to carry out routine PMs to discover the cause of death or for pathological research, 'unless there are express objections', and noted that these examinations had not conformed to the provisions of the Anatomy Acts. Furthermore tissues were often removed in the course of such examinations for the purposes of grafting and research. The Bill was to ensure that the Anatomy Acts did not in any way prohibit PMs carried out by a medical practitioner for the purposes of discovering or confirming the cause of death, medical or pathological research or education, or removal and retention of tissue for grafting, teaching or research. It was nevertheless desirable, the Instructions stated, that PMs carried out for medical or pathological purposes should be subject to similar authorisation as in s.1 of the Corneal Grafting Act, 1952.⁷⁷

There are several features, and some inconsistencies, in the Instructions to Counsel (which will have relevance later in this narrative), both as to the place of 'consent' and to the desirability of following the provisions of the Corneal Grafting Act 1952 and/or the then recent New Zealand legislation.

First, there was no mention in the Instructions of 'consent' (except for the need for the coroner's 'consent' in certain circumstances). Instead, the everyday practice of carrying out post-mortem examinations, 'unless there were express objections', was described. This was in contrast to the case which the Home Affairs Committee had approved, where the supporting Memorandum had mentioned consent explicitly⁷⁸. In the first paragraph of that Memorandum, headed 'Need for Bill', the first sentence approached the subject somewhat obliquely: 'It is uncertain

⁷⁷ Ibid.

⁷⁸ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

whether the removal of tissue from a dead body is lawful, even where consent has been given: and further, if retention with consent is lawful, whose consent is required⁷⁹. Later in the Memorandum, when discussing post mortem examinations, the need for consent was expressed unequivocally:

It would be desirable to...cover the retention, with consent, of anatomical specimens for teaching and research...Any such provision should apply to the retention (with consent) for purposes of teaching or research, of specimens removed during post mortem examinations carried out outside the Anatomy Act, as well as during anatomical dissection.⁸⁰

There were repeated references in the Instructions to Counsel to the provisions of the Corneal Grafting Act and the need for the Bill to incorporate its provisions. At the same time, Counsel was asked to note that the amendments made to the New Zealand Medical Act, 1908 by the Medical Amendment Act, 1954, 'followed to some extent the Corneal Grafting Act, 1952'. Specific attention was drawn to the new s.24A of the 1908 Act.⁸¹

When s.1(2) of the Corneal Grafting Act 1952 and s.24A of the New Zealand Medical Act 1908 (as amended)('the NZ Act') are compared there is little difference in the conditions attached to 'removal for therapeutic purposes.' Both Acts provided that a person, or the party lawfully in possession may authorise the removal of the eyes ['or any other part of the body' at s.24A of the NZ Act] from the body for therapeutic purposes unless the person in lawful possession had reason to believe that a) the deceased had expressed a prior objection and had not withdrawn it subsequently; or b) that the surviving spouse or any surviving relative objected. In s.1(2)(b) of the 1952 Act this objection had been stated directly in the phrase 'objected to the deceased's eyes being so dealt with'; in s.24A of the NZ Act the

⁷⁹ Ibid.

⁸⁰ Ibid.

⁸¹ One may also recall, as a measure of what was in the mind of the drafters of the Instructions, the correspondence with the New Zealand Department of Health saying 'we contemplate something very much on the lines of your Act'⁸¹.

proviso was ‘ that there was no reason to believe that the surviving spouse or any known relative required that the body be buried or cremated without such [tissue]removal’.

However, the amended NZ Act, unlike the Corneal Grafting Act 1952, had a further section, s24B, which legalised non coronial post mortems by providing for a post mortem examination for the purposes of medical research or the teaching of pathology to be carried out, with similar provisos to be satisfied as were to be operative in the removal of tissue for therapeutic purposes- with the important requirement that ‘the surviving husband or wife, or if there is no husband or wife known to be surviving and there is known to be a relative, any such relative, *consents (my emphasis) to a post mortem examination*’⁸².

3.3.1 Whatever happened, in drafting the Bill, to ‘retention’ and ‘consent’?

It will be noted that the Instructions to Parliamentary Counsel referred to ‘retention’ but not (except in a limited sense) to ‘consent’-in contrast to the memorandum to HAC, discussed above, which had specifically recognized the need for consent⁸³. Because both concepts were later to play such a prominent role in the scandals at Bristol⁸⁴ and Liverpool (Alder Hey)⁸⁵, as will discussed in detail in later chapters, it is important to trace now why neither term came to appear on the face of the Bill or in the subsequent Act.

On receipt of the instructions from the Ministry of Health, Parliamentary Counsel who was responsible for drafting the Bill (HF Rowe), raised some points in preliminary correspondence, which are worth quoting directly because, in my view

⁸² New Zealand Statutes. *The Medical Amendment Act 1954*, s. 2(2) (inserts s.24B into The Medical Act 1908).

⁸³ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

⁸⁴ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000.

⁸⁵ The Royal Liverpool Children’s Inquiry Report. Printed by order of the House of Commons, January 30 2001.

(and published by me elsewhere⁸⁶), they represent the very beginning of the ‘tissue retention’ controversies of later years. Rowe wrote:

I hope it will not be necessary to authorise the retention as well as the removal of tissue. Since the law does not recognise a right of property in a dead body it is difficult to see why such a provision should be necessary. S.13 of the Anatomy Act 1832 requires provision to be made for the interment of bodies removed under the Act...If this is all the law bearing on the point we can surely forget about retention? What the section requires is disposal of ‘such body’ ie a body which has been dissected. One does not have to go into details to see that, in the nature of things, the body cannot be as complete as it was before it was removed for ‘anatomical examination’. This is perhaps a matter of degree and I am not suggesting that the section would allow you to withhold whole limbs from interment; but so long as what was interred is ‘such body’, in ordinary parlance, I should have thought that the letter as well as the spirit of the law would be obeyed, notwithstanding that some part is retained. I need not remind you that the observations of Portia J on a related subject have been severely criticised by jurists.⁸⁷

I have been unable to find any challenge from the Ministry to Counsel’s proposal to remove ‘retention’ from the Bill. Instead one may note the response of the senior civil servant involved in preparing the Instructions, on receipt later of copies of the draft Bill (which contained no ‘consent’ and no mention of ‘retention’). ‘Thank you for... the prints of the very neat Bill you have drafted. It seems to us to cover admirably all that is required’.⁸⁸

Neither in Counsel’s preliminary letter, nor in any further correspondence about the draft Bill, was ‘consent’ mentioned, save where the role of the coroner was being discussed. Instead, there was a telling section in Counsel’s letter, which showed that, in his mind, legislation about postmortems was being clearly linked to the provisions of the Anatomy Act 1832. Rowe wrote:

Post mortem examinations seem to be rather more difficult than the removal of parts of the body. It would be easy enough (although probably not worthwhile) to

⁸⁶ McNeish AS. *Anticipating the Redfern inquiry: a historical note about tissue retention and consent*. J Clin Pathol 2009; 62(10):958-959.

⁸⁷ The National Archives. Ref MH58/497. Letter from HF Rowe (Office of the Parliamentary Counsel) to SD Musson, October 11, 1960.

⁸⁸ The National Archives. Ref. MH58/497. Letter from SD Musson to HF Rowe, October 21, 1960.

say something about post mortems carried out for the sake of finding or confirming the cause of death. When it comes to post mortems for the purposes of medical research and education I wonder how much of the 1832 Act can survive. This is perhaps the most difficult point, and a discussion would be very helpful.^{89 90}

The Anatomy Act 1832 did not refer to 'consent'. Rather, when referring to the veto of relatives in regard to an 'Anatomical Examination' which otherwise had been legitimised under the terms of the Act, it stated at sections 7 and 8: '[u]nless the surviving Husband or Wife, or any known Relative of the deceased Person, shall require the Body to be interred without such Examination'⁹¹. It is of interest that this is the form of words used in the New Zealand Amendment Act 1954 ('the NZ Act'), an Act to which Counsel's attention had been specifically drawn. It is clear, however, that Counsel ignored the use of 'consent' as it appeared elsewhere in the NZ Act, but chose instead to be influenced by the Instructions that had been given to him which had indicated that it was considered desirable that postmortems carried out for medical or pathological purposes 'should be subject to similar authorisation as in s.1 of the Corneal Grafting Act, 1952'⁹² (which required 'an absence of objection' from spouse or relatives).

There was one internal memorandum within the Ministry regarding consent which, in retrospect, went to the heart of a major misunderstanding which would be revealed at the Bristol Inquiry forty years later⁹³, but which, at the time of drafting the Bill, did not receive an extensive airing. The memorandum concerned the use of tissues from bodies subject to coroners' post mortem examinations, and had been written following a meeting between officials and the Minister about the draft

⁸⁹ The National Archives. Ref MH58/497. Letter from HF Rowe (Office of the Parliamentary Counsel) to SD Musson, October 11, 1960, op.cit.

⁹⁰ I have been unable to find evidence that further discussion ensued on this point.

⁹¹ *Anatomy Act, 1832* (c.75). ss7 and 8.

⁹² The National Archives. Ref. MH 58/497. *Human Tissue grafting Bill: instructions to Parliamentary Counsel*. Ministry of Health, op.cit.

⁹³ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, op.cit.

Bill and a subsequent conversation with an official from the Home Office. The note is worth quoting in full.

Provided the consent of the coroner is obtained in each individual case, the Home Office would not see any objection to the removal of tissues for therapeutic, educational or research purposes, either before, during or after a post mortem examination ordered by a coroner. You [SD Musson, Principal Assistant Solicitor of the Ministry of Health's legal division] consider that this is already covered by the terms of the draft bill but that we would want to ensure that, in such cases, the necessary consents were obtained under clause 1.⁹⁴

The context in which this memorandum was written was mainly a concern that tissue from victims of road traffic accidents (whose deaths would fall within a coroner's jurisdiction) should be able to be used for grafting.

It would appear that the Ministry officials who had drawn up the Instructions to Parliamentary Counsel, who were the same officials as had supplied briefing notes for the Minister in preparation for the meetings of the Home Affairs Committee, had also overlooked, when drawing up these Instructions, much earlier guidance from the Ministry of Health. As had been summarised in the Minister's briefing notes under 'provisions relating to consent', in 1952 the Ministry of Health had advised Hospital Boards and Management Committees that, the provisions of the Corneal Grafting Act 1952 notwithstanding, 'it was realised that it might be difficult and embarrassing to seek consent [for removal of eyes] so soon after death, but this was thought to be better than the alternative of relying on absence of objection'.⁹⁵ It is possible that the minds of officials really had been suffused by the hope, expressed in a still earlier internal memorandum, that, 'as enlightenment progresses public opinion will advance to the point where the consent of relatives need not be specifically sought'.⁹⁶

⁹⁴ The National Archives. Ref. MH58/497. Memorandum from D Emery to SD Musson, November 23, 1960.

⁹⁵ The National Archives. Ref. MH58/497. *Grafting of human tissue: notes for Minister*, July 1960, op.cit.

⁹⁶ The National Archives. Ref MH58/497. Memorandum from SI Smith to NM Goodman, [?initial] Henderson, SD Musson, June 22, 1960.

And so it was that neither ‘retention’ nor ‘consent’ appeared in the Bill which came before Parliament in late December 1960, by which time it had become mechanically possible (in experimental animals) to transplant organs, including lungs, kidneys, liver, and even heart, although immune rejection remained an impenetrable barrier to prolonged graft survival.⁹⁷ Indeed, in the months before the Bill came before Parliament, there had been newspaper reports of ‘another’ successful transfer of a kidney from one identical twin to the other⁹⁸, the first successful kidney transplant between two unrelated persons⁹⁹, and the award of the Nobel prize to Medawar and Burnett for the discovery of ‘acquired immunological tolerance’¹⁰⁰ (the basis of avoiding graft rejection). The stage was truly set.

4. The Human Tissue Act 1961 (‘1961 Act’).¹⁰¹

4.1 ‘Legitimation’: passage of the 1960-61 Human Tissue Bill (‘the Bill’)¹⁰²

At 10.56pm on the evening of December 20, 1960, in the House of Commons, the Parliamentary Secretary to the Minister of Health, Miss Edith Pitt MP, introduced the 1960-61 Human Tissue Bill at Second Reading, whose purpose was two-fold: first, to authorise, subject to a number of safeguards, the removal of parts of human bodies after death for therapeutic purposes or for purposes of medical education or research; and second, to put beyond doubt the legality of postmortem examinations, carried out by, or on the instructions of, registered medical practitioners.¹⁰³ Miss Pitt’s opening speech, which described the Bill as ‘[one which

⁹⁷ Woodruff MFA. *The transplantation of tissues and organs*. Oxford. Blackwell Scientific Publications, 1960.

⁹⁸ *The Times*. September 9, 1960, p7.

⁹⁹ *Ibid.*, September 8, 1960, p 9.

¹⁰⁰ *Ibid.*, October 21, p12.

¹⁰¹ *Human Tissue Act 1961*. (1961, c. 54.)

¹⁰² *Human Tissue Bill 1960* (Bill 46). December 6 1960.

¹⁰³ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1231.

is] mainly concerned with the removal of doubt, but [which] may nevertheless be described as wholly beneficial and in some cases a life-saving measure.¹⁰⁴, set a tone of optimism and confidence which permeated the ensuing debate. Most MPs who spoke that evening focused on organ and tissue transplantation. Questions about the clauses that concerned post mortem examinations were largely for the purpose of clarification only, and provoked little discussion.

A striking illustration of the change in attitude that must have occurred throughout the 1950s, towards cadaveric transplantation at least, was given by Kenneth Robinson MP early in the debate during Second Reading of the Bill. Having reminisced about the circumstances in which the Corneal Grafting Act 1952 had been passed following a Private Member's Bill, he said: 'We have come some way in that today this Bill is being brought forward openly and officially by the Minister of Health as a Government Measure. This is a revolution in thought that we can all welcome'.¹⁰⁵

The Bill had three clauses. Clause 1 authorised, subject to important safeguards, the removal of any part of a dead body for therapeutic purposes, or for purposes of education and research. Clause 2 made lawful postmortem examinations carried out by, or on the instructions of, a doctor and performed for the purposes of determining or confirming the cause of death, or for investigating the nature of underlying disease or abnormality in the interests of teaching and research; thereby removing doubts about the legality of such examinations under the Anatomy Act 1832. Clause 3 amended the 1832 Act by permitting a body which had been anatomically examined under that Act to be cremated.

The atmosphere throughout the second reading of the Bill in Parliament was uniformly supportive of the objects of the Bill, and at times it bordered on the euphoric. Although the driving force behind the development of new legislation was the wish to enhance opportunities for transplantation, the needs of research

¹⁰⁴ Ibid.

¹⁰⁵ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1236.

and education were also recognised in the debate. Miss Edith Pitt MP, when presenting the Bill, emphasised the importance of disseminating knowledge and encouraging research¹⁰⁶, and of putting beyond doubt the lawfulness of what the medical profession required for the improvement of treatment, education and research.¹⁰⁷ Miss Joan Vickers MP endorsed these points, recognising that, not only could tissues be used to cure people who were ill, but they could also be used for research into diseases about which little was known.¹⁰⁸ To the mind of Lord Balniel MP, it was infinitely wonderful that, by this Bill, medical science would be able to create something approaching the immortality of the living cell, because the living cell would be able to be transferred from generation to generation, creating with it new health.¹⁰⁹ Dr Horace King MP suggested that the Government might raise the matter with the United Nations, with the aim of building up, as part of world civilisation, a great tissue bank whereby the dead would be helping the living.¹¹⁰

The tone of the evening was perhaps best summarised by the view of Miss Vickers MP that the name of the Bill was unfortunate, and should be changed to the 'Human Aid to Medical Science Bill'.¹¹¹

There was a delay of nearly six months before the Committee stage in the House of Commons was reached, balked by other [non tissue related] controversies.¹¹²

During the Committee stage, nine amendments were proposed, which focused on: a definition of 'last illness'; a wish to define the Hospital Management Committee as 'the person in lawful possession'; a requirement that the person in lawful possession 'shall' (rather than 'may') authorise; the possible illegality of moving the

¹⁰⁶ Ibid., 1232.

¹⁰⁷ Ibid., 1235.

¹⁰⁸ Ibid., 1239.

¹⁰⁹ Ibid., 1246.

¹¹⁰ Ibid., 1243.

¹¹¹ Ibid., 1238.

¹¹² Medical notes in Parliament. *Bills in danger of extinction*. BMJ 1961; 2(5243): 59-60.

body from one hospital to another in order that research may be carried out; a consent [sic] form, agreeing to the use of body parts in the case of death while in hospital, to be endorsed by the relatives; a need to specify procedures to determine death; ability for donor to specify the purposes for which his or her body parts will be used; the need for publicity to increase the number of donors; the need ensure that the jurisdiction of coroners was not encroached upon.¹¹³ The Minister of Health, in response to a question about the amendments from the Chief Whip before the Committee stage of the Bill, had written 'There are nine altogether. None is wrecking. I would propose to accept two or three for peace's sake'¹¹⁴. This exchange gives a small insight into how amendments may be viewed by the relevant Ministry, and is a partial illustration of Drewry's point that, by the time a Bill reaches Parliament it will already have been subjected to much discussion and negotiation, so that 'Ministers are usually reluctant to concede new amendments'^{115 116}. In the end, no amendment to the Bill was accepted.¹¹⁷

The Bill's passage through the House of Lords stages was equally smooth^{118 119 120}, with no amendments. As in the Lower House, such debate as there was concentrated on organ transplantation: with Peers welcoming the advances in science, and the opportunity no longer to need despair that one's life's work had been valueless to the community- because the Bill would allow another chance after death in this world.¹²¹

¹¹³ Ibid.

¹¹⁴ The National Archives. Ref. MH58/497. Memorandum from J Enoch Powell to Sir Martin Redmayne, March 21, 1961.

¹¹⁵ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110, p108.

¹¹⁶ This feature of 'legitimation' will appear prominently in the considerations in Chapter Four.

¹¹⁷ (1961) 643 Parl.Deb. (Hansard, 5th series), HC 819- 851.

¹¹⁸ (1961) 233 Parl.Deb. (Hansard, 5th series) HL 54- 69.

¹¹⁹ (1961) 233 Parl.Deb. (Hansard, 5th series) HL 545.

¹²⁰ (1961) 233 Parl.Deb. (Hansard, 5th series) HL 1051-1053.

¹²¹ (1961) 233 Parl.Deb. (Hansard, 5th series) HL 61.

There were only two significant contributions in the House of Lords concerning 'consent', which gave further illustration of the prevailing attitudes of the time. Lord Newton, when introducing the Bill at Second Reading, referred to the Minister of Health as having been:

[a]t great pains to consider the feelings of those who may have scruples about its provisions. There are careful safeguards. I know that some people think they are too careful. But, my Lords, even though public sentiment to-day may be far removed from what it was in 1829 or 1832, it is still essential, in my judgment, to avoid the risk of causing offence. To cause offence would not only be wrong but might even defeat the whole object of the exercise.¹²²

Lord Amulree, a medical doctor, having stressed the importance of post mortem examinations for investigation or research, recalled the manner in which 'obtaining' a post mortem was carried out in his younger days, and compared it with then current practice as he observed it:

One wonders whether the actual mechanism for obtaining a post-mortem is not now a little complicated and difficult. When I was young it was in a way simpler, but perhaps rather more callous. A notice was put up at the entrance to the hospital saying that supposing a patient were to die in the hospital a post-mortem examination would be carried out provided the relatives did not object. That sounds somewhat callous, I agree, but I wonder whether it is more callous or more difficult than what is done at the present time. When a patient dies the examination has to be carried out fairly soon after death and sometimes the relatives are approached by a rather embarrassed and often young doctor with a request that a post-mortem examination should be carried out. It is difficult for relatives to make up their minds within such a short time of the death of someone who is dear to them, and on a number of occasions they refuse because they say, quite sincerely, that their relative has suffered enough and they do not want anything more to be done. I wonder whether something more approaching the other practice could not be made possible, because no relative need, or should, be able to see any of the signs of the examination when the body is given back to them for burial.¹²³

¹²² (1961) 233 Parl.Deb. (Hansard, 5th series) HL 55.

¹²³ (1961) 233 Parl.Deb. (Hansard, 5th series) HL 65.

The proceedings in the House of Lords were completed after Third Reading on July 26, 1961, the Human Tissue Act 1961 received Royal Assent the next day and was in force two months later.¹²⁴

4.2 Further consideration of aspects of the 1961 Act which would reappear as issues of concern in the years to come.

4.2.1 Retention of organs and tissues.

With regard to retention, the view of Counsel prevailed, as described above, in that the Bill (and the 1961 Act) ‘made provision with respect to the use of body parts of deceased persons’, whereby a person, or after death the person in lawful possession, could authorise ‘removal...for use’ of any part of the body for therapeutic purposes or for medical education or research. It is arguable that the minds of MPs were so concentrated on organ transplantation, a procedure in which the organ is taken and has to be used with the minimum of delay, that ‘removal for use’ appeared to describe an operational necessity, and the concept of ‘retention’ did not arise. Yet it has to be noted that, in the years following the Corneal Grafting Act 1952, ‘banks’ of corneas had been established in several important Eye Hospitals¹²⁵, without the term ‘retention’ appearing in that Act, and without adverse comment subsequently.

The brief prepared by officials for Miss Pitt contained one reference to retention.¹²⁶ Miss Pitt adhered faithfully to that brief by stating in the early paragraphs of her introduction of the Bill the importance of encouraging the dissemination of knowledge and the progress of research by ‘the study and, if need be, the retention of parts of the body, essential for this purpose’.¹²⁷ However, when she came to

¹²⁴ *Human Tissue Act 1961*, (1961, c. 54.)

¹²⁵ Billingham RE, Rycroft BW. *The preservation of the donor graft*. In: Rycroft BW (ed.) *Corneal Grafts*. London, Butterworth & Co. (Publishers) Ltd., 1955, at p201.

¹²⁶ The National Archives for Scotland. Ref.HH 61/1055. *Human Tissue Bill: brief for second reading*. December 16, 1960.

¹²⁷ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1232.

introduce the contents of the Bill, clause by clause, 'retention' did not reappear. When outlining the clause on post-mortems (the section which would lead to so much grief forty years later), Miss Pitt confined her remarks to emphasising that the purpose of the Bill was to set to rest the doubts that such examinations, which were carried out for the purpose of establishing the cause of death or of investigating the existence of any abnormal condition of the body, were entirely lawful.

4.2.2 'No objection'.

With regard to 'no objection' as compared to 'consent' during passage of the Bill through the House of Commons, it is possible that MPs were deflected by remarks made by the Under Secretary, Miss Pitt, early in her introduction of the Bill. She drew attention to the requirement to 'make such reasonable enquiry as shall be practicable', a requirement which had been absent from the Corneal Grafting Act 1952, and then recalled the strong advice which had been given by the Ministry to hospital management about that Act, that they should not rely on the powers given in the Act to remove eyes in the absence of known objection, but, wherever relatives were available, to seek their consent.¹²⁸ Miss Pitt went on to say that it was proposed to recommend to hospital authorities to adopt the same procedure of obtaining the consent of relatives where they were available in relation to any part of the body as authorised by the present Bill.¹²⁹ No speaker returned subsequently to this issue. [The document (H.M.(61) 98)¹³⁰ that was later sent to Regional Boards, Boards of Governance and Hospital Management Committees was at variance with Miss Pitt's expressed proposal. H.M.(61) 98, issued by the Ministry of Health on September 19, 1961, one week before the Human Tissue Act 1961 came into force, stated:

¹²⁸ The National Archives. Ref. MH58/502. *Corneal Grafting Act*. NHS Memorandum RHB(52)77,HMC(52)70,BG(52)74. June 26, 1952, para 4.

¹²⁹ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1233.

¹³⁰ Ministry of Health. H.M.(61)98. *National Health Service: Human Tissue Act 1961*, para 8.

The nearest relative available should be asked if he objects, or has reason to believe that any other relative would object, but hospital authorities are not expected to ask that relative for a statement that no other relatives object. Every care must be taken to record, and give effect to objections from patients or relatives...]¹³¹

Lord Balniel had said in his speech in the Commons ‘Permission under the Bill has to be obtained from any surviving relative. My Rt. Hon. Friend (the Minister of Health) shakes his head, but I think I am right- that permission has to be obtained from the spouse or any surviving relative’.¹³² Later, in his closing speech, the Minister corrected his noble Friend, pointing out that the expression ‘permission of a surviving relative’ was not strictly accurate. ‘The reference is to having “no reason” after “reasonable enquiry” “to believe” that “any surviving relative” objects’.¹³³ The Minister did not enlarge on Lord Balniel’s misreading, or perhaps misinterpretation, of the wording of the Bill, (nor did it become clear how many MPs, if any, endorsed his Lordship’s interpretation of the Bill), but instead went on to deal with the scope of ‘any surviving relative’, which in fact had been his Lordship’s substantive point.

A small number of speakers took the opposite tack and regretted that the Bill would allow relatives to veto the wishes of the deceased. This was said by the Minister to be a misreading. In correcting it, the Minister said that the surviving relative only came in where there had been no specific desire known of the deceased person, and where therefore it was right to be sure that the deceased had not objected himself to his body being so used, and that this being done would not ‘outrage the surviving spouse or any- I repeat any- surviving relative’.¹³⁴ Earlier, in response to a question as to why ‘any surviving relative’ had not been defined, the Minister believed that it would be wrong to need to inquire into the degree of consanguinity of any relative who expressed objection, because he was ‘convinced that far more harm would be done to the cause which the House of Commons had at heart that

¹³¹ Ibid.

¹³² (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1247.

¹³³ Ibid., 1256.

¹³⁴ Ibid., 1257.

night by a single case in which a strongly held scruple was overridden than a temporary loss of opportunity'.¹³⁵ The emphasis on the respect which the negative views of *any* surviving relative should be shown, together with Miss Pitt's earlier indication that it would be preferable to seek positive consent (a recommendation repeated by Lord Newton when introducing the Bill in the House of Lords¹³⁶), are clear indications to me that the Government had wished such reasonable inquiry as may be practicable to be made assiduously, and for strongly held objections to be respected without demur.

4.2.3 Expressions of concern from members of the public.

After Second Reading of the Bill, the Ministry received a number of letters from members of the public which have been preserved in the National Archives.^{137 138}

¹³⁹ All expressed concerns: many were abusive. One is worthy of quotation, because its contents could have contributed to the debate, then and subsequently. The writer had proposed that only written permission from the donor should be acceptable. He was suspicious about the scale of 'such reasonable inquiry as shall be practicable', opining that 'no surgeon is likely to make more than perfunctory efforts to defeat his own object'.¹⁴⁰ The official reply restated the objects of the Bill, and indicated the Minister's view that, if, in the years ahead, sufficient people bequeathed their eyes, then the involvement of relatives would be spared.¹⁴¹ I have found no evidence, direct or indirect, that these expressions of 'public opinion' had any influence on the content of the Bill, or on the debates: a situation in complete

¹³⁵ Ibid., 1256.

¹³⁶ (1961) 233 Parl. Deb. (Hansard, 5th series) HL 57.

¹³⁷ The National Archives. Ref. MH58/497. Letter from HC Evans to the Prime Minister (Rt Hon Harold Macmillan MP), undated.

¹³⁸ Ibid. Letter from N B---[illegible] to 'Ministry of Health', July 4, 1961.

¹³⁹ Ibid. Letter from WL Mancey to the Minister of Health. January 2, 1961.

¹⁴⁰ Ibid.

¹⁴¹ Ibid. Letter from PH Hardwick to WL Mancey, undated.

contrast to that which would be dominant in the aftermath of the ‘organ scandals’ forty years later and discussed in Chapters Four and Five.

4.2.4 ‘The person in lawful possession’.

4.2.4.1 Identity.

Several members of both Houses emphasised the need for clarity in defining the identity and scope of responsibility of ‘the person lawfully in possession of the body’ who may under the Act (s.1) authorise removal of any part of the body for purposes made legal under the Act¹⁴²; and whose authorisation was necessary, under s.2, before a (non- coronial) PM could be carried out.¹⁴³ The phrase had had its origin in the Anatomy Act 1832, where, at s.7, the relevant person had been defined as ‘any Executor or other Party having lawful Possession of the Body of any deceased Person, and not being an Undertaker or other Party intrusted (sic) with the Body for the Purpose only of Interment.’¹⁴⁴

Kenneth Robinson MP ‘had not been able to discover very much about this person who appeared for the first time in the Anatomy Act’ except to understand that he was not the next of kin, but might be the executor, a group of persons, a body corporate, the master of a workhouse or even a mortuary keeper (acting as agent for some authority).¹⁴⁵ In reply, the Minister of Health reminded the House that in law there was no property in a dead body. He had been advised that the person in legal possession ‘would include’, in the case of a person dying in hospital, a hospital authority, but not a mortuary attendant.¹⁴⁶ The Minister made no comment about the other examples on Robinson’s list.¹⁴⁷ In the House of Lords, at Second Reading,

¹⁴² *Human Tissue Act 1961*, s.1(2).

¹⁴³ *Ibid.* s.2(2)

¹⁴⁴ *Anatomy Act 1832*, s.7.

¹⁴⁵ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1237.

¹⁴⁶ *Ibid.* 1254.

¹⁴⁷ There is further discussion about these points in Chapter Two.

Lord Newton had indicated that the ‘person’ in lawful possession, although not defined in the Bill, was, in the case of a hospital, the managers, until the executors or relatives come to claim the body.¹⁴⁸ A wish, by way of a proposed amendment at Committee stage in the House of Commons that the Bill should define that, in the case of a death in hospital, the hospital management committee or equivalent was the body ‘in lawful possession’, had been resisted. The Minister said that such designation could have denied the relatives or the executors possession of the body and could have allowed the hospital committee to take their stand against all comers.¹⁴⁹

4.2.4.2 Does the person in lawful possession have discretion?

The question of whether the person in legal possession had discretion in discharging his or her duties was considered in both Houses. Both clauses 1(1) and 1(2) of the Bill stated that the person ‘may’ authorise removal of the body, or its parts. In the House of Commons, the Minister emphasised that there was no question of vetoing a deceased person’s declared wishes.¹⁵⁰ In the Upper House, Lord Newton, replying for the Government, said that, if it were made compulsory by substituting ‘shall’ for ‘may’, there would have to be a penal clause in the Bill – and to punish non-compliance would be inappropriate in the circumstances.¹⁵¹ Substituting ‘shall’ for ‘may’ had also been raised at the Committee stage in the House of Commons, but an amendment had been resisted.¹⁵²

5. Summary.

The approach taken in the 1961 Act was permissive, and overtly utilitarian, and aimed to enhance opportunities, particularly for transplantation, but also for

¹⁴⁸ (1961) 233 Parl. Deb.(Hansard, 5th series), HL 57.

¹⁴⁹ (1961) 643 Parl. Deb. (Hansard, 5th series), HC 836.

¹⁵⁰ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1257.

¹⁵¹ (1961) 233 Parl. Deb. (Hansard, 5th series), HL 69.

¹⁵² (1961) 643 Parl. Deb.(Hansard, 5th series) HC 823.

education and research. By building on the experience of the Corneal Grafting Act 1952 (which had recognised that there was a small minority of altruistic individuals who desired to benefit mankind by putting their eyes to use after death), it established a mechanism whereby the deceased's wishes, expressed during life, could be respected. Hope was expressed by several members during the debates that, over time, increasing numbers of people would indicate their wish to have their organs and tissues used after death.^{153 154} The need for publicity and 'propaganda' to increase public awareness was repeatedly emphasised by both Houses, with the hope that it would result in increasing numbers of people willing to permit their body, or its parts, to be used under the provisions of the Act. The hope was that relatives would come to share the views expressed by Lord Balniel MP. His Lordship had resolved his initial instincts, 'some of the most deeply felt instincts of man'¹⁵⁵ - that the human body, once life has been extinguished from it, should be treated with the utmost dignity and respect, and that, pending burial or cremation, it should be left in peace- by the knowledge that tissues and organs from the dead could in future be used to bring health (he hoped for happiness also) 'to those who, because of misfortune or disease, are deprived of the good health that most of us enjoy'.¹⁵⁶

The account so far has supported the usefulness of Drewry's model of the law making process, or at least of the first three (of five) steps, which have taken the analysis as far as 'legitimation'. The boundaries between the steps may have appeared a little blurred, in that, for example, the internal exchanges among the civil servants when assembling components of the 'inspiration' phase were 'deliberative', and soon began to contain the outline of what would become the framework for new legislation- the stage of 'formulation'. However, from the evidence so far, the model is sound, and is applicable to the task in hand.

¹⁵³ (1961) 643 Parl. Deb. (Hansard, 5th series), HC 842.

¹⁵⁴ (1961) 233 Parl. Deb. (Hansard, 5th series), HL 1053

¹⁵⁵ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1245.

¹⁵⁶ Ibid.

As predicted by Drewry, it has been difficult to identify a single source for the original idea that led to new legislation. However, I believe it has been possible to untangle to some extent the 'confusing mixture of different possibilities' which Drewry described as the usual outcome of such an endeavour¹⁵⁷.

With regard to the unsatisfactory state of the law *per se* as a primary factor in triggering new legislation, there is no question that the success of the 1952 Act brought, at the same time, its narrowness into focus- at least for those who were knowledgeable about such matters. Dr George Godber, the then Deputy Chief Medical Officer, in a letter in late 1959 about bone banking, recognised that 'we are up against the old (sic) problem of the legality of taking human tissue from cadavers'¹⁵⁸. Professor MFA Woodruff, a distinguished renal surgeon, had been able to draw attention to the Medical Amendment Act 1954 in New Zealand as a shining example of enlightened legislation but of no help to patients in the United Kingdom.¹⁵⁹ Senior figures in the medical Royal Colleges had been concerned, and had communicated their concern to the highest law officers in the land in 1958. One of their number, the President of the Royal College of Surgeons of England, was also, *ad hominem*, the Consultant Adviser in Surgery to the Ministry of Health, which double appointment reinforces, it may be noted in passing, apparent evidence of a close and interconnected advisory (and sometimes advocacy) network surrounding the Ministry.

The position of the SAMOs, agents of the Ministry of Health in each Health Region of England and Wales, was particularly uncomfortable as they apparently tried to reconcile their professional allegiance (as medically qualified doctors working in proximity to clinical colleagues) with their employment as government officials. Dr Godber, to whom they reported, described their dichotomous position in regard to tissue banks in early 1960 as being aware of various attempts to maintain tissue

¹⁵⁷ Drewry G. *Law-making systems: how to compare*. Statute Law Review 2008; 29(2): 100-110 op.cit., p108.

¹⁵⁸ The National Archives. Ref. FD23/2008. Letter from GE Godber to FJC Herralld, November 5, 1959.

¹⁵⁹ Woodruff MFA. *Legal aspects of homografting*. Lancet 1960; 275(7129):874, op.cit.

banks, while ‘avoiding learning too much because they were really uncertain of the legal position’.¹⁶⁰

It is interesting to observe the ‘blind eye’ that had been turned in several quarters throughout the decade that preceded the decision to legislate. It had occurred, on advice, in Parliamentarians, as recounted by the Rt. Hon. Kenneth Robinson MP.¹⁶¹ It had been found in the senior law officers in both England and Scotland, at least as recorded in Ministry of Health memoranda. It had almost certainly been a feature of coronial practice, although the evidence for complicity or acquiescence is indirect. It certainly had been the shared view of senior ministry officials who had believed that an attempt to clarify the legal position would have made the then current work in surgical research difficult before it could be concluded that the work did have a future in established clinical practice.¹⁶²

Alongside those ‘in the know’, one can imagine that there must have been many conscientious doctors and researchers who had gone about their daily routine unaware that their work might have been of questionable legality. Even when new legislation was before Parliament, there were those who thought it would be of little importance. An internal memorandum of the time between colleagues at the MRC reported that ‘the Human Tissue Bill has now passed its Second Reading but is not being given great priority because it will have little importance in practice’.¹⁶³ Here perhaps is a clue which helps to confirm that the ethos of the legislation was permissive, ‘to put beyond doubt what the medical profession requires’, in the words of Edith Pitt MP¹⁶⁴.

¹⁶⁰ The National Archives. Ref FD23/2008. Letter from GE Godber to FJC Herrald, February 23, 1961.

¹⁶¹ (1960) 632 Parl. Deb.(Hansard, 5th series), HC 1235.

¹⁶² The National Archives. Ref. MH58/497. Letter from GE Godber to JE Pater, November 18, 1959, op.cit.

¹⁶³ The National Archives. Ref. FD9/4607. Memorandum from JE Hay to (?initial) Whittaker, [undated] 1961.

¹⁶⁴ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1235

It is difficult to express on paper the power of advances in scientific and clinical research to generate excitement and focused commitment in its professional exponents and devotees. The climate was described graphically if parochially by a distinguished Professor of Pathology in the early 1950s, that 'the last fifty years have seen greater advances in the treatment of disease than in all the rest of the five hundred years since this [Glasgow] University has been founded [in 1451], and that that progress has been almost wholly the outcome of pursuit of knowledge in the basic sciences'.¹⁶⁵ In the field of tissue grafting, the prime focus of the legislation, the publicity given to early successes in kidney transplantation and the award of the Nobel prize for fundamental work in the field were timely, to say the least. This excitement had been picked up by civil servants, who described tissue grafting as a practice which was already of importance in saving or prolonging life, and which was likely to develop further and increase in importance.¹⁶⁶ Focused commitment, combined perhaps with the sentiment that nothing should be allowed to stand in the way of medical progress, was exemplified by the tone of Dr Seddon's letter to the MRC, already referred to, 'And now, just when we are ready to put [bone banking] on a proper footing, this legal question crops up...if the MRC and the Ministry of Health do not move soon then I think we shall have to consider taking independent action and damning the consequences'.¹⁶⁷ Indeed, this letter, and the surrounding issues concerning freeze dried bone for grafting, may be seen as true tipping points in the decision to proceed with legislation.

It is difficult to be certain about the role of the Press in shaping or timing the legislation. There is no doubt that, during early months of 1960, Ministry officials were aware of: 'the advantages of choosing our own time rather than risk being

¹⁶⁵ Cappell DF. *Muir's textbook of pathology: Preface*. Cappell DF (Ed.). 6th edition. London and Edinburgh. Edward Arnold and Co., 1951, p iv.

¹⁶⁶ The National Archives. Ref. MH58/497. *Grafting of human tissue: notes for Minister*, July 1960, op.cit.

¹⁶⁷ The National Archives. Ref. FD 23/2008. Letter from HJ Seddon to FJC Herrald, April 1 1960.

forced into action by some mischance'¹⁶⁸; and 'the increasing use of tissue (which naturally receives publicity in the medical press) makes it clear that action will need to be taken soon'¹⁶⁹; and 'the interest indicated by recent articles in the medical and lay press make it not impossible that we may be challenged'¹⁷⁰. The late inclusion in the Bill of provisions regarding post mortem examinations appears from the archives to have been influenced by the chance misbehaviour of an errant mortuary attendant, albeit against a background of some general unease about whether or not the saving by virtue of s.15 of the Anatomy Act 1832 applied to hospital post mortems.

The archival papers which relate to the formulation of the Bill have similar emphases to the Parliamentary debates which followed, namely, that this was a piece of legislation which was required to allow the exciting developments in tissue and organ transplantation to succeed; and that the legalising of hospital post mortem examinations was a tidying up exercise. To my reading, it was the primacy of 'grafting' in everyone's mind which led to 'retention' and 'consent' being lost from the face of the Human Tissue Act 1961.

I have already suggested that the terms of the Act- removal of tissue for use- fitted the operational reality of a transplant procedure in which the concept of 'retention' was irrelevant. With regard to the absence of 'retention' as it might otherwise relate to hospital PMs, it would have been common knowledge to those who understood the detail of what was involved that tissue would be retained for microscopic and other detailed examination *as part of the normal PM process (my emphasis)*. Such persons with expert knowledge would have seen no need to embellish a reference to the process, and I stress process, of post mortem examination with the term 'retention'. With regard to coronial post mortems, Rule

¹⁶⁸ The National Archives. Ref MH 58/497. Letter from GE Godber to JE Pater, January 29 1960, op.cit.

¹⁶⁹ The National Archives. Ref. MH58/497. *Grafting of human tissue: notes for Minister*, July 1960, op.cit.

¹⁷⁰ The National Archives. Ref. MH58/497. Memorandum from SI Smith to D Emery, undated (?June 1960)

6 (later 9) of the Coroners Rules required that the person making a post mortem examination shall have made provision, so far as was possible, for the preservation of material which in his opinion bore upon the cause of death for such period as the coroner thought fit.¹⁷¹ It would be many years later before it emerged that communication between pathologist and Coroner (Procurator Fiscal in Scotland), in retrospect self evidently needed to determine the required period of ‘preservation of material’, was imperfect, or even absent from routine practice (see Chapters Four and Five). In 1960, details of what was involved in a PM would have been unknown to the majority of Parliamentarians, and perhaps to Parliamentary Counsel, and any possible advantages of amending the wording of the Bill in this regard could not have been recognised. Further, the minority of Parliamentarians with medical qualifications may have wished, as would emerge later as a widespread medical view, to spare their colleagues from the details of what happened at post-mortems.

It is likely that the use by Parliamentary Counsel of the content of the Corneal Grafting Act 1952 as a template for the Human Tissue Bill was the main explanation for the use of ‘no objection’ in the Bill. In addition, it may have been easy for readers of the Bill to have invested the two terms, ‘consent’ and ‘no objection’, with an equivalence in their minds- a mistake which Lord Balniel had made when he used the phrase ‘permission of relatives’ before having to be corrected by the Minister. It will be recalled that, the concept of an absence of objection notwithstanding, that it had been the explicit intention of the Government, as stated by Miss Pitts MP at second reading in the House of Commons, to give to hospitals the same advice as had been given to them after the passage of the Corneal Grafting Bill, namely that that they should actively seek the consent of all available relatives [for grafting to be carried out]. The intention to reissue such advice was reiterated by Lord Newton in the House of Lords.¹⁷² I have been unable to find evidence that such advice *was* given to hospitals. Instead, circular H.M. (61)

¹⁷¹ *Coroners Rules, 1953* (S.I. 1953, No. 205.)

¹⁷² (1961) 233 Parl. Deb. Hansard, 5th series), HL 57.

98, which was issued to hospital authorities one week before the Human Tissue Act 1961 came into force, and which has already been referred to above, was couched in terms of 'objections'¹⁷³. [It should be noted for reference that, in 1975, H.M.(61)98 was superseded by a circular from the Department of Health and Social Security (DHSS), HSC(IS)156, which was sent to Regional Health Authorities, Area Health Authorities, Boards of Governors, and Family Practitioner Committees.¹⁷⁴ The purpose of the new circular, issued fourteen years after the 1961 Act had come into force, was to 'clarify points of doubt which have arisen from experience of operating the Act'. The document reiterated the earlier position, namely that, when the views of surviving spouse or nearest relatives were being sought, 'specific consent is not necessary, merely an absence of objection'¹⁷⁵. I shall return more fully to this document and its significance in Chapter Two.]

Finally, what of the likely longevity of the 1961 Act, which had been launched in high hope? Dr Dickson Mabon MP believed that the general terms of the Act were such as would be able to meet almost any foreseeable developments in medical science.¹⁷⁶ In contrast, Baroness Summerskill supposed that, a hundred years hence, the Act would be seen as unprogressive because it had been unable to anticipate the tremendous progress that had come about in the meantime.¹⁷⁷ Was either right?

¹⁷³ Ministry of Health. H.M.(61)98. *National Health Service: Human Tissue Act 1961, op.cit.*, para 8.

¹⁷⁴ Department of Health and Social Security. HSC(IS) 156. *Guidance circular to NHS Authorities: Human Tissue Act 1961*. June 1975.

¹⁷⁵ *Ibid.*, para 11.

¹⁷⁶ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1252.

¹⁷⁷ (1961) 233 Parl. Deb. (Hansard, 5th series), HL 60.

CHAPTER TWO.

Human Tissue Act 1961: execution, application and feedback.

1. Preamble: the desirability of post- legislative scrutiny.

The main driving force behind the 1961 Act was the need to legitimise organ transplantation. At the time, clinical feasibility was virtually confined to kidneys, but doctors hoped that it would become possible in due course to be able to transplant other organs and tissues as well. Two Parliamentarians had taken opposing views as to whether or not the provisions of the Act would prove in the long run to be adequate to meet the consequences of further and inevitable advances in clinical science.^{1 2} Assessing who was right would require ‘feedback’.

Within Drewry’s ‘systems’ model of the legislative process, the composite of feedback and its analysis could be termed post-legislative scrutiny. The components of a feedback loop might include experiences of those professionally involved in implementing or interpreting the legislation, the response of the public to the legislation as experienced ‘on the street’, and the activities of the mass media in interpreting or influencing public opinion.³ However these measures fall far short of a *systematic* approach to post -legislative scrutiny, an area of activity which has been reviewed in recent years by both the House of Lords Select Committee on the Constitution⁴ (‘HL Select Committee’) and the Law Commission.⁵

In evidence to HL Select Committee in 2004, Jean Corston MP, Chairman of the Joint Committee on Human Rights, wrote:

¹ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1252.

² (1961) 233 Parl. Deb. (Hansard, 5th series), HL 60.

³ Drewry G. *Legislation*. In Ryle M, Richards PG (eds.) *The Commons under scrutiny*. Third edition. London, Routledge, 1988, at p125.

⁴ House of Lords Select Committee on the Constitution. 14th Report of the session 2003-04. *Parliament and the legislative process*. HL Paper 173-1. Volumes I and II.

⁵ Law Commission (Law Com No.302). *Post-legislative scrutiny*. Cmd 6945, October 2006.

As legislators, we need to pay as much attention to what happens after we have finished our specialised task of making the law as we do to the process by which we achieve the law. The professional deformation against which we perhaps have to be most wary is supposing that legislating is the most effective way to achieve our ambitions, and that law making is a precise science which can result in a perfect product. Our responsibility does not begin with a Bill's introduction into Parliament or end with the Royal Assent.⁶

One might have expected that a process with the importance ascribed by Corston would already have been used regularly, or even systematically. Evidence given to HL Select Committee suggested otherwise. As Sir Michael Wheeler-Booth and Professor Vernon Bogdanor put it, 'all too often Parliament forgets about legislation once it has reached the statute book'.⁷ The Select Committee's Report recognised that there were occasions when some post-legislative scrutiny had occurred but, it was 'patchy at best'⁸, and tended to occur because of a realisation that something had gone wrong.⁹

The HL Select Committee defined post-legislative scrutiny as:

[a] broad form of review, the purpose of which is to address the effects of the legislation in terms of whether the intended policy objectives have been met by the legislation, and if so, how effectively. However, this does not preclude consideration of narrow questions of a purely legal or technical nature.¹⁰

and recommended that:

Most Acts, other than Finance Acts, should normally be subject to review within three years of their commencement, or six years following their enactment, whichever is the sooner.¹¹

⁶ House of Lords Select Committee on the Constitution. 14th Report of the session 2003-04. *Parliament and the legislative process*. HL Paper 173-1, op.cit, Volume I, p42, para 166.

⁷ Ibid., p42, para 167.

⁸ Ibid.

⁹ Ibid., p42, para 168.

¹⁰ Ibid., Part 2, para 2.4.

¹¹ Ibid., p44, para 180.

The Government agreed in principle, subject to resources being available, and provided that the process of post legislative scrutiny did not prevent the Government from carrying out the work it was elected to do.¹² The Law Commission was asked to consider the options which could strengthen post-legislative scrutiny further. The Commission's recommendations will be considered further in Chapter Six.

The HL Select Committee and the Law Commission reported in 2004 and 2006, respectively, many years after the era of implementation of the Human Tissue Act 1961. In the light of the HL Select Committee's finding of only patchy post-legislative scrutiny in the ten years before 2004 covered by its Report, it would be unreasonable to expect evidence of a systematic process of review of the 1961 Act in the 1960s and 1970s. Nevertheless, there will inevitably have been at least an erratic flow of information back to the Ministry of Health and its successor Departments as to whether or not the objectives of the 1961 legislation were being achieved, and whether any problems had occurred. I believe that it is not too fanciful to imagine the flow of information as accumulating in a Departmental 'in tray', over which officials would at least have cast an eye from time to time, and might, or might not, have been spurred to further action.

The main purpose of this Chapter is three-fold: first, to determine what accumulated in the 'in tray' and what responses, if any, followed; second, to follow the Law Commission's definition of post-legislative scrutiny and consider whether and to what degree the intended policy objectives of the 1961 Act were met; third, to consider narrow questions of a purely legal or technical nature, as relevant.

2. The 1961 Act: execution and application in relation to developments in transplantation.

2.1 Clinical developments.

¹² House of Lords. Select Committee on the Constitution. 6th Report of Session 2004-5. *Parliament and the legislative process: the Government's response*. Report. HL114. Appendix 1, p4, para 3-4.

The main driver behind the 1961 Act had been the need to make possible, within the law, foreseeable developments in cadaveric tissue and organ transplantation. Two biological obstacles then stood in the way of further clinical development: the structural and functional deterioration of tissues in the hours following death which rendered them useless as transplants; and the biological defence mechanisms in the recipient of a transplant which tended to 'reject' the foreign tissue by destroying it. Finding ways of overcoming the process of rejection would prove to be a continuing challenge over the ensuing decades (and indeed has not been completely solved to this day). In contrast, it was quickly realised that the early post mortem deterioration of tissues could be overcome by *speed of removal* of the tissues or organs after death, to be followed either by immediate transplantation into a recipient or placing in an effective storage facility.

Within the decade following the 1961 Act, kidney transplantation had reached the development stage and was becoming an established therapeutic measure. Grafting of other organs, such as liver, heart, and larynx, had become possible by the late 1960s but had still to be considered to be in the research phase. Tensions had arisen between: the desire of surgeons to obtain more kidneys to treat more patients; the need for speed in obtaining organs as soon as possible after death; 'delays', as seen through surgical eyes, in the difficult, and still novel, area of identifying potential donors among the dying; the presence (and sometimes the absence) of relatives; identifying and having discussions with 'the person in lawful possession'; making reasonable and practicable enquiries; in addition to ensuring that complex clinical arrangements were in place.

Examination of some of the provisions of the 1961 Act can help to explain some of the practical difficulties encountered by transplant surgeons.

2.2 Uncertainties about the 1961 Act revealed.

2.2.1 The power to donate a body for medical purposes.

There were two provisions of the 1961 Act which dealt with the power to donate. The first covered the situation where the donor had made an express wish before death:

s.1(1) If any person, either in writing at any time, or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of it be used after death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of the body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.¹³

The need for speed of communication meant that it was essential for the family doctor and the close relatives to know in advance of the deceased's wishes, and this was not always the case- for example, direction in a will, although well meaning, was useless. It was for this reason that voluntary 'donor card' schemes began to be discussed, with the Automobile Association being the first body to present such cards to the public.¹⁴ There followed several years of divided opinion as to whether or not signed cards fulfilled the requirements of s.1(1) of the 1961 Act.¹⁵ The Medical Defence Union advised its members that it did not¹⁶, while a senior judge, speaking extra-judicially, and several academic commentators, opined that it did.^{17 18} Further, it should be noted that the person lawfully in possession was not bound to carry out the deceased's wishes. He or she was empowered but not obliged to act: if there appeared to be any reason for withholding permission, rational or not, he or she could do so.¹⁹

¹³ *Human Tissue Act 1961*, s.1(1).

¹⁴ Automobile Association. *Drive. No.4. (New Year)*, 1968.

¹⁵ Editorial. *Kidney donation and the law*. *BMJ* 1973;3:360-62.

¹⁶ Addison PH. *Human Tissue Act*, *BMJ* 1970;1 (5695):516.

¹⁷ Edmund Davies, Lord Justice. *A legal look at transplants*. *Proc. Roy. Soc. Med.* 1969; 62: 633-38, p 637.

¹⁸ Myers D. *The human body and the law*. Edinburgh. Edinburgh University Press, 1970, at p 108.

¹⁹ Dworkin G. *The law relating to organ transplantation in England* *MLR* 1970; 33(4); 353-377, p 366.

The second provision dealt with the (then and now) more common situation where the deceased had not made an express request:

s.1(2). [T]he person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe-

(a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it: or

(b) that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.²⁰

Surgeons, concerned with speed of removal, found the requirements of s.1(2) to be a hindrance. First, who was 'the person in lawful possession of the body' who could give them permission to proceed? Second, who were the surviving relatives who could object? Third, what inquiries was the person in lawful possession required to make in order to comply with the Act?

2.2.2 The identity of 'the person in lawful possession of the body'.

The term 'person in lawful possession of the body' had its origin in the Anatomy Act 1832, which referred to 'the executor or other party having lawful possession of the body'.²¹ In *R v Feist*²², it had been held that the master of a workhouse was the person in lawful possession of the body of an inmate for the purposes of permitting anatomical examination under the Anatomy Act 1832. It was possible that the poor law authority itself, rather than its agent, should have been identified as the 'person in lawful possession'.²³ Nevertheless the case confirmed that someone other than the executor or administrator may be in lawful possession of a body.

²⁰ *Human Tissue Act 1961*, s.1(2).

²¹ *Anatomy Act*, 1832, s.7.

²² *R v Feist* (1858) Dears. & B. 590.

²³ Skegg PDG. *The interpretation of the Human Tissue Act 1961*. Med. Sci. Law 1976;16(3): 193-9, p195.

Of great practical importance was the legal position when a person died in hospital. Could a hospital authority be capable of being in lawful possession? It will be recalled that Parliament had resisted the case for defining the hospital authority, in the case of hospital deaths, as the body in lawful possession for fear that this could be interpreted as an enforceable right to possession against the executors.²⁴ Although in general a dead body cannot be owned, the law did recognise a right to possession and was prepared to protect that possession. The key case was *Williams v Williams*²⁵, in which Kay J affirmed that English law recognised no property in a corpse, but that, *prima facie*, the executors were lawfully entitled to possession and were responsible for the burial of a dead body.²⁶ In *R v Fox* the executors were able to enforce their right to possession against a gaoler who had refused to hand over the body of a dead prisoner.²⁷ But the fact that the executors or administrators had a better right to possession than the person in whose custody the body lay did not mean that the latter person was not in lawful possession until someone with a better claim came along.²⁸

Further, as argued by Lanham²⁹, there were cases^{30 31 32 33} which, in aggregate, supported the conclusion that, in common law, the person who had actual physical custody of the body had lawful possession (and the duty of disposal of it) until someone with a higher right (for example, an executor or a parent) claimed the

²⁴ 643 Parl. Deb. (Hansard 5th series) HC, 836.

²⁵ *Williams v Williams* (1882) 20 Ch.D. 659.

²⁶ *Ibid.* at 664.

²⁷ *R v Fox* (1841) 2 Q.B. 246 at 246.

²⁸ Lanham D. *Transplants and the Human Tissue Act 1961*. Med. Sci. Law 1971; 11(1): 16-24, p18.

²⁹ *Ibid.*, at pp18-20.

³⁰ *Ambrose v Kerrison* (1851) 10 C.B. 776.

³¹ *Bradshaw v Beard* (1862) 12 C.B. (n.s.) 244.

³² *R v Vann* (1851) 2 Den.325.

³³ *R v Stewart* (1840) 12 Ad. & El. 773.

body.³⁴ Although not authoritative in law, this conclusion had been supported by the statement in Parliament during the passage of the 1961 Act that ‘in the absence of executors, there is a common law duty to see that the body is buried and the person lawfully in possession is normally the occupier of the premises where the body lies, or the person who has the body’.³⁵ Support also came from the wording of s.1(7) of the 1961 Act which stated that:

s.1(7). In the case of a body lying in a hospital, nursing home or other institution, authority under this section may be given on behalf of the person having control and management thereof by any officer or person designated for that purpose by the first-mentioned person.³⁶

This provision clearly presumed that the hospital authorities were normally in lawful possession of a body lying in hospital. Belief that this was the position in law had been encouraged by Circular HM(61)98 which had been sent to Hospital Management Committees (HMC) and Boards of Governors (BG) by the Ministry of Health at the time when the Human Tissue Act 1961 came into force, which advised, in the case of deaths occurring in hospital, that, until relatives claimed the body, the HMC or BG or anyone designated so to act on their behalf, was ‘the person lawful possession’, and therefore could lawfully authorise, subject to the conditions of s.1(2) of the 1961 Act, the removal for use a part of the body.³⁷

It was the duty of the person in lawful possession to make inquiry. There were tensions as between hospital authorities who were not clear as to the span of their obligation to inquire, and surgeons (especially those who, in their hearts, supported the introduction of amending legislation to require ‘contracting out’ of potential donors).

2.2.3 The meaning of ‘such reasonable inquiry as may be practicable’.

³⁴ Lanham D. *Transplants and the Human Tissue Act 1961*. Med. Sci. Law 1971; 11(1): 16-24, op.cit., p19.

³⁵ (1961) 643 Parl. Deb. (Hansard 5th series), HC 835.

³⁶ *Human Tissue Act 1961*, s1(7).

³⁷ Ministry of Health. H.M.(61)98. *National Health Service: Human Tissue Act 1961*, para 6.

In determining the span of enquiry required by the law, the key words were 'reasonable' and 'practicable'. To help to characterise 'reasonable' inquiry, it might have been helpful to consider what was 'unreasonable'. In one view, it would have been unreasonable to inquire of young children, or even of a very distressed spouse or parent whose health might have been detrimentally affected in consequence, or who was seriously ill as a result of the accident from which the potential donor had died.³⁸ As to making inquiry 'as may be practicable', Skegg opined that this must be determined with reference to the purpose, specified in the Act, for which it was desired to use the organ.³⁹ By this reading, the urgency surrounding transplantation, and the wish to ensure that the organ was as fresh as possible, would have implied that lesser inquiry needed to be made than, say, in a case where the extracted tissue was intended for the purposes of education. At best, this was a controversial view. A better reading would have placed the need to inquire as an obligation to respect the wishes of the relatives, and to avoid the risk of harm to the wider cause. The latter view was supported by Dworkin: the practicability of the inquiry must relate to the steps taken to trace the relatives, and not to the practicability of using the body, since the basis of the provision was to allow the relative to object if he or she so wished.⁴⁰ [It will be recalled that the Minister had confirmed in Parliament that the obligation to seek objections had been deliberately drawn broadly, and the term 'any surviving relative' undefined⁴¹].

Further dilemmas were posed. If the identity of the deceased was not known, could the body be used? If the surviving spouse or other close relatives expressed consent, must the hospital fear a more distant relative claiming that he or she would have objected had an opportunity been given?

³⁸ British Transplantation Society. *The shortage of organs for clinical transplantation: document for discussion*. BMJ 1975;1:251-5, p253.

³⁹ Ibid.

⁴⁰ Dworkin G. *The law relating to organ transplantation in England* MLR 1970; 33(4); 353-377, op.cit., p 367.

⁴¹ (1960) 632 Parl. Deb. (Hansard 5th series), HC 1256.

It is of interest that, although HM(61)98 had advised that 'relative' should be interpreted in the widest sense to include those who claimed a quite distant relationship⁴², the wording of that circular could be interpreted as suggesting that inquiry about the views of distant relatives could be sought through a close relative. As stated, 'the nearest relative available should be asked if he objects or has any reason to believe that any other relative would object, but hospital authorities are not expected to ask that relative for a statement that no other relatives object.'⁴³

There were calls from the transplant community for the Act to be amended to clarify the breadth of meaning of 'relative' and to clarify whether there were circumstances in which it might be deemed that no inquiry was practicable.⁴⁴ The attention of officials was drawn to the clear provisions of s.44B(2)(b) of the Victoria State Medical Act 1958 as amended by the Medical (Organ Transplants) Act 1968, which provided that:

[t]he person lawfully in possession shall consult the first in order of priority of the following persons available at the time of making inquiry, and may authorise removal if the person available did not object, or there was no reason to suppose objection on the part of a prior class, that is (in order) spouse, adult son or daughter, a parent, adult brother or sister, a guardian of the deceased.⁴⁵

These matters were brought to the attention of certain Parliamentarians who determined in the late 1960s that changes to the legislation were required to deal with 'difficulties' within transplant procedures.

2.3 Pressures to amend legislation with regard to transplantation, 1968-73.

2.3.1 The efforts of Parliamentarians.

Sir Gerald Nabarro, Tam Dalyell and Norman St John Stevas, Members of Parliament, made a number of attempts, singly and in concert, to introduce Private

⁴² Ministry of Health. H.M.(61)98. *National Health Service: Human Tissue Act 1961*, op.cit., para 8.

⁴³ Ibid.

⁴⁴ Report of the Special Committee on Organ Transplantation of the Joint Consultants Committee. *BMJ* 1970; 1(5698): 750-1, p 751.

⁴⁵ Medical (Organ Transplants) Act 1968, No.7745, State of Victoria, Australia, December 10, 1968.

Members' Bills to redress what they perceived to be inadequacies in the 1961 Act as it related to, specifically, kidney transplantation. The main stimulus for their action was the reported shortage of donor kidneys for transplantation, and the main obstacle they wished to overcome was the apparent difficulty of obtaining the permission of relatives within the brief window of time after death in which the kidney would remain viable.

On March 13, 1968, the Conservative Member of Parliament Sir Gerald Nabarro MP, an enthusiastic proponent of Private Members Bills (he introduced six in twenty years⁴⁶), sought leave in the House of Commons to introduce a Private Members Bill, to be called the 'Renal Transplantation Bill'. The Bill would have permitted the removal from the dead of a kidney or kidneys for therapeutic purposes, unless there had been reason to believe that the deceased, during his or her lifetime, had instructed otherwise.⁴⁷ Sir Gerald believed that kidney transplantation had reached a stage of such technical feasibility as to justify amendment of legislation for that procedure immediately, and thought that his Bill, if successful, would condition public opinion in favour of later, wider amending legislation for organ transplantation⁴⁸; noting that the entire civilised world had been moved by the then very recent medical achievement of successful heart transplantation⁴⁹. In spite of an occasional dissenting voice⁵⁰, the Bill was supported through First and Second Readings.⁵¹

During Second Reading, the Minister for Health, Rt Hon. Kenneth Robinson MP, said that, in his view, the Human Tissue Act 1961 at the time of its enactment had gone as far as had been reasonable at that time to strike a balance between facilitating

⁴⁶ Nabarro G. *NAB1: portrait of a politician*. Oxford, Robert Maxwell-Publisher, 1969, p 289.

⁴⁷ (1968) 760 Parl. Deb. (Hansard 5th series) HC, 1377.

⁴⁸ *Ibid.*, 1380.

⁴⁹ The first successful human to human heart transplant had been performed in Cape Town, RSA, on December 3, 1967.

⁵⁰ (1968) 760 Parl. Deb. (Hansard 5th series) HC, 1380.

