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**THE REGULATION OF BRITISH MEDICAL PRACTICE**

**By Kenneth Alastair Meechan**

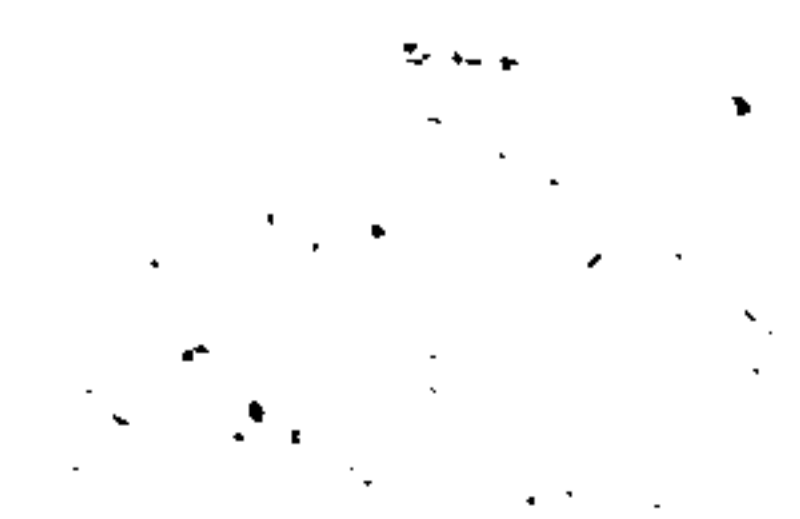
**Submitted for the Degree of Ph.D**

**at the School of Law,**

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***For Heather***



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LIST OF ABBREVIATIONS USED

ACHCEW	Association of Community Health Councils, England and Wales
AHA	Area Health Authority
A-G	Attorney General
BMA	British Medical Association
CA	Court of Appeal
CC	County Council
CS	Court of Session
DC	District Council
DPA	Data Protection Act (1998 unless otherwise specified)
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
FHSA	Family Health Service Authority
FOI	Freedom of Information
FPC	Family Practitioner Committee
GMC	General Medical Council
GP	General Practitioner
HA	Health Authority
HB	Health Board
HC	High Court
HCJ	High Court of Justiciary
HFEA	Human Fertilisation and Embryology Authority
HL	House of Lords (Judicial Committee)
HMA	Her Majesty's Advocate
HMC	Hospital Management Committee
HRA	Human Rights Act 1998
IC	Information Commissioner
IH	Inner House (Court of Session)
IOC	Interim Orders Committee (GMC)
NHS	National Health Service
OH	Outer House (Court of Session)
PC	Privy Council (Judicial Committee)
PCC	Professional Conduct Committee (GMC)
PPC	Preliminary Proceedings Committee (GMC)
RHA	Regional Health Authority
RMO	Responsible Medical Officer
SPM	Serious Professional Misconduct
ULTRA	Unrelated Live Transplant Regulatory Authority

## ABSTRACT

This thesis begins by considering that modern medicine as a profession has tremendous scope for both good and ill, and as an enterprise consumes a vast amount of the national wealth. Against this background, the thesis considers how and why medicine is regulated, and what the effects of this regulation are. The study aims to assess the regulation of the medical profession against the interests of the state, the profession, and the consumers of health care, to see whether the regulatory mechanisms adopted adequately safeguard the interests of all parties concerned with the practice of medicine.

The methodology chapter spells out the analytical techniques which the bulk of the thesis utilises and delimits the scope of the research to cover only bodies having a legal genesis and which are universal in application. A series of “core evaluation criteria” are identified against which the four regulatory mechanisms are assessed.

Chapters 3 to 6 contain the bulk of the actual research into the four main areas of regulatory endeavour which the study considers; each is analysed in turn in terms of the purpose, mechanism and effect of the regulatory machinery being considered and then assessed against the core evaluation criteria.

Finally, the conclusions chapter draws together the different threads which the sector-specific analyses have identified as being points of concern, and the system as a whole is evaluated to see whether the interests of the relevant stakeholders are adequately safeguarded, to identify any regulatory gaps which exist in the present system, and to point out the direction which anyone seeking to improve the system should consider.

## UPDATE ON RECENT DEVELOPMENTS

As explained in Chapter 2, this Thesis is not primarily concerned with regulatory mechanisms which exist purely within the National Health Service (NHS). However, a number of changes within the NHS have the potential for impacting on medical regulation more widely, and in particular on the conduct of civil litigation relating to medical malpractice.

In late 1997, the newly-elected Labour government published two White Papers<sup>1</sup> on further reform of the NHS, or, to be more specific, on abolishing the internal market which had been created by the National Health Service and Community Care Act 1990. In addition, however, another key point in the White Papers was a new emphasis on what is known as “evidence-based medicine” or EBM for short (although neither expression is used in the Scottish White Paper) with a view on avoidance of resources being diverted into treatments of no proven efficacy<sup>2</sup>. This commitment underlay the creation of a number of new quangos concerned with quality of care - the National Institute of Clinical Excellence, the Commission for Health Improvement (in England and Wales; see sections 19 to 22 of the Health Act 1999), a Nursing and Midwifery Practice Development Unit and a Scottish Health Technology Assessment Centre (in Scotland). Clinical governance and medical audit, the two main approaches adopted by the NHS to attempt to improve quality of care and treatment, are now an inextricable part of the NHS' structure. In terms of Section 18 of the Health Act 1999,

“It is the duty of each Health Authority, Primary Care Trust and NHS trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals.”<sup>3</sup>

It remains to be seen to what extent this new explicit statutory duty to provide quality control mechanisms accelerates the spread of medical audit and related discipline, although a number of bodies have been established in the NHS with a view to improving standards. It is not intended to discuss these bodies in any great detail, but for completeness they should be mentioned. The bodies are geographically limited, and different bodies perform broadly comparable tasks in Scotland and England.

For England and Wales, the two main bodies responsible for quality issues in the NHS are the National Institute for Clinical Excellence (NICE), and the Commission for Health Improvement (CHI). NICE was set up as a Special Health Authority for England and Wales on 1 April 1999 with the role of providing patients, health professionals and the public with authoritative guidance on current “best practice” covering both individual health



technologies (including medicines, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions.<sup>4</sup> CHI was established in terms of the Health Act 1999, and started operating on 1<sup>st</sup> April 2000. It has a role which is complementary to that of NICE, being principally concerned to ensure that the health service bodies which it reviews are complying with their duties under Section 18 of the Act by implementing proper systems of clinical governance. One aspect of this is to ensure that the health service bodies which it inspects are, in fact, implementing the best practice guidance issued by NICE. There is a degree of overlap in some areas where good clinical practice merges into good operational management. The clearest example of this is in the field of medical audit (considered *infra*), on which subject NICE and CHI have issued joint guidance<sup>5</sup>. NICE and CHI are currently scheduled to be merged into a single organisation, to be known as The Commission for Healthcare Audit and Inspection (CHAI).<sup>6</sup> It has been suggested that CHAI will perform a more explicitly regulatory role than CHI did, to its detriment<sup>7</sup>. The omission of the word “Improvement” from the new body’s title has also provoked adverse comment<sup>8</sup>. It is proposed that CHAI will also have responsibility for the private sector and as such would have merited full analysis in Chapter 5 had it been operational within the timescale considered by this Thesis.

In Scotland, the counterpart of CHI is the Clinical Standards Board for Scotland (CSBS). The CSBS was established as a special Health Board in April 1999. The Board’s system of assuring quality and accreditation is designed to complement the duty to demonstrate proper systems of clinical governance imposed by the Health Act 1999 section 51(1). The work which in England and Wales is carried out by NICE is, in Scotland, undertaken by several different bodies including the Clinical Resource and Audit Group (CRAG), the Scottish Intercollegiate Guidelines Network (SIGN), and the Health Technology Board for Scotland (HTBS). All of these bodies seek to provide national guidance on best practice within their particular areas of concern, and again the CSBS system of audit and inspection pays particular attention to whether other parts of the NHS are implementing the guidelines issued by these bodies; the audits carried out by CSBS are also intended to complement those of other bodies such as the Scottish Health Advisory Service (SHAS), the Mental Welfare Commission, Audit Scotland and the work of professional regulatory bodies<sup>9</sup>.

Central to the approach of these quality assurance systems is what is referred to as “medical audit”. This merits some mention in its own right (as it is not exclusively concerned with the NHS) and is considered below.

In 1996, an article published in the British Medical Journal included a list of no less than 25 quality/management initiatives which were underway in the NHS at that time<sup>10</sup>. The

article made no attempt to assess the value of these initiatives in terms of improving standards, but noted that critics of the health care quality management industry

“...questioned the extent to which patients have benefited from the up to £1 billion spent in the NHS on various forms of audit, service standard setting, data monitoring, and other types of quality initiative since the start of the 1990s.”<sup>11</sup>

As we will see in the introduction and methodology chapters, it is important that regulatory mechanisms take due account of the resources which those mechanisms themselves use up. If, as suggested above, quality control systems in the NHS cost one billion pounds from 1990 to 1996, it has to raise questions as to whether or not appropriate value for money tests have been applied to all (or indeed to any) of these initiatives, or to the more recent statutory extension of clinical governance across the NHS. There is an additional suggestion that even with this level of expenditure, the quality control initiatives do not really provide anything like a proper assessment of how good the NHS, or any part of it, actually is:

“The real scandal is... the fact that the NHS has no money for quality assurance. At present audit is done by isolated enthusiasts on the backs of envelopes. ‘Scandals’ arise because a doctor tries to extract a few figures out of a pile of notes for a research project and discovers something that doesn’t look quite right. Before it can be statistically verified by someone vaguely numerate, it hits the press.”<sup>12</sup>

Medical audit is still a relatively recent innovation in the regulation of medicine in Britain, so it may be helpful to begin with some definitions<sup>13</sup>. Thus,

“Medical audit is widely used as shorthand to describe all or part of the complex process of measuring, evaluating, attempting to improve and monitoring change in the quality of care provided by doctors. Some advocates of audit argue that it should be used much more specifically because ‘medical audit is a precise and scientific term describing a well-defined and rigorous discipline.’ They see audit as a specialised part of quality assurance, referring to practitioners themselves reviewing the care they provide, usually with an emphasis on its technical rather than interpersonal aspects, and with the aim of improving its quality.”<sup>14</sup>

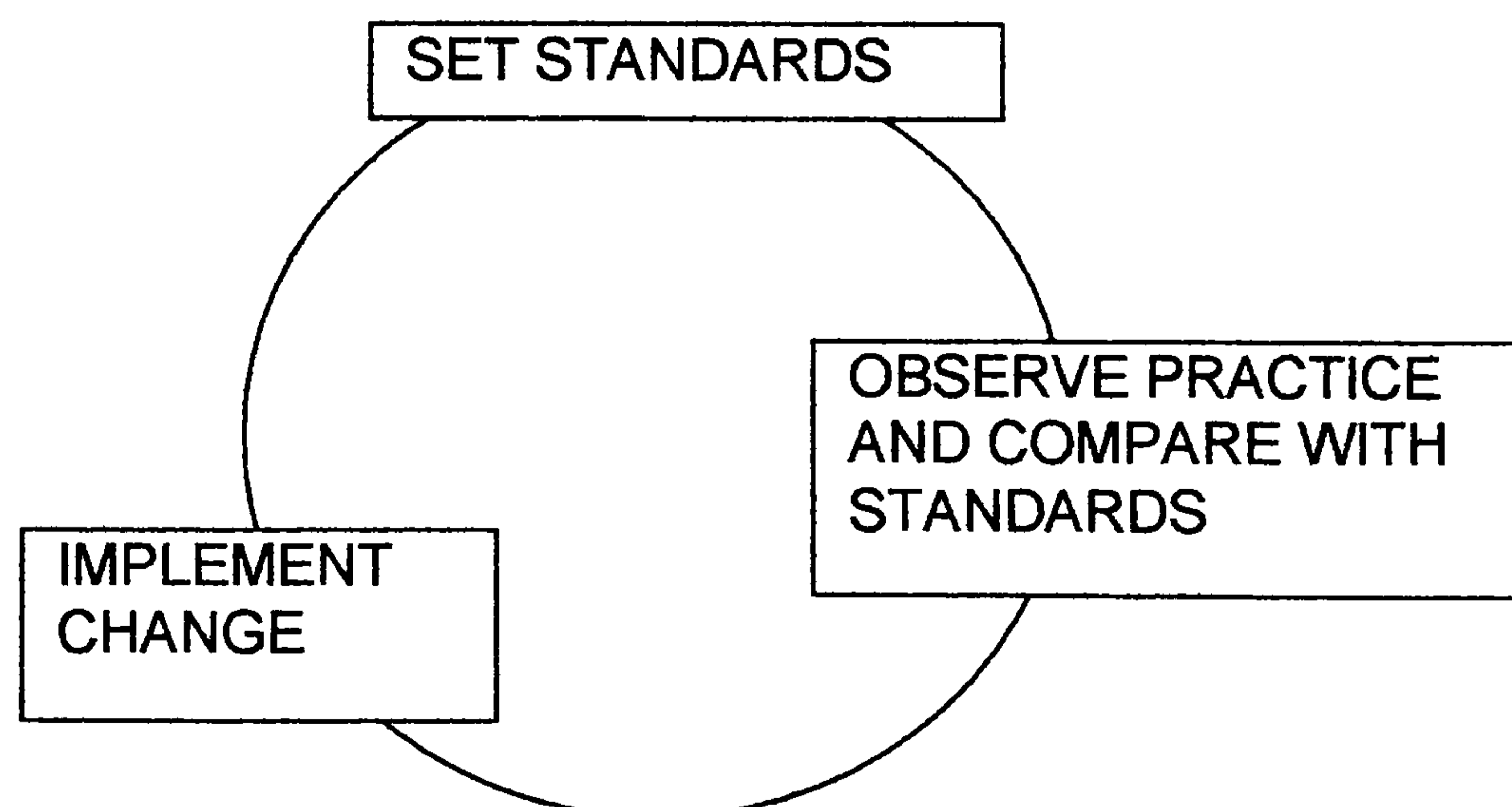
In the wider sense, then, medical audit is a term applied to any of a range of methods by which the actual clinical practice of physicians is scrutinised by other parties. As will be seen in subsequent Chapters, medical audit is virtually unique in penetrating the veil of

“clinical autonomy” which seeks to exclude clinical practice from the jurisdiction of most of the regulatory machinery.

Any quality assurance mechanism must display certain essential features in order to function properly. These are that the mechanism must be capable of:

- 1: Specifying the concept of quality which is to be assessed and assured;
- 2: Actually setting targets, or standards;
- 3: Measuring current practice: and
- 4: Translating these results into practice.<sup>15</sup>

In the case of medical audit, the desire to make assessment more objective led to development of a two-pronged approach based on criteria and standards<sup>16</sup>. “Criteria” indicates the things to be measured, by which quality can be assessed; *i.e.* what is it that the doctor actually does that we are assessing? “Standards” represent the previously-agreed-upon level of attainment which indicates quality. If the criteria of a particular doctor attain the requisite standard, then we can say that the doctor has achieved quality in his or her treatment. This, of course, begs the question of what happens if the doctor fails to attain the standard set, which leads to a second key feature of medical audit: in order that it should result in improvement in (or assurance of) the quality of care, medical audit must include a degree of feedback. This has been characterised by Shaw<sup>17</sup> as the “cycle of audit”, as shown below:



This concept of a “cycle of audit” is now widely accepted<sup>18</sup>, since audit, to be successful, “must include a mechanism for implementing change where problems are identified.”<sup>19</sup>

Medical audit became contentious because its systematic introduction into the NHS coincided with the creation of the “internal market” in the 1990s, and audit was perceived as being part of a government agenda aimed at reducing the power of the medical profession. The troubled history of medical audit in the UK was not helped by comparisons with developments in the US, where medical audit had evolved into a system of “utilisation review” by which health insurers sought to restrict the costs of the medical treatment ordered by physicians<sup>20</sup>. However, while we might have expected some professional opposition to medical audit (for the simple reason that audit goes right to the heart of medical practice in that it scrutinises the clinical activities of doctors), in fact the professional organisations, and most notably the Royal Colleges, have made a number of pronouncements strongly in favour of it<sup>21</sup>.

The systematic form of medical audit now undertaken in Britain requires there to be a baseline standard against which the level of clinical activity observed in the course of an audit is compared. It is in this area that we see a development which may ultimately change the conduct of medical malpractice forever.

In “pure” medical audit, the information gathered firstly in the course of establishing the baseline, and secondly in comparing a particular doctor’s activities to this yardstick, is gathered to enable remedial action to be taken in the event of a shortfall in performance. However, having acquired such information, there are a number of alternative uses to which it can be put.

The most obvious use is to introduce some form of resource monitoring, in order to prevent treatment not deemed adequate as a way of saving money. Thus, in the US, a Utilisation Review nurse routinely has to be consulted before treatment under the Medicare and Medicaid programmes is authorised<sup>22</sup>. This obviously goes beyond the realms of audit, and represents a considerable reduction in clinical freedom of a type which British doctors have yet to experience. Another use concerns the revalidation proposals being introduced by the General Medical Council (GMC), considered as a postscript to Chapter 5. Under these proposals, participation in a modified form of medical audit will become a prerequisite to continued registration as a medical practitioner by the GMC.

One particular potential use of medical audit which most advocates of medical audit are opposed to concerns the use of audit results in the course of litigation. Medical audit, even in its purest form, provides indicators of the quality of medical care. This gives rise to a number of medico-legal issues. As is seen in the chapter discussing litigation, one of the most significant barriers to successfully bringing an action for medical negligence is

that the plaintiff or pursuer must show that there exists an accepted course of treatment, which the doctor negligently departed from<sup>23</sup>. The essential problem for the aggrieved patient is that a “wall of silence” may be erected by doctors unwilling to be seen criticising a colleague, and so he or she may find it impossible establish an accepted course of treatment, and so the claim will generally fail.

The significance of medical audit here is that, under the auspices of the appropriate body, an approved standard of care will have been promulgated, with which to compare audit criteria. The argument, advanced initially by John Evans<sup>24</sup>, is that these standards could be adduced as evidence of what constituted the legally-acceptable standard of care. He notes further that, in a legal climate increasingly predisposed to the notion of openness of records in legal proceedings, the documents detailing these standards are unlikely to be immune to the courts’ powers of discovery. For doctors, this is a double-edged sword. On the one hand, it simplifies (in theory) at least one part of the bringing of a successful malpractice claim against doctors. On the other, it raises the prospect that any course of treatment carried out in accordance with such standards is almost certainly going to be deemed non-negligent by a court - particularly given the courts’ reluctance to question accepted medical practice<sup>25</sup>. Evans postulated this theoretical approach in 1991, when medical audit was still in its early days and there was no central body with overall responsibility. The intervening eleven years of litigation have tended to prove him wrong inasmuch as the reported cases of medical negligence have not proceeded on the basis of either the medical audit findings in respect of a particular doctor, nor on the basis of medical audit protocols and standards against which that doctor’s practice was or could be compared. However, since 1991 we have seen a change in the regulatory landscape through the creation of NICE and CHI. In essence, we now have a government agency with a specific statutory remit for setting down in clear and unequivocal terms what is or is not to be regarded as good medical practice.

The prospect of medical audit findings (as opposed to the protocols underpinning such audit) being used as evidence in court proceedings is opposed by the professional bodies; the Royal College of Physicians comments that:

“Confidentiality is a prime consideration. The identity of patients discussed should never be revealed or capable of being traced, both to protect the anonymity of individual patients and to avoid any danger of documents used in audit being employed in legal proceedings.”<sup>26</sup>

Certainly, if audit were conducted in such a way as to make any connection between audit findings and a particular patient genuinely impossible to establish, then the issue becomes

hypothetical. In practice, however, such a separation cannot be created because at least one person - the doctor in question - will know who the patient is. If a court really wanted access to medical audit records, then it could get it (barring a Contempt of Court by the doctor, which seems unlikely, or else by the doctor denying, and being believed in his denial, that the patient's case has never been the subject of discussion. Such an approach is obviously unsatisfactory to all parties). Increased rights of access to files under the Data Protection Act 1998, considered in Chapter 7 *infra*, may also exacerbate this problem.

Whether a court will ever order such disclosure is open to speculation. There are two countervailing pressures here. From the patient's perspective, medical audit findings may constitute valuable evidence in support of his claim, and it would be unjust to deprive him or her of this evidence. This is all the more true if it were the case that compliance with medical audit standards were a complete (or near-complete) defence to a finding of negligence. In effect, the doctor would be in a no-lose situation: if he complied with the standards, he produces the records and is exonerated; if he did not, he refuses to produce them and the plaintiff or pursuer must rely on other methods to infer or prove negligence. Only if a court were willing to infer negligence in the face of non-production of records would this not be the case, and this seems unlikely in the present climate. However, it has been pointed out that the only grounds under which medical audit protocols would be immune from discovery would be a public interest defence<sup>27</sup>, but this is irrelevant given that NICE routinely publishes its protocols and seeks to give them the widest possible publicity<sup>28</sup>. Accordingly, the guidelines produced by a government agency tasked precisely with the job of issuing best practice are in the public domain and could accordingly be relied on in proceedings for medical litigation. And while NICE itself has been constituted as a special health authority and is accordingly part of the NHS (and so, in accordance with the methodology of this Thesis outwith the scope of the detailed scrutiny which follows), it would be hard to argue that its guidance is not equally applicable to private and voluntary health care. The guidance which it issues could therefore be relied on in any proceedings, including those against private health care providers. We therefore have the situation where an NHS regulator exerts a wider influence on the regulation of health care (through the medium of the civil courts).

At the time of writing, this theoretical possibility does not seem to have been widely explored, and the writer has been unable to find any decided cases where clinical guidance of the type just described (whether published by NICE or by any of the other bodies who previously promulgated medical audit protocols) has been led in evidence in a medical negligence case, far less any cases where such evidence was decisive for the outcome of the case. At this time, therefore, the influence which NICE or its successor

may exert on civil litigation (and through such litigation, on the practice of medicine generally) is as yet hypothetical. Should such a development occur, however, it would represent another example of the increased regulation of the medical profession.

## Notes on update on recent developments

- <sup>1</sup> *The new NHS: modern - dependable* (1997) Cmnd 380; *Designed to Care* (1997) Cmnd 3811
- <sup>2</sup> A useful introduction to the world of EBM can be found in L Ridsdale, *Evidence-based general practice: a critical reader* (1995)
- <sup>3</sup> Section 51(1) of the Act imposes an identical duty on Scottish NHS bodies
- <sup>4</sup> NICE website <http://www.nice.org.uk/cat.asp?c=137> (accessed 3 April 2002)
- <sup>5</sup> NICE, *Principles for Best Practice in Clinical Audit*, (2002); the full text is available on-line at <http://www.nice.org.uk/pdf/BestPracticeClinicalAudit.pdf> (accessed 3 April 2002)
- <sup>6</sup> Following on from proposals in Department of Health, *The NHS Plan: next steps for investment, next steps for reform* (2002)
- <sup>7</sup> K Walshe, "Power with responsibility" HSJ 7 June 2002, 25
- <sup>8</sup> Comments at the British Association of Medical Managers' annual conference 2002, reported in HSJ 20 June 2002, 13
- <sup>9</sup> CSBS website <http://www.clinicalstandards.org/faq.html> (accessed 3 April 2002)
- <sup>10</sup> D Taylor, "Quality and professionalism in health care: a review of current initiatives in the NHS", *BMJ* 312 626 (9 March 1996) 626
- <sup>11</sup> *Ibid.*, 628
- <sup>12</sup> "Doing the rounds", *Private Eye* 985 (17 September 1999), 12
- <sup>13</sup> A recent and comprehensive review of published articles relating to medical audit can be found in Appendix XI of NICE, *Principles for Best Practice in Clinical Audit, op. cit.*, by R Baker *et al.*
- <sup>14</sup> J. Hughes and C. Humphrey, "Medical Audit in General Practice," 1990, p.5; quoting D.H.H. Metcalfe, "Audit in general practice," *BMJ* 1989, 299, 1293-4
- <sup>15</sup> T. Jost, "The necessary and proper role of regulation to assure the quality of health care", (1988), *Houston Law Rev.*, 25, 525
- <sup>16</sup> A. McBride, "Medical audit: A Critical Review" in S. McVeigh & S. Wheeler (eds.), *Law, Health and Medical Regulation* (1992), p.196
- <sup>17</sup> C. Shaw, (1980) "Aspects of Audit" 280 *BMJ*.1256, 1314, 1361, 1443 and 1509, esp. at 1444
- <sup>18</sup> See, for instance, M. Marinker, "Performance review and professional values", in D.A. Pendleton, T.P.C. Schofield & M. Marinker (eds.), *In pursuit of quality*, (1986)
- <sup>19</sup> Royal College of Physicians, *op. cit.*, p.3
- <sup>20</sup> For an introduction to utilisation review, see M Moran and B Wood, *States, regulation and the medical profession* (1993), 61. It has been suggested that utilisation review has such a profound impact on the level of health care services actually delivered that the utilisation review companies should themselves be regulated: M.J. Field & B.H. Gray, "Should we regulate 'Utilisation management'?" , *Health Affairs*, 8(4), 103-12 (1989)
- <sup>21</sup> See Royal College of Physicians, *op. cit.*, ; DA Pendleton, TPC Schofield, M Marinker *op. cit.*
- <sup>22</sup> Although this does not affect the fundamental responsibility of the physician for his or her patient: *Wickline v State of California* (1986) 228 Cal Rptr 66
- <sup>23</sup> *Hunter v Hanley* 1955 SC 200; *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118; and see Chapter 4 generally.



<sup>24</sup> Legal adviser to Trent RHA; his views are described and analysed by A McBride, *loc. cit.*, 205-8

<sup>25</sup> Kennedy & Grubb, *op.cit.*, p.452; and see generally Chapter 5, *infra.*

<sup>26</sup> RCP, *op.cit.*, p5

<sup>27</sup> A McBride, *loc. cit.*, 206

<sup>28</sup> For details of how NICE seeks to publicise its guidance (and involve the public in the making of that guidance), see <http://www.nice.org.uk/cat.asp?c=129> (accessed 19 September 2002)

## Chapter 1: Introduction:

### I: Policy background:

In June 1998, the then Secretary of State for Health for England and Wales, Frank Dobson, announced that a public inquiry would be held into the management of the care of children who had received complex cardiac surgery at the Bristol Royal Infirmary from 1984 to 1995 – management which had left at least 29 children dead and resulted in the General Medical Council taking action against two of the doctors concerned<sup>1</sup>.

In January 2000, British Prime Minister Tony Blair announced a proposed spending increase for the UK's National Health Service ("NHS") which would take total annual spending on the NHS to some £57 billion<sup>2</sup>. The 2002 budget statement proposed taking the annual spending level to £105.6 billion by 2007-8<sup>3</sup>. This figure does not even include the sums spent on private health care in the UK, or money spent on health care by British citizens elsewhere in the world.

In February 2000, Dr. Harold Shipman, a general practitioner working for the NHS, was convicted of the murder of fifteen of his patients, amidst fears that he may have murdered as many as 297 people over thirty years' practice<sup>4</sup>.

And on a single day in England, nearly 700,000 people visited their doctor.<sup>5</sup> This was a typical day.

These examples show the sheer scale, in human and financial terms, of the modern medical profession and its related professions and activities. They also show the potential for causing great harm which the modern practice of medicine possesses.

Against this background, it is unsurprising that the practice of medicine is regulated – by the state, by bodies set up by the state for this purpose, by the courts, and by those who practise medicine themselves. Fellow medical professionals can reasonably be expected to have an interest in maintaining the integrity of the profession's generally high public esteem and reputation. Patients clearly have an interest in knowing that those who would treat them are properly able to do so. The professions who assist doctors are regulated – in part by doctors. The drugs and other treatments which represent the tools of the medical trade are themselves regulated and may be subject to resource shortages. Those who claim to have suffered at the hands of doctors may seek to hold them accountable, or at least seek to hold them liable in a financial reckoning. Those

who pay for the exercise want to make sure that their money is being well spent. Ultimately, all these factors are concerned with ensuring that the medical practice which takes place is “good” medical practice, from the point of view of those concerned.

This thesis takes as its starting point the wide range of bodies and interests involved, in varying degrees of formality, scope and compulsion, in regulating the practice of medicine in Britain. The question arises, against this background, as to how well these disparate pressures and interests can co-exist. It is that question which this thesis seeks to address – are the inherent conflicts of interest between the assorted regulators, and the different purposes for which medical practice is regulated, so great as to make a coherent and effective approach to regulation impossible? It seems reasonable, without going into any detailed scrutiny, to assume that different mechanisms for regulating how medicine is practised will have different objectives in mind. It is only a little beyond this starting point to consider the possibility that these objectives might turn out to be different, and only a little beyond that to consider that these different objectives might be mutually incompatible. This thesis is intended to test that possibility.

The working hypothesis underpinning this thesis is as follows:

**“Does the present system of regulation of medical practice in Great Britain provide adequate safeguards for the interests of patients, doctors and the State?”**

The “medical practice” which this question is considering is discussed next; the way in which this thesis seeks to answer the question is described in the final section of this Chapter.

## **II: Scope of Research:**

In seeking to answer the question posed by this working hypothesis, this thesis will conduct what in many respects is similar to the technique known as a “SWOT” analysis, *i.e.* it will consider in turn the strengths, weaknesses, opportunities for and threats to those having an interest in the system of medical regulation of that existing system. The nature of a SWOT analysis is that it is a tool for improvement, and ultimately this thesis hopes to be able to provide pointers for the policy-makers who are able to institute changes which could lead to improvements in the system. The nature of the study is such that improvements in some areas may have to be bought at the expense of others.

Geographically, the study is restricted to Scotland, England and Wales. At various points, reference is made to approaches utilised further afield – either as an aid to assessing how a currently open question might be addressed by the British regulators, or as a comparison showing how else a particular issue could be approached. Medicine is an international discipline, and the issues raised within this study are common to many (and in some cases, virtually all) parts of the world. Temporally, the study starts in prehistory and extends in the main to June 2001. At this point, however, the devolution settlements created by the Scotland Act 1998 (and, to a lesser extent for the purposes of this Thesis, by the Government of Wales Act 1998) had begun to bed in. One consequence of devolution is that it is no longer possible to identify a consistent UK-wide government agenda for health, as had been possible up to that point. The introduction of free personal care for the elderly in Scotland<sup>6</sup> is an example of this growing trend towards more diversity. A small amount of later material (up to September 2002) has, however, been included where possible and relevant.

The precise subject matter covered is discussed in more detail in the next chapter; however, in general, all the formal mechanisms whose purpose is the regulation of medical practice in this country are considered, together with some of the less formal ones having a quantifiable impact. The main focus of the study is the regulation of medical practice where it affects the adult patient having full mental capacity. That said, it also considers a number of the problems inherent in medical practice as it affects those not enjoying full capacity, and the mechanisms which seek to address those problems. The mechanisms included in the study are those which regulate the entire body of medical practice as a whole. However, in a study of medical regulation in Britain, it is important to note the distinction between medical practice taking place under the auspices of the NHS (which accounts for the overwhelming majority of medical care which takes place in Britain) and medical practice taking place outwith it, in private medical practice. The NHS itself has a complex set of regulatory mechanisms, although many of these lack the properties of the global regulatory systems with which this thesis is particularly concerned. NHS-specific mechanisms clearly have limited scope, but given the sheer scale of the NHS and its activities, it is impossible to ignore these mechanisms completely. An outline of the key NHS regulatory systems is therefore included in Chapter 3. Quasi-medical activities such as dentistry, optometry and nursing, as well as the various forms of alternative (or complementary) medicine are not examined in detail, although again reference is made to these areas as appropriate. Likewise, the practice of medicine is also subject to a number of peripheral controls, such as those on the availability and licensing of pharmaceuticals, and the rules governing liability for products used in the course of medical treatment. These arguably do not

have the regulation of medicine as their principal purpose, and are not discussed in detail as a result. The inclusion of other mechanisms which also do not have medical regulation as an explicit objective is explained in Chapter 2.

### **III: Structure of thesis:**

The structure of the thesis is, to a large extent, determined by the various regulatory mechanisms which it examines.

Chapter 2 sets out the methodology underpinning this study. It examines the nature of regulation as a concept and provides a philosophical background. It analyses the different approaches to the concept of regulation which can be taken, and, against this evaluation, breaks down the system of regulation into a number of discrete areas which form the basis of later chapters. It then identifies a series of what are called “core evaluation criteria”. These are the yardsticks of success which the bulk of the thesis measures the existing system against. The method of measuring is to consider each regulatory mechanism identified in terms of its purpose, its mechanism, and its effect. This approach is explained and refined, and the structure of the later chapters is mapped out. These later chapter will apply the approach in question to the regulatory mechanisms being evaluated.

Chapters 3 through to 6 are the substantive studies of the global regulatory mechanisms currently extant. They follow a similar structure of firstly considering the purpose of the mechanism (if it has an explicit purpose at all); secondly, of describing, in some detail, what the mechanism actually is and how it works; and thirdly the actual effects which the mechanism has in practice. Each chapter concludes by then applying the analysis described in Chapter 2 to the mechanism which has just been examined.

Chapter 3 looks at the criminal law, and in particular the relatively limited use which has been made of the criminal law as a regulatory tool in this area. Criminal law is considered first because, while it is of limited (but significant) relevance as a regulatory tool in its own right, it is often the mechanism used to ensure that people and organisations involved in the health care system subscribe to the authority of other regulators.

Chapter 4 moves on from this to look at the civil law, and in particular how the civil courts have been used as a regulatory tool in the context of litigation brought against those who practise or are responsible for the practice of medicine. The legal tests applied by the

courts are considered in some detail, and the chapter also proceeds to consider some of the problems inherent in using civil courts as a regulatory tool at all.

Chapter 5 looks at the statutory regulatory bodies, *i.e.* those bodies established or recognised by statute who have a role in regulating the practice of medicine. The main focus is on the General Medical Council, but a number of other bodies exist which are also considered, albeit not in detail.

Chapter 6 considers the other main method of regulation utilised by the State – that of direct statutory regulation. This covers areas where Parliament has seen fit to make direct changes to the law so as to alter the legal footing of a particular form of treatment – either through the legalisation of what was previously illegal, or the criminalisation of what was previously legal. Direct statutory regulation may also be used to vary the civil rights of the respective parties, which accounts for a significant proportion of this chapter.

In Chapter 7, we revisit the core evaluation criteria and assess how the system as a whole fares against these yardsticks – and how this performance could be improved in each area, and at what cost. Chapter 7 provides an overview of the existing regulatory regime, considered in terms of the seven evaluation criteria rather than in terms of structural or functional distinctions. It then goes on to reach some conclusions and provide an answer to the working hypothesis. This overview considers what the main problems identified are and touches on possible ways of addressing these shortcomings. It concludes with a look at what policy initiatives might be applied (and by whom) in the field of medical regulation in the future.

## Chapter 1 notes

<sup>1</sup> The Inquiry has a comprehensive website at [www.bristol-inquiry.org.uk](http://www.bristol-inquiry.org.uk) detailing background, remit etc. (Last accessed 1 September 2002)

<sup>2</sup> Interview, *Breakfast with Frost*, 20 January 2000

<sup>3</sup> Chancellor of the Exchequer, Budget statement to Parliament, 17 April 2002

<sup>4</sup> Department of Health, *Harold Shipman's clinical practice 1974-1998: a clinical audit commissioned by the Chief Medical Officer*, 2001

<sup>5</sup> NHSE, *A guide to the National Health Service* (1996), 5

<sup>6</sup> In terms of the Health and Community Care (Scotland) Act 2002

## Chapter 2: Methodology

### I: Introduction:

In Chapter 1, a working hypothesis was posited, namely that this thesis considers whether the present system of regulation provides adequate safeguards for those concerned in the health care system. This question is, of course, open-ended, and as such it is necessary to limit the scope of the research in question.