⁵¹ (1968) 762 Parl. Deb. (Hansard 5th series) HC, 810.

the possible use of organs to save another life and the feelings and religious beliefs of the dead person's family; and that changes which may be desirable to keep pace with advances of medical science would not be generally acceptable unless such feelings were treated with due respect.⁵² The Minister was clearly sympathetic to the idea that new legislation might be needed. Having acknowledged that there was a clear need for safeguards, he told MPs that he was awaiting advice from a private conference he had convened, before deciding on the precise form new legislation should take, in the event of the conference advising, as he believed was likely, that some change in the law was desirable.⁵³

2.3.2 The 1968 Conferences and immediate aftermath.

The private, multidisciplinary conference which the Minister had convened accepted at its first meeting in March 1968 that s.1(2) of the Human Tissue Act 1961 restricted the availability of donor organs to an extent that prevented the treatment of patients who would otherwise die. However conference also recognised that there were people, including those of certain religious groups, who would object to removal of their own, or a relative's, organs after death.⁵⁴ After further discussion, it was agreed that if neither the deceased nor next of kin had expressed any objection, the views of other relatives need not be sought; but that if either the deceased or next of kin had objected, that objection had to be respected. With regard to the 'road traffic accident case', opinion was divided about whether or not it should be permissible, where no relatives could be contacted within a short time of death, and the prior wishes of the deceased were not known, to remove organs for transplantation (but not for other purposes).⁵⁵

⁵² (1968) 762 Parl. Deb. (Hansard 5th series) HC, op.cit., 832.

⁵³ Ibid., 833.

⁵⁴ (1968) 761 Parl. Deb. (Hansard 5th series) HC, 216.

⁵⁵ (1968) 767 Parl. Deb. (Hansard 5th series) HC, 49-50.

In a meeting with his officials, held to discuss the conference recommendations, the Minister, further informed by independent polls of public opinion⁵⁶, concluded that public opinion would not support the removal of organs without permission.⁵⁷ A few days later the Minister used a written answer to a Parliamentary Question to publish the conclusions of his conference and to announce that, while he accepted that it should not be necessary to seek the views of relatives other than the next of kin, he was not convinced that the suggestion about the recording of objections could be made effective at that stage.⁵⁸ Privately, the Minister had noted that the content of Sir Gerald's Bill had gone further than the proposals made by the conference, and decided then to stop the Bill at Committee stage.⁵⁹ Whether or not these reasons were passed on is not clear- Sir Gerald recorded in his autobiography that it was only a lack of Parliamentary time which prevented his Bill's further progress.⁶⁰

Nonetheless, officials at the Ministry of Health had been sufficiently exercised by Sir Gerald's efforts, and by the conclusions of the conference, to begin the process of obtaining permission to prepare a Bill which would have amended the Human Tissue Act 1961 in respect of all human tissue, providing that: where the wishes of the deceased were unknown, inquiries need only to be made as to objections held by the deceased or his next of kin; for the purpose of the Act, the hospital authority was the person in lawfully in possession of the body of a person who had died in hospital until the body was claimed by a person entitled to do so. A memorandum

⁵⁶ The National Archives. Ref. MH150/399. Document D1. *Draft. Human Tissue (Amendment) Bill: memorandum by the Minister of Health.* Undated.

⁵⁷ The National Archives. Ref. MH150/399. Document D1A. *Meeting to consider the conclusions of the second meeting of the Conference on the Transplantation of organs and their effect on the Renal Transplantation Bill.* June 14, 1968.

⁵⁸ (1968) 767 Parl. Deb. (Hansard 5th series) HC, 50.

⁵⁹ The National Archives. Ref. MH150/399. Document D1A. *Meeting to consider the conclusions of the second meeting of the Conference on the Transplantation of organs and their effect on the Renal Transplantation Bill.* June 14, 1968, op.cit.

⁶⁰ Nabarro G. *NAB1: portrait of a politician.* Oxford, Robert Maxwell-Publisher, 1969, op.cit., p 301.

was prepared for submission to the Cabinet Home Affairs Committee.⁶¹ However, at a preliminary meeting between the Lord President of the Council, Rt Hon Fred Peart MP, and the Secretary of State for Social Services, Rt Hon Richard Crossman MP, it was concluded that it was not yet possible to judge which way public opinion would move on the transplant question, and therefore the time was not ripe to introduce legislation which would bring about a major change in the law. It was minuted that 'possibly it might be appropriate for the Government itself to introduce more substantial legislation in a year or two's time'.⁶²

As had been anticipated⁶³, Sir Gerald Nabarro was not a man who was readily rebuffed. Early in the next Parliamentary session he sought to introduce an amended Renal Transplantation Bill, which included proposals for a national 'opt out' registry.⁶⁴ At Second Reading on January 31 1969 the Under-Secretary of State in the Department of Health and Social Security, Julian Snow MP, opposed the Bill on the grounds that: public opinion 'had not progressed far enough'.⁶⁵ The Bill was subsequently voted down.

It was next the turn of Mr Norman St John Stevas MP. On February 26, 1969, his Organ Transplants Bill, to cover the transplant of all organs, had its first (and only) reading.⁶⁶ He sought to establish the primacy of the deceased's wishes, and a veto on relatives' views being considered. His Bill was denied a Second Reading on no fewer than ten occasions over the next four months, and was then dropped.

2.3.3 Advisory Group on Transplantation Problems ('MacLennan'), and its outcome.

⁶¹ The National Archives. Ref. MH150/399. Document D15. *Human Tissue(Amendment) Bill: memorandum by the Secretary of State for Scotland and the Minister of Health*. October 1, 1968.

⁶² Ibid. Document D18. Notes of a meeting (between the Lord President and the Minister of Health), October 8, 1968.

⁶³ Ibid.

⁶⁴ (1968) 774 Parl. Deb. (Hansard 5th series) HC, 511.

⁶⁵ (1969) 776 Parl. Deb. (Hansard 5th series) HC, 1796, 1799.

⁶⁶ (1969) 778 Parl. Deb. (Hansard 5th series) HC, 1737.

Although the efforts of individual MPs had failed, Ministers were clearly of the opinion that some form of amended legislation would be required. In December 1968, the Health Ministers had invited Sir Hector MacLennan, then currently President of the Royal Society of Medicine (and who had chaired the Minister's conferences), to chair an on-going Advisory Group on Transplantation Problems which included professionals, ethicists and lay members ('*MacLennan*').⁶⁷ At its first meeting on February 14, 1969, the Secretary of State for Health and Social Security said that he hoped to have early advice from them which would enable him to introduce legislation early in the next Parliamentary session.⁶⁸ *MacLennan* was given no formal terms of reference, 'so that complex problems with medical, legal and moral aspects could be considered broadly'.⁶⁹

The *MacLennan* Report was unsatisfactory in that it identified problems but failed to identify solutions. Uncertainties in the law were met by articulating a series of questions which needed to be answered, but by whom was not made clear.⁷⁰ Tensions within *MacLennan* had prevented any firm recommendations- only a set of options was produced.^{71 72 73}

The advice of *MacLennan* was relayed to the Cabinet in a memorandum from the Health Ministers.⁷⁴ Cabinet took the view that the public would find the recommendation of the [slim] majority of the Advisory Group, who had advocated

⁶⁷ The National Archives. Ref. MH150/399. *Organ transplants: Secretary of State's seminar*. Letter from JAW McDonald to [?initial]Warner, December 13, 1968.

⁶⁸ The National Archives. Ref. MH150/399. Document D29. Memorandum from MJ Hewitt for Secretary of State (per[?initial] Matthews). April 23, 1969.

⁶⁹ Advisory Group on Transplantation Problems. *Advice on the question of amending the Human Tissue Act 1961*. July 1969. Cmnd. 4106, p3.

⁷⁰ Ibid., p4.

⁷¹ Ibid., p6.

⁷² Ibid.

⁷³ Ibid., p8.

⁷⁴ The National Archives. Ref. CAB129/142. Memorandum C(69)75. *Advice from the Advisory Group on transplantation problems* (Authors: Crossman RHS, Ross W, Thomas G). July 7, 1969.

an ‘opt out’ approach, wholly unacceptable, and would object to the proposal that the rights of the hospital over the body of a deceased person should be clarified. The Cabinet agreed that the advice should simply be published, but not as a White Paper, and with no statement.⁷⁵ These decisions were later described by a commentator as allowing the advice of *MacLennan* to gather dust.⁷⁶

The quality of the advice from *MacLennan* must have been a disappointment to the Secretary of State, because he had taken the anticipatory step of securing a place in the draft legislative programme for the 1969-70 Parliamentary session for a Human Tissue Act (Amendment) Bill.⁷⁷ In March 1969 the Bill was deleted from the list, on the grounds of lack of Parliamentary time⁷⁸, but a month later it was placed on the reserve list, where it remained until the then current administration changed as a result of the General Election in June 1970.⁷⁹

2.3.4 A miscellany of other factors

2.3.4.1 The further efforts of Parliamentarians

MacLennan was not quite dead. In May 1971, Tam Dalyell MP sought leave to introduce a Bill under the Ten Minute Rule, with all-party support, ‘to implement the recommendations of the Committee chaired by Sir Hector MacLennan on the transplant of human organs’.⁸⁰ Mr Dalyell’s Bill favoured the ‘contracting in’ option, about which, he said, it was important to let the public know that it had the support

⁷⁵ The National Archives. Ref. CAB128/44. CC(69) 32. Conclusions of a Meeting of Cabinet, July 10, 1969.

⁷⁶ Kennedy IM. *Further thoughts on liability for non-observance of the provisions of the Human Tissue Act 1961* Med. Sci. Law 1976; 16 (1): 49-55.

⁷⁷ The National Archives. Ref. CAB134/2839. Document FLG((69)1. *Future legislative programme 1969-70*. Note by secretaries to the Ministerial Committee on Future Legislation, February 11, 1969.

⁷⁸ The National Archives. Ref. CAB134/2839. Minutes of Meeting of the Cabinet Ministerial Committee on Future Legislation. March 27. 1969.

⁷⁹ The National Archives. Ref. CAB 128/45. CC(70)22. Conclusions of a Meeting of Cabinet, approving C(70)61 (Future Legislative Programme), May 14, 1970.

⁸⁰ (1971) 817 Parl. Deb. (Hansard 5th series) HC, 1082.

of the country's leaders and was not just the notion of a few crack-pot professors of surgery.⁸¹ To further his belief in the need for publicity, Mr Dalyell had published news of his proposed Bill in the *New Scientist*.⁸² Although Mr Dalyell's Bill was approved for Second Reading it did not progress to that stage. One month later, in response to a Parliamentary Question, the Prime Minister (Rt Hon Edward Heath MP) indicated that his Ministers were continuing to keep under review proposals to amend the Human Tissue Act 1961, but that the Government had no plans at that time to legislate.⁸³

In November 1971, Sir Gerald Nabarro MP, perhaps hoping for a favourable response from his (now) colleagues in Government, indicated to the Secretary of State, Rt Hon Sir Keith Joseph Bt MP, that he wished to table his Bill, modestly amended from that of the previous session, three weeks later!⁸⁴ A flurry of correspondence followed, which ended by the Secretary of State's setting out in a letter what had become the Ministry's 'line', namely that it would be wrong to amend the Act, and there was no necessity to do so, in order to secure an improved supply of organs for transplantation.⁸⁵ The fact that around 200 transplants were by then being carried out each year without legal challenge suggested that it was not the law itself that was the chief obstacle. Motivation and education were needed, and steps were being taken urgently to establish whether an effective and acceptable donor recruitment scheme could be devised.⁸⁶ Sir Gerald agreed to cooperate.⁸⁷

⁸¹ Ibid., at 1084.

⁸² Dayell T. *Westminster scene: To tidy up transplant procedure*. *New Scientist and Science Journal* 1971; 50(753):525.

⁸³ (1972) 819 Parl. Deb. (Hansard 5th series) HC, 229.

⁸⁴ The National Archives. Ref. MH150/399. Letter from G Nabarro to K Joseph, November 10, 1971.

⁸⁵ The National Archives. Ref. MH150/399. Memorandum (M48) from LH Brandes to [?initial] Weeple, December 21, 1971.

⁸⁶ The National Archives. Ref. MH150/399. Letter from K Joseph to G Nabarro, February 4 1972.

⁸⁷ The National Archives. Ref. MH150/399. Letter from G Nabarro to K Joseph, February 12, 1972.

In February 1972 Tam Dalyell was still pursuing his wish for amended legislation.⁸⁸

In reply to a Parliamentary Question, The Secretary of State said that, after careful consideration, he had concluded that the provision of an adequate supply of kidneys was not a question of legislation but of motivation and education.⁸⁹

As far as the transplant community was concerned, practical routines gradually developed within the existing law. Transplant surgeons were in practice unwilling to take organs for transplantation until the relatives had been interviewed. Indeed the British Transplantation Society in 1975 proposed and later adopted a code of practice which required 'the informed consent of available relatives'.⁹⁰

2.3.4.2 The Report of the Committee on death certification and coroners⁹¹
(Broderick Report; '*Broderick*').

Broderick and the Peel Report (see next section), while still in gestation, were used by Ministers as additional reasons why Parliament should delay consideration of the proposals being put forward by Sir Gerald Nabarro and Tam Dalyell. The conclusions of *Broderick* that were relevant to human tissue legislation did not call for new legislation in this area, but were of interest because of its recommendation that the Coroner should refuse consent to removal of organs only if the possibility of criminal proceedings made it necessary to preserve the body for evidence. That part of *Broderick* was later taken up by the Home Office who issued a Circular in 1977⁹² which gave guidance on the circumstances in which a coroner should delay

⁸⁸ (1972) 831 Parl. Deb. (Hansard 5th series) HC, 251.

⁸⁹ Ibid.

⁹⁰ British Transplantation Society. *The shortage of organs for clinical transplantation: document for discussion*. BMJ 1975;1:251-5 op.cit., at p252.

⁹¹ The Report of the Committee on death certification and coroners. Cmnd 4810, 1971, paras 17.20-17.34.

⁹² Home Office. Circular No. 65, 1977.

or refuse giving his or her consent for the removal of material for transplantation, in circumstances where his own or other legal considerations were involved.^{93 94}

2.3.4.3 Report of the Advisory Group on the use of fetuses and fetal tissue for research⁹⁵ (Peel Report; '*Peel*'), December 1971.

Peel noted that there was then no statutory duty to obtain permission of parents for the use of fetal tissue for research, but equally no statutory power to ignore parents' wishes. The Group felt that undue distress might be caused to parents if there were a specific requirement for their consent to be given for research, and suggested that the difficulty should be overcome by adding to the form of consent for the operation (termination) an appropriate clause which offered an opportunity to declare any special directions about the disposal of the fetus. Officials in the Department of Health and Social Security (DHSS) noted that, if this recommendation provoked a hostile reaction by the public, and there was a balance of opinion in favour of a statutory requirement to seek consent, there would be pressure for an early amendment of the 1961 Act on this point.⁹⁶

3. Contraventions of the 1961 Act.

A small number of clinical cases in the 1960s and 1970s alerted officials in DHSS to contraventions of the 1961 Act and the need to take remedial action. In addition, a body of evidence accumulated which suggested that at least some pathologists, and others, did not fully understand the law.

3.1 Clinical cases.

⁹³ Matthews P, Foreman JC. *Jervis on the Office and Duties of Coroners*. 11th edition. London. Sweet and Maxwell, 1993, 6:57-59, citing Home Office Circular (No.65, 1977).

⁹⁴ Legal Correspondent, British Medical Journal. *Coroners and transplants*. BMJ 1977; 1 (6073): 1418.

⁹⁵ Department of Health and Social Security. *The use of fetuses and fetal tissue for research: Report of the Advisory Group (Chairman Sir John Peel)*. HMSO, 1972.

⁹⁶ The National Archives. Ref. MH150/399. Document D49: *Human Tissue Act 1961*, December 1971. Appendix II: *Sources of recommendations and pressure for amending legislation*, para 8(a).

3.1.1 The 'Couve de Murville' case.⁹⁷

The first complaint on record concerned a deliberate disregard of the provisions of the 1961 Act. On October 17 1968, Andrew Skeffington MP wrote to the Rt Hon Kenneth Robinson MP, Minister of Health, about an elderly lady who had died in Hillingdon Hospital.⁹⁸ She had only distant relatives whom the hospital had been unable to contact. The next day a hospital official spoke to the son of one of these relatives and asked permission to take eyes for research. He gave an unequivocal refusal. Two days later when the relatives arrived to arrange the funeral, they discovered that the eyes had been removed. Investigation instigated by the Minister eventually decided that: 'a step daughter and her son' were not 'relatives' within the meaning of s.1(2)(b) of the Act; and that Dr Couve de Murville, a locum Senior House Officer from Mauritius, had claimed no knowledge of the need for consent. He had been reprimanded by the consultant, and had later moved overseas. The Minister issued a note of deep regret to the family.

Dr Couve de Murville (CdM) was reported by an official to the General Medical Council. The reply gave a flavour of the thinking, and the procedures, of that august body at that time.

The President has carefully considered the matter, and appreciates your reasons for writing to the Council. The Council could however only take action in this matter if the circumstances were such as to raise a question whether the doctor had been guilty of infamous conduct in a professional respect. In the opinion of the President this question is not raised by the matters set out in your letter, and the Council accordingly could not intervene in exercise of their disciplinary jurisdiction.⁹⁹

⁹⁷ The National Archives. Ref. MH150/401. *DHSS: Contraventions of the Human Tissue Act 1961*. Documents D1-D4.

⁹⁸ Ibid. Document DI PSO 206/14. Letter from Andrew Skeffington MP to Rt Hon Kenneth Robinson MP, October 17, 1968.

⁹⁹ Ibid. Document D4. Letter from Registrar, General Medical Council to JAW McDonald (DHSS), February 3 1969.

At the same time officials in the DHSS began to explore wider issues. These and subsequent Departmental activities are summarised below at section 4.

3.1.2 Mrs AH Howard, deceased.¹⁰⁰

On July 8 1970, Mr L Howard wrote to the Home Secretary about his recently deceased wife.

My wife, who had spinal muscular atrophy, died unexpectedly on June 30 1970. Dr J Turpin [a clinical assistant in the hospital] ordered a post mortem. On the morning of her death, and again the next day, Dr Turpin asked me to agree to cerebral tissue being taken and sent to the National Hospital for Nervous Diseases in Queen Square, London.

I categorically refused on both occasions.

In spite of this, tissue was taken. This was confirmed by the local hospital pathologist, who said that tissue had been taken on instruction of Dr Turpin – who denies this.

I wrote to the Coroner.¹⁰¹

During the subsequent inquiry by the Home Office, the Deputy Coroner for Montgomeryshire confirmed that the tissue had not been taken on his authority.¹⁰²

An official of the DHSS whose advice was sought asked rhetorically whether consent under s.2 of the Human Tissue Act constituted authority for removal of tissue under s.1(2). He opined that ‘whilst we have had advice that it does not, Government Departments cannot of course give a binding interpretation of a statute’.¹⁰³

Mr Howard received an official apology.

3.1.3 Patrick Joseph O’Sullivan, deceased.¹⁰⁴

¹⁰⁰ The National Archives. Ref. MH150/401. *DHSS contraventions of the Human Tissue Act 1961*. Correspondence regarding Mrs AH Howard, deceased.

¹⁰¹ Ibid. Letter from Howard L to Home Secretary, July 8, 1970.

¹⁰² Ibid. Letter from Deputy Coroner, Montgomeryshire to Miss L Noble (Home Office), August 27 1970.

¹⁰³ Ibid. Memorandum from DB Oliff (DHSS) to Miss L Noble (Home Office), undated.

¹⁰⁴ Ibid. Document D32. Patrick Joseph O’Sullivan, deceased.

Mr O’Sullivan died in hospital 12h after a road traffic accident. His kidneys were removed without permission, and the relatives only learned of the transplant procedure during the inquest. The hospital claimed that they had made repeated efforts to trace relatives through the police, and while the patient was in intensive care, but without success. The police evidence on the breadth of their enquiry was opaque. The hospital had contacted the coroner for advice. According to a hospital spokesman the Coroner ‘gave permission’ for the kidneys to be removed after death ‘provided the necessary conditions of the Human Tissue Act 1961 had been fulfilled’.

A later enquiry by the Regional Hospital Board concluded that the hospital had acted in good faith.

3.1.4 Nigel Peter Ford, deceased.¹⁰⁵

This case provoked a Parliamentary Question in the House of Commons¹⁰⁶, much press comment, and correspondence to the DHSS from members of the public.¹⁰⁷ Nigel Ford, a 17y old youth, was badly injured in a road traffic accident and died in a Birmingham hospital. His parents were on holiday overseas. The surgeon concerned gave permission for the youth’s kidneys to be removed for transplantation without having obtained consent from anyone. The surgeon told the inquest that the kidneys had to be taken within an hour of death, and he had accepted at the time that attempts made to contact relatives had been adequate.

A year later, the Joint Parliamentary Under-Secretary of State, Dr David Owen MP, wrote to the MP of one of Ford’s relatives to say that, having considered full reports, he did not feel that any action should be taken in this case. However it was his intention that further advice should be issued to health authorities later that year, ‘because of the concern expressed by transplant surgeons that they need

¹⁰⁵ Ibid. Documents D27-30, D33. Nigel Peter Ford, deceased.

¹⁰⁶ (1973) 860 Parl. Deb. (Hansard, 5th series) HC, 561.

¹⁰⁷ The National Archives. File MH150/401. Documents D29-30.

guidance on the interpretation of the Human Tissue Act'.¹⁰⁸ [This guidance subsequently appeared in June 1975 as HSC (IS)156¹⁰⁹].

3.1.5 Michael McEldowney, deceased.¹¹⁰

The issues in this case were well summarised by a headline in the *Sun*: 'Swop team operated on man who wasn't dead: coroner probes case of crash victim.'¹¹¹ Mr McEldowney, who had been injured in a road traffic accident, and whom two doctors presumed dead, began breathing again in the operating theatre of a Birmingham hospital when an attempt was made to remove his kidneys for transplantation. Strenuous efforts to resuscitate him failed and he died 15h later.

The jury at the Inquest returned a verdict of death by misadventure and added the following rider:

We would recommend that the provisions of the White Paper [sic- reference to the *MacLennan* Report] of July 1969, suggesting safeguards in the procedures under the Human Tissues (sic) Act 1961, be implemented by law, especially in respect of the certification of death by two doctors and the creation of formal records. We further suggest that, in transplant cases, one of the doctors certifying death should be of consultant status.¹¹²

The coroner sent a copy of the verdict and rider to the Chief Medical Officer, Sir Henry Yellowlees, who replied that he would ensure that the matter received careful consideration within the Department.¹¹³

3.2 The Human Pituitary Collection.

¹⁰⁸ Ibid. Letter from David Owen MP to Hugh Rossi MP June 9, 1974.

¹⁰⁹ DHSS. Health Service Circular (interim series) HSC(IS)156 *Guidance circular to NHS Authorities: Human Tissue Act 1961*. June 15, 1975.

¹¹⁰ The National Archives. Ref. MH150/653. *Contravention of the Human Tissue Act 1961*.

¹¹¹ *The Sun*, February 27, 1974.

¹¹² National Archives. Ref. MH150/653. *Inquest on Michael McEldowney*. Coroner's Court, Birmingham. February 25, 1974.

¹¹³ Ibid. Letter from H Yellowlees to G Billington. March 29, 1974.

Largely as a result of the transplantation cases described above, the DHSS issued guidance to NHS Authorities in June 1975 by way of circular HSC(IS)156 to clarify points of doubt that had arisen from experience of operating the 1961 Act. The need for authorisation of the person in lawful possession was emphasised.¹¹⁴ In addition the circular recommended that, with regard to PMs under s.2 of the Act, consent forms might routinely include a brief general reference to the removal of tissue for the purpose of s.1 of the Act.¹¹⁵ Within a year, it became clear that this advice had not been universally followed. The revelations involved the Human Pituitary Collection.

In 1966 the Medical Research Council (MRC) had established a clinical trial of Human Growth Hormone (HGH) in children with growth failure and HGH deficiency. The results were highly successful, and by 1976 450 patients were being treated. DHSS officials advised Ministers that the time had come to effect a smooth transition from the trial stage to service development within the NHS through central machinery centred on DHSS. The paper noted that approximately 60,000 pituitary glands were required to be obtained each year at autopsy to produce enough processed HGH for the then current patients, and that this number was projected to rise to around 100,000 in the coming years. The total number of autopsies being carried out in England and Wales each year was estimated to be 130,000.¹¹⁶

On August 29 1976 a popular newspaper carried the headline 'Body Robbers Scandal – we expose a hospital's traffic in human flesh'.¹¹⁷ A mortuary technician at Nottingham General Hospital had revealed that he and his colleagues routinely collected and stored pituitary glands in batches of 500, at which point they were

¹¹⁴ Department of Health and Social Security. June 1975 (HSC(IS)156): *Guidance circular to NHS Authorities regarding the Human Tissue Act 1961*.

¹¹⁵ *Ibid.*, para 17.

¹¹⁶ The National Archives. Ref. MH150/405. Paper 46A: *Human Growth Hormone: Draft submission to Ministers*, October 25, 1976.

¹¹⁷ *The People*, August 29, 1976.

dispatched to a laboratory for payment of £100. The money was divided among mortuary staff. It was alleged in the article that this practice had taken place without permission of the relatives. It was further alleged that, when the attention of the senior pathologist had been drawn by the investigating journalist to the requirements of the Human Tissue Act 1961, he had replied that the Act 'applies only to transplantation, as opposed to mushing up a little gland'.¹¹⁸ An MRC spokesperson was reported as saying that consent was necessary, and that MRC accepted tissue on the assumption that pathologists had been complying with legislation and with guidance laid down by DHSS. Twenty pence (20p) per gland was paid as a handling charge to cover the extra labour incurred by the technicians.

The Shadow Health Minister, Dr Gerald Vaughan MP, described the practice as 'appalling...a sophisticated form of body snatching'.¹¹⁹ The Secretary of State wrote to Dr Vaughan, committing his Department to producing a new standard post-mortem consent form and to issuing a further Health Circular.¹²⁰ These documents appeared subsequently in August 1977 as (HC(77)28) and attachments.¹²¹

3.3 Continued ignorance of, and non-compliance with, the law.

3.3.1 Evidence that the problem was widespread.

Evidence later came to light that non compliance with the guidance of HSC(IS)156 (June 1975) on tissue removal was widespread. Following the Nottingham headlines, the CMO, Sir Henry Yellowlees, sought the advice of Regional Medical Officers (RMOs) about the extent to which Health Authorities had complied with the requirements of the 1961 Act, and specifically about compliance for the

¹¹⁸ Ibid.

¹¹⁹ *Daily Telegraph*, Sunday 30, 1976.

¹²⁰ The National Archives. Ref. MH 150/405. Letter from Rt. Hon. David Ennals MP, Secretary of State for Social Services to Dr Gerald Vaughan MP, September 23 1976..

¹²¹ Department of Health and Social Security. August 1977 (HC(77)28) *Health Services Development. Removal of human tissue at post-mortem examination- Human Tissue Act 1961.*

purposes of therapy, research and teaching. Dr James Scott, RMO for Trent Regional Authority, reported that

[f]rom my enquiries of Area Health Authorities in Trent Region] I regret to say that, for the most part, the advice in HSC(IS)156 has been overlooked... I expect RMOs' replies will generally bear out that [doctors in] Nottingham were not sinners in isolation, and their main fault was being exposed (sic).¹²²

In May 1977 Ms Barbara Rashbass, an MRC official, wrote to Robert Blowers, Secretary of the Royal College of Pathologists (RCPATH):

[following] the unfavourable recent publicity about the Human Pituitary Collection... it seemed to me (BR) that... the need to consider ethical aspects of research involving human tissue as a whole was not too far-fetched. You (RB) thought that this whole issue was one which the College might want to consider.'¹²³

Blowers replied that College Council had established a Working Party (WP) to consider issues of tissue retention.¹²⁴

The WP, in its Report in October 1977, approved in general the DHSS Circular HC(77)28 which had been issued in the meantime¹²⁵, noting that the circular offered guidance on the removal of tissue which *did not appear to be mandatory* (my emphasis). The WP had 'found difficulty' with paragraph 7 of the circular which had clearly indicated that, in coroners' autopsies, permission to remove tissues for therapeutic use, medical education or research must be obtained from the coroner and the relatives. The WP raised the problem of how the relatives' consent was to be obtained for the removal of tissue for non diagnostic purposes at a necropsy to which they had not given legal consent, nor been asked to sign an appropriate form. The WP proposed as a possible solution a consent form for the removal of tissues for non diagnostic purposes which the Coroner's Office could ask

¹²² The National Archives. Ref. MH150/405. Letter from Dr James Scott, Regional Medical Officer, Trent RHA, to Dr R M Shaw, Deputy Chief Medical Officer, DHSS, September 23 1976.

¹²³ The National Archives. Ref. FD/3529. Letter from Barbara Rashbass (MRC) to Robert Blowers (Royal College of Pathologists), May 30 1977.

¹²⁴ Ibid. Letter from Robert Blowers to Barbara Rashbass, July 28 1977.

¹²⁵ Department of Health and Social Security, August 1977 (HC(77)28) *Health Services Development. Removal of human tissue of post-mortem examination- Human Tissue Act 1961*, op.cit.

the relatives to sign, noting that such a mechanism would depend entirely on the good will of the officer concerned. The Report concluded with the cryptic comment that:

[i]t seems to us likely that either selected tissues will be retained under the proviso that they are needed for diagnosis or that valuable material will be lost because no mechanism exists for gaining a relative's consent to their removal.¹²⁶

The Report suggested that College might consider discussing these problems with the Coroner's Society or the Home Office. I have been unable to find any evidence in the RCPATH records made available to me that such discussions took place subsequently.

3.3.2 Royal College of Pathologists: the Bernard Knight review paper.

Evidence continued to accumulate that practising pathologists were uncertain about the legal requirements in connection with the post-mortem retention of tissue. In 1985, as the result of a legal action which had been brought against a pathologist in respect of a coroner's autopsy¹²⁷, the Forensic Pathology Subcommittee of RCPATH commissioned Professor Bernard Knight, a distinguished forensic pathologist, to write a review paper, which was disseminated to pathologists via their College Bulletin.¹²⁸ Knight's paper confirmed that, with regard to coroners' autopsies, the pathologist was required to retain those tissues, and only those tissues, whose examination had relevance in determining the cause of death or an interpretation of the events leading up to death. The retention of tissues for teaching and research was not covered by the coroner's permission *and the coroner could not grant such permission- indeed he could forbid the use of any*

¹²⁶ Royal College of Pathologists. Minutes of Council, October 11 1977, Appendix A.

¹²⁷ I have sought details of this case from officials at RCPATH, and from Professor Bernard Knight (a previous colleague of mine), without success.

¹²⁸ Knight B. *Legal considerations in the retention of post-mortem material*. Bulletin of the Royal College of Pathologists 1985: no.52:3-4.

tissues for such purposes (Knight's emphasis). Positive permission had to be obtained under the Human Tissue Act 1961.¹²⁹

With regard to non- coronial autopsies, to Knight the position was clear. The retention of tissues was exactly the same in its legal aspects as for the donation of tissues for transplantation under the Human Tissue Act 1961.¹³⁰ With regard to determining the absence of objection by a near relative, in the case of a wish to retain tissue for research or educational purposes, Knight recommended that 'the usual post mortem consent form' should have a sub-clause, which could be deleted by the relatives if they so wished, which would allow tissues to be retained for therapeutic, research or teaching purposes. Once signed with the sub-clause intact, opined Knight, the pathologist was entitled to remove and retain any organs which he deemed necessary or suitable for the stated purposes.' He conceded that this recommended practice had not yet (at the time of writing in 1985) been put to the legal test.¹³¹

Despite publication of this authoritative article, the pathologists' dilemma appears to have persisted. In April 1990, RCPATH felt it necessary to republish Knight's 1985 paper for its Fellows and Members, noting that 'the situation regarding the retention of tissues from post-mortem examinations continues to generate letters to the College, and obviously some pathologists are still not clear as to the legal situation.'¹³²

It is difficult to explain why tissues continued to be retained in contravention of the 1961 Act. Continued ignorance of the law played a part. An apparently inexorable

¹²⁹ Ibid. at p4.

¹³⁰ Ibid.

¹³¹ Ibid.

¹³² Royal College of Pathologists. *Registrar's column. Legal considerations in the retention of post mortem material.* Bulletin of the Royal College of Pathologists 1990; no. 70:3.

fall in the number of hospital post-mortems¹³³ and the continued challenges (as doctors saw it^{134 135}) of education and research may also have contributed. Would doctors have behaved differently if there had been sanctions for failure to comply with s.1(2) of the 1961 Act? Academic commentators, by implication, may have so believed when writing in the mid 1970s about the possibility of a case being brought under the then existing law.^{136 137}

Despite his academic analysis, Kennedy in particular concluded that it was extraordinarily difficult to be certain that the fundamental provisions of the 1961 Act could be guaranteed in practice, and that 'such a conclusion should not any longer be allowed to pass unnoticed by those charged with making and changing the law'.^{138 139}

3.4 Radiation studies.

Early in the 21st century two separate examples of research involving tissue taken apparently without consent came to light. These studies had had their origins in the 1950s and 1960s, and are relevant to be considered at this stage of the narrative as further examples of practices which apparently had deviated from the

¹³³ Office for National Statistics. Figures shown adapted from data supplied by ONS to *The Inquiry into the management of care of children receiving complex heart surgery at The Bristol Royal Infirmary ('Bristol Royal Infirmary Inquiry')* in April 2000. Interim Report, May 2000, para 25.

¹³⁴ Tallis R. *Hippocratic oaths: medicine and its discontents*. London. Atlantic Books, 2004, p195.

¹³⁵ Domizio P. In: Armstrong S. *A matter of life and death: conversations with pathologists*. Dundee. Dundee University Press, 2008, p108.

¹³⁶ Skegg PDG. *Liability for the unauthorised removal of cadaveric transplant material* Med. Sci. Law 1974; 14(1):53-7 at p53.

¹³⁷ Kennedy IM. *Further thoughts on liability for non-observance of the provisions of the Human Tissue Act 1961* Med. Sci. Law 1976; 16(1): 49-55.

¹³⁸ Ibid., p54 .

¹³⁹ Kennedy retained these views over the next twenty years, and incorporated them into his recommendations within the Interim Report of the *Bristol Inquiry*, discussed in Chapter Four.

then current legal requirements. One may also try to answer questions of the form 'who knew and when did they first know?'

3.4.1 Strontium 90 ('Sr.90') research.

On Sunday June 17, 2001, the *Sunday Herald* published an article which began 'The thigh bones of more than 2100 children who died during the 1960s in Scotland were secretly removed from their bodies without the knowledge of their parents as part of an international scientific study into the dangers of radiation from nuclear weapon tests'.¹⁴⁰ The Scottish Executive's immediate response was to ask the Independent Review Group on the Retention of Organs at Post- Mortem ('IRG'; 'Review Group'; chaired by Professor Sheila McLean)¹⁴¹, then already in existence and engaged in a review of previous post- mortem practice in Scotland, to investigate the allegations.

The following account relies heavily on the Review Group's Report on Strontium- 90 ('Sr.90') research¹⁴², which itself relied for historical background on a scientific paper published jointly by senior previous investigators in Scotland.¹⁴³ In the early 1950s a global study of Sr.90 (a radioactive product of nuclear bomb testing) began.¹⁴⁴ In July 1957 the MRC became responsible for obtaining samples of human bone in the UK and for their initial processing. The first public report on the study was published in 1957, and *inter alia*, described the results from 59 samples of human bone, many from infants and children. The report was placed in the library of the House of Commons, published in a scientific journal and submitted as

¹⁴⁰ *Sunday Herald*. June 17, 2001.

¹⁴¹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001.

¹⁴² Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Strontium-90 research*. March 2002.

¹⁴³ Arneil GC, Lenihan JMA, Warren J. *Radioactive fallout: the silent hazard to the babies of the world*. Bulletin of the International Paediatric Association 1983;5:20-29.

¹⁴⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Strontium-90 research*, op.cit., para 2.5.

evidence to the UN Scientific Committee on the Effects of Atomic Radiation.¹⁴⁵ The then Prime Minister, Rt Hon Harold Macmillan MP, referred to the importance of this ‘comprehensive’ report.¹⁴⁶ The MRC published annual reports entitled ‘Assay of Strontium 90 in human bone in the United Kingdom’ from 1960 to 1973, covering the research years 1959 to 1970.¹⁴⁷ The Sr.90 research programme was discontinued in 1972.¹⁴⁸

With regard to information and consent, IRG found that the parents would probably have had little, if any, idea of the assumptions which were made by pathologists about what a parental signature on a post-mortem consent form covered or authorised.¹⁴⁹ IRG found no evidence that the passing of the Human Tissue Act 1961 had made any difference to practice- indeed one witness had said that, by 1961, ‘the research had acquired a momentum of its own’.¹⁵⁰

MRC’s understanding appeared to have varied over the years of the study. Correspondence in the late 1950s between the MRC and HM Inspector of Anatomy had illustrated the erroneous belief by MRC that the legality of the collection of the Sr.90 research samples lay in terms of the Anatomy Act 1832. HM Inspector of Anatomy had drawn attention to the fact that it was a common assumption in the pathology community, albeit without legal foundation, that parental (or any) consent to a post mortem examination in essence gave consent to removal of samples for research. He referred to an article in the *British Medical Journal (BMJ)* in 1954 which supported the existence of such an assumption by pathologists.¹⁵¹ MRC told IRG that they were aware of a widespread belief that the 1961 Act

¹⁴⁵ Ibid., paras 2.11- 2.12.

¹⁴⁶ (1957) 575 Parl. Deb. (Hansard, 5th series) HC, 394.

¹⁴⁷ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Strontium-90 research*, op.cit., Appendix 3.

¹⁴⁸ Ibid., para 2.17.

¹⁴⁹ Ibid., para 3.17.

¹⁵⁰ Ibid., para 4.1.

¹⁵¹ ‘Question and answers.’ *BMJ* 1954;2(4900): 1369, at para 4.3.

provided that any consent to a post-mortem examination gave implicit permission to remove tissue for research, citing in support an article in the *BMJ* of September 3, 1966 by its then legal correspondent, which had stated unequivocally that the doctor had no need to consult relatives unless there was some prior reason to suppose that there might be an objection.¹⁵²

In response to the later criticism of the studies, the MRC set up an inquiry chaired by Rabbi Julia Neuberger to look at the ethical concerns which had been raised.¹⁵³

The Inquiry concluded that:

[a] wide range of tissues were often removed during the period for research purposes, without the consent of relatives. However, the boundaries between the requirements of an autopsy to establish the cause of death and those for extending the range of knowledge and understanding of disease are blurred.¹⁵⁴

The MRC issued a press release which conceded that, even allowing for the different attitudes that prevailed in the 1950s, 'the failure to seek consent was unnecessarily distressing to the relatives of people whose bone samples were used'.¹⁵⁵

In the summary of its findings, the Review Group stated that it did not know whether or not there had been any other such studies, and urged anyone with any knowledge of such studies to contact the Review Group as a matter of urgency so that these could be brought into the open.¹⁵⁶ In due course, further such studies did come to light.

3.4.2 Workers in the nuclear industry.

¹⁵² Editorial. *Law and the corpse*. *BMJ* 1966; 2 (5513):595.

¹⁵³ Medical Research Council. *Radiation in MRC supported research in the 1950s and 1960s: Report of a committee of inquiry*. May 1 1998.

¹⁵⁴ *Ibid.*, at p 18, para 5.2.9.

¹⁵⁵ Medical Research Council. *Press release*, June 15 2001. Cited by: Independent Review Group on Retention of Organs at Post-Mortem. *Report on Strontium-90 research*, op.cit., p23, para 5.4.

¹⁵⁶ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Strontium-90 research*, op.cit., p 27, para 6.11.

In August 1986 the *New Scientist* had alerted its readers, under the headline 'Massive plutonium levels found in Cumbrian corpses', to studies based on the bodies of 'typical former workers at the Sellafield nuclear plant' which had revealed concentrations of plutonium hundreds, and in one case thousands, of times higher than in the general population. The study had also found that concentrations of plutonium in the bodies of Cumbrians who had not worked at the plant averaged 50 to 250 percent higher than elsewhere in Britain.¹⁵⁷

In 1972, scientists at the UK's National Radiation Protection Board had been asked by British Nuclear Fuels Ltd to measure the levels of plutonium in tissue removed at autopsy from several of their former employees who had worked in the plutonium processing industry at Sellafield. At that time there was very little information available on the amounts of plutonium present in the bodies of the general public of Great Britain. The scientists decided to collect tissues taken at autopsy from members of the general public who had lived in the hinterland of the Sellafield plant and also from other regions of the country. According to the paper published subsequently on this work by Popplewell and colleagues, 'autopsy tissues were obtained from pathologists acting in coroners' inquests in central Scotland (sic), NE England, W Cumbria and Oxfordshire'.¹⁵⁸ The 'subjects' had to have been at least fifty years old at the time of death, with no previous employment in the nuclear energy industry. Cardiovascular disease had been the cause of death in most cases. Bones, liver and lung were examined by gamma-ray spectroscopy. The authors' summary of their findings was that 'tissues removed from members of the general public [at autopsy] contain significantly higher concentrations of plutonium and Cs-137 in west Cumbrians than in people from three other regions of Great Britain. Several autopsy cases from Cumbria showed unusually high values of plutonium.

¹⁵⁷ Pearce F. *Massive plutonium levels in Cumbrian corpses*. *New Scientist* 1986; 111(1521): 11.

¹⁵⁸ Popplewell DS, Ham GJ, Dodd NJ, Shuttler SD. *Plutonium and Cs-137 in autopsy tissue in Great Britain*. *The science of the total environment* 1988;70: 321-334 at p321-2.

Subsequently it was found that the subjects had been former employees of British Nuclear Fuels'.¹⁵⁹

The importance of this paper to the general themes of this chapter is two-fold. First, the studies of autopsy tissue were carried out in, and published from, a Government research establishment. Second, the authors stated that the tissues were taken from coroners' inquests for what were clearly research studies. It is inconceivable that studies of the tissue content of plutonium and Cs-37 could have formed part of an inquiry into the cause of death of individuals who had not been, or who at the time of autopsy were not believed to have been, workers in the nuclear industry. Were the circumstances of these cases examples of pathologists, wittingly or in ignorance of the law, retaining for research purposes tissue obtained under s.2 of the Human Tissue Act, without respecting s.1? Further, was it possible that, with regard to coronial post-mortems, the coroners concerned has cooperated or had turned a blind eye?

3.4.2.1 The Redfern Inquiry 2010.¹⁶⁰

On April 18 2007, the Secretary of State for Trade and Industry, Rt Hon Alistair Darling MP. told the House of Commons that he had asked Michael Redfern QC to establish the facts and report to him.¹⁶¹ [Michael Redfern QC had chaired the Royal Liverpool Children's Hospital Inquiry which reported in 2001, and which will be discussed in Chapter Four. These proceedings and report have been termed the *Redfern Inquiry* and the *Redfern Report*. I shall refer to the inquiry into workers in the nuclear industry as *Redfern 2*].

Terms of reference for *Redfern 2* were announced on April 26, 2007¹⁶² and were modified ten months later, on February 26, 2008, at the request of Mr Redfern in

¹⁵⁹ Ibid., at p321.

¹⁶⁰ Department of Energy and Climate Change. *Redfern Inquiry into human tissue analysis in UK nuclear facilities*. Volumes 1 and 2. London. The Stationery Office. Ordered by the House of Commons to be printed, November 16, 2010.

¹⁶¹ (2007) 459 Parl. Deb. (Hansard, 6th series) HC, 302.

¹⁶² (2007) 459 Parl. Deb (Hansard, 6th series) HC, 28ws.

the light of the inquiry team's work to that date. The revised terms of reference were, in summary:

[t]o enquire into the circumstances in which, from 1955, organs/tissue were removed from individuals at NHS or other facilities, and sent to and analysed at nuclear laboratory facilities.¹⁶³

Redfern 2 was in gestation for three years. The Report was published on November 16, 2010.

Findings.

The bulk of *Redfern 2* report concerned post mortems on 64 current or former Sellafield workers, of which 60 were coronial examinations. The findings echoed in many ways those of the *Bristol* and *Alder Hey* Inquiries, which reported in 1998 and 2001 respectively, and which are described in detail in Chapter Four. Briefly, *Redfern 2* found that families had little knowledge about the nature of a post mortem examination, and certainly had no understanding that organs might be retained with their permission. In the instant cases, no permission from relatives had been sought, and they had not known that organs had been retained for later analysis of levels of radiation. The Inquiry found that the pathologists concerned, (in common with the pathologists involved in the separate population studies of Popplewell described above) had been 'profoundly ignorant' of the law [the Human Tissue Act 1961] under which they had performed post mortem examinations.¹⁶⁴

Redfern 2 also had significant criticisms regarding the practices of the coroners concerned. One may recall Professor Knight's authoritative article in 1985 in which he reminded pathologists that the retention of tissues for teaching and research was not covered by the coroner's permission and the coroner could not grant such permission- indeed he could forbid the use of any tissues for such purposes.

¹⁶³ (2008) 459 Parl. Deb. (Hansard, 6th series) HC, 69ws.

¹⁶⁴ Department of Energy and Climate Change. *Redfern Inquiry into human tissue analysis in UK nuclear facilities*. Volumes 1 and 2. London. The Stationery Office. Ordered by the House of Commons to be printed, November 16, 2010. Volume 2, p 38, para 122.

Positive permission had to be obtained under the Human Tissue Act 1961.¹⁶⁵

Redfern 2 found that coroners had actively ‘assisted British Nuclear Fuels Ltd, the National Radiation Protection Board and the Medical Research Council to obtain organs for [the] research, heedless of whether the necessary consent was obtained’.¹⁶⁶ This and other deficiencies in coronial practice revealed by the Inquiry were ‘inexcusable’.¹⁶⁷

4. Coroners’ ‘fiefdoms’.

Throughout the archival and other studies that I was able to make concerning the aftermath of the Human Tissue Act 1961, a number of instances came to light which suggested that coronial practice in the years under discussion, as far as tissue retention was concerned, had been inconsistent and, at times, individualistic. Each of the examples has been or will be described as they arise in the chronological narrative. However, there is an argument to present a summary *en bloc*, now, as evidence which accumulated in official ‘in-trays’ and which could (or should) eventually have influenced legislation. [*Redfern 2*, although published in 2010, described practices in the 1960s to 1980s which reinforce the content of this section].

Before the introduction of the Coroners Rules 1984 and the Coroners Act 1988, and for almost all of the period of the cases under question, the activities of coroners were guided by the Coroners Acts 1887 to 1954¹⁶⁸, and the Coroners’ Rules 1953 to 1980¹⁶⁹. Briefly, a coroner may direct or request a registered medical practitioner to make a post-mortem examination to exclude or investigate any criminal or civil

¹⁶⁵ Knight B. *Legal considerations in the retention of post-mortem material*. Bulletin of the Royal College of Pathologists 1985: no.52:3-4, op. cit., at p4.

¹⁶⁶ Department of Energy and Climate Change. *Redfern Inquiry into human tissue analysis in UK nuclear facilities*. Volumes 1 and 2. London. The Stationery Office. Ordered by the House of Commons to be printed, November 16, 2010, op.cit., Volume 2, p39, para 132.

¹⁶⁷ *Ibid.*, p14, para 36.

¹⁶⁸ *Coroners Acts 1887 to 1954* (construed as one with: *Coroners Act 1887* (c.71); *Coroners Act 1892* (c.56); *Coroners Act 1921* (c.30); *Coroners (Amendment) Act 1926* (c.59); *Coroners Act 1954* (c.31)).

¹⁶⁹ *Coroners Rules, 1953* (S.I.1953/205); *Coroners (Amendment) (Savings) Rules 1980*. (S.I. 1980/668).

responsibility for a death not due to natural causes, or one which is sudden, unexpected or otherwise obscure.¹⁷⁰ The medical practitioner may then make a) a post-mortem examination of the body of the deceased; or b) a special examination by way of analysis, test or otherwise of such parts or contents of the body or such other substances or things as ought in the opinion of the coroner to be submitted to analyses, tests or other special examination, with a view to ascertaining how the deceased came by his death; or make both such examinations ; or may request any person whom he considers to possess special qualifications for conducting such a special examination as aforesaid (in the Acts referred to as a 'special examination') to make such special examination.¹⁷¹

The Coroner's Rules 1953 set out requirements regarding the retention of post-mortem material which implied the need for an interaction between the coroner and the examining pathologist, and which would come to feature prominently in the Inquiries from *Bristol* and *Alder Hey*, to be discussed in later Chapters, to *Redfern 2*. The 1953 Rules stated:

A person making a post- mortem examination shall make provision, so far as is possible, for the preservation of material which, in his opinion, bears upon the cause of death for such period as the coroner thinks fit. (Rule 6);

and

A person making a special examination shall make provision, so far as is possible, for the preservation of the material submitted to him for examination for such period as the coroner thinks fit. (Rule 9).

[Confusingly, a later version of the Coroners Rules, in 1984, contained the above Rule 6 as Rule 9, and the above Rule 9 as Rule 12.¹⁷² In the *Bristol*, *Alder Hey* and *Redfern 2* Inquiries, and in the vernacular subsequently, tissue retention at coronial post mortem came to be referred to as 'Rule 9 procedures'.]

¹⁷⁰ Knight B. *The Coroner's autopsy: a guide to non- criminal autopsies for the general pathologist*. Edinburgh and London, Churchill Livingstone, 1986, p1.

¹⁷¹ *Coroners (Amendment) Act 1926*, s.22

¹⁷² *Coroners Rules 1984* (S.I.1984, No.552).

In principle, the requirement for post mortem material to be retained by the pathologist 'for as long as the coroner sees fit' could result one of several scenarios. The pathologist might wait passively until he heard from the coroner 'I no longer have need for you to retain that [specified] material'. This would require the coroner to have knowledge of what, if any, material was being retained. The pathologist might take the initiative and ask the coroner 'do you have a date in mind after which your interest in this [specified] material will have ceased?'; or, as a variant 'I am still holding on to this [specified] tissue- do you want me to continue so to do?'. This would require the pathologist to have known, and have interpreted, the content of 'Rule 9'. Even if one of such exchanges had taken place, consideration would remain about the subsequent fate of the retained material. May the pathologist retain it for his research? Must it be destroyed/disposed of? Should/must it be returned, and if so, to whom?

These are the issues for later Chapters. In general I have been able to find only scant evidence of any such interactions between coroners and pathologists having taken place in the mid twentieth century. Instead, one may recall on the eve of the 1961 legislation 'coroners knowing what was going on but not objecting'¹⁷³; medical officers 'avoiding learning too much'¹⁷⁴; researchers impatient to implement tissue banking¹⁷⁵; attitudes which I submit were swayed by a concern for 'public benefit'. The latter expression was used twice in confidential and informal conversations I had: by a senior retired pathologist who, like his colleagues, 'routinely' retained post mortem tissue for research in the 1960s and 1970s, whether from coronial or non-coronial autopsies; and by a currently practising coroner when explaining variations in the practice of individual coroners.

Further evidence on past practices was given in a letter from Professor Bernard Knight (the author of the 1985 paper for the Royal College of Pathologists) to a senior member of the staff of the MRC at the time of the revelations in 1977 about

¹⁷³ The National Archives. Ref MH 58/497. Letter from GE Godber to JE Pater, January 29 1960

¹⁷⁴ The National Archives. Ref. FD23/2000. Letter from GE Godber to FJC Herrald, February 23 1960.

¹⁷⁵ Ibid. Letter from HJ Seddon to FJC Herrald, April 1 1960.

the collection of pituitaries. Having set out the requirement that the taking of pituitaries from hospital post mortems required the permission of relatives, Professor Knight wrote '[t]he matter is further complicated in coroner's cases [in which] the autopsies are done without the permission of the relatives... Thus the only Act under which pituitaries are taken is the 'Blind Eye Act' which has operated for many years but which, due to the adverse publicity of this past year, is now becoming unsafe'.¹⁷⁶

The evidence in *Redfern 2* was mixed. On the one hand, it was found that coroners had often failed to read post mortem reports and as a consequence remained in ignorance of the inappropriate removal of organs.¹⁷⁷ On the other hand the report found that the relationship between the pathologists, the coroners and the medical officers became 'too close'.¹⁷⁸

5. Continued work by officials to prepare for amending legislation.

5.1 Work with the Joint Consultants Committee and others.

Immediately following the Couve de Murville case (3.1.1 above), a paper (JC65), entitled '*Human Tissue Act 1961: paper by the Department*', was prepared for the Joint Consultants' Committee (JCC).¹⁷⁹ The drafting official noted in an internal memorandum:

I understand that Medical (sic) are unhappy in particular about extending the paper to cover non forensic post-mortems as well as the removal of tissue for therapeutic purposes. But this only reflects the Human Tissue Act itself, which applies the same procedures to both. *Moreover, we have indirect evidence, in the folder*

¹⁷⁶ The National Archives. Ref. FD9/4607. Letter from Professor B. Knight to Professor VHT James (MRC), March 16 1977.

¹⁷⁷ Department of Energy and Climate Change. *Redfern Inquiry into human tissue analysis in UK nuclear facilities*. Volumes 1 and 2. London. The Stationery Office. Ordered by the House of Commons to be printed, November 16, 2010, op.cit., Volume 2, p39, para 127.

¹⁷⁸ Ibid., p39, para 133.

¹⁷⁹ British Medical Association. Joint Consultants Committee. Paper JC65. *Human Tissue Act 1961: paper by the department*. April 22, 1969.

attached¹⁸⁰ and elsewhere, that pathologists have continued to remove tissue at post-mortem for extraneous purposes without specific consent. I do not think that we should go on overlooking this.¹⁸¹ (My emphasis).

Officials had noted in JC65 that the 1961 Act did not create offences for non-compliance, and that, in the case of CdM, the hospital had had 'no mechanism in place for person in lawful possession' in spite of DHSS memorandum HM (61) 98 about the responsibility of Hospital Management Committees or Boards of Governors in this regard.¹⁸² JC65 raised the question about who should be responsible for seeking permission from relatives, both in relation to obtaining organs for transplantation, and for autopsies. With regard to removing tissues during autopsy for teaching or research, there had been 'no complaint yet'.¹⁸³ The paper also noted that 'a strict interpretation of the legal position might require all material removed during an autopsy to be put back in the body'.¹⁸⁴ JC65 recommended that the solution was not to amend the law- 'such provision being difficult to draft and possibly contentious to certain minorities- but by phrasing the form of consent so as to indicate in appropriate cases that material was sought for education and research'.¹⁸⁵

Paper JC65 was pre-circulated for comment. A covering letter from the CMO, Dr George Godber, to the Chairman of the JCC suggested that 'it has become apparent that the provisions of the Human Tissue Act 1961 are not well known at hospital

¹⁸⁰ I was unable to locate the 'attached folder' even after prolonged search in the National Archives.

¹⁸¹ The National Archives. Ref. MH 150/401. Document M14. Memorandum from JAW McDonald to [?initial] Williamson, February 14, 1969.

¹⁸² British Medical Association. Joint Consultants Committee. Paper JC65. *Human Tissue Act 1961: paper by the department*. April 22, 1969, op.cit.

¹⁸³ Ibid.

¹⁸⁴ Ibid.

¹⁸⁵ Ibid.

level'.¹⁸⁶ The President of the Royal College of Surgeons of England responded to the paper:

It is possible that [the proposals] might hinder education and research, as well as being difficult of literal observance. The Dept's paper rightly notes that an amendment of the law to cover present practice would be difficult to draft... A subcommittee of the College set up to consider the matters raised by the Department are of the opinion that, rather than alter the phrasing of the consent form to include this [consent to the autopsy in the interests of research and teaching], that the matter be left as it is at present, in view of the tacit acceptance of present customs by the general public.¹⁸⁷

The response from the Royal College of Pathologists (RCPATH) to the draft paper was largely in support of the *status quo ante*. The response also revealed some confusion in the minds of College officials about the law. 'Strict interpretation of the legal position, as suggested in paragraph 5 of JC65, would be utterly impracticable, if indeed it were true. In our view this is not so, for specific approval is given by s.1 of the Human Tissue Act 1961.'¹⁸⁸ It was of course s.2 of the Act which was at issue. This stimulated an internal memorandum between two officials within the Department: '[Like you] I suspect we are not getting through to the Pathologists, and that they aren't getting the point... the point we were on was that consent to an autopsy did not automatically convey consent to the removal of a part.'¹⁸⁹

The JCC set up a Special Committee on Organ Transplantation which reported in January 1970¹⁹⁰, and which subsequently published its conclusions in the *British Medical Journal*.¹⁹¹ The Committee had confined its deliberations to questions left

¹⁸⁶ The National Archives. Ref. MH150/401. Letter from Chief Medical Officer to Chairman of Joint Consultants Committee, April 14 1969.

¹⁸⁷ British Medical Association. Joint Consultants Committee. Paper JC91. July 25, 1969.

¹⁸⁸ Ibid. Paper JC93.

¹⁸⁹ The National Archives. Ref. MH150/401. Memorandum from WG Robertson to C Dennis (DHSS) September 4 1969.

¹⁹⁰ British Medical Association. Minutes of the Joint Consultants Committee, January 27, 1970, para 49.

¹⁹¹ *Report of the Special Committee on organ transplantation*. BMJ 1970;1 (5698): 750-51.

unanswered by *MacLennan*. Their conclusions were in favour of ‘contracting in’ and unanimously opposed to ‘contracting out’ as ‘premature’. The Committee favoured amending the Human Tissue Act 1961 to define a hierarchy of relatives to be consulted. Although there was a view that the plain intention of the 1961 Act had been that the wishes of the deceased, where known, should be paramount¹⁹², the Committee recommended that objection of relatives should explicitly be allowed to trump the express wish of the deceased for that his or her organs be taken for use.¹⁹³

5.2 Any amending legislation should be broadly drawn.¹⁹⁴

By the end of 1971 the activities of Parliamentarians and other bodies described above had prompted a revision and updating by officials of possible amending legislation¹⁹⁵, building on the work in the Department that had already been undertaken during the previous Government.¹⁹⁶ Although the stimulus to examining the contents of possible legislation had continued to be the problems identified by transplant surgeons and their supporters (see recommendations of *MacLennan*), it was the Department’s view that any amending legislation should not be confined to transplantation alone (including provisions with regard to live donors) but should be as least as broad as the Human Tissue Act 1961 itself.¹⁹⁷ Areas identified where a revision of legislation should be contemplated included: authorisation for removal of tissue; definition of ‘relatives’; definition of ‘enquiries’; procedures to certify death; statutory recognition of bequests; live donors; consent of the Director of

¹⁹² Edmund Davies, Lord Justice. *A legal look at transplants*. Proc. Roy. Soc. Med. 1969:62: 633-38 at p 636.

¹⁹³ *Report of the Special Committee on organ transplantation*. BMJ 1970:1(5698); 750-51, at 751.

¹⁹⁴ The National Archives. Ref. MH150/401. Document D49, December 1971, op.cit., para 4.

¹⁹⁵ Ibid. Document D49: *Human Tissue Act 1961*, December 1971, with appendices; also Memoranda M47, M48, M51, M53.

¹⁹⁶ Ibid. Document D29A. WG Robertson, *Draft consultation document*., May 16, 1970.

¹⁹⁷ Ibid., Document D49, December 1971, op.cit., para 4.

Public Prosecutions to prosecution of doctors; offence to sell organs; recovery of implanted devices; autopsies; amendments of Anatomy Acts 1832 and 1871.¹⁹⁸

As matters turned out, there would be no major amendment of the Human Tissue Act 1961 until it was replaced by the Human Tissue Act 2004. [The original s.3, which related to the Anatomy Act 1832 and Cremation Acts 1902¹⁹⁹ and 1952²⁰⁰, was repealed by the Anatomy Act 1984. Section 1(4) was amended, and s.1(4A) and (10) added, by the Corneal Tissue Act 1986.²⁰¹ The Human Organ Transplants Act 1989²⁰² had its origins in a ‘kidneys for sale’ case. By regulation, a new supervisory body, the Unrelated Live Transplant Regulatory Authority (ULTRA) was established²⁰³. Other minor amendments were made by general health and community care legislation.]

The importance of the work undertaken by officials in the early 1970s was that their conclusions and recommendations remained on file and were available to those involved in the stages of inspiration, deliberation, and formulation of what became the 2004 Act. This is discussed further in Chapter Four.

5.2.1 Post mortem examinations (‘post mortems’; ‘PMs’; ‘autopsies’).

Of particular note were the issues identified by officials in 1971 in regard to autopsies in the following terms:

The procedure required in s.2(2) for [non- coronial] autopsies is the same as that for donations under s.1 for therapeutic purposes, medical education or research, namely, express consent or absence of objection by the deceased or his relatives. It is held upon Parliamentary Counsel’s advice that consent to an autopsy does not

¹⁹⁸ Ibid. Document D49, Appendix III: *Possible points for inclusion in legislation*.

¹⁹⁹ *Cremation Act 1902*. (1902, c.8.)

²⁰⁰ *Cremation Act 1952*. (1952, c.31.)

²⁰¹ *Corneal Tissue Act 1986*. (1986, c.18).

²⁰² *Human Organ Transplants Act*. 1989 (1989, c.31).

²⁰³ *Human Organ Transplants (Unrelated Persons) Regulations 1989* (SI 1989/2480) s.2(3).

ipso facto authorise removal of tissue beyond what is essential for the purposes of the autopsy.²⁰⁴

[This was an interpretation by Departmental officials²⁰⁵ of Counsel's advice given during drafting of the Human Tissue Act 1961 and discussed in Chapter One, against the need to include the term 'retention' in the 1961 legislation²⁰⁶]. It matters little that Counsel's letter perhaps allowed an alternative interpretation to be put on it with regard to consent for retention from that taken by the official when drafting advice in 1971, in that 'retention' [of small portions of tissue] was seen by Counsel as an inevitable consequence of an examination, rather than as an extra procedure. More important is that the phrase 'consent to an autopsy does not *ipso facto* authorise removal of tissue beyond what is essential for the purposes of the autopsy' entered official files.

The Departmental paper continued:

It follows from this that a doctor wishing to carry out both an autopsy and removal of tissue, say for other research, should, in strict law, obtain explicit consent to both purposes. There is some indication that this is not always sought, and there has been some controversy. It is possible that pathologists and others carrying out scientific autopsies are motivated by a desire to spare distressed relatives as much as possible, but this is a source of misunderstanding and possible friction. Three options are possible. First, the wording of s2(2) could be amended to bring it into line with what is thought to be medical practice, that is, a relative would agree to a post-mortem and removal of tissue. Second, the opposite course would be to tighten the wording to make sharper what is understood to be the present effect of the law. Third, the issue could be left, but sooner or later there might be an awkward case weakening public confidence in the profession. On the other hand, it is not clear that the medical profession would welcome the publicity likely to accompany discussion of a change since this is delicate ground for them.²⁰⁷

²⁰⁴ The National Archives. Ref. MH150/399. Document D49, December 1971. Appendix III: *Possible points for inclusion in legislation*, op.cit.

²⁰⁵ The National Archives. Ref. MH150/399. Memorandum (M41) from MWM Ormerod to WG Robertson, September 29, 1970.

²⁰⁶ The National Archives. Ref. MH150/399. Letter from HF Rowe (Office of the Parliamentary Counsel) to SD Musson, October 11, 1960.

²⁰⁷ The National Archives. Ref. MH150/399. Document D49, December 1971. Appendix III: *Possible points for inclusion in legislation*, op.cit.

Events twenty five years later would prove the prescience of these words.

6. Summary.

The challenges posed by developments in transplantation had been the driving force behind the Human Tissue Act 1961. It is not surprising therefore that it was further questions raised by transplantation practice which challenged the adequacy of that legislation. These questions proved Dr Dickson Mabon MP to have been wrong in his predictions about its adequacy in the long term.

In the absence of any systematic post-legislative scrutiny (a usual state of affairs for the time), evidence of problems accumulated gradually and patchily, led by the pleas of the transplant surgeons. In the mid to late 1960s, Government was still conditioned to determining 'what the doctors require'; so that, when questions began to be raised about the definition of 'the person in lawful possession', and the span of relatives who needed to be consulted after such reasonable inquiry as was practicable, the Government responded by setting up two broadly based advisory conferences, followed by *MacLennan*. Both the lead Ministers who were involved during this period, Rt Hon Kenneth Robinson MP and Rt Hon Richard Crossman MP, clearly expected that new revised legislation would be needed to meet the doctors' wishes.²⁰⁸

In the event, what emerged from Robinson's conferences, and from *MacLennan*, was a need for caution. The voice of the public had begun to be heard, and that expressed significant disquiet about the possibility of organs being removed under an 'opt out' scheme favoured by the more vocal transplant surgeons. The need for explicit consent began to be articulated. This led Robinson to conclude that public

²⁰⁸ (1968) 762 Parl. Deb. (Hansard 5th series) HC, op.cit., 833.

opinion would not support the removal of organs without permission²⁰⁹ - a view endorsed by Cabinet.²¹⁰

In 1968 Robinson had said in the House of Commons that, in his view, the Human Tissue Act 1961 at the time of its enactment had gone as far as had been reasonable at that time to strike a balance between facilitating the possible use of organs to save another life and the feelings and religious beliefs of the dead person's family; and that changes which might be desirable to keep pace with advances of medical science would not be generally acceptable unless such feelings were treated with due respect²¹¹ - a very different tone and balance from the 'give doctors what they require' debates only seven years previously at the time when The Human Tissue Act 1961 was introduced. It was this dawning awareness of the need to carry public opinion that was the major reason why successive governments in the late 1960s and early 1970s stopped the initiatives of the MPs Nabarro, St John Stevas and Dalyell to introduce amending legislation. Instead, after a period when waiting for the (largely irrelevant) *Broderick and Peel* reports was used as a stalling mechanism by Ministers, a mantra was developed which thereafter intoned repeatedly the need for motivation and education of the public, with a view to devising an acceptable and effective scheme for voluntary donation.^{212 213 214}

The publicity given to the cases (Ford, Howard, O'Sullivan, McEldowney) in which doctors had allegedly transgressed the provisions of the 1961 Act, and the letters of

²⁰⁹ The National Archives. Ref. MH150/399. Document D1A. *Meeting to consider the conclusions of the second meeting of the Conference on the Transplantation of organs and their effect on the Renal Transplantation Bill.* June 14, 1968.

²¹⁰ The National Archives. Ref. CAB128/44. CC(69) 32. Conclusions of a Meeting of Cabinet, July 10, 1969.

²¹¹ (1968) 762 Parl.Deb. (Hansard 5th series) HC, 832.

²¹² The National Archives. Ref. MH150/399. Letter from K Joseph to G Nabarro, February 4 1972.

²¹³ Ibid. Minutes of Parliamentary Secretary (Health) meeting. February 18, 1972

²¹⁴ (1972) 831 Parl.Deb. (Hansard 5th series) HC, 251.

protest which were sent subsequently from the public to Ministers^{215 216 217 218 219}, must surely have influenced at least Departmental thinking. This can be seen in the draft legislation which officials prepared in the early 1970s (but which in the event was never revealed), in which such matters as authorisation for removal of tissue, procedures to certify death, and procedures to allow the prosecution of doctors (all of which had been raised by members of the public), were outlined.²²⁰ This apparent awareness of public concern stood in contrast to the response of officials to letters of concern from the public, sent around the time of introduction of the 1961 Act, which were ignored or politely rebuffed.^{221 222 223}

Within the evolving transplantation narrative, an ignorance of the relevant law was revealed on the part of doctors who were involved. Dr Couve de Murville had said directly that he did not know of the need for consent from the relatives before taking corneas. In the O'Sullivan case, the hospital authorities had been uncertain about the extent of their obligation to seek objections. More worryingly, the surgeon in the Ford case had indicated, by the speed with which he had proceeded to harvest a kidney after death, a lack of understanding of the *purpose* of making a proper inquiry of the relatives—a purpose set by the Minister of Health in terms that

²¹⁵ The National Archives. Ref. MH150/401. Document D27. Letter from L Howard to Home Secretary, July 8, 1970.

²¹⁶ Ibid. Document D28. Letter from A Coulston to Sir Keith Joseph MP (Secretary of State), July 19, 1973.

²¹⁷ Ibid. Letter from LS Ashley to Sir Keith Joseph MP (Secretary of State), July 20, 1973.

²¹⁸ Ibid. Letter from E Donohoe to Prime Minister (Rt Hon Edward Heath MP), July 20, 1973.

²¹⁹ The National Archives. Ref. MH150/653. Letter from LS Ashley to Rt Hon Barbara Castle MP, December 6, 1975.

²²⁰ The National Archives. Ref. MH150/399. Document D49: *Human Tissue Act 1961, December 1971*. Appendix III: *Possible points for inclusion in legislation*.

²²¹ The National Archives. Ref. MH58/497. Letter from HC Evans to the Prime Minister (Rt Hon Harold Macmillan MP), undated.

²²² Ibid. Letter from WL Mancey to Rt Hon Enoch Powell MP (Minister of Health), January 2, 1961.

²²³ Ibid. Letter from N B[illegible] to 'Ministry of Health', July 4, 1961.

far more harm would be done by a single case in which a strongly held scruple was overridden than by a temporary loss of opportunity.²²⁴ The doctors in the Ford case apparently overrode a clearly stated objection, with the result that, to judge from the volume of adverse press and public response, harm *was* done to the cause of transplantation.

In part mitigation, it is relevant to remember the difficulties that *MacLennan* had had with understanding the implications of the Human Tissue Act 1961 as worded with regard to the taking of organs for therapeutic purposes, and which they had resolved only into a series of questions. Who was the person in lawful possession? In the period between death and the claiming of the body by executors or next of kin, did the hospital have possession, or did possession by the executors or next of kin start at the moment of death? Was it permissible under the law to remove organs if no enquiry is 'practicable' within the very short time after which organs become unusable? Did the right to object subsist literally in 'any surviving relative', no matter how remote the kinship?²²⁵ These questions would not be resolved in statute law until the passing of the Human Tissue Act 2004.²²⁶

Ignorance of the Human Tissue Act 1961 was not confined to transplant surgeons, nor to an understanding of the wording of those sections of the Act which were relevant to transplantation. It will be recalled from Chapter One that that Act had had sections added which related to post-mortem examinations in order to settle previous uncertainty about the legality of non-coronial post mortems.²²⁷ This issue was eventually resolved within the 1961 Act at s.2(1):

s.2(1) 'Without prejudice to section fifteen of the Anatomy Act 1832 (which prevents that Act from being construed as applying to post mortem examinations directed to be made by a competent legal authority), that Act shall not be

²²⁴ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1256.

²²⁵ Advisory Group on Transplantation Problems. *Advice on the question of amending the Human Tissue Act 1961*. July 1969. Cmnd. 4106, p4.

²²⁶ *Human Tissue Act 2004*, (2004, c.30).

²²⁷ The National Archives. Ref. CAB134/80. Memorandum by the Secretary of State for Scotland and the Minister of Health. H.A.(60) 105, op.cit.

construed as applying to any post- mortem examination carried out for the purpose of establishing or confirming the causes of death or of investigating the existence or nature of abnormal conditions.²²⁸

The legislation dealt with the *fact* and the *purpose* of a post mortem examination but said nothing about the *procedure* or the *content* of such an examination. If, as I propose, doctors regarded ‘retention’ as an integral part of a post mortem examination rather than as an extra procedure, then at least some of the gaps in communication between doctors and relatives about PMs, revealed in later ‘organ scandals’, might be better understood. However, there was also an ignorance of the law on the part of medical practitioners as revealed by: overlooking the content of DHSS circular HC (IS)156 by Regional Medical Officers and their staff; there being a difference between removing organs for transplantation and ‘mushing up a little gland’ in the mind of a pathologist; uncertainty within the Medical Research Council as to the boundaries between the requirements of an autopsy to establish the cause of death and those for extending the range of knowledge and understanding of disease, as revealed by the Neuberger Inquiry into radiation studies²²⁹; and the fact that, as late as 1990, the retention of tissues from post-mortem examinations continued to generate letters to the Royal College of Pathologists, and led to the conclusion by the executive of that College that ‘obviously some pathologists are still not clear as to the legal situation.’²³⁰

It must have been of some embarrassment to Government that several of the transgressions of the Human Tissue Act 1961 which accumulated in the ‘in-tray’ had arisen from government establishments. The Medical Research Council had been in charge of the Human Pituitary Collection, and when it emerged that pituitaries had routinely been taken at post mortem without consent, the best that a spokesman for the Council could say was that the MRC relied upon pathologists to conform to

²²⁸ *Human Tissue Act 1961. s.2(1).*

²²⁹ Medical Research Council. *Radiation in MRC supported research in the 1950s and 1960s: Report of a committee of inquiry.* May 1 1998, op. cit.

²³⁰ Registrar’s column. *Legal considerations in the retention of post mortem material.* Bulletin of the Royal College of Pathologists 1990; no. 70:3.

the law. As to the MRC's involvement in radiation studies, where again tissue (bone) was taken without consent, IRG concluded that 'most parents signing [a PM consent form] would have had little idea of the assumptions which were made at that time by pathologists about what that signature covered or authorised'²³¹. The Neuberger inquiry conceded that the boundaries between the requirements of an autopsy to establish the cause of death and those for extending the range of knowledge and understanding of disease were blurred.²³² Most striking of all [albeit in retrospect] was the involvement of government institutions, and coroners, in the taking of tissues for research without consent revealed in November 2010 by *Redfern 2*. Ignorance of the law, and the mores of the time with regard to 'informed' consent, extended well beyond the medical profession.

The main purpose of this Chapter was three-fold: first, to determine what accumulated in the 'in tray' following the introduction of the Human Tissue Act 1961 and note what responses, if any, followed (as a prelude to considering the possible role of factors other than 'organ scandals' in Bristol and Liverpool as 'inspiration' for new legislation- see Chapter Four); second, to assess whether the intended policy objectives were met, and if so, how effectively; third, to consider narrow questions of a purely legal or technical nature, as relevant. In overall conclusion, the evidence has confirmed that, as was common during the years following the introduction of the Human Tissue Act 1961, there was no systematic post-legislative scrutiny. Instead, a series of problems arose, which were met by piecemeal responses. The problems had their origins partly in developments in transplantation, partly in ignorance of the existing law by practitioners and Government research departments, partly in difficulties in interpreting the letter of the law (a law that would later be described as be 'obscure, uncertain and

²³¹ Independent Review Group on Retention of Organs at Post-Mortem. *Report on Strontium-90 research*, op.cit., para 3.17.

²³² Medical Research Council. *Radiation in MRC supported research in the 1950s and 1960s: Report of a committee of inquiry*. May 1 1998, op.cit., p 18, para 5.2.9.

arcane')²³³, and, importantly, partly because the voice of the public began to be heard in official circles.

It is to the rising importance of that public voice, and its implications for public policy, that the next Chapter turns.

²³³ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000. Letter accompanying the Interim Report from the chairman and members of the Inquiry to the Chief Medical Officer of England, May 2000.

CHAPTER THREE

A profession under pressure? Or sailing unconcernedly towards the rocks?

Preamble.

In 2000, the Panel in the Bristol Royal Infirmary Inquiry (whose findings will be considered in detail in Chapter Four) concluded, with regard to their findings concerning post mortem tissue retention, that:

[t]here was in essence, a professional arrogance, justified when necessary by the recourse to traditional paternalism...[f]undamentally, there was a social and ethical time bomb waiting to go off. It is no surprise that the explosion of anger, when it came, was huge. The cause lay in two conflicting attitudes [as between parents and the profession]¹.

Was this an accurate and fair description of the then relations between the public and the medical profession, whose standing Parliament had so trusted 40 years previously as to legislate for what the medical profession *required* (my emphasis) for the improvement of treatment, education and research²? If there was such a dramatic shift in attitudes, to what might it be ascribed?

There are three 'players' in the following account: 'society'; patients; and the medical profession. Their interrelations are complex, and each will appear, leave the stage, and reappear in a veritable 'dance to the music of time'³. The chapter begins in the UK with an examination of public attitudes to medicine from two perspectives: relationships between medicine and the state; and changing doctor-patient relationships. Consideration is then given to what might be expected of a

¹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: Interim Report: Removal and retention of human material. May 2000, p9, paras 32-33.

² (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1235.

³ Powell A. *A dance to the music of time: a cycle of twelve novels*. London. Heinemann, 1951- 1975.

good doctor, including the role of trust. The importance of professional regulation is examined and the performance of the General Medical Council is assessed. Next, comparisons with the USA are made, in an attempt to identify both universal and nation-specific factors which might have been operating. The chapter then moves from doctor/patient/medicine/health themes to explore (necessarily briefly) some broader societal factors of potential relevance. The chapter concludes with an examination of how the medical profession coped with, and responded to, these societal pressures, as the millennium approached.

1. Attitudes towards the medical profession in the UK.

Elston noted in 1991 '[t]he paucity of recent detailed empirical studies by medical sociologists of the major institutions of British medicine. Research into the professional organisations and the institutions of medical education and collegiate control have been conspicuous by their absence in recent years'⁴.

With that rather discouraging start, the following paragraphs seek to examine the UK position from two perspectives: first, a changing relationship between the state and medicine; second, the challenge to medicine from the articulate 'consumer'.

1.1 Relations between the state and medicine.

1.1.1 Influential critiques.

The concordat between the state and the medical profession was scarcely questioned during the first thirty years of the NHS. However, in the mid 1970s concern over continuously escalating costs led to marked financial constraints and proposals to ration resource allocation between regions and focus spending on national priorities.⁵ At about the same time, a number of critiques appeared which arguably could have combined to dent confidence and optimism about the future. Dollery described the end of an 'era of optimism' about the contribution that high

⁴ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, p84.

⁵ Elston MA. *Medical autonomy: challenge and response*. In: Barnard K, Lee K (eds.) *Conflicts in the National Health Service*. London. Croom Helm. 1977, pp 26-51.

technology medicine was making to health. Evidence of diminishing returns in terms of reducing adult mortality, the iconoclastic epidemiology of McKeown and Cochrane, and the more dramatic claims of epidemic iatrogenesis of Illich may have contributed to a climate in which questioning of the efficiency and effectiveness of medicine's use of resources could become a more legitimate activity for politicians. In addition, and discussed later, the 1970s saw the beginnings of a rise in concepts of patient autonomy/consumerism in health.

Colin Dollery, one of the foremost clinical scientists of his generation, entitled a monograph on clinical science 'The end of an age of optimism'.⁶ Writing in 1978, he described the mood of the preceding 30 years in these terms:

Some of the early achievements in the treatment of infections were so miraculous as almost to surpass belief. They, literally, changed the world...it was a time of optimism. Science appeared to have the salvation of the world in its hand and mankind could look forward to an era of healthy ease and modest prosperity...[but now] the mood has changed...[there are] doubts about the future of affluence...problems seem larger and solutions to them more elusive. Crash programmes on cancer and stroke have made only a modest impact on their targets. The validity of claims made about past successes has been questioned. Both the morality and the cost effectiveness of scientific medicine have been challenged. Care in the community seems more readily attainable and comfortable than the chance of high technology cure in a modern hospital. The age of optimism has ended.⁷

Dollery identified that, amongst 'the barrage of criticism' of medical science, some voices stood out. He drew up a 'charge list' and listed the charges against the names of the chief 'witnesses', as follows: conspiracy against the public (Ivan Illich)⁸; callous lack of concern (Maurice Pappworth)⁹; irrelevance of medical

⁶ Dollery C. *The end of an age of optimism: medical science in retrospect and prospect*. Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1978.

⁷ Ibid., pp 1-2.

⁸ Illich I. *Limits to medicine. Medical nemesis: the expropriation of health*. London. Marion Boyars, 1976.

⁹ Pappworth MH. *Human guinea pigs*. London. Routledge and Kegan Paul, 1967.

practice to health (Thomas McKeown)¹⁰; credulous acceptance of new procedures and drugs (Archie Cochrane)¹¹; technological inhumanity (public and press); lack of application to real health problems (Department of Health and Social Security)¹². It is beyond the scope of the present account for me to attempt to play the role of Counsel for either the prosecution or defence. Instead, it is appropriate to try to assess briefly the wider influence of the charges and the witnesses.

The sense of immense confidence in the eventual conquest of disease which had come from discoveries such as penicillin and streptomycin had not been confined to medical scientists. It had found strong expression in the views of politicians and the public. As Dollery said, this was the age of Beveridge and Bevan as well as Fleming and Waksman.¹³ Unreasonable expectations were fed by uncritical claims and a reaction was bound to happen. Physicians who had been happy to accept the credit for 'cures' that were the result of the placebo effect and regression upon the mean, rather than to specific measures, were faced with the charge that their efforts had had little positive effect and might even be counterproductive. As so often occurs in debates, overstatement on one side was met with overstatement on the other, and moderating voices were poorly heard.

For example, the arguments of McKeown, that by far the greater part of the improvement in life expectancy over the preceding 150 years had been due to improvements in sanitation, housing and nutrition, and that the role of medicine and medical science had been minor, received wide and sympathetic hearing from reviewers¹⁴ who took little notice of rebuttals from authors such as Beeson¹⁵,

¹⁰ McKeown T. *The role of medicine: dream, mirage or nemesis?* Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1976.

¹¹ Cochrane AL. *Effectiveness and efficiency. Random reflections on the National Health Service.* Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1977.

¹² Dollery C. *The end of an age of optimism: medical science in retrospect and prospect.* Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1978, op. cit., p27.

¹³ Ibid., p 87.

¹⁴ Ibid., p14.

Godber¹⁶ and Lever¹⁷. Among those influenced by McKeown's arguments was Ian Kennedy, who would acknowledge this in his Reith Lectures published five years later.¹⁸ It is of interest that McKeown, in subsequent conversations with Dollery, was said to have come to believe that he had presented his arguments leaning too far one way to counteract the excessive claims of medical scientists who he had felt were leaning much too far in the other direction.¹⁹

Ivan Illich's book *Limits to Medicine* opened with the challenging sentence 'The medical establishment has become a major threat to health'.²⁰ He made four main charges against the medical care system: much disease is doctor-induced; the social organisation of medicine has a health denying effect; there is 'cultural iatrogenesis', whereby the medical enterprise saps the will of people to 'suffer their reality'; and, in the political dimension, pathogenic medicine is the result of industrial overproduction that paralyses autonomous action- but one example of the destructive dominance of industry over society. In a new preface to a reprint of his book in 1995, Illich clarified his purpose. 'I used medicine as a paradigm for any mega-technique that promises to transform the *condition humana*. I examined it as a model for any enterprise claiming, in effect, to abolish the need for the art of suffering by a technically engineered pursuit of happiness'.²¹

¹⁵ Beeson PB. *McKeown's 'The role of medicine': a clinician's reaction*. Milbank Memorial Fund Quarterly. Health and Society 1977; 55: 365-372.

¹⁶ Godber G. *McKeown's 'The role of medicine': comments from a former Chief Medical Officer*. Milbank Memorial Fund Quarterly. Health and Society 1977; 55: 373-378.

¹⁷ Lever AF. *Medicine under challenge* Lancet 1977; 1(8007): 352-353.

¹⁸ Kennedy I. *The unmasking of medicine*. London. George Allen & Unwin, 1981, p xi.

¹⁹ Dollery C. *The end of an age of optimism: medical science in retrospect and prospect*. Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1978, op. cit., p15.

²⁰ Illich I. *Limits to medicine. Medical nemesis: the expropriation of health*. London. Marion Boyars, 1976, op.cit., p3.

²¹ Smith R. Review. *Limits to medicine. Medical nemesis :the expropriation of health*. BMJ 2002; 324(7342): 923, citing: Illich I. *Limits to medicine*. Marion Boyars, 1995.

It is difficult to assess the long term influence of Illich's writing. In the short term, we know that one medical student, Richard Smith, later a distinguished editor of the *British Medical Journal*, was so moved by hearing Illich's lecture in 1974, 'a passionate man surrounded by the fossils of the academic hierarchy in Edinburgh', that he had 'the closest I ever came to a religious experience' and dropped out of medical school for three days.²² In 2002, Smith found in his re-reading of *Limits to medicine* that '[its] power is undiminished and its prescience remarkable. What was a radical polemic in 1974 is in some sense mainstream in 2002. Medicine does seem to have overreached itself and some reining in will benefit not only patients but doctors'.²³

Others were divided on the question of Illich's long term influence. To his obituarist in *The Times*, Illich was not a realistic planner towards his goals ['of freedom, equality and fraternity']. Instead he gradually retreated into thought rather than action, preferring on his rare visits to the UK the company of university professors to any investigation of real social conditions. 'His attacks on professions, neatly paradoxical as they were, often failed to make direct contact with life on the ground in mass society'.²⁴ In the view of Bunker, Illich's attack had been largely ignored by the medical profession and there was little if any evidence that it has affected the growth of the medical establishment.²⁵ To Scott-Samuel, Illich was 'well ahead of his time' in identifying the health hazards of the medicalisation of society, but felt that, in retrospect, his thesis of the disabling of society through the direct dominance of professionalism and industrialisation was over-simplistic, and certainly gave insufficient credit to the achievements of medicine. 'But as a preacher of revolution in the politics of health, he had few equals'.²⁶ Ian Kennedy,

²² Smith R. Review. *Limits to medicine. Medical nemesis :the expropriation of health*. BMJ 2002; 324(7342): 923.

²³ Ibid.

²⁴ *The Times*. London. December 5, 2002.

²⁵ Bunker JP. *Ivan Illich and medical nemesis*. J Epidemiol Community Health 2003; 57(12): 927.

²⁶ Scott-Samuel A. *Less medicine, more health: a memoir of Ivan Illich*. J Epidemiol Community Health 2003; 57(12): 935.

although he would not ‘necessarily’ endorse the views of Illich, was clearly influenced by Illich’s conclusion that the whole of medicine was a moral exercise, when coming to his own recognition of the ‘medico-moral’ dimension to many medical decisions.²⁷

There is an interesting anecdote about Illich when he was not being ‘charismatic’ with ‘compelling rhetoric’. In 1976, he gave a series of lectures at the University of California at Los Angeles (UCLA) on ‘iatrogenesis’ before a sceptical and at times resentful medical audience. At the end of his last lecture, a questioner opined that his approach to medicine, medical professionals and medical institutions had been entirely negative, and asked how medical professionals could improve, rather than harm, the health of people and society. ‘The question prompted Dr Illich to formulate, apparently for the first time, a proposal to use the best (most efficient) modern medical technology to enrich popular culture so as to improve the ability of people to cope on their own with disease and disability, and their ability to help maintain their own health’. This prompted the reporter to hope that, not only had UCLA had the benefit of Illich’s thinking, but that UCLA may have helped guide that thinking ‘into more constructive channels’.²⁸

1.1.2 National policy and medical decisions.

Although it may be plausible to suggest that the writings of McKeown, Illich, Cochrane and others (a form of literature dubbed ‘those antidoctor books’²⁹) created a climate in which questioning of the efficiency and effectiveness of medicine’s use of resources could become a more legitimate activity for politicians, it is difficult to substantiate such a hypothesis directly. It is certain that the *economic climate* in the late 1970s forced such reappraisal –against a background of frustration about the collective inability of the centre to influence activities on

²⁷ Kennedy I. *Treat me right: essays in medical law and ethics*. Oxford. Clarendon Press, 1988, p 19 (footnote), and pps21, 23.

²⁸ Morgan MT. *Letter to the Editor (untitled)*. New Engl J Med 1976; 294(17): 960.

²⁹ Ingelfinger FJ. Editorial. *Those anti-doctor books*. New Engl J Med 1976; 294(8):442-443.

the ground.³⁰ Further, the Secretary of State for Health and Social Security, Rt Hon Richard Crossman MP (and his successors) were faced with the effect on the acute medical sector of what Klein had termed 'growing scarcity in an era of growth'³¹. This state of affairs was first recognised by Enoch Powell in 1966 in his immensely influential book *Medicine and Politics* as 'the infinity of demand', when he described as 'absurd' the idea that there was a definable amount of health care which was 'needed' and which, once met, would result in no more being demanded.³²

According to Klein, the way in which central policy makers reacted to the economic pressures on the NHS was significant as much for what they did not do as for what they actually did. In the reorganisation of the NHS in 1974, certain policy options were 'automatically' ruled out. There was no move towards controlling or even investigating the decisions of clinicians, in contrast to the USA where an open ended budgetary system had led to a series of attempts to introduce a formalised system for reviewing medical decisions. The doctrine of clinical autonomy continued to reign supreme. Even the Health Service Commissioner, whose office was set up in 1974 to deal with patient complaints, was explicitly barred from dealing with cases involving questions of clinical judgment.³³

Although the 1974 reorganisation of the NHS, devised with the goal of managerial efficiency, was constructed to ensure that the influence of 'expertise' continued, the ever deepening economic crisis that marked the years after 1973 profoundly transformed the situation. In Klein's analysis, one casualty of the new politics was the faith in technocracy that had marked the end of the 1960s and the beginning of the 1970s, so that there was a re-politicisation of issues which had previously been

³⁰ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, p62.

³¹ Ibid., p53.

³² Powell JE. *Medicine and Politics*. London. Pitman Medical, 1966, pp 26-27.

³³ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, op. cit., p67.

defined as belonging properly to the realm of the expert. Inevitably politicians had to handle the conflicts brought about by competing claims for resources. Moreover, the challenge to expertise was reinforced by another powerful emerging trend which began in the late 1960s and gained ever increasing prominence through the 1970s – namely, the emphasis on the values of ‘participatory democracy’ and a revolt against centralised bureaucracy. This was a development whose contributory factors had been well analysed in the USA³⁴ (which will be further considered in section 3 of this chapter), and which, in Klein’s view, were equally relevant in the UK.³⁵ While successive governments were reorganising the civil service, local government and the NHS on criteria based on the values of efficiency, simultaneously a groundswell of opposition to these values was making itself felt.³⁶

By the late 1970s, the revolt against expertise and a rising interest in participatory democracy, combined with a polarisation of politics and, above all, commitments to reducing public expenditure, were to have a major influence in the health care policy arena.³⁷ Although the process of change was gradual – a dawning realisation that the perceptions and assumptions which had for so long shaped health care policy needed to be adapted to the new environment – in my view there were a number of discrete episodes which altered in the UK, perhaps forever, the relationship between the medical profession and government, and the image of doctors in the eyes of the public.

Against a background of rising trade union militancy in the NHS during the early 1970s, in October 1975, for the first time in the history of the NHS, doctors took industrial action. Breaking with all precedent, junior doctors in Leicestershire

³⁴ Beer S. *In search of a new public philosophy*. In King A (ed.) *The new American political system*. Washington D.C. American Enterprise Institute, 1978.

³⁵ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, op. cit., pp81-82.

³⁶ Ibid.

³⁷ Ibid., p82.

withdrew their labour in a pay dispute, an action which subsequently spread to the rest of the country.³⁸ The outcome of the dispute was the introduction of an industrial-type contract for junior hospital doctors with overtime payments for virtually all hours worked over a basic 40 hour week. The concept of a doctor as someone who took responsibility for his or her patients at all times of the day or night was gone. At the same time, consultants were already embroiled in a battle with the Government over their contracts and private practice. They too adopted militant tactics. Their 'sanctions' began as threats only³⁹, but escalated so that for sixteen weeks, to a greater or lesser extent around the country, consultants 'worked to contract'. Outpatient sessions were cancelled, and waiting lists grew. In some places casualty departments closed on alternate weekends, and more than one patient found themselves anaesthetised and then not operated on because the surgeon's time was 'up'.⁴⁰ An editorial in the *British Medical Journal* identified the use of sanctions as 'a regrettable decline in professional self esteem which could permanently damage relations between doctors and the public'.⁴¹

As described by Timmins, there was a real clash of personalities in the dispute: the burning determination of the Rt Hon Barbara Castle MP, Secretary of State at the DHSS, versus the leader of the negotiators for the BMA, the surgeon Anthony Grabham. 'He brought to the previously gentlemanly conduct of government/doctor negotiations all the icy fire of a Tebbit- like shop steward, operating to a brief'.⁴² Assessment of Grabham's performance over the years has varied greatly- from being the best negotiator the BMA ever had to 'the man who

³⁸ Treloar S. *The junior hospital doctors pay dispute 1975-1976: an analysis of events, issues, conflicts*. J Social Policy 1981; 10 (1): 1-30.

³⁹ Leading article. *CCHMS: Consultants meet to discuss Queen's Speech*. BMJ 1975;4(4996): 593-595.

⁴⁰ Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, p336.

⁴¹ Editorial. *Industrial action by doctors*. BMJ 1975; 4(4996): 544.

⁴² Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, op. cit., p338.

single-handedly did more damage to British medicine than any other' according to the anonymous words of a senior doctor in the DHSS.⁴³

Eventually the dispute was settled by the intervention of the Prime Minister, Rt Hon Harold Wilson MP, and the involvement of Lord Goodman as chief mediator, but not without a cost. The adoption of industrial sanctions seems to me to have represented a profoundly important shift in the position of the medical profession, from a profession which 'earned' its respect and influence through a calling to serve the public, with its attendant privileges and restraints, to being just another group of workers in the NHS. This is to echo the words of Sir Theodore Fox, a past editor of the *Lancet* and a much respected medical figure, writing in late 1976 'either they are industrial workers who strike on any provocation, or they are members of a profession who strike on none'.⁴⁴

Long term damage was undoubtedly done. Dr Derek Stevenson, Secretary of the BMA, tried to limit the damage done by both junior and senior doctors as best he could in frequent appearances on television. But the violence of the doctors' language, the misogyny with which Barbara Castle had been attacked as 'the Red Queen', and, most damaging of all, the sanctions which the profession had applied to patients, seriously undermined the standing of doctors with both the public and politicians. At the same time the profession was split, many members having had no part in the action.⁴⁵ There were a large number of resignations from the BMA, including Sir George Godber, the then recent past Chief Medical Officer, who stated that he was no longer willing to be a member of an organisation which was prepared to pursue its objectives by methods harmful to patients.⁴⁶ As expressed by Timmins 'their moral authority to condemn industrial action by others in the

⁴³ Ibid.

⁴⁴ Fox TF. *Industrial action, the National Health Service, and the medical profession*. *Lancet* 1976; 308(7991): 892-895, p894.

⁴⁵ Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, op. cit., p340.

⁴⁶ Godber G. *The Times*. December 31, 1975.

NHS had gone, and the Tories, as much as Labour, marked the BMA down as a deeply troublesome and offensive trade union, a professional cabal which...seemed to have too much power and needed to be cut down to size'.⁴⁷

And cut down to size they were. According to Elston 'doctor bashing' and calls for reform became major sports in the mass media.⁴⁸ Indeed the BMA felt obliged to protest publicly, virtually accusing the Secretary of State for Health of complicity in 'what appears to be a deliberate attempt...to denigrate the work of doctors and undermine them in the public eye'.⁴⁹

Over the next dozen years, the medical profession was excluded completely from consultations on a range of changes in the health services, including, most notably, the major reorganisation set out in the White Paper *Working for patients*⁵⁰ (whose proposals were described by Klein as 'a turning point in the history of the NHS, a deliberate repudiation of the past'⁵¹). The ebullient Secretary of State for Health, Rt Hon Kenneth Clarke MP, was clear about his approach to the BMA. 'We had to pull them into the mud with us and make clear this was just another trade union, actually one of the nastiest I have dealt with, and battle it out'.⁵² The underlying, vastly increased and 'incontrovertible' ambition of the Government, in the view of Brazier and colleagues, was to control doctors on behalf of the central state.⁵³

⁴⁷ Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, op. cit., p341.

⁴⁸ Elston MA. *Medical autonomy: challenge and response*. In: Barnard K, Lee K (eds.) *Conflicts in the National Health Service*. London. Croom Helm. 1977, op. cit., p60.

⁴⁹ BMA Affairs. 'Lazy doctors' headlines anger BMA. *BMJ* 1988; 297(6656):1132.

⁵⁰ Secretaries of State for Health, Wales, Northern Ireland and Scotland. *Working for patients*. Cmnd 555. London. HMSO, January 1989.

⁵¹ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, op. cit., p167.

⁵² Clarke K. Interview with Timmins N. In Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, op. cit., p466.

⁵³ Brazier M, Lovecy J, Moran M, Potton M. *Falling from a tightrope: doctors and lawyers between the market and the state*. *Political Studies* 1993; 41: 197-213, p 205.

It is difficult to assess the overall effect in the eyes of the public of a battle, fought in the headlines, between the Government and a profession which challenged many of the Government's proposals^{54 55}. The BMA mounted an expensive campaign that included large posters which asked 'What do you call a man who ignores medical advice? Mr Clarke'⁵⁶; to be followed by Clarke's public rebuttal by announcing that his answer to the question was 'Healthy'.⁵⁷ This reply conveyed concisely the scepticism which characterised Clarke's term of office towards the BMA's claims to professional disinterestedness and the right to a central place in policy making.

The *National Health Service and Community Care Act 1990*⁵⁸ which arose from *Working for patients*, marked a double defeat for the medical profession. Not only was it the end of an era in which there was a medical veto in the health policy process, but the doctor's voice in the local administration of health care was also weakened.⁵⁹ The failure to include the Government's own Chief Medical Officer as an ex officio member of the newly created NHS Board symbolised for some the displacement of the profession from the centre of health policy making.⁶⁰

It has long been recognised that the man or woman in the street may take a very different view of 'doctors' from 'my doctor'.⁶¹ It is to that personal relationship that I now turn.

⁵⁴ BMA affairs. *BMA launches campaign against White Paper*. BMJ 1989; 298 (6674): 676-9.

⁵⁵ Vallance-Owen AJ. *The BMA after NHS review*. BMJ 1989; 298(6689): 1661-1662.

⁵⁶ Timmins N. *The five giants: a biography of the welfare state*. London. Fontana Press, 1996, op. cit., p741.

⁵⁷ Clarke K. *Speech at Conservative Party conference*. October 10, 1989.

⁵⁸ *National Health Service and Community Care Act 1990* (1990, c. 19.)

⁵⁹ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, op. cit., p172.

⁶⁰ *The Independent*. May 15, 1989.

⁶¹ Gaffin B and Associates. *What Americans think of the medical profession: report of a public opinion survey*. Chicago, American Medical Association, 1955.

1.2 Doctor-patient relationships.

1.2.1 The rise of the articulate consumer.

The late 1970s witnessed not only the end of an era of optimism about scientific medicine, but also, and perhaps not unconnectedly, the 'end of an era of the passive patient'. Instead, there arose the beginnings of active and increasingly sophisticated 'consumerism'⁶², a concept neatly summarised by Lupton:

In all usages of the notion of the patients *qua* consumers, regardless of political orientation, the dominant and privileged representation is that of dispassionate, thinking, calculating subjects [who are] rational economic decision makers with complete sovereignty over the choice of how to use their resources to their best advantage.⁶³

It was later argued that factors operating to encourage 'consumerism' on both sides of the Atlantic included: increased lay knowledge about medicine; declining deference to experts in society at large; changing patterns of morbidity, including a startling increase in chronic (as compared to acute) diseases as the dominant concern in practice; and a rise of psychological explanations for illness, leaving the physician dealing with the uncertainties of psychosomatics.^{64 65} All these changes were modifying social expectations about doctor-patient relationships towards respect for a patient's views, and mutual participation in decision-making.⁶⁶ It is clear that the medical profession did not adapt quickly enough.

⁶² Stevens R. *The future of the medical profession*. In Ginsberg G (ed.) *From physician shortage to patient shortage: the uncertain future of medical practice*. Boulder, Colorado. Westview, 1986, p76.

⁶³ Lupton D. *Consumerism, reflexivity and the medical encounter*. *Soc Sci Med* 1997; 45 (3): 373-381, p374.

⁶⁴ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, op.cit., p77.

⁶⁵ Burnham JC. *American medicine's golden age: what happened to it?* *Science* 1982; 215(4539): 1474- 1479, at p1476.

⁶⁶ Szasz T, Hollander MH. *A contribution to the philosophy of medicine: the basic models of the doctor-patient relationship*. *Arch Int Med* 1956; 97: 585-592.

Sir Donald Irvine, a Past President of the General Medical Council, certainly took the view that, during the 1980s, a conservative profession became increasingly out of step with the expectations of both government and the public.

Even though throughout the whole of the 20th century, the profession was vigorously progressive in developing medical science and technology, it remained deeply conservative in matters of attitude and human relationships...[t]he medical profession missed the point- and it was certainly not the only one to do so- that paternalism, even when it was benign, was becoming less acceptable in a consumer society in which patient/customer/client autonomy was emerging as the new order.⁶⁷

The outcome was 'society and patients moving out of respecting a profession and its practitioners simply by historical right and traditional relationships, leaving the doctors behind, floundering in surprise'.⁶⁸ A decline in respect coincided with calls for accountability- itself a symptom of the changing structure of 'exchange relations' in medical care.⁶⁹ It is of interest that the Social Science Citation Index (SSCI), which arranges all papers in the social science literature by the subject area of the title, first used the term 'accountability' in 1969, when there were two articles. In 1974 there were 89 references. Between 1969 and 1981 a total of some 700 books and papers on accountability were indexed.⁷⁰

1.2.2 The particular contribution of Ian Kennedy to the debate.

For his Reith Lectures, broadcast by the BBC in 1980, Ian (later Professor Sir Ian) Kennedy chose as the overall title '*The unmasking of medicine*'. In the preface to the lightly edited version of the lectures, published in 1981⁷¹, he explained why he had chosen that title. His purpose was

⁶⁷ Irvine D. *The doctor's tale: professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, pp5-6

⁶⁸ Ibid., pp37-38.

⁶⁹ Betz M, O'Connell L. *Doctor- patient relationships and the rise in concern for accountability*. Social Problems 1983;31(1): 84-95, p84.

⁷⁰ Ibid.

⁷¹ Kennedy I. *The unmasking of medicine*. London. George Allen & Unwin, 1981, op. cit.

[t]o ask some questions about the way medicine is thought of and practised, and to offer some ways of responding to what I perceive as problems...clearly, reference to a mask suggests that a face is being presented which hides the real one. My aim is to expose and then examine the real face of medicine...my task is to dispel the myths, so as to discover what the truth might be.⁷²

Also in the preface, Kennedy offered some signposts to his themes: the power of the professional, in contrast to the notion of the self determination of the client (the patient) and his sense of responsibility for himself; accountability of the doctor, and the need to ensure that the decisions of doctors, to the extent that they are not technical, conform to principles acceptable to 'all of us'; the need to recognise that medicine was, at bottom, a political enterprise- if such factors as poverty, malnutrition, stress, unemployment and lack of job satisfaction were heavily implicated in undermining health, it was clear that that these were not matters which doctors could affect.⁷³ He acknowledged as his 'principal sources to whom my debt is great' the writings of Illich⁷⁴ and McKeown⁷⁵ (discussed above), Muir Gray⁷⁶ (a specialist in public health), and Lesley Doyal⁷⁷ (a political economist, Marxist and feminist).

By identifying themes concerning the doctor- patient relationship, professional accountability, non-technical issues acceptable to 'all of us', and the political dimension to health care, Kennedy anticipated, and certainly helped to usher in, the subsequent twenty years of public debate, professional soul searching and political action.

1.2.3 'A good doctor'.

⁷² Ibid., pp viii-ix.

⁷³ Ibid., p ix.

⁷⁴ Illich I. *Limits to medicine. Medical nemesis: the expropriation of health*. London. Marion Boyars, 1976, op.cit.

⁷⁵ McKeown T. *The role of medicine: dream, mirage or nemesis?* Rock Carling Monograph. London. Nuffield Provincial Hospitals Trust, 1976, op. cit.

⁷⁶ Gray JAM. *Man against disease: preventive medicine*. Oxford, OUP, 1979.

⁷⁷ Doyal L, with Pennell I. *The political economy of health*. London. Pluto Press, 1979.

Bound to the consumerist approach is expectation. What is expected of 'a good doctor'? How does one recognise a good doctor in the UK? Much appears to be based on patients' beliefs- that doctors are technically proficient, have good interpersonal skills, and show signs that they are the patients' ally.⁷⁸

Attempts have been made to tease out the various roles which doctors play in society, in order that each might separately be held up to scrutiny and individual judgment. Burnham identified three main roles for physicians: priestly, technical and social.⁷⁹

The priestly function has been described by different authors in different ways. To Burnham the term related to an 'old fashioned' view of doctors as wise, kindly, trusted [usually] men, who took a personal interest in his patients and their families. Branson went further, describing the 'secularisation of medicine' in which the old ways, with their emphasis in faith, were being eroded by a widespread demand in society for self determination.⁸⁰ Veatch described the main ethical principle which summarised the priestly tradition as 'benefit and do no harm to the patient', which led to taking the locus of decision away from the patient and into the hands of the professional.⁸¹

The technical or 'engineering' model arose from the biological revolution, and made the physician into a scientist and a technician, to be judged by his or her knowledge and competence. At its extreme, this model required the doctor to be 'value free'.⁸²

⁷⁸ Mechanic D. *In my chosen doctor I trust*. BMJ 2004; 329(7480): 1418-1419, at p 1418.

⁷⁹ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op.cit., at p1476.

⁸⁰ Branson R. *The secularisation of American medicine*. The Hastings Center Studies 1973; 1(2): 17-28.

⁸¹ Veatch RM. *Models for ethical medicine in a revolutionary age*. The Hastings Center Report 1972; 2(3): 5-7.

⁸² Ibid., p6.

Veatch divided possible 'social' roles into 'collegial' and 'contractual'. He dismissed the collegial model of doctor and patient, in which the physician is the patient's 'pal' with each having common interests and with trust and confidence playing a crucial role, as 'a mere pipedream'. He preferred a more provisional model which would permit equality in the realm of moral significance between patient and physician without making utopian assumptions of collegiality. This he termed 'the contractual model', in which the lay community was given the status of contractor so that day-to-day medical decisions could, with trust and confidence, rest with the medical community.⁸³

In 2002 the *British Medical Journal* set up a web-based debate on what a good doctor is and how one is made. Over 100 people from 24 countries submitted rapid responses.⁸⁴ Everyone had something different to say. Coulter referred to a Europe-wide evaluation of patients' views about general practice⁸⁵ in which the most highly rated aspects of care were: 'humaneness', followed by 'competence/accuracy', 'patients' involvement in decisions', and 'time for care'.⁸⁶ In Coulter's view, patients wanted to trust their doctors but trust had to be earned by treating people as adults, answering their questions, listening to their views and involving them in decisions. This was not an optional extra- failure to accommodate patients' needs for involvement would diminish doctors' standing.⁸⁷

Hurwitz and Vass asked whether the notion of goodness had anything to add to what was wanted from doctors once their competence and performance had been specified and verified. They recognised that, with regard to doctoring, 'good'

⁸³ Ibid., p7.

⁸⁴ British Medical Journal. *Theme issue: What is a good doctor and how can one make one?* Accessed on July 12, 2009, at: www.bmj.com/2002.bmj.com/cgi/content/full/324/7353/DC1

⁸⁵ Wensing M, Jung HP, Mainz J, Olesen F, Grol R. *A systematic review of the literature on patient priorities for general practice care. Part 1: Description of the research domain.* Soc Sci Med 1998; 47(10): 1573-1588.

⁸⁶ Coulter A. *Patients' views of the good doctor: doctors have to earn their patients' trust.* BMJ 2002; 325 (7366): 668-669.

⁸⁷ Ibid., p 669.

increasingly functioned as a descriptive label that denoted having met certain tests of competency, 'poor' meant good intentions but inadequate knowledge or skills, and a 'bad' doctor was one who, however skilled, had bad intentions, undesirable values or suspect motives. Varieties of good, poor and bad doctoring may sometimes coexist in the same individual. However, these authors remained optimistic that becoming a good doctor was not an unattainable ideal. They believed that, through medical education, the skills of the applied scientist and the reflective capabilities of the medical humanist could be married.⁸⁸

The political and social commentator, Polly Toynbee, recognised that the above prescription was a tall order. Commenting on the then recently issued guidance to medical schools by the General Medical Council⁸⁹, she opined that 'if medical schools could indeed turn out doctors moulded to this template, then we should expect a new generation of scholar saints and gentle scientists- wise, knowledgeable, sensitive, collegiate, humble and good beyond imagining'.⁹⁰ Toynbee believed that the GMC document reflected the changing expectations that the public had of how doctors should work. She was supportive of the hope that young doctors of the future could be imbued with the ethos of this new framework for their education, even if, between aspiration and reality, 'human nature intervenes'.⁹¹

Ashcroft had the sceptical thought that compliance with a code was merely the outward form of medical virtue and not the heart of it. He drew attention, as Hurwitz had, that a search for the moral heart of medicine might be aided by study of the medical humanities. Goodness, in the sense of being a good doctor, may not be a matter of degree at all.⁹² Holmes, taking a psychodynamic approach,

⁸⁸ Hurwitz B, Vass A. *What's a good doctor and how can you make one?* BMJ 2002; 325 (7366): 667-668.

⁸⁹ General Medical Council. *Tomorrow's doctors*. London. General Medical Council, 2002.

⁹⁰ Toynbee P. *Between aspiration and reality*. BMJ 2002; 325 (7366): 718-719, p 718.

⁹¹ Ibid., p719

⁹² Ashcroft RE. *Searching for the good doctor*. BMJ 2002; 325(7366): 719.

concluded that 'the search for a good doctor is an illusion- our unconscious minds will make sure of that'. Instead he recommended that, if a doctor, without complacency, can bring his or her good and bad parts together so as to become a 'good enough' doctor, that should bring contentment- not only to the doctor but, more importantly, to patients, 'despite sometimes feeling let down by us'.⁹³ As O'Neill had observed, trust brings with it no guarantees.⁹⁴

In a summary of the debate in the *British Medical Journal*, Tonks observed that for some the notion of a good doctor was simple: it was one who satisfied patients or whom you would trust yourself. For others, defining a good doctor appeared to have been more difficult. Like defining a good car or a good play, it all depended on the perspective. An academic librarian had described a good doctor as 'one who reads and reads and reads'. A professor of bioethics with an interest in history had argued that good doctors are also good historians. Educators had given high priority to being a good teacher, coach and mentor. And a quality improvement specialist had proposed that a good doctor was one who critically examined what he or she did and tried to improve on it. Patients had appeared to want little more than a doctor who listened to them.⁹⁵

One can detect in the replies, and in other surveys of patients' perception of their doctors and of the health care system, the importance of trust, long recognised to be crucial in medical settings⁹⁶, and said in recent reports to be in decline in the UK⁹⁷ and elsewhere in the West⁹⁸.

⁹³ Holmes J. *Good doctor, bad doctor- a psychodynamic approach*. BMJ 2002; 325 (7366): 722.

⁹⁴ O'Neill O. *A question of trust: the BBC Reith Lectures 2002*. Cambridge. Cambridge University Press, 2002, p6.

⁹⁵ Tonks A. *What makes a good doctor and how do you make one? Summary of responses*. BMJ 2002; 325 (7366): 715.

⁹⁶ Clark CC. *Trust in medicine*. J Med Philosoph 2002; 27: 11-29.

⁹⁷ Alaszewski A. *Risk, trust and health*. Health Risk Soc 2003; 5: 235-239.

⁹⁸ Allsop J. *Regaining trust in medicine: professional and state strategies*. Current Sociology 2006; 54: 621-636.

1.2.4 Has there been a decline in trust?

The empirical evidence about a decline in trust in health care, and in doctors, is limited and inconsistent. In Europe there has been some evidence of a decline in trust, but it appeared to vary according to the values and organisation of each country's health care system.^{99 100} The studies of Mechanic support the conclusion that, in the USA, there had been a gradual decline in public trust in health care over the past 25 years.^{101 102} Although a pattern of decline in satisfaction (not necessarily to be equated with trust) with the NHS had been shown over a similar period^{103 104}, trust in doctors in the UK appears to have continued to be strong, at least as compared with other professions. A MORI poll of almost two thousand adults, commissioned by the BMA in late 2000, showed that 89% of the public trusted doctors to tell the truth- more than any other group, including teachers, lawyers and clergymen. The same proportion said they were either very satisfied (36%) or fairly satisfied (54%) with the way that doctors did their jobs- only nurses scored higher.¹⁰⁵

However, the poll gave a warning to doctors to give regard to patients' feelings. Thirty-five percent of respondents thought that doctors paid too little attention to patients' feelings, but 43% disagreed and 19% were undecided. Hospitals as

⁹⁹ Straten GFM, Friele RD, Groenewegen D. *Public trust in Dutch health care*. Soc. Sci. Med. 2002; 55 (2): 227-234.

¹⁰⁰ Wendt C. *Trust in health care systems*. Berl. J Soziol. 2003;13: 371.

¹⁰¹ Mechanic D. *Changing medical organisation and the erosion of trust*. Millbank Quarterly 1996;74(2): 171-189.

¹⁰² Mechanic D. *The functions of limitations of trust in the provision of health care*. J Health Politics Policy and Law 1998;23(4): 661-686.

¹⁰³ Calnan M, Almond S, Smith S. *Ageing and public satisfaction with the health service: an analysis of recent trends*. Soc. Sci. Med. 2003; 57(4): 757-762.

¹⁰⁴ Exley S, Jarvis L. *Trends in attitudes to health care: 1983 to 2001*. London. National Centre for Society Research, 2003.

¹⁰⁵ Ferriman A. *Poll shows public still has trust in doctors*. BMJ 2001; 322 (7288): 694.

institutions fared worse than doctors, with 59% of respondents believing that hospitals paid too little attention to the rights and feelings of patients.¹⁰⁶

Results of surveys by questionnaire depend crucially on sampling, the actual questions asked, and on satisfactory prior validation of the questionnaire. A recent well conducted cross-sectional postal survey by Calnan and Sanford, using a structured questionnaire, had as its objective an examination of how the public assessed trust in health care in England and Wales.¹⁰⁷ The data showed that despite a then recent series of scandals (some of which will form the basis of subsequent chapters in this thesis) 'confidence and trust in orthodox medical and health care practitioners remained relatively high. This is in marked contrast to the low levels of trust and confidence found in health service managers'.¹⁰⁸ The most important factors which contributed to the respondents' overall level of confidence and trust were at the 'micro' or personal level, and were a mixture of technical and interactive considerations. The top 5 of 32 factors were, in order: patients are taken seriously; patients get enough attention; patients will always get the best treatment; doctors always make the right diagnosis; doctors provide patients with good guidance.¹⁰⁹

Nevertheless, the authors concluded that overall levels of trust were relatively low, at least when compared with other indicators of public views such as satisfaction levels, with at least 30% expressing little or no trust that patients *are* taken seriously and given enough attention, rising to 50% of distrust that patients *will* always get the best treatment.¹¹⁰ The fact that the authors concluded, on consecutive pages, that their data indicated 'relatively high' and 'relatively low' levels of trust is itself an indication of some of the shortfalls of questionnaires,

¹⁰⁶ Ibid.

¹⁰⁷ Calnan MW, Sanford E. *Public trust in health care: the system or the doctor?* Qual Saf Health Care 2004; 13: 92-97.

¹⁰⁸ Ibid., p95.

¹⁰⁹ Ibid., table 2, p94.

¹¹⁰ Ibid.

however well constructed. O'Neill pointed out that the questions used by pollsters were not easy to answer. 'The pollsters ask carefully controlled cross-sections of the public whether they trust certain professions or office-holders. Most of us would want to say that we trust *some* but not *other* professionals, *some* but not *other* office-holders, in *some* matters but not in *others*'.¹¹¹

O'Neill, in her Reith Lectures in 2002, found little evidence of a crisis of public trust in institutions or professionals –and no evidence that, on balance, there was more untrustworthy behaviour now than in the past. Since the essential nature of trust was that it had to be placed without guarantees, it would inevitably be misplaced on occasions. However, she found 'massive evidence' of a culture of suspicion¹¹², and a pervading view that the remedy lay in prevention and sanctions- that Government, institutions and the professions should be made more accountable. 'The new accountability culture aims at ever more perfect administrative control of institutional and professional life'.¹¹³ Her fear was that the pursuit of ever more perfect accountability, while providing citizens and consumers, patients and parents with more information, more comparisons and more complaints' systems, could at the same time build a culture of suspicion and low morale, and eventual professional cynicism.¹¹⁴

Mechanic made similar points, noting that, when trust became eroded, public authorities often appointed expert commissions and introduced new rules and regulations to control substandard and unethical behaviour, for the purpose of assuring the public that health services met high standards and doctors could be trusted. Such measures may help, but, according to Mechanic, they usually did not have the high credibility that was accorded to trusted doctors in guiding and

¹¹¹ O'Neill O. *A question of trust: the BBC Reith Lectures 2002*. Cambridge. Cambridge University Press, 2002, op. cit., p9.

¹¹² Ibid., pp17-18.

¹¹³ Ibid., p46.

¹¹⁴ Ibid., p57.

reassuring patients.¹¹⁵ In the UK the body which plays this standard-setting and regulatory role is the General Medical Council. I turn now to a brief overview of its performance in contributing to public confidence in doctors.

1.2.5 The role and performance of the General Medical Council.

The General Medical Council of the UK was established as a result of the *Medical Act 1858*¹¹⁶ with the duty to maintain a register of medical practitioners. It is concerned to set standards for the medical profession and control medical education, and it has powers to discipline errant doctors, including the power to remove from the Medical Register those doctors judged unfit to practise. The GMC embodied the principle of self regulation, long seen as a quintessential characteristic of a profession¹¹⁷.

In the last decades of the 20th century, the GMC, with its large majority of medical (as compared to lay) members, came under sustained criticism, particularly with regard to a perceived inadequacy in the focus and thrust of its disciplinary procedures. Much of this criticism came from patients and relatives, for whom the formidable Mrs Jean Robinson, a lay member of the GMC (with wide knowledge of patients' complaints through her work for the Patients' Association), was long a champion.¹¹⁸ There was substance in Mrs Robinson's complaints- as put in 1989 by Richard Smith, later editor of the British Medical Journal:

[u]ntil very recently, there was truth in the common charge that the Council was more concerned when doctors slept with their patients rather than killed them through incompetence. This has now ceased to be true, and in the past ten years the Council has begun to apply its disciplinary machinery to doctors whose standard of practice has become unacceptably low. It does not, however, yet have

¹¹⁵ Mechanic D. *In my chosen doctor I trust*. BMJ 2004; 329 (7480): 1418-1419, p1418.

¹¹⁶ *Medical Act 1858*. 1858 (c.18.)

¹¹⁷ Goode WJ. *Encroachment, charlatanism and the emerging profession: psychology, sociology and medicine*. American Sociological Review 1960; 25 (6): 902-965, p903.

¹¹⁸ Robinson J. *A patient voice at the GMC: a lay member's view of the General Medical Council*. London. Health Rights, 1988.

any efficient mechanism for weeding out and educating incompetent practitioners.¹¹⁹

Professor Ian Kennedy, a lay member of the GMC ('the Council') and, as has already been indicated, a trenchant critic of medical practices¹²⁰, cast doubt on the adequacy and appropriateness of self regulation of doctors at the end of the 20th century. His views were summarised by Smith. First, the Council had a primary duty to protect the public interest but had no efficient mechanism for asking the public what that interest was. The lay members of the Council clearly represented the public interest, but they existed in a vacuum. They were not elected and had no constituency: rather they were appointed for undefined reasons by the Privy Council. In contrast, more than half the members of Council were doctors, many of them sponsored by the BMA. Second, in the view of Kennedy, it was of concern that the accountability of Council was not to Parliament, but rather to the Privy Council. Furthermore, the media-'the ultimate court in Britain'- were kept at a distance by the GMC. Third, the Council was not seen to secure the public interest-echoing Jean Robinson, too many complaints to the Council were dismissed without lay involvement and without open examination and public scrutiny. Fourthly, and in agreement with Rosenthal¹²¹, Kennedy worried that the extent of the Council's disciplinary activities was determined, not by need, but by the availability of resources.¹²²

Sir Donald Irvine later wrote of his time at the GMC, including his spell as President.¹²³ He endorsed Margaret Stacey's view of the 1980s as 'the era of the

¹¹⁹ Smith R. *Profile of the GMC: the day of judgment comes closer*. BMJ 1989; 298 (6682): 1241-1244, p1244.

¹²⁰ Kennedy I. *The unmasking of medicine*. London. George Allen & Unwin, 1981, op. cit.

¹²¹ Rosenthal MM. *Dealing with medical malpractice: the British and Swedish experience*. London. Tavistock, 1987.

¹²² Smith R. *Profile of the GMC: the day of judgment comes closer*. BMJ 1989; 298 (6682): 1241-1244, p1244.

¹²³ Irvine D. *The doctor's tale: professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, op. cit.

patients' revolt'.¹²⁴ In his version of that revolt¹²⁵, Irvine identified as the most influential figures in the public critique of the GMC (and by extension the performance of the medical profession) to be: Ian Kennedy, whose Reith Lectures in 1981 were a 'wake up call from the public'; Jean Robinson- 'applauded in the consumer world, and certainly got through to ministers whilst being disregarded by doctors'; the political scientist Rudolf Klein, for 'his focus on issues of doctors' accountability'¹²⁶; and, especially, Richard Smith, who in 1989 wrote a highly critical profile of the GMC in the *BMJ* in a series of papers.¹²⁷ The then editor of the *BMJ* had called for an independent inquiry into the issues raised by Smith's articles.¹²⁸

In 1995, the *Medical (Professional Performance) Act* was passed¹²⁹, extending the powers of the GMC to investigate poor performance by doctors. It took until December 2002, and a series of scandals, for a *Medical Act (Amendment) Order*¹³⁰ to be introduced, enabling the introduction of revalidation, new fitness to practise procedures, and a new, smaller, General Medical Council. At the time of writing (August 2010), the operational details of the revalidation process were still being discussed.

1.2.6 Summary and interim conclusions.

Over the last three decades of the 20th century a number of factors combined to change the traditional model in the UK which had left 'medical' decisions to doctors.

¹²⁴ Stacey M. *Regulating British medicine: the General Medical Council*. Chichester. Wiley, 1992.

¹²⁵ *Ibid.*, pp 72-74.

¹²⁶ Klein R. *The politics of the NHS*. London. Longman, 1983, pp158-165.

¹²⁷ Smith R. *Profile of the GMC: the day of judgment comes closer*. *BMJ*1989; 298 (6682): 1241-1244, p1241.

¹²⁸ Lock S. *Regulating doctors: a good case for the profession to set up a new inquiry*. *BMJ* 1989; 299(6692): 137-138.

¹²⁹ *Medical (Professional Performance) Act 1995*. (1995 c.51.)

¹³⁰ *Medical Act (Amendment) Order 2002*. S.I. 2002/3135.

Patients and the wider public grew more educated and better informed (partly by the mass media which developed a keen interest both in medical advances and doctors' failings), and became perhaps not less trusting, but more questioning. The era of 'the passive patient' gave way to a wish for a new set of doctor-patient relationships, in which patients could ask questions, and could treat the answers, not as commands, but as advice to be taken or left. This wish for new doctor-patient relations went at least partly unfulfilled as a consequence, in Irvine's view, of the deeply conservative attitudes of doctors in matters of attitude and human relationships which had persisted throughout the 20th Century.¹³¹ Alongside rising patient expectations came more frequent criticisms about the standard of performance of some doctors and dissatisfaction with the ability of the medical profession to regulate itself.

Government had several roles. First, the establishing of the NHS had created the promise, or certainly the expectation, of health in its widest form. The opening sentences in the Command Paper of February 1944 which presaged a national health service stated:

The Government... intend to establish a comprehensive health service for everybody in this country. They want to ensure that in future every man and woman and child can rely on getting all the advice and treatment and care which they may need in matters of personal health; that what they get shall be the best medical and other facilities available; that their getting these shall not depend on whether they can pay for them, or on any other factor irrelevant to the real need—the real need being to bring the country's full resources to bear upon reducing ill-health and promoting good health in all its citizens.¹³²

With such lofty goals there were bound to be disappointments. Second, the failing economy in the late 1970s brought a sharper questioning of the worth of high technology, and a repoliticisation of matters previously that had previously been left to experts. Third, publicly conducted conflicts between the government and

¹³¹ Irvine D. *The doctor's tale: professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, op. cit., pp5-6.

¹³² Minister for Health, Secretary of State for Scotland. *A National Health Service*. Cmnd 6502, Feb 1944, para 1.

the medical profession grew, and, crucially, the medical profession changed its relations with government (and more importantly, its image in the public's eye), perhaps forever, by taking industrial action which affected clinical services. Fourthly, the beginning of governmental dissatisfaction with the competence (and later questioning the appropriateness) of professional self regulation has often been attributed to the Thatcher government, but in fact has a longer history.¹³³ Last, the 'consumerist' approach of the government in the 1980s and 1990s led to the pursuit of ever increased accountability of, among many others, doctors - a state of affairs which, while providing citizens and consumers, patients and parents with more information, more comparisons and more complaints systems, may at the same time have built a culture of suspicion and low morale.

Such was the UK position in the late 1990s. It is timely to turn to the USA, to explore whether the cauldron of relationships (medicine/state and doctor/patient) which was simmering in the UK had any counterpart elsewhere.