Any discussion of the mechanisms for regulation, control, accountability and dispute resolution in British medical practice must face two fundamental difficulties: firstly, the complex system of legal, quasi-legal, and informal controls which exist; and secondly, the problems inherent in attempting to control any professional endeavour. The regulation of the medical profession displays a considerable number of the problems inherent in regulating any profession, and has a few problems which are unique.

This chapter sets out how these problems will be addressed, and attempts to delimit the scope of the research. The subject area is vast, incorporating aspects of public and private law, philosophy, sociology, political science, management, and legal process. Most of these aspects have individually been the subject of a considerable body of literature. Consequently, it is necessary to spend some time clarifying the position being adopted and the approach to the subject being taken.

For the sake of clarity, it is necessary to expand somewhat on the questions which this thesis seeks to address. The intention is to ask whether the current mechanisms regulating British medicine are an adequate way of safeguarding the rights of individuals and society as a whole, or whether these mechanisms suffer from ineffectiveness and conflicting objectives. Is it clear what purpose these regulatory mechanisms serve, and are these purposes fulfilled? This thesis will examine the proposition that as currently constituted, the practice of medicine in the UK is improperly regulated, since the extant controls are of a disparate nature, lack coherence and co-ordination, and are frequently mutually contradictory in their aims.

A number of assumptions underlie this proposition, and this chapter explores the validity of these assumptions and the philosophical basis of the study as well as establishing the methodology by which it seeks to test the working hypothesis. The nature of regulation as a concept is considered, as is the way in which this concept can best be applied to the bodies currently regulating British medical practice.



## **II: The nature of regulation:**

### **A: What is “regulation”?**

As noted above, a wide variety of disciplines are relevant to the issue of regulating medicine. Similarly, we shall see that there is an equally wide variety of ways in which the concept of regulation is approached. One possible reason for the varied nature of the control mechanisms is that the entire concept raises so many questions:

- Why is medicine regulated at all?
- Why is it regulated in the way it is?
- What are the purposes, mechanisms and effects of these regulations?
- Can these aims be better realised by other mechanisms? and
- What do we mean by “regulation” anyway?

Many of these questions will be touched upon (if not necessarily answered) in the course of this work; however, they are raised here to discuss the ways in which questions of this nature can be approached. The questions also contain a number of assumptions, which should also be considered. In posing these questions, we assume that the questions are, in fact, capable of being answered – that there is an actual motive to be discerned, that the purposes, mechanisms and effects of the system can be assessed and checked for compatibility. These assumptions will be tested throughout chapters 3 to 6. It is possible that not every aspect of the system is capable of being assessed in this way, and it may on occasion be necessary to regard certain aspects as unknown. This is not in itself a problem – it is in itself of interest, and a valid conclusion for a study, to reveal that regulatory mechanisms appear to have been created for no discernible reason, or that they have no quantifiable impact on what happens in practice. However, the present concern is not with what answers are found, but rather with what questions a researcher looking at the regulation of an activity should ask.

Firstly, what does this thesis understand “regulation” to mean? The dictionary definition is not very helpful, stating that “regulation” means “the act or process of regulating”<sup>1</sup>. The word “regulating” is, in turn, defined as meaning:

“to adjust (the amount of heat, sound etc. of something) as required; to control... to bring into conformity with a rule, principal, or usage.”<sup>2</sup>

From this, it would appear that regulation has something to do with exercising control or making adjustments so as to bring something into line with a rule. The dictionary definition is silent on the nature of the control or adjustment and the source of the rules in question. For the purposes of this study, it is considered that these aspects cannot be ignored – we have to know about the rule-makers as well as the rule-enforcers, and it is clearly necessary to look at the nature of the controls or mechanisms for adjusting behaviour.

At this stage, no judgement is offered on who the regulators should be – all those performing general regulatory functions will be considered in this discussion. However, it is necessary to consider who is being regulated. This thesis is, as its starting point, looking at the medical profession – or, put shortly, at doctors. It will be necessary, as part of the definition of what the regulation of medical practice actually means, to examine the concept of medicine as a profession, since in large measure what is being looked at is the regulation of the medical profession. The concept of a profession carries with it certain generally-recognised prerequisites, one of which is a large measure of self-regulation and in particular control of entry to the field<sup>3</sup>. Consequently, professions as a concept, and the particular issue of self-regulation by a profession, will also be considered. The actual systems of self regulation currently in existence are considered in later chapters. The institutional structures within which medicine is practised, in particular the National Health Service (“NHS”), are considered in terms of setting the regulatory background. Given the scale of NHS activity in Britain, it would be impossible to ignore NHS mechanisms completely, but as these mechanisms are only applicable to NHS practice (widespread though that may be) and do not regulate *all* medical practice, they are not analysed as part of the overall structure of this thesis.

It may, in some circumstances, be hard to separate what regulation is from the question of what it is intended to do. Even proceeding on the basis of dictionary definitions, we find that regulation involves control or adjustment in line with rules – but to understand regulation, we need to know which objective is being pursued, and to what end practice is being controlled. This is the “purpose” of regulation, one of the three key elements to each aspect of the system which will be examined. The confusion between regulation *per se* and its purposes is well illustrated by the following discussion of regulation within the context of the (now dismantled) “Internal market” which operated within the NHS from 1991 to 1999:

*“What is the aim of regulation ?*

Regulation is one of the tools to achieve maximisation of the health of the population by the efficient delivery of services through an internal market. *Specific*

*goals for regulation will include the protection of users or consumers, the protection of the taxpayer and the support of the internal market... One of the central tasks of the NHS Management Executive is to 'operationalise' regulation and to use it as one tool for achieving the NHS goals of effectiveness, efficiency and equity. Regulation is not costless. It may have perverse incentives. It should only be undertaken if there are clear benefits. Regulation is not a substitute for day-to-day management, nor should it be used as such. Likewise, regulation is not planning. An internal market may require as much planning as a centralised system, albeit of different forms and possibly involving different groups of actors. Regulation is not a substitute for decisions that have long-term consequences, such as the planning of medical manpower, or the location of specialised facilities. Regulation of particular activities may have similar effects to planning—for example, the expansion of expensive imaging facilities was regulated (belatedly) in the USA and this affected the pattern of provision. Similarly, self regulation by the professions to ensure adequate quality will affect the location and availability of specialist treatments. Regulation will interact with management and planning. Occasionally, regulation may be required when either is deficient."*<sup>4</sup>

Clearly, the approach adopted in this passage explicitly adopts a series of goals for the regulation being discussed therein, and the nature of these goals is inextricably linked to the nature of the regulation in question. This thesis accepts that some recognition of goal orientation is necessary to define regulation; however, it rejects explicit assumption of policy objectives as an essential element. This rejection is based on the analysis which follows, whereby regulation is found to perform certain functions. None of these functions requires a *particular* policy orientation as a prerequisite, although some policy orientation is generally discernible. However, other policy orientations are equally discernible, leading to the conclusion that one can regulate towards different policy objectives *at the same time*, thus leading in turn to the further conclusion that no single policy need underlie the regulatory machinery as a whole. Accordingly, no particular policy objectives are identified as necessary elements of the regulatory system, beyond the policy objective of regulation itself (and on occasion not even that). Rowan-Robinson *et al* have, however, identified some of the policy factors which tend to underpin regulatory efforts and emphasise the necessity of regulation:

"Regulation is necessary to safeguard the environment, to maintain standards of health and safety and to protect the interests of customers, consumers and employees. Thus, whilst steps are being taken to slim down the corpus of regulation and to focus more clearly on its objectives, there seems little doubt that a substantial volume of regulation will remain a feature of our society."<sup>5</sup>

For the purposes of this paper, “regulation” is defined as meaning all or any of the following activities:

- The setting of standards of medical practice
- The upholding of these standards
- The facilitation of medical practice in accordance with these standards
- The provision of systems to allow redress for those who suffer due to a failure to adhere to these standards
- The provision of channels to permit grievances to be aired and disputes resolved
- The provision of systems of investigation to inquire into whether standards are being adhered to or not, whether across the board, at the instigation of the particular regulator itself, or in response to allegations being made/complaints received
- The punishment of those who fail to adhere to the standards, and
- The regulation of the regulatory system itself to ensure that the above tasks are being carried out.

Following on from this, “regulator” and “regulators” are simply references to those bodies and persons who fulfil any of these tasks in relation to medical practice – whether formally or informally. Ultimately, it can refer to the State (in its broadest meaning), or else to the general public or the “public interest”. And the regulation of medical practice in Britain which the working hypothesis refers to means the methods, organisations, persons and rules (both legal or otherwise) by which these regulatory tasks are accomplished, or at least attempted.

In adopting this definition, it is accepted that the dividing line between definitions of regulation and policy statements regarding what to do with the regulatory machinery is a thin one, and that some of the tasks outlined above are at least arguably on the “policy” side of the line. In response, it is argued that these tasks could be regarded as the bare essentials of a regulatory system. For reasons that are explained below, the absence of any of these features renders a regulatory system defective. It therefore appears to represent an acceptable starting point (for the discussion of whether the regulatory system is working properly) to utilise the minimum definition of regulation consistent with meeting the requirements of a regulatory system.

Much of what follows concerns discussions of accountability and liability. As the term is used in this thesis, issues of liability should be approached from the perspective of the person who has (or claims to have) suffered some form of adverse consequence as a

result of some failure in regulated standards. Questions of liability involve attempts to redress the adverse consequences suffered, and deciding who is to provide the redress in question. This is a separate question from that of accountability, which is concerned with identifying the person or agency whose action or inaction resulted in the breach of standards. What happens once the identity is known is dependent on the regulatory mechanism in question. It may not involve any form of liability to the person who suffered as a consequence of the breach; similarly, financial liability falling on a person or organisation does not necessarily involve anyone being held accountable (whether to the victim or anyone else) for the breach in question. Overlaps are possible but not essential.

## **B: The science of regulation:**

Having set out a definition of regulation, it still remains to consider how to study it. A number of disciplines have considered the issue of regulation of particular sectors (and of the health care sector in particular), and approach the study of regulation from very different perspectives.

Thus, one could adopt a sociological standpoint, and study the regulation of medicine as an aspect of the growth of organisational bureaucracy (in the sense of a goal-oriented rational organisation acting within narrowly-defined parameters) which, according to Max Weber<sup>6</sup>, is inevitable in Western capitalistic societies. Hughes<sup>7</sup> considers that NHS bureaucracy has arisen primarily as a method of resource control. While this may be relevant in understanding the approach which NHS mechanisms have adopted, this thesis is concerned with the global regulation of medical practice, not with mechanisms which apply to it only in part. The NHS's prevalent position as supplier of medical treatment in the UK has arguably tended to confuse the approach of legislators who appear on occasion to respond to an identified overall regulatory deficit by focussing on redressing the problem only as it applies to the NHS. Thus, while Hughes' and Weber's approaches are not directly relevant in analysing the overall regulatory landscape, they are important inasmuch as they help to explain why certain systems have only been applied to the NHS and not to the practice of medicine as a whole.

In terms of a Weberian bureaucracy, the NHS is unusual in being a legally-created edifice without regulations, merely discretionary powers given to ministers to create such regulation:

“- an explicit recognition of the medical profession's proper jurisdiction over its own work activities, and of its powers of self-regulation. However, that grant of discretion has always made available other regulatory mechanisms that may limit

professional autonomy quite as effectively as the provisions of statute, and which are now being called upon to do increasing work.”<sup>8</sup>

The issue of professional self-regulation which Hughes touches upon is a recurring theme throughout this topic, and will be dealt with at length in subsequent chapters. The sociological critique of this approach has been provided by Lindblom<sup>9</sup>: a “rational systems model” (such as the NHS, but the critique applies equally to other areas) is frequently guilty of “incrementalism”, meaning it tends to deal with its problems only in a piecemeal, ad hoc fashion, studies only a limited range of solutions, and adopts solutions which are only marginally different from the existing arrangements. In the wider picture, having a number of different agencies responsible for decision-making (as appears to be the situation with medicine) can lead to “disjointed incrementalism”, resulting in an absence of overall strategy. Although this research is conducted from a more legalistic viewpoint than Lindblom’s, the concept of “disjointed incrementalism” is one which will be expanded on in later chapters.

Other approaches place considerable emphasis on the effort invested in a given problem by decision-makers, and the specific options which they have at their disposal when making a decision<sup>10</sup>, or relate decision-making to internal power struggles or external manoeuvring between corporate rationalisers, professional monopolisers, and the community population<sup>11</sup>. In considering the validity of this approach to the present study, it is important to keep the working hypothesis in mind. This study is intended to consider the effectiveness of the current system of regulation against a series of predetermined criteria; it is not directly concerned with the science of policy making, of which these approaches are effectively subsets<sup>12</sup>. As Lindblom himself later acknowledged,

“Policy-making is... a complexly inter-active process without beginning or end.”<sup>13</sup>

Narrower sociological approaches focus on the nature of medicine as a profession, and consider regulation as it applies to such a monopolistic construct, balancing the sometimes-contradictory interests of the state, the public, and members of the profession itself. The functionality of the medical profession is the object of study, rather than the bureaucratic structure within which that profession finds itself. Rueschemeyer<sup>14</sup> considers how professions “strike a bargain” with society, exchanging competence and integrity for freedom from outside interference and competition, substantial remuneration and higher social status. He draws on a tradition which regards professions as social constructs worthy of study in themselves, and which regards medicine either as an unusual aberration from the norm, or as the exemplar against which other professions (or would-be professions) are measured. Thus, while Rudolf Klein notes that,

“medicine provides an example of professional power in an extreme – and in some ways unique – form if only because in the last resort it deals with matters of life and death”<sup>15</sup>,

Downie reminds us that,

“it is important to stress that the concept of a profession is a developing one and a definition must not become solidified around the characteristics of law and medicine ... while surgery is nowadays considered to be a paradigm of a profession it was not always thought to be so.”<sup>16</sup>

The problem can also be approached from the opposite direction, that of the patient or potential patient. The different viewpoints of the lawyer and the philosopher coincide to focus attention on the ways in which the freedom and autonomy of the individual are protected against a paternalistic professional monopoly and a dispassionate bureaucracy. The philosophical standpoint of this study is considered later, but for present purposes, suffice to say that the stance adopted is explicitly pro-patient autonomy. As Douzinas and McVeigh note,

“It is hardly possible to think of any ethico-legal discourse concerning medical practice that does not, at some stage, come to be thought of in terms of autonomy.”<sup>17</sup>

In the present case, emphasis on Kantian notions of personal autonomy<sup>18</sup> leads to critical scrutiny of an enterprise wherein that autonomy is, by the very nature of the exercise, vulnerable. Nor should the scientific foundations of modern medicine blind us to the need for such scrutiny; as McLean observes,

“No discipline and no individual has, or should have, the power to strip others of their liberty to reach out for their aspirations or to stake their legitimate claims. The danger is that human rights take second place to the paternalism or monopolisation of one group substantially because they can claim scientific reasoning as their bedrock.”<sup>19</sup>

This consideration of the need to safeguard autonomy against paternalism leads the philosopher, and through him the private lawyer, to emphasise the importance of the patient’s consent to procedures, and more generally to have a greater say in his situation within the medical enterprise and ensure that his or her rights as an individual are respected. This is a more immediate form of participation than democratic theory requires

him or her to have in the setting of general objectives in health care, which is again within the remit of the political scientist.

The public lawyer takes a wider view than the private lawyer: instead of asking whether the individual's rights have been breached in a particular case, the public lawyer instead asks whether mechanisms exist, and have been followed, which will protect those rights:

“A grievance may relate to a broad policy or to a particular decision, to a clinical or administrative matter, and the actor may be the health authority, the GP, the hospital doctor, or another. The NHS has an equally complex system of both internal and external channels for the expression of grievances involving, for example, hospitals, district health authorities, and the Secretary of State. A first task for the public lawyer is to consider whether this peculiarly intricate system is co-ordinate and efficient or is a net with holes.”<sup>20</sup>

As already noted, this thesis is not concerned with the “intricate system” described by Baldwin in the above passage. However, the systems described in Chapters 3 to 6 are equally complex, and the same tasks can be undertaken in relation to them. Mechanisms for resolving disputes between patients and doctors or other health care providers are an inherent part of any discussion of control and accountability:

“From the point of view of a public lawyer, complaints and their handling are a fundamental aspect of accountability; part of a belief that in a democratic system there must be an opportunity for the public to air and redress their grievances. A lack of effective avenues for complaints is in itself an injustice. It has already been argued that in the modern state the possibility of participating in decision-making through the usual democratic channels has been undermined. Complaints processing may help to alleviate this tendency by allowing decisions to be challenged and investigated, which can in turn provide a wider base of information for decision-making. Complaints procedures may therefore attain a degree of indirect consumer involvement in policy processes as well as contribute to a reputation for fair dealing, and so help legitimise health policy.”<sup>21</sup>

Other aspects of dispute resolution mechanisms necessitate their study: any system of control requires machinery to ensure compliance, and these mechanisms are one of the fundamental ways by which a doctor who transgresses some of the codes purportedly regulating his or her behaviour is brought to task. As will be shown in succeeding chapters, a large number of the regulatory mechanisms require a complaint by someone to trigger their enforcement powers, and this “someone” is most commonly an aggrieved



patient. As Longley notes above, the right to complain about the exercise of power is perceived as a fundamental right in a modern democracy, and is a necessary aspect of making those who exercise that control accountable for their actions. Indeed, this function of increasing accountability through use of complaints mechanisms is one which is stated by some commentators to be crucial in regaining transparency and extending accountability to the service user him- or herself (as opposed to accountability to a third party)<sup>22</sup>. The approaches adopted by the regulators in carrying out that function are considered next.

### **C: Regulatory strategies:**

How, in practice, is medicine regulated? The detailed mechanisms are discussed in the following chapters, but it is appropriate at this point to discuss the strategies which these bodies apply. These strategies have in themselves been the subject of a number of cross-disciplinary studies, and the following is only the barest outline of a large body of work, mostly sociological in nature, which seeks to analyse regulatory strategy.

In discussing regulatory behaviour a distinction can be drawn between the two principal strategies of compliance and deterrence:

“The principal objective of a compliance law enforcement system is to secure conformity with law by detecting violations of law, determining who is responsible for the violation, and penalising violators to deter violators in the future. Whether or not one seeks to redress as well as to prevent harm is an important condition affecting choice of strategy... . Deterrent systems arise when the occurrence of events in time and place are unpredictable, and where their causes are imperfectly understood so that particular preventive action cannot be taken ... . Compliance systems, consequently, are often associated with testing and licensing systems, especially ones that require some demonstration that conformity exists prior to undertaking a particular activity that could cause harm. The licence itself can be seen as a conditional reward: so long as one conforms, one is licensed to be rewarded. Control of medical practice, for example, opts for both licensing practice and sanctioning malpractice; but the critical sanction is the withdrawal of the licence to practice ... The tort doctrines of negligence and liability for harm rest on deterrence strategies. The presumption is that one will exercise ordinary care to avoid the costs of being found liable. Tort doctrines are designed to redress injury and reduce the risk of injury.”<sup>23</sup>

It seems clear, on this basis, that any effective attempt at social regulation must have certain prerequisites: clearly-defined goals, a mechanism for enforcing them, and a properly thought out strategy both to govern the operation of the mechanism and, in part, to determine its form. It should also incorporate adequate complaints mechanisms, supervisory systems and general monitoring in order to assess its effectiveness and provide redress for its failures. As Rowan-Robinson *et al* observe in the course of their study into the use of criminal sanctions as a regulatory tool,

There is no doubt that the way in which a code of regulation is framed can have a bearing on the role of the criminal law in its enforcement. This manifests itself in several ways. First of all, the point at which anti-social conduct becomes criminal varies from regulation to regulation. Unlawful conduct may, for example, be a straightforward matter of omission or commission... Alternatively, and commonly, the legislature may prescribe, generally by statutory instrument, the exact level of performance which must be attained (...) or which must not be exceeded (...). Such precise standards give clear guidance to the potential deviant population, they make detection of offences relatively straightforward and they encourage uniformity in enforcement. On the other hand, detailed regulations may suffer from multiplicity, complexity and, on occasion, obsolescence. And they give rise to "over-inclusion" (in the sense that an offence is committed whether the standard is breached by an infinitesimal amount or by a large amount) and "under-inclusion" (in the sense that by specifying exactly what is required and what is not permitted, there is a risk that damaging practices or products may be left unregulated). Because of the inherent defects of detailed rules, the legislature sometimes opts for imposing standards in more general terms. "Unwholesome," "best practicable means," "reasonable care" are examples. Such general standards allow for a degree of flexibility and responsiveness; their use discourages routine and mechanical prosecution and allows enforcement officers to take account of a variety of factors in deciding whether an offence has been committed; they also avoid the obvious problems of over and under-inclusion and obsolescence which beset detailed standards. However, the use of general standards also has disadvantages. It can be difficult for traders, manufacturers, employers, etc., to know with certainty whether they are complying with the law; it makes enforcement problematic and there is scope for disagreement about whether an offence has been committed; and it can result in a lack of uniformity in enforcement practice. Rather more specific standards may be set at the local level in the form of conditions attached to a licence or certificate of one sort or another... The ability to tailor conditions to the requirements of individual cases confers very considerable discretion upon regulatory agencies in determining standards of conduct. The

advantage of this mechanism is that, more than any other, it enables standards to reflect local circumstances and may even lead to a “negotiated” standard. The disadvantage is that an infringement does not bear the stamp of a breach of a clear legislative standard... The third way in which the framing of the code of regulation may bear on the role of the criminal law is through the provision of alternative sanctions...

The other group of factors which bear on the role of the criminal law in this field is what we describe as “operational factors.” Our research confirms the findings of other research into discrete codes of regulation that the employment of the criminal law is influenced in practice, not only by the form of the legislation, but also by a range of external matters. The provision in a code of regulation for invoking the criminal law cannot, it seems, be viewed in isolation but must be seen as one part of a complex interactive process. There are numerous such factors including, for example, the perception by the regulatory agency of its functions, the level and nature of accountability of the agency, the method of discovering and detecting offences, the nature of the client group and the availability of alternative sanctions... [T]he weight to be attached to any one of these factors appears to vary not just from code to code but from case to case.”<sup>24</sup>

Having said that, at least one recent study of regulatory strategy (admittedly in the rather different context of the regulation of private landlords who commit the offence of unlawful eviction) concludes that

“There has been a recognition that few regulators adopt a strategy which places criminal sanctions at the forefront.”<sup>25</sup>

The factors identified by Rowan-Robinson *et al* have, nonetheless, informed the choice of evaluation criteria which later chapters apply to the existing regulatory system. They also inform the conclusions drawn latterly when, having made assessments of the existing mechanisms against these criteria, alternative approaches are considered. It will only be necessary to consider alternatives if it seems at that stage that the existing arrangements appear to be defective or inadequate in meeting their purposes, or if those purposes are inadequately expressed. As commentators have pointed out,

“As various topical approaches to regulatory reform are discussed, it is important that proposals for change be informed by an understanding of the way regulatory bureaucracies carry out the essential tasks of enforcement. New approaches should reflect knowledge of patterns of enforcement common to many problems of regulation, as well as to practices unique to particular tasks.”<sup>26</sup>

This point is, it is submitted, a well-made one, and proposals for change which are advocated without such a comparative study having been conducted can (for that reason alone) be regarded as flawed.

The analysis concerning regulatory strategies is also inextricably related to the question of analysing the purposes underlying the regulatory machinery. The regulatory machinery governing any particular undertaking can be broken down into the three basic components of purpose, mechanism, and effect; this is explained in more detail below. Given that choice of regulatory strategy is (or should be) informed by the purpose of the regulation in question, properly enunciated purposes appear to be a prerequisite to effective regulation. If one is at the stage of designing a regulatory mechanism, it would appear even more crucial to know precisely what one is attempting to do. It is also important to consider whether or not the regulatory mechanism should be hierarchical or not; alternatives to hierarchical approaches include enforced self-regulation and tripartism (whereby a non public sector organisation is permitted to undertake regulatory tasks<sup>27</sup>.)

Having considered the approach of the regulators to their task, the next section considers the philosophical approach of this thesis to its own task of evaluating the current system.

### **III: Philosophical background:**

As stated in Chapter 1, this thesis intends to examine whether or not the existing system for regulating health care in Great Britain provides adequate safeguards to protect the interests of patients, doctors and the State.

At this stage, it is necessary to expand on some more of the assumptions which are embodied in the hypothesis, and more specifically some of the value judgements which are inherent in any attempt at answering the question posed. The first question is what constitutes an “adequate” safeguard. This point is considered below in the context of the evaluation criteria.

The second, and in many ways more problematic question, concerns what “interests” are (and which ones should be) protected by the system. Patients have a clear interest in receiving the best possible health care – but this might not correspond with the interests of the doctors in question if, for instance, best possible care involved the doctors having to work extremely antisocial hours; and it might not correspond with the state’s interest in keeping costs down. Conversely, improving doctors’ conditions might not correspond with patients’ expectations of service or the state’s interest in improving the health of the

nation. It may also conflict with the interests of other patients (or potential patients) if the “best possible” care in question is tying up scarce resources resulting in those other patients having to wait or go without. Some of this will involve conflicts between what might generally be regarded as “legitimate” interests.

This thesis proceeds by accepting that not all interests should be protected within the system. The proper purpose of a health care system is, it is submitted, to facilitate the best health care provision possible within the outside context factors which confine that system. In an ideal world, doctor and patient would fully and freely co-operate, being in agreement over what was the patient’s best interests. Indeed, there is some evidence to suggest that active collaboration between doctor and patient has certain therapeutic, to say nothing of legal, benefits<sup>28</sup>. Once leaving Utopia, however, this happy picture fades and we are left with the situation of having to deal with an imperfect situation. The imperfections are varied. Firstly, medicine is in itself a highly inexact science<sup>29</sup>, while there are also variations in levels of knowledge among medical practitioners and variations in the frequency with which they commit errors<sup>30</sup>. And those practitioners may well have a system of working which fails, either in specific cases or as a policy, to pay attention to the wishes of the consumers of health care, the patients<sup>31</sup>. There is always the possibility of the maverick who breaks the rules and who must be taken into account when considering these issues. Finally, there is an argument which says that critical scrutiny is required of any enterprise wherein the individual is, by the very nature of the exercise, vulnerable. The philosophical justification for this has been put as follows by Williamson:

“Autonomy comes from a Greek word meaning the self, one’s own, by oneself, self-determining... [W]hat we call autonomy is broadly independence and self-determination. Autonomy in a narrower sense is decision-making. An autonomous decision is one made by the self. It is presumed to be made in the self’s interests, since no one can know what those interests are as sensitively as the self can. The decision can be made with help or advice. But it is still the self’s. The opposite, allowing or asking another person to make the decision, is heteronomy. Paradoxically, heteronomy can be an autonomous choice. Belief in the other’s greater knowledge or expertise; or indifference to the decision; or a strategic purpose in asking or agreeing that someone else make the decision, are choices of that sort. Autonomy’s opposite is dependency... But although people’s autonomy in the wide sense of being able to function as an active agent is reduced by sickness or accident, their ability to take decisions about themselves is not necessarily impaired. (Provided they are not unconscious or demented.)

Rather, the preoccupation with the self that goes with concern or anxiety may enhance it.”<sup>32</sup>

It follows from the foregoing discussion that autonomy is an important concept in the health care system we are discussing, although it is important to note that autonomy is, itself, a complex notion and that there are variations as to what precisely it means. These variations are worth expanding on, and have been summarised as follows:

“There are three main forms of autonomy:

1. Deontological autonomy.
2. Relativistic autonomy.
3. Social autonomy.

The first of these... suggests that the patient has the right to decide for himself or herself between various therapeutic strategies, or to decide if he or she wants treatment at all, or to use health care services at all. Under deontological autonomy, we are free to act responsibly but without taking into account our personal inclinations and attitudes as individuals as to whether we want to act in this way... This is to be compared with the second form of autonomy - relativistic autonomy - in which each individual has a right to adopt his or her own preferences. The individual's own preferences should be taken into account. Here, as compared with deontological autonomy, the patient has the choice as to whether or not his or her preferences are counted... The third form, social autonomy, implies a rejection of individualism (which is endorsed by both deontological autonomy and relativistic autonomy). Values are common - they are social values. Rights and obligations are acquired in social contexts. They determine power and dependence between individuals. And this form of autonomy in turn leads to the notion of societies having a responsibility for the weak.”<sup>33</sup>

It can be seen that, in the first passage, Williamson states that it is open to the individual to choose to allow someone else to make a decision on his or her behalf; it can be seen from the second passage that this version of autonomy is classified as relativistic autonomy if it is accepted that relativistic autonomy encompasses the autonomous wish to delegate the decision to someone else. This version of autonomy is not in accordance with Kant's classical exposition of autonomy, under which individuals act under a “moral imperative” to act autonomously (*i.e.* the individual is morally obliged to make the decision him- or herself) – this is closer to what is described above as deontological autonomy. In this paper, references to “autonomy” will (unless otherwise stated) be references to relativistic autonomy.

Williamson<sup>34</sup> refers to the opposite of autonomy as being dependency. However, in most discussion of the medical field, the opposite concept discussed is seldom dependency, but rather paternalism. This is a matter of focus rather than of definition, since “paternalism” refers to the motivating philosophy of the agency other than the individual. Paternalism is defined as

“The attitude or policy of a government or other authority that manages the affairs of a country, company, community, etc. in the manner of a father, especially in usurping individual responsibility and the liberty of choice.”<sup>35</sup>

This definition does not make particularly explicit one of the key points about paternalism as it relates to the medical sphere: that as an approach to medical practice, it is ethically defensible from the doctor’s perspective, and complies (in general) with the general medical ethical obligations of *beneficence* (i.e. doing good for/to patients) and *non-maleficence* (i.e. not doing harm to patients). Indeed, one of the key points about medical paternalism is that it can (on occasion) be more in accordance with the notion of beneficence than respect for patient autonomy. The patient wants to follow a course which is medically ill-advised. Respect for autonomy permits the patient to do so; paternalism on the part of those responsible for their care might mean that the choice is denied that patient, and the course preferred by the doctors presented as the only available option. In clinical terms, the outcome might be better. In philosophical terms, we have used that patient as the means to an end, not as an end in him- or herself. The doctor’s desire to reach an optimum clinical outcome (typically chosen unilaterally by the doctor) has been allowed to override to patient’s rights, in the name of the best interests of that same patient.

This thesis takes the view that autonomy is important, and that it should be taken into account in the regulation of medical practice. This point is picked up again in the discussion of the evaluation criteria below. However, it is not an absolute right, and other interests also have to be taken into account. In the course of regulating medicine, society acts on the basis of a number of different purposes. Precisely what these other purposes might be is considered below, and in more detail in Chapters 3 to 6 – there are a variety of motives at work. This thesis takes as a starting point the proposition that regulation of the health care system should only be intended to facilitate the continued operation of that system in accordance with the rights and interests which should be protected. This continued operation should involve facilitating what doctors do best and allowing them to practise the skills they have acquired at great trouble and expense, within the limits of the protected interests. The regulation to which doctors are subject should not be of such a draconian nature as actively to impede the proper exercise of medicine, nor lead to the

self-defeating result of encouraging legally motivated “defensive medicine.” (Using that term to mean medical care which is *only* being given with a view to avoid legal liability, and which would not otherwise be clinically indicated.) It should involve ways of safeguarding and promoting the quality of the health care being provided, both as an essential element of the system itself, and as a way of safeguarding the patient’s (protected) interest in receiving quality care. And the interests of other citizens and the state are also of relevance – as are the interests of doctors. Regulation is defective if it prevents doctors from practising good medicine which the patient wants. Indeed, this point is taken as being axiomatic: the only proper purposes of medical regulation can be to ensure that doctors are able freely to exercise their skills and talents, while the patient has a right to such care, and in such a way that his or her own rights are not subverted in the course of the treatment.

This is an explicit acceptance of the moral superiority of autonomy over paternalism, and as such is a value judgement. As with any value judgement, it is incapable of objective justification. The point is made to allow those who agree (or disagree) with this viewpoint to be able to identify the source of any disagreement with the conclusions which follow.

#### **IV: Scope of the regulatory system:**

##### **A: Legal and non-legal regulatory mechanisms:**

The scope of the regulatory mechanisms which will be looked at were described in outline in Chapter 1. This section sets out why the regulatory system has been divided (and in some respects, why it has been delimited) along these lines. It will consider why the approaches are so varied, and also whether this is a logical set of divisions to apply to them. It is not a division found in any official description of what happens in British medicine today, although similar divisions are used in many textbooks on the subject.<sup>36</sup>

In addition to the controls which are the subject matter of chapters 3 to 6, there are a number of other controls which are not listed. A number of these relate to the various ways in which general health policy is established. In general, such fundamental policy issues can be seen as the arena of the politician or political scientist, rather than the lawyer. It is up to the government of the day to determine priorities for health care – indeed, to decide whether to regulate medicine at all, or return to the *laissez-faire* practices of pre-18<sup>th</sup> century medicine. Parliament may act or not in response to the activities of pressure groups and lobbyists, as a consequence of advances in medicine (such as with genetic engineering), changes in social attitudes (such as abortion), or simply because of the interests of an individual MP. The law has a role to play here too,



although the issues concern the public rather than the private lawyer. Constitutional law creates the machinery by which such issues may be legislated on, and administrative law has a role in ensuring that policy decisions are adhered to and delegated authority neither abused nor exceeded (a role which is explored in Chapter 4). In general, however, these are background factors which are also outwith the scope of this work. They are important background factors to be borne in mind, however; in a sense, they create the canvas on which the regulatory machinery is painted.

One of the key issues to decide when setting these limits is whether to have regard to the formal legal status of a mechanism or body, and if so, whether this legal status is to be conclusive of the question of inclusion. The lawyer studying the regulatory framework is confronted with a confusing mosaic of bodies and controls, the legal validity of some of which is perhaps questionable. Much of the activity which superficially passes as regulatory in nature stems from the exercise of discretion or legally-delegated authority. Even the centrality of the law to this picture is seen as debatable. Thus, Longley observes that:

“What is perhaps under-emphasised is that the law is not just, as described, an instrument for achieving goals but is also a means of promoting and ensuring accountability and legitimacy in public decision-making, principles which are fundamental to our ideas of democracy and citizenship.”<sup>37</sup>

In contrast, McVeigh and Wheeler caution us that:

“While lawyers might find it gratifying to have their suspicions confirmed, that law must be at the centre of any discussion of responsibility in regulation, few others could be convinced that law has anything other than a peripheral role to play in the regulation of health and medicine.”<sup>38</sup>

Harvey Teff, meanwhile, suggests that:

“...the law itself cannot effect a substantial change in the routine behaviour of doctors, but it could have some symbolic impact in their perception of what is appropriate in relationships with patients.”<sup>39</sup>

The final school of thought on the subject is summed up by McLean, who notes the gulf between law's possible and actual role:

“...freedom and dignity can indeed be protected against the unwitting presumptions of the modern gurus, and... the best protection is afforded by law and legal process... Concepts of justice, formal and distributive, due process and a tradition of respect for rights are inherent in legal systems and can provide a framework within which complex moral matters can be debated and perhaps even resolved. However, a significant and crucial caveat must be entered here. The argument is not that the law actually does this - rather that it could.”<sup>40</sup>

Ultimately, however, this thesis is only concerned with those regulatory mechanisms which have a discernable legal genesis, since this provides a delimitation to the mechanism which an informal regulator lacks. Inclusion of non-legal regulatory systems (although “influences” might be a more appropriate description) would result in a completely open-ended, and consequently unworkable, analysis.