2. Attitudes to medicine and doctors in the USA.

2.1 'A golden age'?

During the first half of the 20th century, American physicians enjoyed social esteem, prestige, and an admiration for their work that was unprecedented in any age.¹³⁴ By the 1970s, morale in the profession had slumped¹³⁵ in the wake of attacks by articulate and knowledgeable critics. In 1981, a survey of the general public revealed substantial mistrust of doctors and the medical profession as a whole.¹³⁶

¹³³ Brazier M, Lovecy J, Moran M, Potton M. *Falling from a tightrope: doctors and lawyers between the market and the state.* Soc Sci Med 1993; 41: 197-213, p 213.

¹³⁴ Gallup GH. *The Gallup Poll: Public opinion 1935-1971.* New York, Random House, 1972, pp.1152 and 1779-1780.

¹³⁵ Ingelfinger FJ. *Deprofessionalising the profession,* New Engl J Med 1976; 294(6): 334- 335.

¹³⁶ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, citing: American Osteopathic Association. *A survey of medical attitudes towards medical care and medical professionals.* Chicago. American Osteopathic Association, 1981.

Burnham examined different types and levels of criticism of doctors in an attempt to find out what had happened.¹³⁷

In the early years of the 20th century, according to Burnham, a 'golden age' of medicine dawned. In the wake of medical, and particularly surgical, successes, by the early 20th century the public was persuaded to want and expect uniformly well-trained, well paid physicians who themselves set standards of practice.¹³⁸ So effective was favourable publicity about both science and doctors that the American public began to view extensive medical care as a life necessity. Expansion of hospital care at the beginning of the 20th century was an important indication of the change.¹³⁹

However, all was not completely well. By the late 1930s the modern campaign for 'socialised medicine' or compulsory health insurance had begun, and for many decades organised medical groups opposed any change in the structuring or financing of health care delivery. These 'socialised medicine' debates eventually undermined public confidence in medicine as a profession.¹⁴⁰ The heavily financed publicity campaigns in the name of the American Medical Association, and the evident social insensitivity of physician groups, tended to tarnish the doctor as a public figure, and many people began to associate the physician with another familiar stereotype, the small business man who was presumed to be not only grasping but slightly dishonest.¹⁴¹ Indeed the actions of physician groups caused the US Supreme Court in 1943 to refuse officially to recognise doctors' professional claims, and instead to find physician groups, including the AMA, guilty of restraint of 'trade'.¹⁴²

¹³⁷ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit.

¹³⁸ Ibid., p1474.

¹³⁹ Ibid.

¹⁴⁰ Ibid., p1475.

¹⁴¹ Ibid., citing: Lee AM. Psychiatry 1944;7:371.

¹⁴² *American Medical Association v United States*. 317 US 519.

Even those doctors who were striving for high standards inadvertently contributed to an overall lessening of the image of their profession, according to Burnham. Beginning in the 1940s, a number of reformers within the medical profession had worked to expose inferior medical practice and upgrade medicine to a level appropriate for the age of penicillin and high technology. Some of the self criticism revealed through these efforts had been repeated by the general press: the resulting combination of internal criticism and external distrust eventually had a negative effect.¹⁴³

2.2 The end of the golden age in the USA.

The rare public doubters of the medical profession of the 1940s gradually increased in number. By 1954 it was possible to cite a series of sensational articles in mass media magazines attacking not only money making but incompetence in clinical practice.¹⁴⁴ Psychological studies and systematic research on patients, analogous to consumer surveys, had revealed concerns about individual doctor-patient relationships.^{145 146} Throughout the US, grievance committees were set up by local medical societies to try to mediate in physician-patient disputes and ‘bring about some of the professional self policing so notoriously absent theretofore’.¹⁴⁷ In addition other factors were at work, to which physicians were apparently slow to respond. As identified by Burnham, these included the marked rise in chronic (as opposed to acute) diseases as the dominant concern in practice, the greatly increased sophistication of consumers, and the rise of psychological explanations

¹⁴³ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit., at p1475.

¹⁴⁴ Maurer H. *The MD's are off their pedestal.* Fortune, February 1954, p118.

¹⁴⁵ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, citing: Greenberg S. *The troubled calling: crisis in the medical establishment.* New York. Macmillan, 1965, chapter 4.

¹⁴⁶ Amrine M. *Psychology in the news.* Am Psychol 1958; 13(5): 247-248, at p248.

¹⁴⁷ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit., at p1475, citing: Carter R. *The doctor business.* New York. Doubleday, 1958, pp235-238; Riss GB. In Agich (ed.) *responsibility in health care.* Dordrecht. Reidel, 1982.

for illness, 'leaving the physician dealing with the uncertainties of psychosomatics'.¹⁴⁸ It is relevant, Burnham noted, that these criticisms coincided with a more general public scepticism, and with emerging evidence of negative, or at least ambivalent, images of many American institutions which in the 1940s had been beyond reproach, including the city, the automobile, the large family, and the learned professions.¹⁴⁹

As late as the 1950s, the most common criticisms of doctors were 'a failure to take a personal interest in the patient and his family' and 'failure to communicate adequately with the patient'. It was only in later decades that the demand for competence became conspicuous. A further concern emerged in the USA about the imposition of too much medicine, such that not only might tests, procedures, and operations be forced on persons without their understanding the risks¹⁵⁰, but, in addition, patients might be used for experimental purpose without their consent.¹⁵¹

By the 1960s and 1970s, there were challenges, led by the arch critic Illich, about doctors' setting of increasingly arbitrary boundaries to illness, ignoring 'positive' health. With regard to the technical role, the public had become increasingly aware of the possibility of incompetence on the part of doctors, resulting in a steady rise in malpractice suits. There were also darker fears of 'too much medicine', accompanied by widespread accusations of greed. Distrust of the intentions and customs of the medical profession had led new, well educated groups to challenge the monopoly of doctors, and support the rise of new kinds of 'alternative medicine'. The professional counter-voice could be heard from Franz Ingelfinger, the distinguished US physician and editor of the *New England Journal of Medicine*,

¹⁴⁸ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit., at p1476.

¹⁴⁹ Ibid.

¹⁵⁰ Lander L. *Defective medicine: risk, anger and the malpractice crisis*. New York. Farrar, Strauss and Giroux, 1978, p41.

¹⁵¹ Beecher HK *Ethics and clinical research*. New Engl J Med 1966; 274: 1354-60.

who regretted that, to the physician, the task of inspiring confidence and trust became impossible when the patient had been 'indoctrinated to disrespect medical authority', and cited as an example of the 'discontent' of doctors the recent publication of a book entitled 'Talk back to your doctor'.^{152 153}

Exactly where and when a 'final shove off the pedestal' occurred to mark the end of Burnham's golden age, or indeed whether there was an identifiable tipping point, is not certain.¹⁵⁴ Gross traced the new criticism to the first of no fewer than twenty investigations of the New York health system that took place in the third quarter of the 20th century.¹⁵⁵ In 1965 an anonymous writer in *Consumer Reports* dated modern criticism from the publication of a survey conducted in 1958 in which investigators had rated actual physician performance.¹⁵⁶ Burnham believed that the most important date was 1958, when Richard Carter's *The Doctor Business* was published¹⁵⁷, described as 'the first of a number of muckraking books'.¹⁵⁸ Carter's expose/ and others that followed drew heavily on both public investigations and critiques which members of the medical profession had written for internal political purposes. Other observers traced the rising level of adverse comment to unrealistic hopes - 'in later decades, as Americans came to expect their medical profession to furnish comfort, happiness, and well behaved children as well as health, the disillusionment grew'.¹⁵⁹ Whatever the sources, clearly adverse criticism had entered a novel phase by the end of the 1950s and heightened throughout the

¹⁵² Levin A. *Talk back to your doctor: how to demand (and recognize) high quality health care*. New York, Garden City. Doubleday and Company, 1975.

¹⁵³ Inglefinger F. *Deprofessionalising the profession*. New Engl J Med 1976; 294(6): 334-335, p334.

¹⁵⁴ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit., at p1475.

¹⁵⁵ Gross ML. *The doctors*. New York. Random House. 1966, p7.

¹⁵⁶ *Consumer Reports*. March 1965, p 146.

¹⁵⁷ Carter R. *The Doctor Business*. New York. Doubleday. 1958, pp235-238.

¹⁵⁸ Burnham JC. *American medicine's golden age: what happened to it?* Science 1982; 215(4539): 1474- 1479, op. cit., at p1475.

¹⁵⁹ Ibid.

1960s and 1970s, and with it faded the ideal of a group of dedicated scientists producing marvellous cures while at the same time practising as equally dedicated clinicians.

2.3 Summary and interim conclusions.

Perhaps the most interesting of Burnham's conclusions were, first, that it had been the politics of the socialised medicine debate which first planted the seeds of major and pervasive mistrust - or, more accurately, that it was the self-serving attitude of doctors (identified by the public as being at the centre of the campaigns of the American Medical Association) which had provoked a major change in public attitude. This is an example of a factor which also operated in the UK, namely, conflict between the medical profession and government.

Of equal importance was Burnham's second conclusion that those doctors who in the decades after 1945 had spoken out to increase the beneficent results of medicine and upgrade the profession in the direction of the professional ideal, 'unwittingly opened the doors for the latter day critics who attacked not only the priestly pretension but technical performance as well'.¹⁶⁰ Critics in the UK were able to focus on the General Medical Council as the body to attack for failing to regulate medical performance. There was no equivalent body in the US (although pressure resulted in local grievance committees being established) but rather a steady stream of revelations and 'anti-doctor' publications raised similar issues to those in the UK.

The rise of more questioning patients with a wish for more evenly balanced two-sided doctor-patient relationships was common to both sides of the Atlantic. The factor which was prominent in Burnham's account, but had no identified equivalent in the UK, was the perceived financial greed of American doctors as manifest both in the stance that the American Medical Association took in its rejection of 'socialised medicine', and in the fear of the public that doctors were pressing 'too much medicine' on their patients for personal gain.

¹⁶⁰ Ibid.

Perhaps the 'greed' that was shown by doctors in both the USA and the UK was to try to hold on to their professional autonomy in the face of more general societal changes and the challenge to their professionalism. These factors are considered in the next two sections of this chapter.

3. Societal trends.

Elston wrote in 1991 that 'few would dispute the overt questioning of medical autonomy and expertise in the past decade in Britain or that this has intensified in the last two years as the debate over the future of the NHS has gathered momentum'.¹⁶¹ Could this trend have been the outcome, not of specific health related questions, but rather of more generic changes among the public's attitude to expertise or authority, or from even broader cultural trends?

From a vast literature, I have chosen to highlight in necessarily short order three important accounts: Inglehart's empirically based work on transforming cultures of advanced industrial societies^{162 163}; Beer's analysis of the origins of participatory democracy from the 'revolutions' of the 1960s; and the theoretical work of Giddens on the contours and existential parameters of life in 'late' modernity'.^{164 165} [I also touch briefly on a fourth study: the eclectic approach of the Kennedy School of Government at the University of Harvard when exploring the origins of 'why people don't trust Government',¹⁶⁶].

¹⁶¹ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, p60.

¹⁶² Inglehart R. *The silent revolution in Europe: intergenerational change in post-industrial societies*. Amer. Polit. Sci. Rev. 1971 FJ; 65(4): 991-1017.

¹⁶³ Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990.

¹⁶⁴ Giddens A. *Modernity and self-identity: self and society in the late modern age*. Oxford, Polity Press, 1991.

¹⁶⁵ Giddens A. *The consequences of modernity*. Oxford, Polity Press, 1990.

¹⁶⁶ Nye JS, Zelikow PD, King DC (eds.) *Why people don't trust government*. Cambridge, Massachusetts, Harvard University Press, 1997.

My justification for using political studies to examine public attitudes to medicine is the powerful case made by Kennedy that 'medicine is, at bottom, a political enterprise'.¹⁶⁷ I turn first to the empirical studies of Inglehart.

3.1 Inglehart on post-materialism and cultural shift.

As a bridge that could relate the more narrowly defined reasons for changes in the acceptability of 'doctor knows best' to broader trends in societal attitudes, the postulates of the political scientist Ronald Inglehart, which arose from his empirical studies, are attractive. One of Inglehart's main hypotheses is that individuals pursue various goals in hierarchical order, giving maximum attention to the things they sense to be the most important unsatisfied needs at a given time ('scarcity hypothesis').¹⁶⁸ First, material needs like hunger or thirst have to be satisfied. If this is achieved, goals will gradually shift.

Inglehart's data (which relied on a modification of Maslow's hierarchy of human goals¹⁶⁹ as comparator) have expanded over thirty years to become 'a vast, impressive, unique and well-analysed data set'¹⁷⁰, and were based originally on responses to a four item, 'force-choice', survey of public opinion in eight European countries using cross-sectional age cohort data. He discerned two types of response. The first, which he termed 'materialist', was compatible with a value set that placed high priority on economic security and domestic order.¹⁷¹ The second, termed 'post-materialist' or 'post-bourgeois', rated most highly such values as individual improvement, personal freedom, citizen input into government

¹⁶⁷ Kennedy I. *The unmasking of medicine*. London. George Allen & Unwin, 1981, op. cit., p ix.

¹⁶⁸ Inglehart R. *The silent revolution in Europe: intergenerational change in post-industrial society*. Amer. Polit. Sci.Rev. 1971; 65(4):991-1017, op. cit.

¹⁶⁹ Maslow AK *Motivation and personality*. New York, Harper and Row, 1954.

¹⁷⁰ Heisler MO. Review of: Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990, abstracted by the publisher.

¹⁷¹ Inglehart R. *The silent revolution in Europe: intergenerational change in post-industrial society*. Amer. Polit. Sci.Rev. 1971; 65(4):991-1017, op. cit., p993.

decisions, the ideal of a society based on humanism, and the maintenance of a clean and healthy environment.¹⁷²

Post-materialism assumes an on-going transformation of individuals and society which liberates them gradually from the stress of basic acquisitive or materialistic needs, and causes them to evaluate their leaders and their institutions by more demanding standards than were applied in the past. While conditions of insecurity give rise to the 'authoritarian reflex' (the tendency for mass publics to seek and idealise strong, authoritarian leaders), in the more prosperous, stable and democratic industrial societies the authoritarian reflex becomes latent, and confidence in their institutions declines significantly.

An important conclusion from Inglehart's analysis of his original data in 1971 was the existence of an 'intergenerational shift', that is to say, a consistent tendency for younger age cohorts to be more 'post-materialistic' than their elders, surveyed contemporaneously.¹⁷³ By observing the trends in age-related cohort data with regard to materialist/post-materialistic preferences with the economic trends of the country in question in his more comprehensive data analysed some twenty years later¹⁷⁴, Inglehart came to a powerful if controversial conclusion. The relationship between socio-economic preferences and value priorities was not one of immediate adjustment. A substantial time lag was involved, such that one's basic values reflected the conditions that prevailed during one's formative and early adult years.^{175 176} He termed this delayed response the 'socialisation hypothesis', to be laid alongside his previously described 'scarcity hypothesis' discussed above.

¹⁷² Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990, op. cit., pp66- 103.

¹⁷³ Inglehart R. *The silent revolution in Europe: intergenerational change in post-industrial society*. Amer. Polit. Sci.Rev. 1971; 65(4):991-1017, op. cit., p999.

¹⁷⁴ Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990, op. cit., p68.

¹⁷⁵ Ibid., pp74-5.

¹⁷⁶ Ibid., pp83-103.

Taken together, these two hypotheses generated a coherent set of predictions concerning value change. First, while the scarcity hypothesis implied that prosperity was conducive to the spread of post-materialist values, the socialisation hypothesis implied that neither an individual's values nor those of a society were likely to change overnight. Instead, fundamental change in values took place gradually, almost invisibly: in large part it occurred as a younger generation replaced an older one in the adult population of a society.¹⁷⁷

Further analysis revealed that, although post-materialists had higher levels of income, education and occupational status than materialists, they did not show higher levels of subjective well-being. Post-materialists took prosperity for granted and focused on other aspects of life such as politics and the quality of the physical and social environment; further, they applied more demanding standards to them. In addition, the position of elites became more difficult in advanced industrial society. The mass public was becoming increasingly critical of their political leaders, and increasingly likely to engage in 'elite challenging activities'.¹⁷⁸ A major component of the postmodern shift was a turning away from all kinds of authority, because deference to authority had high costs: the individual's goals had to be subordinated to those of a broader authority. Instead, a post-materialist emphasis on self expression and self realisation became increasingly central.¹⁷⁹

3.2 Beer: in search of a new public philosophy.

Beer, whose analysis of US politics of the 1960s was believed by Klein to be fully relevant to the UK¹⁸⁰, described 'the dual revolution of the sixties' in an account of

¹⁷⁷ Ibid., p69.

¹⁷⁸ Ibid.

¹⁷⁹ Ibid., pps 220-1.

¹⁸⁰ Klein R. *The new politics of the National Health Service*. Fourth edition. London. Prentice Hall, 2001, op. cit., pp81-82.

the shift in political sensibilities of that time upon which the following paragraphs rely.¹⁸¹

Beer identified the development of two currents of thought, the technocratic and the counter-cultural. In the 'technocratic takeover', and in the belief that science could transform society, a generation of technically and scientifically trained people in government service began to have a growing influence on the initiation and formulation of public policy, and in the consequent direction of public expenditure.¹⁸² But with the growth in influence of ever more 'professionalism' came, paradoxically, fragmentation of goals, with a greater number of ever more competing programmes. The outcome was that political actors were weakened in their ability to function as a national public.¹⁸³

In the 'romantic revolt' in the 1960s, the romantic impulse was reincarnated, dominated by subjectivity: trust the heart not the head; emotion not reason; spontaneity not calculation, nature not civilisation. Moreover, subjectivity not only controlled the mode of conduct, but also dictated the ends. The important thing was not the fruit of experience, but experience itself; not utility, but sentiment; not wealth or power or any external possession, but feeling. There were also messages for the group, again based on subjectivity. The basis of group life was to be found not in economic need or universal values, but in a common culture, a distinctive way of feeling and acting.¹⁸⁴

The literary and artistic movements which arose quickly acquired a strong political thrust which included, as a goal for America, 'participatory democracy'. The essential and initial meaning was to give power at the level of immediate impact directly to those people who were most affected by government policy- and called for 'maximum feasible participation', defined as 'the participation of the

¹⁸¹ Beer S. *In search of a new public philosophy*. In: King A. (ed.) *The new American political system*. Washington D.C. American Enterprise Institute for Public Policy Research, 1978.

¹⁸² *Ibid.*, pp18, 20.

¹⁸³ *Ibid.*, p22.

¹⁸⁴ *Ibid.*, p23.

program(sic) beneficiaries in policy development, planning and implementation'.¹⁸⁵ Because participatory democracy was taken to mean a decentralisation of authority 'that sometimes appeared to extend down to the lone individual', in practice the results were disorderly, had little cohesion or continuity, rarely followed a calculated strategy and fell victim to endless discussion punctuated by outburst of direct action.¹⁸⁶ Beer concluded that, in that form, participatory democracy could not have a future. Yet in a larger sense, the participatory idea had a profound and lasting effect on American politics- such that it would be unthinkable in the years that followed to find a programme involving regulation or delivery of services in, for example, health, welfare or education, that did not provide for community input.¹⁸⁷

The cases developed by Inglehart and Beer are political analyses which relied in the end on the beliefs, feelings and consequent actions of individuals. A broader, Harvard based, study of 'why people don't trust government', which assessed the effect of economic, social and political factors, with a scope beyond the confines of this Thesis, also acknowledged the importance of long term secular changes in socio-cultural attitudes towards authority and traditional social order.¹⁸⁸

It is therefore appropriate to turn now to examine aspects of life in 'late' modernity as developed by a master in the field of sociology, Professor Anthony Giddens, lately Baron Giddens of Southgate.

3.3 Giddens on modernity and self identity.

¹⁸⁵ Ibid., p26, citing: Jacobs P, Landau S. *The post Huron statement*. In: *The new radicals: a report with documents*. New York. Vintage Books, 1966, pp154-162.

¹⁸⁶ Ibid., p27.

¹⁸⁷ Ibid. P28.

¹⁸⁸ NyeJS, Zelikow PD, King DC (eds.) *Why people don't trust government*. Cambridge, Massachusetts, Harvard University Press, 1997, op. cit.

The following account of the work of Giddens owes much to the scholarly analysis of Michael Calnan and Simon Williams.¹⁸⁹

According to Giddens, modern institutions differ from all preceding forms of social order in terms of their dynamism, the degree to which they undercut tradition, and their global impact. In this respect, 'late' modernity displays an ever increasing degree of 'reflexivity', a key concept of Giddens' which refers to the susceptibility of most aspects of social activity and material relations with nature to chronic revision in the light of new information and knowledge. The outcome is that all beliefs and practices are subject to systematic examination, critical scrutiny and revision in the light of changing social circumstances. Reflexivity becomes a chronic and defining feature of late modernity, with its never ending cycle of reappraisals, reassessments and revisions which span all aspects of modern social life.¹⁹⁰ The overriding emphasis is on *individuals* (my emphasis), and the emergence of new mechanisms of self-identity, which are shaped by- yet also shape- the institutions of modernity. The self is not a passive entity, determined by external influences; in forging their self-identities, no matter how local their specific contexts of action, individuals contribute to and directly promote social influences that are global in their consequences and implications.¹⁹¹

While modernity is a post-traditional order, it is not one in which 'the sureties of tradition and custom have been replaced by the certitude of rational knowledge'.¹⁹² Rather, doubt becomes a pervasive feature of modern critical reasoning, forming a general existential dimension of the contemporary social world. As Giddens argued, in circumstances of increased reflexivity, uncertainty and choice, the notions of trust and risk become particularly pertinent. Trust becomes a crucial

¹⁸⁹ Williams SJ, Calnan M. *The 'limits' of medicalization?: modern medicine and the lay populace in 'late' modernity*. Soc.Sci.Med.1996; 42 (12): 1609-1620.

¹⁹⁰ Ibid., p1612.

¹⁹¹ Giddens A. *Modernity and self-identity: self and society in the late modern age*. Oxford, Polity Press, 1991, p2.

¹⁹² Ibid., p2-3.

‘medium of interaction’ with modern abstract systems and sources of authority and expertise, here generating ‘that “leap into faith” which practical engagement demands’.¹⁹³ However, while the nature of modern life is deeply bound up with mechanisms of trust in abstract systems, it requires a special form of trust, namely an ‘active’ trust which, in contrast to previous eras, has to be continuously ‘won’ and ‘retained’ in the face of growing uncertainty. Moreover, active forms of trust presuppose autonomy on the part of the individual, since compliance is freely given rather than being anchored in external constraints.¹⁹⁴

Giddens further noted that there are many different relations between lay experience and abstract systems which coexist in the contemporary era:

Attitudes of trust, as well as more pragmatic acceptance, scepticism, rejection and withdrawal, uneasily coexist in the social space linking individual activities and expert systems.¹⁹⁵

There is growing awareness of risk within society¹⁹⁶, and this includes a growing public concern about the risks of modern medicine, and the limitations of expertise.¹⁹⁷ These possibilities were expressed by Giddens himself in the following terms: ‘Widespread lay knowledge of modern risk environments leads to an awareness of the limits of expertise and forms one of the ‘public relations’ problems that have to be faced by those who seek to sustain lay trust in expert systems’.¹⁹⁸

Living in high modernity becomes, to an ever increasing degree, influenced by the media, and systems of mass communication, both printed and electronic, play a key

¹⁹³ Ibid., p2.

¹⁹⁴ Giddens A. *Beyond left and right*. Oxford, Polity Press, 1994, p14.

¹⁹⁵ Giddens A. *Modernity and self-identity: self and society in the late modern age*. Oxford, Polity Press, 1991, op.cit., p7.

¹⁹⁶ Beck U. *Risk society: towards a new modernity*. London. Sage, 1982.

¹⁹⁷ Williams SJ, Calnan M. *The ‘limits’ of medicalization?: modern medicine and the lay populace in ‘late’ modernity*. Soc.Sci.Med.1996; 42 (12): 1609-1620, op.cit., p1615.

¹⁹⁸ Giddens A. *The consequences of modernity*. Oxford, Polity Press, 1990, op. cit., pp130-131.

role. Here Giddens sees the interpenetration of self development and social and global systems becoming ever more pronounced- the 'mediation of experience'.¹⁹⁹ People are continually bombarded with media messages: processes which have a crucial bearing upon the knowledge base and reflexivity of the lay populace in contemporary Western societies. Not only do the media contribute to the demystification of science and technology, they also contribute to the growth of a critically informed lay public, and in doing so act as important 'cultural intermediaries', arbitrating between the competing claims of social and scientific rationality.

According to Giddens, growth of a critically informed public leads to the gradual introduction of a further mechanism of self- identity which he terms 'reskilling', defined as 'the reacquisition of knowledge and skills, whether in respect of the intimacies of personal life or wider social involvements [arising as] a pervasive reaction to the expropriating effects of abstract systems'.²⁰⁰ In simpler terms, individuals become used routinely to filter and act upon a variety of information relevant to their life situation: '[i]nformation produced by specialists (including scientific knowledge) can no longer be confined to specific groups, but becomes routinely interpreted and acted on by lay individuals in the course of their everyday action...[i]ndividuals are likely to reskill themselves in greater depth where consequential transitions in their lives are concerned or fateful decisions have to be made'.²⁰¹

3.4 Summary and interim conclusions.

It would be foolish to claim that the above, necessarily brief, sampling of a huge literature did more than identify a few signposts towards what might have been happening in the second half of the 20th century to some societal attitudes outside

¹⁹⁹ Giddens A. *Modernity and self- identity: self and society in the late modern age*. Oxford, Polity Press, 1991, op.cit., pp23-27.

²⁰⁰ Ibid., p7.

²⁰¹ Ibid.

the health field. Nevertheless, I submit that it is possible that the factors identified did indeed contribute to changing attitudes towards medicine and doctors.

The most powerful of Inglehart's observations for present purposes was his identification of time trends, in which 'the rules have changed', such that the public of the developed world are evaluating their institutions by more exacting standards than in the past. Further, his finding that the most important factor underlying change over time was a (relatively) steady 'intergenerational shift' in attitudes encourages a search for gradualist phenomena, rather than a big bang, to explain changing attitudes to medicine. Add to that his finding that the attitudes of a generation were moulded in their formative and young adult years, and one can arrive at a plausible explanation for differing attitudes today towards the NHS between the elderly and the youthful. The patients who used the NHS from 1948 to, say, the mid 1970s, would have been those who grew up and remembered the lack of health care before 1948, and would have looked upon the NHS as a desirable 'materialistic acquisition', in Inglehart's terms. In contrast, younger people have grown up with the NHS, and have taken its material benefit as 'a given'. They have begun to apply their post-materialist values and attitudes to the NHS and have become more demanding and more critical and expect higher standards. Although more able to make political systems respond to their needs by being more articulate and politically active, post-materialists in Inglehart's analysis did not register higher levels of satisfaction with politics. This finding maps well to the rising volume of complaints about the NHS and to the social background of the sternest critics of the GMC.

Because Inglehart's studies are based on survey data, a word of caution is in order. Any effort to measure the value priorities of the mass public by means of survey research must be approached with modest expectations. Low correlations between items and low stability over time seem inherent in survey research-not necessarily because people do not have real attitudes, but partly because survey research must

contend with a relatively high component of error in measurement.²⁰² It has been known for many years that ordinary citizens are capable of expressing a coherent political outlook in a series of leisurely, in depth interviews.²⁰³ However the cost is prohibitive to take this approach to large populations.

The public opinion survey can have certain advantages, even when studying basic attitudes and values. It can provide very large numbers of cases, which for example can allow reliable intergenerational comparisons, and control for, say, social background. The mass survey can provide representative national samples - extremely useful if one wished to know what was happening to a society as a whole. The random error inherent in survey research tends to be cancelled out in large samples, especially if multi-item indicators are used.²⁰⁴

Unfortunately there are few automatically generated measures of how people translate their attitudes into behaviour, and survey research can be looked upon as a fall back.²⁰⁵ Different questions produce different answers (for example, asking about 'trust', compared to 'confidence', compared to 'satisfaction'), and the context of a poll can affect even the most scientifically selected samples. What cannot be easily dismissed are consistent and inexorable shifts in answers to the *same* questions. For example, there was a consistent trend of falling confidence in government shown by all polls of public opinion in the US, and this was replicated by the results of focus groups.²⁰⁶

²⁰² Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990, op. cit., pp130-131.

²⁰³ Lane R. *The politics of consensus in an age of affluence*. Amer.Polit. Sci. Rev. 1965; 59(4): 874-895.

²⁰⁴ Inglehart R. *Cultural shift in advanced industrial society*. Princeton N.J., Princeton University Press, 1990, op. cit., p131.

²⁰⁵ Nye JS, Zelikow PD. *Reflections, conjectures and puzzles*. In: Nye JS, Zelikow PD, King DC (eds.) *Why people don't trust government*. Cambridge, Massachusetts, Harvard University Press, 1997, op. cit., p254.

²⁰⁶ Ibid., citing: *Citizens and politics: a view from Main Street America*. Dayton. Kettering Foundation, 1991.

The dichotomy of the 1960s in the USA allowed both a ‘technocratic takeover’ and a ‘countercultural revolution’, in Beer’s account . Although both were short lived in pure form, their influence lived on. In the UK especially, the rise of medical technology brought about a repoliticisation of health priorities, driven by economic pressures. That, and the subsequent loss of blind faith in the promises of technology itself were felt in the UK ten years later as Dollery’s ‘end of an era of optimism’. In contrast, the rising post-materialist emphasis on self expression and self realisation continued to resonate on both sides of the Atlantic. The influence of ‘participatory democracy’, although the name itself was no longer used, lived on, as can be seen in the ‘community input’ into US health programmes; and nearer home, in areas ranging from the more recent emphasis in the NHS Constitution for England on patient and public engagement (PPE)²⁰⁷, the revised composition of the General Medical Council with a much increased proportion of lay members, the emphasis on communication and interpersonal skills within programmes of medical education and training, to the commitment of government itself to consult as part of an essential and important aspect of its working methods.²⁰⁸

In a search for *why* there has been a shift from ‘doctor knows best’ in recent decades, at both a political and a personal level, it seems to me that Giddens’ model makes an important contribution. As put by Lupton, a ‘reflexive’ actor will actively calculate, assess, and if necessary counter the knowledge and autonomy of experts with the object of (in the present case) maximising the value of services for health care.²⁰⁹ One can imagine this process taking place both in the person that is the individual patient during a medical consultation, and even in the collective minds of officials at the Department of Health. Giddens’ account of ‘active’ trust which needs to be sought and retained by professionals and given by lay persons, in the face of uncertainty and risk, rings true in the context of a medical encounter.

²⁰⁷ Department of Health. *The NHS Constitution for England*. January 21, 2009.

²⁰⁸ Scottish Government. *About Scottish Government Consultations*. Accessed June 26, 2010 at: <http://www.scotland.gov.uk/Consultations/About>

²⁰⁹ Lupton D. *Consumerism, reflexivity and the medical encounter*. Soc Sci Med 1997; 45 (3) ; 373-381, a p374.

Further, he has explained well how, at a pragmatic level, attitudes of reverence and reserve, approval and disquiet, enthusiasm and antipathy can coexist in ordinary persons when considering high science and technology. As put by Williams and Calnan, the consequence of these developments in thinking has been that, in contrast to the past when science was invested with a considerable degree of mystique, the relationship between medicine and the lay populace has increasingly to be seen as being built around a reflexively organised dialectic of trust and doubt.²¹⁰

The insight about the drive to reskill being especially prominent in the face of 'consequential transitions' resonates with the observations of Elston that in the UK, as in the US, patient and public voices have been most critical of medical science and practice in specific areas. These include areas: where 'consumers' are not ill, as in the management of reproduction; where patients have experiential expertise, or curative medical science has little to offer, as in disability, chronic illness and terminal care; and where rapid scientific developments arouse fundamental societal concerns, for example, transplant surgery or prenatal screening.²¹¹

Last, it is important to note the role of the media as 'cultural intermediaries', in Giddens' model, in demystifying science and contributing to the growth of a critically informed lay public. The importance of the 'information revolution' and the attitude of the press were also judged in the Harvard study to be important factors affecting people's trust in public institutions. I merely note these points now, and will return to a broader account of the role of the media in shaping public opinion when considering 'the scandals' of Bristol and Alder Hey in the next chapter.

²¹⁰ Williams SJ, Calnan M. *The 'limits' of medicalization?: modern medicine and the lay populace in 'late' modernity*. Soc.Sci.Med.1996; 42 (12): 1609-1620, op.cit., p1613.

²¹¹ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, op.cit., pp82-83.

How are issues of 'active' trust, uncertainty, risk, and lay reskilling being handled within the doctor- patient relationship? It was conceded by Williams and Calnan that these latter issues were not easy to study, and would require a combination of empirical large scale surveys with more detailed qualitative and ethnographic approaches to yield richer insights and do justice to the complexity of lay thought as illuminated by Giddens.²¹² In the meantime, we can turn back to the medical profession in the UK to examine whether, by the late 1990s, it was a profession under pressure, or [still] sailing on unconcernedly.

4. Professionalism.

In the light of the evidence in the above sections of changes in society, government and public expectations of medicine and doctors, all of which had had a tendency to destabilise traditional medical certainties, it was not surprising that debate arose at a theoretical level about 'the deprofessionalisation' of medicine, and that, at a practical level, medical leaders should have asked what was to be done.

4.1 The response of the medical establishment in the mid 1990s.

In 1994, the then Chief Medical Officer, Professor Sir Kenneth Calman, wrote in the *British Medical Journal*:

[t]here is increasing public and professional interest in medicine, with questioning of professional standards and the quality of care. Public expectations of the level of service to be delivered are rising. It is timely, therefore to review the role and purpose of medicine and the concept of a profession.²¹³

Sir Kenneth called for a full debate on the purpose of medicine and its basic values, a continuing review of medical education in a time of change, an examination of standards of quality and care in medical practice, further consideration of the

²¹² Williams SJ, Calnan M. *The 'limits' of medicalization?: modern medicine and the lay populace in 'late' modernity*. Soc.Sci.Med.1996; 42 (12): 1609-1620, op.cit., p1619.

²¹³ Calman K. *The profession of medicine*. BMJ 1994; 309 (6962): 1140- 1143, p1140.

future organisation of medicine beyond the year 2000, and a recognition of the responsibility of the profession to take these forward.²¹⁴

A conference of leaders of the profession was organised in response (it is noteworthy that no 'patients' were involved). As subsequently reported, Sir Maurice Shock, former Rector of Lincoln College, Oxford, told the delegates when opening the conference that British doctors had failed to notice that the world around them had changed utterly. Doctors seemed to imagine that they were living in Gladstone's world of minimal government, benign self regulation and a self-effacing state. In fact, Sir Maurice said:

[i]nstead of the rights of man, we have the rights of the consumer, the social contract has given way to the sales contract, and, above all, the electorate has been fed with political promises...about rising standards of living and levels of public service. The appearance of the consumer society, together with medical advances on an unprecedented scale and 'the rise of geriatrics', had meant that 'the doctor is different, the patient is different, and the medicine is different'.²¹⁵

In the face of this warning, Sir Donald Irvine observed that the discussions within the conference revealed 'strongly defensive attitudes and very little insight into the profound nature of the changes that had taken place all around us'.²¹⁶ This view was confirmed by Shock who later wrote that the medical profession had been sluggish in its willingness to change: an appropriate motto might have been 'the status quo is the way forward'. He urged that there was no point in attempting to swim against the tide. This was an age of regulated capitalism in which the consumer was cosseted and protected, encouraged to be articulate, and persuaded of his or her power.

Not that any of this should be taken at face value. We are only too aware that the media, public relations, advertising and politics have made this an age of mirrors. But the basic point is not affected: public support is essential. That must always

²¹⁴ Ibid., p1143.

²¹⁵ Smith R. Editorial. *Medicine's core values*. BMJ 1994; 309 (6964): 1247-1248.

²¹⁶ Irvine D. *The doctor's tale; professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, op. cit., p99.

begin with the patient, but doctors will have to pay an entrance fee to the hall of mirrors.²¹⁷

Would paying this price represent an erosion of professional status?

4.2 Has there been an erosion of the professional status of medicine?

To answer this question requires a prior consideration of what 'a profession' is and what 'professionalism' means.

Sociologists have discussed the nature of the professions at least since the 1930s. Carr-Saunders and Wilson recognised the central role of professions in modern society, arguing that professional associations were stabilising elements, engendering 'modes of life, habits of thought, and standards of judgment which render them centres of resistance to crude forces which threaten steady and peaceful evolution'.²¹⁸ Professions, as essentially altruistic self-governing communities, were seen at that time as the ideological bulwark of liberal democracy.²¹⁹ Talcott Parsons, one of the founding fathers of American sociology, recognised that professions were characterised by 'rationality', by which was meant the setting of standards and the exercise of an authority which was not based on superior 'wisdom' or higher moral character but on superior technical competence- which in turn was limited to a particular field of knowledge and skill (termed 'specificity of function'). Parsons also emphasised that professionals worked objectively without emotional involvement, applying standards and criteria that arose from the objective features of 'the case', regardless of *who* the client was (termed 'universalism' by Parsons).²²⁰

In 1960, Goode analysed the struggle that 'sociology' was then having to become established as a recognised discipline. He defined, from a synthesis of the

²¹⁷ Shock M. *Medicine at the centre of the nation's affairs*. BMJ 1994; 309 (6970): 1730- 1733.

²¹⁸ Carr-Saunders AM, Wilson PA. *The professions*. Oxford, OUP, 1933.

²¹⁹ Armstrong D. *Medicine as a profession: times of change*. BMJ 1990; 301(6754): 691-693, p691.

²²⁰ Parsons T. *The professions and social structure (1939)*. In: *Essays in sociological theory*. Revised edition. Glencoe, Illinois. The free press, 1954, pp38-41.

literature, two core characteristics of a profession: a prolonged specialised training in a body of abstract knowledge; and a service orientation.²²¹ As an occupation became more professionalised, it acquired several features (Goode listed ten) which could be viewed as sociologically derivative from the core.²²² Freidson, in his seminal sociological study *Profession of medicine*²²³ published in 1970, pointed out that five of Goode's 'derived characteristics' referred to autonomy, so that it could be said that Goode's core characteristics were critical criteria for professions insofar as they were said to be causal in producing professional autonomy.²²⁴ Freidson himself laid great store on the overriding importance of autonomy as *the* defining cornerstone of a profession- 'legitimate, organised autonomy, that is, it has been given the right to control its own work'.²²⁵ This autonomy over the technical aspect of his work, he wrote, gave a professional the wherewithal by which to be a member of a 'free' profession, 'even though he is dependent on the state for establishing and sustaining his autonomy'.²²⁶

However, as to a profession's exclusivity in applying its knowledge, Freidson had grave doubts:

It is not justified morally because I believe that human beings, even if laymen, have the right to determine what their own problems are and to have a voice in how they are to be managed. It is not justified functionally, I have argued, because it leads the profession to be blind to its own shortcomings and unable to regulate its practices adequately. From these conclusions follows the question of how the application of knowledge to human affairs by professional experts should be organised in the public interest.²²⁷

²²¹ Goode WJ. *Encroachment, charlatanism and the emerging profession: psychology, sociology, and medicine*. American Sociological Review 1960;25(6): 902-914, p 903.

²²² Ibid.

²²³ Freidson E. *Profession of medicine: a study of the sociology of applied knowledge*. New York. Dodd Mead & Company, 1975.

²²⁴ Ibid., p77.

²²⁵ Ibid., p 71.

²²⁶ Ibid., p46.

²²⁷ Ibid., p371.

Not surprisingly, sociologists have tended to point to Freidson's *Profession of medicine* as marking the point when the image of the medical profession began to tarnish.²²⁸

4.3 Deprofessionalisation.

The concept of medical professionalisation, which appeared mainly in American sociological literature²²⁹, was centred on accounts of the historical development of the power of the medical profession. Elston pointed out that, in discussions about medical power, the concepts of autonomy and dominance were often used interchangeably, whereas an analytical distinction could be made. 'Medical dominance' referred to medicine's authority over others (which according to Starr could be subdivided into social authority, that is, doctors' control over the actions of others through the giving of commands, and cultural authority, that is, the probability that medical definitions of reality and medical judgments will be accepted as valid and true²³⁰), while professional autonomy (following Freidson²³¹) was the legitimated control that an occupation exercised over the organisation and control of its work.²³² In Elston's view, a failure to define clear bench marks and specification of the dimensions of medical power had made assessments of change in that power, as published, a matter of continuing controversy.²³³ 'Loss of power' had been the starting point for alternative accounts termed 'proletarianisation',²³⁴

²²⁸ Armstrong D. *Medicine as a profession: times of change*. BMJ 1990; 301(6754): 691-693, op. cit., p691.

²²⁹ Larson MS. *The rise of professionalism*. Berkeley. University of California, 1977.

²³⁰ Starr P. *The social transformation of American medicine*. New York. Basic Books, 1982, p13.

²³¹ Freidson E. *Profession of medicine: a study of the sociology of applied knowledge*. New York. Dodd Mead & Company, 1975, op. cit.

²³² Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, op.cit., p61.

²³³ Ibid.

²³⁴ Oppenheim M. *The proletarianization of the professional*. Sociological Review Monograph 1973; 20: 213-237.

²³⁵ and 'deprofessionalisation'²³⁶, respectively. With regard to medicine, the proletarianisation thesis placed most emphasis on the changing work conditions of doctors (in an American context), especially in the growth of salaried practice and alleged subordination to managerial control. The deprofessionalisation thesis was built upon the changing doctor- patient relationship, in which an increasingly well-informed laity had brought about a decline in the cultural authority of medicine and in the extent of its monopoly over health- related knowledge²³⁷ and were seeking a collegial model for their relationship²³⁸.

However, Elston opined that, as then formulated, neither of the alternative accounts of diminishing medical power in the USA, although of value in stimulating debate, was amenable to rigorous testing.²³⁹ As examples of questions that could be raised within the models in an NHS context were whether medical managers would become loyal to their 'corporate sponsors' and not to clinical colleagues (as argued by McKinlay and Archer²⁴⁰), that is, proletarianism writ large; or whether Freidson²⁴¹ was right when he said that the widespread adoption of new techniques for monitoring the efficiency of performance and resource allocation did not of itself constitute diminished professional autonomy, because it all depended on

²³⁵ McKinlay J, Arches J. *Towards the proletarianization of physicians*. International Journal of the Health Services 1985; 15: 161-195.

²³⁶ Haug M. *Deprofessionalization: an alternative hypothesis for the future*. . Sociological Review Monograph 1973; 20: 195-211.

²³⁷ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, op.cit., pp62, 75.

²³⁸ Veatch RM. *Models for ethical medicine in a revolutionary age*. The Hastings Center Report 1972; 2(3): 5-7, p7.

²³⁹ Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991,

²⁴⁰ McKinlay J, Arches J. *Towards the proletarianization of physicians*. International Journal of the Health Services 1985; 15: 161-195, op. cit.

²⁴¹ Freidson E. *The medical profession in transition*. In: Aiken LH, Mechanic D (eds.) *Application of social science to clinical medicine and health policy*. New Brunswick. Rutgers University Press, 1986, pp63-79.

what criteria for monitoring and appraisal were used and who controlled any action that ensued.²⁴²

It is arguable that these theoretical models of deprofessionalisation arose after the *de facto* pressures for new doctor-patient relationships. I have already noted the rear guard action of a distinguished American physician who equated 'deprofessionalising the profession' with the difficulties encountered by a doctor in trying to inspire confidence and trust in a patient who had been 'indoctrinated to disrespect medical authority'.²⁴³ This attitude was reflected in 1994 in Shock's charge that the medical profession in the UK had been sluggish in its willingness to change: living up to a motto that 'the status quo is the way forward'.²⁴⁴

Writing in a UK context in 1990, Armstrong found that the medical profession 'faced the very real threat of deprofessionalisation'. His suggested response to this threat required a recognition that in the new climate [of increasing government intervention into the way that health care was provided], there were certain limits to clinical freedom: taking seriously the responsibilities of being self-governing; endorsing voluntarily cost-effective procedures; being willing to allow some kind of external review of its decision making; recognising that the NHS was changing from a paternalistic organisation in which professional and administrative interests decided what 'the consumer' needed to a service that was more responsive to the higher expectations and wishes of patients; respecting the role that other emerging health care professions must play within the service.²⁴⁵ Similar points were made

²⁴² Elston MA. *The politics of professional power: medicine in a changing health service*. In: Gabe J, Calnan M, Bury M (eds.) *The sociology of the health service*. London. Routledge, 1991, op. cit., p74.

²⁴³ Ingelfinger FJ. *Deprofessionalising the profession*, New Engl J Med 1976; 294(6): 334- 335.op.cit., at p334.

²⁴⁴ Shock M. *Medicine at the centre of the nation's affairs*. BMJ 1994; 309 (6970): 1730- 1733, op. cit., at p 1732.

²⁴⁵ Armstrong D. *Medicine as a profession: times of change*. BMJ 1990; 301(6754): 691-693, op. cit., pp692-693.

seven years later in an editorial in the British Medical Journal entitled 'Do professions have a future? Perhaps, if they are not defensive or complacent'.²⁴⁶

5. Overall conclusion.

It was all too little, too late. The rocks loomed ahead.

²⁴⁶ Abelson J, Maxwell PH, Maxwell RJ. Editorial. *Do professions have a future? Perhaps, if they are not defensive or complacent.* BMJ 1997; 315 (7105): 382.

CHAPTER FOUR

‘Five tumultuous years’¹: which culminated in the Human Tissue Act 2004.

Preamble.

This Chapter (concerning England, Wales and Northern Ireland) and the next (concerning Scotland) return to the story of human tissue legislation, with the additional evidence from Chapter Three that by the late 1990s the medical profession had lost the unqualified confidence of the public and government, and to an extent had lost confidence in itself.

This and the following Chapter need to be taken together. From the apparently common trigger of ‘organ retention scandal’, and on a background of shared legislation (the Human Tissue Act 1961), the outcome was two pieces of legislation with distinctly different provisions. It is my central hypothesis that the legal provisions which resulted in England and Scotland will be better explained, both in their similarities and their differences, within an understanding of the *processes* by which new legislation had occurred, the *climate* of the time and the *institutions* and *persons* involved.

In England, there were three major inquiries which individually and collectively made headlines, regarding: children’s cardiac services in Bristol; organ retention at post-mortem in the Royal Liverpool Children’s Hospital; and events which followed the death of Mr Cyril Isaacs in Manchester.

1 ‘Inspiration’.

1.1 Inquiries

1.1.1 Bristol Royal Infirmary Inquiry (‘Bristol’).²

¹ Editorial. *Effective implementation of the Human Tissue Act*. Lancet 2006; 368 (9539):891.

² The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995. *Learning from Bristol*. CM 5207(1), July 2001.

On June 18, 1998, following years of adverse publicity, and pressure from a parents' group (the Bristol Heart Children Action Group (BHCAG)), the Secretary of State for Health, the Rt. Hon. Frank Dobson MP, announced in Parliament his decision to set up a Public Inquiry into children's heart surgery at Bristol, to be chaired by (then) Professor Ian Kennedy.³

During the course of the *Bristol Inquiry*, unexpected information came to light from coincidental parental inquiries regarding organ retention after post-mortem examination.⁴ Initially treated by the Inquiry in a local, Bristol context, the picture changed dramatically when Professor Robert Anderson, a distinguished cardiac morphologist, revealed the scale of the retention of congenitally malformed hearts nationally. He estimated that the largest collection was at Alder Hey Children's Hospital with approximately 2,500 hearts; he himself had built up a collection at the Royal Brompton Hospital of some 2,000; and there were collections at Great Ormond Street Hospital of 2,000, at Birmingham Children's Hospital of about 1,500, and other, smaller collections in Leeds, Bristol, Southampton, Newcastle and Manchester.⁵ Within a week of Professor Anderson's appearance at Bristol, the local^{6 7 8} and national⁹ press became engaged and parental groups formed (for example, Young at Heart in Birmingham; PITY II in Liverpool) primarily to offer mutual support, but also to exert pressure on the authorities. A particularly

³ (1998) 314 Parl. Deb. (Hansard, 6th series), HC 529.

⁴ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*, May 2000, p15, para 49.

⁵ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. Annex A. May 2000, op.cit., p6, paras 16-17.

⁶ *Birmingham Post*, September 28, 1999, p3.

⁷ *Sunday Mercury*, October 10, 1999, p8.

⁸ *Western Daily Press*, September 19, 1999, p6.

⁹ See for example *The Mirror*, September 18, 1999, p21; *Daily Mail*, September 18, 1999, p5; *The Guardian* December 6 1999, p9; *The Times (London)*, 'Features', December 4, 1999.

searching spotlight was to fall on the Royal Liverpool Children's Hospital ('Alder Hey').

The Chief Medical Officer (CMO), Professor Liam Donaldson, at the request of the Secretary of State, instituted a census of all retained tissues throughout the country.¹⁰ He asked the Bristol Inquiry to prepare an Interim Report on organ and tissue retention to help him in his nation-wide investigation. The Interim Report was published in May 2000.

1.1.1.1 *Bristol Interim Report: Removal and retention of human material. ('BIR'; 'the Report').*¹¹

BIR found that, with regard to Coroners' post-mortems (CPM), pathologists had considered that they were entitled to retain, long term, human material such as organs, including hearts, for teaching, research and storage in archives. Human material had also been removed and kept after hospital post-mortems (HPM). Even though, in the past, parents had often agreed to these PMs, they had had no real understanding of what was involved.¹²

BIR also found that the law regulating the removal, retention, use and disposal of human material to be 'obscure, uncertain and arcane'. Two ways forward were identified. Either, as a minimum essential step, a new Code of Practice with appropriate enforcement mechanisms should be introduced; or, desirable but not essential, there should be changes in the law, together with incorporation into law of the proposed Code of Practice.¹³

¹⁰ Department of Health. *Retention of organs at post mortem: census of hospitals in England*. Letter from Chief Medical Officer to Chief Executives of NHS Hospital and Community Trusts, January 1, 2000.

¹¹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. Annex A. An account of the evidence to the Inquiry of the removal and retention of human material at post-mortem. May 2000, op.cit.

¹² Ibid. Covering letter from chairman and members of the Inquiry to Chief Medical Officer for England, May 2000.

¹³ Ibid.

Within the body of BIR and its Annexes¹⁴, there were trenchant criticisms of the attitudes and behaviour of doctors towards post-mortem procedures^{15 16}, as well as detailed analysis of the shortcomings and opacity of the existing law. The result, BIR concluded, was that a social and ethical time bomb had been waiting to explode.¹⁷

1.1.2 The Royal Liverpool Children's [Hospital] Inquiry ('Alder Hey'; 'Redfern').¹⁸

September 7 1999, the day of the Anderson revelation about heart collections in *Bristol*, was a date which would affect the lives of many who lived or worked in Liverpool and would introduce the name 'Alder Hey' to the nation.

The existence of retained hearts generated local media interest. In the first month of enquiries Alder Hey received 618 calls from parents. At the same time, a frantic exercise was begun in the hospital to try to catalogue the specimens satisfactorily, but was greatly hampered by inadequate records and unsatisfactory storage conditions. At a meeting of parents on November 1 1999 they discussed their difficulties in obtaining information from the hospital, with calls not being returned and long delays incurred in securing the return of organs. The Community Health Council told the Chief Executive that she had a disaster on her hands, described as a 'juggernaut rolling down a hill out of control'.¹⁹

Alder Hey was by now overwhelmed at the extent of the crisis.

¹⁴ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. Annex A: An account of the evidence to the Inquiry of the removal and retention of human material at post-mortem. Annex B: Law and guidelines. May 2000.

¹⁵ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*, May 2000, op. cit., p8, para 31.

¹⁶ Ibid., p 9, para 32.

¹⁷ Ibid., p 9, para 33.

¹⁸ The Royal Liverpool Children's Inquiry Report. Printed by order of the House of Commons, January 30 2001.

¹⁹ Ibid., p35, para 3.6.

On December 3 1999 the new HM Coroner for Liverpool, Mr Andre Rebello, told BBC Radio 5 Live that the organ retention at the hospital might have been unlawful.²⁰ On the same day, Lord Hunt, Parliamentary Under Secretary of State (House of Lords), established an Independent Confidential Inquiry under the provisions of the *National Health Service Act (Section 2) 1977*²¹, to be chaired by Mr Michael Redfern QC.²²

1.1.2.1 Findings of the *Redfern* Inquiry.²³

The Inquiry dealt with several matters which to an extent would have benefited from individual consideration, but which came to be seen as a whole, with escalating consequences.

It was found that the actions of the pathologist Professor Dick Van Velzen, between 1988 and 1995, were not only unacceptable within established pathology practice of the time, but were in some aspects illegal as well. His method of performing PMs of infants and children had been to remove virtually all internal organs, whole, from each case, and to retain them 'for later examination'.²⁴ Perhaps most serious was the fact that the examination of these organs had never taken place²⁵, or had been delayed²⁶, or had been incomplete²⁷, or still worse, had been fabricated²⁸, so that no useful clinical or research information had resulted – and there had been no feedback of worthwhile information to the parents or the medical attendants.

²⁰ *Express and Echo (Exeter)*. *New organ claims are probed*. December 3, 1999.

²¹ *The National Health Service Act 1977*. (1977, c.49).

²² *The Times (London)*. *Organ 'outrage' triggers inquiry*. December 4, 1999.

²³ The Royal Liverpool Children's Inquiry Report. Printed by order of the House of Commons, January 30 2001.

²⁴ *Ibid.*, Chapter 8, Part 2, p155, para 10.3.

²⁵ *Ibid.*, Part 3, p178, para 5.2.

²⁶ *Ibid.*, p182, paras 12.2-12.3.

²⁷ *Ibid.*

²⁸ *Ibid.*, Part 9, p306, para 14.1.

These facts alone justified his immediate suspension and subsequent erasure from the Medical Register.²⁹

With the exception of the ‘rogue’ practices of Professor Van Velzen, *Redfern* identified a similar range of problems and uncertainties regarding PM practice as had been identified in BIR including: an absence of explicit consent to, or understanding of, PM examination, and in particular, to a lack of information that organs might be retained (as part of ‘normal’ practice)³⁰; doctors had been genuinely of a mind to spare grieving parents the further upset which they judged an explicit description of the PM process would produce³¹; ‘on the evidence, the medical profession did not properly consider the Human Tissue Act [1961] in the first place’³²; and ‘a clouded view of what the Coroner’s jurisdiction requires of clinicians’.³³ The latter had not been helped by a revealed ‘slackness’ in the procedures of the Liverpool Coroner.³⁴

With regard to organ ‘collections’, it was found that, during the forty pre-Van Velzen years, large collections of hearts, fetuses, body parts, cerebella, and eyes had been established within Alder Hey and the University of Liverpool Institute of Child Health. Each collection had its own history, and all had had their beginnings as resources for research. The overall evidence of prior consent having been given was patchy and scanty.

Both *Bristol* and *Redfern* concerned children and their parents. However, the revelations caused anxieties which extended to the relatives of adults who had died. The case of Cyril Isaacs (deceased) subsequently made headlines.

²⁹ General Medical Council. *Fitness to Practise Panel: hearing (Dick Van Velsen)* June 6-20 2005.

³⁰ The Royal Liverpool Children’s Inquiry Report. Printed by order of the House of Commons, January 30 2001, op.cit, Chapter 10, p361, para 6.1

³¹ Ibid., para 7.2.

³² The Royal Liverpool Children’s Inquiry: Summary and recommendations. Printed by order of the House of Commons, January 30 2001, p3, para 3.

³³ Ibid., p4, para 6.

³⁴ Ibid., p4, para 11.

1.1.3 The 'Isaacs' Report.^{35 36}

Although this Report was not published until May 2003, the complaint which was its starting point had been known to the Secretary of State for Health and the Chief Medical Officer in January 2001. The case was a significant occupant of the 'in-tray': it revealed that the shortcomings of post-mortem procedures extended to adults.

1.1.3.1 Background.

This report was instigated by the chance discovery by Mrs Elaine Isaacs in April 2000 that the brain of her late husband, Mr Cyril Isaacs, had been removed during the PM examination carried out at Prestwich Hospital mortuary on 27 February 1987. Mr Isaacs' brain had been removed without the knowledge or consent of Mrs Isaacs and in clear breach of the requirements of the Human Tissue Act 1961. The Secretary of State for Health, Rt Hon Alan Milburn MP, having learned of the case during the debate in the House of Commons on the *Redfern* Report³⁷, asked HM Inspector of Anatomy, Dr Jeremy Metters, to undertake an investigation.

1.1.3.2 Findings.

Mr Isaacs' brain and many others had been retained as part of an arrangement that had started in 1985 when the Coroner for the North Manchester district had agreed to a proposal that his office staff should identify, from among the deaths reported to the Coroner, those where the brain might be suitable for a 'joint programme' of research of several Departments within the University of Manchester. Dr Metters found that Mr Isaacs' brain had been disposed of after it was decided that it could not be used in the research programme.

³⁵ Department of Health. *Isaacs Report*. Published May 12 2004. Accessed during May 2008 at :www.dh.gov.uk/en/Publicationsandstatistics/PublicationsPolicyAndGuidance/Browsable/DH4095316

³⁶ The facts of the Report, as summarised, are taken from the Department of Health website. No referenced pagination is possible.

³⁷ (2001) 362 Parl. Deb. (Hansard, 6th series), HC 189.

The wider national picture with regard to brain retention was revealed within *Isaacs*. Three types of collection were identified. First, there were a few holdings of brains specifically collected for research. Second, there were brains initially retained for diagnostic purposes, but later used for research. Third, there were ‘accumulations’ of brains, without any research or other use being intended. Some accumulations had occurred simply because neither the Coroner nor the pathologists had given instructions regarding disposal of these brains.

Dr Metters attempted to understand events from the point of view of the practising pathologist.

First, before the Human Tissue Act in 1961, pathologists had been used to removing organs at post-mortems that appeared to be of interest for research or teaching purposes. This practice had continued during the 1960s, little influenced by the Human Tissue Act. Second, pathologists carrying out post-mortems were trained by their seniors and followed their example and practices. Third, some pathologists were reportedly asked by Coroners not to distress relatives by referring in their post-mortem reports specifically to the retention of organs. There is nothing in writing to confirm that such instructions were given... [H]owever, [the author of the Report] is satisfied that some Coroners did ask pathologists to refrain from mentioning organ and tissue retention in their post-mortem reports. Fourth, it is noteworthy that Schedule 10 of the Coroners Rules, which sets out the format for the post-mortem examination report, refers obliquely to organ or tissue retention. The schedule does not require a list of organs and tissues that have been retained.

1.1.4 Commonality of features in *Bristol*, *Redfern* and *Isaacs*.

Although each of the three Inquiries arose because of a particular circumstance, or set of circumstances, the findings were strikingly similar. [Professor Van Velzen stood apart in *Redfern* by virtue of his wilful and criminal falsification of data.]

All three Inquiries found serious inadequacies in communication with relatives about PM examinations. Withholding the details was recognised in *Redfern* to have its origins, at least in part, in well meaning paternalism. With regard to HPMs, 81% had not been told that they could have objected.³⁸ In *Isaacs*, the examination had

³⁸ The Royal Liverpool Children’s Inquiry: Summary and Recommendations. Printed by order of the House of Commons, January 30, 2001, op.cit., p22, para 3.3.

been carried out in the face of objection from Mrs Isaacs, and was thereby illegal. In *Bristol* parents were found to have been asked to sign papers very soon after the death of their child, and after, at best, brief discussion, when many had been clearly and understandably unable to comprehend what was being put to them.³⁹

It was common to *Bristol* and *Redfern*, and central to *Isaacs*, that relatives were unaware that organs might have been, and usually had been, retained. That the discovery provoked shock was understandable. What at first sight may be less clear is why the collective response escalated to the point where multiple funerals were felt by the families to be necessary – even to the extent of interring glass microscope slides of tissue. These matters are considered in more detail below.

The PM examinations which gave rise to most concern were those in the coroners' jurisdictions. Pathologists had believed, erroneously, that they were entitled to retain, long term, organs and tissues for teaching, research or archiving. *Redfern* berated the medical profession because '[they] did not properly consider the Human Tissue Act 1961 in the first place'.⁴⁰ *Isaacs* found 'a major misunderstanding of the Human Tissue Act and the Coroners' Rules.' The Interim Report of *Bristol* (*BIR*) found the law regulating the removal, retention, use and disposal of human materials to be 'obscure, uncertain and arcane'.⁴¹ The coroners themselves had a case to answer in each centre. In *Redfern*, 'slackness' of coronial procedures was found to be a contributory factor. In *Isaacs*, the Coroner's Office in one district was actually responsible for identifying to the clinicians cases which might be suitable for brain research. Dr Metters in *Isaacs* '[found] it hard to believe that [the coroner] did not know'. *BIR* concentrated on an analysis of law relating to the activities of coroners and said little about the conduct of the Bristol Coroner

³⁹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, op. cit., p12, para 42.

⁴⁰ The Royal Liverpool Children's Inquiry Report. Printed by order of the House of Commons, January 30 2001, op.cit., Chapter 10, p365, para 9.13.

⁴¹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000. Covering letter from chairman and members of the Inquiry to the Chief Medical Officer of England, May 2000.

within the context of the Inquiry. [In *Bristol*, two medical witnesses gave evidence which was at variance with the account of the then coroner⁴².]

Taken together, the common factors revealed by the three Inquiries would of themselves have called for stronger guidelines to the medical and coronial professions, perhaps coupled to new proportionate legislation. In addition, there were further factors which, I argue, may have influenced the climate in which new legislation was sought.

1.2 Further ‘inspiration’ factors which influenced the climate in which new human tissue legislation was brought forward.

1.2.1 *Bristol* Interim Report, Annex B.⁴³

Professor Kennedy and colleagues examined in detail the then existing law and guidelines and identified many of the shortcomings and uncertainties already discussed in Chapter One. The Report stated that the ruling principle regarding the removal, retention, use and disposal of human material must be respect for the dead child and for the concerns and, to the extent allowed by law, the wishes of the parents.⁴⁴ Two options were offered: either to produce an enforceable (and enforced) Code of Practice⁴⁵, or ‘Option 2’:

If it were decided that new law is necessary and if parliamentary time could be found, a twofold approach could be adopted. Specific concerns could be met through amending or clarifying the existing law. In addition, the scheme of consents proposed above as a code of practice could be given statutory form by being incorporated into the new law as a schedule, or by stipulating in the law that

⁴² BBC News. *Coroner in the dark on organ retention*. October 19, 1999. Accessed on December 8, 2009, at: http://news.bbc.co.uk/1/hi/health/background_briefings/the_bristol_heart_babies/479696.stm

⁴³ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. Annex B: Law and guidelines. May 2000.