A final consideration in setting the limits of the regulatory systems under discussion is universality of application. This thesis is concerned purely with mechanisms which apply to all medical practice (at least in theory, since not every doctor will undertake practice in a field subject to some of the regulatory mechanisms discussed). The main consequence of this approach is to exclude from the scope of the study mechanisms which have been set up within the NHS, a point considered below in more detail.

#### **B: Main mechanisms excluded from study:**

Having established the parameters of the study, it is fair to note that there are some exceptions to the rule. Some of these exceptions almost deserve to be included because of the marked effects which they have despite their lack of legal formality or universality. However, this lack of formality also leads to difficulties in quantifying or assessing the impact which these exceptions have, and so while they are mentioned here, they are not subjected to the detailed analysis of the more formal mechanisms.

The most important of these influences was briefly mentioned above – that of professional self regulation. It is not intended here to rehearse the sociological discussions concerning what is and is not a profession. However, it is important at this juncture to note that one of the hallmarks of a profession is that it should have certain forms of self regulation entrusted to it by the state. In the case of the UK, the “official” aspect of professional self regulation is carried out through the auspices of the General Medical Council, or GMC. The GMC is discussed in Chapter 5. There is, however, another facet of self regulation which, falling outwith the scope of the formal machinery, is not included in the substantive analysis. This relates to the fact that there is rather more to self-regulation than the

“official” organs, of which the GMC is simply the most obvious. There is also a less formal side to professional self-regulation, described by Rosenthal as follows:

“The process of ‘self-regulation’ has both formal and informal manifestations. The formal mechanisms are easily identified. They include selection for admission to medical school, systems of medical education and testing, registration (licensure), speciality credentialing and formal disciplinary activities. These are relatively visible organizations and processes in many societies... The criteria for entrance to medical school are potentially the most powerful tools for effective self-regulation the profession has. The characteristics of those admitted to medical education are a key basis for future behaviour... There are regulations governing disciplinary procedures and there are stated codes of professional behaviour and etiquette. The GMC, empowered by Parliament to carry out these functions but financed and controlled by the profession, is a prime example of exclusively professional self-discipline and regulation. These are the recognized mechanisms of professional self-regulation... Learning and maintaining appropriate collegial and professional behaviour is an intrinsic element of professional self-regulation and self-discipline. The inculcation of appropriate norms of behaviour, towards a colleague and as a professional, is as important as the science and art of medicine, although it is learned through a socialization process rather than classroom lectures. Through the behaviour of faculty, doctors on the wards, the informal exchange of experiences and observations, and the formal statements of professional organizations, students and young doctors learn what is expected of them as professionals and colleagues. Experienced doctors are presumably reminded of these norms throughout their careers.”<sup>41</sup>

This socialisation process appears to have a substantial effect on how doctors act, according to Rosenthal on the basis of extensive confidential interviews. But it is not, in any formal way, a regulatory mechanism. Crucially, in terms of whether to include it in the scope of this thesis, it is not a mechanism which is in any realistic way subject to being adjusted by any particular group, organisation or interest. Whatever the strengths or drawbacks of this aspect of professional self-regulation, it is not one which is subject to variation at anyone’s behest. There is, according to the methodology being followed, no reason to include such unquantifiable and uncontrollable factors within the primary elements of the regulatory system being assessed.

Another major omission concerns the effect on the practice of doctors of various external influences. This includes such things as guidelines given by professional societies and defence organisations. It also has to include the activities of pharmaceutical companies in

attempting to persuade doctors to prescribe their own products, often done in the guise of education, although ongoing moves by both the present and previous governments to restrict doctors to a small list of generic medicines seem likely to have curtailed much of this activity. Doctors complain that these restrictions infringe on their clinical freedom, but as Downie notes:

“... if clinical freedom is the freedom to spend other people’s money without any audit then it ought to be curtailed. A profession can still be independent within the constraints set by the cashier.”<sup>42</sup>

The single largest exclusion concerns NHS internal mechanisms<sup>43</sup>. In the UK, the overwhelming majority of medical practice takes place under the aegis of the NHS, and it would therefore arguably have been appropriate to include these mechanisms. They affect (in theory) most doctors and the majority of clinical activity. However, we are assessing the overall adequacy of the regulatory system. A regulatory system which depends on mechanisms of limited applicability and scope is, almost by definition, deficient in that it fails to address the regulation of medical practice outwith the scope of these limited mechanisms. It is, however, impossible to ignore the existence of the NHS systems. The pervasive nature of NHS activity has influenced the activities of other regulators, and so the approach of these other regulators to NHS practice (in particular, the role of the civil courts) is included within the main body of the study where appropriate.

Finally, it should be noted that this thesis is concerned to adopt an overarching view of the regulatory system as it applies to medical practice as a whole. For this reason, a number of mechanisms which only affect highly specialised areas of medical practice, and which would otherwise have satisfied the inclusion criteria, have been omitted from the detailed study which follows. The remits of these mechanisms, and explanations as to why they are not included in the main body of the thesis, are given at appropriate points *infra*.

### **C: The regulatory mechanisms included:**

A number of shaping factors have already been discussed which influence the bodies included in this section (and accordingly included in chapters 3 to 6). In some measure, the bodies included are the mirror of those excluded.

Firstly, the definition of regulation itself serves to exclude some bodies, such as those under the Vaccine Damages Payments Act 1979: mechanisms which do not carry out any regulatory function have been excluded. As a corollary to this, the presumption is that

any body/mechanism which, at first appearance, appears to satisfy one or more of the eight aspects of regulation should be included.

Secondly, the exclusion of non-legally based mechanisms also excludes a number of informal mechanisms. This leads to the conclusion that any legally-based mechanism should be included.

Thirdly, the regulatory bodies included should all enjoy universal jurisdiction. The main effect of this is to exclude NHS bodies, but it also serves to exclude other regulatory bodies which only apply to specific fields, such as the Mental Welfare Commission which is concerned purely with the care of persons subject to compulsory mental health detention. The corollary to this exclusion is that bodies having universal jurisdiction should be included. As will be seen in Chapter 5, only one body (the GMC) actually satisfies these criteria.

Fourthly, regulatory behaviour can be based on compliance models or deterrence models. This creates a presumption that bodies seeking to impose compliance with or deterrence from certain types of behaviour within the health care system should be included.

Each of these can be regarded as a filter rather than as an admission criterion; in other words, only those organisations/systems/mechanisms which, on a provisional analysis, appeared to satisfy all four criteria have been included. This exercise produced a list of four different areas:

- Criminal law
- Civil litigation
- Regulatory bodies, and
- Direct statutory regulation

The division of the categories was based on which aspects of the definition of regulation the mechanism in question appeared to seek to address. For ease of reference, the activities which this thesis takes as falling within the definition of “regulation” are as follows:

1. The setting of standards of medical practice
2. The upholding of these standards
3. The facilitation of medical practice in accordance with these standards

4. The provision of systems to allow redress for those who suffer due to a failure to adhere to these standards
5. The provision of channels to permit grievances to be aired and disputes resolved
6. The provision of systems of investigation to inquire into whether standards are being adhered to or not, whether across the board, at the instigation of the particular regulator itself, or in response to allegations being made/complaints received
7. The punishment of those who fail to adhere to the standards, and
8. The regulation of the regulatory system itself to ensure that the above tasks are being carried out.

As will be seen, there is a considerable degree of overlap in the regulatory activities which the various aspects of the system undertake; nonetheless, this approach led to division on the following grounds:

- Criminal law (which essentially refers to the actions of the criminal courts) has as a key function activity 7 – punishment. It has ancillary purposes relating to setting and upholding standards, and arguably provides a grievance channel. The investigative machinery is outside the health care system, although it is capable of responding to complaints from within.
- Civil litigation (here referring to the actions of the civil courts in adjudicating on disputes brought before them) is principally concerned with activity 4 – redress for those who suffer. Like the criminal law, it also has functions relating to setting and upholding standards and providing a grievance channel. Certain specialised forms of litigation can be used to control the activities of the system as a whole (or of parts of it), or investigate adherence to standards.
- Regulatory bodies have activities 1 and 2 at their heart, with possibly an element of activity 3, facilitation of good medical practice. Depending on the regulatory body, there may (in theory) be virtually any or all of activities 4 to 8 as an addition, or ancillary, to the standard setting/upholding activity. None of the bodies examined paid significant attention to these ancillary activities.
- Direct statutory regulation is arguably subsumed within the other categories, since Parliament can only make things actionable in either the civil or criminal courts, or set up a specific body to perform the policing function instead. Its inclusion as a separate category is because of the difference in actors concerned. Chapter 4 considers the actions of the criminal courts, although these actions may be as a result of particular activity being made criminal by Parliament. The distinction is that this chapter is considering areas where it is Parliament which has laid down the parameters of the conduct in question, and not delegated the matter to the

courts (civil or criminal) or to some other actor such as a regulatory body. There remains a considerable overlap between this chapter and others, since much of the direct statutory regulation concerned will be enforceable in the courts at the behest of someone alleging a failure to adhere to Parliament's new standards. The crucial point is that Parliament has decided to take matters into its own hands. This can relate to any of the regulatory activities mentioned above.

As can be seen, some activities are undertaken by more than one regulatory mechanism, and some mechanisms (indeed most, if not all) undertake more than one regulatory activity.

In parallel with the overlap in regulatory functions, it is also the case that a single incident can fall within the jurisdiction of more than one piece of regulatory machinery. Thus, a particular negligent act could result in both civil liability and attract the attention of the GMC. It is conceivable (if improbable) that a single incident could violate the rules of all of these. However, the importance of the distinctions lies not in their functional differences, but in their underlying purposes. Again, there is a degree of overlap here: litigation, statutory regulatory bodies and the criminal law all afford the public protection from, and redress against, an unqualified person professing to be a doctor. Yet one can still perceive differences in the form and degree of motive for doing so; the criminal law seeks to discourage and punish such a dangerous form of fraud; the GMC (in addition to wanting to protect the public) could reasonably also be expected to be concerned with ensuring continued public confidence in its members. It therefore does not want unqualified persons besmirching the reputation of the medical profession. The civil law's major concern in such a case is to provide compensation for the fraudster's patients if and when (as is likely) something goes horribly wrong. Until it does go wrong, and a complaint is made, it is quite conceivable that such a person could escape the authorities' notice almost indefinitely; this shows the importance of complaints procedures. Thus, despite certain superficial similarities in motive, there are quite discernible differences.

#### **V: Purpose, mechanism, and effect:**

Throughout this thesis, the component parts of the regulatory system will be analysed in terms of a tripartite division: *purpose*, *mechanism*, and *effect*.

"*Purpose*" indicates the motives, explicit or otherwise, which provide the impetus behind any particular regulatory measure; as will be seen in later chapters, many regulatory measures may not, in fact, have been intended as such.

*“Mechanism”* is the actual structure through which the actors seek to give effect to the measure, however informal that structure happens to be in practice. A mechanism could be a corporate structure set up by primary legislation with full-time staff and impressive premises, or it could be a line in a contract. The unifying theme is that the mechanism is intended to be the conduit by which regulatory purpose is (or is supposed to be) turned into regulatory effect.

*“Effect”* covers what happens as a consequence of the measure; this may or may not coincide with the original motive, and may have unexpected consequences or “side-effects”, beyond what was intended. The analysis of regulatory effects carries a number of methodological difficulties

Each of these will be looked at in turn.

#### **A: Purpose:**

To a large extent, analysis of the purposes of the regulatory mechanisms involves identifying which of the regulatory tasks the mechanism is intended to carry out, although it is necessary to go beyond the bare bones of the definition in this respect. The purposes underlying control mechanisms are important for a number of reasons.

Firstly, without explicit recognition of motive, any analysis of the effectiveness of a measure must necessarily be deficient: how can effectiveness be measured except against the yardstick of what was intended? This, of course, also requires some knowledge of the outcomes of the process, although the outcome measurement is principally subsumed in considering the *effects* of regulatory mechanisms.

Secondly, in order to evaluate the working hypothesis described in Chapter 1, it is necessary to consider whether the various structures are at odds with each other – which again requires their purposes to be known, although it also presupposes some knowledge of the effects of these measures.

Thirdly, in determining appropriate regulatory strategies for a mechanism, it also appears beneficial to have explicit purposes to inform the choice of strategy. This also appears to be true of the choice of regulatory mechanism.

The analysis of underlying purposes behind the regulation will consider possible motives ranging from what might be regarded as the patently obvious to what must be conceded as amounting to the extremely hypothetical. In general, these assorted motives fall into



five families, sometimes overlapping, sometimes conflicting. The categories are, broadly, as follows:

- A: Public policy grounds – protecting individuals, the public, the medical profession, etc.
- B: Ideologically motivated – encouraging equitable access to medicine, encouraging market forces, upholding patient autonomy, etc.
- C: Penally-motivated – punishing wrongdoers, and having them seen to be punished.
- D: Financially motivated – curtailing rising costs of health care, giving financial redress to the victims of mishaps, allocating costs and resources, etc.
- E: “Selfish” motives – ensuring professional autonomy, maintaining the medical monopoly, reducing doctors’ liability, etc.

There is also the fact that any particular initiative can have a multiplicity of underlying purposes, not all (or any) of which will have been openly acknowledged. To take an example of this, the changes in NHS structures which resulted from the National Health Service and Community Care Act 1990 were introduced primarily in an attempt to curtail the rising costs of health care, on the assumption that commercially competitive practices tend to make more efficient use of resources than uncompetitive ones<sup>44</sup>. This was part of a global trend highlighted by Rosenthal and Frenkel:

“Everywhere countries are searching for strategies to slow the growth rate of health care budgets, from incentives for greater productivity and effectiveness, to stimulating free-market competitive dynamics”<sup>45</sup>.

Thus, the changes can be seen to fall into Category D above, *i.e.* they were financially motivated. However, the actual mechanism adopted, that of introducing free-market concepts into an area previously untouched by them, clearly has ideological overtones, and therefore also falls into Category B. Such multiplicity of motives and purposes is, as subsequent chapters will show, also a common feature of attempts to regulate this field. While the example relates to the NHS, it is also true elsewhere.

The lack of explicit acknowledgement of purposes underlying certain initiatives gives rise to a methodological problem: how does one identify the purposes underlying a regulatory mechanism when these purposes are nowhere expounded?

To an extent, this question is answered on an *ad hoc* basis within the appropriate sections of chapters 4 to 7, where the way in which the specific purposes for the mechanism under discussion was identified is described. Taken more generally, however, most mechanisms will be seen to have at least some sort of “headline” purpose, although ascertaining subsidiary purposes is often more problematic. Most subsidiary purposes considered in the later chapters have been discovered through analysing the detailed mechanisms themselves, and considering what the mechanism appears to be trying to do. It is accepted that this can create a certain amount of self-fulfilling prediction: if this thesis analyses how well a regulatory mechanism achieves its purposes, and derives those purposes from looking at what the mechanism is intending to do, then there will inevitably be a very close match between purpose and effect.

This point is, to an extent, true in that there could reasonably be expected to be such a match. However, it also misses the point in some respects. Ascertaining purpose from the mechanism does not necessarily prejudge the issue of how well those purposes are, in fact, realised. Secondly, and as noted, this approach is only required in terms of subsidiary purposes. There is, in general, a supervening explicit purpose, and this explicit purpose will (one might suppose) have influenced the structure of the mechanism more than an implicit purpose. Accordingly, the match between unclear intentions or purposes which have been deduced, and the identifiable effects of these subsidiary purposes might not be so close after all.

The law is no stranger to such a process of inferring motive from observable action. As will be seen in Chapter 4, the main part of the criminal law requires the existence of a criminal state of mind, or *mens rea*, before conduct which is subject to criminal sanctions will result in the courts actually holding a person guilty of the crime. However, it is a relatively rare occurrence to have direct evidence as to whether an accused person intended to commit a crime or not, and the courts proceed in the main by inferring their motive from their observed actions. Similar rules pertain in areas of social security law which aim to curtail perceived abuses by limiting means-tested benefit entitlement for people who have deliberately reduced their capital so as to qualify for the benefit in question<sup>46</sup>. It is again extremely rare to have any direct evidence that the deprivation of capital which occurred was for purposes of securing benefit as opposed to any other reason, and so again those responsible for decision-making within this field must draw inferences from the observable facts. The significance of this is that if the law considers it can legitimately draw inferences in this way, then (it is submitted), it is equally legitimate for a study such as the present one to do likewise.

**B: Mechanism:**

“Mechanism”, as noted above, means whatever means have been adopted to turn purposes into effects. It also refers to mechanisms which have simply evolved or developed in response to a changing situation, without there necessarily being any deliberate policy designed to do so. This can arise as a result of the disjointed incrementalism discussed earlier. Clearly the purposes of such mechanisms are by definition more difficult to identify.

In terms of the nature of the study of mechanisms, these form the bulk of the material in chapters 3 to 6. The disparate nature of the mechanisms in question makes it extremely difficult to adhere to any form of template in conducting these studies; but the general pattern followed is to start off by considering, in more detail than in this chapter, the precise scope of the mechanism being discussed. As is seen, some regulatory mechanisms contain overlaps with each other which unavoidably remain despite the delimitations outlined above between the different mechanisms. There are also interactions between the different mechanisms which are, in general, outlined at the outset of each chapter. Other areas of overlap or interaction are explained in the body of the chapter, if doing so fits the internal structure of the chapter in question more logically.

The next step is to explain the genesis of the mechanism in question, explore its more obvious manifestations, and then proceed to look in more detail at the aspects of the mechanism which appear to have the most significant impact on medical practice, or which appear to be attempting to exert such an influence.

The genesis looked at is, in terms of those bodies established by law, to consider the foundation statutes and regulations, followed by internal policy documents or rules of procedure or equivalent. The analysis proceeds to see how these “black letter law” rules are, in fact, applied by the mechanism; the *de facto* exercise of (or failure to exercise) a theoretical power is, for purposes of this thesis, of more significance than the theoretical position. A policy of non-interference, where such is discovered, is of significance in its own right, since there is an extant regulatory mechanism which appears to be systematically unused. This, however, is not the same as being of no effect. A mechanism may not have to *do* anything because of the possibility that the very existence of the mechanism provides sufficient deterrent value to achieve the desired objectives without any further activity being required. This element is more properly covered by consideration of *effect*, however.

**C: Effect:**

In many respects, the analysis or consideration of the effects of the regulatory bodies discussed generates the most problematic methodological issues.

In theory, practical effects would require major empirical studies to assess, and even such studies would be highly difficult due to the inherent difficulty in isolating the effect of one particular element in what is a highly complex, multi-dimensional arena. Some might question whether such an analysis could even be carried out at all.

This thesis is not based on any original empirical work, but instead utilises the empirical studies already published by other researchers. The existing work is not wholly comprehensive across the range of mechanisms studied, however, and some of the discussion of effect is conjectural. Is conjectural assessment of the effects of the regulators sufficient? It is submitted that, for the purposes of this thesis, it is sufficient. To reconsider the working hypothesis again, it is intended to determine whether the existing regulatory system as a whole provides adequate safeguards for the interests of those involved. In terms of answering this question, it is necessary to have some knowledge of what the existing system actually does; it is not, it is submitted, necessary to be able to pinpoint and quantify every aspect of every mechanism within that existing system. This thesis looks at the system as a whole, and at the internal conflicts within that system. It is consistent with this approach to take a relatively “broad brush” approach to what the effects of each component are, and in the absence of published empirical studies it is also consistent to make an educated guess, against a detailed background of how the mechanism functions, as to the effects of that mechanism. Where the effects of a mechanism are being estimated in this way, specific attention is drawn to the fact. In terms of the conclusions to be drawn at the end of this thesis, it seems that one incontrovertible conclusion will be that there has been insufficient study of how well the (time- and resource-consuming) regulatory mechanisms which already exist actually fulfil their designated or assumed functions.

The effects of regulatory activity which will be considered are all the consequences (so far as can be ascertained) of the activity. This covers not only the success (or lack thereof) of the activity in achieving its purposes, ostensible or otherwise; it also covers unexpected or unintended consequences of the activity - consequences which could be described as “regulatory side-effects”. This is of significance because part of the root cause of any disjointed incrementalism discovered within the regulatory framework may be as a result of unforeseen consequences of regulatory activity elsewhere in the system, rather than of failure on the part of an instant decision maker to take account of the bigger picture. A full

consideration of regulatory effect is therefore necessary to assist in identifying the underlying causes of any regulatory failure which is detected in the following chapters.

The main reason for considering effect, however, is to enable the working hypothesis posited in Chapter 1 to be tested. An “adequate” safeguard can only, by definition, be one which has the desired regulatory effect. It is this regulatory effect which those establishing mechanisms are trying to achieve - the mechanism itself is merely a means to an end. It is also necessary to consider effect in ascertaining whether the identified regulatory purposes are, in fact, being achieved.

However, consideration of the *purpose-mechanism-effect* division does not, in isolation, provide sufficient tools to enable the hypothesis to be fully tested. Identifying purposes, examining the mechanisms put in place to carry out those purposes, and measuring the effect of those mechanisms, still does not answer the question as to whether the regulatory system is “adequate” in carrying out its tasks. The issues arising from this are considered next.

#### **VI: The core evaluation criteria:**

To reconsider the working hypothesis of this thesis, it is concerned with the adequacy of the safeguards provided by the existing medical regulatory system in Britain. The extent of the system under consideration, and the interests to be safeguarded, have already been considered. The question then follows on from this: how does one determine what constitutes an “adequate safeguard”?

Part of the problem is that different users will have different perceptions of what health policy is supposed to be about, and consequently different views as to what norms regulatory systems should be aiming to secure compliance with. This point is highlighted in the following passage:

“...it is necessary to examine the performance of the NHS from different perspectives: using different currencies of evaluation leads to different figures at the end of the balance sheet. But this is inevitable: as evaluation stems from different values, different people will use different exchange rates between the different currencies of evaluation.

‘If the aim of the NHS is defined to be to eradicate disease and disability, then it is self-evidently a failure; if, however, its role is defined as being to minimise human suffering, then it can be reckoned as being a reasonable success story. If the aim is defined to be to limit public expenditure, the

NHS is a triumphant success story when measured against other health care systems in the Western world; if, in contrast, the aim is defined to be to maximise the total supply of health care, the NHS's performance is distinctly less impressive. If the aim is defined to be to ration scarce resources in an equitable fashion, then the NHS is at least a comparative success; if the aim is defined to be to achieve responsiveness to consumer demands, then the NHS fails to meet it.'

There can, then, be no definitive evaluation of the NHS. This makes it vital that the criteria of evaluation are specified clearly." <sup>47</sup>

Again, what is true of attempts to evaluate regulation within the NHS is equally applicable to evaluations of non NHS bodies. In establishing the adequacy of the existing regulatory system there is a preliminary point to dispose of: is it a necessary starting point to establish some idea of what regulation should be about? The discussion above concerning the nature of regulation asked whether it was necessary, for the purposes of that definition, to identify regulatory goals. The question was answered in the negative in that context. In the present context, goal identification or the assumption of a specific policy orientation is only necessary as a prerequisite to the next logical step of asking whether the mechanism in question has, in practice, achieved the desired policy outcome to any measurable extent. This leads us directly to the first of our evaluation criteria. In addition, in the foregoing discussion certain aspects which were deemed worthy of reflection in the evaluation criteria were identified. Others arise as an inevitable consequence of the definition of regulation which has been adopted.

In defining regulation, eight different regulatory activities were identified. As seen above, not all regulatory mechanisms will perform all of the different activities. However, it is submitted that whichever activity the mechanism in question is undertaking, the starting point for evaluating how well it safeguards the protected interests is to ask how well the mechanism fulfils the regulatory activity which it seeks to undertake. Thus, the first evaluation criterion is *effectiveness*. In measuring this aspect, each part of the regulatory machinery will be assessed so as to ascertain the regulatory functions which it carries out, and then the effects of that mechanism analysed to provide an assessment of whether and how well the purposes have been met.

Secondly, the discussion of philosophical aspects of medical treatment above explicitly accepted patient autonomy as being worthy of protection and enhancement. The second evaluation criterion is therefore *respect for patient autonomy*. This aspect will be assessed by considering whether the regulatory mechanism in question has (a) a system designed to evaluate what the wishes of the patients affected actually are, (b) whether

these wishes are, in fact, respected, and (c) whether any non-observation of patient wishes has a valid and reasonable objective justification.

Third, in considering which interests should be protected, it was stated that regulation should not be of such a nature as to interfere with the practice of medicine where that practice accorded due respect to the rights of those involved. This leads to the third evaluation criterion, which is *avoidance of undue interference with good medical practice*. The definition of “good” medical practice requires some expansion. For the purposes of this thesis, “good medical practice” means medical activity which is demonstrably of clinical benefit to the patient, and which is the course of treatment which, if the patient could be brought up to the level of knowledge concerning potential risks, benefits, alternatives and inherent uncertainties as the doctor treating him or her (or alternatively, of a “reasonable” doctor), the patient would have chosen for him- or herself. The point concerning a reasonable doctor is included to cover the situation where the doctor, for whatever reason, is proposing a course of action which the responsible bulk of medical opinion disapproves of. It can be seen from this that for the purposes of this thesis, medical practice is taken as a desirable activity. This is the explicit assumption of another value judgement, since other opinions exist as to the desirability of medical practice. However, this thesis does not align itself with Ivan Illich’s proposition that the practice of medicine has become a social problem in itself.<sup>48</sup>

Fourth, it should be recalled that resources are finite within the health care system – and that regulatory mechanisms are one of the demands made on these finite resources. Based on the analysis of which interests should be safeguarded, it seems safe to conclude that those concerned (patients, doctors, the state) would rather resources were utilised in providing medical treatment rather than being tied up unnecessarily in regulatory mechanisms. At what stage regulatory mechanisms become “unnecessary” in terms of their utilisation of resources is another value judgement. However, it is not (it is submitted) objectionable to state as a proposition that if the same regulatory activities can be achieved with fewer resources, this is preferable to using more resources to achieve the same end. On this basis, the fourth criterion is that of *efficiency*. In stating this, it is also to be noted that “efficiency” as a concept is subject to a variety of interpretations, although limitations of space preclude a full discussion of the issues. For present purposes, this thesis adheres to the definition of “productive efficiency” provided by Bartlett and Le Grand<sup>49</sup>. This definition allows measures of quality to be taken into account when assessing efficiency, and does not necessarily equate “most efficient” with “cheapest”.

The remaining evaluation criteria are not ones which arise as a result of the definitions and values explicitly assumed thus far. Instead, it is necessary to consider extraneous sources and consider what has been regarded as an important feature of a regulatory system by other commentators or in other contexts.

The starting point here was provided by a study conducted by the Association of Community Health Councils for England and Wales (ACHCEW<sup>50</sup>). ACHCEW has listed five criteria for complaints handling: visibility, accountability, accessibility, impartiality and fairness, and effectiveness and speed.<sup>51</sup> While ACHCEW intended this list to be applied to NHS complaints procedures, they provide a useful starting point for consideration of what other elements an “adequate” regulatory system should possess.

The major point of consideration for the remaining criteria is, however, found by casting a net far wider. In Chapter 6, one of the areas of direct statutory regulation considered in detail is the Human Rights Act 1998. This Act “gives further effect to” parts of the European Convention on Human Rights, including Article 6: the right to a fair trial. While it may seem incongruous to consider fair trial safeguards as providing applicable safeguards for the overall regulatory system affecting British medical practice, consideration of the text of Article 6, and the relevant jurisprudence of the European Court and Commission of Human Rights on its meaning, may suggest otherwise.

Article 6(1) states that:

“1. In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law. Judgement shall be pronounced publicly but the press and public may be excluded from all or part of the trial in the interest of morals, public order or national security in a democratic society, where the interests of juveniles or the protection of the private life of the parties so require, or to the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice.”<sup>52</sup>

The relevance here is in understanding the definition of the phrase “determination of his civil rights and obligations.” This expression is analysed fully in Chapter 6, but for present purposes it is sufficient to state that it extends far beyond the scope of what the word “trial” is commonly taken to mean in the legal systems of the UK, and arguably far beyond its meaning in the English language<sup>53</sup>. Access to health care may or may not be a civil right which enjoys the protections of Article 6(1), but coercive measures aimed at those



working within the health care sphere almost certainly are, and so are (or will be) subject to the provisions of the Article.

These provisions can be broken down into a number of categories, and it is possible to see a degree of overlap with the ACHCEW criteria listed above. Thus, to take certain elements of Article 6(1) in turn:

- “...*everyone is entitled to...*” – this aspect corresponds to ACHCEW’s criterion of *accessibility*, there being little point in having regulatory mechanisms if those they are intended to benefit cannot in reality utilise them;
- “...*a fair and public hearing...*” – this corresponds to ACHCEW’s *fairness*;
- “...*within a reasonable time...*” – this corresponds to ACHCEW’s *speed*;
- “...*by an independent and impartial tribunal...*” – this corresponds to ACHCEW’s category of *impartiality*;
- “...*established by law.*” This has no direct counterpart with ACHCEW’s list. However, depending on how the tribunal is established, this may bring with it a degree of *accountability*. Establishment by law may also be a factor in ensuring that the tribunal is *effective*, which has already been identified as one of the evaluation criteria being used in this thesis.
- “*Judgement shall be pronounced publicly...*” – this corresponds (at least in part) with ACHCEW’s criterion of *visibility*.

In terms of the ACHCEW list, there are no direct counterparts in Article 6(1) with the elements of *accountability* and *effectiveness*. Since the category of *effectiveness* has already been identified for inclusion, discussion of this lack of overlap can be kept to a minimum. The principal reason for Article 6 being silent on the issue of effectiveness is that the issue of effective remedies for violations of Convention rights is to be found in Article 13 of the Convention, not Article 6<sup>54</sup>. The nature of the Convention is that the Convention itself, together with its enforcement organs, provides the mechanism for holding those making decisions covered by the safeguards afforded by Article 6 accountable for their decisions. Indeed, the whole point of the Convention is to allow national governments to be held accountable for their actions and inactions before an

international tribunal, and to be so held at the behest of individuals (including their own citizens) rather than at the behest of other states.

It can therefore be seen that accountability is an important concept in international human rights law. Accountability to the European Court of Human Rights in Strasbourg is a notional form of accountability, but it is also a very distant one. Only the UK government can be taken to task there, not necessarily the part of the state apparatus which the citizen genuinely has a grievance with. The logic is that the state ultimately has responsibility for the ordering of its internal affairs, and should therefore accept responsibility for those whom it has allowed to escape domestic accountability. While the logic of this may be impeccable from the perspective of the international jurist, there are a number of problems from a domestic perspective. The state may ultimately be responsible for the situation which has arisen (although this presumes an omnipotent state, which is clearly not the case), but this theory shields those whose actions are being complained about from direct scrutiny.

Accountability has a number of facets directly related to the definition of regulation. Grievance systems, systems of investigation into non-adherence with standards, punishment, and (potentially) systems for redressing suffering may all require those who are responsible for a particular situation to be identified and, if necessary, required to explain themselves. Given the importance of this in international law, its inclusion in ACHCEW's list, and its necessary functions within the regulatory tasks, our next evaluation criterion is, therefore, *accountability*.

As a prerequisite to this accountability, it is necessary that the person wishing to hold someone accountable should know about the system, and be able to make use of it. The next evaluation criterion is therefore *visibility*. Notions of openness and transparency in decision-making are, it is submitted, increasingly perceived as important factors in establishing the legitimacy of a body or organisation in the public eye, and the visibility criterion is included expressly to reflect these values. Beyond the intrinsic value which this inclusion attributes to openness and transparency, however, there is also a potential practical aspect to the visibility of an organisation: if no-one knows about a mechanism, then they will be unable to utilise whatever the mechanism does, and the protections offered by it may (unless the mechanism functions perfectly in all cases without external stimulus) become illusory as a result. The visibility of a mechanism can also have implications for the effectiveness of a system, since any deterrent effect which something has will also be lost if no-one knows about it. Visibility is taken as a separate criterion from the other aspects of Article 6(1) considered below because, for the reasons just mentioned, it is considered that the visibility requirement of a regulatory mechanism in

carrying out a variety of the regulatory tasks (setting/upholding standards, grievance channels/dispute resolution) go far beyond the “open court” provisions of Article 6, which were designed to guard against covert governance and secret decision-making by the executive<sup>55</sup>.

The final criterion is an amalgamation of most of the remaining elements of Article 6(1) together with the rest of ACHCEW's list. This criterion can be described as *overall fairness*, and incorporates within it the various aspects of accessibility (since if one side is denied access to a mechanism, this is unfair to that side), together with the right to a fair hearing by an impartial arbiter within a reasonable timescale.

The use which will be made of these seven criteria is considered in the next, final, section.

## **VII: Summary:**

This chapter has attempted to set out the limits of this study, the methodology by which the study is undertaken, and the key concepts, definitions and values which underlie the study. A series of benchmarks have been established by which the existing system will be evaluated. This concluding section explains to what use these evaluations will be put.

Four substantive chapters of this thesis will subject the existing regulatory machinery to detailed scrutiny. This scrutiny will analyse in turn the purpose, mechanism and effect of each of these four component parts of the system, and measure how well that mechanism and its apparent effects compare to the seven core evaluation criteria described above. Thus, each of these four chapters has a concluding section summarising the purpose, mechanism and effect of the regulatory machinery being considered, and continues to have seven sections analysing and summarising how well it fares on each individual evaluation criterion. This provides a measurement of the success or otherwise of that particular aspect of the system in meeting its own goals. Each of these chapters also has a section summarising the regulatory tasks which the mechanism in question fulfils, either in whole or in part and whether by design or inadvertence.

In order to assess the adequacy or otherwise of the regulatory system as a whole, however, a slightly different approach is required. The overall success of the system involves more than the sum total of the successes and failures of the component parts of the system, since this would firstly fail to identify any failures in coverage, secondly fail to identify any unnecessary duplication of effort between different parts of the system, and thirdly fail to highlight any conflicting pressures within the system. The consequence of

this is that merely looking at the sum of the parts would fail to answer the working hypothesis spelled out in Chapter 1.

Accordingly, Chapter 7 revisits the definition of regulation, and examines in turn each of the regulatory tasks identified above. The regulatory tasks are cross-referenced as to the effectiveness of those parts of the system identified as having a role in that regulatory task. In this way, a comprehensive picture is built up in Chapter 7 as to how well each task is being performed by the existing system. If the regulatory tasks identified above are sufficiently comprehensive in their scope (and it is submitted that they are), then this cross-sectional analysis should succeed in identifying the problematic areas where there is either unnecessary duplication of regulatory tasks, or where there is a regulatory gap. The analysis will not, it is conceded, identify conflicting pressures; nor will it provide any tools for policy-makers as to how improvements could be made.