⁴⁴ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, op. cit., p39, para 125.

⁴⁵ Ibid., pp40-47, paras 131 -175.

the code of practice issued from time to time by the appropriate government department must be observed.⁴⁶

The ensuing paragraphs in Annex B identified specific matters which a new law should address. These included: the importance of the Coroners Act 1988 and Coroners Rules 1984; communication between Coroner and parents; responsibility for retained tissues after Coroner is *functus*; tissue blocks and slides; DNA; parents' rights; the need for explicit consent in hospital PMs, with a Code of Practice as a schedule to the putative new legislation; breach of provisions of law should attract legal sanctions; the right to possession and control of tissue after parental consent should vest in the pathologist [with consequent legal issues of title, commerce, intellectual property rights to be resolved].⁴⁷

The recommendation of 'Option 2', and the specific issues listed above, bore a striking congruence with the provisions of the later Human Tissue Bill 2003-4, the content of the subsequent Parliamentary debates, the issues which attracted forceful lobbying, and the 'omissions' from the Human Tissue Act 2004 identified later by legal scholars. All these matters will be discussed later in this Chapter. At this stage, I submit that the evidence for the *Bristol* Interim Report having been an important 'inspiration' (and source of later 'formulation') is considerable.

1.2.2 A commitment to parents: the CMO's 'Summit' meeting on organ retention.⁴⁸

This meeting was held in London on January 11 2001. Its purpose, according to the CMO, was to draw on experiences from the past so as to 'come up with ideas and solutions for the future and look forward'.⁴⁹ Whatever was the desired purpose of the meeting, it was characterised throughout by angry contributions and

⁴⁶ Ibid., p47, paras 176.

⁴⁷ Ibid., pp47-50, paras 177-193.

⁴⁸ Department of Health. *Transcript of Chief Medical Officer's Summit. Thursday January 11, 2001.* CMO Transcrip2t[1].pdf. Obtained on February 11, 2010 from CMO's Private Office.

⁴⁹ Ibid., p2.

interjections from some parents, and (mainly) defensive and apologetic speeches from the medical profession.

There was [in retrospect] a remarkable contribution from Mrs Michaela Willis, chair of the National Committee concerned with Organ Retention (NACOR), speaking of the need to change future practice. As noted (*verbatim*) in the transcript of the Summit:

There must be an immediate change in the law. The rules governing hospital and coroners' post mortems must be the same. Doctors must be obliged to seek fully informed consent from families for the examination of the relative's body and the retention of every item of material. Contravention must lead to disciplinary action and rights to damages. A new criminal offence of selling human material or profiting from its use [is required]. There should be a national inspectorate which should be set up to monitor practices in all hospitals and to administer a national register of all human material.⁵⁰

This described with some accuracy the structure and content of the Human Tissue Bill 2003-4 introduced some three years later.

Almost the last word was given to a lay participant, Mr Fergus Walsh, the BBC's health and science correspondent, who said, to repeated bursts of applause:

The mistakes that have happened in the past are appalling... The way the Government and the medical profession respond to this scandal is crucial...[These are] the final views that Liam Donaldson will hear before he goes back to see Alan Milburn. We should listen to the families more than anyone else.⁵¹

The CMO responded 'We do have to change the law. We do have to put in measures that bite and work. We must, whatever we put in place, pass one simple test and that test is two words, "never again"'(Applause).⁵² The CMO gave an assurance to the meeting that its proceedings would help to shape his advice to ministers on future regulations for organ retention.

⁵⁰ Ibid, p4.

⁵¹ Ibid., p52.

⁵² Ibid., p55.

I believe it is not fanciful to conjecture that the emotion of the Summit, exemplified in Walsh's summary, was communicated to the Secretary of State, and in turn fed into his presentation of *Redfern* to Parliament two weeks later. Evidence later in this chapter will indicate that a 'commitment to parents and relatives' by the Government reappeared at all subsequent stages of the legislative process. [The content of Ms Willis' presentation from NACOR suggested that the process had already begun].

1.2.3 Public opinion and the Press.

The scale of the early response to the events in Bristol and later Alder Hey can be gauged from the volume of newsprint that was produced. A computer search in 'Nexis' in April 2008 of 'organ retention' revealed that between November 1999 and November 2000 there were 258 articles on the subject in the national press and 774 in regional newspapers. The tone of the articles can be summarised in three headlines of the time. 'Parent's heartache at being told child may have been cremated without her heart'⁵³; 'Hospital that set up 'library' of tragic babies may be sued: parents act as the agony of losing a child returns'⁵⁴; 'An 18 year wait to lay a cot-death baby to rest'.⁵⁵ [Although the timing of publication of the *Isaacs* Report on May 13 2003 placed its contents firmly in the 'in-tray' of draft legislators, it made fewer headlines than *Bristol* and *Redfern*. It may have been that retention of (elderly) adult brains was less newsworthy than comparable practices which involved infants and children. In addition, the Report may have been partly driven from the front pages by the fact that it appeared on the very day the Clare Short MP, the International Development Secretary, resigned from the Government because of her opposition to the Iraq War.⁵⁶]

⁵³ *Express and Echo (Exeter)*, February 10, 2000.

⁵⁴ *Daily Mail*, November 26 1999.

⁵⁵ *The Scotsman*, May 11, 2000.

⁵⁶ *The Times (London)*, May 13, 2003.

The media response during the months leading up to the publication of *Redfern* was as nothing compared with the storm which erupted in the Press on January 31 2001, hours after the Secretary of State, Rt Hon Alan Milburn MP, had released its contents to a hushed House of Commons⁵⁷. According to a 'Nexis' search in December 2009 (of 'organ', 'tissue', 'retention', 'children', 'infants', 'scandal'), supplemented by on site searches in the British Library newspaper collections, there were at least 117 separate articles in the national newspapers on that day. The majority of the newsprint was, understandably, devoted to the findings in Liverpool itself, and concentrated on the reaction of parents ('unforgivable pain of organ scandal parents'⁵⁸), and the verdict on Professor Van Velsen ('a catastrophic betrayal of trust; organ horror doc; Dr Liar; Frankenstein'⁵⁹). In addition, however, there was extensive coverage of the CMO's Census⁶⁰ [discussed below at 1.2.5] ('child organ scandal: illegal body parts held all over the country'⁶¹). The sum was 'a disgrace beyond imagining'⁶², and represented 'truly the darkest day in the proud history of the National Health Service'⁶³.

Commendably, there were a few articles in a few newspapers which, even on the day following the revelations of *Alder Hey*, sought to look forward. Particularly impressive to me was the contribution of David Robson in *The Express* who anticipated many of the debates to come (as well as the content of several subsequent sections of this Thesis) when he wrote:

⁵⁷ (2001) 362 (Parl. Deb., Hansard, 6th series), HC 175.

⁵⁸ *The Express*, Jan 31, 2001, p8.

⁵⁹ *Daily Star*, January 31, 2001.

⁶⁰ Department of Health, Department for Education and Employment, Home Office. *Report of a census of organs and tissues retained by pathology services in England: conducted in 2000 by the Chief Medical Officer*. London. The Stationery Office, 2001.

⁶¹ *The Independent (London)*, January 31, 2001, p6.

⁶² *The Guardian*, January 31, 2001, p2.

⁶³ *The Sun*. Leading article: *A question of consent*. January 31, 2001.

Our first thought about Alder Hey will be with the parents, who feel themselves brutalised, but our second thought should be that several valuable things will emerge: there may be a change in the culture of medicine, the sort of change that comes through policy often precipitated by disaster. Equally important is an increased recognition by us that our attitude to corpses should be examined. Organs are essential to science: their removal with consent is not an offence against the dead or the living. Quite the contrary, it should be seen as a contribution.⁶⁴

1.2.4 The response of the Secretary of State, Rt Hon Alan Milburn MP to *Redfern*.

It is more than likely that the Secretary of State held the view that the relationships between the content of the Report, his views, and their handling by the press might be important in shaping public opinion, and this may have influenced his approach. There were comments in the press about his choice of words and oratorical style as he presented *Redfern* in the House of Commons. As described by Simon Hoggart in the *Guardian*:

[w]e do not often hear demotic English in Parliament, so the words made the goose pimples almost painful, and the chill in the pit of the stomach even worse.⁶⁵

An anonymous features writer in the *Times* took a different view of Mr Milburn's performance.

It was essential to shed light on what happened at Alder Hey. But the hysterical and overwrought language used by Mr Milburn is the reverse of helpful [and] ensured that the ...atmosphere was as highly charged as possible. This lurid touch was the last thing needed by either doctors or parents. He should have been trying, in the interests of everyone involved, to calm the various parties so that the vital work of rebuilding trust could have as easy a beginning as possible.⁶⁶

⁶⁴ Robson D. Leading article: *Alder Hey may force us all to change our views about corpses; the hope we must take from tragedy*. *The Express*, January 31, 2001, p12

⁶⁵ Hoggart S. Sketch: *A disgrace beyond imagining unites the house*. *The Guardian*, January 31, 2001, p2

⁶⁶ *The Times* (London). Feature: *Overwrought response*. January 31, 2001.

A similar view was later expressed by the President of the Royal College of Physicians (RCP) about what he perceived as the ‘hyperbolic’ language of the Secretary of State.⁶⁷

Two further documents were published alongside *Redfern*, both from the Chief Medical Officer, as follows.

1.2.5 The Chief Medical Officer’s Report of the census of retained organs and tissues conducted throughout England during 2000. (‘CMO’s Census’).⁶⁸

This Report revealed that a total of approximately 54,300 organs, body parts, still-births or fetuses were held by pathology services at the end of 1999 which had been retained from PMs between 1970 to 1999; nearly half the total organs retained were brains and a sixth were hearts.⁶⁹ Not surprisingly, these findings added to the press furore.

1.2.6 The Chief Medical Officer’s Advice on the removal, retention and use of human organs and tissue from post-mortem examination (‘CMO’s Advice’).⁷⁰

The Government chose to accept the CMO’s recommendation that:

[a]s soon as possible, there should be a more fundamental and broader revision of the law, encompassing the taking, storage and use of human tissue from the living and the dead, and introducing an independent system of regulatory control. To be comprehensive, this should encompass aspects of coroners’ practice. It should shift the emphasis from ‘retention’ to ‘donation’ to signal a new relationship with the public and bereaved families.⁷¹

⁶⁷ Hoffenberg R. *Medical arrogance*. Clinical Medicine 2001; 1(5):330-340.

⁶⁸ Department of Health, Department for Education and Employment, Home Office. *Report of a census of organs and tissues retained by pathology services in England: conducted in 2000 by the Chief Medical Officer*. London. The Stationery Office, 2001, op.cit.

⁶⁹ Ibid., p 1.

⁷⁰ Department of Health, Department for Education and Employment, Home Office. *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*. London. The Stationery Office, 2001, op. cit.

⁷¹ Ibid., p41, Recommendation 6.

The principles underlying the CMO's advice included respect, informed consent, and adequate information, and certainly chimed with public opinion, BIR, the CMO's Summit, the language of *Redfern*, and a need to be 'true' to the bereaved parents. Indeed the Secretary of State paid tribute to a parent, Mrs Michaela Willis (Chair of the National Committee on Organ Retention), and others who 'have helped to contribute to the CMO's recommendations'.⁷² The emphasis on 'consent' was derived from these sources, and in addition, was congruent with a more widely expressed concern by the Government of the day, and articulated by the Secretary of State in October 2001, that 'for public services to command public confidence today, they have to give greater control and more [informed] choice to the people who use them'.⁷³ One month later the Department of Health had reinforced the importance of 'patient-centred consent practice' in a circular to be acted on by all Health Authorities and Trusts in the NHS.⁷⁴

If more evidence were needed of the influence of bereaved parents in 'inspiration', it came from the Secretary of State:

I think there is consensus on what the parents really want. They want an apology and an explanation and to know that those who are responsible for what happened to them and their families will be brought to book. Above all, they want to know it will not happen again and that action will be taken quickly to prevent it from happening again. We are committed to taking that action.⁷⁵

With the Government's decision to change the law the end of the 'inspiration' phase had been reached. Sadly, I have not found it possible to identify a *positive* contribution from the medical profession to this phase, unless it could be said that errant behaviour revealed in (in particular) *Redfern* and *Isaacs* was a positive stimulus to the inclusion of sanctions in the new legislation! Because I believe, and

⁷² (2001) 362 (Parl. Deb., Hansard, 6th series), HC 182.

⁷³ Speech by the Rt Hon Alan Milburn MP, Secretary of State, to the Fabian Society, October 21, 2001. Obtained from Health Services Management Centre, University of Birmingham (Professor Christopher Ham).

⁷⁴ Department of Health. HSC 2001/023: *Good practice in consent: achieving the NHS Plan commitment to patient-centred consent practice*. November 22, 2001.

⁷⁵ (2001) 362 (Parl. Deb., Hansard, 6th series), HC 183.

will try to argue later, that an absence of positive medical/scientific input at the early stages of the legislative process (perhaps it was positively not welcomed) led to otherwise avoidable conflicts, it is appropriate to add a note at this point in the narrative about the state of the profession in the months before and after the publication of *Redfern*.

1.2.7 A postscript about the medical profession at the end of the 'inspiration' phase.

Chapter Three has already suggested that by the millennium the medical profession had lost the unqualified confidence of the public and government, and to an extent had lost confidence in itself. *Bristol, Alder Hey and Isaacs* did not improve matters.

1.2.7.1 Royal Colleges and individual doctors.

The Royal College of Pathologists (RCPATH), the body at the professional centre of the storm, had earlier given a Statement to the *Bristol* Inquiry which, to my reading, had contained a mixture of fact, explanation, discomfort, and, in places challenge.⁷⁶ RCPATH had also emphasised the existence a Working Party of their College which had been set up *in 1995, four years before the Inquiry* (RCPATH's emphasis) to produce authoritative advice to the profession by way of guidelines for the retention of tissues and organs at PM examination.⁷⁷ The RCPATH Guidelines were published in March 2000⁷⁸, by which time the revelations in Bristol and Liverpool were well underway. The Guidelines were described in the *Bristol* Interim Report as 'long awaited'⁷⁹, but were dismissed as inadequate, stating:

⁷⁶ Royal College of Pathologists. *Statement to the Bristol Royal Infirmary Inquiry from the Royal College of Pathologists*. March 18, 1999. (Inquiry document WIT 0054 0001.)

⁷⁷ Ibid.

⁷⁸ Royal College of Pathologists. *Guidelines for the retention of tissues and organs at post-mortem examination*. March 2000,

⁷⁹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, op.cit., p28, para 99.

[The College] could have proposed that their changes be put into statutory form, on the ground that professional guidelines were not sufficiently binding. After all, previous guidelines have not been conspicuously well-observed. The College chose not to do so. It is a matter of considerable concern whether guidelines, on their own, issued by the very professional body seen by some as having lost trust, will suffice to recapture this trust. We doubt it.⁸⁰

RCP indicated to the CMO their view that the response by the public, press and politicians to Bristol and Alder Hey had failed to recognise properly the importance of the study of PM tissue for good clinical practice, education and research.⁸¹ RCP conceded that specific consent for the retention of organs and tissues had not usually been sought. This had not been because of an intention to deceive or conceal the purpose, but because it had been assumed that acceptance of such actions was implicit in the consent given to the process of autopsy. Further, 'we do not believe that most people giving consent to autopsy believed that every piece of tissue was returned to the cadaver prior to burial or cremation.'⁸²

While many of the official medical responses were positive or in places feisty in tone, there is no doubt that, at the level of individual practitioners (especially histopathologists), the immediate outcome was a severe loss of morale, with feelings that were a mixture of defensiveness and bewilderment, and accompanied in some cases by (doomed) attempts to explain to a hostile audience the benefits of post-mortem examinations.⁸³ Paediatric pathologists, in particular, suffered abuses: some received threatening phone calls to their homes, while others found their children being bullied at school because of their parents' profession.⁸⁴

A few were more robust in their responses. John Bennett, a distinguished senior physician, wrote: 'The study of whole organs (fresh, or preserved in jars) and

⁸⁰ Ibid., p30, para 109.

⁸¹ Royal College of Physicians (London). Council paper 01/18. *Response to the CMO's draft paper on retention of organs and tissues at post-mortem*. January 17, 2001.

⁸² Ibid.

⁸³ Armstrong S. *A matter of life and death: conversations with pathologists*. Dundee. Dundee University Press, 2008, pp1, 18.

⁸⁴ Ibid., p1.

histological slides has been an integral part of medical education for centuries, and every undergraduate medical school had a pathology museum of which it was often justifiably proud'.⁸⁵ The President of the Pathology Society sought to distance the practice of the 'overwhelming majority of pathologists' from those exposed in Alder Hey, stating that 'pathologists generally are scrupulous about ensuring that full permission for autopsy is given and that the permission form mentions that tissue may be retained'.⁸⁶

1.2.7.2 The response of the medical press to the Inquiries.

The *British Medical Journal* accepted the charge of medical paternalism, and asked 'what have we learned from the Alder Hey affair?' The answers were that all doctors needed to be educated about how to obtain appropriate consent, and must understand that patients wanted to be partners in decision making. Further, doctors' behaviours which were deemed important needed to be 'continuously (sic) monitored to ensure adherence with standards'.⁸⁷ Not surprisingly, this editorial provoked a flurry of emailed 'Rapid Responses' to bmj.com with a wide range of content, from support, through specific counter points, to 'unfair criticism'.⁸⁸

Perhaps the most balanced of the early medical commentaries came in a leader in the *Archives of Disease in Childhood* by Professor (later Sir) David Hall, President of the Royal College of Paediatrics and Child Health. Although many doctors, including himself, had initially thought that this was just another 'doctor bashing' story, he had come to realise that *Alder Hey* was probably as cataclysmic an event in British medicine as *Bristol*, and 'the culmination and, perhaps, the final demise of what we have thought of as benign medical paternalism'. The lessons to be learned would

⁸⁵ Bennett JR. *The organ retention furore: the need for consent*. Clin. Med. 2001; 1(3): 167-171 at p167.

⁸⁶ Hunter M. *GMC suspends former Alder Hey pathologist*. BMJ 2001;322(7282): 320.

⁸⁷ Bauchner H, Vinci R. Editorial: *What have we learned from the Alder Hey affair? That monitoring physicians' performance is necessary to ensure good practice*. BMJ 2001; 322 (7282): 309-310.

⁸⁸ British Medical Journal. *Rapid responses*. Accessed on January 21, 2010 at: <http://www.bmj.com.ezproxyd.bham.ac.uk/cgi/eletters/322/7282/309>

require modifying consent procedures, embracing the concept of patients as partners, developing techniques for limited postmortem examinations, clarifying the law- but above all, finding a method for the profession to say a collective 'sorry'.⁸⁹

2. 'Deliberation and formulation'.

2.1 Retained Organs Commission (ROC; 'the Commission').⁹⁰

The publication of *Redfern* exacerbated public indignation and, crucially, parental anger and distress which required urgent attention. In response the Government established the Retained Organs Commission, through which, by its very existence, the Government further confirmed a commitment to parents. The ROC was established by the Secretary of State for Health as a Special Health Authority on January 30 2001, and came into being formally on April 1 of that year. It was chaired by the legal academic, Professor Margaret Brazier, and functioned until March 31, 2004. The Commission contributed to the deliberative and formulating phase, but also did much more.

A drily worded catalogue of the important tasks given to ROC- to manage the process of organ return in the NHS, provide advocacy and information for families, consult on and propose a regulatory framework for 'collections', advise Ministers about the changes needed in the law- fails to capture the scale of the emotional burden that would fall on the Commission acting perhaps as a 'lightning conductor'. Its weight can be sensed in the words of Professor Brazier in her final report:

Three challenging years...the Commission came into being because of the hurt done to so many families...the pain caused by organ retention was graphically demonstrated to us in all our meetings with relatives...however painful some

⁸⁹ Hall D. *Reflecting on Redfern: what can we learn for the Alder Hey story?* Arch Dis Childh 2001; 84 (6): 455-456.

⁹⁰ National Health Service: Retained Organs Commission. *Remembering the past, looking to the future. The final report of the Retained Organs Commission including the summary accountability report for 2003/2004.* Department of Health Publications, March 2004.

meetings may have been, the opportunity to exchange views and engage in frank discussion enhanced the work of the Commission.⁹¹

My view that this aspect of the Commission's activities was among its most important is given credence by a paper written by Brazier wearing her academic hat, in response to a provocative argument by Harris that, *inter alia*, 'the role of consent in posthumous organ retention is highly problematic' and, even if valid, needed to be weighed against the usefulness to which body parts could be put in the public interest.⁹² Brazier, having declared an interest as Chair of the ROC, 'fundamentally' disagreed with Harris, and suggested that his analysis of the ethical issues arising from the controversies surrounding organ retention was incomplete:

[Harris] overlooks the context in which revelations about organ retention came about. Deeply held religious and cultural beliefs are not accorded the weight they deserve. The value accorded to respect for the dead, acknowledged throughout the world and through history, is virtually ignored. He does not fully address...the claims of bereaved relatives to respect for their loss and protection from emotional distress and psychiatric harm...[N]early two years of meeting families whose relatives' organs were taken without any genuine consent on their part has offered me insight into the impact of organ retention which has radically affected [the views I hold].⁹³

The views of the ROC were much influenced by the fervent wish of parents from Bristol and Alder Hey that the experiences they had suffered must never happen again, and in due course must have fed directly into the process of new legislation, perhaps particularly in the need for informed consent and for sanctions for transgression.⁹⁴ The ROC's formal advice to Government about regulation and legal reform was issued in June 2003, and was concentrated on three specific areas: the

⁹¹ National Health Service: Retained Organs Commission. *Remembering the past, looking to the future. The final report of the Retained Organs Commission including the summary accountability report for 2003/2004*. London, Department of Health Publications, March 2004, p1.

⁹² Harris J. *Law and regulation of retained organs: the ethical issues*. *Legal Studies* 2002; 27(4) 527-549, p531.

⁹³ Brazier M. *Retained organs: ethics and humanity*. *Legal Studies* 2002; 27(4): 550- 569, pp550-551.

⁹⁴ National Health Service: Retained Organs Commission. *Remembering the past, looking to the future. The final report of the Retained Organs Commission including the summary accountability report for 2003/2004*. London, Department of Health Publications, March 2004, p53, paras 5.27, 5.28.

legal status of tissue blocks and slides⁹⁵; the use and disposal of unclaimed and unidentifiable human remains⁹⁶; and a regulatory framework for museums, archives and collections of bodies and their parts.⁹⁷[Note of December 2010. I have been unable to obtain these ROC documents despite enquiries to the Department of Health, the National Archives, and, indirectly, to two members of ROC].

2.2 A ‘fundamental and broad review’ of the law (Recommendation 6, CMO’s Advice).

Between 2001 and mid 2002, the Department of Health undertook a review of the law on human organs and tissues taken from both adults and children, as had been recommended.⁹⁸ The starting point must have begun earlier, since the CMO’s Advice to Government on January 31, 2001 had already recommended a review of the law:

[e]ncompassing the taking, storage and use of human tissue from the living and the dead, and introducing an independent system of regulatory control. To be comprehensive, this should encompass aspects of coroners’ practice.’⁹⁹

2.2.1 The primacy of consent.

I have already identified (at 1.2.1 above) the influence of the *Bristol* Interim Report (BIR) on review of the law, and which, *inter alia*, established the ‘ruling principle’ of

⁹⁵ National Health Service. Retained Organs Commission. *Recommendations on the legal status of tissue blocks and slides. Advice paper.* June 2003.

⁹⁶ National Health Service. Retained Organs Commission. *Advice to the Department of health on the use and disposal of unclaimed and unidentifiable human organs and tissue.* June 2003.

⁹⁷ National Health Service. Retained Organs Commission. *A proposed framework for the regulation of museums, archives and collections of human bodies, body parts, organs and tissue.* June 2003.

⁹⁸ Department of Health. *Progress in policy archive.* Accessed February 9, 2010 at: <http://www.dh.gov.uk/en/Aboutus/MinistersandDepartmentLeaders/ChiefMedicalOfficer/Archive/ProgressOnPolicy/index>

⁹⁹ Department of Health, Department for Education and Employment, Home Office. *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer.* London. The Stationery Office, 2001, op.cit., p41, Recommendation 6.

consent¹⁰⁰. The CMO's advice subsequently regarding respect and informed consent was compatible not only with the Inquiry reports but also with a general commitment of the Department of Health to 'patient-centred consent practice'¹⁰¹ - which in turn reflected a deeper trend within society in favour of personal autonomy and informed choice, discussed in Chapter Three. However, as I try to show in the 'legitimation' section below and in Chapter Five, other factors could, and did, play a significant role in modifying the 'ruling principle'.

2.2.2 The origins of the decision to include 'tissues from the living' within new legislation.

It remains something of a puzzle as to why the CMO took the decision to recommend to Ministers that tissue from the living should be included in the proposed legislation- a decision described as 'surprising' in a later academic analysis¹⁰², and questioned by Lord Turnberg in the House of Lords as to whether it was needed¹⁰³.

We know from BIR that control of tissue banks 'and the like' had been on the CMO's mind. By July 2002 there would also have been early proposals for EU legislation on Departmental desks, concerning the quality and safety of cells and tissue from the living used for therapeutic purposes¹⁰⁴ and which eventually led to Directive 2004/23/EC of the European Parliament and of the Council in March

¹⁰⁰ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, op. cit., p39, para 125.

¹⁰¹ Department of Health. HSC 2001/023: *Good practice in consent: achieving the NHS Plan commitment to patient-centred consent practice*. November 22, 2001.

¹⁰² McHale J. *The Human Tissue Act 2004: innovative legislation- fundamentally flawed or missed opportunity?* Liverpool Law review 2005; 26: 169-178, p 171.

¹⁰³ (2004) 664 (Parl. Deb., Hansard 5th series), HL 380.

¹⁰⁴ OJ C227 E 24.9.2002, p505.

2004¹⁰⁵. The Directive, binding on the UK Government, contained concepts and requirements which could be seen as also relevant to legislation regarding tissues from dead people (and which, incidentally, mapped well to the recommendations of BIR), including : tissue and cell [use] should be founded on the philosophy of voluntary and unpaid donation¹⁰⁶, taking into account the Convention for the protection of human rights and dignity of the human being¹⁰⁷; mandatory consent or authorisation requirements [of each Member State], including giving all appropriate information to donors and relatives, should have been met¹⁰⁸. The Directive required: ‘penalties for infringements’ which had to be ‘effective, proportionate and dissuasive’¹⁰⁹; a ‘designated competent authority’, to be responsible for implementation, a system of accreditation, authorisation and licensing, inspections and control measures.¹¹⁰

Third, some of the recommendations in 1995 of the Nuffield Council on Bioethics (on ethical and legal questions concerning medical and scientific uses of human tissue)¹¹¹ would have resonated in the minds of officials faced with the problems raised in *Bristol* and *Alder Hey*. For example it was recommended that, where tissue was removed in the course of medical treatment, consent to treatment should be taken to include consent to disposal, storage and ‘any other ethically acceptable’ use of removed tissue.¹¹²

¹⁰⁵ Directive 2004/23/EC of the European Parliament and of the Council of March 31, 2004: *on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*. OJ 2004 L102/48.

¹⁰⁶ Ibid. Preamble, para 18.

¹⁰⁷ Ibid. Preamble, para 22

¹⁰⁸ Ibid. Chapter 2. Article 13(1)(2).

¹⁰⁹ Ibid. Chapter 5. Article 27.

¹¹⁰ Ibid. Chapter 1. Article 4(1).

¹¹¹ Nuffield Council on Bioethics. *Human tissue: ethical and legal issues*. London. April 1995

¹¹² Ibid. Para 13.37, p134

It is just possible that the inclusion of tissues from the living in the ‘fundamental and broad review’ was (merely) an attempt at a complex tidying operation. A senior civil servant, Hugh Whittall, who was intimately involved in all stages of the legislation, gave a fascinating glimpse of Departmental thinking during that review in a meeting of the Human Genetics Commission - information which I obtained through the Freedom of Information Act 2000 (FOIA)¹¹³:

We were faced with the current legislative position which is quite a patchwork. We have several different pieces of legislation which are operative, we have areas that are not covered by legislation at all. These have different regulatory approaches as well...what we have found is sometimes anomalous, sometimes inconsistent, but certainly rather patchy.¹¹⁴

A ‘tidying up’ which incorporated a wide range of legislation might also be congruent with the description by the late Sir Harold Kent QC, Parliamentary Counsel, of the differing interests of a minister, in comparison to a draftsman, as to the content of a Bill:

The draftsman seeks to confine the Bill strictly to matters requiring an alteration of the law. The department is conscious that the Minister would like to make a Parliamentary splash; it also knows that administration is sometimes helped by being able to refer to an Act of Parliament; so it wants to put as much as possible into the Bill.¹¹⁵

2.2.3 Possible influence of the ‘in tray’ (see Chapter Two).

Although the relevant files in the National Archives that relate to the Departmental review will remain closed until at least 2031, it is possible to make an informed guess as to their likely contents. Lying in wait for officials and ministers would have been the contents of what I have termed the ‘in-tray’ prior to 2000. Chapter Two described a series of problems which arose and which had been met by piecemeal responses. Recalling Drewry’s five stages of the legislative process¹¹⁶, these events

¹¹³ *Freedom of Information Act 2000*. (2000, c.36.)

¹¹⁴ Human Genetics Commission. Plenary meeting transcript. *Item 5: Update on the Human Tissue Bill (H. Whittall)*. London, November 12, 2003. FOI DE490186. McNeish. 12/10/2010.

¹¹⁵ Kent HS. *In on the act: memoirs of a lawmaker*. London. Macmillan London Limited, 1979, p44.

¹¹⁶ Drewry G. *Law-making systems-how to compare*. Statute Law Review 2008; 29(2): 100-110.

represented recurring, albeit largely unplanned, 'post legislative scrutiny' which had identified shortcomings in the law, and which had resulted in several attempts by officials to produce draft amending legislation.¹¹⁷ The influence ascribed by Drewry of 'the public's response to legislation- particularly their complaints and bad experiences'- in this case from *Bristol, Alder Hey* and *Isaacs*- would have supplied overwhelming further 'feedback' to Government and taken the legislative process full circle- returning to 'inspiration' and 'formulation'¹¹⁸- with an added sense of urgency.

In addition, there would have been more recent Departmental activity which would, separately, have brought 'errant doctors' and, separately 'human tissue' and 'coroners' to the forefront, and may just have added still more to the 'in-tray': the erasure by the GMC in 1998 of Rodney Ledward, a consultant gynaecologist and a man with a 'god like attitude' who had ignored previous disciplinary hearings and a formal warning.^{119 120} ; specific recommendations in the Shipman Inquiry (on death certification, and the investigation of death by coroners) of direct relevance to officials and ministers as they determined a course of action following *Redfern*.¹²¹
¹²² The removal of hands on the coroner's instructions for identification purposes after the 1989 Marchioness disaster, revealed by, and criticised in, the report of

¹¹⁷ National Archives. Ref. MH150/399. Document D49: *Human Tissue Act 1961*, December 1971, with appendices; also Memoranda M47, M48, M51, M53, op. cit.

¹¹⁸ Ibid., p109

¹¹⁹ Department of Health. *An inquiry into quality and practice within the National Health Service arising from the actions of Rodney Ledward*. Published June 1 2000. Accessed on January 26, 2010 at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4093337

¹²⁰ Ibid., sections 20-23, 27-32, at pp133-136 and 255-265

¹²¹ *The Shipman Inquiry* (chaired by Dame Janet Smith). Fifth report: *Safeguarding patients: lessons from the past- proposals for the future*. Cm 6394. December 9, 2004.

¹²² *The Shipman Inquiry* (chaired by Dame Janet Smith) Third Report: *Death certification and the investigation of deaths by coroners*. Cm 5854. July 14, 2003.

Lord Justice Clarke in March 2001¹²³, would also have been of then current concern. It is of course impossible to say whether or not these extreme cases contributed to the Department's 'inspiration' phase of new human tissue legislation, but they cannot have helped the medical (or coronial) cause. Last, the opening of Gunther von Hagens' 'Body Worlds' exhibition had provoked much debate.^{124 125} However remote this exhibition was from the day to day work of the Department of Health, one may conjecture that a new file had been opened.

2.2.4 Litigation on behalf of parents.

The information in this section was obtained from the NHS Litigation Authority.¹²⁶

These proceedings, of great importance to the affected families, are mentioned only briefly in this Thesis because they took place during the phase of deliberation and formulation, but with the plausible hypothesis that the litigation kept the needs of parents at the forefront.

For the record, there were two separate legal actions. First, the Royal Liverpool Children's Litigation (RLCL), which was settled after confidential mediation on September 25-27, 2002. 98% of the RLCL Claimants accepted the settlement terms of a global compensation figure (i.e. a figure for the whole group, to be split as the group decided) plus a number of non-financial remedies. Second, a separate 'Nationwide' Group Litigation Order (NOGL) was created following service of a second set of proceedings on Leeds Health Authority, with four test cases from four centres. The trial commenced on 26 January 2004, in London before Mr Justice Gage. It concluded on 18 February 2004 [by which time the Human Tissue Bill had passed Committee Stage in the Commons]. The Claimants failed in their attempt to establish a new tort of 'wrongful interference' as a result of which, the Coroners'

¹²³ Public Inquiry into the identification of victims following major transport accidents: report by Lord Justice Clarke. Cm 5012. March 2001. Volume 1, p55, paras 13.2-13.4.

¹²⁴ PreuB D. *Body worlds: looking back and looking ahead*. Ann Anat 2008; 190: 28-32.

¹²⁵ Lee JA. *Over my dead body*. Lancet 2004; 364 (Suppl.1): 52-53.

¹²⁶ National Health Service Litigation Authority. Email to ASMcNeish, March 10, 2010.

Post Mortem (CPM) cases failed (approximately 40% of the total cohort). They succeeded in establishing that there was a duty of care owed to parents which was breached in the Hospital Post Mortem (HPM) cases; however, only one of the HPM claimants succeeded in establishing that they had sustained foreseeable psychiatric injury. Damages were awarded¹²⁷. Separately, at mediation on September 27-28, 2004, a confidential lump sum settlement to the Group was agreed in principle. In addition, the NHS Litigation Authority (NHS LA) agreed 'best endeavours' on certain non-financial outcomes including apologies where these had not already been provided. 98% of the claimants accepted the damages settlement.¹²⁸

In total, 1089 claims were settled under the RLCL. 2060 claims had issued on the NOGL group register of which 860 CPM claims were dismissed. All cases were indemnified by the NHS Litigation Authority on behalf of the NHS trust members of its schemes.¹²⁹

2.3 Consultation: 'Human Bodies, Human Choices' ('HBHC').¹³⁰

The outcome of the Departmental review was a document, 'Human bodies, human choices', which was launched in July 2002. It had the unusual subtitle of 'a consultation report'. Although the format of the document was consultative, much of the content was declarative, and many of its 142 questions sought refinements to issues apparently already decided. The document was explicitly built around the Government's prior acceptance of the CMO's Advice such that the fundamental principles and regulatory regime of the Anatomy Act 1984 would be applied to all retention of human tissue, and that new legislation would provide a statutory process for regulating all aspects of obtaining, storage, use and disposal of all

¹²⁷ *AB and others v Leeds Teaching Hospital NHS Trust and another* [2004] EWHC 644 (QB).

¹²⁸ National Health Service Litigation Authority. Email to ASMcNeish, March 10, 2010, op.cit.

¹²⁹ Ibid.

¹³⁰ Department of Health, NHS Department of the Welsh Assembly Government. *Human bodies, human choices: the law on human organs and tissue in England and Wales- a consultation report*. July 1, 2002.

tissues and organs, including the establishment of a single, regulatory body.¹³¹ The issues in HBHC were grouped into five broad headings: the scope of the definition of 'organs and tissue', consent, uses of organs and tissue, oversight and compliance, and specialized uses (transplantation, fetal tissue, gametes, cell lines and stem cells).

The outcome of the HBHC process was a summary document in April 2003 from the Department of Health ('the Summary')¹³² with the analysis of each broad topic given under three heads: aspects generally agreed; aspects where there were 'differences' or 'reservations' among respondents; and key messages for the development of new legislation. It must have been difficult to summarise accurately a process where 231 written replies had been received and over 200 individuals had attended the associated workshops and conference. It would be understandable if certain opinions or advice were outweighed by contrary views, or even became lost in the 'noise'. In the next four paragraphs I have tried to follow the passage through the consultative process of certain views expressed by the Wellcome Trust ('WT', 'the Trust'), not only because it is a major research body (and whose voice might have been expected to be heard within a consultation which was concerned that, *inter alia* 'the legitimate needs of...medical science are safeguarded in all our interests'¹³³), but because it happened that some of the matters raised by the Trust within HBHC came eventually to occupy a great deal of parliamentary time during the legitimisation phase proper.

In the months preceding the HBHC consultation there had been two consultations to which WT had already responded, one from the Retained Organs Commission on unclaimed organs and tissue¹³⁴ and the other on a draft interim statement on organ

¹³¹ Ibid., p26, para 4.1.

¹³² Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. London. Department of Health Publications, April 2003.

¹³³ Ibid., p16, para 2.7.

¹³⁴ NHS Retained Organs Commission. *Consultation document on unclaimed and unidentifiable organs and tissue and a possible regulatory framework*. February 2002.

and tissue use from the Department of Health itself.¹³⁵ WT opined rather tetchily that it would have seemed appropriate to provide feedback on these previous inquiries, in order to try and achieve a common opinion and to avoid numerous repetitions of the same points.¹³⁶ In direct response to HBHC, WT confined itself to ‘add[ing] further comment’¹³⁷ – perhaps an error of judgment. For present purposes I have shared WT’s assumption that responses to previous consultations were considered as part a greater consultation process. In the next paragraph each proposal by the Trust is followed in italicised brackets by the Departmental response in the Summary.

With regard to ‘definitions’, WT proposed that ‘human tissue’ as a term should be defined in the legislation and that this definition should *exclude* body fluids, standard tissue blocks and slides, certain ‘replicable tissues’ such as blood, small amounts of skin, teeth, hair, and non-cellular material. ‘Surgically discarded tissue’ should also be excluded from the legislation, as should cell lines and stem cells.¹³⁸ *[Departmental response in Summary: ‘Although there was a general view that discarded material should form a separate category, views differed as to whether it should therefore be excluded from legislation. Key message: ‘Discarded’ human material should form a separate category, but with any new law still taking into account the uses to which it could be put, for example, through genetic testing*¹³⁹*].*

With regard to ‘consent’, the Trust, within a stated ‘strong support for an open and transparent system based on informed consent’, considered that it would be ethical, with safeguards, to perform an autopsy without consent where there was a

¹³⁵ Department of Health. *Use of human organs and tissue: a draft interim statement for consultation*. January 2002.

¹³⁶ Wellcome Trust. *Department of Health consultation on ‘Human bodies, human choices’: Wellcome Trust response*. October 2002, p1, para 4.

¹³⁷ *Ibid.*, p1, para 3.

¹³⁸ *Ibid.*, p 2, para 6.

¹³⁹ Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. London. Department of Health Publications, April 2003, op.cit., p10, para 2.4.

pressing clinical/scientific need such as when an individual may have died from a notifiable disease with implications for public health.¹⁴⁰ *[Views were divided on what should happen if no consent could be obtained for a proposed hospital post mortem. Some felt that a hospital post mortem should be carried out if it would serve a greater public good and there was no reason to believe the deceased person would have objected. Others were against proceeding without consent. Key message: Consent should be the basis for new legislation and any regulatory system established¹⁴¹].*

With regard to 'use', WT argued for the continuing importance of tissue archives: 'It cannot be overemphasised that medical diagnoses are not made once and for all with complete accuracy. They must be subject to continuing review, often over periods of many years, as knowledge advances'.¹⁴² *[There were divided views on whether... tissue blocks and slides should be distinguished for the purposes of disposal after a post mortem. Many people felt that... tissue blocks and slides should be retained as a matter of course, perhaps indefinitely. Consent for this retention should be included in consent to the post mortem. Other respondents, however, were anxious that...tissues should be returned after a post mortem and that the wishes of the 'next-of-kin' be respected in disposal. Key message: Any new legislation should allow for different levels of consent for different uses of human organs and tissue, for example, for quality assurance, retention of tissue blocks and slides, and use of human tissue in research.¹⁴³].*

In addition, WT, while 'fully supporting the establishing of a regulatory authority supported by an Inspectorate and an effective regulatory framework'¹⁴⁴, proposed

¹⁴⁰ Wellcome Trust. *Department of Health consultation on 'Human bodies, human choices': Wellcome Trust response*. October 2002, op.cit., pp3-4, paras 11, 14.

¹⁴¹ Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. London. Department of Health Publications, April 2003, op.cit., p11, para 2.7.

¹⁴² Wellcome Trust. *Response to NHS Retained Organs Commission's consultation document-dated February 2002- on unclaimed and unidentifiable organs and tissue and a possible regulatory framework'*. April 2002, p1, para 4.

¹⁴³ Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. London. Department of Health Publications, April 2003, op.cit., p13, para 2.10.

that ‘the Human Tissue Authority (HTA) should have the facilitation of research for the benefit of the public as one of its core objectives’; and that the membership of the HTA should include ‘appropriate scientific representation’.¹⁴⁵ [*The Summary of responses regarding the HTA contained no mention of research or of the composition of its membership*].¹⁴⁶

One recognises that the Department must have been faced by competing views, on a background of a commitment to the families of ‘never again’. The above evidence supports a conclusion that in a number of areas of importance to the research community, the advice of that community was, at best, diluted.

2.4 An absence of pre-legislative scrutiny.

What should have been the next stage? A range of MPs of all parties had hoped that there would have been an opportunity for ‘pre-legislative scrutiny’ of a draft Bill.¹⁴⁷ This would have allowed all parties concerned with the practicalities of a piece of legislation and its future interpretation to determine whether a Bill would be likely to serve its purpose.¹⁴⁸ Instead, in September 2003 the Department of Health published, with an introduction from the Chief Medical Officers for England and for Wales, an eight page document titled ‘Proposals for new legislation on human organs and tissue’ (‘the Proposals’)¹⁴⁹ which set out ‘[what] we would expect to be incorporated in the legislation’. In passing one may note the [by now]

¹⁴⁴ Wellcome Trust. *Response to NHS Retained Organs Commission’s consultation document-dated February 2002- on unclaimed and unidentifiable organs and tissue and a possible regulatory framework*. April 2002, p5, para 19.

¹⁴⁵ *Ibid.*, p5, para 20.

¹⁴⁶ Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. London. Department of Health Publications, April 2003, op.cit., p15, paras 2.14- 2.16.

¹⁴⁷ (2004) 416 (Parl. Deb., Hansard 6th series), HC 996.

¹⁴⁸ *Ibid.*

¹⁴⁹ Department of Health, Welsh Assembly Government. *Proposals for new legislation on human organs and tissue*. Department of Health, September 2003.

rejection of the WT views on tissue blocks and slides. The Proposals expected that, in the new legislation:

Consent would be required before organs, tissue or cells could be taken from living patients or from deceased persons, and subsequently stored and used for specified purposes. Tissue blocks and slides made from tissue samples for microscopic examination would be subject to the same rules as any other tissue.¹⁵⁰

There were further meetings with professional organisations, but only in the spirit of explanation and foretaste. The Human Tissue Bill was introduced in the House of Commons on December 3, 2003¹⁵¹, to be followed, as it turned out, by many further months of lobbying and negotiation between scientists and politicians before the Human Tissue Act 2004 reached the Statute Book.

3 ‘Legitimation’: passage of the Human Tissue Bill 2003-4(‘the 2003-4 Bill’; ‘the Bill’).¹⁵²

3.1 Purpose of the Bill.

The contrast between the language used to introduce the Human Tissue Bill in 1960 with that used to introduce its successor could not have been starker. In 1960, Miss Edith Pitt MP, when presenting the 1960 Bill, had emphasised the importance of disseminating knowledge and encouraging research¹⁵³, and of putting beyond doubt the lawfulness of what the medical profession *required* (my emphasis) for the improvement of treatment, education and research.¹⁵⁴ On January 15, 2004, Ms Rosie Winterton MP, Minister of State for Health, said at Second Reading of the 2003-4 Bill:

The origins of the legislation lie in the distress, grief and anger felt by families in Bristol and Liverpool when they discovered that the organs of their deceased loved

¹⁵⁰ Ibid., p3.

¹⁵¹ (2003) 415 (Parl. Deb., Hansard 6th series), HC 507.

¹⁵² *The Human Tissue Bill* (Bill 9 of 2003-4). December 2003.

¹⁵³ (1960) 632 (Parl. Deb., Hansard, 5th series), HC 1232.

¹⁵⁴ Ibid., 1235.

ones had been retained without consent. The *Bristol*, *Alder Hey* and *Isaacs* inquiries demonstrated that that had taken place on a large scale. It was a tragedy for the families affected and it was unacceptable. The aim of the legislation is to ensure that it will not happen again.¹⁵⁵

As described in the Explanatory Notes which accompanied the Bill, its purpose was to provide a consistent legislative framework for issues relating to whole body donation and the storage and use (and, for deceased persons, the removal) of human organs and tissue, all activities to be underpinned by the fundamental principle of consent.¹⁵⁶ The Bill would repeal and replace the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they related to England and Wales. It would also repeal and replace the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.¹⁵⁷

3.2 Support from the National Committee relating to Organ Retention (NACOR).

NACOR was given early sight of the proposed Bill. Reportedly, it was ‘broadly speaking, delighted with the helpful, proposed legislation, ensuring that families whose loved one has to undergo a post-mortem in the future, can be assured that proper consent, backed with comprehensive information- will allow them choice and the opportunity to donate organs and/or tissues as a ‘gift’, incorporated within what will be mandatory practice.’¹⁵⁸ This response was perhaps not surprising, since the chair of NACOR, as early as the CMO’s summit, had spoken of changes needed in future practice which bore a close resemblance to those now on the face of the Bill (see 1.2.2, this Chapter). The chair of NACOR added to an official: ‘[With regard

¹⁵⁵ (2004) 416 (Parl. Deb., Hansard, 6th series), HC 984.

¹⁵⁶ Explanatory Notes: Bill 9-EN, December 3, 2003, para 4. Accessed February 3, 2010 at: <http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm>

¹⁵⁷ Ibid., para 8.

¹⁵⁸ House of Commons Library. *The Human Tissue Bill. Bill 9 of 2003-04*. Research Paper 04/04, January 9, 2004, p40, citing: NACOR: *Initial comment on the new Human Tissue Bill*. December 8, 2003.

to consent] we need black and white, and no chance of grey, so that the words ‘never again’ as stated by the CMO really do apply’.¹⁵⁹

3.3 Support at Second Reading House of Commons (HC): with three areas of concern identified.

At Second Reading, there was broad cross-party support for the proposed measures. Criticisms by MPs were largely concentrated in three areas.

3.3.1 Complex and unclear drafting.

There was (in my view) justified criticism of the way the Bill had been drafted, as exemplified by ‘the Bill is remarkably difficult to navigate, given that it is meant to lend clarity to the obscurities relating to the removal, storage and use of body parts.’¹⁶⁰; and ‘complexity is not an excuse for opacity’¹⁶¹.

3.3.2 Lack of pre-legislative scrutiny.

There were repeatedly expressed regrets (or stronger) that there had been no pre-legislative scrutiny- this theme reappeared at all stages of the passage of the Bill. The origin of this discontent lay in an adjournment debate in the House of Commons on April 29, 2003, when in response to pressure from Andrew Lansley MP that there should be early publication of a draft Bill that would allow pre-legislative scrutiny which would include public and professional input¹⁶², the then Parliamentary Under Secretary for Health, Hazel Blears MP, responded ‘I can give the Hon. Gentleman the undertaking that we hope to publish the draft Bill for Parliamentary scrutiny before the summer recess.’¹⁶³ The later recanting by Dr Stephen Ladyman MP, Parliamentary Under Secretary for Health, explaining that

¹⁵⁹ Ibid., p40, para 2.

¹⁶⁰ (2004) 416 (Parl. Deb., Hansard 6th series), HC 1038.

¹⁶¹ Ibid., 1025.

¹⁶² (2003) 404 (Parl. Deb., Hansard 6th series), HC 271.

¹⁶³ Ibid., 276.

drafting resources had been unavailable, rang rather hollow.¹⁶⁴ Revealingly, Ladyman continued 'we therefore had to make a judgment call- do we balance the need for scrutiny against the needs of the families who are demanding that we make progress? We decided that making progress was more important than publishing the Bill in draft'.¹⁶⁵

3.3.3 An adverse effect on research and education?

The third, and major, area of concern was the possibility that the Bill as drafted would adversely affect research and education. Some also warned of the dangers of 'overreaction'.^{166 167 168} At the same time, an atmosphere of suspicion of medical researchers was voiced or implied by some, and exemplified by Ms Liz Blackman MP, who, having listened to an interview on Radio 4 between the Minister and 'a member of the scientific fraternity' [the Chief Executive of the Wellcome Trust], sought and received an assurance from the Minister that during the passage of the Bill she would resist any attempt to soften the guidance and protocols in relation to the removal of tissue as well as organs, and that consent would also remain the watchword in that regard.¹⁶⁹

3.4 Subsequent passage of the Bill: themes and chronology.

3.4.1 Introduction to a 'tug of war'.

Although it was the stated intention of the Government that the Bill was intended to achieve a balance between the rights and expectations of individuals and

¹⁶⁴ (2004) 416 (Parl. Deb., Hansard 6th series), HC 1043.

¹⁶⁵ Ibid.

¹⁶⁶ (2004) 416 (Parl. Deb., Hansard 6th series), HC 1038.

¹⁶⁷ Ibid., 1013.

¹⁶⁸ Ibid., 1003.

¹⁶⁹ Ibid., 986.

families, and broader considerations¹⁷⁰, opinion was expressed both within Parliament¹⁷¹ and by outside bodies¹⁷² and commentators¹⁷³ that the Human Tissue Bill, as originally drafted, leaned too far towards the protection of individuals and families, and away from requirements that would ensure that important research could continue to be carried out. A virtual tug of war ensued, the analysis and outcome of which forms the majority of the remainder of this Chapter.

[Although subsequent sections of this Chapter will concentrate on the clinical, science, teaching and research debates, it is also relevant to note the overall scale of the changes from the original Bill which were sought by the opposition and by lobbyists. At the Committee stage in the House of Commons, 46 groups of amendments were proposed.¹⁷⁴ When the Bill returned on Report, and as a result of debate during eight sessions in Standing Committee G, the government tabled 99 new clauses and amendments, all of which were passed.¹⁷⁵ The House of Lords, after Second Reading, two days of further debate in Grand Committee, Report and Third Reading, approved a further 71 amendments.¹⁷⁶ These were passed at the final debate in the House of Commons on November 10 2004, some eleven months after the Human Tissue Bill had been first read.¹⁷⁷]

3.4.2 Structure of the Bill (as introduced).

The structure of the Bill was complex, with three parts and eight schedules.

¹⁷⁰ Explanatory Notes: Bill 9-EN, December 3, 2003, para 4. Accessed February 3, 2010 at: <http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm>

¹⁷¹ (2004) 664 (Parl. Deb., Hansard 5th series), HL 385.

¹⁷² Wellcome Trust. Press release. *Medical research under threat from new bill*. January 14, 2004.

¹⁷³ Furness P, Sullivan R. Editorial: *The human tissue bill: criminal sanctions linked to opaque legislation threaten research*. BMJ 2004; 328 (7439): 333-334.

¹⁷⁴ Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, January 27, 2004, col. 4.

¹⁷⁵ (2004) 423 (Parl. Deb., Hansard 6th series), HC 30.

¹⁷⁶ (2004) 666 (Parl. Deb., Hansard 5th series), HL 396-422.

¹⁷⁷ (2004) 426 (Parl. Deb., Hansard 6th series), HC 860-896.

Part 1 was titled 'The removal, storage and use of human organs and other tissue for scheduled purposes'. Part 2 sought to regulate activities involving human tissue through the 'The Human Tissue Authority'(HTA), a body with powers to license, inspect, regulate transplants, prohibit [commercial dealings], and issue Codes of Practice. Part 3, titled 'Miscellaneous and general', contained, *inter alia*, clauses of central importance to practitioners which dealt with: preservation for transplantation, surplus tissue, offences relating to non-consensual analysis of DNA, and purposes for which DNA may be analysed without consent.

3.4.2.1 Why was the Bill so drafted?

Knowledge of the structure and a reading of the accompanying Explanatory Notes¹⁷⁸, together with the Departmental document published in September 2003 and discussed above, give insight into the emphases that were likely to have been given to drafting Counsel.

I believe it plausible to suggest that the instructions to Parliamentary Counsel contained as the first priority the requirement to address directly the concerns and wishes of the aggrieved parents and relatives which had arisen from the detail of their experiences (as a blunt paraphrase: 'they took and kept my [daughter's heart/husband's brain] for research without asking my permission. That should be illegal and they should be punished. It must never be allowed to happen again'). This could explain the content of Part 1, which was as follows:

Clause 1. The following activities shall be lawful if done with appropriate consent: storing and subsequently using a body for 'scheduled purposes'; removing, storing and subsequently using for scheduled purposes 'relevant material' which came from the body... Clause 2. 'Appropriate consent': children. Clause 3. 'Appropriate consent': adults. Clause 4. Nominated representatives. Clause 5. Prohibition[and defined as a punishable offence] of activities without consent. Clause 6. Restriction of activities in relation to donated activities. Clause 7. Existing holdings. [Their use

¹⁷⁸ Explanatory Notes: Bill 9-EN, December 3, 2003, para 4. Accessed February 3, 2010 at: <http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm>

to be allowed for Schedule 1 purposes without consent. Note in passing: this is a clause, as with others in this section, significantly influenced by the work of the Retained Organs Commission].

The fact that the early clauses in the Bill were so formulated virtually dictated that the structure of the rest of the Bill would appear somewhat disjointed to, say, a medical reader (who might have expected that [as in the later Human Tissue (Scotland) Bill-see Chapter Five], the clauses would have been headed ‘Transplantation’, ‘Autopsies’, ‘Anatomy’ etc).

3.4.3 ‘The foundation of the Bill’.

Part 1, clause 1, was described in the Explanatory Notes as ‘the foundation of the Bill’¹⁷⁹. It linked the requirements on consent, summarised above, to the activities covered by the Act (‘scheduled purposes’) at Schedule 1. Schedule 1(1) set out eight ‘purposes normally requiring consent’, and Schedule 1(2) listed four ‘purposes not normally requiring consent’. Because the ‘purposes’ on these two lists, and their relation to the need for consent, became such a focus for debate as the Bill passed through its various stages, it is timely to set them out in detail.

Schedule 1.¹⁸⁰

Scheduled purposes.

Part 1: Purposes normally requiring consent.

1. Anatomical examination
2. Determining the cause of death
3. Education or training relating to human health, or research in connection with disorders or the functioning of the human body, (other than education or training which is incidental to medical diagnosis or treatment).

¹⁷⁹ Explanatory Notes: Bill 9-EN, December 3, 2003, para 10. Accessed February 3, 2020 at <http://www.publications.parliament.uk/pa/cm200304/cmbills/009/en/04009x--.htm>

¹⁸⁰ Human Tissue Bill. Bill 9, 2003-04. Published December 3, 2003. Accessed February 3, 2010 at: <http://www.publications.parliament.uk/pa/cm200304/cmbills/009/2004009.htm>

4. Establishing after a person's death the efficacy of any drug or other treatment administered to him.
5. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
6. Public display.
7. Research in connection with disorders or the functioning of the human body.
8. Transplantation.

Part 2: Purposes not normally requiring consent.

9. Clinical audit.
10. Education or training which is incidental to medical diagnosis or treatment.
11. Public health monitoring.
12. Quality assurance.

3.4.4 Committee Stage (HC).

3.4.4.1 Concerns of the biomedical community.

The first one and a half sessions in Standing Committee G were spent in debate on Part 1 and Schedule 1.

First, Andrew Lansley MP explained why the opposition had felt it necessary to table no fewer than 46 groups of amendments.

The range of amendments...indicate the uncertainty and lack of clarity felt about the Bill, particularly in the medical research community,... the pharmaceutical industry, clinicians and pathologists, who are concerned about the practical implications of the legislation...[A]lthough the intentions and purposes are supported, as far as I can see, their implementation is not attracting the same support across the medical and research community, so we have a job to do.¹⁸¹

[The weeks following publication of the Bill in December 2003 had seen a flurry of activity in a number of prominent medical and research bodies, as they struggled to produce their critiques and express their reservations in time to try to influence the

¹⁸¹Parl. Deb.(HC). Standing Committee G. Official Report, 2003-4, vol. VI. *Human Tissue Bill*, January 27, 2004, col. 4.

passage of the Bill. At first the responses were piecemeal. The BMA¹⁸², Royal College of Pathologists (RCPATH)¹⁸³, Royal College of Physicians(RCP)¹⁸⁴, Academy of Medical Sciences¹⁸⁵, Wellcome Trust¹⁸⁶ and other bodies had each submitted a brief and commentary on the Bill. The major concerns to emerge included: scope of the requirement for consent (including requirements in research, and in mentally incapacitated adults); possibility of presumed consent in transplantation; use of 'residual' tissue; education and training in research; the nature of 'DNA offences'; sanctions for non compliance; restriction on the commercial use of tissues; duties of coroners; composition and responsibilities of the proposed Human Tissue Authority. There was not complete agreement among the bodies, at least initially, on all points].

3.4.4.2 Unsuccessful attempts to modify Part 1, Schedule 1.

Opposition members tried to probe the meaning of 'appropriate' consent¹⁸⁷, and to insert the concept of 'generic' consent in research and education¹⁸⁸. Most important, it was proposed that Schedule 1(3): '[purposes of] education and training relating to research...' should be moved to Schedule 2, and thus not require consent.¹⁸⁹ All these proposals were rejected by Government. Dr Stephen

¹⁸² British Medical Association. *Human Tissue Bill: Second Reading, House of Commons, January 15, 2004*. December 2003.

¹⁸³ Royal College of Pathologists. *Human Tissue Bill: Second Reading briefing document, December 22, 2003*. And: *Human Tissue Bill: a question of balance*. January 2004.

¹⁸⁴ Royal College of Physicians. *Human Tissue Bill: response from the Royal College of Physicians*. January 2004.

¹⁸⁵ Academy of Medical Sciences. *Statement on the Human Tissue Bill*. January 2004.

¹⁸⁶ Wellcome Trust. *The Human Tissue Bill- Second Reading 15 January 2004: summary of main points from the Wellcome Trust*. January 2004.

¹⁸⁷ Parl. Deb.(HC). Standing Committee G. Official Report, 2003-4, vol. VI. *Human Tissue Bill*, January 27, 2004, col.5-18, esp.col. 8.

¹⁸⁸ *Ibid.*, col. 11.

¹⁸⁹ *Ibid.*, col. 59.

Ladyman MP, Parliamentary Under Secretary for Health reiterated Government policy in what came to be a memorable phrase:

If we are to have a Bill based on the firm principle that people must have consented or understood why the material was collected and what it would be used for, that principle must run through the entire legislation-as *a golden thread* (my italics) that is not broken at any point...[The] amendments would break that thread.¹⁹⁰

There was an unsuccessful attempt by the opposition to have 'epidemiological research' explicitly recognised as part of 'public health monitoring', and thus placed in Schedule 2.¹⁹¹ Dr Evan Harris made the first of several attempts to have the concept of 'presumed consent' accepted in relation to potential transplant donors.¹⁹² During a later debate about Government amendments intended to simplify issues relating to DNA analysis, Harris raised, but did not pursue, his observation that 'the ethics and law surrounding the analysis of a person's DNA for the clinical benefit of someone else have not been raised'.¹⁹³ This important area would be returned to later.

3.4.4.3 The proposed Human Tissue Authority (HTA).

The intention was clear from the CMO's Advice, and confirmed in HBHC, that there should be overarching regulatory machinery, modelled on the fundamental principles and regulatory regime of the Anatomy Act 1984 and Anatomy Act Regulations 1988.¹⁹⁴ The medical and research community accepted throughout the need for such a body. Their concerns about the HTA related to the composition of

¹⁹⁰ Ibid., col. 66.

¹⁹¹ Ibid., col. 71-3.

¹⁹² Ibid., col. 115.

¹⁹³ Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, February 5, 2004, col. 252.

¹⁹⁴ Department of Health, Department for Education and Employment, Home Office. *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*. London. The Stationery Office, 2001, op. cit., p41, Recommendation 6.

the membership, the scope of its activities and the potential scope and burden of the licensing regime. Schedule 2 of the Bill provided that:

The Secretary of State shall exercise his power to appoint members of the Authority to secure that at all times not less than half of the members are persons who do not have, and have not had, a professional interest in any of the kinds of activity within the remit of the Authority.¹⁹⁵

The medical and research bodies pressed that membership of the HTA should explicitly include persons with ‘appropriate experience in the use of human material for research’¹⁹⁶. Amendments in this vein regarding membership were proposed in Committee¹⁹⁷ (and later in House of Lords¹⁹⁸) but were resisted by the Government. As to HTA’s scope, amendments in Committee to allow limitation, restriction or exclusion of named activities from time to time¹⁹⁹ again were resisted.²⁰⁰ Probing amendments in regard to the complexity, burden, and cost of licensing, revealed government’s commitment to ‘lightness of touch’²⁰¹, ‘flexibility’²⁰² and ‘cost recovery only’²⁰³.

3.4.5 Activities during the gap between Committee stage and Report/Third Reading (HC).

The Committee stage concluded on February 5, 2004. An almost unprecedented gap of nearly five months followed before the Bill was returned to the House of

¹⁹⁵ Human Tissue Bill. Bill 9, 2003-04. Published December 3, 2003. Schedule 2(2).

¹⁹⁶ Academy of Medical Sciences. *Statement on the Human Tissue Bill*. January 2004.

¹⁹⁷ Parl. Deb.(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, February3, 2004, col. 147.

¹⁹⁸ (2004) Parl.Deb. 664 (Hansard, 5th series) HL, 493GC.

¹⁹⁹ Parl. Deb.(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, February3, 2004, col. 162.

²⁰⁰ Ibid.

²⁰¹ Ibid., 163.

²⁰² Ibid., 170.

²⁰³ Ibid., 173.

Commons for Report and Third Reading.²⁰⁴ During these months, further rounds of discussion and lobbying took place, and the Government shifted its position in several aspects, such that, a few days before the Report stage, the Wellcome Trust felt able to issue a press release headed 'Sensible balance in Human Tissue Bill' which described 'a [now] sensible balance between protecting the rights and confidentiality of patients and their families and the need to safeguard research that will provide benefits for health in the future'.²⁰⁵

Perhaps the most important confidential meeting was that held on March 9, 2004 between the Minister, her officials, and representatives of the medical and research organisations including the BMA, GMC, Wellcome Trust, MRC, and RCPATH, details of which I obtained from the Department of Health through the Freedom of Information Act (FOIA). The BMA²⁰⁶ and the GMC²⁰⁷ had originally supported the blanket requirement for consent as set out in the draft Bill, but by March 2004, they had come to lend their support to the modifications sought by the research community. These related to the proportionality and practicality of the proposals for the use of residual tissue. A memorandum to Ministers issued after the meeting recommended modification to the, until then, requirement without exception for consent for research use of tissue from living patients.²⁰⁸ The memorandum stated that 'Ministers have already agreed that an amendment should be brought to the Bill allowing the use without consent of remnant tissue samples for the purpose of all medical-related education and training. This will satisfy the stakeholders on the first point'²⁰⁹. [This decision was not public

²⁰⁴ (2004) 423 (Parl. Deb., Hansard 6th series), HC 26-104.

²⁰⁵ Wellcome Trust. Press release. *Sensible balance in Human Tissue Bill*. June 18, 2004.

²⁰⁶ British Medical Association. *Human Tissue Bill: Second Reading, House of Commons, January 15, 2004*. December 2003.

²⁰⁷ House of Commons Library. *The Human Tissue Bill. Bill 9 of 2003-04*. Research Paper 04/04, January 9, 2004, p40.

²⁰⁸ Department of Health. *Human Tissue Bill: proposed amendments for research use of tissue from living patients*. March 11, 2004. FOI DE485259. McNeish: attachment redacted. 02/03/2010.

²⁰⁹ Ibid.

knowledge in March 2004 but must have been taken after the considerations in Standing Committee had been further digested by Ministers]. With regard to research, the meeting had considered a number of options for alternative protective mechanisms so that in the case of residual tissue consent would not always be needed. The recommendation which emerged was explained to the House on June 28 2004, during Report.

3.4.6 Report/Third Reading (HC).

3.4.6.1 Agreement to research on residual tissue without consent, with safeguards.

The Minister referred to many direct representations and a media campaign to the effect that obtaining consent to use so-called residual or remnant tissue would be onerous and costly, and thereby stifle research:

We therefore propose to amend the Bill to allow research using material from living patients to go ahead without consent, but with [two] safeguards [ethical approval in accordance with regulations made by the Secretary of State; and conditions such that the researcher must not possess information as to the identity of the person from whom the tissue came]. We believe that these safeguards will maintain the essential principles of the Bill and provide appropriate controls, while allowing medical researchers the access to human tissue that they need.²¹⁰

3.4.6.2 Concerns about non consensual analysis of DNA resolved.

Geneticists had expressed two groups of concerns about non-consensual analysis of DNA²¹¹, which were responded to by Government in two stages. In Committee the Government introduced amendments which would allow appropriate DNA analysis of existing holdings of human material without committing an offence within the Act.²¹² Second, at Report, Government introduced a new clause 7 titled '*Powers of Court to dispense with need for consent*'²¹³ to meet the concerns of geneticists

²¹⁰ (2004) 423 (Parl. Deb., Hansard 6th series), HC 96.

²¹¹ Cambridge Genetics Knowledge Park and King's College Bioethics Research Centre. *Report of human tissue workshop*. King's College, Cambridge, January 20/21 2004.

²¹² Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, February 5, 2004, col. 248.

²¹³ (2004) 423 (Parl. Deb., Hansard 6th series), HC 26.

about situations- albeit infrequent ones- in which individuals were untraceable, but the analysis of their tissue samples was necessary to predict the likelihood of a relative having a genetic condition or to help to diagnose and treat a relative. Clause 46, as it then stood, would have made it an offence to analyse DNA without qualifying consent. The new clause 7 would also meet the exceptional case where the potential benefit to the health of the public of undertaking some research without consent outweighed the risk of harm to the rights of the individuals concerned.²¹⁴ [In the final stage of the Bill's passage, 'untraceable' was extended to include 'non-responding'; and instead of the need for a court order to dispense with the need for consent, a direction from the Human Tissue Authority was substituted.]²¹⁵

3.4.6.3 Education and training in research remained problematic.

Other significant modifications to the Bill were introduced at Report, following cases made in Committee. References to education and training were moved from Part 1 to Part 2 of Schedule 1 (with consequential amendments to clause 8 and schedule 5).²¹⁶ However, use of residual human tissue for education and training in research techniques, 'which is a more easily distinguished topic', would remain subject to consent.²¹⁷ Although the Minister went on to say that members of the academic, teaching and research communities had indicated that they were satisfied that this approach would allow them access to the tissue that they needed for research and education²¹⁸, this turned out not to be the case, and the issue was later debated at length in the House of Lords²¹⁹ (see below).

²¹⁴ Ibid.

²¹⁵ (2004) 426 (Parl. Deb., Hansard 6th series), HC 869.

²¹⁶ Ibid., 98

²¹⁷ Ibid.

²¹⁸ Ibid.

²¹⁹ (2004) 665 (Parl. Deb., Hansard 5th series), HL 1064-1078.

3.4.6.4 Two further amendments (a) DNA and mental incapacity b) payments by the pharmaceutical industry).

Government introduced amendments to correct the surprising omission from the draft Bill of any mention of mentally incapacitated adults. These amendments ‘bridged the gap’ between the likely date of enactment of the Human Tissue Act and the later enactment of the Mental Capacity Act²²⁰. By a new clause 8, the use of tissue and DNA taken from mentally incapacitated adults would be lawful, subject to safeguards.²²¹ An amended clause 29 was also introduced to deal with a number of concerns from the pharmaceutical industry about what could be seen as legitimate payments.²²²

3.4.6.5 Progress made, but unfinished business remained.

Andrew Lansley MP paid tribute to ‘outside bodies’, which included medical, research and family support groups, who had used opposition MPs to make points in Committee. ‘[A]lthough we put their proposals on the table before Ministers we got limited shrift. However, our persistence seems to have paid off’.²²³ Lansley finished with a caution. ‘Ministers may be tempted to assume that, given the positive reception that all the amendments considered today were given, it is the end of the story.’²²⁴ As the paragraphs below will show, the House of Lords did indeed have something more to say.

3.4.7 Second Reading, House of Lords (HL).

3.4.7.1 Further briefing from the research community.

To try to inform the Second Reading debate in the House of Lords on July 22 2004, a briefing note was prepared by the Wellcome Trust and issued in the joint names of

²²⁰ *Mental Capacity Act 2005*. (2005 c.9).

²²¹ (2004) 423 (Parl. Deb., Hansard 6th series), HC 34.

²²² *Ibid.*, 115.

²²³ *Ibid.*, 119.

²²⁴ *Ibid.*, 120.

the Academy of Medical Sciences, the Association of Medical Research Charities, Cancer Research UK, MRC and the Wellcome Trust- collectively the might of the medical research establishment.²²⁵ These bodies, while welcoming the amendments introduced at Report Stage in the House of Commons ‘which addressed the majority of our concerns that the Bill was unduly restrictive in relation to medical research’, nevertheless opined that there was still more to be done to ensure that the Bill was workable, effective, proportionate and clear, and so gain the confidence of the public (sic).²²⁶ It was a measure of the persuasiveness of the views expressed in the briefing paper, and the influence of the institutions that lay behind these views, that each point was addressed by Their Lordships in the several stages of the Bill’s passage through the Upper House.

3.4.7.2 Identification of issues requiring further resolution.

At Second Reading, Lord Turnberg, having acknowledged that the Bill had already been much improved by the efforts of Ministers and officials to listen to the scientific and medical community, asked first whether it was necessary to include tissues from living patients in the Bill. ‘After all, if one wants to do research now on such tissues, one must always have ethics committee approval, and that will be given only where consent has been, or will be, obtained from patients, or where the tissues have been anonymised’.²²⁷ His Lordship expressed [residual] fears for research and teaching, related to how ‘consent’ and ‘anonymity’ were interpreted; and questioned the wisdom of seeking to separate education and training for research from education more generally when those are treated separately and differently under Parts 1 and 2 of Schedule 1. He identified that more discussion would be needed on several aspects of DNA research; and questioned the appropriateness of the High Court as the body to be asked to make a judgment on

²²⁵ Wellcome Trust, Academy of Medical Sciences, Association of Medical Research Charities, Cancer Research UK, Medical Research Council. *Briefing note on the Human Tissue Bill: pending Second Reading in the House of Lords on 22 July 2004*. July 2004.

²²⁶ *Ibid.*, pp1-2.

²²⁷ (2004) 664 (Parl. Deb., Hansard 5th series), HL 380.

whether public interest is of such overwhelming importance as to outweigh the interests of an individual who cannot give consent.²²⁸ Concluding Second Reading, Lord Howe endorsed the need for further debate on the issues identified by Lord Turnberg. In addition, His Lordship found as very unsatisfactory the fact that the proposed new coroners' rules were not available, especially those related to organ retention, to ensure congruence with the Bill.²²⁹

In the weeks between Second Reading and Grand Committee in the House of Lords, the Wellcome Trust and its partner organisations (see above) had prepared yet another briefing paper.²³⁰ This paper suggested that the most important (to their organisations) of several issues still outstanding was the need to remove the requirement for consent from 'education and training relating to research', activities which in practice, the paper averred, would be difficult to distinguish from education and training relating to health (which by that stage in the Bill had become exempt from the need for consent).

3.4.8 Grand Committee (HL).

3.4.8.1 Continuing Government 'caution'.

In Grand Committee the issues raised at Second Reading and in the latest briefing from the Wellcome Trust were explored in detail in erudite debate²³¹, against a background in which continuing Ministerial caution was perceived. Lord Clement-Jones, early in the discussions, had 'this awful feeling that, as we go through the

²²⁸ Ibid., 381-382.

²²⁹ (2004) 664 (Parl. Deb., Hansard 5th series), HL 424.

²³⁰ Wellcome Trust, Academy of Medical Sciences, Association of Medical Research Charities, Cancer Research UK, Medical Research Council. *Briefing note on the Human Tissue Bill: pending Grand Committee in the House of Lords on 15/16 September 2004*. Undated.

²³¹ (2004) 664 (Parl. Deb., Hansard 5th series), HL GC405-464, GC465-524; (2004) 665 (Parl. Deb., Hansard 5th series), HL GC1-56.

Bill, ministerial caution...will be a real problem and a barrier to common sense and practical solutions'.²³² Lord Jenkin of Roding was very disturbed by:

[t]he reluctance of the Minister to concede anything on any of the arguments that have been advanced, notwithstanding the huge distinction of a number of Members of the Committee who really do know what they are talking about...and the virtual unanimity of the support which has existed for a number of the amendments.²³³

His Lordship warned that the Minister could find himself with amendments carried against Government on Report. That indeed turned out to be the case.

3.4.9 Report (HL).

3.4.9.1 Use of tissue for education in research techniques.

Baroness Neuberger proposed an amendment to permit the use of tissue without consent for the purposes of education in research techniques, if the tissue had come from a living person and had been anonymised.²³⁴ Seven of Their Lordships made speeches in support. As Lord Turnberg put it 'the distinction between research and training for research is much clearer than that between training for research and training for professional purposes'.²³⁵ In a lengthy reply for the Government, Lord Warner forcibly restated the 'golden thread' argument about the importance of consent throughout the clauses of the Bill, and concluded by saying 'the Government are unable to accept the amendments, would not be able to accept them in future and would need to seek to reverse them at a later stage if they were passed today'.²³⁶ Notwithstanding this powerful rebuff, Baroness Neuberger pressed her amendment to a vote, and it was carried by 148 to 112.²³⁷

²³² (2004) 664 (Parl. Deb., Hansard 5th series), HL GC422.

²³³ Ibid., GC427-428.

²³⁴ (2004) 665 (Parl. Deb., Hansard 5th series), HL 1064.

²³⁵ Ibid., 1068-9.

²³⁶ Ibid., 1077.

²³⁷ Ibid., 1078.

Nine days later, at Third Reading in the House of Lords on November 3, 2004, Lord Warner proposed Government amendments to replace Baroness Neuberger's at the Report stage. This represented a considerable Government *volte face*.

I am therefore now introducing amendments to remove those passed on 25 October and replace them with government amendments to achieve a similar but, I hope, more consistent and clear effect... we propose to include all education and training in Part 2 of the schedule...research training is simply re-absorbed into the general category of education or training relating to human health.²³⁸

In welcoming these amendments, Earl Howe was delighted that 'perhaps the single largest point of contention that we were faced with when the Bill arrived in this House' had been so satisfactorily resolved.²³⁹ Lord Jenkin of Roding added that 'this is a justification for the very long processes that we use in Parliament to put new legislation on to the statute book.'²⁴⁰ And so it was that, by subsuming education and training in research within education and training in human health, the concerns of academe were met without Government having to juxtapose the word 'research' with 'no consent needed'.

3.4.10 Third Reading (HL)

3.4.10.1 Further amendments resisted.

Further groups of amendments were resisted by government which could be thought of as 'unfinished business' from a list of academically voiced concerns. Of particular interest within the context of this Thesis was an amendment which would have made it permissible in certain identified cases for small pieces of tissue to be retained without consent after a coroner's post-mortem, to allow for possible forensic re-examination in the future.²⁴¹ Lord Warner, for the Government, put the objection as follows:

²³⁸ (2004) 666 (Parl. Deb., Hansard 5th series), HL 397.

²³⁹ Ibid., 398.

²⁴⁰ Ibid.

²⁴¹ Ibid., 406.

[The amendment] wholly undermines the fundamental principle on which the Bill is based...individuals, or those who were close to a person who has died, should have the right to determine the uses to which bodily material is put....We cannot risk recreating [the circumstances that gave rise to the need for the legislation in the first place].²⁴²

That decision would turn out to be at variance with the provisions of the Human Tissue (Scotland) Act 2006. I shall return to this issue in Chapter Five.

3.4.11 The last lap.

On November 10 2004 the Bill, accompanied by 71 amendments from the House of Lords, returned to the House of Commons for the last time.²⁴³ All were accepted- the last amendments in a lengthy and hard fought process which had sought to find 'an acceptable balance between the rights and expectations of individuals and families and broader considerations, such as the importance of research, education, training, pathology and public health surveillance of the population as a whole'²⁴⁴.

Five days later, on November 15 2004 the Human Tissue Act 2004 received Royal Assent²⁴⁵ and came fully into force on September 1 2006, drawing to a close 'five tumultuous years of negotiation'²⁴⁶.

3.5 Commentaries on the 2004 Act.

The immediate response in the medical press was in general one of relief, but with riders attached. The headline in the *Lancet* editorial was 'Effective implementation of the Human Tissue Act'²⁴⁷ while the *BMJ*, in a signed editorial by Furness, (a distinguished pathologist and later to be President of RCPATH), carried the sub-title

²⁴² Ibid., 409.

²⁴³ (2004) 426 (Parl. Deb., Hansard, 6th series), HC 860-896.

²⁴⁴ Department of Health, NHS Department of the Welsh Assembly Government. *Human bodies, human choices: the law on human organs and tissue in England and Wales- a consultation report*. July 1, 2002.

²⁴⁵ *Human Tissue Act 2004*. (2004, c.30.)

²⁴⁶ Editorial. *Effective implementation of the Human Tissue Act*. *Lancet* 2006; 368(9739):891.

²⁴⁷ Ibid.

‘reassurance for relatives, at a price’²⁴⁸. The *Lancet* described what had emerged after a difficult negotiation process as a piece of legislation that grappled with fundamental questions about the ethical use of human samples in biological research- issues which would grow with the increasing popularity of large scale, long-term genetic epidemiology studies , including a proliferating number of biobanks. It was to be hoped that more light would be shed on wider debates as the specifics of the Act were ‘hammered out’ by Research Ethics Committees(RECs).²⁴⁹ Furness also pointed to the crucial role of RECs, which, he said, now had a statutory duty to decide ‘not just whether research without consent was unethical, but whether or not it was illegal’. The ‘price’ of the new legislation included controls on tissue from the living which ‘had not been demanded by any public outcry’ and which were absent from Scottish legislation.²⁵⁰ Furness described fears among professionals of the risk of criminal sanctions, which had already induced defensive practices that were not in the best interests of patients.²⁵¹

Other commentators had their own views.

Price did not approve of the ‘substantial concessions’ made to the Bill at Report stage which ‘unnecessarily’ diluted the ‘philosophical coherence’ of the legislation.²⁵² According to his account, the medical and scientific community had ‘alleged’ that vital research would be compromised (he cited in support three newspaper headlines²⁵³ and made no reference to any briefing papers having been produced by the clinical scientists to support their concerns). Price made an

²⁴⁸ Furness P. Editorial. *The Human Tissue Act: reassurance for relatives, at a price*. BMJ 2006; 333(7567): 512.

²⁴⁹ Editorial. *Effective implementation of the Human Tissue Act*. Lancet 2006; 368(9739):891.

²⁵⁰ *Human Tissue (Scotland) Act 2006*. (2006, asp 4.)

²⁵¹ Furness P. Editorial. *The Human Tissue Act: reassurance for relatives, at a price*. BMJ 2006; 333(7567): 512.

²⁵² Price D. *The Human Tissue Act 2004*. MLR 2005; 68(5): 798-821, p800.

²⁵³ Ibid, p800, footnote 16.

allegation of his own, that Government had undoubtedly been very exercised by the prospect of researchers being tempted abroad if human tissue use was 'over-regulated' in the UK.²⁵⁴ As a result, he opined, the interests of the living became subjugated in the debate, with matters of principle being partially (and 'needlessly') compromised for utilitarian ends. 'These dilutions of the requirement for consent beg fundamental questions as to robustness of the central principle of consent in the Act'.²⁵⁵

Bell also expressed concern that the 'fundamental principle' of informed consent had been surrendered in the 2004 Act, but his arguments centred on transplantation and on an *absence* of successful amendments to the Bill.²⁵⁶ Bell's concerns related to s.43 of the 2004 Act which made it lawful for hospital authorities to take steps 'for the purpose of preserving the part for use for transplantation and to retain the body for that purpose'.²⁵⁷ The practical technique in question was 'cold perfusion', whereby an organ, say a kidney, could be perfused with cooling fluid through a cannula inserted immediately after death in an attempt to maintain the organ as 'viable' for transplantation while efforts were made to obtain consent to the organ being removed. Bell argued that acceptance of cold perfusion was but a step towards 'presumed consent'. His points had been explored through probing amendments at Committee stage in the House of Commons which were resisted by Government.²⁵⁸

Bell viewed the entire legislation as 'inevitably' a complex balance between respect for the individual and broader societal benefit. Liddell and Hall considered the matter in depth within their scholarly assessment of the policy which underpinned

²⁵⁴ *Ibid.*, p819.

²⁵⁵ *Ibid.*

²⁵⁶ Bell MDD. *The UK Human Tissue Act and consent: surrendering a fundamental principle to transplantation needs?* J Med Ethics 2006; 32: 283-286.

²⁵⁷ *Human Tissue Act 2004*, s.43(1)(a)(b).

²⁵⁸ Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, February 5, 2004, col. 235-241.

the 2004 Act.²⁵⁹ These authors' starting point was a belief that, on legally controversial issues, legal policy should be based on 'norms which represent an intersection amongst competing ethical positions ['an overlapping consensus']'.²⁶⁰ They examined the amendments that were made during the Bill's passage, described earlier in this Chapter, as a struggle for an 'appropriate' balance which had led to some striking shifts in the government's legislative goals as well as some entrenched limits.²⁶¹ Their conclusions were that, because an overlapping consensus emerges only 'through sustained deliberation with a heightened sense of moral reciprocity', the outcome (the 2004 Act) could be considered as a significant but incomplete success towards achieving such a consensus.

In more detail, Liddell and Hall found that the government, by tending to proselytize a strict view that to use tissue without consent fundamentally disrespected a person and, by fiercely justifying its proposal on these grounds, failed to offer reasons which would reasonably persuade those who argued that the opinion of the immediate physical donor should not be privileged substantially beyond third persons in need or the public system of health and welfare.²⁶² However, in these authors' view, the new legislation could be considered as a thorough attempt to tailor a law that all citizens could concede was reasonable, even though it did not wholly comport with their particular moral beliefs.²⁶³

A similar position was reached by Lord Jenkin of Roding, perhaps through a less academic route. During the Grand Committee stage, His Lordship had been disturbed by 'the reluctance of the Minister to concede anything on any of the arguments that have been advanced, notwithstanding the huge distinction of a number of Members of the Committee who really do know what they are talking

²⁵⁹ Liddell K, Hall A. *Beyond Bristol and Alder hey: the future regulation of human tissue*. Med L Rev 2005; 13(2): 170 -223.

²⁶⁰ Ibid., p173.

²⁶¹ Ibid.

²⁶² Ibid., p177.

²⁶³ Ibid., p180.

about²⁶⁴. Later, at Third Reading, and after Government had made a major concession following defeat on an important amendment that ‘education on research techniques need not require prior consent’ [discussed earlier], the same Lord Jenkin of Roding added that ‘this is a justification for the very long processes that we use in Parliament to put new legislation on to the statute book.’²⁶⁵ By my reading, the Government had held out, almost to the last, to ‘the golden thread’ argument (‘fierce justification’ in Liddell and Hall’s terms) and were defeated (not ‘persuaded’) by a powerful lobby led by the Wellcome Trust and championed by Baroness Neuberger, as part of Lord Jenkin’s ‘very long processes’.

Other commentators commented on the scope of the Act. Brazier and Fovargue considered whether the Act might have sought to do too much. By incorporating the storage, use and removal of the body and its parts from the living and the dead, and addressing transplantation in one Act, it was possible that insufficient attention had been paid to the particular issues raised by these individual practices and procedures.²⁶⁶ At the same time, these authors opined that an addition to the legislation, namely a presumed consent system for organ donation, could [with advantage] have been considered.²⁶⁷

McHale joined Price and Bell in seeing danger in that the amendments made during the legitimisation process may have swung too far from respect for individual autonomy and towards respect for the researcher.²⁶⁸ Further, McHale regretted the ‘lost opportunity’ to have considered a regulatory system for ‘the commercialization of tissue, intellectual property rights, genetic testing,

²⁶⁴ (2004) 664 (Parl. Deb., Hansard 5th series), HL GC 427-428.

²⁶⁵ (2004) 666 (Parl. Deb., Hansard 5th series), HL 397.

²⁶⁶ Brazier M, Fovargue S. *A brief guide to the Human Tissue Act 2004*. Clinical Ethics 2006; 1: 26-32, at p31.

²⁶⁷ Ibid.

²⁶⁸ McHale J. *The Human Tissue Act 2004: innovative legislation-fundamentally flawed or missed opportunity?* Liverpool Law Review 2005; 26: 169-188, at p186.

confidentiality and privacy'²⁶⁹, citing a recommendation of Kennedy and colleagues in the *Bristol Interim Report*²⁷⁰.

3.6 Conclusion.

I have tried to show that the 2004 Act was the result of a complex legislative process in which, during the phases of 'inspiration', 'deliberation', 'formulation' and 'legitimation', the effects of past history, the climate of the time, and the differential influence of certain institutions and individuals could be seen in complex interplay. The outcome, in respect of clinical science, education and research, was less of 'an overlapping consensus' reached through 'sustained deliberation with a heightened sense of moral reciprocity', than a 'score-draw' after a fiercely fought contest. It is understandable that the Minister wished to conclude with multiple handshakes:

We wanted the Bill to be based on consent, not least because of the very tragic events at the Alder Hey and Bristol hospitals...We also wanted to convince the research and medical community that we were not trying to stifle some of the excellent work being done. I believe that the Bill achieves all that now... it will give the medical and research community confidence that it is operating in an environment that they understand, and one that they know that others understand as well. Our task has been to get the balance right between those two very important principles. I think that the Bill achieves that.²⁷¹

Could matters have been handled better? That question will be considered in Chapter Six. Could matters have been handled differently? The answer lies in Scotland.

²⁶⁹ Ibid., p187.

²⁷⁰ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*, May 2000, op.cit., p40, para 129.

²⁷¹ (2004) 426 (Parl. Deb., Hansard, 6th series), HC 896.

CHAPTER FIVE

Tissue legislation in Scotland: ‘a more proportionate response’¹?

On March 16 2006, the Human Tissue (Scotland) Act 2006 (‘2006 Act’) received Royal Assent.² The purpose of this chapter is to explore why, with factors operative in the ‘inspiration’ phase of the 2006 Act apparently similar to those which preceded the Human Tissue Act 2004 (‘2004 Act’), the deliberation, formulation and legitimisation phases were so different in tone and content.

1. Background.

News of Professor Anderson’s revelations in September 1999 about widespread ‘holdings’ of hearts retained at PM in England and Wales, and the trenchant criticisms in the *Bristol* Interim Report which followed, of course reached Scotland. The press became engaged³, and public concern grew in relation to six hospitals in particular: The Royal Hospital for Sick Children, Glasgow (‘Yorkhill’); Royal Hospital for Sick Children, Edinburgh; Southern General Hospital, Glasgow; Aberdeen Royal Infirmary; Stirling Royal Infirmary; Crosshouse Hospital, Kilmarnock.⁴ By early December 1999, Yorkhill Hospital’s medical director admitted that the hospital may have failed to explain fully that individual organs might have been removed during PM examinations.⁵

2 Response of Scottish Executive.

2.1 Independent Review Group on Organ Retention (‘IRG’; ‘the Group’).

¹ Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-203, p202.

² *Human Tissue (Scotland) Act 2006*. (2006 asp 4.)

³ For example: *Daily Record News: Baby’s heart buried nine years late*. June 20, 2000; Sunday Mail, News. *Catalogue of shame at Yorkhill*. September 3, 2000.

⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001. Appendix 2 (‘The Preliminary Report of February 2001’), 3.1(26), p82.

⁵ BBC News. *Hospital in organs admission*. December 6, 1999. Accessed on April 27 2010 at <http://news.bbc.co.uk/1/hi/scotland/552678/stm>.

By August 2000 parents at Yorkhill began to press the Scottish Executive to hold a public inquiry into organ retention.⁶ On September 22, 2000, the Minister for Health and Community Care, Ms Susan Deacon MSP, announced the setting up of an independent review group, to be chaired by the legal academic, Professor Sheila McLean.⁷

The Independent Review Group on Organ Retention had as its formal remit:

[t]o review previous post-mortem practice in Scotland, in particular in relation to organ retention, and current documentation on consent and guidance, taking account of developments across the UK; to develop a Code of Practice for Scotland with particular emphasis on issues of informed consent and the most effective mechanism for keeping that Code of Practice under review; and to clarify current legal issues with a view to making recommendations.⁸

The membership of the Review Group was designed to reflect a range of expertise and incorporated medical professionals, experts in legal and ethical issues, and parents. The independence of the Group 'was maintained through its predominantly non-NHS membership'.⁹

2.1.1 The work of IRG: crucial to 'inspiration', 'deliberation' and 'formulation'.

Understanding IRG's work in some detail may help to explain why its Reports were formally acknowledged to have been influential in determining the eventual form and content of the 2006 Act.¹⁰

⁶ BBC News. *Parents call for organs inquiry*. August 25, 2000. Accessed on April 27 2010 at <http://news.bbc.co.uk/1/hi/scotland/895250/stm>.

⁷ BBC News. *Organ retention policy review*. September 22, 2000. Accessed on April 27 2010 at <http://news.bbc.co.uk/1/hi/scotland/937117/stm>.

⁸ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 4.3(32), p84.

⁹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p4, para 1.

¹⁰ Scottish Parliament. *Human Tissue (Scotland) Bill: Policy Memorandum*. June 3, 2005, p 9, para 39. Accessed June 2, 2010 at: <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-introd-en.pdf>

IRG's worked in two main phases, together with a later Phase 3 which audited progress in implementing certain of the recommendations made in the Preliminary Report¹¹. Phase 1 was essentially an inquiry into past practices, and led to a 'Preliminary Report', with recommendations, on February 6, 2001.¹² The 'Final Report', the culmination of Phase 2, reviewed the existing law and made recommendations, and was published in November 2001. IRG adopted a methodology that, it was pledged, would be characterised by 'complete openness and transparency'. In keeping with this commitment, the IRG website was constructed in a user-friendly manner which allowed ready access to the public, and the present researcher, of all proceedings, discussions and background papers.¹³

2.1.1.1 Phase 1: methodology and findings.

IRG gathered information concerning past PM procedures using four main mechanisms. First, written evidence was sought from around 150 organisations and individuals-the latter because of particular expertise in aspects of medicine, law and ethics. In addition, all primary care and acute NHS trusts in Scotland were contacted and asked to provide detailed information relating to numbers of organs retained, and past and present consent procedures. Second, advertisements were placed in the press (believed on advice to ensure coverage of approximately 75% of the population) inviting members of the public to share their views and experiences with the Group. In order to facilitate responses, a 'relatives' questionnaire' was also drawn up for those who wished to use it. Where the express permission of the individuals concerned was granted, letters, emails and completed questionnaires were made available on the IRG website and from the Secretariat. Third, oral evidence was heard during 23 oral sessions from a total of 59 individuals representing bereaved individuals and parent support groups, hospital trusts,

¹¹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Phase 3.* November 2003.

¹² Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Preliminary Report.* February 2001.

¹³ Review Group on Retention of Organs at Post-Mortem. Home page. Accessed on June 2, 2010 at: <http://www.sehd.scot.nhs.uk/scotorgrev/>

representatives of the Crown Office and Procurator Fiscal Service, the British Medical Association, the Royal College of Nursing, Strathclyde Police, pathologists, paediatricians, neuropathologists, autopsy technicians, funeral service providers, and those involved in considering or carrying out research which involved use of retained organs. Transcriptions were made available to the public. Fourth, visits were made to a number of hospitals where it was known that organs had been retained.¹⁴

The findings of IRG in respect of organ and tissue retention at post-mortem and of a relative absence of 'informed' consent were, not surprisingly, similar in kind if not in scale to the position in England and Wales already described in Chapter Four: considerable distress had been caused to relatives, aggravated by the difficulties associated with trying to find out whether any organs continued to be retained and the fate of those organs; there had been mistakes in recording of information in hospitals, and a lack of effective communication.¹⁵ [The inquiry of Trusts throughout Scotland 'in the short time available' had revealed that a total of 5960 organs were being retained at that time. Most were hearts or brains, and there was 'absolutely no evidence' of any cases of retention of a body's entire set of organs.¹⁶ An independent audit, recommended by IRG and later undertaken on the instructions of the Auditor General for Scotland, revealed that the accurate figure was 10862- the discrepancies being explained mainly by more accurate counting and the addition of museum specimens.¹⁷]

Although IRG found no evidence of the 'shocking practices' discovered at Alder Hey, there was no doubt in its collective mind that past practice in Scotland had led to a

¹⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), 5.1-5.3 (37-42), pp 85-86, op.cit.

¹⁵ Ibid., 1 (1), p75.

¹⁶ Ibid., 8.3 (64), p 93.

¹⁷ Auditor General for Scotland. *Organ retention validation review: a report to the Scottish Parliament*. Audit Scotland, March 2002. Exhibit 5, p8.

significant breakdown in trust between relatives and the medical profession.¹⁸ It had been clear from early in IRG's inquiries that 'the fundamental issue of concern' about hospital post-mortems (HPMs) related to consent.¹⁹ There was a related need for relatives to be properly informed as to whether a post mortem was being instructed by the Procurator Fiscal or being requested by the hospital itself.²⁰ Although consent of relatives was not required for Fiscal post-mortems (FPMs), IRG found that past practice in relation to those PMs had been 'seriously deficient' in a number of respects. The majority of representations to the Group had related to alleged failures of the Fiscal service in the past to provide information and listen to concerns from parents.²¹

2.1.1.2 Phase 1: recommendations.

IRG came to a shared view that PM examination should properly be regarded as an integral part of patient care which continued after death. It followed that the conduct of PMs was an issue of clinical governance with ultimate responsibility for the process resting with the chief executive of the relevant NHS Trust.²² This conclusion, which may have been influenced by those in the Review Group with practical involvement with organ transplantation, would come to have far reaching consequences within the subsequent legislative process.

The Preliminary Report made 18 recommendations, mainly about HPMs, which were intended to ensure that the role of relatives, particularly parents, in the PM process was recognised and respected.²³ The emphasis throughout was on specific consent (which could be withdrawn) for each stage or procedure. Full information

¹⁸ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report.* November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 1(4), p75.

¹⁹ Ibid., 1(5), pp75-76.

²⁰ Ibid.

²¹ Ibid., 8.2(56), p91.

²² Ibid., 1(17), p78.

²³ Ibid., 2(23 – 25), pp 80-82.

should be provided by a senior member of the medical staff or another appropriate person at every stage for those who wanted it, but those who did not want information should not have it forced on them.

A time limit of 5 years was recommended on retention of organs then currently retained, to ensure that families had sufficient time to consider their choices. During that period, relatives should have every opportunity to reclaim organs or tissue blocks/slides, if they so wished, and their entitlement to do so should be made clear by a wide variety of methods including sensitive advertising, public information notices on television, use of GP surgeries, libraries and other means. Under no circumstances should relatives be approached by the hospital regarding the current retention or disposal of organs about which they will have no knowledge. Relatives should be given every opportunity to inquire, but the wishes of those who do not wish to know must be respected.

Remarkably, in May 2001 IRG received a communication from representatives of the major parent support groups, expressing their concern that the recommended 5 year moratorium on the use of unclaimed organs and tissue might result in valuable research being unable to proceed during that time, with potentially harmful consequences for families and individuals.²⁴ As a consequence, IRG modified their recommendation, such that, as part of the continuing campaign to inform relatives of their rights in this respect, it should be made clear that research which was non-destructive (defined as observational, or through taking only minute pieces of tissue) and important (defined as likely to contribute to understanding of diagnosis or therapy) may be carried out on currently retained tissue after a period of one year (later revised, after consultation, to six months²⁵) from the start of the 5-year period.²⁶

²⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report.* November 2001, op. cit., p24, para 47.

²⁵ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Phase 3.* November 2003, p13, para 22.

²⁶ *Ibid.*, p25, para 48.

In accordance with its remit, IRG produced a Code of Practice for Hospital Post-Mortems, accompanied by template consent forms and information leaflets for use throughout Scotland.²⁷ Of crucial importance, IRG recommended that the Clinical Standards Board for Scotland should be encouraged to incorporate a standard relating to the PM process in their generic standards as the most effective way of monitoring implementation of the Code of Practice for HPMs.²⁸

IRG's recommendations concerning HPMs were addressed to the Minister of Health and Community Care. In addition, the Group made recommendations regarding FPMs for the Lord Advocate to consider²⁹ which arose from their firm view that FPMs must be dealt with in as sensitive a manner as were HPMs.³⁰ Issues identified included the need for relatives to be informed (as fully as the Fiscal's justiciary role would allow) about the nature and purpose of a FPM by staff trained to undertake sensitive discussions. Steps should be taken to close the then present communication gap between the Fiscal, pathologist and relatives at the point where the Fiscal had decided that organs retained were no longer required for his purposes.³¹

2.1.1.3 The early response of the Scottish Executive.

Shortly before the Preliminary Report was published, IRG held a public meeting in Glasgow on January 25, 2001. The Minister for Health and Community Care was not present, which provoked adverse criticism from the audience. The next day the Minister gave public assurances that the removal of organs without consent was a practice that had no place in any hospital in Scotland or elsewhere, and that new procedures were already in place which required a family's permission if any

²⁷ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report.* November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 9.1 (78-85), pp 97-102; and Appendices 5 and 6.

²⁸ Ibid., 2 (25q).p 82.

²⁹ Ibid., 9.2 (86-92) pp 102-104.

³⁰ Ibid., 1 (13), p77.

³¹ Ibid., 9.2 (87, 90) pp 102-103.

organs were to be retained. 'I want everyone- families and clinicians- to be in no doubt that this process must be followed'.³² On publication of the Preliminary Report, the Scottish Executive gave a commitment to implement all its recommendations.^{33 34} In the Scottish Parliament two days later, the Minister of Health and Community Care said, in response to a question, 'we are now taking forward a significant programme of measures to improve communication and consent procedures and to change the culture'. The Minister added, perhaps somewhat prematurely, 'we are backing that with major changes to the law'.³⁵

2.1.1.4 Phase 2: method of working.

Phase 2 entailed considering current legal provisions and making detailed recommendations for change. IRG's method of working was to identify the issues that needed to be addressed, picking up on the concerns expressed by families and health professionals about the current legal framework. Each of these topics formed the subject of a position paper written by the member or members of the Group with the greatest expertise in that subject. Each paper reviewed the state of the law in relation to that issue and outlined any ambiguities or deficiencies, as well as offering proposals for legislative change where appropriate. Once IRG's recommendations had been clarified, a meeting was held on October 15, 2001 with parents' support groups to explain to them the way in which its thinking had been evolving and to test the degree to which it satisfied the need to be sure that there

³² *The Herald (Glasgow)*. Deacon's new pledge over organs: Health Minister promises that parents must give their consent. January 29, 2001, (by-line David Steele), p8.

³³ The Scottish Government. Press release. *Deacon signals major improvement in NHS communication and consent: organ retention group recommendations to strengthen families' rights*. February 6, 2001. Accessed July 5, 2010 at: <http://www.scotland.gov.uk/News/Releases/2001/02/bf1f06be-89f1-4046-8372-5cb0dad18a16>

³⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p6, para 1.

³⁵ Scottish Parliament. *Official Report*. February 8, 2001, col. 1124.

could be no recurrence of past practice. Those who attended the meeting appeared to be satisfied with the thinking outlined.³⁶

2.1.1.5 Recommendations in 'Final Report' of Phase 2.

2.1.1.5.1 New legislation needed for Scotland.

Because the Human Tissue Act 1961 had not been listed in Schedule 5 to the Scotland Act³⁷, and therefore was not reserved to the Westminster Parliament, the Scottish Parliament had the competence to amend the Act as it applied to Scotland. Taking advantage of that situation IRG made as its first recommendation:

Given the problems both of style and of content in the Human Tissue Act 1961, the Review Group strongly recommends that it should be replaced by new legislation taking full account of our recommendations.³⁸

[It was noted that some issues, such as regulation of the health professions, data protection and genetics, were reserved to Westminster; and that the Review Group had taken this into account in shaping its recommendations.³⁹]

2.1.1.5.2 Authorisation.

The major recommendations concentrated on the law as it related to hospital post-mortem examinations, and centred on the need for 'authorisation', coupled to the imposition of a legal penalty for failure to obtain authorisation or to depart subsequently from the terms of any authorisation given⁴⁰. The concept of 'authorisation' had been developed and strongly preferred by IRG to 'consent' during its discussions, and the Final Report emphasised that '[w]e are firmly

³⁶ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p5, para 5.

³⁷ *Scotland Act 1998*. (1998, c. 46.) Schedule 5: Reserved matters.

³⁸ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p14, para 27.

³⁹ Ibid.

⁴⁰ Ibid., p22, para 32.

committed to its use'.⁴¹ The reasoning of IRG proceeded in several stages, and began with consideration of the position of the infant or young child. First, it was noted that the authority granted to parents by the common law of consent was confined to decisions which were in the 'best interests' of their child.⁴² IRG found it 'understandably difficult' to use the notion of 'best interests' in the context of the deceased. IRG recognised but ultimately rejected the argument that, since the post-mortem examination of a child may be in the best interests of surviving or future family members, and since the interests of many others may be enhanced by accurate diagnosis, sound medical research and the proper education and training of doctors, the deceased child as a member of the family concerned, or simply of the 'human family', had a continuing interest (albeit not an experienced one) in these benefits of his or her brief life and untimely death accruing to others.⁴³ But this interpretation of interests, while possible, was also contestable. In the view of IRG, it expanded the concept too broadly to be safely used in the context of any attempt to develop the common law understanding of parental consent, which interpreted 'best interests' in terms of benefit accruing to the child himself or herself.⁴⁴

IRG explored other possible routes to explain the legitimacy of the role of parents 'clearly and unequivocally'. It rejected a property-based model, holding the view that- irrespective of whether or not a deceased person remained a person for legal purposes- it would be 'inappropriate' to use the language of property about what had once been a person.⁴⁵ IRG next explored 'possession'. Although this was a term familiar in law (and could be found in the Human Tissue Act 1961 (in which a person could be 'in lawful possession of the body')), IRG believed the concept of

⁴¹ Ibid., p16, para 3.

⁴² *Children Act 1989*. (1989, c.42). s1(3); See also *Re C (a minor) (wardship: medical treatment)* [1989] 2 All ER 782.

⁴³ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p29, para 11.

⁴⁴ Ibid.

⁴⁵ Ibid., p30, para 13.

possession to be 'inadequate to clarify and reinforce the very real interests' that parents had in their children, even after their death.⁴⁶

IRG was in much greater accord with an analysis of the family unit which drew in particular on the obligations and powers which flowed from the concept of parenting itself, quoting Page:

parenthood is seen as having a special value *in itself* and not simply as a means to the care and protection of children and the continuation of the human race. This special value attaching to parenthood constitutes the ultimate foundation of parental rights⁴⁷;

and Schoeman:

[t]he relationship between parent and infant involves an awareness of a kind of union between people which is perhaps more suitably described in poetic-spiritual language than in analytical terminology. We *share ourselves* with those with whom we are intimate...this makes for non-abstract moral relationships in which talk about rights of others, respect for others, or even welfare of others, is to a certain extent irrelevant.⁴⁸

IRG opined that if parental decision making in respect of a deceased child could be thought of as deriving from the value of parenting, then it could be logically distanced from the constraints which arose from the legal concept of parental consent, most notably the requirement to act in the best interests of the child. By viewing the relationship between parent and child in this way, rather than simply as an amalgam of legal rights, obligations and interests, the parental role was placed in the right context.⁴⁹ Further, recognition of the intimate bond between parent and child, and the privacy of the family unit (as espoused within Article 8 of the Human Rights Act 1998⁵⁰ reinforced the priority of parental decision- making even

⁴⁶ Ibid., p30, para 14.

⁴⁷ Page E. *Parental rights*. Journal of Applied Philosophy (1984); 1(2): 187-203 at p196.

⁴⁸ Schoeman F. *Rights of children, rights of parents, and the moral basis of the family*. Ethics 1980; 91(1): 6-19 at p8.

⁴⁹ Ibid., p 30-31, para 15.

⁵⁰ *Human Rights Act 1998* (1998,c.42), Schedule 1. Part 1. Article 8.

after death.⁵¹ IRG concluded that the use of the word ‘authorisation’ rather than ‘consent’ strengthened the role of parents in decision-making and clarified the scope of their (legally valid) decision-making powers. ‘Authorisation’ also met the concerns of parents who did not wish to receive information about post-mortem examinations and/or the subsequent removal and retention of organs and tissue, but who did not object to these practices, because ‘authorisation’ was not constrained by the requirement to have prior provision of, in this case unwanted, information.⁵²

IRG further recommended that amendments to the law were needed to make clear that parents should have ultimate authority to authorise or refuse retention and use of organs and tissues, the underlying principles being identical to those of authorisation for a post-mortem examination itself. Information about the examination given at the stage of seeking authorisation must give clear understanding that a properly conducted post-mortem *will require* (IRG’s emphasis) removal and retention of certain parts for 4 to 6 weeks. This should lead to discussion about a range of possible funeral arrangements.⁵³ If parents did not wish to be given information, and refused to authorise a post-mortem, this must be respected. If they did not wish to be given information, but nevertheless did authorise retention and use, IRG recommended that such organs and tissue may be retained and used for legitimate education and research.⁵⁴

With regard to post-mortem examination, including retention and use, of a ‘mature child’ (recognised in Scots law to be legally competent to enter any transaction when aged 16y⁵⁵ and to have certain specific legal capacities from the age of 12y⁵⁶)

⁵¹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p31, para 16.

⁵² Ibid., p31, para 17.

⁵³ Ibid., p20, para 22.

⁵⁴ Ibid., pp 20-21, paras 24-25.

⁵⁵ *The Age of Legal Capacity (Scotland) Act 1991*. (1991, c.50), s1(1)(b).

⁵⁶ Ibid., s2(2), s2(3).

or an adult, IRG recommended that prior written instructions should be respected, irrespective of the views of relatives. The proposed new legislation should also recognise the validity of verbally expressed wishes in the presence of two witnesses at any stage in life (provided this had not been subsequently retracted). Where there had been no prior express wish, authorisation should be sought from the most senior available in a hierarchy (to be developed) of relatives and 'those with the closest relationship to the deceased person'.⁵⁷

2.1.1.5.3 Tissue blocks and slides.

IRG dealt separately with issues concerning tissue blocks and slides. The Group had previously opined that tissue blocks and slides may induce a different 'personal' response as compared with organs.⁵⁸ In addition, it was emphasised that the revised information leaflet and forms for authorisation which were already being introduced throughout Scotland, as recommended in the Preliminary Report⁵⁹, had made it no longer possible to retain blocks and slides without authorisation.⁶⁰ This view led IRG to an important recommendation: that provision of authorisation to conduct a post-mortem would, unless expressly refused by those with the authority to provide it, necessarily include agreement to the preparation of blocks and slides; and that interest in these prepared blocks and slides should pass to the hospital authority who may retain and use them as part of the hospital record, or for legitimate education and research.⁶¹ [This recommendation was in accord with the conclusions elsewhere of the Nuffield Council on Bioethics.⁶²]

⁵⁷ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., pp21-22, paras 29-31.

⁵⁸ Ibid., p47, para 63.

⁵⁹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 9.1(84), p 101, and Appendices 5 and 6.

⁶⁰ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p47, para 65.

⁶¹ Ibid., p50, para 74.

⁶² Nuffield Council on Bioethics. *Human tissue: ethical and legal issues*. London. April 1995, p 126, para 13.12.

2.1.1.5.4 Medical education and research.

IRG made several important recommendations about medical education and research (the value of which had been supported by all parent groups in their evidence⁶³). First, the form authorising a hospital post-mortem should state clearly that any authorisation for research use may be either specific or general, and that a later change of mind would be respected. Information about research uses should be freely and publically available. Second, the Group noted that in some circumstances non-invasive research may be conducted on retained slides in order to improve diagnosis, and cited with approval a specific example of then recent research on retained slides of lung tissue from ‘cot death’ infants.⁶⁴ ‘Such non-structured research does not require ethics committee approval, and we do not recommend that it should.’⁶⁵ This advice would lead later to significant differences between the law in England and Wales, and Scotland, with regard to Sudden Infant Death Syndrome (SIDS), and is discussed further below. Next, IRG recognised in principle that financial issues could arise regarding the use of retained organs and tissues for research use. The Group was against the use of concepts such as ‘ownership’, while recognising that it was no longer appropriate to suggest that the human body had no value in financial terms. Clarification of the law in this area was recommended.⁶⁶ Last, IRG was critical of the adequacy of scrutiny of research, and proposed a range of measures to improve the competence and performance of Research Ethics Committees.⁶⁷

2.1.1.5.5 Organ donation.

IRG strayed from its brief by noting that some of the issues dealt with in the Final Report, particularly the weight to be given to the wishes of the deceased as

⁶³ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report.* November 2001, op. cit., p23, para 36.

⁶⁴ Green MA. *Time to put ‘cot death’ to bed.* BMJ 1999; 319(7211):697-698.

⁶⁵ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report.* November 2001, op. cit., p24, para 43.

⁶⁶ Ibid., p24, para 44.

⁶⁷ Ibid., pp23-24, Paras 39-41.

opposed to their surviving relatives, were central to the process of seeking agreement to organ donation, even though attitudes to organ transplantation and post-mortem examination may be very different.⁶⁸ It was recommended that the Scottish Executive, in implementing any changes to existing legislation as a result of the Final Report, would need to give careful consideration to reformulating the legislative basis for organ donation, either by way of a clarified combined Act or by a stand-alone statute dealing with transplantation. IRG indicated that it was aware that the Scottish Parliament's Health & Community Care Committee had, by chance, already begun to consider the law in respect of organ transplantation.⁶⁹

2.2 Response of Scottish Executive to the Final Report.

2.2.1 Consultations.

The Final report was published on November 23, 2001. On that day the Minister for Health and Community Care underlined the Executive's commitment to change the legislation, with formal consultation on the Report as the next stage.⁷⁰

Consultations closed on March 31 2002, and revealed broad support for the approach which had been taken by the Review Group.⁷¹ Over the next two years, the Scottish Executive kept in close touch with the steps being taken in England and Wales towards revised human tissue legislation, principally through a senior Scottish official's presence as an observer during all stages of the Department of Health's planning and implementation process for the 2004 Act.⁷²

At the same time, the Executive pursued a path towards separate Scottish legislation by consulting further, and separately, on: legislation relating to post-

⁶⁸ Ibid., p9, para 19.

⁶⁹ Ibid., p10, para 19.

⁷⁰ The Scottish Government. News release. *Reform proposed for hospital post-mortems*. Nov 23 2001. Accessed on June 29 2010 at: <http://www.scotland.gov.uk/News/Releases/2001/11/660>

⁷¹ Scottish Executive Health Department. *Consultation paper on the legislation relating to hospital post-mortem examinations*. November 24, 2003, p2, par 8.

⁷² Department of Health. Freedom of Information Team. Email to AS McNeish, ref. DE00000537219. September 20, 2010.

mortem examinations⁷³; legislation relating to retention of organs⁷⁴; existing provisions and licensing arrangements of the Anatomy Act 1984⁷⁵; legislation relating to organ and tissue donation and transplantation⁷⁶. [With regard to organ transplantation, it should be noted that both IRG in its Final Report⁷⁷, and the [coincidental] report of the Scottish Transplant Group in 2002⁷⁸, had preferred that any new legislation regarding transplantation should be separate from any legislation concerning post-mortem examinations. As will be seen below, the Executive decided to separate these issues within a single Bill⁷⁹]. The Executive also began a process of consultation with the Crown Office and Procurator Fiscal Service which would lead eventually to improvements in communication between Procurator Fiscals, doctors and relatives⁸⁰, and to agreed standards for Fiscal post-mortems.⁸¹

2.2.2 Compensation made to parents.

⁷³ Scottish Executive Health Department. *Legislation relating to hospital post-mortem examinations: analysis of consultation responses*. Scottish Executive Social Research, 2004.

⁷⁴ Scottish Executive Health Department. *Retention of organs at post-mortem: analysis of the responses to the consultation on the Review Group Phase 3 Report*. Research findings no.3/2005. Scottish Executive Social Research, 2005.

⁷⁵ Scottish Executive Health Department. *Analysis of the responses to consultation on existing provisions and licensing arrangements for the Anatomy Act 1984*. Scottish Executive Social Research, 2005.

⁷⁶ Scottish Executive Health Department. *Legislation relating to organ and tissue donation and transplantation: analysis of consultation responses*. Scottish Executive Social Research, 2004.

⁷⁷ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p10, para 19.

⁷⁸ Scottish Transplant Group Report. *An organ donation strategy for Scotland*. (Crown Copyright 2002). June 2002, p50.

⁷⁹ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, col. 2092.

⁸⁰ Scottish Parliament. *Official Report*. Health Committee, 25th meeting, Second Session. October 25, 2005. Submission from the Solicitor General for Scotland. Paper HC/S2/05/25/08.

⁸¹ Scottish Government, Crown Office and Procurator Fiscal Service, Royal College of Pathologists. *Code of practice and performance standards for forensic pathologists dealing with suspicious deaths in Scotland*. November 2007. Crown Copyright 2007.

Although compensation is unlikely to have been a significant influence on the development of new legislation, the following details, made available by the Central Legal Office of NHS National Services Scotland, are included for the purposes of comparison with agreements reached in England (see Chapter Four, 2.2.4).

A scheme for compensation was agreed by the Scottish Executive on what seems to have been a ‘formally informal’ basis. There was no primary or subordinate legislation involved. The parents were not required to prove any actual loss or damage, but were eligible to participate if it was confirmed that they had a child who had undergone post mortem and whose body parts had been retained. The money came from the Executive and not the Health Boards, but the Central Legal Office administered the scheme during 2003-4.⁸²

A single litigant pursued a separate case. The case did not proceed to a final hearing on the evidence, but there was a Procedural Roll Debate in the Court of Session on the competency of the action.⁸³

3. ‘Legitimation’: the Human Tissue (Scotland) Bill (‘The Bill’).

3.1 Scottish legislative process: passage of a Public Bill.

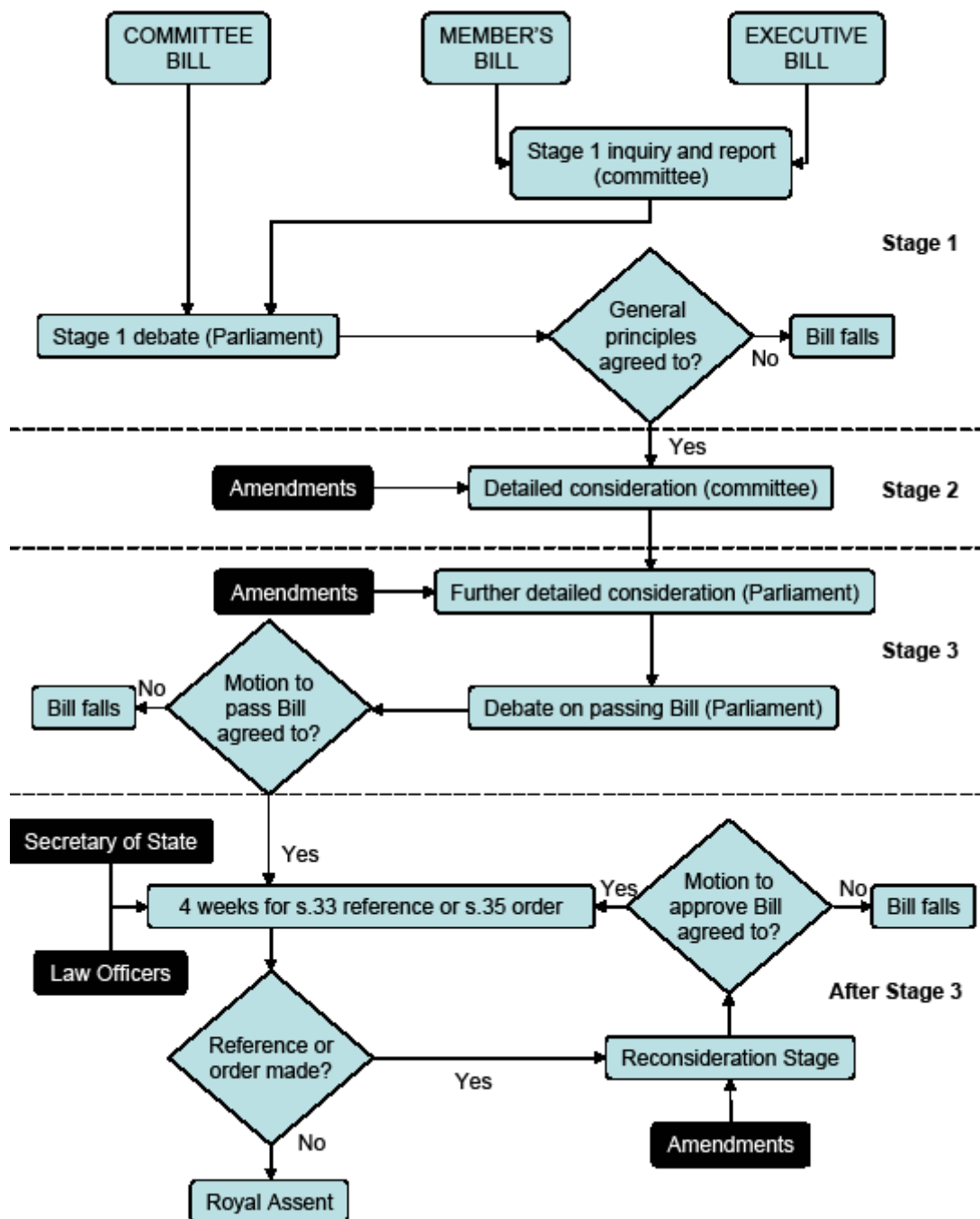
Inserted below is a diagrammatic summary of the stages in the passage of a Public Bill through the Scottish legislative process.⁸⁴

⁸² NHS National Services Scotland: Central Legal Office. Email to ASMcNeish from Robertson C, October 1, 2010.

⁸³ *Stevens v Yorkhill NHS Trust*. 2006 S.L.T. 889

⁸⁴ The Scottish Parliament. *Understanding the legislative process*. Accessed on May 23, 2010 at: <http://www.scottish.parliament.uk/business/bills/documents/StagesinthepassageofaPublicBill.pdf>

Stages in the passage of a Public Bill



Of relevance is the definition of an Executive Bill, which is 'a public Bill introduced by a Cabinet Secretary or Minister of the Scottish Government to give effect to

Executive policy’.¹ Much informed by IRG’s Reports, supplemented by the extensive and multilayered consultative process outlined above, a draft Executive Bill, titled the *Human Tissue (Scotland) Bill [SP Bill 42]*, was prepared and introduced in the Parliament on June 3, 2005 by Andy Kerr MSP. Stage 1 commenced on September 8, 2005 with the Health Committee as the lead committee. The Stage 1 (general principles) debate took place on November 30 2005, Stage 2 comprised further meetings of the Health Committee to consider amendments during December 2005 and January 2006, and the Bill was passed following the Stage 3 parliamentary debate on February 2, 2006. Royal Assent was given on March 16, 2006.²

3.2 Policy Memorandum regarding the Human Tissue (Scotland) Bill.³

The development of policy by the Scottish Executive to which the Bill was intended to bring effect was set out (as was required by Rules⁴ under the Scotland Act 1998) in a Policy Memorandum which accompanied the Bill as introduced.

3.2.1 Overall policy intentions.

The policy intention was to repeal for Scotland the Human Tissue Act 1961 and replace it with legislation containing ‘distinct provisions appropriate to Scotland’ relating to organ donation and transplantation from deceased donors, and to hospital post mortem examinations; to amend and incorporate in the new legislation the provisions in the Human Organ Transplants Act 1989 relating to living donors; and to amend the Anatomy Act 1984 to broaden the definition of ‘anatomical examination’; to address public concerns about use of bodies and body parts in public displays, and to allow the post of HM Inspector of Anatomy for

¹ Ibid. Accessed on May 23, 2010 at:
<http://www.scottish.parliament.uk/business/bills/understanding.htm>

² Ibid. Accessed on May 23, 2010 at:
<http://www.scottish.parliament.uk/business/bills/billsIntrodS2/billsIntrod-s2-02.htm#HumanTissue>

³ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit.

⁴ *Scotland Act 1998*. 1998 (chapter 46.) Chapter 9: Rule 9.3.3 (c).

Scotland to continue following changes made by the Human Tissue Act 2004.⁵ The legislation would make provision to allow the Scottish Ministers to arrange with a public authority anywhere in the UK to assist them with certain of their functions under the Bill, and, by regulations, power to amend the Act in order to give effect to Community obligations relating to material consisting of human cells.

3.2.2 Transplantation.

It is striking, in a Bill whose origins lay in considerable part in the distress caused by organ and tissue retention at post-mortem, that the first section should be concerned with transplantation. Further, the first clauses in this first section set out the *duties of Ministers* (my emphasis) in this regard:

s.1(1) It is the duty of the Scottish Ministers to (a) promote, support and develop programmes of transplantation; (b)) promote information and awareness about the donation for transplantation of parts of a human body.⁶

The Executive's intention was that 'the new legislation for Scotland should be firmly rooted in the positive attitudes towards organ and tissue donation and transplantation held by 90% of the population'.⁷ At the same time, the aim was to ensure that the position in Scotland remained consistent with that of the rest of the UK.⁸ The intention was to apply the concept of 'authorisation', as developed by IRG, 'in order to recognise that this is an active decision taken by someone in a position of control'.⁹ Arguments in favour of 'presumed consent' had been considered by the Executive but were rejected, first because it was important that the fundamental principle on which organ donation rested should be consistent throughout the UK, but equally from the Executive's belief that offering organs as a

⁵ Ibid., p1, paras 2-3.

⁶ Scottish Parliament. *Human Tissue (Scotland) Bill (as introduced)*. SP Bill 42. Second Session (2005).

⁷ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p3, para 9.

⁸ Ibid., p4, para 17.

⁹ Ibid., p3, par 9.

‘gift’ was an important concept to help maintain public confidence and support for transplantation at its (then) 90% level.¹⁰

3.2.3 PM examinations.

The Policy Memorandum confirmed that the provisions in the Bill were intended to give expression to the principles set out by IRG¹¹, and thereby fulfilled a commitment to change the law which had first been given in the autumn of 2000¹². The approach of including the minimum in primary legislation, as recommended by IRG, had been assisted by the acceptance by the Executive that a HPM should properly be regarded as part of the continuum of care provided by NHS Scotland; as a consequence of which NHS Quality Improvement Scotland had already implemented the recommendation in IRG’s Preliminary Report by developing clinical standards for the HPM process, made mandatory in all NHS hospitals.¹³

With regard to HPMs, the examination itself and the purposes for which retained material may be used must be ‘authorised’ by an adult with capacity, a mature child, a nominee, the deceased’s ‘nearest relative’ [from a hierarchy]. In the case of children under 12, or between the ages of 12 and 16 who had left no wishes, authorisation must be given by the person or persons having parental rights or responsibilities in respect of the child.¹⁴ The framework of authorisation would be underpinned by standard authorisation forms and information leaflets which had already been developed for use throughout Scotland (and whose content would be specified in Regulations to be made under the Bill).¹⁵ The forms would make a clear distinction between: retention of tissue blocks and slides, the creation of which was, *as a fact* (emphasis in Memorandum), an integral part of the post-mortem

¹⁰ Ibid., p6, para 22.

¹¹ Ibid., p9, para 30.

¹² Ibid., p9, para 38.

¹³ Ibid., p9, paras 38-39.

¹⁴ Ibid., p10, para 42.

¹⁵ Ibid., p10, para 43.

examination and which would form part of the deceased person's medical record; and organs, which should only be retained in exceptional circumstances, and which therefore would require separate and specific authorisation. This distinction, the Memorandum stated, also reflected 'the much greater emotional significance of organs'.¹⁶

3.2.4 An absence of provision regarding tissue from the living.

A striking feature of the Bill was that, in contrast with the Human Tissue Act 2004, it contained no provisions in respect of surplus or residual tissue from the living. This was not an oversight. The Policy Memorandum explained:

Tissue donation from the living is a different matter from living organ donation. Bone and other tissue are usually regarded as waste products, in that they would normally be discarded from an operation or a diagnostic investigation such as a biopsy. Provisions relating to surplus or residual tissue appear in the Human Tissue Act 2004. The Executive's policy, however, is that the arrangements for the authorisation of the use of surplus tissue can be dealt with satisfactorily by guidance and an appropriate authorisation form. It sees no need to introduce measures in this area more stringent than those which apply to the consent a living person gives to the carrying out of an operation. These proposals were included in the consultation and no representations have been received objecting to this approach. The guidance will, however, be consistent with that issued by the Human Tissue Authority under the 2004 Act, since obtaining and using human tissue for research purposes should be neither easier nor more difficult in Scotland than other parts of the UK. There is the further safeguard that all research involving human tissue will always require the approval of a Research Ethics Committee.¹⁷

3.2.5 Penalties.

One of the main criticisms of the 1961 Act was that it contained no penalties for non-compliance with the regime it set out for HPMS. The Bill addressed that criticism directly by including penalty provisions. The level of penalties equated to those set out in the 2004 Act.¹⁸

¹⁶ Ibid.