The second half of the concluding analysis therefore revisits the core evaluation criteria and measures how each criterion is matched by the system overall, and revisits what proposals were canvassed in earlier chapters which would enhance each particular criterion (and at what cost, if any, to the other evaluation criteria). Thus, a comprehensive picture will be built up showing which criteria the current system scores well on, which it scores badly on, and how any particular aspect could be enhanced. This, ultimately, is the mechanism which is used to answer the original working hypothesis. This thesis sets out to analyse the adequacy of the safeguards incorporated into the existing regulatory system. An adequate system of regulation is taken to be one which does two things: firstly, it must have mechanisms in place which carry out all the regulatory functions identified in this chapter. Secondly, the mechanisms it possesses must satisfy all the evaluation criteria in the course of carrying out their regulatory functions. Chapter 7 draws together the two main strands of summary, and concludes on that basis as to whether the question asked should be answered in the positive or the negative. On the assumption that not everything looked at will prove to be perfect, the thesis will finally touch on some of the proposed variations which would have the most marked influence in terms of enhancing the system's performance by improving its assessment relative to certain criteria without significant adverse impact on others.

## Chapter 2 notes

- <sup>1</sup> Collins *Dictionary of the English Language* (2<sup>nd</sup> ed., 1986)
- <sup>2</sup> *Id.*
- <sup>3</sup> B Roberts, "Education", in P Worsley (ed.), *Introductory Sociology* (2<sup>nd</sup> ed., 1977), 246-8
- <sup>4</sup> C Propper and A Hopkins, "Regulation of the market in the new NHS" in A Hopkins (ed.), *Regulation of the market in the new NHS: competition and the common good* (1994), 110; emphasis added.
- <sup>5</sup> J Rowan-Robinson, P Watchman and C Barker, "Crime and regulation", [1988] Crim LR 211
- <sup>6</sup> M Weber, "Bureaucracy and Law", 1946; "The theory of Social and Economic Organisation" (1947) in *From Max Weber : Essays in Sociology*
- <sup>7</sup> D Hughes, "Regulating the use of NHS Resources : An Organisational Perspective" (1989) in R Dingwall (ed.), *Socio-legal Aspects of Medical Practice*
- <sup>8</sup> *Id.*, 49.
- <sup>9</sup> CE Lindblom, "The Science of Muddling Through" 1959 Public Law Review 19, 79-88; *The Intelligence of Democracy*, 1965.
- <sup>10</sup> E Friedson, "The changing nature of professional control" (1984) Annual Review of Sociology 19, 1-20.
- <sup>11</sup> R Alford, *Health Care Politics*, 1975
- <sup>12</sup> For an analysis of theories of decision-making, see J Lane, *The public sector: concepts, models* (2<sup>nd</sup> ed., 1995).
- <sup>13</sup> CE Lindblom and EJ Woodhouse, *The policy-making process* (3<sup>rd</sup> ed., 1993), 11
- <sup>14</sup> D Rueschemeyer, "Professional autonomy and the social control of expertise" (1983) in R Dingwall & P Lewis (eds), *The Sociology of the Professions*
- <sup>15</sup> R Klein, *Complaints Against Doctors* (1973), 8.
- <sup>16</sup> RS Downie, "Professions and professionalism", 1990 Journal of Philosophy of Education vol. 24 No 2 147-159, 148.
- <sup>17</sup> C Douzinas & S McVeigh, "The tragic body" (1992) in S McVeigh and S Wheeler (eds), *Law, Health and Medical Regulation*, 1.
- <sup>18</sup> I Kant, *Fundamental Principles of the Metaphysics of Ethics*, (1785)
- <sup>19</sup> SAM McLean, *Old law, new medicine: medical ethics and human rights* (1999), 15
- <sup>20</sup> R Baldwin, "Public law and the National Health Service" (1989) in R Dingwall (ed.), *Socio-legal Aspects of Medical Practice*, 44
- <sup>21</sup> D Longley, *Public Law and Health Service Accountability*, 1993, 67.
- <sup>22</sup> S Kerrison and A Pollock, "Complaints as accountability? The case of health care in the United Kingdom" [2001] P.L. 115
- <sup>23</sup> AJ Reiss Jr., "Selecting strategies of social control", in K Hawkins & JM Thomas (eds), *Enforcing Regulation*, 1984, 24, 26-29.
- <sup>24</sup> J Rowan-Robinson et al, *loc. cit.*, 212-6, references omitted; and see N Cunningham, "Negotiated non-compliance: a case study of regulatory failure" (1987) 9 Law and Policy 69 for another study reaching similar conclusions.

- <sup>25</sup> D Cowan and A Marsh, "There's Regulatory Crime, and then there's Landlord Crime: from 'Rachmanites' to 'Partners'", 2001 MLR 831, 831
- <sup>26</sup> K Hawkins & JM Thomas (eds), *op. cit.*, vii.
- <sup>27</sup> C Scott, "Analysing regulatory space: fragmented resources and institutional design" [2001] P.L. 329
- <sup>28</sup> See for instance, H Teff "Consent to medical procedures: paternalism, self-determination or therapeutic alliance?" 101 LQR 432; Gutheil *et al* "Malpractice prevention through the sharing of uncertainty: Informed consent and the therapeutic alliance", 1984 NEJM 49; Egbert *et al*, "Reduction of post-operative pain by encouragement and instruction of patients" 1964 NEJM 302; 896.
- <sup>29</sup> Precisely how inexact is discussed by S Daniels, "The pragmatic management of error and the antecedents of disputes over the quality of medical care" in R Dingwall and P Fenn (eds.), *Quality and regulation in health care: international experiences* (1992)
- <sup>30</sup> On which see M Rosenthal, *The incompetent doctor: behind closed doors* (1995), particularly Chapter 2
- <sup>31</sup> Practices falling into this category are catalogued in C Williamson, *Whose standards? Consumer and professional standards in health care* (1992)
- <sup>32</sup> C Williamson, *op. cit.*, 54-56; references omitted.
- <sup>33</sup> G Mooney, *Key issues in health economics* (1994), 176-7
- <sup>34</sup> *Ibid*
- <sup>35</sup> Collins Dictionary, *op. cit.*
- <sup>36</sup> J Jacobs and JV Davies, *Sweet & Maxwell's Encyclopaedia of Health Services and Medical Law*, 1987.
- <sup>37</sup> D Longley, *op. cit.*, 4.
- <sup>38</sup> S McVeigh & S Wheeler (eds), *op. cit.*, 1992, vi.
- <sup>39</sup> H Teff, *loc. cit.* at 453
- <sup>40</sup> SAM McLean, *op. cit.*, 20
- <sup>41</sup> M Rosenthal, *op. cit.*, 5-6
- <sup>42</sup> RS Downie, *loc. cit.*, 153
- <sup>43</sup> A concise summary of NHS internal regulatory mechanisms is given by Kerrison and Pollock, *loc. cit.*
- <sup>44</sup> Most of these changes were themselves significantly amended by the Health Act 1999.
- <sup>45</sup> M Rosenthal AM Frenkel (eds), *Health Care Systems and their Patients: An International Perspective*, 1992.
- <sup>46</sup> See, for example, Regulation 7 of the Housing Benefit (General) Regulations 1987, and Sections 21-22 of the Health and Social Services and Social Security Adjudications Act 1983
- <sup>47</sup> M Powell, *Evaluating the National Health Service Reforms* (1997) 189-190, quoting R Klein, *The politics of the NHS*, (2<sup>nd</sup> edition, 1989), 177-8
- <sup>48</sup> I Illich, *Limits to Medicine : Medical Nemesis, The Expropriation of Health* (1977)
- <sup>49</sup> W Bartlett and J Le Grand, "The theory of quasi-markets" in Bartlett and Le Grand (eds.), *Quasi-markets and social policy*, (1993), 14-15

- <sup>50</sup> Community Health Councils were established to provide a “lay” (non-professional) voice within the NHS in England and Wales; Community Health Councils perform the same function in Scotland.
- <sup>51</sup> ACHCEW, *NHS Complaints Procedure : A Review by ACHCEW* (1990)
- <sup>52</sup> The remainder of Article 6 is only applicable to criminal matters, although “criminal” in this context also has an autonomous meaning within Convention jurisprudence which is wider than the domestic law classification of matters as criminal rather than civil.
- <sup>53</sup> Conversely, the civil rights referred to also have an autonomous Convention definition which is arguably far narrower than domestic law would expect.
- <sup>54</sup> Controversially, Article 13 is not included within the Human Rights Act 1998; the government’s explanation for this omission was that the Act in itself provided an effective remedy for those who had suffered from a violation of their convention rights.
- <sup>55</sup> The basic Convention provisions, and their original purposes, are discussed in Chapter 6.

## Chapter 3: Criminal Law

### I: Introduction:

This Chapter represents the first of the substantive chapters of the thesis in that it seeks to analyse a specific regulatory mechanism in detail, in terms of the “purpose/mechanism/ effect” division, and against the seven core evaluation criteria identified in Chapter 2. The mechanism in question is that of the criminal law.

This Chapter will set out the scope of the criminal law, or at least those parts of it which are considered as a regulatory mechanism, and outline briefly the main rules of the criminal law which affect the practice of medicine. This chapter will briefly describe how the criminal law has been deployed to enforce the medical monopoly mentioned in Chapter 2, and also the way in which that same law has been used to ring-fence the scope of acceptable medical practice. In this context, the use of the criminal law as a regulatory tool represents the most extreme step which a modern liberal democracy can take: criminalisation of conduct can legitimately be regarded as representing the application of “coercion through monopoly of the means of violence”<sup>1</sup> which the state, representing the sovereign power, enjoys over those within its jurisdiction<sup>2</sup>. Finally, and in common with the analyses of other mechanisms which follow, this chapter will consider whether the current mechanisms regulating British medicine are an adequate way to safeguard the rights of individuals and society as a whole, or whether these mechanisms suffer from ineffectiveness and conflicting objectives.

Ultimately, it is possible to regard the criminal law as the foundation of all medical regulation. Subsequent chapters will describe the various regulatory systems which impact on the practice of medicine in the UK, but it is the criminal law which ensures that those who practice medicine are registered by the State, and it is on this registration that much of what follows in successive chapters ultimately depends. Professional self-regulation, for instance, can only have any meaningful effect if those to be regulated are members of that profession. Similarly, litigation against a doctor is only likely to be worthwhile if the doctor either has substantial assets of his own, or else has an institutional employer or insurer who can meet the claims against him. The unqualified practitioner is precluded from working for institutional employers, and unlikely to have insurance, save by deliberate misrepresentation of his status (which would, in any case, have the effect of rendering the policy ineffective<sup>3</sup>); he is probably also more likely to actually harm his patients; and accordingly it is against such unqualified persons that criminal sanctions are deployed.



However, it is also quite possible for registered medical practitioners to fall foul of the criminal law in the course of their duties, and this chapter also considers this. And of course, doctors (like everyone else) may commit crimes entirely outwith the scope of their professional practice. Such convictions may well attract the attention of the GMC's disciplinary machinery, but this is properly looked at as regulation by the GMC and not by the criminal law *per se*; such instances are discussed in Chapter 6. Accordingly, this chapter makes no attempt to summarise the whole body of the criminal laws of Scotland and England<sup>4</sup> as they apply to the general public as well as to doctors.

## **II: The scope of the criminal law:**

### **A: Defining criminal law:**

In discussing the criminal law as applicable to medical practice and the regulation of medicine, it is probably worth noting at the outset that this is, in general, the specific application of a body of rules of general applicability to the medical sphere, and that there is no specific criminal code for medical matters. The dictum of Devlin J in his address to the jury in *R v Adams*<sup>5</sup> has never been challenged as an accurate statement of the law in this respect:

"[There is] not any special defence for medical men; it is not because doctors are put into any category different from other citizens for this purpose. The law is the same for all..."

Having thus established there is no specific body a criminal law to consider, however, it is necessary for the purposes of this chapter, to consider exactly what the criminal law actually *is* that we are discussing. This preliminary point is, perhaps surprisingly, not so easy to dispose of as might be imagined: criminal law is not a concept admitting of an easy definition. Thus, as Gordon notes,

"The terms 'crime' and 'criminal law' are well known but it is not easy to give a comprehensive definition of them, or to state clearly the difference between criminal and civil law."<sup>6</sup>

Gordon's own definition is somewhat circular, stating that the criminal law is

"That branch of the law which deals with acts, attempts and omissions of which the state may take cognisance by prosecution in the criminal courts."<sup>7</sup>

although he concedes that any definition of criminal law as the subject matter of criminal procedure is not wholly satisfactory, but inevitable given that it is the existence of an offence within the criminal law, and no other factor, which gives any act the property of being a crime.<sup>8</sup> Glanville Williams too concedes the apparent circularity of his definition that

"A crime (or offence) is a legal wrong that can be followed by criminal proceedings which may result in punishment."<sup>9</sup>

but gets out of it by pointing out that it is perfectly possible to define criminal procedure without ever having to resort to any definition of crime. As to what types of acts will actually (or at least potentially) result in criminal proceedings, both writers concede that the only answer to this is to study substantive criminal law to see what actions either the legislature or the courts have felt sufficiently strongly about to actually classify as a crime.<sup>10</sup> The question of why lawmakers decide to do this is (at least on a superficial level) somewhat easier to answer, and for the present purposes may actually provide a more useful answer to the question of what a crime actually is:

"The criminal law is primarily concerned with the question whether wrongdoers are to be punished (or compulsorily treated)."<sup>11</sup>

The foregoing analyses attempt to explain and define the domestic legal classification of a particular matter as being criminal in nature, rather than civil or administrative (or, indeed, as conduct requiring no legal recognition and having no legal consequences whatsoever). A broader approach to the question can be taken instead. It is possible to define criminal charges not by reference to the procedure adopted, but instead by the impact or potential impact of the proceedings on the person against whom they are directed. This is the approach adopted by the European Court of Human Rights in deciding whether the safeguards of Article 6 of the European Convention on Human Rights are applicable to a particular set of proceedings<sup>12</sup>. Finally, Alldridge advocates a refreshingly simple approach to the question: "A command backed by a sanction is the dominant model for the imposition of duties by the criminal law."<sup>13</sup>

## **B: The mechanisms of criminal procedure:**

We have considered some of the approaches adopted to answering what criminal law actually is. It is now necessary to consider what the mechanism adopted to give effect to the criminal law consists of. For purposes of this thesis, it is unnecessary to consider

more than the barest outline of criminal procedure, since for present purposes it is of more significance to consider the nature of the activities deemed to be criminal or not, rather than the procedure by which an accused person is determined to have committed the crime in question or not. This area would only be of regulatory significance if the procedural rules were such as to render successful prosecution impossible (or nearly so) in practice, since the protections afforded by the criminal law would therefore be rendered illusory. Accordingly, topics such as the rules of evidence for criminal trials, and the rules of court surrounding the conduct of criminal trials, will not be considered.

For someone to end up being processed by the criminal law and its mechanisms, it is first necessary for the crime in question to be reported. The criminal courts in the UK are all adversarial in nature, meaning that the judiciary play no part in the investigation of crime (unlike most mainland European jurisdictions, which regularly feature investigating magistrates). The courts are therefore dependent on external agencies to recover evidence of the crime, and on external agencies (not, in general, the same agencies any more) to bring that evidence before the court. The investigating agency for most crimes is the police. While the police in Britain are institutionally separate from the court system, it is convenient for the purposes of this thesis to regard them as the internal investigatory system of the criminal law. This allows police investigation to be regarded as falling within the scope of this chapter, in a way which is conceptually different from how other regulatory bodies might uncover evidence of criminal activity in the course of other regulatory investigations or monitoring.

The principle mechanism of the criminal law is that if a person is accused of committing a criminal offence (the subject of what particular acts or omissions are deemed to be criminal is considered *infra*), they may be prosecuted. Prosecution in Scotland is only by the Crown, represented by the Lord Advocate and local procurators-fiscal.<sup>14</sup> In England and Wales, there has been a historical trend (accelerating more recently) away from individual prosecution to a model more closely resembling the Scottish situation. Thus, while at the beginning of the 19<sup>th</sup> century some 80% of prosecutions were brought by victims of crime, the gradual introduction of police forces resulted (over a long period) in those police forces taking on the role of prosecutor in the majority of cases.<sup>15</sup> Nowadays, the overwhelming majority of prosecutions are brought by the state. State prosecutions are handled by the Crown Prosecution Service (CPS), substantially replacing the police. Numerous other public authorities also have the power to prosecute for breach of the law which the body in question is charged with regulating. In addition, there still remains the established tradition of private prosecutions by private

individuals, although the Crown Prosecution Service now has the statutory power to take over any private prosecution<sup>16</sup>.

Assuming that prosecution proceeds, and the alleged offender is not instead “diverted” from prosecution by one of a growing number of non-court-based disposals of conduct which is capable of being prosecuted<sup>17</sup>, then ultimately the case will come before a criminal court. The court structures are different in Scotland as opposed to England and Wales, but both jurisdictions have a defined hierarchy of criminal courts, hearing increasingly serious allegations and enjoying increasingly extensive powers of sentencing the accused in the event of a guilty verdict. Lower courts typically consist of a judge only (who may or may not be legally qualified, and who may sit as part of a panel), whereas higher courts tend to have a legally-qualified judge advising a jury of laypersons who are responsible for determining disputed questions of fact, and ultimately for passing a verdict of guilty or not guilty<sup>18</sup>. Appeals (principally on points of law) lie to appellate courts, and a conviction can be overturned if new evidence emerges suggesting that a miscarriage of justice has occurred. Both jurisdictions have established bodies to examine allegations of such miscarriages of justice, and if satisfied that one may have occurred, to refer the matter to a court for review. The rule against “double jeopardy” means, however, that the converse does not apply: in general, once a person has been through a trial for an alleged offence but not convicted at the end of the trial, they cannot be tried for the same offence again. Retrials are a possibility if a conviction is overturned, and may result in a fresh conviction.

The accused person enjoys the presumption of innocence, and the onus of proving that an offence has been committed lies on the prosecution. For a conviction to be passed, it is necessary for the prosecution to prove the case “beyond reasonable doubt”. This is a higher standard than is necessary for civil cases of the type discussed in Chapter 4, *infra*, which depend (in general) on a finding on the balance of probabilities.

If, at the end of the trial, the accused person is found guilty of the offence in question, they are then sentenced<sup>19</sup>. Sentence is determined by the judge, not the jury (if there is a jury). Commonly a “plea in mitigation” will be submitted by the accused or his/her lawyer, in an attempt to persuade the court to impose a lesser sentence. Prosecutors rarely make an equivalent submission to the court; the prosecutor has already been able to influence the sentencing options through the choice of which court to institute proceedings in. In rare circumstances, the prosecutor may disagree with statements made in mitigation (which, by definition, may not include any statement inconsistent with the accused having committed the offence in question, since there has already been a

guilty verdict or plea). In such cases, a proof in mitigation may then take place before sentence is passed.

Sentences vary in severity from absolute discharge (which does not even count as a criminal conviction) or admonition up to a sentence of life imprisonment (although this does not actually mean that the person convicted is supposed to spend the rest of their life in prison, as the name might suggest). Previously, the most severe sentence was capital punishment, now effectively abolished for all offences<sup>20</sup>. Other sentences of yesteryear, such as corporal punishment or transportation (itself introduced as an alternative to capital punishment<sup>21</sup>) have also been abolished or fallen into desuetude. In between life imprisonment and absolute discharge, in terms of severity, are sentences of financial penalty (or “fines”) which tend to be used at the lower end of the spectrum. However, very large fines can be used in regulatory areas such as pollution control or health and safety at work where the offenders are likely to be corporate bodies. Confiscation orders, designed to deprive certain offenders (most notably drug smugglers and dealers) of the proceeds of their criminal activity, are a specialised form of financial penalty. For individuals (as opposed to corporate bodies), imprisonment usually exists as an alternative to payment of the fine. There are custodial sentences of less than life, which can include being released on licence or parole, and alternatives to custody such as probation or community service. A range of treatment orders can be made in respect of drug addicts and persons suffering from psychiatric disorders. Certain offences may result in the person convicted being entered on the sex offenders’ register, which imposes duties to notify the police of your whereabouts after release from prison (the UK being highly unusual in not requiring its inhabitants to tell the state authorities where they live at any given time<sup>22</sup>). Other offences may result in an entry being made in the child protection register, which will automatically trigger social work/social services intervention in the family. Finally, in relation to certain regulatory offences committed by persons carrying out an activity under some form of registration or permit, the criminal proceedings may withdraw or restrict the licence or permit. The most common form of this is seen under Road Traffic legislation, where conviction for motoring offences may also result in the licence holder being disqualified from driving for a period of time. This approach is also used in other areas such as being a company director or the holder of a landfill site operator’s licence under the Waste Management Licensing Regulations. In such areas, the criminal courts are themselves acting as a direct regulatory body, by restricting the ability of the person convicted to carry out the regulated activity. For purposes of this thesis, however, it is important to note that this approach has not been adopted in relation to medical practice. No criminal court in the UK has power to strike someone off the register of medical practitioners.

This is not to understate the importance of criminal convictions. As noted above, criminal conviction requires a far stricter standard of proof than civil proceedings, and for that reason a criminal conviction will constitute almost irrefutable evidence in any other proceedings. Thus, it is almost impossible, following conviction, to argue in other proceedings that you did not do the thing you were convicted of. This can make the outcome of those other proceedings extremely predictable, if they depend principally on findings of fact. This would apply to matters such as a professional misconduct hearing before the GMC, or a civil claim for damages following negligent surgery. What the subsequent regulatory body, civil court or whatever actually does with these facts is, however, another matter and is considered in later chapters.

The foregoing discussion provides the briefest of outlines of what the system of criminal law consists of and what it does; we consider next *why* it does so.

### **III: The purpose of criminal law:**

There is a problem in identifying a “purpose” to criminal law which is intrinsically linked to the difficulty in defining the nature of criminal law discussed *supra*. It is this: in essence, the classical approach to defining criminal law utilised by British commentators (taking the comments by Gordon and Glanville Williams *supra* as reasonably typical of this school of thought) is to define criminal law by reference to the jurisdiction of the criminal courts. This means that something is a crime because it is conduct of which the criminal courts can take cognisance and pass appropriate sentences. However, it says nothing about the content of that law, and to revert to the basic principles outlined in Chapter 2, it is only by reference to content that we are able to ascertain purpose. The circularity of this approach is occasionally acknowledged by commentators:

“We conceive criminal law very broadly as one way in which a society – in this case that of England and Wales – both defines or constructs, and responds to, ‘deviance’. Immediately a problem arises. If we understand deviance to mean behaviour which departs from social norms recognised by criminal law, the notion is circular: criminal law claims to respond to deviance, yet deviance (for the purposes of criminal law) can only be defined by looking to criminal law itself. Evidently, we have to look outside criminal law to get any grip on its nature and significance.”<sup>23</sup>

The traditional academic approach to the study of criminal law has been described as the “doctrinal approach”, and its key tenets have been described as follows:

“Doctrinal criminal law consists of a set of ideas about responsibility together with a conception of the proper scope of the criminal law. It also includes a method, differentiating the results of actual or posited cases, for its elaboration... Criminal law, unlike any other area of legal discourse, was isolated from any question about what happened next... [T]he purpose of the system (in terms of what was to be achieved by the infliction of punishment) was pretty much irrelevant.”<sup>24</sup>

Clearly, such an approach has little to commend itself to this aspect of this thesis, although the analytical tools of doctrinal legal analysis are utilised in other aspects.

A slightly different approach to the subject is taken by one of the leading authors of textbooks on English criminal law, Professor Sir John Smith (whose textbook structures fit almost exactly the model for doctrinal criminal law). In the opening passage of one of the standard works on the subject, the purpose of criminal law is expressed in the following terms:

“The criminal law is no more an end in itself than the law of procedure and evidence through which it is enforced. Our criminal law has grown up over many centuries and the purposes of those who have framed it, and of those who have enforced it, have undoubtedly been many and various. Consequently, it is not easy to state confidently what are the aims of the criminal law at the present day. The authors of a completely new code of criminal law are, however, in a position to state their objectives at the outset. ‘The general purposes of the provisions governing the definition of offenses’ in the American Law Institute’s Model Penal Code might be taken as a statement of the proper objectives of the substantive law of crime in a modern legal system. The purposes are:

- ‘(a) to forbid and prevent conduct that unjustifiably and inexcusably inflicts or threatens substantial harm to individual or public interests;
- (b) to subject to public control persons whose conduct indicates that they are disposed to commit crimes;
- (c) to safeguard conduct that is without fault from condemnation as criminal;
- (d) to give fair warning of the nature of the conduct declared to be an offense;
- (e) to differentiate on reasonable grounds between serious and minor offenses’<sup>25</sup>

There are a number of points here which deserve particular note. Firstly, the criminal law in isolation is simply a theoretical intellectual construction. Without enforcement and

application, it is deprived of meaning or effect. Criminalisation of particular conduct is manifestly not the same as preventing that conduct from occurring<sup>26</sup>. It is merely stating that if someone commits the prohibited act (or whatever), and is found out by or reported to someone capable of prosecuting them in the criminal courts, that they might then actually be so prosecuted. If found guilty they might then face some sort of penal or financial sanction, *i.e.* be sentenced. The sanction might be sufficiently inconvenient or unpleasant to discomfit the person in question beyond whatever they gained from committing the prohibited act. This account, be it noted, contains a large number of conditional elements. However, they are conditional in any crime, and not particular to medical regulation.

The second point to note is this: it is obvious from the passage that Professor Smith clearly considers that the criminal law does not, in fact, possess one single overarching purpose. Instead, it seems that different people have had different purposes in mind at different times. Given Smith's distinction between those who frame the criminal law (*i.e.* legislators and judges) and those who enforce it (*i.e.* the police, prosecution services, assorted regulatory bodies, judges again) it would seem quite conceivable that they actually have distinct motives within the same time frame. This, potentially, could result at best in disjointed incrementalism in the development and application of the criminal law. At worst it could result in internal contradictions and conflict within the system.

Even within this short and concise description of what a criminal legal system *should* do, there are also some internal stresses, if not outright contradictions. Purpose (b) is stated to be that of subjecting to public control persons whose conduct indicates that they are disposed to commit crimes. Purpose (c) is to safeguard conduct that is without fault from condemnation as criminal. Yet there is a difficulty if we consider the person whose track record indicates that he or she may well be likely to commit crimes – or perhaps, at some stage, we will be able to detect a genetic predisposition to criminal activity. To what extent are preventive measures of a coercive nature to be allowed? The more coercive the measure is - the more akin, perhaps, to the sort of measures which the European Court would tend to classify as “criminal” for the purposes of the safeguards of the European Convention on Human Rights – then the more acute this tension becomes.

These criticisms are, ultimately, quibbling with the detail. On a larger scale, one might observe that none of the avowed purposes given involves the punishment of wrongdoers. This, it might be noted, represents an application of the theory of regulatory strategy selection described in Chapter 2 *supra* as it applies to the criminal sphere. In the context of this thesis we have already outlined in general terms some of



the purposes to which medical regulation is directed, so what Smith describes is, for our purposes, effectively a sub-set of regulatory purposes. All the purposes listed in the above passage at least theoretically have a place in the regulation of medical practice.

In attempting to answer the question of what criminal law is actually trying to do, one might look to certain theories of jurisprudence. Different jurisprudential schools of thought arrive at different conclusions, none of which provides a completely satisfactory explanation (unsatisfactory inasmuch as other writers active in the same field construct and defend competing and often conflicting theories of their own). The main contenders in this debate are summarised by Lacey, Wells and Meure<sup>27</sup>, who conclude that none of the main jurisprudential theories provides a wholly satisfactory account of the purposes of criminal law. In particular, none is capable of explaining its purposes without reference to wider historical and societal pressures. As Alldridge notes,

“In attempting to understand criminal law not as a timeless set of examples on which to work out the implications of positions in moral philosophy but as a complex set of social phenomena, comparative and historical considerations are enormously significant.”<sup>28</sup>

This, unfortunately, leaves us with a gap when assessing the effectiveness of criminal law in meeting its purpose, when that purpose is so poorly defined. There is also, as was noted in passing, the incredible difficulty in displaying empirically what effect criminal law actually has in reducing the incidence of the conduct which is criminalised<sup>29</sup>. We are therefore forced to revisit the regulatory tasks outlined in Chapter 2 *supra*, which can be summarised as setting and upholding standards of medical practice, the facilitation of medical practice in accordance with these standards, provision of systems for redress, investigation and the airing of grievances, the punishment of those who fail to adhere to the standards, and the regulation of the regulatory system itself to ensure that the above tasks are being carried out.

The discussion of the purposes of criminal law, while inconclusive in determining a single, overarching purpose, is still sufficient to allow us to say, with some confidence, which of the regulatory tasks it undertakes. We will see that the criminal law's purposes, in this context, include the setting of the very minimum standard of medical practice necessary to avoid the treatment being criminally negligent. It appears that the law's functions here are unlikely to include upholding these minimum standards, save inadvertently (inadvertently because the doctor must previously breach a different regulatory mechanism's standards before coming to the attention of the criminal law.)

The role of criminal law in this situation can only be to provide leverage to a different mechanism, and it is not performing a separate function in these instances. Since other mechanisms impose higher standards of care than the criminal law, it is not proposed to analyse the criminal law's functions in setting and upholding standards of care.

Criminal law does nothing to facilitate medical practice, with the minor exception (minor in theory, very real to those affected) of applying criminal sanctions against individuals who threaten medical staff with violence or commit violent offences against them. This is treated as part of the general legal/constitutional background for purposes of this thesis.

The only redress mechanism within the criminal law is the possibility of a criminal court making a compensation order against someone convicted of a crime. However, this is very much a peripheral activity for the criminal justice system, and cannot be regarded as its principal function given the existence of the parallel system of civil courts (largely staffed by the same personnel) with compensation as a predominant purpose; accordingly, this chapter will not concentrate on the effectiveness of criminal law as a mechanism for providing redress for victims (although this was historically one of the original functions of the criminal law at the time when the distinction between civil and criminal law was relatively undeveloped).

Does criminal law exist to provide a grievance channel for victims? As will be seen below, there is a growing "victim's rights" movement within the UK and beyond arguing for enhanced status for victims of crime within the system. At a commonsense level, the person who makes a formal complaint to the police about something can reasonably be regarded as having a grievance against the alleged perpetrator which they want "something done about". For this reason, criminal law will be assessed for its effectiveness as a grievance mechanism<sup>30</sup>.

Does criminal law provide an investigatory system into whether standards are being adhered to? The answer here would appear to be a qualified "yes". As was noted above, many of the functions of the criminal law can only be achieved by reference to the system of penal sanctions, the execution of which is by bodies technically outwith the formal court system which applies the law. Similarly, the criminal law can only function by reference to an external system of investigating and reporting agencies – most notably, though not exclusively, the police. In Chapter 2, it was noted that these investigatory mechanisms lay outwith the medical sphere. However, the necessary existence of these reporting agencies as adjuncts to the mechanism of the criminal law means that they can reasonably be analysed within the context of the criminal law,

although they will necessarily be assigned a relatively minor role given this externality. A caveat also requires to be entered here. The effectiveness of bodies designed to investigate and report breaches of the criminal law can, for present purposes, only really be measured by their success or otherwise in bringing successful prosecutions. If there is an allegation of criminality then in general all other regulatory mechanisms are put on hold pending the outcome of the criminal investigation and any ensuing prosecution and trial. There are reasons for this, principally connected to the *sub judice* rule whereby it may be a punishable contempt of court to publish anything suggesting that a person accused of a crime is guilty. The person accused will also (understandably) be unwilling to cooperate with other investigations into what has happened if such cooperation could result in the discovery of evidence which might be unfavourable come the trial.

Criminal law manifestly sets out to punish those who fail to meet its standards even if, as we have seen, its reasons for doing so may occasionally be unclear.

Finally, there comes regulation of the regulatory system. Criminal law is only concerned with other regulatory systems if there is criminal conduct within those other parts – for instance, perjury before a GMC hearing, or gross dereliction of duty by a public officer. While such safeguards may help ensure the efficacy of the other regulatory tools, it is also significant that criminal law involvement would only ever be precipitated by a breach of the rules of the other regulatory mechanism. Criminal law is being utilised to underscore the effectiveness of other regulatory mechanisms, not providing a regulatory tool in its own right. Its sanctions are aimed at those being regulated rather than the regulators, so the functions of the criminal law in ensuring compliance with other regulatory mechanisms will not be considered here. However, the point is far from academic in application, and the question of whether or not a regulatory mechanism has criminal sanctions behind it can reasonably be expected to impact on its effectiveness, or at least its perceived legitimacy or seriousness. It can also impact on the choice of regulatory strategy<sup>31</sup>.

The remainder of this chapter will consider those forms of conduct which may attract criminal proceedings. The general criminal law is considered before the specific rules on medical procedures.

## IV: Criminal law as applied to doctors:

### **A: Assault and related offences:**

#### 1: Introduction

It might be thought odd by some to consider the law of assault as being of particular relevance to the medical profession, which, by and large, is composed of upstanding and respected members of society, and not of habitual criminals<sup>32</sup>. But medical practice is almost invariably an invasive procedure (with the possible exception of psychiatric treatment<sup>33</sup>). In this context, one immediately thinks of surgery as the most clearly invasive; but any touching of another person may potentially be an assault, and even an unwanted kiss could found proceedings<sup>34</sup>. The substantive laws of Scotland and England diverge widely on the exact elements of assault; and while it is possible to define the law of Scotland in the sentence "any attack upon the person of another is an assault"<sup>35</sup> (subject to the caveat of then having to define "attack", and going on to explain the myriad aggravations, mitigations and defences Scots law recognises), any discussion of the English law inevitably gets bogged down in a discussion regarding the distinction between assault and battery, and the overlap with and distinction from a number of other offences such as affray or under the (not always logical) provisions of the Offences Against the Person Act 1861, and in particular Sections 20 or 47<sup>36</sup>.

Consequently it is not intended to give an exhaustive treatise on the laws of Scotland and England which regulate the issue of violence and threats between individuals. Instead, this section will concentrate on those principles, common to both systems, by which the general rules are ameliorated in the case of medical treatment. The word "assault" is used throughout to indicate a crime occasioned by actual or anticipated physical contact between people; it is not used in any technical sense, and most of what this section refers to as an "assault" would in reality constitute a battery in English law<sup>37</sup>; the Scottish term "assault" covers situations which would be battery in England, as well as assault itself and various statutory offences.

The purpose of these offences was usefully summarised by Robert Goff LJ:

"The fundamental principle, plain and incontestable, is that every person's body is inviolate. It has long been established that any touching of another person, however slight, may amount to a battery. So Holt CJ held in 1704 that "the least touching of another in anger is a battery"... The breadth of the principle reflects

the fundamental nature of the interest so protected; as Blackstone wrote in his Commentaries, "the law cannot draw the line between different degrees of violence, and therefore totally prohibits the first and lowest stage of it; every man's person being sacred, and no other having a right to meddle with it, in any the slightest manner." The effect is that everybody is protected not only against physical injury but against any form of physical molestation."<sup>38</sup>

It is now clear that legitimate medical treatment does not constitute criminal assault or any of the related offences, but the exact way in which the law justified such intervention has been the subject of some debate<sup>39</sup>. Partly this is because doctors are not generally prosecuted for treating patients, so the rule or principle whereby they were not committing the crime of assault had to be drawn by analogy or inference from statements made in other contexts, *i.e.* either from assault charges based on non-medical grounds, or from civil judgements.

## 2: Basic elements of criminality: *Actus reus* and *mens rea*:

To start with basics, all crimes must involve elements of *mens rea* and *actus reus*<sup>40</sup>: as it is usually put, *actus non facit reum nisi mens sit rea*<sup>41</sup>. Those seeking to justify the legality of medical treatment must therefore negate the presence of one or both of these elements, or else advocate a specific exception to the general rule in the nature of a defence to the charge or a departure from the generality. Of course, the three elements (*actus reus*, *mens rea*, lack of stateable defence) are interrelated; and since each can provide a potential way out of criminalising medicine, a few points will be made on this. Thus, Williams notes that

"...when a crime requires *mens rea*, an *actus* cannot be legally *reus* (in the sense of involving criminal responsibility) unless there is *mens rea*. Therefore it may appear self-contradictory to say 'There is an *actus reus* but no *mens rea*' "<sup>42</sup>

but ultimately adopts the same solution to that reached by Gordon:

"...it is possible and convenient to treat the lack of *mens rea* as different from any other 'defeating' factor. The term '*actus reus*' can then be used for situations which would be criminal were they accompanied by *mens rea*; a term is necessary for all the objective or external ingredients of a crime, and '*actus reus*' is the obvious one to use."<sup>43</sup>

Similarly, the exact classification of recognised defences to criminal charges is also hard to pin down analytically:

"*Actus reus* includes, in the terminology here suggested, not merely the whole objective situation that has to be proved by the prosecution, but also the absence of any ground of justification or excuse... (though not including matters of excuse depending on absence of *mens rea* ). " <sup>44</sup>

The point being that *actus reus*, being a criminal act<sup>45</sup>, cannot logically occur except in the presence of *mens rea* and the absence of a defence. Such an analysis may be logically impeccable, but does create semantic difficulties:

"There is however something to be said for having terms to describe the particular elements of a crime without thereby invoking all the possible defences. If the Latin expressions are regarded merely as technical terms which do not in themselves necessarily import guilt, the difficulty of so using them disappears. Professor Lanham has said,

'As a matter of analysis we can think of a crime as being made up of three ingredients, *actus reus*, *mens rea* and (a negative element) absence of a valid defence.'

According to that view a person may commit an *actus reus* with *mens rea* but not be guilty of the crime in question because of the existence of a defence." <sup>46</sup>

Notwithstanding the adoption of this approach, the particular offences relating to assault present certain analytical difficulties. For instance, judicial utterings defining the various offences seldom draw such distinctions (which are legally irrelevant so long as all the elements are present).

However, if we approach the concept of *actus reus* as a discreet element, standing alone from the presence or absence of *mens rea*, it becomes relatively easy to define the *actus reus* of assault charges, at least for the present purposes. It is the touching of another person, or, here, the touching of a patient by a doctor. (Questions of evil intent or of things being done "in anger" will be discussed as forming part of the *mens rea* of the charge.) Clearly, in virtually all medical examinations and treatment, we have the first leg of a criminal charge: the doctor has "touched" the patient, which satisfies the *actus reus* for assault. However, it would also equally be possible to define "touching" as meaning "any touching outwith a medical context"; if we do this, then even *actus reus* would be absent. In the event, the courts were felt for some time to have applied a very broad

limitation to the concept of *actus reus* (in this case, for battery) in a way which actually included medical treatment within the exception; the passage in question also moves between a number of the categories, and neatly displays some of the analytical difficulties:

"...nobody can complain of the jostling which is inevitable from his presence in, for example, a supermarket, an underground station or a busy street; nor can a person who attends a party complain if his hand is seized in friendship, or even if his back is (within reason) slapped... Although such cases are regarded as cases of implied consent, it is more common nowadays to treat them as falling within a general exception embracing all physical contact which is generally acceptable in the ordinary conduct of daily life."<sup>47</sup>

Medical treatment, so the argument ran, amounted to such "physical contact which is generally acceptable in the ordinary conduct of daily life", and consequently did not constitute the *actus reus* for battery. This was the conclusion of the Court of Appeal in *Wilson v Pringle*<sup>48</sup> which, it might be thought, was doing violence to the whole concept of "touching" for the sake of judicial pragmatism. As it turned out, Lord Goff got a chance to overrule this interpretation of his remarks, holding that

"Medical treatment, even treatment for minor ailments, does not fall within that category of events [*i.e.* contact in the ordinary conduct of daily life]"<sup>49</sup>

So the limitation of the scope of *actus reus* given in *Wilson v Pringle* does not provide the explanation as to why medical treatment does not amount to the crime of assault.

In any event, it might be thought that *mens rea*, or at least the absence of it on the part of a doctor, would provide a much more promising line of reasoning. If the touching need be "in anger" or "hostile," then a doctor need have nothing to fear. The leading case in Scotland held that the essence of assault was "touching" with evil intention to injure<sup>50</sup>; and one would seriously doubt if any reputable doctor acting in the proper exercise of providing medical care could ever be convicted on such a basis.<sup>51</sup> As far as English law is concerned, there has been a move away from the requirement to prove or display hostility. Thus, in *Collins v Wilcock*:

"We observe that, although in the past it has sometimes been stated that a battery is only committed where the action is 'angry, or revengeful, or rude, or insolent' (see Hawk PC c62 s2), we think that nowadays it is more realistic, and

indeed more accurate, to state the broad underlying principle" [that every person's body is inviolate] "subject to the broad exception" [that contacts as a result of ordinary daily life are not criminal].<sup>52</sup>

Hostile intent was considered by the Court of Appeal who stated that the WPC in *Collins*

"... touched the woman deliberately, but without an intention to do more than restrain her temporarily. Nevertheless, she [the police officer] was acting unlawfully and in that way she was acting with hostility."<sup>53</sup>

This appears to create the somewhat circular argument that hostility is a necessary ingredient to battery, but that this requirement is satisfied by the unlawfulness of the act. So if you act *prima facie* unlawfully by committing the *actus reus* of battery, then the *mens rea*, or at least that part of it requiring hostility, will be inferred or implied by the very unlawfulness of the act in question. This could be seen as moving towards a form of strict liability, which the courts probably did not intend to do. The decision is also somewhat hard to reconcile with the statement of Lord Lane CJ that

"The mental element necessary to constitute guilt [of assault] is the intent to apply unlawful force to the victim. We do not believe that the mental element can be substantiated by simply showing an intent to apply force and no more."<sup>54</sup>

which view was approved by the Privy Council<sup>55</sup>. But the Court of Appeal's views in *Wilson v Pringle* were approved by the House of Lords. Lord Jauncey of Tullichettle stated that

"If the appellant's activities in relation to the receivers were unlawful they were also hostile and a necessary ingredient of assault was present."<sup>56</sup>

In most circumstances, the House of Lords' view (being that of the superior court) has to be preferred<sup>57</sup>. So it seems that in determining the *mens rea* of assault, it is necessary to look beyond both the intention to inflict the force, and the lack of hostile motivation behind this intention. And since neither *mens rea* nor *actus reus* provide an adequate answer in themselves as to the lawfulness of a course of action, it is necessary to look at the third limb, *i.e.* either some general exception to the rules concerning criminality, or else a specific pleadable defence.



### 3: Basic elements of criminality: consent and other defences:

In the first case, it is common in most medical practice for the doctor to seek the consent of the patient prior to treating him or her<sup>58</sup>. Is this consent a valid defence to criminal charges being laid against the doctor?

To answer this, it is necessary to consider the extent to which the law accepts the consent of a victim as a defence to the charge of assault or battery. In Scotland, the situation has never been satisfactorily resolved, even in the general situation.<sup>59</sup> The Scottish courts have rejected the distinction which English law effectively imposes between what may and may not validly be consented-to: in Scotland, any intention to do bodily harm vitiates consent<sup>60</sup>, whereas, as will be seen below, English law distinguishes between the degree of harm intended or probable<sup>61</sup>. The Court of Appeal's refinement of these principles, subsequently approved by the House of Lords<sup>62</sup>, appears to move closer to the Scottish position:

"...It is not in the public interest that people should try to cause, or should cause, each other bodily harm for no good reason. Minor struggles are another matter... [I]t is an assault if actual bodily harm is intended and/or caused. This means that most fights will be unlawful regardless of consent."<sup>63</sup>

Many of the cases involving consensual wounding related to sadomasochistic practices. In general, these were homosexual activities, provoking a comment by Aldridge that "moral evaluations of the behaviour in question" have been a factor in the law's development<sup>64</sup>. This led to the criminalisation of consensual wounding, affirmed by the House of Lords in *R v Brown*<sup>65</sup> being challenged (unsuccessfully) before the European Court of Human Rights<sup>66</sup>.

The ultimate rationale behind the final conclusion of the Court of Appeal in *R v Brown supra*, whereby medical treatment was singled out for particular mention, seems to be that as medical procedures are not intended to harm, the general rule (consent is no defence to assault) is disapplied. In that case, the Court held that:

"Nothing which we have said is intended to cast doubt upon the accepted legality of... reasonable surgical interference... These apparent exceptions can be justified as ... needed in the public interest."<sup>67</sup>

Thus, the law seems to be that medical treatment fulfils all the criteria for the crime of assault; but rather than try to twist the definitions of those elements of the crime in such a way as to exclude medical treatment (which would inevitably involve doing some violence to those general principles), the judges have instead adopted a pragmatic approach of saying, in effect, "medicine is not a crime however much it might look like one on the criteria we have established." Indeed, Gordon explicitly accepts that this is the case<sup>68</sup>.

It is still necessary to look at all the elements of the crime in deciding the lawfulness of a course of treatment, since it is clear from the above discussion that a doctor would still commit an offence if he operated without consent (where consent can be given), or if he acted maliciously or went beyond the bounds of "reasonable surgical interference"<sup>69</sup>. The courts have held that the justification for medical treatment is that of necessity, not consent, the treatment being in the best interests of the individual and also in the public interest.<sup>70</sup>

But the defence of necessity is limited in its scope<sup>71</sup>. If medical treatment is justified by necessity rather than consent of the patient, does this mean that it is lawful in the *absence* of consent? There are two situations to consider here. The first is where the patient is unable to consent - whether through unconsciousness, youth, or mental incapacity. In a case relating to mental incapacity, the House of Lords held that treatment in such cases is lawful if in the best interests of the patient, it then being covered by the defence of necessity<sup>72</sup>. Such a conclusion is easy to defend on humanitarian grounds; as Lord Brandon said in that case,

"The common law would be seriously defective if it failed to provide a solution created by the problem created by such inability to consent... In my opinion, the solution to the problem which the common law provides is that a doctor can lawfully operate on, or give other treatment to, adult patients who are incapable, for one reason or another, of consenting to his doing so, provided that the operation or other treatment is in the best interests of such patients."<sup>73</sup>

A more problematic case arises when the patient is competent to give consent, but fails or refuses to do so. In certain circumstances (such as rolling up your sleeve and holding your arm out towards a syringe-wielding doctor) consent will be implied or inferred from the patient's actions; in such a case, there is effectively a real consent, albeit unspoken<sup>74</sup>. However, such a situation has to be regarded as somewhat exceptional, and the law in general is slow to accept the notion of implied or inferred consent. A

different question arises when the patient refuses to consent, or fails to give consent in circumstances where consent cannot be inferred. Is the defence of necessity sufficient, on paternalistic grounds, to justify medical intervention which a competent adult patient refuses to consent to? The Court of Appeal said that, in general, it was not:

"An adult patient who... suffers from no incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it, or to choose one rather than another of the treatments being offered... The fact that... no medical treatment of an adult patient of full capacity can be undertaken without his consent, creates a situation in which the absence of consent has much the same effect as a refusal."<sup>75</sup>

This principle was recently reaffirmed by the Dame Butler-Sloss P in the highly publicised case of *B v An NHS Hospital Trust*<sup>76</sup>. From all this, it seems that the criminal law safeguards the doctor who gets the consent of his patient. But does the criminal law similarly protect the patient whose refusal to consent will harm someone else? In spite of the language of *Re T* which spoke of unequivocal rights, Butler-Sloss LJ (as she then was), referring to a Canadian case, agreed with the principles set out therein which

"excluded from consideration the interest of the state in protecting innocent third parties..."<sup>77</sup>

Seizing on this loophole, and on similar restrictions noted in *Re T* by Lord Donaldson MR, the former President of the Family Division, Sir Stephen Brown, authorised a hospital to carry out an emergency Caesarean section on a non-consenting pregnant woman which was necessary to save her life, and that of her unborn child<sup>78</sup>. This was an emergency application in which time constraints left neither the court, nor Counsel arguing the case, much time to canvass the authorities on maternal-foetal conflict of interest<sup>79</sup>. It is not intended to enter that debate here, since only the final outcome (that doctors could legitimately treat such a patient) is of importance in regulating medical practice; but it certainly leaves a gaping hole in the laws of assault which are intended to secure freedom from unwanted bodily interference. As was said of the decision,

"It has massive implications for the status of women in regarding them as chattels and ambulatory wombs. It is so potentially intrusive as to reduce women back to the status of slaves."<sup>80</sup>

This subject is revisited in Chapter 4 *infra*.

#### 4: Sex-change operations and cosmetic surgery:

In some respects, these are subject to the same legal difficulties as beset live organ transplants, only without the benefit of such clear-cut societal approbation to justify their legitimacy. However, the case of *Corbett v Corbett*<sup>81</sup> appears to accept the legitimacy of sex-change operations, and they are now available on the NHS. Similarly, the practice of cosmetic surgery is now so well-established that it seems highly unlikely that a judge would declare it to be criminal now, particularly since it confers a benefit on the patient, albeit a social and not strictly medical one<sup>82</sup>. The Law Commission was certainly of the view that such operations were legal<sup>83</sup>. This view was reached notwithstanding the case of *Bravery v Bravery*<sup>84</sup> where Lord Denning expressed the view that such operations were illegal in spite of the man's consent; this decision has never been overruled, although clearly it is no longer good law. Family planning (including sterilisation) has been available on the NHS since 1967<sup>85</sup>. The only major restriction is that the courts would probably balk at the prospect of a deliberate (consensual) mutilation<sup>86</sup>, and Parliament has specifically outlawed one form of this<sup>87</sup>.

#### **B: The law of homicide:**

Homicide is relevant here in a very specific way. It is intended to discuss the laws of homicide only insofar as they affect medical practice in the following ways: the liability of doctors for the death of patients in the normal course of treatment, the role of doctors as regards the selective non-treatment of neonates, and the situation where "life-support" machines may be turned off, or where terminally-ill patients are allowed to die or assisted in dying.

##### 1: The basic law of homicide:

As with assault, or perhaps even more so, there is a huge divergence between Scots and English law on the subject of homicide. For instance, Scots law is still found in the common law principles of Institutional writers and decided cases, whereas English law has seen considerable statutory development; the former rule of English law that death must follow within a year and a day of the injury being inflicted on the victim<sup>88</sup> is unknown in Scots law. However, some general principles are common to both systems, and this section will focus on these general principles rather than the more technical discussions of causation, foreseeability *etc.* which can bedevil discussions of this topic.

Homicide is the killing of another human being, and is not necessarily a crime<sup>89</sup>. Criminal

homicide is split into two categories: murder is the more serious, the lesser type being called culpable homicide or manslaughter<sup>90</sup>. The distinction was formerly important because while murder was a capital offence, manslaughter and culpable homicide were not. Since the abolition of the death penalty<sup>91</sup>, the distinction is perhaps of less importance, although murder still carries a mandatory sentence of life imprisonment, whereas the sentence for the other charges is a matter for judicial discretion, from absolute discharge to life imprisonment.

Murder, at its most basic, has been defined as

"...when a man... unlawfully killeth... any reasonable creature *in rerum natura* under the king's peace, with malice foresought, either expressed by the party or implied by law, so as the party wounded, or hurt etc. die of the wound, or hurt, etc. within a year and a day after the same."<sup>92</sup>

This, of course, is an English definition, and many of its elements are inapplicable in Scotland, where the crime is perfected by committing an act which kills and was meant to kill<sup>93</sup>, although in both countries it is accepted that a certain degree of recklessness as to the probable consequences of an act is sufficient *mens rea* for murder<sup>94</sup>.

Culpable homicide and manslaughter are both complex, multi-faceted offences in application. The crimes consists of the same *actus reus* as for murder (*i.e.* killing another human being). The distinction lies in the fact that for culpable homicide or manslaughter, there is either the absence of one of the necessary elements of murder, or the presence of some mitigating factor or excuse. The main differences between the crimes in the two countries stems from the differing requirements of *mens rea* for murder; much of what is technically murder in Scots law constitutes manslaughter in England because of lack of evidence as to specific intent or malice aforethought. The practical differences are smaller than might be imagined due to Crown Office practice<sup>95</sup> whereby a number of offences are charged as culpable homicide notwithstanding the letter of the law; these include a number of situations covered by statute in England such as infanticide<sup>96</sup> or suicide pacts<sup>97</sup>. Conversely, the Homicide Act 1957 introduced a number of mitigating factors which serve to reduce murder to manslaughter in circumstances which Scots law had long recognised at common law, particularly diminished responsibility<sup>98</sup> and provocation<sup>99</sup>. However, the defence of voluntary intoxication, which has been the subject of English judicial expansion (or "merciful relaxation") in the last century or two<sup>100</sup> has faced a major judicial restriction in Scotland in recent years<sup>101</sup>. There are in addition a number of statutory offences involving homicide, such as causing death by reckless

(now dangerous) driving<sup>102</sup>. These offences are of a disparate nature and will only be considered as necessary in the following discussion.

## 2: Liability for the death of a patient:

If a patient dies in the course of treatment, the first question to be asked is the purely factual one of cause of death. If the cause of death was something other than natural causes, then a murder investigation may be undertaken; and even if natural causes were the proximate cause of death, the issue of inadequate treatment or care may still arise. If a doctor deliberately kills a patient, this is murder as described above; the special arguments which apply in the case of neonates and the terminally ill are discussed *infra*.

One subtlety of the law as regards "deliberate killing" should be mentioned at this point: in terms of the general principles outlined above, the *actus reus* of homicide consists of acts (or, rarely, omissions) causing the death of another person. "Causing" death includes accelerating it; as has been pointed out,

"Since we are all fated to die at some time, every instance of killing is an instance of accelerating death." <sup>103</sup>

As far as doctors are concerned, in this area they benefit from the application of the ancient theological concept known as the doctrine of double effect<sup>104</sup>. Very broadly, this states that if an act has two consequences - one good, one bad - then it is permissible to suffer the bad consequence in order to attain the good objective. While this may look like saying "the ends justify the means", it has been accepted as legitimising giving terminal patients pain-relieving but inadvertently life-shortening medication<sup>105</sup>. The case which recognised the doctrine of double effect, *R v Adams*<sup>106</sup>, is best known nowadays for that legal decision; but at the time, the case was notorious – principally because Dr Adams was mentioned in the wills of 132 of the patients to whom he administered palliative care or helped "ease the passing"; this led many contemporary observers to think Dr Adams had, in fact, murdered his patients and had "got away with it"<sup>107</sup>. The subject of deliberate murder of a patient is considered below in the context of the effects of the criminal law. The principal discussion here is in relation to doctors who act within the confines of acceptable medical activity, or attempt to. To what extent is the doctor liable if the patient dies as a result of inadequate care, or as a result of mischance in the course of a legitimate course of treatment?

Discussion of this point involves entering the debate on causation and the criminal law.

In essence, medical treatment of a condition will not act as a *novus actus interveniens* which breaks the causal link between the cause of a condition (for example an assault on someone who is rushed to casualty but dies in spite of the treatment given) and its ultimate consequence, the death of that patient<sup>108</sup>. From this it follows that the doctor's inability to save the victim's life neither exculpates the original assailant from liability for murder (or equivalent)<sup>109, 110</sup> nor renders the doctor himself liable for it - assuming that the treatment is not defective. If the treatment is defective in some way, then there might be a civil action against the doctor<sup>111</sup>; but this in itself will not *necessarily* break the causal chain between assault and death, nor necessarily expose the doctor to prosecution.

For the doctor to be liable himself, he must not just be guilty of negligence judged by the civil standard: he must satisfy the criteria outlined above for the offences of homicide<sup>112</sup>. As far as the original assailant is concerned, the possibility of negligent treatment of the victim is reasonably foreseeable, and he must therefore accept the consequences of this should it materialise<sup>113</sup>. Only if the treatment is so extremely wrong as to constitute an independent cause of death does it amount to a *novus actus interveniens*<sup>114</sup>. But this in itself does not mean the doctor is liable for homicide, since legally the effect of a *novus actus* is to break the causal chain, not to put a new accused at the end of it. The intervening treatment could be of such a novel or risky nature as to constitute a *novus actus* without ever being criminally reckless or negligent<sup>115</sup>. It is worth noting that refusal by the victim to accept medical treatment is not a *novus actus*<sup>116</sup>, but it is submitted that unjustified failure on the part of a casualty unit to offer treatment would be.

As far as the doctor's liability for homicide in the event of non-treatment is concerned, the laws of Scotland and England only impose criminal liability for omissions where the person is under a legal duty to act<sup>117</sup>. The question of a duty on doctors to treat is discussed in Chapter 4; there is very little by way of a general obligation on doctors to treat passers-by, and so failure to treat such a person would not amount to homicide (although the GMC could be expected to take a dim view of the matter). As regards an existing patient, there clearly is a duty to treat, and on general principles a sufficiently culpable failure to give treatment could amount to criminal homicide. In the more extreme situation of abandonment in mid-surgery<sup>118</sup>, the liability of the surgeon for his omissions would be compounded by the doctrine of liability for failure to avert a danger which have yourself created<sup>119</sup>. The highly confused area of discontinuing life-support measures raises a number of specific complexities which are considered below.

Finally, there is the possibility that the patient dies simply because of the negligence or recklessness of the attendant physician. The law of involuntary manslaughter was

restated by the House of Lords: to be convicted of manslaughter as a result of medical negligence, it is necessary for the prosecution to prove

1. the existence of a duty to the victim (not usually a problem in medical cases, but recall that there is no duty on a doctor to treat anyone who is not a patient<sup>120</sup>);
2. breach of the duty causing death (an evidential matter informed by the civil standard of breach of duty of care); and
3. gross negligence which the jury consider justifies a criminal conviction.<sup>121</sup>

In essence, then, a doctor will only face prosecution following the death of a patient:

- (a) if he fails to treat them at all, in circumstances where he clearly owed the patient a duty of care, and where the consequences of this failure are reasonably foreseeable;
- (b) where, having undertaken to treat a patient, he discontinues that treatment without having made suitable arrangements for their care;
- (c) where his treatment is defective to the extent that, as a matter of factual causation, the defective treatment and not the underlying illness or injury is the cause of death, and that in causing the death the doctor had been guilty of gross negligence justifying a criminal conviction; or
- (d) where the doctor intended to kill the patient. It is this last possibility that will now be considered.

### 3: Intentional killing of neonates and the terminally ill:

Murder by doctors is rare but, as the Shipman case demonstrated, it does happen on occasion. Deliberately killing someone outwith the clinical setting is, as noted above, likely (in the absence of a defence such as insanity) to constitute murder whether the person doing the killing be a doctor or not. Causing death by gross negligence is perhaps more common, although it is an incidence only measurable in terms of the level of prosecution activity and concomitant rate of conviction:

“Manslaughter prosecutions against doctors were once unheard of. Between 1925 and 1989 there were no successful prosecutions. But in 1990 three doctors, all anaesthetists, were charged – and two were convicted. We can only speculate on the reasons for this sudden activity... [M]anslaughter prosecutions are still rare, and successful ones rarer. But police investigation into healthcare has become more common.”<sup>122</sup>



It is when the killing occurs with a clinical justification that complications arise; this most commonly occurs in relation to neonates and those suffering from a terminal illness.

This is one of the most emotive areas of medical practice, and one in which medical practice and the criminal law come most sharply into conflict. The ethical issues which it generates have been the subject of a large body of literature, and it is not intended to go into these issues here<sup>123</sup>. The following discussion will accordingly make a number of controversial points without necessarily addressing all the issues and complexities surrounding them; this is in the interests of brevity, since a full discussion would merit a thesis in its own right, and would in any case add little to our understanding of the regulatory role of the criminal law.

As noted above, *R v Adams*<sup>124</sup> held that it was not criminal to shorten a patient's life in order to alleviate suffering; this has been the legal mainstay justifying palliative care ever since. The main problem, however, arises in relation to patients who could be kept alive by medical intervention, but where the doctors stay their hand. Typically, this arises in two cases, that of defective neonates (which is taken here to mean neonates born alive but who suffer from such major abnormalities as would have permitted their abortion up to the moment of birth), and the terminally ill adult patient, who may or may not be competent to make decisions regarding treatment (or even conscious). Ethically it is possible to distinguish them since the adult may have previously expressed a preference, and also has a set of value systems and beliefs on which to base a "substituted judgement" which the neonate lacks<sup>125</sup>; but the law makes no such distinctions except where a person specifically refuses further lifesaving treatment. If the patient does so, not only will the doctor not be exposed to criminal sanctions, but it is his duty to discontinue the treatment.<sup>126</sup>

The law in this area was clarified by the House of Lords in the case of Anthony Bland<sup>127</sup>: if a patient is brain-stem dead, they are legally dead and no liability follows for discontinuing treatment. If they are in a persistent vegetative state, (or by implication suffering some other long-term debilitating mental illness of sufficient gravity) then the doctor is entitled (following application to the court<sup>128</sup>) to withhold treatment. *Bland* is an extremely complex case, and while its importance cannot be overstated, most of the intricacies of the arguments in the House of Lords are not of immediate relevance; consequently, it will not be discussed in detail at this point. What it makes clear is that, while euthanasia (in the sense of "mercy-killing", whether voluntary or otherwise) is not legal in this country<sup>129</sup>, there are certain circumstances under which a doctor is no longer required to prolong a patient's life. *Bland* also resolved a long-running medico-legal

debate over whether stopping life-prolonging treatment amounted to an act or an omission<sup>130</sup>, holding that it amounted to an omission and therefore carried no criminal culpability<sup>131</sup>.

Conversely, there are still situations where a doctor, even one acting in accordance with accepted medical practice, can face criminal prosecution. Thus in the celebrated case of *R v Arthur*<sup>132</sup> a consultant paediatrician, in accordance with the wishes of the mother of a baby with Down's syndrome, prescribed dihydrocodeine and "nursing care only" for the baby, which thereafter died. Dr Arthur was tried for murder (reduced to attempted murder on evidential grounds), and only acquitted by the jury after a very favourable summing-up by Farquharson J., which is highly dubious in that it did not address the issue of homicide by omission when under a legal duty. In any case, it is now open to doctors, parents or local authorities to petition the courts for permission to withhold certain forms of treatment in such extreme cases<sup>133</sup>, which would preclude prosecution<sup>134</sup>. And while the ethics of these cases continue to be debated, from the doctor's point of view all he need know is that if he wants to avoid prosecution, he should get a court order first. Nor has the Human Rights Act 1998 changed this position<sup>135</sup>.

#### 4: Euthanasia and assisted suicide:

The final aspect of the law of homicide focuses more on the patient than on the doctor, and concerns the issue of euthanasia. As was seen above in the general discussion, the law in the UK<sup>136</sup> does not recognise euthanasia. If the person has not consented to having their life shortened, what is happening will be murder (or culpable homicide/manslaughter). If they have consented, it will still be necessary to justify the palliative care in terms of the doctrine of double effect to avoid committing murder, since consent in itself is not a defence to a charge of murder<sup>137</sup>. In terms of the Suicide Act 1961, it is an offence to aid, abet, counsel or procure suicide<sup>138</sup>. Thus, the doctor who gives a patient drugs to enable that patient to commit suicide commits an offence, although it has been pointed out that it could be difficult to prove that the doctor gave the drugs intending the patient to take an overdose<sup>139</sup>. However, the law here accepts a distinction between committing suicide which, while no longer itself a criminal offence, is generally not regarded as a legitimate course of action, and refusing treatment. An adult of full mental capacity has the absolute right to refuse medical treatment, even if the result of this refusal is inevitably death<sup>140</sup>. Accordingly, in these circumstances not only does the doctor not commit an offence if he or she discontinues treatment, but an offence may be committed if the treatment is in fact continued<sup>141</sup>.

### **C: Other offences committed in the medical sphere:**

The discussion thus far has focused principally on the law relating to personal physical integrity as that aspect of autonomy is protected (albeit inadvertently) by the criminal laws of Scotland, England and Wales. Clearly, there are other offences which doctors can, and on occasion do, commit under the guise of medical practice. These other offences (such as improper sexual contact with a patient who is under anaesthesia, or done in the guise of medical examination) differ from the discussions of assault and homicide because there is no professional justification for the commission of this latter group of offences. The fact that the offence is committed by a doctor is, far from being an exculpatory factor, more likely to be seen as an aggravating factor because there will often be an element of breach of trust involved. As these offences are beyond the proper scope of medical practice, and are typically committed covertly rather than within the accepted framework of the law, it is not intended to analyse any of these peripheral offences in detail.

The scope of “peripheral” offences which can be committed under the guise of proper medical practice is theoretically limitless. The doctor making house visits might well pilfer from a patient; but a discussion of the laws of theft would add little to our understanding of how medicine is regulated. Suffice to say, for present purposes, that the general law of the land will not excuse a crime because the person committing the act in question is a doctor – unless the act in question is regarded as falling within the proper sphere of medical activity. If it is within this sphere, conviction is unlikely. If not, conviction may follow.

One particular form of criminal conduct within the medical sphere which has come to the awareness of the general public recently is in relation to fraud. This falls into two separate categories: “classical” fraud involving the fraudulent claiming, taking or retaining of money which you are not entitled to, and a more specifically medical form of fraud, research fraud. Financial fraud is estimated to have cost the NHS approximately two billion pounds recently, and research fraud has been described as “endemic” in both the UK and US<sup>142</sup>. For present purposes, fraud with the intention of securing financial benefit for yourself, or which is to the detriment of someone else<sup>143</sup> is a criminal offence. Research fraud, unless intended for example to defraud a sponsor into providing more funds, is not a criminal offence<sup>144</sup>.

Finally, one particularly acrimonious debate concerned whether doctors could prescribe contraceptives, or give advice and counselling on contraception, to persons (almost

invariably girls) under the age of 16. It is a criminal offence to have intercourse with someone under the age of 16<sup>145</sup>, and so there was the possibility that a doctor who gave contraceptives could be regarded as having incited the commission of an offence (*i.e.* unlawful sexual intercourse), or having aided and abetted in its commission. The issue was ultimately resolved in the civil courts in favour of the legality of such prescribing<sup>146</sup>.

### **V: Statutory Restrictions on Medical Procedures:**

By way of clarification, this section is perhaps best understood as describing restrictions on certain activities of a medical or quasi-medical nature so that in general they may only lawfully be carried out by a registered medical practitioner; this underpins the point made above that the criminal law is used principally to ensure that individuals are subject to the jurisdiction of the appropriate licensing authority, the GMC. As such, it could equally have been headed "Restrictions which statute imposes on everyone who isn't a registered medical practitioner." The restrictions which statute places on registered medical practitioners are discussed in Chapter 5 *infra*.

### **A: Unqualified Practice:**

Historically, the allopathic medical profession (practitioners of what is now referred to as biomedicine, *i.e.* conventional medicine as opposed to alternative or complementary medicine) secured its leading position among various branches of healers through the Medical Act 1858; this prevented unqualified persons from holding themselves out as doctors, if not actually from practising the healing arts.

Presently this monopoly is enforced through the provisions of Part VI of the Medical Act 1983<sup>147</sup>. The specific privileges granted to registered medical practitioners are listed in Sections 46 (power to recover medical fees), 47 (exclusive right to be employed as a medical practitioner by state and all other non-voluntary establishments) and 48 (certificates only valid if signed by a fully-registered practitioner). These privileges are identical to those granted to the medical profession in 1858. The criminal "teeth" safeguarding these provisions are to be found in Section 49, which provides that anyone holding him- or herself out as a registered medical practitioner but who is not so registered commits an offence and is liable on conviction to a fine not exceeding level 5 on the standard scale (currently £5000)<sup>148</sup>. While this fine may be relatively small compared to what a bogus practitioner might hope to earn, the fact that he or she is unable to recover any fees charged, coupled with the fact that he or she will be held liable by the civil courts as though fully qualified<sup>149</sup>, must serve as a powerful disincentive

to would-be quacks. It should be noted, however, that unlike vets<sup>150</sup>, who enjoy a professional monopoly in the true sense of the word, doctors are not uniquely entitled to practise medical arts; their monopoly is in reality perhaps better described as "brand protection."

However, there are certain other privileges conferred by the status of registered medical practitioner. Thus, only a registered doctor can prescribe Prescription Only Medicines<sup>151</sup>, and doctors are immune from most of the restrictions imposed by the Medicines Act 1968. That Act does, however, make considerable use of criminal sanctions to regulate this area of medical activity:

"It is evident that, while the Act defines a number of offences, all of which may come within the ambit of the lawyer, very few of these involve directly the doctor... - indeed they are specifically excluded from the majority of the provisions."<sup>152</sup>

Only a registered medical practitioner may remove tissue from dead body<sup>153</sup>, which includes conducting post-mortem examinations. Lastly, it is only a registered medical practitioner who is allowed to sign any of a large number of official certificates, most of which relate to the medical condition of the person to whom the certificate relates<sup>154</sup>. In these cases, the point of having a doctor sign the certificate is obvious; and where doctors are allowed to sign non-medical certificates, it has been suggested that it is the criminal fraud inherent in falsely certifying something, and the professional consequences of such a conviction, that justify doctors being granted these privileges:

"Which is why, for example, a doctor's signature is accepted as a good supporting guarantee on a passport application form. It's not because doctors are regarded as sea-green incorruptibles, but because they stand to lose so much if caught out in a misdemeanour."<sup>155</sup>

From the viewpoint of the criminal law, the importance of these restrictions on certification largely affects non-doctors, who will generally commit some form of criminal fraud or forgery, or violate the statute under which the certificate is required if they sign such a certificate, in addition to possible prosecution under the Medical Act for holding themselves out as being registered practitioners. From the doctor's perspective, this merely underscores the importance of ensuring that they remain on the Register at all times they are practising medicine.

## **B: Certification of death:**

Two certificates in particular are of medico-legal significance. The first concerns the law of abortion, discussed in the next section; the other involves the certification of death.

The Scottish procedure in this area<sup>156</sup> is markedly different from that found in England<sup>157</sup>, largely due to the absence of the office of Coroner in Scotland.<sup>158</sup> In either country, the process requires a medical certificate of death, which only a registered medical practitioner may issue; and in England and Wales the attending doctor is under a statutory duty to issue it.

The criminal law's involvement is that depending on the cause of death certified by the doctor, there may or may not follow investigation by the Coroner or at the behest of the Procurator Fiscal, possibly resulting in a murder inquiry. Doctors are therefore entrusted with a role at the heart of the criminal justice system, although in this case it is on the side of the prosecuting authorities, rather than as their targets. However, this particular aspect of the system falls down if it is the doctor certifying the death who has himself killed the person in question (as with Harold Shipman). This area of the law is currently under active review with the objective of closing this loophole and preventing any repetition.

## **C: Abortion:**

Abortion is considered in this section because, while the common law crime of abortion in Scotland<sup>159</sup> and the offences under Sections 58 and 59 of the Offences Against the Person Act 1861 (as amended) in England and Wales apply to anyone, it is only the registered medical practitioner who has a legal defence under the Abortion Act 1967.