¹⁷ Ibid., p6, para 24.

¹⁸ Ibid., p11, para 47.

3.2.6 Inspection and regulation.

The Executive had decided that it was unnecessary to provide for a system of inspection and regulation of HPMs such as was provided in the Human Tissue Act 2004, in part in recognition of the deterrent effect of the penalty provisions, but largely because of the role of NHS Quality Improvement Scotland had been undertaking, since 2003, in reviewing performance against its HPM standards.¹⁹ The standards had been developed with strong input from family support groups, and were mandatory on those in the NHS providing this service. In addition, the on-going reviews against standards included strong representation from those who were not health professionals.

The Bill nevertheless secured that the Scottish Ministers could ask the Human Tissue Authority to exercise any of its functions in Scotland on their behalf, including those of inspection and regulation, if it were thought necessary to do so.²⁰

3.2.7 Examinations instructed by the Procurator Fiscal.

With regard to FPMs, the Bill provided that tissue samples retained should become part of the deceased person's medical record once the Fiscal had indicated that they were no longer required for his or her purposes, and could be retained and used for diagnostic purposes and audit without the need for authorisation from the nearest relative. Tissue samples or whole organs no longer needed for the Fiscal's purposes could be used for research, education or training, provided proper authorisation had been given for these uses.²¹ The Memorandum emphasised that the Crown Office and Procurator Fiscal Service were aware of the importance of good communication with the family, especially of the need to inform them whether any organs had been retained as a result of the post-mortem examination. The new arrangements for the authorisation of educational or research use of

¹⁹ NHS Quality Improvement Scotland. *Standards for management of post-mortem examinations in Scotland*. First published March 2002. Revised March 2003.

²⁰ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p12, para 49.

²¹ Ibid., p11, para 44.

organs or tissue samples no longer needed for the Fiscal's purposes would require a process of clear notification by the Fiscal that his or her purposes were complete, and this was provided for in the Bill.²²

3.2.8 Anatomical examination.

The policy intentions in the Bill with regard to anatomical examination reflected the outcome of the prior consultation on the Anatomy Act 1984.²³ The definition of 'anatomical examination' in the 1984 Act should be amended so that it would not be restricted to dissection but to any act that is done for [surgical] teaching, training, studying or research purpose on a body. The Bill also addressed public concerns over the use of bodies and body parts in public exhibitions under the guise of education or art. An attempt had been made to display bodies as part of the 2003 Edinburgh Festival Fringe, and considerable controversy had been raised elsewhere in the UK [as discussed in Chapter Two] by the "Bodyworks" exhibition. However, the 1984 Act as then framed did not allow any action to be taken to prevent such displays so long as the bodies had been acquired and dissected outside the UK. The policy intention was therefore to take on sole power for Scottish Ministers to licence the public exhibitions of anatomical specimens, or public dissections, for the purpose of education, training and research into morphology.²⁴ The third principal intention was to establish structures to enable the post of HM Inspector of Anatomy for Scotland to be continued following legislative changes in England and Wales.²⁵

3.2.9 Miscellaneous provisions.

²² Ibid., p12, para 48.

²³ Scottish Executive Health Department. *Analysis of the responses to consultation on existing provisions and licensing arrangements for the Anatomy Act 1984*. Scottish Executive Social Research, 2005, op. cit., p4.

²⁴ Ibid., p16, paras 71-72.

²⁵ Ibid., p17, para 73.

In addition, the Bill made provision to regulate the importation of dead bodies or body parts and to prohibit the use of such bodies for financial gain, in line with changes in the rest of the UK.²⁶

3.2.10 Arrangements by Scottish Ministers for assistance.

The 2005-6 Bill and subsequent 2006 Act were helped to remain relatively slim and focused by a policy intention²⁷, and later provision²⁸, that Scottish Ministers may make arrangements with other UK public authorities to undertake any of their functions. In practice, the Scottish Government arranged for the HTA, on its behalf, to: approve transplants from living donors; license organisations that use human tissue to treat patients; and sanction analysis of DNA without consent in specified circumstances.²⁹

3.3 The Health Committee (see also 3.5.2).

A noteworthy feature of the legislative process in Scotland is the importance of the committees within Stage 1 of the legitimisation process itself. Extensive scrutiny is given to a Bill by the 'lead' committee before it comes before Parliament for debate. Following the introduction of the Bill on June 9 2005, it was referred to the Health Committee ('the Committee') which, a few days later, decided to obtain written views over the summer months from a wide range of bodies about the draft. Beginning on September 8, the Committee began Stage 1 formally, and held a total of nine meetings over the next two months at which written and oral evidence was considered. The Deputy Minister for Health and Community Care and his officials, Professor Sheila McLean (chair of IRG), John Forsythe (chair of the Scottish Transplant Group), HM Inspector for Anatomy, and the Solicitor General

²⁶ Ibid., p17, para 74.

²⁷ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p4, para 17; p 12, para 49.

²⁸ *Human Tissue (Scotland) Act 2006*, s.54(1)(2)(3).

²⁹ British Medical Association. *Human tissue legislation: guidance from the BMA's medical ethics department*. September 2006, pp7-8.

for Scotland were followed by a stream of witnesses which included representatives of two parents' associations, a diversity of health bodies, the Procurator Fiscal Society, the Law Society of Scotland, the Medical and Dental Defence Union, four Royal Colleges, BMA, MRC, Wellcome Trust and other research bodies, the Scottish Commission on Bioethics, the Mental Welfare Foundation, Scottish Museums, and a number of expert witnesses *ad personam*.

The discussions of the Committee with witnesses were extensive and discursive. All proceedings and submitted papers were published in the Official Report of the Health Committee.³⁰ The outcome of the Committee's work in Stage 1 was the publication on November 22, 2005 of its detailed, 9500 word, Stage 1 Report on the Human Tissue (Scotland) Bill.³¹

The Committee reported in the following terms:

The Committee acknowledges that the Bill deals with important issues which require to be handled sensitively. While the Committee supports the Bill, it has throughout this report made a series of recommendations about how it might be improved and about action to be taken to support effective implementation. The Committee asks that the Deputy Minister notes the contents of this report and responds positively to its recommendations.

With this caveat, the Committee recommends to the Parliament that the general principles of the Bill be approved.³²

3.4 Parliamentary stages of the Human Tissue (Scotland) Bill.

The Stage 1 Report, accompanied by Explanatory Notes³³ and a Policy Memorandum³⁴ from the Executive, and further briefing papers from the Scottish

³⁰ Scottish Parliament. *Official Report*. Accessed on June 2, 2010 at: <http://www.scottish.parliament.uk/business/committees/health/meetings.htm>

³¹ Scottish Parliament. Health Committee Report (SP Paper 451). *Stage 1 Report on the Human Tissue (Scotland) Bill. 19th Report 2005 (Session 2)*. Accessed on June 2, 2010 at: <http://www.scottish.parliament.uk/business/committees/health/reports-05/her05-19-01.htm>

³² *Ibid.*, p1.

³³ Scottish Parliament. *Human Tissue (Scotland) Bill: Explanatory Notes*. June 3, 2005. Accessed June 2, 2010 at <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-introd-en.pdf>

Parliament Information Centre (SPICe) on each of the three main sections of the Bill^{35 36 37}, were used to prepare MSPs in advance of the Stage 1 (general principles) debate on November 30, 2005. The principles of the proposed legislation were introduced by the Deputy Minister for Health and Community Care, Lewis Macdonald MSP, who affirmed that:

The bill is rooted in a strong process of consultation and seeks to respond to the views that we have elicited both from health care professionals and from the general public, while recognising that views sometimes conflict and that there is then a need for a balanced judgment...³⁸

The Minister emphasised that the legislation was based on the ‘fundamental principle’ of authorisation³⁹, and highlighted two objectives in particular: restoring confidence in the post-mortem examination process (a procedure which ‘positively benefits the living’); and boosting organ donation rates.⁴⁰ In the debate which followed, a total of fifteen MEPs spoke, all in support. The tenor was captured by the Minister who, in closing the debate, said that he had a strong sense of a consensus in the chamber, both on the general principles of the Bill and on the

³⁴ Scottish Parliament. *Human Tissue (Scotland) Bill: Policy Memorandum*. June 3, 2005, op.cit. Accessed Jun2 2010 at: <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-introd-pm.pdf>

³⁵ Scottish Parliament Information Centre. Briefing.: SB 05-44. *Human Tissue (Scotland) Bill. Organ donation and transplantation (posted 30.8.05)*. Accessed June 2, 2010 at: <http://www.scottish.parliament.uk/business/research/briefings-05/SB05-44.pdf>

³⁶ Scottish Parliament Information Centre. Briefing.: SB 05-45. *Human Tissue (Scotland) Bill. Post mortem examinations and organ-tissue retention (posted 30.8.05)*. Accessed June 2, 2010 at: <http://www.scottish.parliament.uk/business/research/briefings-05/SB05-45.pdf>

³⁷ Scottish Parliament Information Centre. Briefing.: SB 05-45. *Human Tissue (Scotland) Bill. Amendment of the Anatomy Act 1984 (posted 30.8.05)*. Accessed June 2, 2010 at: <http://www.scottish.parliament.uk/business/research/briefings-05/SB05-46.pdf>

³⁸ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1) November 30, 2005, col. 21220.

³⁹ Ibid., col. 21221.

⁴⁰ Ibid., col.21224.

sensitivities which would require to be acknowledged and respected during later stages of the Bill's progress.⁴¹

The Stage 2 process, which has analogies with 'Committee Stage' scrutiny in Westminster, began with a formal, point by point written response from the Minister to the issues raised by the Health Committee in its Stage 1 Report. This was followed by papers which listed amendments to the Bill⁴² brought forward by the Executive as a result of three strands of argument which had arisen from: the Stage 1 Report, written and oral evidence given to the Health Committee by institutions or individuals, and points raised in the Stage 1 debate in Parliament. The Health Committee itself sat twice, with the Minister and officials in attendance.⁴³ The major Executive amendments concerned disability and incapacity, in particular: to make provision for authorisation or withdrawal of authorisation by a person who was blind or unable to write; and provisions to ensure that adults with incapacity would be given the same degree of protection as children in relation to organ donation for transplantation.⁴⁴ In addition to Executive amendments, all of which were accepted by the Committee, ten groups of amendments were brought forward by members of the Committee, acting in some instances as spokesperson for Parliamentary colleagues or an outside body. All were withdrawn or defeated in a vote. In addition, the Minister, having heard further discussion, agreed to bring forward further amendments at Stage 3.

⁴¹ Ibid., col. 21262.

⁴² Scottish Parliament. *Official Report*. Health Committee. Supporting papers: 1st and 2nd Marshalled List of Amendments for Stage 2 of the Human Tissue (Scotland) Bill. 32nd meeting, 2005 (December 20, 2005) and 2nd meeting 2006 (January 17, 2006). Accessed June 5, 2010 at: <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-stage2-ml.pdf> and <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-stage2-ml2.pdf>

⁴³ Scottish Parliament. *Official Report*. Health Committee: Meeting Papers and Official Reports. 32nd meeting, 2005 (December 20, 2005) and 2nd meeting 2006 (January 17, 2006). Accessed June 5, 2010 at: [http://www.scottish.parliament.uk/business/committees/health/2005 and 2006.htm](http://www.scottish.parliament.uk/business/committees/health/2005%20and%202006.htm)

⁴⁴ Scottish Parliament. *Human Tissue (Scotland) Bill. Summary of Executive amendments, Stage 2.* (HC/S2/05/32/14). December 20, 2005.

The Stage 3 debate in Parliament on the Bill, as amended at Stage 2⁴⁵, took place on February 2, 2006, and included consideration of a further, largely technical, list of amendments brought forward by the Executive, and, separately, of three proposals by MSPs⁴⁶. As had occurred in the late stages of the debates in Westminster on the Human Tissue Bill, the major issue moved from the backbenches took the form of a last ditch attempt to introduce provisions for 'presumed consent' for organ transplantation. As in Westminster, the motion was defeated (18 /87)⁴⁷. The Human Tissue (Scotland) Bill was passed electronically and unanimously at 17.02h.⁴⁸

Six weeks later, on March 16, 2006, the Human Tissue (Scotland) Act 2006 received Royal Assent.⁴⁹

3.5. Further scrutiny of aspects of the 2006 Act.

3.5.1 Why separate legislation for Scotland?

Why did Scotland decide to legislate separately from England, Wales and Northern Ireland? The reasoning was set out during the second meeting of the Health Committee at Stage 1.⁵⁰ First, and probably most important, was the fact that 'we could', in that legislation in these matters had been devolved [and that the Minister

⁴⁵ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill, Stage 3. February 2, 2006. Accessed on June 5, 2010 at:
<http://www.scottish.parliament.uk/business/officialReports/meetingsParliament/or-06/sor0202-02.htm#Col22946>

⁴⁶ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill. Marshalled list of amendments selected for Stage 3 (posted 30.1.06). Accessed on June 5, 2010 at:
<http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-stage3-g.pdf>

⁴⁷ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill, Stage 3, op.cit., col. 22955. Accessed on June 5, 2010 at:
<http://www.scottish.parliament.uk/business/officialReports/meetingsParliament/or-06/sor0202-02.htm#Col229455>

⁴⁸ Ibid., col. 23075.

⁴⁹ *Human Tissue (Scotland) Act 2006*. (2006 asp 4.)

⁵⁰ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, col. 2092-2113, op.cit.

had made a very early public commitment to changing the law⁵¹]. Second, there had already been important background work undertaken by Professor McLean's IRG and the Scottish Transplant Group. By 2003, as a result of a recommendation in the Preliminary Report of IRG, standards for hospital post mortem examinations had already been developed and published by NHS Quality Improvement Scotland⁵² and had become mandatory throughout the NHS in Scotland. Further, both IRG and STG had recommended legislation for transplantation separate from post mortem examinations. A senior Health Department official told the Health Committee that 'I would like to think that the approach that we have taken has enabled us to focus and fine-tune the provisions [for Scotland]'. He continued:

It is terribly important, however, that there should be a broadly consistent approach across the United Kingdom, and all the health departments have been working closely together on the primary legislation and, even more so, on the regulations and codes of practice that underpin them. That is important in relation to living transplantation, where we want the Human Tissue Authority, set up under the 2004 Act, to discharge that function for Scotland. It did not make sense to set up a separate body in Scotland, given the numbers involved.⁵³ [see also 3.2.10, above].

Professor McLean added three further reasons for having specific Scottish legislation: IRG, in comparison to *Bristol* and *Alder Hey*, had been asked to consider post-mortems in adults [she did not mention *Isaacs*]; the law in Scotland, compared to England and Wales, differed in respect of older children; and 'finally, there was an opportunity to modify the basis on which people opted into the system'.⁵⁴

As a senior official had indicated, the Executive was aware of the need to seek to ensure that legislation in Scotland was congruent with that elsewhere in the UK. As put by the Deputy Minister during the stage 1 debate:

⁵¹ Scottish Parliament. *Official Report*. February 8, 2001, col. 1124.

⁵² NHS Quality Improvement Scotland. *Standards for management of post-mortem examinations in Scotland*. First published March 2002. Revised March 2003, op.cit.

⁵³ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, op.cit., col. 2097.

⁵⁴ Ibid.

There is equivalent legislation in the Human Tissue Act 2004, which applies south of the border. Although the bill reflects Scottish circumstances, we have also worked hard at official level with colleagues in the Department of Health to ensure that the principles in both sets of legislation are the same and that there is, as far as possible, a consistent approach. We recognise that that is important both for members of the public and for health care professionals who will have to work with both pieces of legislation.⁵⁵

3.5.2 The role of Committees within the Scottish Parliament.

The Scottish Parliament's *Guidance on Public Bills* sets out an invariable procedure, under Rules within the Scotland Act 1998⁵⁶ (see also diagram at 3.1, above). In Stage 1, once a bill has been introduced, the Parliamentary Bureau refers it to whichever committee has the bill within its remit. The lead committee's role is to report to the Parliament on the general principles of the bill, to inform the Stage 1 debate on the principles. Provided there is Parliamentary acceptance of the principles, the bill is referred back to the lead committee for detailed 'line by line' consideration. It is at this stage that the Committee will consider amending the bill. During the first and second stages, committees may take evidence and request information from ministers (who may respond in writing or in person). Finally, the amended bill, if passed out of the committee, is then referred to the whole chamber. At this third stage, the chamber may pass the bill or refer it back to the committee for further 'stage two consideration'.^{57 58}

According to the analysis of Johnston, the Scottish Parliament had been 'bold and innovative in facilitating access and participation' during its first decade of

⁵⁵ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1) November 30, 2005, col. 21263.

⁵⁶ Scottish Parliament. *Standing orders of the Scottish Parliament*. 3rd Edition (4th revision, June 2009). Chapter 9, Rule 9.6(1).

⁵⁷ Scottish Parliament. *Guidance on public bills*. Stage 1, para 2.23, 2.25, 2.29. Accessed September 2, 2010 at: <http://www.scottish.parliament.uk/business/bills/billguidance/gpb-c.htm>

⁵⁸ Carman C, Shephard M. *Committees in the Scottish Parliament*. In (Jeffrey C, Mitchell J (eds.) *The Scottish Parliament 1999-2009: the first decade*. Edinburgh. Luath Press (jointly with the Hansard Society), 2009, op.cit., at p22.

existence.⁵⁹ Committees had firmly established themselves as ‘the engine room of the parliament’.⁶⁰ The scrutiny role of a committee, ostensibly to look at the ‘general principles’, had tended to look much more closely at bills and might include suggestions for amendments to the Executive. This, Johnston opined, had allowed for much greater public involvement in the legislative process than existed at Westminster.⁶¹ The details of the consultations undertaken by the Health Committee (see 3.3 above) give support to Johnston’s view, in so far as tissue legislation is concerned.

3.5.3 The wider consultative process.

The openness and thoroughness of the consultation process, the ready public availability of background, briefing and evidentiary documents and transcripts of all proceedings, were impressive. It has transpired that this was not because the issue of post-mortems and human organs was especially sensitive (although it was) but because of the general approach to consultation adopted by the Scottish Government and promulgated on their web site ‘*About Scottish Government Consultations*’.⁶² Three abstracts give a flavour:

Consultation is an essential and important aspect of Scottish Government working methods;

Copies of all the responses received to consultation exercises (except those where the individual or organisation requested confidentiality) are placed in the Scottish Government library at Saughton House, Edinburgh;

Within the consultation section of the Scottish Government website there is a full list of all closed consultations and a listing of forthcoming consultations. The ‘closed’ section will, in future, provide details about the outcome of consultations and have links to any reports produced from the consultation exercise.

⁵⁹ Johnston J. *The legislative process: the Parliament in practice*. In Jeffrey C, Mitchell J (eds.). *The Scottish Parliament 1999-2009: the first decade*. Edinburgh. Luath Press (jointly with the Hansard Society), 2009, at p29.

⁶⁰ Ibid.

⁶¹ Ibid.

⁶² Scottish Government. *About Scottish Government Consultations*. Accessed June 26, 2010 at: <http://www.scotland.gov.uk/Consultations/About>

Further, it is evident that steps were taken in the case of tissue legislation to keep witnesses, once involved, 'in the picture'. Several experts who gave evidence to the Health Committee were subsequently informed of evidence given by later witnesses and were asked to produce further papers as a result. In addition, a senior Health Department official attended several consecutive meetings of the Scottish Council of the Royal College of Pathologists during 2004 and early 2005, both to give information and hear comments about the evolving legislative content.⁶³

It is of course easier to proceed in the manner described above in an electorate of 5million as compared to 55 million. The origins of the approach can be found in the third of four key principles upon which operations of the Scottish Parliament were based:

The Scottish Parliament should... develop procedures which make possible a participative approach to the development, consideration and scrutiny of policy and legislation.⁶⁴

3.5.4 Authorisation.

A major feature of the Human Tissue (Scotland) Act 2006 is its reliance on 'authorisation' rather than 'consent'. As 'consent' was 'the golden thread' within the Human Tissue Act 2004, so 'authorisation' became the central theme in the Scottish legislation. As discussed above, the concept of authorisation had its origins in the work of the IRG where consideration of 'best interests' had seemed to be an inappropriate approach to the parental responsibilities towards their dead child, and IRG had become 'committed' to an authorisation process.⁶⁵ Because the remit of IRG extended to consideration of post-mortems in adults as well, it appeared

⁶³ Royal College of Pathologists. Scottish Regional Council. Minutes of: September 23, 2004, at 13.5; December 7, 2004, at (a); March 15, 2005, at (a).

⁶⁴ Megaughin E, Jeffrey C. *Introduction: the first decade in perspective*. In Jeffrey C, Mitchell J (eds.) *The Scottish Parliament 1999-2009: the first decade*. Edinburgh. Luath Press (jointly with the Hansard Society), 2009, op.cit., at p11.

⁶⁵ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p16, para 3.

logical to the Group to extend the use of ‘authorisation’ to all (non Fiscal) post-mortems, and to organ donation. At the Health Committee meeting on September 8, 2005, Professor McLean was ‘particularly pleased’ that the Bill had adopted the concept of authorisation rather than that of consent, because ‘the concept of authorisation reflects more clearly than did the traditional concept of consent the location of the authority that we believe should be vested in people’.⁶⁶ Further, she was ‘delighted’ that the British Medical Association had withdrawn its concern that there should be absolutely the same approach throughout the UK and had endorsed the notion of authorisation.⁶⁷

There was an interesting exchange between the Deputy Minister for Health and Community Care and the Solicitor General during a meeting of the Health Committee at Stage 1. The Minister, having defined ‘to authorise’ as meaning ‘to give legal authority and to enable’, added that ‘the Bill does not seek to narrow that down or to apply it in exactly the same way to each of the processes involved’.⁶⁸ The Solicitor General supported this approach, saying:

Authorisation is a generic, uniform concept, but it is subject to a variety of different tests in the legal context, some of which are more robust than others. It is a policy issue whether the tests that are applied in a particular category are subject, for instance, to witnesses or to subscription or to a variety of other tests. It has to be a matter of what works in individual circumstances and what is practicable and desirable.⁶⁹

Perhaps the most subtle, and potentially far reaching, distinction adduced by IRG was that ‘authorisation’ was not constrained by the requirement to have prior information, and thus would meet the situation in which [parents] did not wish to receive information about post- mortem examinations and/or the subsequent

⁶⁶ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, op.cit., col. 2097

⁶⁷ Ibid., col. 2097-2098.

⁶⁸ Scottish Parliament. *Official Report*. Health Committee. 25th meeting, Second Session. October 25, 2005, col. 2312.

⁶⁹ Ibid.

removal and retention of organs and tissue, but did not object to these practices.⁷⁰ (Sensitivity to the needs of those who ‘did not want to know’ was a recurring theme within the legislative process in Scotland. This is further discussed below). The concept and use of authorisation was accepted by the Scottish Executive as representing ‘an active decision taken by someone in a position of control’⁷¹. Its usage was emphasised by Lewis Macdonald MSP, the Deputy Minister, when he introduced the Bill during the Stage 1 debate in Parliament.⁷²

3.5.5 Age of legal capacity, and consent/authorisation.

There is a significant difference in the detail about ‘authorisation’ that appeared on the face of the Human Tissue (Scotland) Act 2006 compared to the way in which ‘consent’ was dealt with in the Human Tissue Act 2004.

During the many debates which led to the 2004 Act, there were several attempts to have made explicit in the 2004 Act what was meant by ‘consent’ and what information would be required to make it valid. These attempts were resisted on the grounds that standards or conventions might vary over time⁷³, and that it would be better to leave these matters to guidance from the Human Tissue Authority. Part 1 of the 2004 Act specified those activities for scheduled purposes which shall be lawful if done with ‘appropriate’ consent. There were separate groups of sections which specified the circumstances supporting ‘appropriate consent’ in adults⁷⁴ and children, whether competent⁷⁵ or incompetent⁷⁶.

⁷⁰ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p31, para 17.

⁷¹ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p3, para 9.

⁷² Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1). November 30, 2005, col. 21221.

⁷³ Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, January 27, 2004, col. 5-18.

⁷⁴ *Human Tissue Act 2004*, s 1(3).

⁷⁵ *Ibid.*, s1(2)(2).

The comparable provisions in the 2006 Act reflected, first, that legal capacity to enter into any transaction in Scots law is reached at the age of 16y⁷⁷; and second, that children over the age of 12y have legal capacity in certain respects, such as testamentary capacity, consent to the making of an adoption order, and ‘consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment’.⁷⁸ This had led IRG to recommend enthusiastically that there should be separate provisions in the human tissue legislation for children over the age of 12y, as compared to adults, and children under 12y. This tripartite grouping was carried through into the Human Tissue (Scotland) Bill, where the concept was well supported, but carefully debated.⁷⁹ The outcome was that the sections of the 2006 Act which dealt with authorisation by a child over the age of 12y contained extra precautionary features, to the extent, for example, of defining the procedures to be adopted in the case of a blind 12y old who had to employ a signatory on his behalf.⁸⁰

3.5.6 Post-mortem examination as part of a continuum of care: ramifications for standards of practice.

3.5.6.1 Hospital post-mortems.

The recommendation by IRG which had perhaps the widest ramifications was that post-mortem examination should be treated as part of the continuum of care of a patient. Accepting this concept led the Scottish Executive in late 2001 to ask the Clinical Standards Board, (which on January 1, 2003 merged with other bodies to

⁷⁶ Ibid., s1(2)(3)(c).

⁷⁷ *The Age of Legal Capacity (Scotland) Act 1991*. (1991.c.50). s1(1)(b).

⁷⁸ Ibid., s2(2), s2(3), s2(4).

⁷⁹ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, op.cit., col 2102-2106. See also Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1). November 30, 2005, col 21238-9.

⁸⁰ Scottish Parliament. *Official Report*. Health Committee. 32nd meeting, Second session. Dec 20, 2005, col 2435.

become a Special Health Board, named NHS Quality Improvement Scotland(QIS), and charged with the setting and monitoring of standards throughout the NHS in Scotland⁸¹), to develop standards for hospital post mortem examinations upon which the performance of all hospital managements could be regularly monitored.

The outcome was the publication in March 2003, three years before legislation, of a comprehensive document '*Standards for Management of Post- Mortem Examinations*', which set out standards for: pathology practice for hospital post mortems; authorisation and information; storage handling and disposal; record keeping; education.⁸² These were the first set of regulatory and monitory standards that the Health Department required the services to comply with and in 2005 they remained the only set of standards that had a mandatory element to them.⁸³ By the time that legislation had been introduced, local reports had already been published of performance against the 2003 standards, as had a national overview which drew together common themes from the local reports⁸⁴ – the latter by a Project Group reporting to the NHS QIS Board on which, among others, the health professions, parents, and the laity were well represented.⁸⁵

The 2003 *Standards* document specified that both the post mortem examination and report should follow the [most recent] guidelines set by the Royal College of Pathologists.⁸⁶ From the concept of extending a continuum of care to include post-mortems, as recommended by IRG, came directly the importance of the hospital

⁸¹ NHS Quality Improvement Scotland. <http://www.nhshealthquality.org/nhsqis/37.140.141.html>

⁸² NHS Quality Improvement Scotland. *Standards for management of post-mortem examinations in Scotland*. First published March 2002. Revised March 2003.

⁸³ Scottish Parliament. *Official Report*. Health Committee, 21st meeting, Second Session. September 13, 2005, col 2131.

⁸⁴ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p12, para 49.

⁸⁵ NHS Quality Improvement Scotland. *Standards for management of post-mortem examinations in Scotland*. First published March 2002. Revised March 2003, op.cit., p13-14, section 5: *Membership of the Project Group for the management of post-mortem examinations*.

⁸⁶ Ibid., p 28, Standard 1a.

maintaining good records, which, in the case of postmortems, required as set out in the 2003 *Standards* document ‘the retention and secure storage of tissue blocks and glass slides as part of the medical record of the deceased’⁸⁷. This was later provided for in the 2006 Act at s.28(3) and s.28(4).⁸⁸

With regard to standard authorisation forms and information leaflets, two sets were introduced by NHS QIS, based on draft proposals contained in IRG’s Phase 3 Report⁸⁹; one set for the parent/guardian of a deceased baby or child under 16y, and a second set for the nominated representative/nearest relative of a deceased adult.⁹⁰ The Executive, according to a consultation paper from the Scottish Executive Health Department of April 2006, emphasised that the content of authorisation forms and information leaflets could be specified by Regulations under s.52 of the Human Tissue (Scotland) Act 2006; and the possibility that the Executive ‘may decide’ in the light of experience of using the forms, to incorporate them in Regulations, was repeated in the Health Department letter, promulgated throughout the NHS in Scotland to introduce the new legislation and its implications.⁹¹ In the event, to date no Regulations have been made. Instead the use of standard forms and leaflets is the responsibility of the Chief Scientist Office, part of the Scottish Government Health Directorates.⁹²

In the rest of the United Kingdom, policy for consent for post-mortem examination is determined by the Human Tissue Authority’s (HTA) ‘*Policy on consent for post-*

⁸⁷ Ibid., p36, Standard 3a.

⁸⁸ *Human Tissue (Scotland) Act 2006*, s.28(3), s.28(4).

⁸⁹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Report on Phase 3*. November 2003, Appendix 3, p93.

⁹⁰ NHS Quality Improvement Scotland. *National overview: management of post-mortem examinations*. February 2005, Section 2, p45 et seq.

⁹¹ Scottish Executive Health Department. NHS HDL (2006) 46. *Human Tissue (Scotland) Act 2006: a guide to its implications for NHS Scotland*. July 20, 2006, p8, para 40. Accessed July 7, 2010, at: http://www.sehd.scot.nhs.uk/mels/hdl2006_46.pdf

⁹² Chief Scientist Office (Scotland). Accessed on July 7, 2010, at: <http://www.cso.scot.nhs.uk/>

mortem examination and tissue retention under the Human Tissue Act 2004, and the related Codes of Practice.⁹³

3.5.6.2 Fiscal post-mortems.

IRG had also recommended that standards for Fiscal post-mortems, both with regard to issues of communication and to the conduct of the examination itself, should be comparable to those for hospital post mortems.⁹⁴ Follow up by the Scottish Executive and the Crown Office and Procurator Fiscal Service (COPFS) led first, in 2001 and 2002, to revised guidance to Procurators Fiscal regarding better communication⁹⁵ and in 2007 to publication of a code of practice and a set of standards for forensic pathologists, agreed jointly with the Royal College of Pathologists.⁹⁶ This joint document stated that ‘the Scottish Government and the College recommend that all pathologists follow the *Guidelines on Autopsy Practice*⁹⁷ published by the Royal College of Pathologists in 2002’.⁹⁸ From this it followed that tissue blocks and slides should be retained following Fiscal post-mortems as part of the medical record of the deceased, and, without further authorisation, could be revisited at a later date if need be, for purposes of [refining the] diagnosis- exactly

⁹³ Human Tissue Authority. *Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004*. Accessed on July 7, 2010, at: <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyonconsentforpost-mortemexaminationandtissueretention.cfm>

⁹⁴ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 (‘The Preliminary Report of February 2001’), op. cit., 2 (25q), p82.

⁹⁵ Scottish Parliament. *Official Report*. Health Committee, 25th meeting, Second Session. October 25, 2005. Submission from the Solicitor General for Scotland. Paper HC/S2/05/25/08, op.cit., p3, and Appendix A.

⁹⁶ Scottish Government, Crown Office and Procurator Fiscal Service, Royal College of Pathologists. *Code of practice and performance for forensic pathologists dealing with suspicious deaths in Scotland*. November 2007. Crown Copyright 2007, op.cit.

⁹⁷ Royal College of Pathologists. *Guidelines on autopsy practice. Report of the Working Group of the Royal College of Pathologists*. London. The Royal College of Pathologists, 2002.

⁹⁸ Scottish Government, Crown Office and Procurator Fiscal Service, Royal College of Pathologists. *Code of practice and performance for forensic pathologists dealing with suspicious deaths in Scotland*. November 2007. Crown Copyright 2007, op.cit., p12, para 6.2.

the scenario which had been described with approval by IRG in relation to cot deaths⁹⁹. This endorsement by the Scottish Government of professionally derived standards and practices was strengthened when, the decision having been taken by COPFS to invite tenders to supply a forensic pathology service on a national basis throughout Scotland, the Invitation to Tender document issued by COPFS stated that ‘all autopsies should be performed ...following best medical practice and, where appropriate, which are in accordance with any guidelines issued by the Royal College of Pathologists and the Scottish Executive Justice Department’.¹⁰⁰

The 2006 Act provided that, as soon as ‘the manager of the establishment where the examination was carried out’ received notice from the Procurator Fiscal that tissue samples were no longer needed to be retained for his purposes, the samples ‘fell to be retained’ as part of the medical record of the deceased person¹⁰¹ and may be used for diagnosis, audit or obtaining information relevant to the health of another person (or, with authorisation, for education, training or research).¹⁰²

This close working in Scotland of the Executive, COPFS and RCPATH towards a common goal and agreed standards stood in striking contrast to the disjunction that occurred in England between the passage of the Human Tissue Bill and the revision of the Coroners’ Rules. In the House of Lords, during Second Reading of the Human Tissue Bill, Baroness O'Neill of Bengarve put a question:

I ask the Minister why this Bill has been brought forward before legislation to revise the Coroners' Rules.... Why was it thought more urgent to reorganise the vast range of uses of human tissues taken from patients for clinical reasons than to clarify and limit coroners' authority to determine subsequent use of tissue lawfully removed post mortem? If we are worried about the events of Alder Hey—clearly we have reason to be—our first move should surely be to address those

⁹⁹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, op. cit., p24, para 43.

¹⁰⁰ Scottish Government. Crown Office and Procurator Fiscal Service. *Invitation to Tender: Provision of forensic and non-forensic pathology services*. Tender reference PCM/04/16. 2004, para 28. Obtained through FOISA, July 18, 2010.

¹⁰¹ *Human Tissue (Scotland) Act 2006*, s.38(2).

¹⁰² *Ibid.*, s.39 (a), (b).

issues rather than to write new laws for the entire range of pathology services for living patients within and beyond the NHS...

It has been said that this Bill constructs a sledgehammer to crack the proverbial nut, but that, unfortunately, it misses the nut. I do not think that we can reshape the hammer to ensure that it really hits the nut because for that we would also need to reform the Coroner's Rules, but I hope that with close attention we may be able to do a little to mitigate the damage potentially caused by hyper complex legislation.¹⁰³

In reply the Minister, Lord Warner, was able only to say:

The noble Baroness, Lady O'Neill, asked why the Bill is coming before the coroners' legislation. We are working closely with colleagues in the Home Office on that. As I said, the revised Coroners' Rules will be brought forward. I assure Noble Lords that we will ensure that those new rules are wholly consistent with the Bill.¹⁰⁴

In a later commentary, Professor Sir James Underwood, who had been President of the Royal College of Pathologists (PRCPath) during the passage of the Human Tissue Bill, was particularly critical of 'the imperfect dovetailing' of the Coroners Rules (as amended) with the Human Tissue Act 2004, which represented, in his view, 'a lamentable flaw' in the new legislation. 'The Human Tissue (Scotland) Act 2006 deals in a more integrated manner with post-mortem examinations ordered by a Procurator Fiscal.'¹⁰⁵ The Coroners (Amendment) Rules 2005 were presented only a few weeks before they were due to come into force. Coroners were informed by circular about the amended Rules on May 10, 2005, only 21 days before the mandatory implementation date.¹⁰⁶ Because of this short notice, Sir James, as PRCPath, appealed to the Home Secretary for a postponement of the

¹⁰³ (2004) 664 (Parl. Deb., Hansard 5th series), HL 394.

¹⁰⁴ Ibid., 428.

¹⁰⁵ Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-203, op. cit., pp200-201.

¹⁰⁶ Home Office. Circular 25/2005. *Coroners (Amendment) rules 2005*. Accessed July 7, 2010 at: <http://webarchive.nationalarchives.gov.uk/20100418065544/http://www.homeoffice.gov.uk/about-us/publications/home-office-circulars/circulars-2005/index10bd.html?d-7095067-p=4>

implementation date, but his letter was never acknowledged.¹⁰⁷ Within a few weeks, responsibility for coroners had moved to the Department for Constitutional Affairs.

3.5.7 Tissue from the living.

The major problem which had been identified in both *Bristol* and *Alder Hey* (the proximate origin of both the 2004 and 2006 Acts) was the absence of 'consent'. This had led to consent becoming 'the golden thread' which ran through the Human Tissue Bill, and resulted, as discussed in Chapter Four, in hundreds of hours of meetings, briefings and adversarial debate seeking to modify this blanket requirement in a number of specific circumstances. Many of the arguments in Westminster related to exemption from the need for consent as provided for in the Human Tissue Bill to be applied to the taking and use of 'surplus' tissue from the living. This problem did not arise in Scotland, because the Scottish Bill contained no provisions concerning surplus tissue. The Scottish Executive's Policy Memorandum on the Human Tissue (Scotland) Bill as it related to surplus or residual tissue '[saw] no need to introduce measures more stringent than those which apply to the consent a living person gives to the carrying out of an operation'.¹⁰⁸ In support of this stance, the Memorandum stated that these proposals had been included in the Executive's pre-legislative consultation and that no representations objecting to the proposals had been received.¹⁰⁹ In fact the prior consultation had not asked any specific questions about surplus tissue. Instead the consultation paper had stated, as an apparent matter of fact, that '[t]issue donation from the living is quite different from live organ donation. Bone and other tissue is often regarded as a

¹⁰⁷ Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-203, op. cit., p201.

¹⁰⁸ Scottish Parliament. *Human Tissue (Scotland) Bill: Policy Memorandum*. June 3, 2005, op.cit., p6, para 24. Accessed June 2 2010 at: <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-introd-pm.pdf>

¹⁰⁹ Scottish Parliament. *Human Tissue (Scotland) Bill: Policy Memorandum*. June 3, 2005, op.cit., p6, para 24. Accessed June 2 2010 at: <http://www.scottish.parliament.uk/business/bills/42-humanTissue/b42s2-introd-pm.pdf>

waste product in that it would normally be discarded’.¹¹⁰ The consultation paper had indicated that the Executive would rely on standard authorisation forms and patient information leaflets on the use of ‘surplus’ tissue which were being developed by the Scottish Medical and Scientific Advisory Committee. These documents were to be scrutinised by the Health Department to ensure that the contents were broadly consistent with the arrangements for such tissue in the Human Tissue Bill, taking ‘full account’ of the relevant points raised in the debates on the Bill in the Westminster Parliament.¹¹¹

In the Scottish Parliament, in the Stage 1 debate, the proposed approach to tissue from the living was judged by Brian Adam MSP to be ‘one of the reasons why the Human Tissue (Scotland) Bill is so much better than the Human Tissue Act 2004’.¹¹² To date I have been unable to find evidence of any external advice to the Scottish Executive regarding the need, or not, for new legislation on tissues from the living. During his speech, Brian Adam MSP (who was a member of the Health Committee which had produced the Stage 1 Report on the Bill) also said:

I wish to talk about what is not in the Bill, probably as a consequence of the very sensible procedures that we have adopted. *In the early stages, thought was given to the need for authorisation or consent...to be given for the use of ante-mortem material for any purpose*(my emphasis). That purpose would have had to be specified every time that a person went to the doctor and had a blood specimen taken...I am delighted- as, indeed, are many people in the medical and associated professions- that we dropped all that nonsense.¹¹³

The implication is that at sometime early in the drafting or consultative process, advice, perhaps from the medical profession, was received and marked.

Alternatively, it may be that the protracted debates in Westminster on the need for legislation on living tissue had an influence in Scotland, if indirectly. Indeed, Lord

¹¹⁰ Scottish Executive. *Legislation relating to organ and tissue donation and transplantation: a consultation paper*. March 18, 2004, p21, para 58.

¹¹¹ Ibid.

¹¹² Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1). November 30, 2005, col 21250.

¹¹³ Ibid.

Turnberg's speech at Second Reading in the House of Lords could have been taken as a template for the later Scottish decisions:

The Bill very reasonably and rationally distinguishes between tissues and organs taken from dead bodies and samples taken from living patients at operation—appendices, tonsils, cancers and the like. One might think that all that was needed in the Bill was a stringent set of regulations for post-mortem organ retention in response to the Alder Hey and Bristol scandals, and that the useful research of tissues taken at operation could have been left out of the Bill.

After all, if one wants to do research now on such tissues, one must always have ethics committee approval, and that will be given only where consent has been, or will be, obtained from patients, or where the tissues have been anonymised;¹¹⁴

To which the Minister, Lord Warner, responded, invoking attitudes of the public and researchers to tissue from the living which were at variance with the evidence I have been able to identify^{115 116}:

Arguing the distinction between tissue from the deceased and from the living overlooks the fact that the public do not always make that same distinction.

A number of noble Lords have asked why we cover tissue from the living and do not just concentrate on the coroner's area and tissue from deceased people. That assumes that the present arrangements are satisfactory... They are muddled, and they cause concern for many medical researchers.¹¹⁷

3.5.7.1 Sources of prior advice?

In some ways, the elusiveness to me of detectable sources of prior advice to the Scottish Government on tissues from the living is comparable to a similar absence of detectable sources from the Chief Medical Officer's *Advice on the Removal, Retention and Use of Human Organs and Tissue from Post-mortem Examination* which was presented to Parliament in Westminster in January 2001. That document baldly stated as 'background' that 'questions have also arisen about the

¹¹⁴ (2004) 664 (Parl. Deb., Hansard 5th series), HL 381.

¹¹⁵ Parl. Deb.,(HC). Standing Committee G.Official Report, 2003-4, vol. VI. *Human Tissue Bill*, January 27, 2004, col. 8.

¹¹⁶ Wellcome Trust. *Department of Health consultation on 'Human bodies, human choices': Wellcome Trust response*. October 2002, p2, para 6.

¹¹⁷ (2004) 664 (Parl. Deb., Hansard 5th series), HL 425.

importation of human material for teaching purposes, the commercial use of tissue and *the controls on taking, using and storing tissue and organs removed from the living both for therapeutic or research purposes*'(my emphasis). That is the only sentence in the report to give support to the CMO's 'Recommendation 6' that 'as soon as possible, there should be a more fundamental and broader revision of the law, encompassing the taking, storage and use of human tissue *from the living* (my emphasis) and the dead and introducing an independent system of regulatory control'.¹¹⁸

Contrary decisions about living tissue having been taken, apparently behind closed Departmental doors in Edinburgh and London, the practical consequences were: in Scotland, standards for taking and using tissue from the living became the responsibility of the Chief Scientist Office, through its clinical and research governance arms. Throughout the rest of the United Kingdom, responsibility came to rest with the Human Tissue Authority.

3.5.8 Awareness of parental sensitivities.

Throughout the process which led to the 2006 Act, there were a striking number of references to the importance of being sensitive to the wishes of those parents and relatives who did not object to post-mortem examination but who did not want to be given information. This concern appeared in the IRG Preliminary¹¹⁹ and Final Reports¹²⁰, was repeated during the proceedings of the Health Committee¹²¹,

¹¹⁸ Department of Health, Department for Education and Employment, Home Office. *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*. London. The Stationery Office, 2001, op.cit., p41, Recommendation 6.

¹¹⁹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post- Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 1(10), p77.

¹²⁰ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post- Mortem. Final Report*. November 2001, op. cit., pp20-22, paras 24-25, 33.

¹²¹ Scottish Parliament. *Official Report*. Health Committee. 21st meeting , Second Session. September 13, 2005. Paper HC/S2/05/21/14: Submission from the Scottish Council for Bioethics.

featured in the Policy Memorandum for the Human Tissue (Scotland) Bill¹²², and eventually found its way into guidelines¹²³.

As far as I have been able to determine the origins of this approach lay in written and oral evidence given to IRG by parents and members of the lay public, for example 'Permission should be asked prior to post-mortem being carried out, but it is not necessary to go into details. This could involve too much information and could be distressing'.¹²⁴ The authors of one letter, a Mr and Mrs D Knowles, he a moral philosopher and she a school teacher, whose baby had died of congenital heart disease, particularly impressed the Review Group, and they were invited to expand on their thoughts in oral evidence. Mr and Mrs Knowles had previously written:

[We] have followed the press reports [about Bristol] and listened to interviews with relatives of dead children and representatives of parents' groups, all of whom have deplored the practice of removal, retention and disposal of organs without full consent being given to these processes at every stage. We thought that these parents' groups were not speaking for us...

The Bristol inquiry report said it could not square the circle of meeting the demands of the parents who do not want to know and the parents who do, and so decided the issue in favour of those who do (or rather, those who said retrospectively that they would have preferred full knowledge and the opportunity of informed consent).

The Scottish Review Group can do better than this.¹²⁵

IRG took the views of Mr and Mrs Knowles very seriously. The transcript of the exchanges during their oral evidence ran to 18 pages and 13,500 words. The

¹²² Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p10, para 41.

¹²³ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post- Mortem. Report on Phase 3*. November 2003, op.cit., p8, para 3. See also Appendix 3, p118.

¹²⁴ Review Group on Retention of Organs at Post-Mortem. *Letters to the Review Group from relatives and members of the public*, p3. Accessed on July 7, 2010 at: <http://www.sehd.scot.nhs.uk/scotorgrev/Documents/Letters.PDF>

¹²⁵ Ibid., pp7-10.

message which the Group accepted was encapsulated by Mrs Anne Knowles when she said:

There may be other people who do want [to have full information] and I think that has to be a very personal thing which is why if you have a code of practice it has to be sensitive to a huge spectrum of people's emotions and sensitivities.¹²⁶

I believe that the Knowles evidence, given so impressively, is likely to have been a significant factor in the 'authorisation/consent' discussions within the Group, and led to the recurring references throughout to 'those who do not wish to know', described above, and which was captured in the Policy Memorandum.¹²⁷ [Knowles later expanded his ideas and made an alternative proposal to 'an oppressive code of practice' in a thought provoking paper which involved 'a practice of agreement'.¹²⁸]

4. Summary and overall conclusions.

Professor Sir James Underwood, Past President of the Royal College of Pathologists, a man who had been closely involved with the genesis of the Human Tissue Act 2004 and who had served on the Human Tissue Authority wrote in 2009 that: 'The Human Tissue (Scotland) Act 2006 is a more proportionate response to the past problems arising from post-mortem organ retention'¹²⁹; a view which was also taken by the Joint Parliamentary Committee on the Human Tissue and Embryos (Draft) Bill ¹³⁰. I have come to share that view.

¹²⁶ Review Group on Retention of Organs at Post-Mortem. *Transcript of evidence of Mr and Mrs Knowles at a meeting of the Review Group*. January 16, 2001. Accessed on July 9, 2010 at: <http://www.sehd.scot.nhs.uk/>

¹²⁷ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, op. cit., p10, para 41.

¹²⁸ Knowles D. *Parents' consent to the post-mortem removal and retention of organs*. *Journal of Applied Philosophy* 2001;18(3): 215-227, pps224-226.

¹²⁹ Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. *Bulletin of the Royal College of Pathologists* 2009; no.147: 198-203,op.cit., p202.

¹³⁰ Joint Committee on the Human Tissue and Embryos (Draft) Bill (Session 2006-07). Volume 1: Report. The Stationery Office, 2007, p36, para 114.

The Human Tissue (Scotland) Act 2006 has a number of significant differences from, and consequences of, the Human Tissue Act 2004, particularly in regard to the concept of authorisation, retention of tissue blocks and slides for diagnostic purposes, aligning of standards for hospital and Procurators Fiscal post-mortem examinations, and the use of surplus tissue and other tissue from the living. If there was a central driver to the shape of the Scottish legislation, I believe it may be found in the conclusion reached early in the deliberations of IRG that post-mortem examination should properly be regarded as an integral part of patient care which continued after death. The conduct of post-mortems was an issue of clinical governance with ultimate responsibility for the process resting with the chief executive of the relevant NHS Trust.¹³¹ The need to retain good clinical records ('tissue blocks and slides'), the development of clear standards and audit of performance followed logically thereafter.

As to comparison of processes between Edinburgh and Westminster, two factors stand out. The first is procedural, and relates to the extensive early scrutiny which is built into the Scottish Parliamentary system; and which led in the specific instance to the extensive work of the Health Committee during Stage 1 and to its Stage 1 report, prior to the first debate 'on principles' in the Scottish Parliament. The second is also to an extent procedural, but perhaps also cultural, and relates to the openness and the thoroughness of the consultative process at all stages, from Independent Inquiry to Parliamentary Act. Nothing illustrates this better than the seriousness with which the views of two, thoughtful, bereaved parents were taken.

Last, it is impossible to say whether or not the absence of Ministerial hyperbole in the early stages of the Scottish organ 'scandal', in comparison to the public attitude struck by the Rt Hon Alan Milburn MP to *Alder Hey*, had an influence in the manner in which officials, professionals, and parents' representatives went about their work subsequently. If such influences existed, they must surely have favoured the more

¹³¹ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), op. cit., 1(17), p78.

Northerly events. This view may have been shared by Baroness Cumberledge who, during Second Reading of the Human Tissue Bill in the House of Lords, said:

Looking back at what happened, it is interesting that the concern was centred on post-mortem practice, whereas much of the Bill is not about post-mortem practice but ante-mortem practice. I very much agree with my noble friend Lord Jenkin, who said that when the issue blew up the Government's response exacerbated the situation... as legislators, do we not have to be careful not to over-react but to get the balance right?¹³²

¹³² (2004) 664 (Parl. Deb., Hansard, 5th series), HL 399.

CHAPTER SIX

Further analysis, conclusions and recommendations.

1 Recapitulation.

The purpose of this Thesis has been to examine, through analysis of the contribution of forces, interests, issues, organisations and individuals, the development of policy and associated legislation over the past half century regarding human tissue, and in particular the research use of tissue. This Chapter attempts to summarise and further highlight the important factors and to reach some overall conclusions.

The approach, it is submitted, has been aided by having used throughout the Thesis a 'systems' and 'framework' methodology. The justification for its use is several-fold. Drewry presented his 'systems' model as being a useful means of comparing the law-making systems and processes of different countries.¹ England and Scotland have different legislative systems; and a comparison of social attitudes and relationships in the UK between 1961 and 2000 appeared at times to be a description of the prevailing culture of two different countries. The methodology has had the further advantages identified by Hogwood and Dunn: it is *dynamic*, aids the identification and study of *interactions*, and is *flexible*, in that it allows existing knowledge to be systematised without precluding the integrating of future insights.²

Drewry emphasised that the systems approach encouraged questions rather than pretending to provide cut and dried answers.³ This has certainly been the case in the present study, although the possibility that some answers have emerged along the way is not precluded!

2 Further analysis.

¹ Drewry G. Law-making systems- how to compare. Statute Law Review 1993; 29(2): 100- 110.

² Hogwood BW, Gunn LA. *Policy analysis for the real world*. Oxford. OUP, 1984, pp 24-26.

³ Drewry G. Law-making systems- how to compare. Statute Law Review 1993; 29(2): 100- 110, op. cit., p 110.

2.1 Factors operating on both sides of the English- Scottish border as ‘inspiration’ for new legislation.

2.1.1 ‘Normal’ post-mortem practice, including organ ‘collections’, combined with misunderstanding of an ‘uncertain’ law.

The *Bristol*, *Redfern* and *Isaacs* inquiries revealed, with regard to post-mortem examinations, a set of practices, relationships and beliefs that were to be found throughout the UK. Before the Human Tissue Act in 1961, pathologists had been used to removing organs at post-mortems that appeared to be of interest for research or teaching purposes. In addition, by the late 1950s the feasibility had arisen of taking tissues for the emerging science of transplantation. Although the passing of the 1961 Act imposed a discipline on transplantation practice, the customary habit of retaining tissues of interest continued in the decades thereafter, little influenced by the Act. It was to an extent learned behaviour, with doctors in training following the example and the practices of earlier years set by their seniors. The revelation in 1999 by Professor Robert Anderson of the existence of organ ‘collections’ was a seminal moment.⁴ In addition, there was widespread ignorance or at least misunderstanding of the relevant law, which, from the evidence that the Royal College of Pathologists felt it necessary to reissue Bernard Knight’s 1985 guidance in 1990 (Chapter Two, 3.3.2), persisted into the 1990s.⁵ The Human Tissue Act 1961 was found by *Bristol* to be ‘obscure, uncertain and arcane’, but this ‘fact’ was not offered by that Inquiry as a mitigating factor in favour of doctors within the ‘social and ethical time bomb’ which was said to have existed. In Scotland, the Independent Review Group (IRG) also found evidence of a paternalistic attitude of doctors towards post-mortem examination but ‘no

⁴ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. Annex A. May 2000, p6, paras 16-17.

⁵ Registrar’s column. *Legal considerations in the retention of post mortem material*. Bulletin of the Royal College of Pathologists 1990; no. 70:3.

evidence that past practice was motivated by anything other than the tradition of medicine in seeking to improve care of future patients'.⁶

Within my present studies I found evidence (see Chapter One, and published elsewhere⁷), that the Ministry of Health's instructions to Parliamentary Counsel in 1960 for the Human Tissue Bill had identified the requirement that both 'retention' of tissue and 'consent' of relatives should be provided for in the draft legislation, but that, after correspondence between Counsel and Ministry officials, both terms had been omitted from the Bill and subsequent Act. 'Tissue retention' and 'consent' became the central issues in the headline-provoking inquiries 40 years later. It is therefore at least arguable that their omission from statute was a contributory factor to the 'misunderstanding' of doctors of the law relating to retention of tissue from coronial autopsies⁸. Of course this explanation could not be applied to those doctors who admitted privately to having never read the provisions of Human Tissue Act 1961⁹, but might at least have influenced the teaching of junior colleagues by those who had done so.

The variation in practice within coronial 'fiefdoms' revealed by the inquiries cannot have helped doctors towards a uniform understanding of the law. In *Redfern*, 'slackness' of coronial procedures was found to be a contributory factor. In *Isaacs*, the Coroner's Office in one district had been actually responsible for identifying to the clinicians cases which might be suitable for brain research. Further, the author of *Isaacs* was satisfied from indirect evidence that some coroners had asked pathologists to refrain from mentioning retention in their post-mortem reports. In

⁶ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), 8.2 (52), p89.

⁷ McNeish AS. *Anticipating the Redfern Inquiry: a historical note about tissue retention and consent*. J Clin Pathol 2009; 62: 958-959.

⁸ Department of Health. *Isaacs report: the investigation of events that followed the death of Cyril Mark Isaacs*. Accessed August 25, 2010 at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4064681

⁹ Private conversations.

Bristol there was conflicting evidence given by clinicians and the then current coroner as to what guidance the previous coroner had given. With regard to Scotland, I have been able to find only indirect evidence within the IRG report which pointed to some inconsistencies of practice of Procurators Fiscal in the past¹⁰, but gave no hint of complicity or a ‘blind eye’ having been turned.

2.1.2 Issues of communication and consent.

All the Inquiries revealed that there had been a lack of awareness among the public of what a post-mortem examination entailed, and that even where ‘consent’ (technically ‘non-objection’) had been recorded it could not have been, in many instances, an informed decision. Doctors freely admitted to having used euphemisms or imprecise language when seeking consent, their honestly-held motivation having been to spare grieving relatives further distress.¹¹ This motivation was accepted in *Redfern* and the Scottish IRG Report, within an approach labelled ‘paternalistic’ and judged to be outmoded in the year 2000. The harsher analysis of Kennedy and colleagues in *Bristol*, that doctors had shown ‘arrogance born of indifference’, was sharply rebutted by the President of the Royal College of Pathologists as an ‘ill considered opinion’.¹² Pathologists had long believed that organ and tissue retention was an integral part of the post-mortem process, a point emphasised by Bennett.¹³ A joint report from the Royal Colleges as early as 1991 had advised that obtaining ‘permission’ for a post-mortem should include information about the benefits for ‘teaching and research’. It further advised that the consent form ‘must allow relatives to permit a full autopsy

¹⁰Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 (‘The Preliminary Report of February 2001’), 9.2 (90), p103.

¹¹ The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Interim Report: Removal and retention of human material*. May 2000, p29, para 102.

¹² Underwood JCE. Human Tissue Legislation in the United Kingdom: the need and prospects for amendment. *Bulletin of the Royal College of Pathologists* 2009; no.147: 198-202, at 198.

¹³ Bennett JR. *The organ retention furore: the need for consent*. *Clin. Med.* 2001; 1(3): 167-171 at p 169.

examination or to restrict the examination, or the use of tissue, in keeping with the Human Tissue Act 1961'.¹⁴

Throughout the period 1960- 2000, the relevant professional bodies, such as GMC, RCP and RCPATH operated on both sides of the border, and exerted a largely conservative influence- whether or not they fully merited Maurice Shock's attribution of a motto 'the status quo is the way forward'¹⁵. I have tried in Chapter Three to place doctors' 'failures' as revealed in the Inquiries within the failure of the profession to recognise that paternalism, even when it was benign, had become less acceptable in a society in which 'patient/customer/client autonomy was emerging as the new order'¹⁶: thus leaving far behind Miss Pitt's call in 1961 that [Parliament] must give the doctors what they required for improvements in treatment, education and research¹⁷. While failure, or at least a tardiness, of doctors in the latter part of the 20th century to incorporate adequate information giving and consent seeking into their day to day practice was widespread, and caused understandable distress among individual parents, it does not fully explain, in my view, the explosion of public emotion generated by the revelations of, in particular, *Bristol* and *Alder Hey*- emotions which were undoubtedly a major 'inspiration' for the legislation which followed. Additional factors may have been at work, which are considered immediately below at 2.1.3 to 2.1.5.

2.1.3 The collective pressure exerted by parents and relatives.

Put starkly, parents were the true *fons et origo* of the 2004 and 2006 legislation. From Mrs Helen Rickard's discovery in Bristol that her deceased daughter's heart had been retained there arose the parents' group, led by Mrs Michaela Willis, who

¹⁴ Royal College of Pathologists. *The autopsy and audit: Report of the joint working party of the Royal College of Pathologists, Royal College of Physicians of London, Royal College of Surgeons of England*. August 1991.

¹⁵ Shock M. *Medicine at the centre of the nation's affairs*. BMJ 1994; 309 (6970): 1730- 1733 at p1732.

¹⁶ Irvine D. *The doctor's tale: professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, p5.

¹⁷ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1235.

successfully lobbied the Secretary of State for Health to set up the *Bristol Inquiry*. That Inquiry shone a light on Alder Hey Hospital, whose parents' group, PITY II, created headlines and inexorable pressure for a further Inquiry. Parents' groups elsewhere in England and Wales added their voices. In Scotland, a single request from an [anonymous to me] mother to Yorkhill Hospital about whether there were any stored 'tissues' from her previous stillborn child led, within eight months, to demands to the Health Minister from a range of parents' groups for an inquiry into organ and tissue retention.

Into this brief account must be added the name of Mrs Elaine Isaacs. Her persistence in seeking information about what had happened to the brain of her dead husband led to a nation-wide inquiry and the recognition that organ retention from adult PMs without consent had been a customary practice.

2.1.4 The Press.

That the press played a role in the 'inspiration' phase on both sides of the border cannot be doubted. Ever since the recognition in 1840 by Thomas Carlyle of 'the Fourth Estate',¹⁸ numerous academic studies have confirmed the importance of the press in influencing public opinion^{19 20 21 22 23}, itself an important trigger for new legislation in Drewry's model. In a fascinating study directly relevant to the press

¹⁸ Carlyle T. *The hero as man of letters: Johnson, Rousseau, Burns (Lecture V, May 19, 1840)* In: On heroes and hero worship <http://www.victorianweb.org/authors/carlyle/heroes/hero5.html>, retrieved January 10, 2010 ([Project Gutenberg](#). Scanned and proofed by Ron Burkey (rburkey@heads-up.com). The text is taken from the printed "Sterling Edition" of Carlyle's *Complete Works*, in 20 volumes.)

¹⁹ Lundberg GA. *The newspaper and public opinion*. Social Forces 1926; 4(4):709-715 at p709.

²⁰ McCombs ME, Shaw DL. *The agenda-setting function of the mass media*. Public Opinion Quarterly 1972; 36(2): 176-177.

²¹ Page GI, Shapiro RY, Dempsey GR. *What moves public opinion?* American Political Science Review 1987; 81(1): 23-43 at p24.

²² Carey S, Burton J. *Research note: the influence of the press in shaping public opinion towards the European Union in Britain*. Political Studies 2004;52: 623-640.

²³ Burstein P. *The impact of public opinion on public policy: a review and an agenda*. Political Research Quarterly 2003; 56(1): 29-40.

coverage of the 'organ scandals', Mutz and Soss found that a newspaper campaign, although limited in its ability to bring about changes in the opinions of individual members of the mass public, had significant effects on citizens' *perceptions* of the salience the community as a whole attached to an issue, and on their *perceptions* of the dominant climate of opinion.²⁴ Williams and Calnan described three different functions which the media may perform within the mediation of contemporary experience.²⁵ My review of the press output on the day following publication of *Redfern* revealed strong 'consumerist' tendencies, with a few laudable attempts in addition to 'get behind the facts'. It would be wrong to ascribe motives of 'mass manipulation' on the day- although one recalls the charge of at least one journalist that the Secretary of State had taken prior steps to ensure that the pre-report atmosphere was as highly charged as possible.²⁶ The outrageous behaviour of one rogue pathologist, Van Velsen, and the sometimes (to my eye) intemperate language used in *Bristol* to describe doctors, also played their part.

The press had also played a role, but a different one, in the genesis of the 1961 Act. First, in this period when the wonders of science were extolled, newspapers carried headline accounts about successful organ transplants which must have caught public imagination. [It caught the imagination of Miss Joan Vickers MP who suggested that the Human Tissue Bill should have been named the Human Aid to Medical Science Bill.²⁷] Second, correspondence in the medical press around 1960 about practical difficulties in undertaking kidney transplantation was picked up by the national press under such headlines as 'Grafting operations raise problems. Legislation needed.'²⁸ Third, there is evidence that officials, when preparing the case in 1960 for 'tissue grafting' legislation, had been imbued with a sense of

²⁴ Motz DC, Soss J. *Reading public opinion: the influence of news coverage on perceptions of public sentiment*. Public Opinion Quarterly 1997; 61(3): 431-451.