It is not intended here to go into the complexities of the abortion debate, which raises some of the most problematic and contentious issues in the entire medico-legal field, and generates the most impassioned and embittered debate<sup>160</sup>. For the present purposes, what is important is the outcome of this debate as displayed by the law which has emerged as a "compromise in a debate where there is no consensus."<sup>161</sup>

The actual offence of abortion was to carry out any of a number of acts done with a view to procuring a pregnant woman to miscarry. Thus, in Scots law it was stated that it is a crime to "cause or procure abortion whether by drugs or by instruments or violence"<sup>162</sup>; in England, the offence was defined in Sections 58 and 59 of the Offences Against the

Person Act 1861. It should be noted that the law of Scotland required that the woman be pregnant at the time; it was not, at common law, illegal to attempt to cause the miscarriage of a woman who was not pregnant<sup>163</sup>. This is in marked contrast to the specific rule of Sections 58 and 59. Another divergence between Scots and English law in this field concerns the culpability of the pregnant woman herself: Section 58 of the 1861 Act states that

"Every woman, being with child, who with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing, or shall unlawfully use any instrument whatsoever with like intent... shall be guilty of an offence."

In contrast, the case law in Scotland, although unclear, appears to point to a general rule that the pregnant woman herself can be art and part guilty<sup>164</sup> in the crime of abortion or attempted abortion committed by another person (as in England<sup>165</sup>); but there are no modern cases in which the woman has been convicted of an independent offence<sup>166</sup>. Most commentators are of the opinion that such a charge is *theoretically* competent<sup>167</sup>. The lack of reported cases is due firstly to the fact that conviction of a third party abortionist is in practice only possible with the cooperation of the woman, and secondly to a relatively liberal Crown Office prosecution policy (which can have a significant impact on Scottish criminal practice<sup>168</sup>). Indeed, referring to the case of *R v Bourne*<sup>169</sup>, which clarified the legality of therapeutic abortion in England, it has been suggested that

"...it is doubtful if Mr Bourne would have achieved his object of clarifying the issue had he performed a 'test' abortion in Scotland because the authorities would not have prosecuted him." <sup>170</sup>

It is important to note that both the 1861 Act and the common law of Scotland were silent on the question of therapeutic abortion. The decriminalisation of such procedures was introduced in England and Wales by the Infant Life Preservation Act 1929, which provided that there was an exception to criminal liability for abortions performed "in good faith and for the purpose only of preserving the life of the mother." The extent to which this permitted abortion was clarified by the case law, most dramatically *R v Bourne*. Mr Bourne, an eminent gynaecologist, performed an abortion on a 14 year-old who was pregnant as a result of multiple rape, then announced the fact to the authorities. He was tried and acquitted following what is generally regarded as a favourable address to the jury by Macnaghten J, who stated that

"The unborn child in the womb must not be destroyed unless the destruction of that child is for the purpose of preserving the yet more precious life of the mother." <sup>171</sup>

The 1929 Act was primarily concerned with closing a perceived loophole whereby it was felt that the 1861 Act did not prevent the child being killed in the process of birth<sup>172</sup>; but it also introduced a presumption that any foetus of 28 weeks' development was viable, *i.e.* capable of independent existence<sup>173</sup>. The upshot of this was that therapeutic abortion was only possible up to the 28th week - in England and Wales. The first official legalisation of abortion at all in Scotland came with the Abortion Act 1967, but even once this came into effect, the non-applicability of the 1929 Act meant that there was technically no time limit at all to therapeutic abortion in Scotland until 1990, when the Human Fertilisation and Embryology Act 1990 was passed.

The 1967 Act extends to both Scotland and England, and effectively replaces the previous case law: Section 5 specifically states that "anything done to procure the miscarriage of a woman is unlawfully done unless authorised by Section 1 of the Act."

Section 1 of the Act states that no offence is committed if the abortion is carried out by a registered medical practitioner and two such practitioners are of the opinion either that continuing the pregnancy would entail risk to the life of the woman, or risk causing physical or mental injury to the woman or any existing children, or else that there is a substantial risk that the child if born would be seriously handicapped. The section further provides that the doctors may take into account the woman's actual or reasonably foreseeable environment<sup>174</sup>, that the actual abortion must be carried out in an NHS hospital or other place approved by the Health Minister or Secretary of State<sup>175</sup>, except that in an emergency it may be carried out anywhere and on the basis of a single doctor's opinion<sup>176</sup>. The Act further provides that persons having a conscientious objection to abortion are not obliged to participate in treatment authorised by the Act, but subject to the proviso that the conscientious objection clause does not apply in emergency situations<sup>177</sup>. This clause has been held not to apply to persons who do not actually participate in the treatment terminating the pregnancy, *e.g.* to a secretary whose job included typing abortion referral letters<sup>178</sup>. However, the general immunity conferred by the Act, while it is restricted to registered medical practitioners, has been held to include other members of the health care team acting under the instructions of such a practitioner and in conformity with accepted medical practice<sup>179</sup>. The "morning-after pill" (emergency contraception taken after intercourse) has been held not to be an



abortifacient<sup>180</sup>. Lastly, there are reporting obligations imposed on doctors carrying out abortions; it is a criminal offence to fail to comply with these<sup>181</sup>.

Only one doctor has been successfully convicted under the 1967 Act<sup>182</sup>; in that case, the doctor had not actually examined the patient. At the trial, no mention was made of the fact that, at least in parts of Britain, abortion is effectively available on demand<sup>183</sup>. The doctors who approve abortion on demand point to the fact that, particularly in the first trimester, abortion is always safer than continuing the pregnancy to term<sup>184</sup>.

It is also clear from the foregoing that it is ultimately doctors, and not the pregnant women, who decide whether or not to permit abortion to take place. Similarly, the law does not grant the father any rights to object to the proposed abortion<sup>185</sup>. The European Convention on Human Rights has also been deployed in this context, albeit without success on the part of the applicants. Thus, the former European Commission on Human Rights<sup>186</sup> left open whether or not the protections afforded by Article 2 of the Convention extend to fetuses<sup>187</sup>, and the European Court has yet to rule on the subject. The High Court in England has recently refused an attempt to use Article 2 of the Convention to prevent an abortion from taking place<sup>188</sup>.

The Human Fertilisation and Embryology Act 1990 brought about a number of changes to abortion law. Firstly, the time limit for abortion (*i.e.* the point at which a foetus is presumed to be viable) was reduced from 28 weeks to 24 weeks<sup>189</sup>; again, it should be noted that in Scotland, this was the first introduction of any time limit. However, there were three exceptions to this rule, *i.e.* abortion can be carried out right up to the moment of birth in cases where it is necessary to prevent grave permanent injury to the health of the mother, or where continuing the pregnancy would threaten her life; it also applies in cases where there is a substantial risk that the child, if born, would suffer from "such physical or mental abnormalities as to be seriously handicapped" - which is the same wording as one of the grounds under the 1967 Act. It is in such cases that the question of liability for death after birth arises. The 1990 Act also clarified the legality of selective reduction of pregnancies, which may have been illegal under the 1967 Act (as there was a *prima facie* case of criminal foeticide, but no termination of pregnancy entitling the doctor to the protection of the 1967 Act). Lastly, the 1990 Act extensively regulates the areas of infertility treatment and embryo research; and while there are criminal penalties attaching to violations of these rules, these rules fall under the auspices of the Human Fertilisation and Embryology Authority and are considered in Chapter 5.

## **D: Organ Transplantation:**

As noted above, one of the privileges (in the legal sense of the word) of being a registered medical practitioner is that you are entitled to remove tissue from a dead body<sup>190</sup>. However, the law regulating this is exceedingly unclear; for instance, it has been pointed out that there is no clear definition of who the person "lawfully in possession" of a dead body actually is, this being the only person who can authorise tissue removal<sup>191</sup>. Such authorisation may only be given by that person either where the deceased consented to the particular use during their life, or where the person lawfully in possession has no reason to believe that the deceased or their surviving spouse or any relative objected or had expressed any objections<sup>192</sup>.

There are no clear sanctions for breaching the terms of the Human Tissue Act 1961<sup>193</sup>, although these do seem to include criminal conviction<sup>194</sup>. The former controversy surrounding the use of "beating heart" donors appears to have largely subsided, and the courts have accepted that brain-stem death is legally death<sup>195</sup>. The main legal obligation imposed on doctors removing tissue is to verify by personal examination that the body is actually dead<sup>196</sup>, and, if the hospital is lawfully in possession of the body, to make "such reasonable enquiry as is practicable" to discover if the deceased or his surviving spouse or relatives have or had any objections to the body so being used<sup>197</sup>. As noted earlier, recent adverse publicity surrounding the discovery of wholesale "organ harvesting" by clinicians in a number of children's hospitals on the basis allegedly defective or non-existent parental consent (or "authorisation", consent being an inappropriate term in the absence of full information having to be provided to the authorising individual and lack of any benefit to the deceased<sup>198</sup>) means that this area of law is also under active scrutiny at the moment<sup>199</sup>. One of the key recommendations of the Scottish review is that the Human Tissue Act 1961, which is supposed to regulate this area, is in urgent need of repeal or substantial revision<sup>200</sup>. Accordingly it is not intended to go into the subject in more detail.

Different criteria are involved when tissue intended for transplant is removed from living donors. As regards regenerating tissue, most commonly blood, there is little problem: the donor soon regenerates the lost blood and is back to normal. As regards non-regenerative organs, only the kidneys are suitable for transplant from a live donor, and this discussion will focus specifically on the criminal aspects of this procedure. Removal of any other major organ would result in the death of the donor, and the consent of the victim is no defence to a murder charge<sup>201</sup>.

The common law, unsurprisingly, has historically had very little to say on the issue of live donor transplantation, since the procedure has only been possible since 1954. As has been seen, the common law has only very slowly produced any consistent legal rationale to medical practice generally, and these difficulties are exacerbated in the case of donating an organ. Any justification of surgical intervention based on the benefits which it is intended to confer on the patient is arguably inapplicable to organ donation. The main legal difficulty centres on the crime of mayhem, or maim, since consent was never a defence to this charge<sup>202</sup>. Maim was an offence in English law<sup>203</sup> whereby the King was deprived of a fighting man by the loss of any of a variety of parts of that man's body. These are described by Skegg<sup>204</sup>, who doubts whether organ donation would qualify; in any case, the offence is probably obsolete<sup>205</sup>. However, even allowing that such operations are legal at common law, there are now additional statutory controls on this.

The Human Organ Transplants Act 1989 was passed in the aftermath of a "kidneys-for-sale" scandal. In essence, the Act makes it a criminal offence to trade in human organs<sup>206</sup>, makes it an offence to transplant organs from any person into someone who is not either closely genetically related to the donor<sup>207</sup> or, in the absence of such relationship, where the transplant is not approved by the Unrelated Live Transplant Regulatory Authority<sup>208</sup>. There is considerable uncertainty over the use of child organ donors in this country<sup>209</sup>.

Finally, there is the subject of xenotransplantation, *i.e.* the use of non-human organs in humans. This is presently unregulated by formal law, but the government has set up an expert group to consider the issues and decide whether legislation is required and if so, what form it should take<sup>210</sup>.

## **VI: The effects of the criminal law:**

This section will seek to assess, in necessarily general terms, the effects of the criminal law in achieving its assigned regulatory functions, *viz.* providing a channel for grievances, a mechanism to investigate allegations of failure to adhere to agreed standards, the punishment of those who are deemed to have failed so to adhere, and regulation of the regulatory bureaucracies themselves. As was noted *supra* in discussing the purpose of the criminal law,

“...empirical evidence suggests that the reductive effects of criminal processes (although extraordinarily hard to assess) are meagre, and casts doubt on the validity of characterising criminal law primarily in instrumental terms.”<sup>211</sup>

Clear distinctions between the perceived effects of the criminal law, and the reasons for the law in question (particularly when a long-standing rule is changed) intended by the legislators, can be seen throughout history. Thus Anglo-Saxon juries tempered the severity of new Norman offences<sup>212</sup>, a practice continued through the centuries to the later 18<sup>th</sup> century with particular focus on the punishments of death or transportation<sup>213</sup>.

The death penalty makes a useful subject to consider the effects of a particular measure of the criminal law, and to highlight some of the reasons why these are hard to assess. Commenting on the Parliamentary debates in 1982 concerning a proposed re-introduction of the death penalty for certain crimes, Sorrell points out that the statistical evidence deployed by proponents of capital punishment represented at best very weak evidence of the deterrent effect of that sanction<sup>214</sup>; other commentators go further and cite international studies indicating that abolition of the death penalty is more commonly followed by a decrease in homicide rates<sup>215</sup>.

Just because deterrence theory fails to provide an adequate justification for capital punishment is not to say that it should be abolished; we may wish to keep it for purely retributive purposes, for instance. However, for present purposes what this example shows is that when looking at this reasonably narrow point of focus, there is no consensus on what will happen if we choose option (a) rather than option (b). The situation is very narrow, consisting of what happens to a person convicted of the specific offence of murder, and where the debate is a binary one of death versus life imprisonment<sup>216</sup>. If consensus is unachievable, and conclusive empirical evidence unavailable, in this one narrow question, then it would seem that we can reasonably conclude that there is no single answer as to how effective the criminal law is in achieving its assigned purposes. The analysis which follows is therefore a subjective one, informed by the analysis of the mechanisms of the criminal law given above.

The effects of the criminal law in terms of medical regulation can reasonably be assessed by looking at three “target” groups in terms of the different aspects of regulatory task being undertaken. These groups are the regulated themselves (*i.e.* doctors), the regulators (*i.e.* those operating other parts of the regulatory bureaucracy), and those who stand to benefit from the regulation, (*i.e.* the general public as being actual or potential patients of the doctors.)

## **A: Effects on doctors:**

The criminal law's involvement with doctors typically arises within four discrete areas:

- Where the doctor's offence is clandestine and committed under the guise of medical treatment;
- Where the doctor (perhaps, though not necessarily, supported by a body of opinion within the profession) regards his/her conduct as acceptable but which the law does not accept as lawful;
- Where the offence arises because medical activity has gone wrong; and
- Where the offence is not connected to the fact that the offender happens to be a doctor.

Each of these separate areas will now be considered, with the exception of the last. If an offence is not connected to the fact that it happens to be a doctor who has committed it, this is not really connected to the regulation of medicine and is therefore outwith the scope of this thesis.

### 1: Clandestine offences:

The case of Harold Shipman exemplified the ability of doctors to commit serial offences under the guise of their proper professional activities, at the same time as showing up a major deficiency in the laws concerning death certification. In considering whether the criminal law has a regulatory function in respect of such types of incidence, the Shipman case will be used as a running example simply because it is recent, well-known, and has provoked a significant degree of commentary over what went wrong and what lessons can be learned. Nor is Shipman's case a completely unique one; at least one commentator has observed that:

“...medicine has arguably thrown up more serial killers than all the other professions put together, with nursing a close second... [T]here are enough recorded instances of multiple murders by doctors (real or bogus) to make at least a prima facie case that the profession attracts some people with a pathological interest in the power of life and death.”<sup>217</sup>

To recap: Shipman was a general practitioner practising single-handed in Hyde, near Manchester. He was convicted on 31 January 2000 of fifteen counts of murder. All his victims were elderly patients of his, murdered by injection with diamorphine in the course

of other treatment. There was no possible clinical justification for the injections. He also falsified patient records and incorrectly completed death certificates in an attempt to conceal his crimes. While convicted on fifteen counts of murder, there were (and are) suspicions that he killed a far higher number. A Department of Health audit suggested that the correct figure was likely to be 236 murders<sup>218</sup>.

Firstly, how was Shipman caught? The daughter of one of his victims became suspicious of the fact that her mother had changed her will in favour of Dr Shipman shortly before her death<sup>219</sup>. It was this which triggered the police investigation, not the massively high mortality figures for Dr Shipman's patients which were only revealed by a clinical audit conducted after his conviction<sup>220</sup>. In attracting police attention through benefiting from the will of a deceased patient, Shipman was following the path of Dr Adams over thirty years previously: it was financial concerns, not patient mortality figures, which resulted in Dr Adams being investigated and prosecuted in 1957<sup>221</sup>. The criminal law clearly provided a channel for the suspicious daughter to channel her suspicions into, but the investigatory mechanisms of the criminal legal system had been unable to identify any of the previous 235 (or 297<sup>222</sup>) suspicious deaths. The decision not to prosecute Shipman for any further offences<sup>223</sup> meant that for the relatives of his supposed other victims, the official inquiry into the incident will be the only channel available for them to discover what happened. The inquiry itself generated litigation, the original decision to hold a private inquiry being overturned on judicial review, and the Health Secretary ultimately opting for a full judicial inquiry under the chairmanship of a High Court judge<sup>224</sup>.

Secondly, what has happened to Shipman? In the first instance he was sentenced to life imprisonment with the unusual recommendation by the trial judge that he spend the rest of his life behind bars. In this context, one can detect elements of retribution as well as protection of the public. The GMC then moved quickly to strike Shipman off the register of registered medical practitioners, although he is clearly unable to practise medicine from inside prison and consequently not in a position to commit any further offences of the type he was convicted of.

Whether the sentence following conviction is greater (in terms of impact on the doctor) than the actions of the other regulators in response to the conviction is dependent on the severity of the offence. Here, life imprisonment with a recommendation of never being released is the most severe sanction available to the state, and is clearly more significant than any other sanction which flows from the conviction (principally, as here, this will mean being "struck off" by the GMC). For less heinous offences, this may not be

the case. Even a murderer, in normal circumstances, can reasonably expect to be released from prison at some stage. A white-collar criminal with no previous convictions can reasonably hope to avoid a custodial sentence at all. In such circumstances, while the criminal law has provided the system for punishment of the criminal, the ongoing protection of the public is only partially served by this mechanism. The public protection function in such cases is that, while the existence of possible conviction and sentence has manifestly failed to deter the individual from committing the offence in the first place, it may serve to deter them from doing it again. The theory is underpinned by the fact that detection and conviction are, for that person, now more than a theoretical possibility. Furthermore, detection is more likely because, having a track record, they are more likely to come under scrutiny and if they are, in fact, convicted again the court will take the previous conviction into account and tend to impose a more severe sentence. Whether these suppositions are correct is, as noted above, unknown and virtually unknowable. And whether these prospects represent more of a deterrent than the possibility of being struck off/sued/dismissed from your job or post is, for precisely the same reasons, also unknown.

One thing that did come out of the Shipman case is that the criminal law is a very good mechanism for getting at the root of a problem, but only if one is able to provoke it into responding at all. Earlier concerns about Shipman saw him subjected to the scrutiny of the GMC, and administrative scrutiny by the local health authority, neither of which unearthed what was happening. Only the full murder investigation did this, and that was only provoked by Shipman's inept attempts to forge a will. Earlier complaints to the police and other authorities went largely unheeded. In terms of the law's response to the clandestine medical offender, this means that in practical terms someone else really has to spot that something is amiss.

## 2: Offences where professional conduct is regarded as unlawful:

This category of offence can occur where there is a time lag between the offences being created or recognised, and a medical procedure being devised which runs counter to the rules of the criminal law. Sterilisation given above is an example of this – Lord Denning's dictum in *Bravery v Bravery*<sup>225</sup> has never been overruled, and the doctor carrying out male sterilisation for contraceptive reasons commits an offence. The criminal law in this area is clearly lagging well behind developments in medicine, and in society generally.

A more common occurrence of this type of offence arises in areas which may be emotive and where the lack of any societal consensus has made legislating difficult. The trial of Dr Arthur exemplifies this type of “offence”, as did the trial of Dr Bourne. Both doctors were acquitted, which might be indicative of the fact that if what is done enjoys a degree of professional support then juries are more prepared to accept this than the formal rule-makers. Modern juries are, in this respect, following in the ancient tradition of selectively disapplying formal rules which they regard as being too severe in the circumstances. The law *technically* does not countenance or permit euthanasia, but arguably a jury recognises what is happening and refuses to label the doctor as murderer in those circumstances. In retaining the jury for such situations, the criminal law builds in a system allowing flexibility in application where adherence to the strict rules would produce what many would regard as an injustice. Prosecutorial discretion can achieve the same end. It is also probably a reflection that offences falling into this category are controversial, and tend to relate to subjects such as abortion and euthanasia where there is no consensus in society. The acts of juries in acquitting in such cases may, as much as anything else, be a reflection of the fact that criminal courts are not, nowadays, generally regarded as the best place to debate the rights and wrongs of social policy or comparative ethics. The trial of Dr Cox<sup>226</sup> (who injected a patient with a lethal dose of potassium chloride) does not quite fit this pattern, since he was convicted of attempted murder. What distinguished Dr Cox’s actions from those of Doctors Adams and Bourne was that there was no recognised therapeutic value in injecting potassium chloride and therefore no scope for the principle of double effect referred to previously. In the event, Dr. Cox still received a very lenient reaction from both the criminal court and the other regulators<sup>227</sup>.

### 3: Offences caused by medical practice going wrong:

As was seen above, the criminal law’s involvement in this type of offence typically arises where a patient has died as a result of alleged incompetence on the part of the doctor; it could equally apply in cases of non-fatal injury.

As to the test applied before there is criminal involvement, we have seen that as a preliminary the courts will inquire as to whether what was done was in accordance with a body of professional opinion, *i.e.* apply the civil test of quality. Only if the action in question fails the civil test, and is unsupported by any such body of opinion, will the court inquire further to see if the failure in standards was so bad as to merit criminal sanction.



Given that the prosecuting authorities only appear to prosecute where there has been loss of life, and that the ensuing prosecution is therefore typically for manslaughter, the effects of conviction are always going to be quite severe. Even if the sentence is light (as it typically is in cases of medical manslaughter), the trials typically generate a large amount of publicity and, as with convictions for clandestine offences, are likely to invoke a response from other regulators. Again, this other response might ultimately have a more marked impact on the doctor than the criminal sentence, but it is again the trigger of criminal prosecution which has provoked the response.

The distinction between criminal law tests and civil tests for the same malpractice is that criminal law, while taking the civil standard as a starting point, goes on to consider whether what has happened is deserving of criminal punishment. In this context, therefore, the criminal law is setting the minimum standard of medical treatment – the ground level below which it is not merely actionable but criminal to go.

#### **B: Effects on other regulators:**

Arguably one of the main uses of the criminal law in the field of medical regulation has been to create offences in relation to other regulatory bodies. As we have seen, it is an offence to carry out a range of activities (including holding yourself out as a physician) unless you are a properly-registered medical practitioner. It is in this way that the criminal law is used to underpin the jurisdiction of other regulators (principally, of course, the GMC). From this perspective, the effect on the other regulators is that they can say “submit to our jurisdiction or face the wrath of the criminal courts”. Whether and to what extent this affects the effectiveness of that other mechanism is considered in the analysis of those other mechanisms.

There are, in fact, very few parts of the criminal law directly impacting on the functions of other regulators acting in their capacity as regulators. Possibly the only really relevant provision is the ancient offence of wilful neglect of duty<sup>228</sup>. The offence has been defined as follows:

“... a public officer, who neglects his duty, violates an obligation undertaken to the Sovereign and is punishable for that act as for an offence...”<sup>229</sup>

The practical application of this is that someone entrusted with a regulatory function could, if they wilfully fail to carry out that function, be guilty of an offence. So far as the writer has been able to ascertain, no-one involved in medical regulation has ever been

so charged. Accordingly, it would appear that the criminal law has very little to say about the activities of regulators.

### **C: Effects on patients and the public:**

If nothing else, the criminal law is the final resort for those who have serious concerns. The problem is in getting those concerns taken seriously by those having responsibility for carrying out investigations and bringing prosecutions.

A successful prosecution is generally welcomed by the victims, although this may be tempered by unhappiness at what may be seen as a lenient sentence. If the case results in additional official action aimed at preventing a recurrence, this too is likely to be welcomed.

The problem is that the system disempowers the victim. Someone raises a concern with the authorities (usually the police). However, if the police fail to take these concerns seriously, there is little more the individual can do. In the absence of official investigation, private prosecution of a doctor is wholly impractical. The prosecution similarly follows its own agenda, and victims are notoriously poorly served by the criminal justice system<sup>230</sup>. In essence, the system treats the victim of crime simply as a potential witness and source of a complaint, with no status beyond that. There is no right to be consulted by investigating or prosecuting authorities, no right to address the court (or indeed even be told of the trial, if you aren't needed as a witness), and no right to be told when the person who committed the offence is being released from prison.

However, society in general is better served than the individual victim. Trials receive publicity, and society discovers that the doctor who transgresses is duly discovered and punished. To what extent the protection afforded by the criminal law is illusory requires better data concerning clinical outcomes than the system currently generates. Unless we routinely measure how good or bad a doctor is, we cannot be sure whether or not crimes are being committed. Whether the resources such measurement and monitoring would take are regarded as worthwhile will depend on the extent to which doctors committing crimes are regarded as aberrations or as an ongoing and real possibility; and even answering that question requires more monitoring than currently takes place. Whatever the result of the debate over enhanced scrutiny of doctors, it does seem to be the case that the monitoring system will not be a part of the criminal justice system, but that the criminal law will remain to punish transgressions that the other mechanisms uncover.

## **VII: Summary and conclusions**

### **A: Purpose:**

There are a number of purposes apparent in the analysis of the criminal law, falling generally into the categories of public protection and punishment. Criminal law attempts to carry out a number of functions, *viz.* providing a channel for grievances, an investigatory system, the regulation of other regulators, and, in part, the setting and upholding of standards. The main function of the criminal law, however, remains that of punishing wrongdoers and having them seen to be punished. The particular reasons for the infliction of this punishment are as mixed and variable for punishing the miscreant doctor as they are for punishing any other criminal – which is to say a complex and seldom articulated combination of deterrent, protective and retributive motives.

### **B: Mechanism:**

The criminal law relies almost entirely on external reporting before it takes cognisance of alleged criminal acts (taking the police as being an integral part of the criminal justice system for this purpose). A decision is then taken on whether to prosecute (and if so, in which court and on which charges). The trial then follows in accordance with the rules applicable to crime in general, and under the terms of the general criminal law. This can cause conceptual difficulties in some cases. Ultimately a verdict is reached; if the verdict is guilty, the stricter evidential rules mean that the conviction will be almost irrefutable evidence of the facts to which it relates for all other purposes. The doctor convicted is then sentenced; in a conviction for any charge apart from murder, this sentence is effectively at the discretion of the judge as restricted by the terms of the statute creating the offence (if a statutory offence) and the powers of the particular court.

### **C: Effect:**

The effects of the mechanisms we have outlined are, by their very nature, hard to quantify. If the deterrent effects of the criminal law were perfectly realised, we would presumably have no crime. But it is very hard, analytically, to separate this phenomenon from what would happen instead if we had a complete failure in the investigatory functions of the criminal law. It is hard to say what is the absence of crime as opposed to the failure to detect it. Certainly, few doctors seem to be convicted of serious crime, although a disproportionate number of serial killers appear to be involved in the medical sphere.

Conversely, the fact that doctors are, on occasion, convicted in the courts is evidence pointing to the fact that aspects of the system work, and are seen to work. Ultimately, the biggest single effect of the rare, high profile medical prosecution may well be to reinforce how unusual such prosecutions are. The reasons for this rarity cannot, as we have said, be identified without a lot more information on what actually happens in the course of medical treatment.

#### **D: Comparison with Core Evaluation Criteria:**

In Chapters 1 and 2, we identified seven core criteria against which each segment of the medical regulatory framework would be measured. The criminal law will now be assessed against each of the evaluation criteria in turn.

##### 1: Visibility:

The purposes for which the criminal law exists are generally highly visible in terms of legislative or judicial declarations about this or that; what is less clear is how these actually translate into practice. This is particularly the case when different parts of the system appear to proceed on the basis of different motives.

The mechanisms of the criminal law are highly visible. The substantive content of the criminal law is also visible, if somewhat opaque to the non-specialist and difficult for the layperson to access. The nature of the decision-making bodies and officials and criteria for decision-making within these mechanisms, particularly on issues such as decisions to prosecute, are however almost impossible to analyse and question. Some aspects, such as jury deliberations, are expressly protected so as to retain secrecy in terms of why a particular decision was reached. (Judicial decisions, in contrast, are at least generally capable of being appealed, and judges are generally expected to provide reasons).

The effects of the criminal law are highly visible in many respects, and completely invisible in others. Criminal trials being conducted in public are, of course, very visible – but virtually everything prior to the trial is kept a secret. The existence of contempt of court rules, although intended to ensure the fairness of the ensuing criminal trial and prevent prejudice, can have the effect of stifling discussion of the wider issues until the trial is concluded. In general, however, the effects of the criminal law are probably best seen by their absence than their presence. No crime may look identical to unidentified crime, but most people would, it is submitted, prefer to have no crime than to have lots

of crime being detected and punished. It is, however, true that at present we do not know which situation we are in, and in this context the investigatory systems can be criticised.

Overall, the criminal law is considered to be acceptable in terms of visibility, although there is scope for improvement in terms of the openness of investigating and prosecuting authorities.

## 2: Accountability:

There are differences in the degree of accountability of those who operate the existing system, some of which are inescapable due to the nature of the system.

At the highest level, responsibility for the passing of criminalising (or decriminalising) legislation lies with Parliament, which is accountable to the general public through the normal mechanism of the ballot box. "Law and order" is a staple election debate, although this typically relates more to the numbers of police on the beat and whether crime figures are rising or falling than to the particular terms of criminal legislation. In Chapter 2 it was suggested that the theory of parliamentary scrutiny led to an illusory system of oversight, and nothing in the debate over the criminal law gives cause to detract from that conclusion.

The prosecuting and investigating authorities are, in general, only subject to administrative control from within their own departments, although the recent removal of blanket immunity for negligent investigation of crime<sup>231</sup> might improve accountability in time.

The judges who make many of the key decisions in the criminal law are, by definition, not accountable for their decisions. In the particular sphere of judicial independence, this is unsurprising since a judge accountable for his or her decisions is unlikely to be classed as impartial. This is not to say there should be no redress against judges who reach unpopular and/or perverse decisions. In the UK, this is provided for by means of recourse to the appellate courts, with review commissions and the possibility of Executive pardon as the long-stop guarantors of the rights of the accused. The rights of victims are not similarly protected, although it is accepted that any move in the direction of victims' rights can impact adversely on the accused and that a difficult balancing exercise is required. While criticism can be levelled at individual judges, it is difficult to reconcile judicial accountability with judicial independence. For this reason, despite

recognising that improvements are possible, it is concluded that the judicial aspects of the system are adequately (if poorly) accountable; however, the other aspects of the system are regarded as being deficient in this respect.

### 3: Overall Fairness:

As explained in Chapter 2, the category of overall fairness incorporates a number of aspects including impartiality, accessibility, and speed of decision-making. In relation to the criminal law, all these issues arise.

Firstly, the courts are generally taken to be the epitome of impartial decision making. Whether one agrees with that assertion or not, it is true that the courts are institutionally designed so as to be as impartial as any piece of state apparatus can be. They are therefore deemed to satisfy the “impartiality” limb of this criterion.

As regards accessibility, there is the possible difficulty of getting the authorities to respond to allegations or complaints. Any failure in terms of accessibility is, however, as result of the failure in accountability within that part of the system, so no criticism is made under this heading.

In terms of speed, there are time limits within which prosecutions must be brought. For common law offences with no formal time limit, the incorporation of Article 6 of the European Convention means that all trials must be brought within a reasonable time. There is therefore no problem under this heading from the point of view of the accused, although prolonged investigations may be distressing for victims and complainers. Overall, however, the system seems adequate in respect of the applicable timescales.

In terms of fairness generally, persons who face criminal prosecution enjoy all the safeguards found in Article 6, and any remaining unfairness within the system is unlikely to survive the inception of the Human Rights Act 1998 for long. However, we have already considered the lack of rights enjoyed by victims and complainers, who could well argue that the system is unfairly weighted against them. Ultimately, this is a policy decision involving balancing competing rights. While recognising that much could be done to improve the status of victims within the criminal justice system (and in particular, there appears to be no good reason for not implementing measures having no adverse effect on the accused, such as court date notification) these measures are peripheral to the central functions of the criminal law. Accordingly, the criminal law is deemed to satisfy the requirements of overall fairness.

#### 4: Effectiveness:

We have already seen that the practical effects of the criminal law are, in some respects, unquantifiable. This section is therefore concerned only with the quantifiable effects. From what we can observe, does the criminal law do what it sets out to achieve?

The answer here would appear to be yes: the criminal law has mechanisms in place to describe what is or is not acceptable conduct, how to determine if someone has committed unacceptable conduct if they dispute the allegation, and a system of means of disposal aimed at punishing the criminal and deterring him/her and others from any future wrongdoing. While the deterrent goal in particular is imperfectly realised, the other aspects manifestly perform their assigned functions. Crimes are reported, evidence gathered and presented in court, verdicts passed and sentences handed down. Whether this activity reduces the incidence of crime in the medical sphere is a different question, as is the question of whether the investigatory systems could do more to discover crime. However, the criminal law, as noted above, sets the minimum threshold for acceptable standards of medical practice. There would, it is submitted, be a need for this standard even if no medical crime ever actually took place. While the content of the standard laid down may be hard for the non-specialist to ascertain, the standard is there and can be discovered. In general, therefore, it is considered that the criminal law is sufficiently effective.

#### 5: Efficiency:

Criminal courts are expensive. Harold Shipman's trial lasted four months, requiring the presence of judge, jury, court officials, solicitors and counsel for both prosecution and defence, police, witnesses and relatives of the deceased to be present for that time. The costs of such trials easily run into millions of pounds.

Are courts efficient? The organisation of criminal courts is centred on judicial time on the bench, which can lead to inefficiencies: huge amounts of lawyer and witness time can be wasted waiting for a judge to become available. This stems from the court officials' experience in estimating that a certain proportion of both criminal trials and civil proofs will not proceed due to last minute settlements or plea bargains, or the failure of a key party or witness to appear. With this knowledge behind them, the court lists are drawn up featuring far more cases than the available judges can possibly hear. It is when the estimate as to non-proceeding matters is not right that delays occur. While a system

which would always prefer parties to sort matters out by themselves will inevitably have a degree of slack being generated, the system of over-subscribing the court lists does not seem to be the best response to this. Judicial time on the bench may be maximised, but this is at the expense of the far greater number of people whose time is not used efficiently. It is therefore concluded that the criminal law is not efficient.

#### 6: Avoidance of undue influence with good medical practice:

It is necessary to subdivide this category somewhat, to reflect the different ways in which doctors come into the realm of the criminal law.

Firstly, where the doctor's offence is clandestine and committed under the guise of medical treatment, it would seem unarguable that the functions of the criminal law do not interfere with good medical practice. It may be that future steps intended to prevent clandestine offending by doctors turn out to be so intrusive or time-consuming as to interfere with good medical practice, but no-one appears to have suggested that that is the case at present.

Secondly, where the offence arises because medical activity has gone wrong, again it seems unarguable that there should be a standard below which it is criminal to continue acting, and within the definition of good medical practice given in Chapter 2, nothing in the criminal law's response to this form of conduct appears objectionable.

Thirdly, we have the category of offence which is committed (or at least prosecuted) because while the conduct of the doctor is supported by a body of opinion within the medical profession (or by a body of public opinion), it is not conduct currently recognised as being lawful. Does the criminal law serve to interfere with good medical practice in this category? To answer this, it is necessary to consider the definition adopted in Chapter 2: "good medical practice" means medical activity which is demonstrably of clinical benefit to the patient, and which is the course of treatment which, if the patient could be brought up to the level of knowledge concerning that treatment as the doctor treating him or her (or alternatively, of a "reasonable" doctor), the patient would have chosen for him- or herself. Whether the criminal law's involvement in the areas we are currently considering violates that principle will depend on the specifics of the intervention in question. Thus, if we consider whether a non-lifesaving abortion can be performed on a 14 year-old rape victim, the relative complication rates of continued pregnancy and childbirth versus medically-performed abortion point clearly in favour of abortion (assuming, of course, that that is what the patient wants); and a criminal law



preventing this from happening is in conflict with this principle. Other examples are perhaps less clear; the non-treatment of a severely handicapped neonate, for instance, is now supposed to be based on the best interests of the child (recognising that this is a difficult test to apply for a neonate) and if properly applied actually incorporates all the substantive elements of good medical practice. The criminal law, in adopting this test, thus avoids interfering with good medical practice as here defined. Consensual non therapeutic injury is currently illegal, but none of the reported cases appear to involve medical practitioners. One can only speculate as to how the criminal courts would respond to the doctor, reported recently in the media, who agreed to amputate the healthy limb of a person suffering from a mental disorder which caused them to want the limb removed; ultimately, the doctor was not prosecuted. On general principles, a criminal offence would be committed unless the procedure could be shown to be of benefit to the patient – presumably psychological benefit, as it was plainly of physical disbenefit. (On a separate aspect, one might also question the person’s mental capacity to give a valid consent in these circumstances; capacity is considered in Chapter 4 *infra*.) Following this, the activity would be illegal if of no benefit (but would also then fall outwith our definition of good medical practice), and legal if it were of benefit (which would also mean it fell into our definition). Accordingly, it appears that again there is no undue interference with good medical practice. This is subject to the caveat that while these examples all satisfy this evaluation criterion, it is a very case-specific area and the criminalisation of other procedures could violate this principle.

#### 7: Respect for patient autonomy:

As we have seen, the criminal law of assault is the main way in which the laws of the UK uphold the principle of physical autonomy. However, closer scrutiny of the substantive and procedural rules of the criminal law requires a certain amount of backtracking from this starting point. Thus, the concept of criminalising “victimless” crimes, such as consensual sadomasochistic practices, is putting an imposed societal norm above the individual’s autonomy. The investigative machinery underpinning the criminal law is also capable of carrying out intrusive surveillance and searches, seriously impacting on both the physical integrity and also the informational autonomy<sup>232</sup> of those affected<sup>233</sup>.

In terms of patients as victims of crime, as noted above the system substantially disempowers the victim, and this is also showing a clear disregard of respect for patient autonomy.

Accordingly, this section concludes that while ostensibly protecting patient autonomy through the substantive criminal law, the criminal law provides inadequate safeguards for autonomy as a result of defects and shortcomings in its procedural side.

### **E: Conclusions:**

The criminal law appears to have a role in medical regulation which is at once peripheral and crucial. It is peripheral insofar as there is no body of specifically medical criminal law, and the criminal law's involvement in medical regulation involves the application (sometimes in a very strained way) of rules of general applicability. It is central because in the final measure it is the criminal law which defines the bedrock standard of medical care, and which punishes the most severe examples of breaches by medical professionals of the rules which govern their conduct.

The activities of the criminal law in carrying out these tasks are highly visible, although there is much which is decided behind the scenes and is not subject to public scrutiny, and the contents of the law are hard to ascertain in some areas. While the possibility of making an allegation of criminal conduct is open to anyone, what then happens is outwith the individual's control and cannot be challenged effectively. The system places no particular importance on victims as anything other than potential witnesses. While the court system itself is scrupulously fair to the person accused, there are certain aspects of the system which could be improved from a victim perspective without impacting on that fairness in any way. The court system itself does get the job done, and is therefore *effective*, although it seems to be extremely *inefficient* in how it goes about achieving these functions.

In substantive terms, the criminal law does not, in general, interfere with good medical practice, although both substantive and procedural rules can overrule individual autonomy in some ways – despite a fundamental starting point of respecting that same autonomy. The courts themselves are, in practical terms, unaccountable although there is an inherent conflict here between accountability and the independence and impartiality required of decision-makers. Arguably the pendulum has swung too far in the direction of structural independence resulting in too little accountability.

Earlier in the chapter, we identified the regulatory tasks undertaken by the criminal law as being the provision of channels to permit grievances to be aired and disputes resolved, elements of setting (and upholding) standards of medical practice, the provision of systems of investigation to inquire into whether standards are being adhered

to or not, and (most obviously) the punishment of those who fail to adhere to the standards. Closer scrutiny indicates that the criminal law does not appear to play a significant part in policing the rest of the regulatory system, although it is used to underpin those other parts. While achieving these goals tolerably well, there is scope for improvement.

Firstly, the standing of victims could easily be improved, in accordance with our notions of respect for autonomy. Some moves in this area (such as having victim impact statements) could conceivably have an adverse impact on the accused, but others such as simple notification of court dates would not. Improving the way in which courts operate so as to minimise the amount of time wasted by everyone involved would benefit everybody, but it might actually be necessary to spend more to achieve the desired efficiency savings (recalling that “most efficient” does not necessarily equate to “cheapest”).

The accountability of many of those involved is inadequate and decisions by prosecutors and investigators are both hidden and hard to challenge. Whether freedom of information laws will change this is as yet uncertain, but the exemptions in both the UK<sup>234</sup> and the Scottish<sup>235</sup> legislation would be permissive of allowing a culture of secrecy in these organisations to continue. These measures are considered further in Chapter 6. Judicial accountability is another problem area, but it may be that this aspect is irreconcilable with fairness to the accused.

Finally, it is a fundamental principle in European jurisprudence that criminal laws should be

“...formulated with sufficient precision to enable any person to foresee to a reasonable degree the consequences of his acts.”<sup>236</sup>

As was seen above, particularly in relation to those activities defensible in medical terms but which nonetheless resulted in prosecution, there is a degree of uncertainty within the existing criminal law. It may be that codification of the criminal law is a better way to ensure that the content of the criminal law is more easily accessible to those who are bound by its terms.

## Chapter 3 Notes

- <sup>1</sup> P. Worsley and R Fitzhenry, "Social stratification: class, status and power" in P Worsley (ed.), *Introductory sociology* (2<sup>nd</sup> ed., 1977), 460
- <sup>2</sup> WW Sharrock, "The problem of order" in P Worsley (ed.), *loc. cit.*, 479-480
- <sup>3</sup> 2 Bell, *Prin.* § 474, 522; *Comm. I.*, 665; *Zurich General Accident etc. Co. v Leven* 1940 SC 406
- <sup>4</sup> Unlike the generally-equivalent provisions of the civil law as they affect medicine, it should be appreciated that Scottish criminal law remains highly distinct from English, although since most of the crimes covered in this chapter are substantially similar, this distinctiveness may not be readily apparent to English readers. An overview of Scottish criminal law can be found in Jones & Christie, *Criminal Law*, (1992), a fuller discussion in Gordon, *Criminal Law of Scotland*, (1978, with supplement to 1992); Scottish criminal procedure is covered in detail in Renton & Brown, *Criminal Procedure according to the law of Scotland*, 6th ed (1996 with updates) by GH Gordon and C Gane
- <sup>5</sup> (1957) 1 CLR 365; the case is discussed in more detail below.
- <sup>6</sup> Gordon, *op. cit.*, 13
- <sup>7</sup> *Ibid.* p 15. Note that prosecution by the state has been the norm in Scotland for some time, and that while private prosecutions are possible, they only succeed about once per century: see *X v Sweeney & Ors.* 1982 JC 70, 1983 SLT 48, 1982 SCCR 161
- <sup>8</sup> He cites, in this context, J Michael & M. Adler, *Crime, Law and Social Science*, (London & New York, 1933), 5, and MR Cohen, *Reason and Law*, (Glencoe, Ill., 1950) 25
- <sup>9</sup> G. Williams, *Criminal Law: The General Part* (2<sup>nd</sup> ed. 1961) 14
- <sup>10</sup> Williams *op. cit.* 16; Gordon §1-05.
- <sup>11</sup> Williams *op. cit.* 13
- <sup>12</sup> D Gomien, *Short Guide to the European Convention on Human Rights* (2<sup>nd</sup> edition, 1998), 37-38; reference is made *inter alia* to *Delcourt v Belgium* (1970) Series A No. 11 and *Engels v the Netherlands* (No. 1) (1976) 1 EHRR 647
- <sup>13</sup> P Alldridge, *Relocating criminal law* (2000), 165
- <sup>14</sup> There are also statistically-insignificant private prosecutions, averaging about one per century; given their rarity, they will not be considered as a regulatory tool. The only other prosecutions of note are by education authorities, who can prosecute parents in respect of their failure to have their children educated: Education (Scotland) Act 1980, as amended.
- <sup>15</sup> KJM Smith, *Lawyers, legislators and theorists: developments in English criminal jurisprudence 1800-1957* (1998), 42-3
- <sup>16</sup> Under the Prosecution of Offences Act 1985
- <sup>17</sup> Such as "fiscal fines" – fixed penalties for minor offences deemed too trivial to prosecute – psychiatric diversion programmes, social work intervention and the like.
- <sup>18</sup> In Scotland, there is also the "not proven" verdict, which can be returned in circumstances where a "not guilty" verdict would be appropriate in England and Wales.
- <sup>19</sup> In Scotland, it is technically necessary for the prosecution to move the court to sentence before the court is able to do so.

- <sup>20</sup> Although arguably not completely; see the comments by Shrimpton, *infra.*, fn91. The abolition was principally effected by the Murder (Abolition of Death Penalty) Act 1965, with the Human Rights Act 1998 Section 21(5) abolishing it in relation to the few remaining areas where it had been competent after 1965.
- <sup>21</sup> JC Smith, *Smith and Hogan's Criminal law* (9<sup>th</sup> ed., 1999), 7
- <sup>22</sup> Registration duties are imposed on householders only in relation to assessment of certain local taxes, and for purposes of electoral registration (but cf *R v City of Wakefield Metropolitan Council and Anor. ex parte Robertson* QBD [2002] 2 WLR 889, holding the requirement violated the Data Protection Act 1998 and Human Rights Act 1998), and for census purposes which rely purely on statistical aggregations of the data
- <sup>23</sup> N Lacey, C Wells and D Meure, *Reconstructing criminal law: text and materials* (1990), 1
- <sup>24</sup> P Alldridge, *op. cit.*, 2
- <sup>25</sup> JC Smith, *op. cit.*, 3
- <sup>26</sup> JC Smith, *op. cit.*, 4
- <sup>27</sup> N Lacey, C Wells and D Meure, *op. cit.*, 3-6, references omitted.
- <sup>28</sup> P Alldridge, *op. cit.*, 24
- <sup>29</sup> Lacey *et al* refer, in this context, to A Ashworth, *Sentencing and penal policy* (1983), pp23-24, 335-346
- <sup>30</sup> For a discussion of the apparent increase in people resorting to criminal law as a grievance channel, see R Wheeler, "Medical manslaughter: why this shift from tort to crime?" 2002 NLJ 593
- <sup>31</sup> N Cunningham, "Negotiated non-compliance: a case study of regulatory failure" (1987) 9 Law & Policy 69
- <sup>32</sup> But see Kinnell, *infra* fn218, on the preponderance of serial killers in the medical profession
- <sup>33</sup> And on occasion even then, if it involves the use of compulsory treatment or restraint; the complexities of this specialised area are considered in Chapter 6
- <sup>34</sup> *Dungey* (1864) 4 F&F 99 at 102, 176 ER at 487; Gordon §29-01
- <sup>35</sup> Macdonald *op cit.* 115
- <sup>36</sup> Various other offences being dealt with extensively by Glanville Williams *op. cit.*, Chapters 6 and 7; and see Smith & Hogan, Ch.18
- <sup>37</sup> Hawkins *Pleas of the Crown* i. 1.10 states that "every battery includes an assault"; while Glanville Williams' disagrees with this (*op. cit.* 137n), the terminology remains convenient.
- <sup>38</sup> *Collins v Wilcock* [1984] 3 All ER 374 (references omitted); Goff LJ subsequently doubted whether the act had to be hostile: *Re F* [1990] 2 AC 1, discussed below and in Chapter 4, *supra*.
- <sup>39</sup> See PDG Skegg, "Medical procedures and the crime of battery" [1974] Criminal Law Review 693
- <sup>40</sup> Excepting crimes of strict or absolute liability, which are both rare and irrelevant for the present purposes.
- <sup>41</sup> Literally "an act does not make a man guilty at a crime unless his mind also be guilty": Coke, *Institutes*, ch 1, fo 10, quoting the *Leges Henrici* and St Augustine.

- <sup>42</sup> Williams *op. cit.* 33
- <sup>43</sup> Gordon *op. cit.* §3-04
- <sup>44</sup> Williams *op. cit.* 18
- <sup>45</sup> Subject to the recognised difficulty in defining “act” which this work does not intend to go into:  
see Williams 33-34 and Gordon §3-10 on this
- <sup>46</sup> Smith & Hogan *op. cit.*, 4, quoting Lanham, [1976] Crim. LR 276
- <sup>47</sup> Collins v Wilcock, *op. cit.*, per Robert Goff LJ
- <sup>48</sup> [1986] 2 All ER 440, [1987] QB 237
- <sup>49</sup> Re F [1990] 2 AC 1
- <sup>50</sup> Smart v HMA 1975 SLT 65
- <sup>51</sup> However, there appears to be no Scottish authority *at all* on the legality of medical treatment;  
notwithstanding the statement above, Gordon §29-40 is of the opinion that lack of *mens rea* is  
not the primary justification for surgical intervention.
- <sup>52</sup> per Robert Goff LJ
- <sup>53</sup> Wilson v Pringle [1987]1 QB 237 at 253
- <sup>54</sup> Gladstone Williams (1983) 78 Cr App Rep 276 at 280
- <sup>55</sup> Beckford v R [1987] 3 All ER 425, per Lord Griffiths.
- <sup>56</sup> R v Brown [1993] 2 All ER 75
- <sup>57</sup> The exception being that the Privy Council is the supreme court in determining devolution  
issues, and also in determining appeals from decisions reached by the General Medical  
Council (although this latter jurisdiction is being removed)
- <sup>58</sup> The three main exceptions to this relate to emergencies, incompetent adults, and children, and  
are discussed at length in the context of the civil law in Chapter 4; the principles and rules  
stated therein are probably equally applicable to the criminal law. The statutory rules under  
Mental Health Legislation are discussed in Chapter 6.
- <sup>59</sup> Gordon §29-39
- <sup>60</sup> Smart v HMA *supra cit.*
- <sup>61</sup> Kenny, *Outlines of the Criminal Law*, (15th ed, ), 181; footnotes omitted
- <sup>62</sup> R v Brown, *supra*
- <sup>63</sup> Attorney-General's Reference (No. 6 of 1980) [1981] QB 715 at 719
- <sup>64</sup> P Alldridge, *op. cit.*, 125-6, contrasting the treatment of sadomasochistic heterosexual activity in  
R v Wilson [1997] QB 47
- <sup>65</sup> [1994] 1 AC 212
- <sup>66</sup> Laskey, Jaggard and Brown v UK (1997) 24 EHRR 39
- <sup>67</sup> *Ibid.*
- <sup>68</sup> Gordon §13-19
- <sup>69</sup> Quite how “unreasonable” the surgery would have to be is considered (in the context of organ  
donation and sex change operations) later; but to found a criminal charge, it would probably  
have to be something more than merely unorthodox treatment.
- <sup>70</sup> F v West Berkshire HA [1989] 2 All ER 545
- <sup>71</sup> R v Dudley & Stephens [1881-5] All ER Rep 61

- <sup>72</sup> *F v West Berkshire HA, supra cit.*; in Scotland, such interventions are now covered by the Adults with Incapacity (Scotland) Act 2000, discussed in Chapter 6
- <sup>73</sup> *Ibid.*
- <sup>74</sup> *O'Brien v Cunard SS Co.* (1891) 28 NE 266
- <sup>75</sup> *Re T (Adult: refusal of treatment)* [1992] 4 All ER 649
- <sup>76</sup> [2002] EWHC 429 Fam
- <sup>77</sup> The reference is to the judgment of Mr. Justice Robins JA in *Malette v Shulman* (1990) 67 DLR (4th) 321, Ontario Court of Appeal
- <sup>78</sup> *Re S (adult: refusal of medical treatment)* [1992] 4 All ER 671, (1992) 9 BMLR 69
- <sup>79</sup> The terminology “maternal-foetal conflict” has itself been criticised: SAM McLean, *Old law, new medicine: medical ethics and human rights* (1999) 51-2
- <sup>80</sup> I. Kennedy, *The Times*, 14 October 1992
- <sup>81</sup> (1970) 2 All ER 33; and see also *Cossey v UK* (1991) 13 EHRR 622
- <sup>82</sup> Although one can argue that it is psychologically beneficial. This may be the case in some cases, but it is far from clear that these represent more than a small minority of elective procedures (as opposed to post-trauma reconstructive surgery) and it seems highly unlikely that *all* cosmetic surgery procedures have a clinical psychological justification.
- <sup>83</sup> Law Commission, *Consultation paper no. 25: Criminal law: consent in the criminal law* (1995), paras. 8.1 ff
- <sup>84</sup> [1954] 3 All ER 59
- <sup>85</sup> National Health Service (Family Planning) Act 1967, as amended
- <sup>86</sup> G Williams, *op. cit.* 538-9, and see *R v Brown, supra cit.*
- <sup>87</sup> Prohibition of Female Circumcision Act 1985, discussed in Chapter 6.
- <sup>88</sup> Abolished by the Law Reform (Year and a Day Rule) Act 1996
- <sup>89</sup> e.g. if inflicted on the Queen’s enemies in time of war, or judicial execution, or if as a result of an Act of God. For a discussion of a five-fold division of homicide, see Gordon §23-09
- <sup>90</sup> In Scotland and England respectively; the expression “second-degree murder” used in the US has much the same meaning.
- <sup>91</sup> Abolition, that is, for everyone except judges who refuse to acknowledge the supreme authority of Parliament – a remedy last applied to Sir Thomas More and which, according to one commentator, is still available to Parliament: M Shrimpton, “Implied and express repeal”, 2001 NLJ 450
- <sup>92</sup> Sir Edward Coke, *Inst.* iii 47
- <sup>93</sup> Hume, 1254; Macdonald, 89
- <sup>94</sup> *HMA v Rutherford* 1947 JC 1; *Brennan v HMA* 1977 SLT 151; the English position is less clear: *Walters* (1841) Car. & M. 164, 174 ER 455; *DPP v Smith* [1961] AC 290; but cf Criminal Justice Act 1967 s.8, although this leaves the specific question of recklessness open; and *Hyam v DPP* [1974] 2 All ER 41
- <sup>95</sup> Much of which was expressed in the Minutes of Evidence of the Royal Commission on Capital Punishment 1949-51, see especially Q 5428.

- <sup>96</sup> Infanticide Act 1938; Crown Office practice seems to be to presume the presence of diminished responsibility in such cases; see Gordon §25-02
- <sup>97</sup> Homicide Act 1957 s.4, as amended by the Suicide Act 1961
- <sup>98</sup> 1957 Act s.2; a rule allowing mental weakness to mitigate sentence in non-capital crimes was long accepted in Scots law, but was first applied as a principle specifically allowing a jury to return a verdict of culpable homicide in a murder charge in the case of *Alex. Dingwall* (1867) 5 Irv. 466, although at this stage diminished responsibility was regarded as just one of several possible mitigating circumstances; see generally Lord Keith, "Some Observations on Diminished Responsibility", 1959 JR 109
- <sup>99</sup> 1957 Act s.3, although the doctrine was known to English common law prior to this; see the early cases referred to in the judgment of Lord Diplock in *DPP v Camplin* [1978] 2 All ER 168. In Scotland, the plea seems to have been accepted as an aspect of self-defence by Hume, 1. 223, and not as a separate plea until about 1760; Burnett, *A Treatise on Various Branches of the Criminal Law of Scotland* (1811), 14. For a historical overview see Gordon §25-13
- <sup>100</sup> *DPP v Beard* [1920] AC 479 *per* Lord Birkenhead at 494, affirmed in *DPP v Majewski* [1976] 2 All ER 142
- <sup>101</sup> *Brennan v HMA* 1977 SLT 151. This was a "Full Bench" of seven judges, virtually the most authoritative ruling possible in Scottish criminal law, which overruled a previous five-judge decision following *DPP v Beard*: *Kennedy v HMA* 1944 JC 171. Note that there is no appeal to the House of Lords in Scottish criminal cases, so the only way to overrule a previous Full Bench is to set up an even Fuller Bench; see Walker, *The Scottish Legal System*, (5th ed., 1981), 374. This is subject to the provisions of the Scotland Act 1998, under which "devolution issues" can be referred to the Privy Council, even in relation to criminal trials.
- <sup>102</sup> Traffic Act 1972 s.1; now the Road Traffic Act 1988 S.1 as amended by the Road Traffic Act 1991 s.1
- <sup>103</sup> Williams, 325
- <sup>104</sup> P Byrne, "Homicide, medical ethics and the principle of double effect" in P Byrne (ed.), *Ethics and law in health care and research*, (1990)131-159
- <sup>105</sup> *R v Adams* [1957] Crim LR 365; the issue is discussed in more detail below
- <sup>106</sup> *Supra* fn5
- <sup>107</sup> Although he may also have been the victim of a conspiracy: see P Barham, "Doctors of death", *The Guardian* 27/1/2000
- <sup>108</sup> See the discussion of the authorities on this point in JC Smith, *op. cit.*, 342-4
- <sup>109</sup> Which was the fundamental issue in *Finlayson v HMA* 1979 JC 33 - a reasonable course of treatment does not break the causal chain, even when it consists of turning off a life support machine. The point that the victim was already dead at this point seems not to have been discussed.
- <sup>110</sup> *R v Smith* [1959] 2 QB 35
- <sup>111</sup> see *Barnett v Chelsea & Kensington HMC* [1969] 1 QB 428, discussed in Chapter 4



- <sup>112</sup> Recognising, of course, that in medical treatment, probability of death ensuing does not indicate the *mens rea* for murder: see the judgement of Lord Hailsham LC in *Hyam v DPP supra cit.*
- <sup>113</sup> *Jas. Wilson* (1838) 2 Swin. 16
- <sup>114</sup> *R v Jordan* (1956) 40 Cr. App. Rep 152; *R v Cheshire* [1991] 3 All ER 670
- <sup>115</sup> Gross negligence manslaughter is considered *infra*
- <sup>116</sup> *R v Blaue* [1975] 1 WLR 1411
- <sup>117</sup> *R v Gibbins & Proctor* (1918) 13 Cr App Rep 134; this appears to be the law in Scotland, although there is little authority on the point; see Gordon §§ 3-34 - 3-37
- <sup>118</sup> See *Burnett v Layman* 133 Tenn. 323, 181 S.W. 157 (1915)
- <sup>119</sup> *R v Miller* [1983] 1 All ER 978; *Jas. Paterson Duff*, Cr. App. Ct May 1979, unreported.
- <sup>120</sup> Barring the possibility of arguing for such a duty under the *ius quaesitum tertio* long recognised in Scots law; this is considered in Chapter 4 *infra*
- <sup>121</sup> *R v Adomako and others* [1994] 3 All ER 79, [1994] 3 WLR 288
- <sup>122</sup> G Wilder, "Dial M for Manslaughter", HSJ 2 September 1999, 10; and see also R Wheeler, *loc. cit.* who considers that the trend may be part of a political move to discredit the medical profession. As noted *supra*, gross negligence can theoretically ground a charge of murder in Scotland, but not in England.
- <sup>123</sup> Leading works on the subject include: J Glover *Causing death and saving lives* (1977), J Harris, *The Value of Life* (1985), JK Mason *Human life and medical practice* (1989), AV Campbell, *Moral dilemmas in medicine* (1975)
- <sup>124</sup> *Supra*, fn5
- <sup>125</sup> Barring the case of the person who has reached adulthood without ever having been legally competent, whose case may more fairly be identified with that of the neonate except in terms of long-term prognosis.
- <sup>126</sup> *Per* various judgements in *Re T and Airedale NHS Trust v Bland* [1993] 1 All ER 821, discussed *infra*; this was reiterated in *B v An NHS Hospital Trust, supra cit.*
- <sup>127</sup> *Airedale NHS Trust v Bland, supra cit* ; the decision was followed in Scotland in the case of *Law Hospital NHS Trust v Lord Advocate & Another* (1996) 2 FLR 407 (the Janet Johnston case)
- <sup>128</sup> In England and Wales
- <sup>129</sup> Nor has the Human Rights Act altered this – *R v DPP ex parte Pretty* [2002] 1 FLR 268, [2002] 1 All ER 1, a decision effectively affirmed by the European Court of Human Rights: *Pretty v UK* ECtHR 29 April 2002, unreported.
- <sup>130</sup> See PDG Skegg, "The termination of life support measures and the law of murder" (1978) 41 MLR 423
- <sup>131</sup> Although since the doctors were under a duty to treat Anthony Bland, on the general principles already noted they should still have incurred liability for this omission on other grounds, a point noted in passing by Lord Mustill.
- <sup>132</sup> (1981) 12 BMLR 1
- <sup>133</sup> *Re J (a minor) (wardship: medical treatment)* [1990] 3 All ER 930, [1991] Fam 33.

- <sup>134</sup> Subject to a minor caveat that the Scottish civil courts have declined to make declarations which would be binding on the criminal law, the immunity from prosecution in such cases being dependent on the concurrent approval of the Lord Advocate: *Law Hospital NHS Trust v Lord Advocate & Another*, *supra cit*
- <sup>135</sup> *NHS Trust A v M* [2001] Lloyd's LR Med. 28
- <sup>136</sup> Unlike the Netherlands, which is virtually unique in having an official law permitting physician assisted suicide after years of operating such procedures informally.
- <sup>137</sup> But will be a mitigating factor if the person is killed as part of a suicide pact: Homicide Act 1957, section 4
- <sup>138</sup> Section 2
- <sup>139</sup> M Brazier. *Medicine patients and the law* (2<sup>nd</sup> ed, 1992), 448
- <sup>140</sup> *B v An NHS Hospital Trust*, *supra cit.*; *Re T (adult: refusal of medical treatment)* [1992] 4 All ER 649; the possible exception to the rule for pregnant women was considered *supra*
- <sup>141</sup> See e.g. *Malette v Shulman* (1988) 63 OR (2d) 243, a Canadian case where the doctor was held to have committed a civil battery
- <sup>142</sup> B Mahendra, "Doc brief: the humbling of the medical profession – causes and a cure" 2000 NLJ 1403 (29/9/2000)
- <sup>143</sup> Including putting the possessions of someone else at risk, even if you ultimately intend to refund them or make them more money: see JC Smith, *op. cit.*, 290-1
- <sup>144</sup> Fraudulent falsification of safety trials could conceivably ground a prosecution for reckless endangerment; the writer is not aware of any examples.
- <sup>145</sup> Sexual Offences Act 1956, section 6
- <sup>146</sup> See Chapter 4, *infra*
- <sup>147</sup> Discussed in more detail in Chapter 5
- <sup>148</sup> Criminal Justice Act 1991 Section 17
- <sup>149</sup> *Ruddock v Lowe* (1865) 5 F&F 519; see Chapter 5, *infra*
- <sup>150</sup> Section 19 of the Veterinary Surgeons Act 1966 makes it an offence for anyone not a registered vet to practise veterinary surgery, subject to certain minor exceptions.
- <sup>151</sup> Medicines Act 1968 s. 58; Medicines (Prescription Only) Order 1977, S.I. 1977/2127
- <sup>152</sup> JK Mason, *Forensic Medicine for Lawyers* (2<sup>nd</sup> ed., 1983), 245
- <sup>153</sup> Human Tissue Act 1961, s.1(4); and see *A v Lennox-Wright* [1973] Crim. LR 529; most of the regulatory aspects of cadaver tissue transplantation also apply to live donor transplantation and are considered under that heading below.
- <sup>154</sup> e.g. statutory sick pay claims for more than five days' illness.
- <sup>155</sup> D. Gould, *Examining Doctors: Medicine in the 1990s*, (1991), 110
- <sup>156</sup> Registration of Births, Deaths and Marriages (Sc.) Act 1965
- <sup>157</sup> Births and Deaths Registration Act 1953, as amended
- <sup>158</sup> Most of whose forensic investigative functions are performed by the procurator fiscal, who, it has been said, does not wish to accept responsibility for mortality statistics: JK Mason, *op. cit.*

- <sup>159</sup> First recorded in the case of *John Fenton*, 1763, but possibly dating to 1627: see Gordon §28-02
- <sup>160</sup> The parliamentary debates preceding the Human Fertilisation and Embryology Act 1990, discussed below, are a good example of this; and for examples of certain activists in the debate falling foul of the criminal law, see *DPP v Clarke & Others* [1992] Crim. LR 60 and *DPP v Fidler & Moran* [1992] Crim LA 62.
- <sup>161</sup> M. Brazier, *op. cit.*, 289
- <sup>162</sup> Macdonald, *A Practical Treatise on the Criminal Law of Scotland*, 5th ed. 1948 by J Walker & DJ Stevenson, 114; founding on cases cited by Alison, *Principles and Practice of the Criminal Law of Scotland*, (2 vols.1832-3), i, 628-629
- <sup>163</sup> *HMA v Anderson* 1928 JC 1; *HMA v Semple* 1937 JC 41 similarly held that administering non-abortionificants (believing them to be abortificants) to a pregnant woman was also not criminal, although this appears to be at odds with the general rule of Scots law as regards impossibility as a defence: see *Lamont v Strathern* 1933 JC 33, and generally Gordon §6-49 and literature cited thereunder. English common law appears to be similarly unclear as to the general question of attempting impossible crimes: see Smith & Hogan *op. cit.* Chapter 15
- <sup>164</sup> Art and part guilt in Scots law is broadly equivalent to aiding and abetting the commission of an offence.
- <sup>165</sup> Two cases saw the woman charged: with aiding and abetting (*R v Sockett* (1908) 72 JP 428) and conspiracy (*R v Whitchurch* (1890) 24 QBD 420)
- <sup>166</sup> *Jessie Webster* (1858) 3 Irv, 95 saw such a charge being dropped by the Crown after objections were taken to the relevancy.
- <sup>167</sup> Gordon §28-03, Macdonald 114; Mason implicitly accepts this in stating that “In both England and Scotland, a woman must be shown to have been pregnant before she can be charged with self-inflicted criminal abortion”: JK Mason, *op. cit.*, 194.
- <sup>168</sup> On the subject of Crown Office’s *de facto* lawmaking powers, see Gordon §0-04, S Moody & J Tombs, *Prosecution in the Public Interest*, (1982), and AV Sheehan, *Criminal Procedure* (1990).
- <sup>169</sup> [1939] 1 KB 687, discussed below. There is a widely differing report of Macnaghten J’s address to the jury in [1938] 3 All ER 615
- <sup>170</sup> Mason, *op. cit.*, 194
- <sup>171</sup> [1938] 3 All ER at 620, but not in the 1939 report (see footnote 169)
- <sup>172</sup> Which appears to have been an offence at common law in Scotland: *HMA v McCallum* (1858)3 Irv. 187; but *cf HMA v Scott* (1892) 3 White 240
- <sup>173</sup> Which is a legal, not a medical, use of the term. The Act is also guilty of a number of other terminological inexactitudes whose meanings are ambiguous: see Mason, *op. cit.*, 193
- <sup>174</sup> Section 1(2)
- <sup>175</sup> Section 1(3); the criteria for the approval of such non-NHS clinics were the focus of early controversy and were scrutinised by an official committee: *Report of the Committee on the Working of the Abortion Act* Cmnd. 1974/5579, (the Lane Report) which led to changes in the system for approval.