²⁵ Williams SJ, Calnan M. *The 'limits' of medicalization? Modern medicine and the lay populace in 'late' modernity*. Soc. Sci. Med. 1996; 42 (12): 1609-1620, at p 1615.

²⁶ The Times (London). Feature: *Overwrought response*. January 31, 2001.

²⁷ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1238.

²⁸ *The Scotsman*. November 1, 1960.

urgency, or at least unease, 'because the interest in the subject indicated by recent articles in the medical and lay press make it not impossible that we may be challenged [as to the legitimacy of grafting operations]'.²⁹

2.1.5 A desecration of the dead, as a factor?

The 'stories' of Bristol, Alder Hey, and Yorkhill carried lurid headlines. Laurance asked rhetorically, in respect of the *Alder Hey* Inquiry, what was the appropriate emotional response to the grim revelations? It seemed to him that the normal grief that bereavement brings to parents and relatives had become supercharged by the knowledge that a wrong had been committed. All the pain of loss had been translated into anger at those responsible for what was portrayed as a desecration of the dead- and in turn to demands for retribution.³⁰

The area is complex, and a thorough review of attitudes to death, dead bodies, autopsy, dissection and burial is beyond the scope of this Thesis. According to the historian Ruth Richardson, dissection represented to popular belief a gross assault upon the integrity and identity of the body *and* upon the repose of the soul, each of which- in other circumstances- would have been carefully fostered.³¹ Today, attitudes are ambivalent. To some, 'they're just dead bodies', with a view that what happens to the body after death is of no consequence after life has left it.³² Yet a hospital Chief Executive in Bedford was forced to resign in 2001 after seven corpses had been stored on the floor in the hospital chapel because a broken door had rendered the auxiliary mortuary unusable, and photographs had appeared in the press. Relatives were 'understandably distraught'.³³ Savulescu, reminiscing in

²⁹ National Archives. Ref. MH58/497. Memorandum from SI Smith to D Emery, undated [?June 1960].

³⁰ Laurance J. *Health check: in sorrow and in anger*. *The Independent* (London), December 14, 2000, p8.

³¹ Richardson R. *Death, dissection and the destitute*. London. Routledge and Kegan Paul, 1987, p76.

³² The New Statesman. *They're just dead bodies*. January 22, 2001.

³³ Abbasi K. Editorial: *Death underfunded: the mortuary service needs resources, not resignations*. *BMJ* 2001; 322 (7280): 186.

another context, expressed well the belief that pervades all cultures, albeit with a variety of modes of expression, that 'we should show respect for the dead'.³⁴

Bristol and *Alder Hey* had an extra dimension in that most of the organs belonged to children, and their taking perhaps emphasised the tragic and emotional aspects of their premature death.³⁵ This view is supported by a substantial academic literature.^{36 37 38 39 40 41 42}

2.1.6 Medical science and society.

As discussed, particularly in Chapter Three, by the 1990s 'the [role of] the doctor was different, the patient was different and medicine was different'⁴³, changes to which doctors were slow to respond: while science (as examples: the feasibility of tissue banks; genetic diagnosis) was progressing inexorably, albeit without unquestioning public trust.⁴⁴

2.1.7 A wish for recompense and retribution?

³⁴ Savulescu J. *Death, us and our bodies: personal reflections*. J Med Ethics 2003; 29(3): 127-130 at p128.

³⁵ The Royal Liverpool Children's Inquiry Report. Printed by order of the House of Commons, January 30 2001, op.cit., Chapter 14, p408.

³⁶ English V, Sommerville A. *Presumed consent for transplantation: a dead issue after Alder Hey?* J Med Ethics 2003;29(3): 147-152 at p148.

³⁷ Webb T. *Alder Hey: looking for the diagnosis*. Accessed May 10, 2010 at: <http://www.bmj.com.ezproxid.bham.ac.uk/cgi/eletters/322/7282/309#12874>

³⁸ Black D. *Coping with loss: the dying child*. BMJ 1998; 316(7141): 1376-1378.

³⁹ Parkes CM, Weiss RS. *Recovery from bereavement*. New York, Basic Books, 1983.

⁴⁰ Patel P. *What have we learned from the Alder Hey affair? That we still fear death and dying*. Accessed May 10, 2010 at: <http://www.bmj.com.ezproxid.bham.ac.uk/cgi/eletters/322/7282/309#12913>

⁴¹ Sque M, Long T, Payne S, Roche WR, Speck P. *The UK post-mortem organ retention crisis: a qualitative study of its impact on parents*. J R Soc Med 2008; 101: 71-77.

⁴² Brazier M. *Retained organs: ethics and humanity*. Legal Studies 2002; 27(4): 550- 569, pp550-551.

⁴³ Smith R. Editorial. *Medicine's core values*. BMJ 1994; 309 (6964): 1247-1248.

⁴⁴ Haerlin B, Parr D. *How to restore public trust in science*. Nature 1999; 400 (6744): 499.

The financial settlements made to parents in England (Chapter Four, 1.2.7) and in Scotland Chapter Five, 2.2.2) are recorded in this section as ‘inspiration’ factors, in the sense that they represented yet another commitment by government to right a wrong. In passing one may also note the difference in ‘style’ between a litigious approach in England and a blanket compensation scheme adopted by the Scottish Executive.

2.2 Cross-border differences acting within the ‘inspiration’ phase for new legislation.

2.2.1 The ‘in-tray’.

I proposed in Chapter Two, that, in the absence of systematic post-legislative scrutiny in the 1960s to 1990s (a usual state of affairs at that time), there would nevertheless have been at least an erratic flow of information back to the Ministry of Health and its successor Departments as to whether or not the objectives of the Human Tissue Act 1961 were being achieved and whether any problems had occurred; information which might, or might not, have been a stimulus to further action. This I termed the ‘in-tray’.

Although the 1961 Act applied throughout the UK, and although certain contents of the in-tray were relevant nation-wide (for example, difficulties in interpreting ‘such reasonable inquiry as was practicable’; a wish by some, including the MPs discussed in Chapter Two, to increase organ donors by opt out legislation; increasing awareness in Parliament of public opinion), all the individual cases of contravention of the provisions of the 1961 Act, as revealed by my searches in The National Archives at Kew (with files from 1980 being the most recently declassified), occurred in *England* (see Chapter Two: Couve de Murville; Ford; O’Sullivan; McEldowney; ignoring by Regional Medical Officers and their officials of DHSS circular HC (IS)156, revealed at the time of the ‘pituitary collection headlines’) – all of which, together

with the pressure of Sir Gerald Nabarro and colleagues in Westminster, had led officials to draft amending legislation.⁴⁵

In contrast, a conscientious search of files in Edinburgh of the National Archives for Scotland, using the same search terms as used in Kew, revealed no such examples of errant doctors or transplantation irregularities. (These Archives contained copies of the draft proposals for amending legislation drawn up by officials in London in 1970-71, a legal opinion for the Scottish Home and Health Department about the legality of obtaining pituitary glands at post-mortem⁴⁶ and a copy of the Scottish version of an NHS circular sent to all Health Boards in 1975⁴⁷ following the problems with the MRC's Human Pituitary Collection).

2.2.2 The Reports, and early government response.

More direct differences, and certainly pertinent to a comparative analysis of the 'inspiration' phase in Scotland and England, can be found in the Inquiry reports about organ retention, both in the scale and practice of retention and in the language used. Consider first the language of the *Bristol* Interim Report:

We may regret that those standards were the product of a small group of professionals talking to themselves. We may agree that they reflected a degree of professional arrogance. We may lament that they displayed a lack of interest in, or paternalism towards, the views and feelings of parents. But that was how things were⁴⁸;

phrasing interpreted by a legal correspondent of a medical journal that "doctors' arrogance born of indifference' was to blame⁴⁹, and described by the President of

⁴⁵ National Archives. Ref. MH150/399. Document D49: *Human Tissue Act 1961*, December 1971, with appendices; also Memoranda M47, M48, M51, M53. Also Document D29A. WG Robertson, *Draft consultation document.*, May 16, 1970.

⁴⁶ The National Archives for Scotland. Ref. HH102/1010. Scottish Home and Health Department. *Human Tissue Act: Post Mortems*. Memorandum by M. Maclean. March 17, 1976.

⁴⁷ Scottish Home and Health Department. NHS circular 1975 (GEN) 34. *Human Tissue Act 1961*.

⁴⁸ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 ('The Preliminary Report of February 2001'), p17, para 56.

⁴⁹ Dyer C. *Doctors' arrogance blamed for retention of children's organs*. BMJ 2000;320 (7426): 1359.

Royal College of Pathologists as ‘the strident and almost sneering tone of the Report’.⁵⁰

Next, the findings with regard to medical practice at Alder Hey Hospital (which had been aggravated by coronial ‘slackness’ and wide ranging failures of management) were believed by *Redfern* to reveal that:

[t]he practice [of organ retention without consent] arose from a sense of paternalism on the part of the medical profession which served to conceal retention in the supposed best interest of the parents’⁵¹; ‘a further aggravating feature has been Professor Van Velzen’s behaviour... He must never practise again.’⁵²

In contrast, the Independent Review Group found with regard to practice:

[n]o evidence in Scotland of the shocking practices discovered at Alder Hey⁵³; [a]bsolutely no evidence of any cases of retention of a body’s entire set of organs⁵⁴; in some cases [hearts and brains] may not yet have been used for education or research purposes, but this does not mean they will not be used for these purposes in the future. Their potential value is considerable⁵⁵;

and with regard to the conduct of doctors:

[i]n the past, the medical profession has taken a paternalistic attitude towards post-mortem examinations⁵⁶...Nonetheless, it should be stated that we have found no evidence that past practice was motivated by anything other than the tradition of medicine in seeking to improve care of future patients⁵⁷.

⁵⁰ Ibid.

⁵¹ The Royal Liverpool Children’s Inquiry Report. Printed by order of the House of Commons, January 30, 2001. Chapter 15, p444, para 1.

⁵² Ibid., para 4.

⁵³ Scottish Executive Health Department. *Independent Review Group on Retention of Organs at Post-Mortem. Final Report*. November 2001, Appendix 2 (‘The Preliminary Report of February 2001’), 1 (4) p75.

⁵⁴ Ibid., 8.3 (66) p 93.

⁵⁵ Ibid.

⁵⁶ Ibid., 8.1 (52) p 89.

⁵⁷ Ibid.

I believe it plausible to suggest that the readership of these Reports, which would have included, as appropriate, the Secretary of State for Health in England and the Minister for Health and Community Care in Scotland, could have been ‘inspired’ towards different responses.

2.2.3 The Human Tissue Act 1961 was not listed in Schedule 5 to the Scotland Act 1988.⁵⁸

It is possible that the decision of the Scottish Parliament to take its own line was a product of nationalism and the calendar. The passing of the Scotland Act 1998⁵⁹ was followed by the election of the first Scottish Parliament on May 6, 1999, with assumption of full legislative powers on July 1 of that year. Thus, when events at Bristol and Alder Hey were revealed, and subsequent revelations at Yorkhill Hospital and elsewhere in Scotland followed, they came to the attention of a young Parliament with no ‘baggage’, faced with an issue upon which the power to legislate had been devolved, and with a desire to fulfil the First Minister’s wish that the Parliament ‘[should strive] to do right by the people of Scotland; to respect their priorities; to better their lot; and to contribute to the commonweal’.⁶⁰ This hope was reflected in the ‘delight’ of Brian Adam MSP in the Stage 1 debate on the Human Tissue (Scotland) Bill that ‘on this occasion the Executive has chosen not to go down the harmonisation route [with the Westminster Parliament] but to deal with the situation in our own way. We have our own practices and our own needs’.

⁶¹ Perhaps the youth of the Scottish Parliament and its absence of ‘baggage’ may be exemplified by another contributor to the Stage 1 debate, Helen Eadie MSP: ‘In the past six years, there will have been moments when individual MSPs have felt that the legislation they were passing was the most important of all. The part of

⁵⁸ *Scotland Act 1998*. 1998 (c. 46.) Schedule 5: Reserved matters.

⁵⁹ *Scotland Act 1998*. 1998 (c. 46.)

⁶⁰ Scottish Parliament. *Opening ceremony: speech by Donald Dewar MSP*. July 1, 1999. Accessed on August 27, 2010 at: <http://www.scottish.parliament.uk/vli/history/firstDays/1999opening4.htm>

⁶¹ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1). November 30, 2005, col. 21250.

the bill that deals with organ retention that can lead to transplantation is, for me, the most critical that we have ever passed'.⁶²

The passage of the 2006 Act, although important, was achieved through 'standard procedures', and fitted within a more general perspective of the work of the Scottish Parliament during its first decade published in 2009:

The imagery of the new [political process] may have been overdone, but that does not mean that no progress has been made in realising some of the optimism and idealism that accompanied the establishment of the Scottish Parliament. [T]he mix includes real positives: in opening up the parliament to citizens and interest groups (not just 'the usual suspects'), in taking equal opportunities more seriously, in moving some way to using the parliament's committees to realise the founding principles, and in holding government to account.⁶³

2.3 Factors important in 'deliberation and formulation'.

I have been able to verify this process in some detail with regard to the Human Tissue Act 1961, through papers in The National Archives identified in Chapter One. In my study of the 2004 and 2006 Acts direct scrutiny of recent internal Departmental or Cabinet papers was not possible because they will remain classified at least until 2034- 6. Nevertheless, it has been possible to construct a coherent account of the process, for the purposes of comparison, from publicly available documents supplemented by specific requests under the Freedom of Information Acts for England and Scotland. Significant differences emerged of time and place.

2.3.1 The role, and perceived status, of the medical profession.

A striking difference between the 1961 Act and the later Acts, and to an extent between the 2004 and 2006 Acts themselves, was in the role of the medical profession. As discussed in Chapter One, during the period leading up to 1961 doctors were in the driving seat. Sir George Godber, the Chief (initially Deputy

⁶² Ibid., col. 21252.

⁶³ Megaughin E, Jeffery C. *Introduction: the first decade in perspective*. In Jeffrey C, Mitchell J (eds.) *The Scottish Parliament 1999-2009: the first decade*. Edinburgh. Luath Press (jointly with the Hansard Society), 2009, at p 14.

Chief) Medical Officer for England, was at the centre, seeking the advice of Presidents of Royal Colleges as to whether it would be timely to introduce legislation, responding to lobbying from prominent medical scientists (including attending private lunches of the ‘great and the good’ at the Athenaeum), and making a major contribution to the content of a Bill ‘to give the doctors what they required for the improvement in treatment, education and research’⁶⁴. I have been unable to find evidence for any lobby or voice from the public as a significant part of these deliberations.

In the process that led towards the 2004 Act, the Chief Medical Officer for England (‘CMO’: Professor, later Sir, Liam Donaldson) played a prominent but very different role from Sir George Godber: conducting a census of retained organs, issuing interim advice, and producing very influential Advice to Parliament⁶⁵. Although the latter document was entitled ‘[Advice from the CMO on] the removal, retention and use of human organs and tissue *from post-mortem examination*’ (my emphasis), the advice extended more widely to include a recommendation that ‘as soon as possible, there should be a more fundamental and broader revision of the law, encompassing the taking, storage and use of human tissue *from the living* (my emphasis) and the dead and introducing an independent system of regulatory control’⁶⁶. I have found no evidence that the views of the medical profession had been sought in the preparation of that Advice; nor did they enjoy an ‘insider’ role in later consultations (see Chapter Four). Indeed it may not be too fanciful to describe doctors, as seen through official eyes, as a profession in disgrace at that time. [The profession itself was bewildered and defensive, and morale was sapped.⁶⁷ It took many months before anything approaching a coherent medical voice began to re-

⁶⁴ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1235.

⁶⁵ Department of Health, Department for Education and Employment, Home Office. *The removal, retention, and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*. London, The Stationery Office, 2001.

⁶⁶ *Ibid.*, p 41, Recommendation 6.

⁶⁷ Armstrong S. *A matter of life and death: conversations with pathologists*. Dundee. Dundee University Press, 2008, pp1, 3.

emerge.] Again by contrast with 1961, in 2000 the voice of the public through patient groups and the media was heard by all.

Although the evidence I have been able to obtain was indirect, it appeared that the medical profession was involved earlier, and more closely, in pre-legislative events in Scotland than was the case in England. As outlined in Chapter Five, in late 2001, even before the Phase 2 recommendations of IRG had been received, the Scottish Executive had asked the then newly established NHS Clinical Standards Board (CSB) to take account of the recommendation in IRG's Preliminary Report that post-mortem examination should be treated as part of the continuum of patient care. The outcome was the publication of comprehensive regulatory and monitoring standards in March 2002 (made definitive one year later)⁶⁸. The point of relevance to the present discussion is that the Deputy Chief Medical Officer for Scotland, Dr Janet Steele, and a senior official from the Executive were observers on the CSB, a body with a prominent medical membership. It seems likely that these two officials would have been exposed to an understanding of 'medical thinking'. Perhaps it was for that reason that the Chief Medical Officer for Scotland allowed his Deputy to take the lead, in partnership throughout with senior officials, in the consultative stages of the legislative process. It is plausible to suggest that, through knowledge gleaned from the work of CSB, Dr Steele and officials had developed networks of medical advice to whom they could turn. In addition there was ample evidence of overt medical involvement in later stages, as discussed in Chapter Five and in the following paragraphs.

2.3.2 The scope and method of consultation.

In the 'deliberation and formulation' phase of preparation of the 1961 Act, the consultations that took place were almost entirely with the medical profession, which is understandable in the context of legislation which was being planned as *enabling*, by legitimising then current practices. Within the stage of 'deliberation

⁶⁸ NHS Quality Improvement Scotland. *Standards for management of post-mortem examinations in Scotland*. First published March 2002. Revised March 2003.

and formulation’ of the 2004 and 2006 legislation, still further differences between Westminster and Edinburgh began to emerge. In Whitehall, as indicated above, the decision about the scope of a proposed revision of the law to encompass tissue from the living and the dead, and with the insertion of regulatory control, had apparently already been taken by the Department of Health by early 2001 as signposted in the CMO’s Advice, and had been endorsed by the ‘fundamental and broad review’ of the law on human organs and tissues undertaken by the Department of Health later that year.⁶⁹ Only after that internal process had been completed did the formal consultation document *Human Bodies, Human Choices* (HBHC) appear.⁷⁰ A summary of the responses to the consultation was published by the Department of Health in April 2003.⁷¹ In September 2003, an eight page document, ‘Proposals for new legislation on human organs and tissue’ (‘Proposals’), was published under the names of the CMOs for England and Wales which stated that ‘through the consultation responses and associated workshops, together with a major national conference, a large degree of consensus developed’.⁷² The scope of the proposals ‘expected to be incorporated in the legislation’ was set out. A further series of meetings was held with professional groups over the following month by way of explanation and foretaste before the Bill (‘the 2003-4 Bill’) was introduced in December 2003.

In contrast, the Scottish Executive awaited the recommendations of the independent body which it had established, and the outcome of subsequent formal consultation, *before* determining the principles of the new legislation with regard to

⁶⁹ Department of Health. *Progress in policy archive*. Accessed February 9, 2010 at: <http://www.dh.gov.uk/en/Aboutus/MinistersandDepartmentLeaders/ChiefMedicalOfficer/Archive/ProgressOnPolicy/index>

⁷⁰ Department of Health, NHS Department of the Welsh Assembly Government. *Human bodies, human choices: the law on human organs and tissue in England and Wales- a consultation report*. July 1, 2002.

⁷¹ Department of Health. *Human bodies, human choices: summary of responses to the consultation report*. April 2003.

⁷² Department of Health, Welsh Assembly Government. *Proposals for new legislation on human organs and tissue*. Department of Health, September 2003, p1.

post mortems.⁷³ The consultation, as it turned out, revealed broad support for the approach.⁷⁴ Again in contrast to the process in England and Wales where the publication of responses to HBHC and a national conference was followed by the *Proposals* document as a *fait accompli*, in Scotland there was a second round of formal consultations [on all three major strands of the eventual Bill. [For present purposes the discussion is confined to issues concerning PMs]. This second round confirmed that the principles which would underpin the new legislation would be those identified by IRG, and sought further views on specific issues. Most of the 85 bodies consulted were those as might be expected (for example, Department of Health, Crown Office (Edinburgh), BMA, Church of Scotland, NHS Trust Chief Executives, Royal Colleges, Scottish Organisation in Relation to Organ Retention (SORRO), Scottish Cot Death Trust). However, also on the list of those consulted were several named individual University Departments of Pathology, Neuropathology, and General Practice, whose Heads had a special interest or expertise of direct relevance to the inquiry. By these means it could be said that the views of the medical profession were well heard. The Scottish Executive went still further in obtaining the views of pathologists and keeping them informed. During the ‘formulation’ stage of the Bill (‘the 2005-6 Bill’), Will Scott, senior civil servant in the Executive, attended several meetings of the Scottish Council of the Royal College of Pathologists, where he sought advice and answered questions.⁷⁵

2.3.3 Role of ROC and IRG.

The composition of membership of the Retained Organs Commission⁷⁶ (ROC) and IRG was remarkably similar. The most interesting comparative point in the present

⁷³ The Scottish Government. News release. *Reform proposed for hospital post-mortems*. Nov 23 2001. Accessed on June 29 2010 at: <http://www.scotland.gov.uk/News/Releases/2001/11/660>

⁷⁴ Scottish Executive Health Department. *Consultation paper on the legislation relating to hospital post-mortem examinations*. November 24, 2003, p2, par 8.

⁷⁵ Royal College of Pathologists. *Minutes of Scottish Regional Council*. September 23, 2004; December 7, 2004; March 15, 2005; September 20, 2005.

⁷⁶ National Health Service: Retained Organs Commission. *Remembering the past, looking to the future. The final report of the Retained Organs Commission including the summary accountability report for 2003/2004*. Department of Health Publications, March 2004.

analysis is how each government used such a group of all the talents. [My ability to compare the two bodies has been limited by the more ready availability of all the IRG papers, in contrast to ROC files. The latter have been electronically archived within the Department of Health files in the National Archives, and their algorithm has a cut off at least one level higher than is to be found in the IRG files. As a result, ROC papers of potential relevance to my studies have been inaccessible.]

On the evidence available to me, ROC's main tasks were to oversee the return of retained organs and tissues to families, address the question of historical and archived organ collections, and to advise Ministers about changes needed in the law relating to post mortems and organ retention⁷⁷. ROC's formal advice, issued in June 2003, was concentrated on three specific areas: the legal status of tissue blocks and slides⁷⁸; the use and disposal of unclaimed and unidentifiable human remains⁷⁹; and a regulatory framework for museums, archives and collections of bodies and their parts⁸⁰. In Scotland, in contrast, the advice of IRG (and another expert independent body, the Scottish Transplant Group) was acknowledged and used by the Scottish Executive as a major determinant of the scope and content of the legislation.⁸¹ In addition, IRG, an investigatory and advisory body, in practice made major contributions to the management of parental grief and the repatriation of organs and tissue- a task on a different scale, though no less important, than that faced by ROC.

2.3.4 The contribution of parents to deliberation and formulation.

⁷⁷ Department of Health, NHS Department of the Welsh Assembly Government. *Human bodies, human choices: the law on human organs and tissue in England and Wales- a consultation report*. July 1, 2002, 1.9, p4.

⁷⁸ National Health Service. Retained Organs Commission. *Recommendations on the legal status of tissue blocks and slides. Advice paper*. June 2003.

⁷⁹ National Health Service. Retained Organs Commission. *Advice to Department of Health on the use and disposal of unclaimed and unidentifiable human organs and tissue*. June 2003.

⁸⁰ National Health Service: Retained Organs Commission. *A proposed framework for the regulation of museums, archives and collections of human bodies, body parts, organs and tissue*. June 2003.

⁸¹ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*. June 3, 2005, p9, para 30.

Both ROC and IRG worked extensively and intensively with grieving parents- work which led to the primacy of respect for parents' views through the concept of 'the golden thread' of consent in England, and 'authorisation' in Scotland. In addition, in England the National Committee concerned with Organ Retention (NACOR) [whose chair, Mrs Michaela Willis, also served on ROC] had input to Department of Health deliberations throughout all phases of legislation.⁸² In Scotland parental groups gave written and oral evidence to the Health Committee during Stage 1 proceedings of the Human Tissue (Scotland) Bill, discussed further below.

In Westminster during Second Reading of the Human Tissue Bill, the Parliamentary Under Secretary for Health, Dr Stephen Ladyman MP, gave a revealing glimpse of the continuing influence of parents as he tried to defend the Government's rescinding of a previous commitment to allow pre-legislative scrutiny of the Bill, saying: '[w]e therefore had to make a judgment call- do we balance the need for scrutiny against the needs of the families who are demanding that we make progress? We decided that making progress was more important than publishing the Bill in draft'⁸³. This sensitivity to parents' continuing 'demands' is a further clear indication that parental contact with Government was being maintained up to that time at the highest level.

Chapter Five highlighted that, at all stages of the legislative process in Scotland, there had been an overt sensitivity to the wishes of those parents and relatives who did not object to post-mortem examination but who did not want to be given information. I proposed that this had had its origin in the work of IRG and specifically, in written and oral evidence given to the Group by certain articulate and persuasive parents. It was pointed out by IRG that the process of authorisation, unlike consent, did not require the prior giving of information, and that this could be of help to those 'non objectors who did not want to know'. I have little doubt that similar views were held by some parents in England (and indeed were

⁸²House of Commons Library. *The Human Tissue Bill. Bill 9 of 2003-04*. Research Paper 04/04, January 9, 2004, p40, citing: NACOR: *Initial comment on the new Human Tissue Bill*. December 8, 2003; and p40, para 2.

⁸³ (2004) 416 (Parl. Deb., Hansard 6th series), HC 1043.

articulated in a few of the many letters to the Press following *Alder Hey*^{84 85}), but I have been unable to detect that their view was influential throughout the ‘formulation’ stage in Westminster. Instead, calls for ‘informed’ consent prevailed uniformly.

2.3.6 The role of officials.

As seen in Chapter One, one was able to appreciate, through archival papers, how all the factors which had contributed to inspiration and deliberation came to be concentrated on the desks of officials in the ‘Bill team’ whose job it was, with Ministers, to formulate Instructions to Parliamentary Counsel and engage in an iterative process thereafter. This exercise was and is both practical and intellectual. Close scrutiny revealed why, from time to time, there could be a connection between a lack of nails and lost kingdoms. It is worthwhile to recall an internal Ministry memorandum from 1960 concerning the use of tissues from bodies subject to coroners’ post mortem examinations, and written following a meeting between officials and the Minister about the draft Bill and a subsequent conversation with an official from the Home Office.

Provided the consent of the coroner is obtained in each individual case, the Home Office would not see any objection to the removal of tissues for therapeutic, educational or research purposes, either before, during or after a post mortem examination ordered by a coroner. You [SD Musson, Principal Assistant Solicitor of the Ministry of Health’s legal division] consider that this is already covered by the terms of the draft bill but that we would want to ensure that, in such cases, the necessary consents were obtained under clause 1.⁸⁶

One may only speculate what might have been a different long term outcome had Musson’s insight been incorporated into legislation. The general point is clear. The astuteness of officials can be a contributory factor in the legislative process.

⁸⁴ *The Times (London)*. Letter from Ross, C. January 31, 2001.

⁸⁵ *Daily Star*. Letter from Diamond D. January 31, 2001.

⁸⁶ National Archives. Ref. MH58/497. Memorandum from D Emery to SD Musson, November 23, 1960.

The lack of access to archived papers from the 2004 and 2006 legislative processes makes it more difficult to assess in any detail the contribution of officials. Two figures can be discerned. In Scotland, Mr Will Scott of the Scottish Executive was identified at a meeting of the Health Committee as being ‘responsible for the part of the bill that deals with transplantation and post-mortem examination’⁸⁷. He earned the gratitude of the Scottish Council of the Royal College of Pathologists for his contributions.⁸⁸ He was the signatory of the consultation letters on transplantation and post mortems. He was almost certainly the point of liaison between the Scottish Executive and the Department of Health on the emerging legislation (information obtained under FOIA)⁸⁹. It seems likely that Will Scott’s contribution to the 2005-6 Bill must have been considerable.

In the Department of Health, officials are numerous. With regard to the Human Tissue Bill 2003-4, Mr Hugh Whittall was identifiable, through documents released through the Freedom of Information Act, as the Bill manager. In a presentation on the ‘likely contents’ of the draft Bill to the Human Genetics Commission, in which Whittall understandably spoke of ‘we’, and ‘the Department’, he gave the nearest account I have been able to find to explain why the span of the legislation was to be so broad (see Chapter Four, at 2.2.2). He described an essentially internal official-driven process⁹⁰ which appears to have been an important factor in the ‘deliberation and formulation’ phase of the 2003-4 Bill.

Drewry emphasised that the boundaries between his various stages of the law-making process were often blurred. Pre-legislative scrutiny sits conceptually on the cusp between ‘formulation’ of a draft Bill and ‘legitimation’. In Scotland it is built

⁸⁷ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. Sept 8, 2005, col 2091.

⁸⁸ Royal College of Pathologists. *Minutes of Scottish Regional Council*. September 20, 2005.

⁸⁹ Department of Health. Freedom of Information Team. *Response to your query (email to AS McNeish)*. Ref. DE 00000537219. September 20, 2010.

⁹⁰ Human Genetics Commission. Plenary meeting transcript. *Item 5: Update on the Human Tissue Bill (H. Whittall)*. London, November 12, 2003. FOI DE490186. McNeish. 12/10/2010.

into Stage 1 of the Parliamentary passage of a Bill. In Westminster, its usage is optional and if it occurs, it takes place before a Bill is introduced.

2.3.7 Pre-legislative scrutiny.

As part of the package of modernisation proposals agreed by the House of Commons in October 2002, the Government made a commitment to publishing more of its Bills in draft and submitting them to a parliamentary committee for pre-legislative scrutiny. This, it was said, would allow thorough consultation on the Bill while it was still in a more easily amendable form, and make it easier to ensure that both potential parliamentary objections and stakeholder views were elicited.⁹¹ In the Cabinet Office's *Guide to legislative procedures*, it is stated that '[w]hen seeking bids for legislation, the Chair of the Legislative Programme Committee will ask Ministers to consider the Bill's suitability for publication in draft'⁹².

One may speculate as to why the Secretary of State, Rt Hon Alan Milburn MP, might have declined this option. He had already made tough and uncompromising statements about the issues, and there had been a long standing commitment to parents which reached back to the CMO's Summit in January 2001 ('never again'), and which was later reiterated by Stephen Ladyman at Second Reading. By his demeanour throughout the preliminaries, I suspect that Mr Milburn would not have been interested in hearing parliamentary objections prematurely which might have forced compromise, and he certainly did not wish to listen to medical stakeholder views. [It is even arguable that his uncompromising stance over a Bill with such wide-ranging provisions over tissue from the dead and the living was but one example of government's determination, as identified by Brazier and colleagues, to 'control' the medical profession.⁹³] It is certainly arguable that, if pre-legislative

⁹¹ Cabinet Office. *Guide to legislative procedures*. October 2004, pp 69-70, paras 18.1, 18.3. Accessed on September 2, 2010 at www.cabinetoffice.gov.uk/.../cabinetoffice/.../guide_legislative_procedure.doc

⁹² Ibid., p70, para 18.2.

⁹³ Brazier M, Lovecy J, Moran M, Potton M. *Falling from a tightrope: doctors and lawyers between the market and the state*. Soc Sci Med 1993; 41: 197-213, p 213.

scrutiny had occurred, as indeed had been committed to by Hazel Blears MP in 2003, much parliamentary time would have been saved and the need for heated debate obviated.

Chapter Five (at 3.5.2) described the importance of the Committees of the Scottish Parliament.⁹⁴ The activities of the lead committee for a Bill, although strictly speaking part of the legitimisation process, include a significant proportion of those functions of a pre-legislative committee commended by the Cabinet Office Guide as desirable. Chapter Five also described in some detail the range of bodies and persons who gave written and oral evidence to the Health Committee. It is sufficient here to commend the open and discursive nature of the meetings, which began with the Convener inviting each witness 'to state briefly their interest in the bill, make a brief comment on the bill - whether they support, are neutral about or oppose it - and raise any other issues that need to be flagged up'⁹⁵; and concluded with the invitation that 'if the witnesses think of something once they have left, they should feel free to get in touch with us again. The clerks will always accept follow-on evidence from witnesses'⁹⁶. This approach allowed the Health Committee to submit an authoritative report to the Parliament which recommended that the general principles of the Bill be approved, subject to a series of recommendations about how it might be improved and about action to be taken to support effective implementation.⁹⁷

The importance of the Committee Report to the business of the Parliament in the Stage 1 debate was captured by Brian Adam MSP when he said: 'Today, we are

⁹⁴ Scottish Parliament. *Guidance on public bills*. Stage 1, para 2.23, 2.25, 2.29. Accessed September 2, 2010 at: <http://www.scottish.parliament.uk/business/bills/billguidance/gpb-c.htm>

⁹⁵ Scottish Parliament. *Official Report*. Health Committee, 21st meeting, Second Session. September 13, 2005, col. 2128.

⁹⁶ *Ibid.*, col. 2164.

⁹⁷ Scottish Parliament. Health Committee Report (SP Paper 451). HC/S2/05/R19. *Stage 1 Report on the Human Tissue (Scotland) Bill*. 19th Report 2005 (Session 2). 'Overall recommendation'. Accessed on June 2, 2010 at: <http://www.scottish.parliament.uk/business/committees/health/reports-05/her05-19-01.htm>

debating a committee's stage 1 report on a bill. It might be better in terms of our procedures, and potentially less contentious—although the bill is not particularly contentious—if the committee convener were to lead the debate on the committee's stage 1 report [rather than the Minister]⁹⁸. He was only gently rebuked by the Minister to the effect that the debate was on the Bill and that the Committee Report was an important contribution.

2.4 Legitimation, in theory and practice.

2.4.1 Overview of the legitimation process: 1961, 2004 and 2006 Acts.

To Drewry, 'legitimation' was Parliament's main legislative function- 'a process which helps to secure public acceptance of, and obedience to, the legislative actions of the state'.⁹⁹ According to this model, Parliament impinges hardly at all in the phases of 'inspiration'; and has only a limited role in 'deliberation and formulation' through (limited) debates on white papers and (chance) social intercourse between MPs and Ministers. The process of 'deliberation' occurs earlier in the legislative process as a complex decision making structure involving interplay among political parties, pressure groups, Departments and the Cabinet, all subject to a variety of social and political forces.¹⁰⁰ The 1961 Act followed Drewry's overall pattern, with all party support. All the 'work', which focused almost entirely on transplantation and in a sense extended the Corneal Grafting Act 1952, had been done during the phases of deliberation and formulation, within which there had been very significant medical input. Legitimation in Parliament, as the Bill passed through both Houses, was largely a process of approval and commendation.

Drewry gave as an exception to the usual pattern of 'legitimation' the passage of the annual Finance Bill, where much was formulated in great secrecy, and with non-

⁹⁸ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill (Stage 1) November 30, 2005, col. 21249.

⁹⁹ Drewry G. *Legislation*. In Ryle M, Richards PG (eds) *The Commons under scrutiny*. Third edition. London, Routledge, 1988, pps 120- 140, op. cit., p126.

¹⁰⁰ Walkland SA. *The legislative process in Great Britain*. London. Allen and Unwin, 1968, op. cit., p 71.

government bodies strictly excluded. This gave peculiar importance to its Parliamentary stages, during which substantial changes were sometimes made following pressure group lobbying of a kind which in the case of most other bills would have happened much earlier.¹⁰¹ In some ways, the passage of the 2003-2004 Bill resembled Drewry's description of the Finance Bill, in that substantial changes were eventually made, and government concessions grudgingly granted, as a result of intense lobbying from the medical and scientific community late in the legislative process.

Heywood, in a consideration of 'group politics', described 'insiders' and 'outsiders', based on the status that groups had in relation to government and the strategies they adopted in order to exert pressure. In this account, insider groups enjoy regular privileged and usually institutionalised access to government through routine consultation or representation on government bodies. Governments may also be inclined to consult groups that possess specialist knowledge and information that assists in the formulation of workable policy. In contrast, outsider groups are consulted at best irregularly and not at a senior level: they are forced to 'go public' in the hope of exerting indirect pressure on the policy process.¹⁰² According to Drewry's legislative model, insider groups are able to make their contribution in the early, deliberative and formulating phases, while outsiders contribute later, if at all.

In the passage of the 2004 legislation, the medical profession played the 'outsider' role, while parents' groups were 'insiders' - a role reversal from what might have been expected as a generality. Parents exerted a powerful influence from the beginning of the process, while the medical and scientific professions tried to exert influence through a lobbying campaign which lasted throughout the eight month legitimisation phase of the Bill's passage through Parliament. The absence of pre-legislative scrutiny, a mechanism which allows both insider and outsider input,

¹⁰¹ Drewry G. *Legislation*. In Ryle M, Richards PG (eds) *The Commons under scrutiny*. Third edition. London, Routledge, 1988, pps 120- 140, op. cit., p 123.

¹⁰² Heywood A. *Politics*. Third edition. Basingstoke. Palgrave Macmillan, 2007, p 297.

played its part. [It might be argued that medicine as an institution had begun to lose its insider status many years before for reasons discussed in Chapter Three. The circumstances of *Bristol* and *Alder Hey*, and public reaction, may have been the final determinants of outsider status].

The legitimisation process in the Scottish Parliament, as judged by the passage of the 2006 Act, conformed in some ways to the Drewry model, in that the provisions of the Bill were largely determined in the deliberation and formulation stages, and which included what appeared to be thorough consultation procedures. Parents' groups were 'insiders', as in England, but the medical voice was also heard. The tone of the Stage 1 and Stage 3 debates had an air of *fait accompli*, with, at the same time, an awareness of the need to ensure the acceptance of the Scottish people. However, the inclusion of the work of the relevant Parliamentary (in this case Health) Committee as the beginning of the legitimisation phase, with papers and detailed discussions with witnesses being freely available in the Official Report, gave a role to Parliament which could be replicated in Westminster if a process of pre-legislative scrutiny were to become the norm.

2.4.2 A comparison of the structure of the 2003-4 and the 2005-6 Bills.

I submit that the comparative structure of the Bills may be a guide to the thinking behind their respective evolutionary phases. Both governments began with a problem arising from post mortems. The Scottish Executive appears throughout to have kept the *needs of the service* as template, while attending to defects in legislation (and clinical practice) revealed by analysis of the problem, and attending to any *necessary* consequential amendments. The resulting 2005-6 Bill was structured round 'activities': Transplantation; Post Mortems; Anatomy. In contrast, the UK Government appears, from the structure of the 2003-4 Bill, to have been driven throughout by a need to answer *first, and serially, the anxieties and wishes of bereaved parents and relatives*. (see Chapter Four 3.4.2.1) As a consequence, in order for a reader to find the provisions regarding a clinical activity, for example transplantation, one would have been required to infer/hypothesise from clause 1(1) that organ transplantation might be an activity lawful with 'appropriate'

consent, and that it might be a 'Schedule 1' activity. Schedule 1, Part 1, indeed listed transplantation as the eighth (of eight) purposes 'normally requiring consent'. Part 2, clause 11, of the Bill confirmed that the proposed Human Tissue Authority had within its remit 'the use, for a scheduled purpose, of 'relevant material' which has come from a human body. Clause 29 prohibited trafficking in organs, and clause 30 imposed restriction on live donor transplantation.

2.4.3 Legitimation in respect of certain provisions: a comparison between 2004 and 2006 Acts.

As a general point, the requirement under Rules for the Executive in Scotland to publish a Policy Memorandum alongside a draft Bill makes it clear to the reader what are the underlying principles and objectives in the Government's collective mind. Having to rely on Explanatory Notes in the case of a Westminster Bill is less satisfactory, especially when the legislation has not been the subject of prior Green or White Papers.

2.4.3.1 The need for broad congruence throughout the UK.

There is ample evidence that the Scottish Executive was aware of the need for, 'as far as possible', a consistent approach within the legislation in Scotland and the remainder of the UK. (Chapter Five, 3.2.10, 3.5.1). This was achieved in large part by 'the close working of all the health departments on the primary legislation and, even more so, on the regulations and codes of practice that underpin them'.¹⁰³ Divergence of approach appeared regarding tissues from the living and in provisions for tissue blocks and slides.

2.4.3.2 Tissues from the living.

With regard to the topics that generated protracted debate, lobbying and negotiation in Parliament with regard to the 2003-4 Bill, there was much focus on Part 1, Clause 1 and Schedule 1 which, collectively, provided for 'purposes normally

¹⁰³ Scottish Parliament. *Official Report*. Health Committee, 20th meeting, Second Session. September 8, 2005, col.2097.

requiring consent'.¹⁰⁴ The debate eventually centred on tissues from the living, and in particular on the need for consent: before using 'surplus tissue from the living' for research; and for carrying out 'education on research techniques' using clinical specimens. The first matter was only 'resolved' in the months after the Committee Stage in the House of Commons, and the Bill subsequently amended to allow anonymised tissue to be used without consent and with the approval of an Ethics Committee, as a result of a confidential meeting on March 9, 2004 between the Minister, Rosie Winterton, and stakeholders from the research and academic communities.¹⁰⁵ The second matter, which arose from the practical day to day difficulty in a pathology department of differentiating between education in diagnostic techniques, which, in the draft Bill, did not require consent, and education in research techniques (on the same tissue specimen) which did require consent, was settled only after the government had to respond to defeat in an amendment in the House of Lords brought by Baroness Neuberger.¹⁰⁶

In Scotland, the need for debate on these issues did not arise, because the 2005-6 Bill had made no provisions concerning surplus tissues from the living. Instead the Scottish Executive's policy was to leave these matters to guidance, and an appropriate authorisation form where necessary.¹⁰⁷

2.4.3.3 Retention of tissue blocks and slides.

2.4.3.3.1 Scotland.

Perhaps no single issue illustrated better the differences in the legitimisation phase of the 2003-4 and 2005-6 Bills than 'the retention of tissue blocks and slides'. As discussed in Chapter Five, the 2006 Act provided that samples of tissue or of an organ removed during a properly authorised [hospital] post mortem would form

¹⁰⁴ Human Tissue Bill. Bill 9, 2003-04. Published December 3, 2003. Part 1, clause 1, schedule 1.

¹⁰⁵ Department of Health. *Human Tissue Bill: proposed amendments for research use of tissue from living patients*. March 11, 2004. FOI DE485259. McNeish: attachment redacted. 02/03/2010.

¹⁰⁶ (2004) 666 (Parl. Deb., Hansard 5th series), HL 397.

¹⁰⁷ Scottish Parliament. *Human Tissue (Scotland) Bill [Sp Bill 42]: Policy Memorandum*, p6, para 14.

part of the medical record.¹⁰⁸ Further, the 2006 Act made provision for the retention and further use of samples from Fiscal post mortems, which would be at variance with the provisions of the 2004 Act. As described in the Explanatory Notes to the 2006 Act:

Part 3. Tissue sample or organs no longer required for Procurator Fiscal purposes:

‘provides for tissue samples no longer required for the Fiscal’s purposes to be retained as part of the deceased’s medical record and used without authorisation for diagnostic and audit purposes, and for such tissue samples and organs no longer required for the Fiscal’s purposes to be used, with authorisation, for education, training or research.’¹⁰⁹

The Health Committee had been ‘generally content’ with the Executive’s plans to issue guidance on how surplus tissue was to be dealt with, and ‘accepted the broad principles and specific provision in relation to tissue samples or organs no longer required for Procurator Fiscal purposes’, including that authorisation should be sought for the purpose of education, training or research, but not for diagnosis or audit.¹¹⁰ As described in Chapter Five, these principles were expressed by specific provisions in the 2006 Act.¹¹¹ The only contribution in the Parliament on the subject of tissue retention and use came from Susan Deacon MSP (the by then past Minister for Health and Community Care who had established the IRG) who was ‘pleased that the bill makes provision for sensitive and sensible arrangements for the use and storage of tissue samples’.¹¹²

¹⁰⁸ *Human Tissue (Scotland) Act* (2006 asp 4) s.28 (3)(4) (5).

¹⁰⁹ *Human Tissue (Scotland) Act* (2006 asp 4). Revised Explanatory Notes. The Stationery Office Limited, 2006, p1.

¹¹⁰ Scottish Parliament. Health Committee Report (SP Paper 451). *Stage 1 Report on the Human Tissue (Scotland) Bill. 19th Report 2005 (Session 2)*, op.cit. ‘Specific provisions in relation to tissue samples or organs no longer required for Procurator Fiscal purposes.’

¹¹¹ *Human Tissue Act (Scotland) 2006*, s.38(2); s.39(a), (b).

¹¹² Scottish Parliament. *Official Report*. November 30, 2005, col. 21249.

Key to the decisions made in Scotland was the close working between the legislators, the Crown Office and Procurator Fiscal Service, and the Royal College of Pathologists to ensure common standards as between hospital and Fiscal post mortem examinations. This had embraced the concept, originally proposed by IRG, that an autopsy was an extension after death of clinical care, and that retention of tissue samples formed part of the clinical record. It followed that, to ensure appropriate standards, retained tissue should be available, without further authorisation, for the purposes of audit or diagnostic review.

2.4.3.3.2 Remainder of UK.

At Second Reading of the 2003-4 Bill in the House of Lords, Baroness O'Neill of Bengarve had asked the Minister to explain why the Bill had been brought forward before legislation to revise the Coroners Rules, saying:

It has been said that this Bill constructs a hammer to crack the proverbial nut, but that, unfortunately, it misses the nut. I do not think that we can reshape the hammer to ensure that it really hits the nut because for that we would also need to reshape the Coroners' Rules.¹¹³

In response the Minister, Lord Warner, said only that Home Office Ministers had confirmed that amendments to the Coroners' Rules would be produced later that year and that the Government would ensure that these new Rules were wholly consistent with the Bill.¹¹⁴

Later, during Third Reading, Baroness Finlay had proposed an amendment which would have permitted tissue blocks and slides from coronial post mortems to have been retained after the coroner was *functus*.¹¹⁵ She cited as examples where access to retained samples would be useful: wrongful convictions, serial failures of care, and comfort to families if new genetic tests could later illuminate the cause of an unexplained infant's death (note: the latter scenario overlaps 'Sudden Infant Death

¹¹³ (2004) 666 (Parl. Deb., Hansard 5th series), col 394.

¹¹⁴ *Ibid.*, col 428.

¹¹⁵ (2004) 666 (Parl. Deb., Hansard 5th series), col 406.

Syndrome-see next section). The Minister, Lord Warner, asked for the amendment to be withdrawn in a response which filled some three columns in *Hansard*. He described the amendment as wholly undermining the fundamental principle [of consent] on which the Bill was based. He called in support a 'powerful' letter from PITY II, the parents' support group from Liverpool, which had registered specifically and in the strongest terms their objections to the proposed amendment. He also quoted from an 'unsolicited' letter he had received from the Chair of the Retained Organs Commission to the effect that 'extending powers to dispense with consent will simply be counterproductive and may result in further and damaging disputes between families and professionals'.¹¹⁶

In contrast to the position in Scotland, the Coroners (Amendment) Rules 2005¹¹⁷ [which were introduced in a 'peremptory' manner¹¹⁸, and without any prior consultations with the pathology profession], having made clear the responsibility of the Coroner to notify the pathologist (and inform the family) of the period for which he required the retention of material for his purposes under the Coroners Act 1988¹¹⁹, required that, at the end of that period, the retained material must be returned to the appropriate person (as specified), disposed of lawfully by the pathologist, or retained with the consent of the appropriate person (as specified) for medical research or other purposes.¹²⁰

Putting the above points from the Coroners (Amendment) Rules 2005 into practice would require close working between pathologists and coroners. Five years later, in late 2010, *Redfern 2* found it necessary to take the view that 'coronial and

¹¹⁶ Ibid., col 409.

¹¹⁷ *Coroners (Amendment) Rules 2005*. S.I.2005/420.

¹¹⁸ Underwood JCE. Human Tissue Legislation in the United Kingdom: the need and prospects for amendment. *Bulletin of the Royal College of Pathologists* 2009; no.147: 198-202, op. cit., at p 200.

¹¹⁹ *Coroners (Amendment) Rules 2005*. S.I.2005/420. Rule 9(5).

¹²⁰ Ibid., Rule 9(8).

pathology practice should be standardised, effective management ensured and the [necessary] framework strengthened'.¹²¹

2.4.3.3.3 Implications for Sudden Infant Death Syndrome ('SIDS').

The difference between Scotland and England regarding retention of tissue blocks and slides has practical consequences in respect of SIDS, to which both IRG (directly) and Baroness Finlay (indirectly) had drawn attention. SIDS is not a diagnosis of the cause of death: it means that the specific cause of death has not been ascertained despite thorough investigation. Retention of tissue could allow the cause of death to be revisited in the light of advances in medical knowledge. On the other hand (although perhaps distressing to contemplate), parents who have knowingly contributed to their infant's death, but which has been attributed after autopsy to SIDS, might be less likely to agree to the prolonged retention of material evidence which could be reviewed.¹²² There is no evidence that there was a different attitude to the specific issue of SIDS parents during the legitimisation process in Scotland and England: rather that in Westminster, adherence to the 'fundamental principle of consent' trumped Baroness Finlay's arguments; while in Scotland, the implications for SIDS emerged as a by-product of a process with origins in quality assurance.

The emergence later of the Coroners (Amendment) Rules 2005 was not preceded by public debate or records accessible to me. One may conjecture that, if the case of SIDS had been given specific consideration, an argument could have been constructed to say: 'The Coroner has accepted the diagnosis of SIDS; the police have said they have no further interest; the body should be returned to the parents for burial.'

¹²¹ Department of Energy and Climate Change. *Redfern Inquiry into human tissue analysis in UK nuclear facilities*. Volumes 1 and 2. London. The Stationery Office. Ordered by the House of Commons to be printed, November 16, 2010. Volume 1, p587 para c).

¹²² Underwood JCE. *Human tissue legislation in the United Kingdom: the need and prospects for amendment*. Bulletin of the Royal College of Pathologists 2009; no.147: 198-202, op. cit., at pp 199-200.

3. Overall conclusions.

The 1961 Act was of its time. It came into being to support the wonders of science, and the prevailing mood was perfectly captured by the wish of Miss Joan Vickers MP that the associated Bill should be named the 'Human Aid to Medical Science Bill'.¹²³ Throughout the legislative process the 'requirements' of the medical and scientific community were dominant, and the views of the public were not sought. Over the next quarter century, shortcomings in the wording of some of the provisions of the Act were revealed through practical problems in the practice of transplantation. There *were* further developments in science, as predicted by Baroness Summerskill in 1961, such as to make the provisions of the Act gradually less adequate to the task. There was ignorance of the content of the Act by the medical profession, for which they were later criticised severely. But this ignorance, or at least 'blind eye', was *not* exclusive to doctors. The findings in this Thesis point also to deficiencies in coronial practice at different times in different places to which, for example, Mr Michael Redfern QC and Dr Jeremy Metters, HM Inspector of Anatomy, drew attention although, unaccountably to me, with dilute criticism only.

These circumstances in sum, as I have tried to argue in Chapters Two and Four, would have led to a perceived need to modify the law at some point.

The proximate triggers to new legislation- the illegal actions of a rogue pathologist (Van Velsen), and disclosure of the widespread practice of pathologists of retaining organs and tissues without express consent- were of different orders of culpability in my view, and would have benefited from individual consideration. Instead, as discussed in Chapter Four (at 1.1.2.1 et seq), the findings came to be seen as a whole, with escalating consequences.

Dick Van Velsen's practices were genuinely shocking as well as illegal, and were indefensible, not only to the press and public, but to the medical profession as

¹²³ (1960) 632 Parl. Deb. (Hansard, 5th series), HC 1238.

well.¹²⁴ In contrast, the widespread ‘routine’ practice of organ and tissue retention at PM without express consent might have been interpretable as [another] example of benign, misplaced or out of date paternalism, which had persisted, as discussed in Chapter Three, within a medical profession which, in Irvine’s words, had ‘strongly defensive attitudes and very little insight into the profound nature of the changes that had taken place all around us’¹²⁵. The view that the 1961 Act was ‘toothless’ in not providing a sanction for non-compliance¹²⁶ (and by implication that such a sanction might have prevented routine tissue retention, if not Van Velsen’s actions) is arguably misplaced. The weight of evidence from the Inquiries and the immediate aftermath support a view that doctors (save Van Velsen) did not ‘transgress’ because of a cavalier disregard for a law [of which they were, in fact, ignorant]. Their response of bewilderment was not one of being found guilty of breaking the law but of genuine shock that their practice was not approved of. What they had lacked was appropriate education and training^{127 128} (See Chapter Four, especially 1.1 3.2).

Of all the factors identified in section 2.1 of this Chapter as operating on both sides of the English-Scottish border as ‘inspiration’ for new legislation, two stand out. The first, ‘pressure exerted by parents and relatives’ is linked to the second, ‘desecration of the dead [children]’ (see also 2.1.5, this Chapter). With regard to the latter, it is poignant now to recall the moving words of Lord Balniel who made

¹²⁴ General Medical Council. *Fitness to Practise Panel Hearing. (Re. Dick Van Velzen)*. June 6-20, 2005.

¹²⁵ Irvine D. *The doctor’s tale; professionalism and public trust*. Oxford. Radcliffe Medical Press, 2003, op. cit., p99.

¹²⁶ Brazier M, Cave E. *Medicine, patients and the law*. Fourth edition. London. Penguin Books Ltd, 2007, section 19.4, p474.

¹²⁷ Bauchner H, Vinci R. Editorial: *What have we learned from the Alder Hey affair? That monitoring physicians’ performance is necessary to ensure good practice*. BMJ 2001; 322 (7282): 309-310.

¹²⁸ Department of Health. *Isaacs Report*. Published May 12 2004. Accessed during May 2008 at :www.dh.gov.uk/en/Publicationsandstatistics/PublicationsPolicyAndGuidance/Browsable/DH4095316

such a sensitive contribution to the Second Reading of the 1960 Bill which brought about the 1961 Act with its subsequently revealed shortcomings:

[The Bill] 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.¹²⁹

Chapters Four and Five have assembled evidence that parents lobbied, were consulted and listened to, and continued to have input and influence throughout the legislative process- indeed came to be regarded as very significant ‘insiders’, whose views and wishes trumped others (see Chapter Four, especially 2.3, and Chapter Five, 2.1.1.2, 3.2.3). The evidence for the influence of parents was most directly observable in England, while in Scotland it appeared to operate particularly through the work and influence of IRG. Parents, as recorded in the transcript of the CMO’s Summit in January 2001, spoke of ‘the one common factor between us is that we have all suffered the grievous loss of a child’ and ‘the one overriding emotion that we all have is the pain caused by the lack of respect and dignity shown to our children’.¹³⁰ The chair of NACOR, Michaela Willis, spoke of changing future practice in a manner which strongly suggested that her organisation was already party to, and influencing, the planning of government policy (see Chapter Four, 1.2.2). Further evidence throughout Chapter Four strongly points to this influence having continued subsequently.

It has been relatively straightforward, if fascinating, to explain the vertical axis, 1952-2006, of this Thesis. The past is another place with different mores and relationships. It has been more difficult to explain why two parts of the United Kingdom, albeit with two legislatures, produced significantly different outcomes. . My hypothesis (see Introduction, 1.2.2) was that answers might lie within a greater understanding of the *processes* by which new legislation had occurred, the *climate* of the time and the *institutions* and even *individuals* who had been involved.

¹²⁹ (1960) Parl. Deb. (Hansard, 5th series) HC 1245.

Transcrip2t[1].pdf. Obtained on February 11, 2010 from CMO’s Private Office, at p 3, per O’Hare J.

Of these possibilities, the climate in 2000, as described in Chapter Three, did not recognise geographical borders [except that, from indirect evidence adduced in Chapter Five, the institution of medicine in Scotland may not have had such opprobrium directed towards it compared to that in England; and there was close working as between the Executive, the Crown Office and RCPATH, with no evidence of comparable relationships in England]. With regard to individuals, it is difficult to overlook the contributions of Professor (later Sir) Ian Kennedy, and the reactions of the Secretary of State, Rt Hon Alan Milburn MP, although it is difficult to quantify their overall influence. With regard to Kennedy, it may not be fanciful to draw a continuous line from his trenchant criticisms of doctors in his 1981 Reith Lectures, through his adverse critique of medical self regulation in the 1990s, to the harsh wording of the findings in *Bristol* and the recommendations in that report about future regulation and changes in the law. The more measured tone of the IRG report in Scotland may be contrasted (whose chair, Professor Sheila McLean, is also a noted critic of the medical profession¹³¹). With regard to Milburn, one must await the availability of official papers under the '30 year rule' before assessing his contribution (and, as an aside in 2010, whether or not there were elements of 'forced choice'¹³² operating in 2001). For the present, it is sufficient to note Milburn's obvious anger, and, to some, his hyperbolic¹³³, hysterical and overwrought¹³⁴ language, as compared, again, to the more measured tones of his counterpart in Scotland¹³⁵, as proxy for his likely influence during the legislative phases.

¹³¹ McLean, Sheila A.M. *A patient's right to know: information disclosure, the doctor and the law*. Aldershot, Dartmouth, 1989.

¹³² Lodge M, Hood C. *Pavlovian policy responses to media feeding frenzies? Dangerous dogs regulation in comparative perspective*. *Journal of contingencies and crisis management* 2002; 10 (1): 1-13.

¹³³ Hoffenberg R. *Medical arrogance*. *Clinical Medicine* 2001; 1(5):330-340.

¹³⁴ Department of Health. *Transcript of Chief Medical Officer's Summit. Thursday January 11, 2001*. CMO ¹³⁴ *The Times (London)*. Feature: *Overwrought response*. January 31, 2001.

¹³⁵ Scottish Parliament. *Official Report*. Human Tissue (Scotland) Bill, Stage 3. February 2, 2001, col. 1124.

It is to a comparison of *processes* that I turn finally, and propose that herein lies the major explanation for the different legislative outcomes in England (with Wales and Northern Ireland) and Scotland, at least with regard to my primary focus on research. [With regard to more general aspects of the 2006 Act, Scotland was fortunate in being able to rely on the provisions of the 2004 Act to regulate DNA analysis, and, through the Human Tissue Authority, to regulate organ transplantation from living donors. This enhanced the opportunity for focus in the 2006 Act]. Within my analysis of Scotland in Chapter Five, two particular processes stood out to explain the differences between the 2004 and 2006 Acts: the thoroughness of [overtly broad based] consultation and the thoroughness of the work of the Health Committee, during Stage 1, in *de facto* pre-legislative scrutiny – both built into the Scottish Parliamentary legislative systems. It was the differences between the 2004 and 2006 Acts with regard to research that impressed the Joint Committee (Chapter Five, at 4.) in favour of the Scottish formulation¹³⁶, and it was the nature of the consultations and ‘pre-legislative’ scrutiny in Scotland which appears from my studies to have determined the approach to research in the 2006 Act. I recognise that consultation may be easier in an electorate of 5 million, as compared to 55 million. Pre-legislative scrutiny, by contrast, is a matter for Parliament.

4. Recommendations.

With diffidence, I hope that the studies in this Thesis may contribute specifically to any wish of Government and the medical/scientific professions to review their processes of consultation and negotiation prior to developing new legislation with an impact on research; and more generally to the case for more regular use of pre-legislative scrutiny of Bills at Westminster. In making the latter proposal I find that I am in good company. Chris Mullin MP, the much admired and independently minded Member of Parliament for Sunderland South, was uniquely granted the

¹³⁶Joint Committee on the Human Tissue and Embryos (Draft) Bill (Session 2006-07). Volume 1: Report. The Stationery Office, 2007, p36, para 114.

privilege of a valedictory speech to the House of Commons as recently as March 25, 2010. He closed with the following words:

Finally, a word to the coming generation of politicians. I have one simple message: take Parliament seriously. If we, the elected, do not, why should anybody else? By all means one should support the programme on which one's party was elected, but we are not automatons. We are not sent here merely to be cheerleaders, or to get stiff necks looking up at the fount of power. We are here to exercise our judgment-to hold Ministers to account for the powers they hold. And that means proper scrutiny. It means insisting that Ministers engage seriously with Parliament, and that they are open to dialogue. It means, so far as possible, insisting that the Government publish legislation in draft so that it might be improved before it is set in stone.¹³⁷

It is to be hoped that Ministers also were listening attentively.

¹³⁷ (2010) 508 (Hansard, 6th series) HC, 485.

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GLOSSARY

Alder Hey: The Royal Liverpool Children's (Hospital) Inquiry.

BG: Hospital Boards of Governors.

BHCAG: Bristol Heart Children's Action Group.

BIR : Interim Report of the Bristol Royal Infirmary Inquiry.

BMA: British Medical Association.

BMJ: British Medical Journal.

Bristol: The Bristol Royal Infirmary Inquiry.

CMO: Chief Medical Officer

COPFS: Crown Office and Procurator Fiscal Service.

CPM: Coroner's post-mortem examination.

DCMO: Deputy Chief Medical Officer.

DH: Department of Health

DHSS: Department for Health and Social Security.

DNA: Deoxyribonucleic acid.

EU: European Union.

FOIA: Freedom of Information Act.

FOISA: Freedom of Information (Scotland) Act.

FPM: Fiscal post-mortem examination.

GMC: General Medical Council.

GP: General (medical) practitioner

HAC: Cabinet Home Affairs committee

HBHC: *Human Bodies, Human Choices* (a consultation document from the Department of Health)

HC: House of Commons

HGH: Human Growth hormone.

HL: House of Lords.

HMC: Hospital Management Committee.

HPM: Hospital post-mortem examination.

HTA: Human Tissue Authority.

IRG: Independent Review Group (on the retention of organs at post-mortem)

Isaacs: An Inquiry into the death of Cyril Isaacs,

JCC: Joint Consultants' Committee.

MP: Member of Parliament.

MRC: Medical Research Council.

MSP: Member of the Scottish Parliament.

NACOR: National Committee relating to Organ Retention.

NAS: National Archives of Scotland.

NGO: Non-Governmental Organisation.

NHS: The National Health Service.

PF: Procurator Fiscal.

PITY II: A Liverpool based parents' support group.

PM: Post-mortem examination.

RCP: Royal College of Physicians (London).

RCPATH: Royal College of Pathologists.

Redfern: The Royal Liverpool Children's (Hospital) Inquiry.

Redfern 2: The Inquiry into human tissue analysis in UK nuclear facilities.

RMO: Regional Medical Officer.

ROC: Retained Organs Commission.

SAMO: Senior Administrative Medical Officer

SIDS: Sudden Infant Death Syndrome.

TNA: The National Archives.

WT: The Wellcome Trust.