- <sup>176</sup> Section 1(4)
- <sup>177</sup> Section 4
- <sup>178</sup> *Janaway v Salford AHA* [1988] 3 All ER 1051
- <sup>179</sup> *College of Nursing v DHSS* [1981] AC 800
- <sup>180</sup> *R v Secretary of State for Health & Another ex parte Smeaton* [2002] EWHC 610 (Admin)
- <sup>181</sup> Section 2
- <sup>182</sup> *R v Smith (John)* (1973) 1WLR 1511, (1974)1 All ER 376
- <sup>183</sup> The Lane Report, *op. cit.*
- <sup>184</sup> Parl. Deb. H of C Vol. 897 cols 773 to 775; legal abortion in 1974 had a mortality rate of 4 per 100,000, compared to 11 per 100,000 for childbirth.
- <sup>185</sup> *Paton v British Pregnancy Advisory Service* [1979] QB 278
- <sup>186</sup> Abolished with effect from 1 November 1998 by the Eleventh Protocol to the Convention
- <sup>187</sup> *Paton v United Kingdom* (1980) 3 EHRR 408
- <sup>188</sup> *Hone v Calthorpe Clinic*, The Times, 23 March 2001
- <sup>189</sup> Section 37
- <sup>190</sup> Human Tissue Act 1961 s. 1(4)
- <sup>191</sup> PDG Skegg, The Interpretation of the Human Tissue Act 1961, (1976) 16 Med Sci Law 193
- <sup>192</sup> Human Tissue Act 1961, sections 1(1) and (2)
- <sup>193</sup> I Kennedy, "Further thoughts on liability for non-observance of the Human Tissue Act 1961" (1976) 16 Med Sci Law 49
- <sup>194</sup> *R v Lennox-Wright*, *supra*. It is arguable that this case would not be followed in future, however.
- <sup>195</sup> *Re A* (1992)3 Med LR 303; *Airedale NHS Trust v Bland supra cit.*; *Finlayson v HMA* 1978 SLT (Notes) 60 accepts this by implication.
- <sup>196</sup> 1961 Act s.1(4); adherence to the tests laid down by the 1976 Conference of Medical Royal Colleges and their Faculties in the UK would undoubtedly satisfy this requirement; note that NHS guidelines on this insist that the diagnosis of brain stem death be made and corroborated by two doctors, both independent of the other, and neither of whom is a member of the transplant team. This practice still does not absolve the doctor removing tissue or organs from his statutory duty of personal inspection, so ultimately three doctors conduct tests.
- <sup>197</sup> Section 1(2), subject to the complications outlined by Skegg, and by Kennedy, *supra*.
- <sup>198</sup> One of the observations of the McLean Report, *infra cit.*, 31-2
- <sup>199</sup> See *Final Report of the Independent Review Group on Retention of Organs at Post-Mortem* (2001) (the McLean Report) for Scotland, and *The Royal Liverpool Children's Inquiry Report*, HC 12-II (2001) (the Alder Hey report) for England and Wales
- <sup>200</sup> McLean Report *ibid.*, 16
- <sup>201</sup> *HMA v Rutherford* 1947 JC 1 (but *cf Smart v HMA* 1975 SLT 65); *Rice* (1803)3 East 581, 102 ER 719
- <sup>202</sup> Hawkins *Pleas of the Crown* (8<sup>th</sup> ed., 1824), Ch 15
- <sup>203</sup> But not, it should be noted, in Scotland.
- <sup>204</sup> PDQ Skegg, *Law, Ethics and Medicine* (1984) 43; and see also PDQ Skegg, "Medical procedures and the crime of battery" [1974] Crim LR 693

- <sup>205</sup> *R v Brown* [1993] 2 All ER 75
- <sup>206</sup> Section 1
- <sup>207</sup> Section 2(1); “closely genetically related” is defined in Section 2(2)
- <sup>208</sup> Section 2(3) and the Human Organ Transplants (Unrelated Persons) Regulations 1989 SI 1989/2480; ULTRA’s role is considered in Chapter 5
- <sup>209</sup> Brazier *op. cit.*, 397-399; Kennedy & Grubb *op. cit.*, 1085-1087
- <sup>210</sup> On the establishment of the ethics advisory group on ethical issues surrounding transplantation of animal organs to humans see *BMJ* vol. 312, 126 (13/1/96)
- <sup>211</sup> Lacey, Wells and Meure, *op. cit.*, 4, citing as authority for the proposition A Ashworth, *Sentencing and penal policy* (1983), 23-24, 335-346
- <sup>212</sup> T A Green, *Verdict according to conscience* (1985), 31
- <sup>213</sup> KJM Smith, *op. cit.*, 45-6
- <sup>214</sup> T Sorrell, *Moral theory and capital punishment* (1987), 32; quoted in Lacey, Wells and Meure, *op. cit.*, 261
- <sup>215</sup> D Archer and R Gartner, *Violence and crime in cross-national perspective* (1984), 136, cited *ibid* 262
- <sup>216</sup> There is an increasing body of academic opinion which feels that having a mandatory sentence *at all* for murder is anachronistic, inappropriate and inflexible, and that there should be judicial discretion for murder sentences as for (virtually) all other offences: see Lacey, Wells and Meure, *op. cit.*, 263-5; JC Smith, *op. cit.*, 351; P Alldridge *op. cit.*, 96
- <sup>217</sup> HG Kinnell, “Serial homicide by doctors: Shipman in perspective” *BMJ* 2000; 321: 1594; for a critique of this, see Stark *et al*, “Opportunity may be more important than profession” (electronic rapid response to Kinnell *loc. cit.*) <http://www.bmj.com/cgi/eletters/321/7276/1594> (accessed 15 April 2001)
- <sup>218</sup> Department of Health, *Harold Shipman’s clinical practice 1974-1998: a clinical audit commissioned by the Chief Medical Officer*, 2001
- <sup>219</sup> The victim was a former mayoress of Hyde, her daughter a solicitor. For an account of the daughter’s investigation into her suspicions see *The Independent* 8 February 2000, supplement p11
- <sup>220</sup> Department of Health, *op. cit.*
- <sup>221</sup> Kinnell, *loc. cit.*, suggests that Adams provided the role model for Shipman as they apparently had a colleague in common.
- <sup>222</sup> Department of Health, *op. cit.*
- <sup>223</sup> Statement by the Director of Public Prosecutions, David Calvert-Smith QC, on 18 February 2000
- <sup>224</sup> The three stages of internal inquiry, judicial review and public inquiry decision being reported at *BMJ* 2000; 320: 410, *BMJ* 2000; 321: 260 and *BMJ* 2000; 321: 784 respectively
- <sup>225</sup> *Supra cit.* fn 84
- <sup>226</sup> *R v Cox* (1992) 12 BMLR 38
- <sup>227</sup> For a summary of post-trial events, see JK Mason and RA McCall Smith, *Law and Medical Ethics* (5<sup>th</sup> ed., 1999), 427

- <sup>228</sup> On possible modern applications of this offence, see P Ferguson, "Wilful neglect of duty" 1997 42 JLSS 67
- <sup>229</sup> Per the Lord Justice-Clerk in *HM Advocate v Adie* (1843) 1 Broun 601, cited *id.*. The English test is apparently identical and was cited with approval in *Adie*.
- <sup>230</sup> P Alldridge, *op. cit.*, 20-22
- <sup>231</sup> *Osman v UK* (ECHR), [1999] 1 FLR 193
- <sup>232</sup> The right to control information about yourself; the concept underpins the Council of Europe's activities on data protection.
- <sup>233</sup> Surveillance is now subject to the provisions of Regulation of Investigatory Powers Act 2000 and the Regulation of Investigatory Powers (Scotland) Act 2000
- <sup>234</sup> Freedom of Information Act 2000
- <sup>235</sup> Freedom of Information (Scotland) Act 2002
- <sup>236</sup> *Steel v UK* [1998] Crim LR 893

## Chapter 4: Civil Law:

### I: Introduction

This chapter will analyse the functions of civil litigation as a regulatory tool. It seeks to determine what effect the existence of litigation has on medical activity, and what role litigation has in solving disputes between doctors and patients. It does not seek to provide a comprehensive study of medical law as shown by litigation; which would merely duplicate work done by others. Detailed analysis of the medico-legal and bioethical issues underlying the bulk of the litigation has no *direct* bearing on the regulation of medicine as it stands and therefore lies outwith the scope of this thesis. This chapter is restricted to analysing the content of medical case law which directly regulates how medicine is practised, or which substantially affects the relationship between doctor and patient.

In terms of scope, this chapter only considers civil litigation, *i.e.* the law regulating,

“Civil wrongs, which lead not to a criminal prosecution but to civil proceedings for damages or other private redress... [A]ll legal proceedings that are not criminal are civil. Civil proceedings are the residual class.”<sup>1</sup>

As we will see, civil litigation encompasses both traditional “private” law actions, as well as “public” law forms of action. These public law forms of action may occasionally be used for essentially private purposes, and vice versa; this is discussed later. This chapter focuses almost exclusively on common law rights and liabilities, direct statutory regulation being considered in Chapter 6. However, breach of statutory duty and rights arising from, or curtailed by, specific statutes are considered within this chapter where appropriate.

Lastly, while the justiciability of the other regulatory mechanisms studied is considered at greater length within the chapters discussing those mechanisms, it is also discussed here in the context of analysing litigation’s role in performing the regulatory task of ensuring that other parts of the regulatory system are functioning properly.

### II: The Basic Functions of Litigation:

#### **A: Background:**

Litigation has been defined as:

- “1: The act or process of bringing a lawsuit;
- 2: To engage in legal proceedings.”<sup>2</sup>

The twofold distinction here is important. A lawsuit can be seen as a contest between two (or more) parties in dispute, whereas legal proceedings do not necessarily require an adversary. As will be seen, both forms have played a role in regulating medicine. But what is important are the words "law" and "legal". Litigation necessarily entails recourse to an adjudicator who will apply a specific set of rules to the problem presented. Precisely what the rules are, and who makes and applies them will vary with time and place.

Litigation originally entailed petitioning the king (or equivalent) for a remedy not open to the ordinary individual. A consistent feature of the development of legal systems is the successive appropriation of remedies against perceived wrongs away from the individual, and granting them instead to the state as represented by its courts. Referring specifically to the situation in early Rome, Thomas noted that:

"...it is fairly clear that the original mode of redressing grievances was self-help. Naturally, with the slightest degree of political development, such redress becomes undesirable; hence, the parties agree to submit their problem for decision to a third person, the state - initially through the king - merely seeing in the first place that here is such a dispute needing to be resolved. Of course, it became established that parties must resort to litigation rather than indulge in self-help..."<sup>3</sup>

Thus, the earliest Roman legislation, the Twelve Tables, (c. 450 BC) allowed an armed thief caught red-handed to be killed by his "victim." However, later legislation and judicial decisions successively reduced the scope of this power, which ultimately became the right to demand a monetary penalty from the thief. At the same time as remedies available to individuals were restricted, so too the laws applied by the decision-makers became more formalised and complex. In Rome, the increasing complexity of the rules (itself largely a product of increased commercial activity) resulted in the emergence of a class of jurists. These jurists were not, on the whole, judges, but merely advised the judges on points of law:



"...the emperors' role came clearly to be that of the chief magistrate, and as they acquired a jurisdiction both at first instance and on appeal, they too called on the legal expertise of the jurists, and included such men in their councils."<sup>4</sup>

Much of what is now regarded as a matter for the civil courts was, therefore, originally criminal in nature. While Roman civil law (at least for personal injuries) never shook off its roots, both Scots and English law have developed considerably<sup>5</sup>. It is, however, interesting to note two developments which have (re)created a degree of overlap in recent years. Firstly, the Criminal Injuries Compensation Scheme, established in 1964 by Crown prerogative, makes *ex gratia* payments to the victims of violent crime. Secondly, the Criminal Justice (Scotland) Act 1980 Part IV<sup>6</sup> (in Scotland) and the Powers of the Criminal Courts Act 1973 (in England) allow criminal courts to make compensation orders to the victims of violent crime, payable by the offender. Any subsequent civil claim, or payment under the compensation scheme, will be reduced by the amount of the order<sup>7</sup>.

In the modern context, then, what are the purposes of litigation? Williams and Hepple summarise them as follows:

- 1: To give the plaintiff what the defendant has promised him, or at least to give him damages for not getting what the defendant has promised.
- 2: To compensate for harm, or to prevent the continuance or repetition of harm.
- 3: To restore to a person what another has unjustly obtained at his expense.
- 4: To punish for wrongs and to deter from wrongdoing.
- 5: To decide the rights of the parties.
- 6: To decide or alter a person's status."<sup>8</sup>

From a Scottish perspective, Walker notes that "Civil proceedings are undertaken to obtain a civil remedy"<sup>9</sup> and then lists ten types of civil remedy competent in the Scottish courts. Elsewhere, he expands on this by stating that

"A claim for a remedy implies the existence of a prior legal right, and infringement thereof, or a prior legal duty and non-implementation thereof."<sup>10</sup>

Of the remedies which can be claimed, we shall see that an action for monetary compensation, or damages, is generally the most important in the medico-legal sphere<sup>11</sup>.

The civil law we are considering is not an undivided whole, but can usefully be broken into a number of distinct categories. This, public law broadly speaking regulates the relationship between the citizen and the state, and, in a more general sense, regulates the structure of the state itself (although this is more usually thought of as constitutional law). Private law regulates the affairs of citizens *inter se*. Both branches are of relevance to the medical setting: doctors and patients, as individuals, have private law duties to, and rights against, each other, enforceable by the courts. The NHS, under which most treatment takes place, is susceptible to public law remedies which may be of value to the individual patient. As will be seen below, it is possible to use public law procedures to redress (or at least address) private law issues, and vice versa. This overlap has led Kennedy and Grubb to assert that,

"Medical law does not respect the traditional compartments with which lawyers have become familiar, such as torts, contracts, criminal law, family law and public law. Instead, medical law cuts across all of these subjects and today must be regarded as a subject in its own right."<sup>12</sup>

They subsequently refine their position by stating that:

"There are common issues which permeate all the problems which arise [in medical law]: respect for autonomy, consent, truth-telling, confidentiality, respect for personhood and persons, respect for dignity and respect for justice... Until these common themes are recognised and reflected in legal thinking and analysis, a coherent approach to the emerging problems in medical law will be difficult... The unifying legal theme is, to us, that of human rights. In our view, therefore, medical law is a subset of human rights law."<sup>13</sup>

The Kennedy-Grubb conceptual approach may provide a new dimension for analysis of future case law, but its value in an analysis of the current law is restricted to providing a critique of the extent to which the law effectively upholds or neglects the rights which the idea of 'human rights' would tend to presuppose. For purposes of the present analysis, therefore, a more traditional approach to classification is adopted.

This approach involves deriving the present rules regarding medical practice from more general rules of common law (particularly Scots common law), although it should be noted that present-day medical law has also been affected by a number of statutes amending the common law position. The majority of cases which make up "British" medical law have been decided by English courts, applying English law. There is,

however, considerable inter-reliance between the two jurisdictions on this subject, and this thesis proceeds on the basis that it is fair to assimilate them into one more generally-applicable whole. Where substantial (as opposed to procedural) differences exist, these are generally explained, or at least referred to; otherwise, the law as described can be regarded as applying equally to both systems, irrespective of the historical origins and legal reasoning behind the decisions actually reached.

## **B: Types of action:**

A multitude of types of action exist. These range from actions seeking to enforce commercial contracts to actions aimed at ending a marriage. This thesis is principally only concerned with a small number of these types.

The most important is the action for personal injury, whereby the person claiming to have been injured alleges that the injury was caused by someone else. The personal injury action is essentially a call to the court to agree with the claimant that someone else was to blame, and to order that other person to make up for the injury caused. The person claiming is variously known as the claimant (as under the new English Civil Procedure Rules), the plaintiff (under the older English rules and still in various Commonwealth countries), pursuer (in Scotland), applicant or petitioner (in certain specialised applications to the court). The person against whom the claim is made is the respondent, defendant, or defender. If there is an appeal, the names change (usually to appellant and respondent, or, in Scotland, to reclaimer and respondent). Personal injury actions are based on the law of tort or delict (also known as reparation). These areas of the law are wider than just physical injury, however, and encompass more generally the notion of having suffered a legal wrong which can include damage to property or hurt to your reputation. Even the law of reparation can be seen as a sub-set of the wider law of obligations: reparation covers obligations arising by force of law, whereas other branches deal with obligations entered into voluntarily. The law of contract (which occasionally appears in the medical sphere) is one such area.

The second main type of action we are concerned with is the declaratory action whereby application is made to the court seeking advance clarification from the courts as to the legality of a proposed course of action. Declaratory actions are something of an exception to the rule that the courts are only interested in resolving real disputes, not theoretical ones or academic points. Declaratory actions sometimes face the difficulty that there is no-one actively opposing the action. The courts typically adjudicate between competing parties, and prefer to have both sides of the argument put to them.

In a large number of these actions there is therefore an appearance by a government-appointed legal officer (such as the Lord Advocate or Official Solicitor) who is appointed to resist the application and provide an adversary.

The third type of action is the action for judicial review. The nature of judicial review as a theoretical construct, and its place as a necessary component of constitutional law, was described by Lord Fraser in *Brown v Hamilton District Council*<sup>14</sup>. It is a legal action which, in general, can only be raised against a public sector body such as central or local government. Judicial review is the public law process whereby the courts scrutinise the activities of quasi-judicial and administrative bodies to ensure that these bodies adhere to the precepts of "natural law" and do not exceed or abuse their jurisdiction. In England judicial review is only competent in the High Court<sup>15</sup>. In Scotland, judicial review may only be sought in the Court of Session<sup>16</sup> and is based on the Court's inherent power to supervise the activities of inferior courts, tribunals, and administrative bodies<sup>17</sup>.

### **C: Regulatory functions:**

Before moving off consideration of the purposes of litigation it is worth noting that the descriptions just given are from the perspective of academic commentators. The judges themselves occasionally express views as to their own perception of their task; thus, Thorpe LJ once described the court's role in declaring the legality or otherwise of proposed courses of treatment for people lacking capacity as follows:

"One of the important functions of the judge is to instil into the situation certainty and finality which the family may well have difficulty in adjusting to but which they can at least accept as the judgment of the appointed impartial authority. Equally it is the function of the judge to protect the medical professionals from the threat of criminal or civil proceedings as a consequence of the exercise of their best endeavours."<sup>18</sup>

The description of medical litigation which follows attempts to describe the law as currently understood, but it is an evolving discipline. Predicting the outcome of the very small minority of disputes which actually find their way to the civil courts is notoriously difficult.

Having seen what the different types of action of relevance to medical regulation are, it is necessary to consider what regulatory tasks these actions may be attempting to fulfil.

The answer to this question varies somewhat depending on the nature of the action in question, but a number of points of general application can be discerned.

Firstly, the personal injury action: this can be seen to provide elements of most of the regulatory tasks identified in Chapter 2. The personal injury action has, in the medical sphere, come to be a means of seeking and providing compensation where the medical treatment in question has fallen below the acceptable standard (how “acceptable” is defined is considered *infra*). Thus, while the principle objective is the provision of a system of redress for those who suffer due to a failure to adhere to acceptable standards, the nature of the action brings with it a number of peripheral functions. Firstly, there is clearly an element of setting and upholding standards, since these standards provide the yardstick for compensation claims. Secondly, the adversarial fault-based nature of civil litigation means that it is for the person seeking compensation to prove that someone is at fault. This means civil litigation incorporates mechanisms to facilitate the acquisition and leading of evidence intended to prove or disprove the allegations, which can be seen as the provision of a system of investigation into whether standards are being adhered to. The act of bringing civil court proceedings can itself be seen as the airing of a grievance by the plaintiff or pursuer, and the award of damages against the party found to be at fault could be seen as punishing them for their failure to adhere to standards.

Not all of these are applicable to the declaratory action. In situations where this is used, the courts are often being asked to set the applicable standards by laying down the law in an area of uncertainty, so clearly such actions have a role in setting standards. As we see from the words of Thorpe LJ quoted *supra*, a perceived function of declaratory actions is to protect doctors from civil or criminal sanction, so there is an element of facilitating medical practice here. The types of issue lending themselves to declaratory actions are not usually alleging a breach or failure by anyone, so unlike personal injury actions the grievance, redress, investigation and punishment aspects are absent. However, inasmuch as a declaration of illegality may be sought that something done by a public sector body with regulatory functions, the declaratory action has some role in regulating the regulatory system.

In general, however, the task of regulating the regulatory system is addressed by the judicial review action. As we have seen, this action is conceived entirely to ensure that persons or bodies entrusted with statutory functions (or the equivalent) both fulfil the tasks entrusted to them and, insofar as they are vested with discretionary powers, to ensure that they exercise that discretion reasonably. This clearly fulfils the final

regulatory task of regulating the regulators: indeed, this is the principle aim of judicial review. Peripheral to this, however, are the provision of a grievance channel and system of investigation into whether standards are being adhered to.

### **III: Procedural rules and remedies:**

#### **A: Civil court procedure**

##### **1: Adjectival law:**

There are two main types of law, known as substantive and adjectival. Substantive law is the law governing the imposition of rights and duties, and of defining crimes. Most of the law referred to in this thesis falls into the category of substantive law. Substantive law originates in Acts of Parliament (including, nowadays, Acts of the Scottish Parliament so far as within the devolved competence of that body<sup>19</sup>), delegated legislation made under the provisions of an Act of Parliament (such as statutory instruments or local bye-laws), legislation made by the institutions of the European Union, and the common law *i.e.* law given effect to by the courts but which has no discernible genesis in any of the other sources. The common law is often referred to as “judge-made law” because the only readily-identifiable source is in the decisions of the courts giving effect to it. However, in constitutional theory the judges merely declare what the common law has always been, and are not supposed to invent new law. The upshot of this is that a judicial declaration of the law, contrary to previous understanding of what the law had been, is retrospective in effect<sup>20</sup> unless this presumption is reversed by statute<sup>21</sup>.

The second category, adjectival law, is purely concerned with mechanisms whereby rights and duties created by substantive law may be vindicated and enforced. As such, it is concerned with issues of who is entitled to bring proceedings before a court, how they get an unwilling opponent to appear, the way in which cases are argued before the court, the rules of evidence applied to what each side is trying to prove (including rules on the acquisition and retention of evidence, and the citing of witnesses), the remedies which the court is able to grant both during and at the conclusion of a case, and the mechanism by which those remedies are enforced. The following sections describe such parts of the adjectival law of Scotland, England and Wales as are necessary to understand the regulatory functions of the courts. It is not intended to describe procedural rules and remedies in any detail, partly on grounds of space, partly because

for present purposes it is only the practical upshot of these rules which affects how medicine is regulated.

Court procedure is one of those areas where Scots and English law part company. To complicate life further, each of the different courts within each jurisdiction has its own procedural rules. Sheriff Court procedure is not the same as Court of Session procedure, nor is High Court procedure the same as County Court. Different procedural streams within courts also exist, the difference being either in terms of the value of the claim (as with the Small Claims procedures which exist in both jurisdictions) or by reference to the type of action being raised (such as the distinct procedure for judicial review which each jurisdiction has).

## 2: Prescription and limitation:

The rules concerning prescription are substantive since they are concerned with the creation of new legal rights or the extinguishment of pre-existing legal rights, whereas the rules on limitation are adjectival since they concern whether a particular right or claim can be enforced by court action. In practical terms, the two approaches have virtually indistinguishable effects and can be treated together. The principal statutes are the Limitation Act 1980 for England and Wales (hereafter "the 1980 Act") and the Prescription and Limitation (Scotland) Act 1973 for Scotland ("the 1973 Act").

The rules on prescription and limitation themselves fall into two categories, positive and negative. Positive prescription is a method by which a legal right or entitlement becomes fortified by the passage of time. This may be at the expense of the rights of someone else, and may overlap with negative prescription. Negative prescription is concerned with the loss of a legal right either through the simple passage of time, or as a result of non-assertion of the right for a particular time. The overlap can be seen in situations of adverse possession of real property (e.g. a house) by someone having an imperfect legal title. In Scotland, this is viewed as a matter of positive prescription whereby an imperfect title coupled with possession for the appropriate period<sup>22</sup> creates a new positive legal right to the property which cannot be defeated by the person previously having a good legal title, that other title being in practice extinguished. In England, the question of adverse possession is instead approached from the perspective of limitation of the right of the owner to recover possession, and accordingly pays as much attention to the dealings between owner and occupier as to the periods of time which have passed in deciding whether the owner's power to recover possession has been lost.

For purposes of this thesis, we are concerned principally with limitation and negative prescription as they relate to the ability of victims of breaches of legal duties (whether duties of care, contractual duties or duties under public law) to raise legal proceedings in respect of those breaches. In essence, the most important thing is to note the existence of these time limits rather than to embark on a detailed discussion of the different periods which apply. Only the headline periods applicable will be discussed.

Firstly, most actions of reparation, including actions for breach of contract, the applicable limitation period is five years in Scotland<sup>23</sup>. In England, the period is six years for general actions for tort and simple contracts<sup>24</sup>. In terms of an action for personal injury, the applicable limitation period is three years<sup>25</sup>. In general, the limitation period runs from the point when the injury was inflicted, which, in the case of a continuing injurious act, means the point when the action ceased. However, an exception to the rule applies where the victim of the harm was unaware of the damage and could not have become aware even if acting with reasonable diligence. In such cases, the three year period only starts to run when the person becomes aware, or could reasonably have become aware, of the injury or negligence giving rise to it<sup>26</sup>. The period can be extended if it is equitable to do so<sup>27</sup>, but if a person is legally-advised, failure to observe the relevant limitation periods will generally result in an action against the solicitor for professional negligence than an extension of the limitation period<sup>28</sup>. In both countries, the limitation period is suspended while the victim of the injury is under suffering from lack of mental capacity<sup>29</sup>. The practical effects of this rule have become substantially less since legal aid rules (discussed *infra*) were amended in 1990 to allow parents to raise actions on behalf of their child but without the parental income being taken into account<sup>30</sup>. There is accordingly no financial disincentive for parents to seek redress on behalf of their children at the earliest opportunity. Lastly, while it is possible to add a new defender in the course of litigation, the claim against a new defender may be time-barred<sup>31</sup>.

### 3: Adversarial proceedings:

There are, in essence, two main types of judicial proceedings: inquisitorial, and adversarial. In an inquisitorial system, the court itself has a major role in gathering evidence, questioning witnesses, and determining the direction the proceedings will go in and how they will progress. It is characterised by the use of “investigating magistrates” as are common in continental European legal systems. In contrast, adversarial systems are more akin to a contest between the two parties. The adversarial approach was described by Lord Justice-Clerk Thomson as follows:



“It is upon the basis of two carefully selected versions that the judge is finally called upon to adjudicate. He cannot make investigations on his own behalf; he cannot call witnesses; his undoubted right to question witnesses who are put in the box has to be exercised with caution... [L]itigation is in essence a trial of skill between opposing parties conducted under recognised rules, and the prize is the judge’s decision... Like referees at boxing contests they see that the rules are kept and count the points.”<sup>32</sup>

In Britain, both the civil and criminal courts proceed on the basis of adversarial proceedings. This means it is incumbent on the claimant firstly to place before the court sufficient evidence to persuade the judge that, on the balance of probabilities, the claimant’s version of events is correct, and secondly to ensure that the legal formulation of the claim is such that, having persuaded the judge as to the facts, the claimant is entitled in law to the remedy sought. The opposing party, meanwhile, is similarly trying to place evidence before the court supporting their own version of events (or at the very least, casting doubt on the claimant’s version) and will be making legal submissions to the effect that what is being argued is legally irrelevant or insufficient to justify the remedy sought.

Disputes in the court essentially boil down to four general types:

- Disputes as to primary factual issues;
- Disputes as to causal connections between primary facts and the effects of them/inferences which can be drawn from them;
- Legal arguments about the nature of the rights and duties in question; and
- Disputes (both factual and legal) as to the extent of the remedy which the court will grant at the conclusion of the case.

In civil proceedings, it is necessary for the claimant to prove their case on the balance of probabilities – that the judge is (or sometimes, the jury are) satisfied that the claimant’s version of events is more likely to be true than the one put forward by the defender. This is a far less exacting test than that imposed by the criminal law, which applies the test of proof beyond reasonable doubt.

The model just described assumes a single claimant and a single defender. However, it is possible for more than person to initiate proceedings, for example where a large group of people allege having been injured by a drug. It is possible to sue a number of different parties, e.g. you may wish to sue the architects, project managers, surveyors, building company and any subcontractors involved in the construction of a defective

building. It is possible to bring an action on behalf of someone else – most commonly, actions by parents on behalf of their children. A defender alleging that the breach of duty was committed by someone else who isn't presently being sued may bring that other party in as a second defender. And in some circumstances, a person with a particular interest in proceedings but who isn't a party to the action may seek to intervene and become a third party to the action. To further complicate matters, it is possible for appeals to be conjoined (heard together) if they raise the same point of law. And it is also possible to sue someone other than the person who breached their legal duties, in accordance with the rules of vicarious liability (considered *infra*), or for someone to step into the defender's shoes in place of the defender. This latter procedure is known as the principle of subrogation, and applies where the damages which the court might award at the end of the day are to be borne by an insurer rather than by the original defender.

#### 4: The law of evidence:

It is not intended to rehearse the laws of either Scotland or England relating to the admissibility of evidence or the forms which that evidence may take. Previously the rules of evidence were highly formalistic in nature and riddled with peculiarities and exceptions to the general rules on admissibility. For present purposes, it is sufficient to note two propositions: firstly, if evidence is relevant to the matter in dispute in the case, it will be held to be admissible in court largely irrespective of the nature of it. Thus, hearsay evidence was formerly inadmissible, but is now generally admissible (if still not very persuasive). The second proposition is that if evidence is admissible, it is also compellable.

Compellable evidence is evidence which you are entitled to have the court's backing in the acquisition of. If this is the evidence of a witness, you will be able to cite the witness formally to appear in court, put them in the witness box and be sworn in, and require them to answer the questions put to them. Civil proceedings have no equivalent to the rule against self-incrimination applied in the criminal courts. Failure to comply with these court-sanctioned requests runs the risk of being held to be contempt of court, which can potentially result in arrest and incarceration. There are only a handful of exceptions to the general rule. Thus, communications between lawyer and client are privileged and neither can be compelled to disclose the content of the communication between them. The privilege has been held to extend to documents produced by post-accident internal investigations where these have been conducted at least in part with a view to potential litigation<sup>33</sup>.

Similar rules apply to physical evidence such as documents: if one party alleges that documents which would tend to support his or her case are in the possession of the other party or someone not a party to the action at all<sup>34</sup>, they can seek an order from the court under the Administration of Justice Act 1972<sup>35</sup> or the Supreme Court Act 1981<sup>36</sup> requiring the person holding the document to produce it to the court. It is necessary to specify the documents sought, not least because failure to comply with an order is punishable as contempt of court and on general principles it is deemed unfair to punish someone for failure to comply with an unclear requirement. So-called "fishing" diligences, attempting to recover any related documents in the hope that they reveal something of use to your case, are frowned on by the courts<sup>37</sup>.

It is worth noting that the procedure under the Administration of Justice Act 1972/Supreme Court Act 1981 is in addition to any other powers entitling a person to recover documents, such as the right to make a subject access request under the Data Protection Act 1998<sup>38</sup>. Some of these other routes give access to the entire file, and so are of interest to potential litigants because "fishing" requests are permitted. These other avenues may therefore be used at the pre-litigation stage as an inexpensive way of deciding whether there is sufficient material to justify raising an action. So far as relevant to medical regulation, some of these other routes are considered in Chapter 6.

Witnesses appearing in civil cases are either put on oath or required to affirm as to the truth of the answers they will give. Deliberately lying under oath is perjury, a serious criminal offence generally regarded as meriting a custodial sentence. To encourage candour, all statements made in the witness box are privileged to the extent that the witness cannot be sued for defamation or slander in connection with what is said in court, a protection extending to fair reporting of what is said in court.

The evidence from witnesses falls into two distinct types: witnesses as to facts, and expert witnesses. A witness to facts can properly only be asked about what they did or did not see/hear/do, and is not entitled to voice opinions or be asked hypothetical questions. Most claimants will be witnesses to the fact of their own alleged loss or injury.

Expert witnesses are in a different position. The function of an expert witness is to provide a specialist opinion to the court on an area of expertise which the judge (always a lawyer by training) lacks sufficient knowledge of to be able to adjudicate on. As such, the expert witness is the servant of the court, not of the party citing him to appear. He or she is therefore required to give a professional best opinion on a point put to him or her,

even if the answer is detrimental to the case of his or her client. In medical cases, expert medical witnesses are ubiquitous. Indeed, since very often the person being sued is a doctor, there is the possibility that the defender may also be an expert witness in his or her own field, although it is clearly harder for such a witness to bring the requisite impartiality to the witness box<sup>39</sup>. Under the new (English) Civil Procedure Rules, there is provision for the appointment of joint experts. However, the overwhelming majority of the cases considered *infra* were brought under procedural rules requiring each party to adduce their own expert evidence, and many of the cases boiled down to what could be described as a battle of experts.<sup>40</sup> The judge's role is to choose between the versions placed before him, and is not to create his own theory of events which neither set of experts contended for<sup>41</sup>. However, no judge is bound to follow expert evidence, even if unopposed, if that expert evidence flies in the face of common sense or contains internal contradictions. Otherwise, it is the judge's job to weigh up the evidence of an expert witness in the same way as the judge must weigh up the evidence of a witness to the facts.

The evidential onus is normally placed on the person averring the existence of a particular set of facts or circumstances to prove them. In general, this will place the onus on the pursuer or applicant rather than the defender. Exceptions to this generality are that if the defender seeks to rely on a particular defence, the onus will be on him or her to prove the defence. A quasi-exception to the rule arises under the maxim *res ipsa loquitur*, namely that things speak for themselves: this arises where a set of circumstances so obviously points to negligence on the part of someone that in effect the evidential onus shifts to them to disprove the negligence; this is discussed in more detail *infra*.

Once the judge has heard all the evidence, and seen all the documentary and real evidence placed before him or her, he or she then makes findings in fact as he or she finds them proved, and issues a decision based on the application of the relevant legal rules (as the judge finds them to be) to these facts. (In jury trials, this decision is for the jury having heard the judge address them on the legal tests to be applied, but the principle is theoretically the same). And on the basis of this decision, the remedy or remedies sought by one or more parties may then be granted.

## **B: Remedies in the civil courts**

In medical cases, the action is usually brought in the superior courts (High Court or Court of Session), and there is seldom an issue as to the competence of the court to grant the

remedy in question. However, the lower courts and some of the different court procedures which exist have limits on the remedies available. The most obvious limitation is in relation to the level of damages which can be awarded; thus, a small claims action is restricted to a maximum value of £750. The threshold on damages in the lower courts is probably the single biggest factor in pushing medical actions into the superior courts, but there are also procedural rules which make the complex subject matter usually raised in medical cases more suited to these fora than to the lower courts. Due to the importance of the subject, damages awards are considered next, then the other remedies which may be granted.

### 1: Awards of damages:

The award of damages is usually the most obvious outcome of a medical case, particularly a medical negligence action. Newspaper headlines are frequently full of stories of people being awarded six and seven figure sums following some medical mishap. At the most basic level, an award of damages is where the court orders one or more defenders in the action to pay a sum of money to one or more pursuers as compensation for the loss or injury suffered by the successful party/parties.

To start with, not all injuries suffered will result in an award of damages. Failure to display existence of a legal duty or to link the breach with the loss or injury will render damages irrecoverable. There is also a category of actions where damages are deemed irrecoverable as a matter of public policy, although the precise scope of this category (indeed, its continued existence at all) is open to question<sup>42</sup>. Further restrictions on the ability to recover damages exist in the distinct but related doctrines of contributory negligence and *volenti non fit iniuria*. These are both related in the pursuer being in some way also responsible for the loss in question. The contributory negligence doctrine is just that – that the negligence of the victim was also a factor in the circumstances which led to the loss. The most common example in the courts nowadays is where the victim of a road traffic accident was not wearing a seat belt at the time, meaning they suffered more serious injuries than they would have otherwise<sup>43</sup>. Historically, contributory negligence was a complete defence to an action, an excessively harsh rule which was met with an accordingly distorted judicial interpretation seeking to ameliorate this harshness<sup>44</sup>. The harshness of the rule was reversed by statute: in terms of the Law Reform (Contributory Negligence) Act 1945, section 1(1), damages are instead reduced on a pro rata basis; in other words, if you are held 60% to blame for the accident, then the damages which you recover will fall to be reduced by 60%. In cases resulting in death, where the person dies partly as the result of his or her own fault and

partly of the fault of any other person, the damages recoverable by dependants may be reduced according to the share of the deceased in the responsibility for the fatal occurrence<sup>45</sup>.

Unlike contributory negligence, the principle expressed in the maxim *volenti non fit iniuria* has not been the subject of statutory alteration. The expression signifies that in the circumstances, the pursuer is deemed to have accepted the risk of the injury which has happened, and is therefore precluded from recovering damages for this injury. The classic instance of *volenti* arises in the course of participants in sports, who are deemed to accept the risks inherent in the sport (so far as permitted by the rules), but it has also been extended to spectators<sup>46</sup>. In the medical context, it is important to realise that a plea of *volenti* requires more than showing that the person injured accepted the risk of injury:

“The question raised by a plea of *volenti non fit iniuria* is not whether the injured party consented to run the risk of being hurt, but whether the injured party consented to run that risk at his own expense so that he and not the party alleged to be negligent should bear the loss in the event of injury. In other words, the consent that is relevant is not consent to the risk of injury but consent to the lack of reasonable care that may produce that risk.”<sup>47</sup>

Finally, the law of damages states that the victim of a legal injury is under a duty to minimise the loss. In effect, the law will not allow you to stand back, let events take their course and then expect to recover damages for losses which, had you taken appropriate steps after the injury happened, you would not have suffered.

## 2: Quantification of damages:

For some legal actions, quantification is easy. If someone damages your car, you will be able to recover the costs of repair and (possibly) the costs of a temporary replacement vehicle. These issues are easy to quantify, in the form of the garage and hire car company bills (and subject to the rule on mitigation). But in medical cases, the injury suffered is, in general, a personal injury. What cost a broken arm? Or being left incapable of having children? Or being left permanently brain damaged?

The theory behind damages awards is that, so far as possible, the claimant is left in the position he or she would have been in but for the legal injury, although there are some limitations on this theory (such as the recent decision of the Court of Appeal that you

cannot recover the specific costs of surrogacy treatment even though you have been negligently rendered infertile<sup>48</sup>). Damages can cover both patrimonial (i.e. financially-quantifiable) loss, and also compensation for pain, injury and other non-patrimonial loss. There is no theoretical role in the UK for a punitive function in punishing the person who is in breach of their legal duties, and as a general rule punitive damages (damages awards explicitly going beyond the terms of what is necessary to achieve just compensation for the harm suffered) are not available in either Scotland or England. (Punitive damages exist in US jurisdictions where they are routinely used to enhance the plaintiff's negotiating position relative to the physician as malpractice insurance does not cover punitive damages<sup>49</sup>). In terms of personal injury, there are three general headings: pain and suffering, loss of faculties and amenities, and shortened expectation of life<sup>50</sup>.

As to how one assesses these things, patrimonial loss is the easier of the two. If you require expensive care following the accident, the costs of this will be recoverable, as are any wages you lose as a result of the accident. This can amount to a huge sum for someone rendered permanently incapable of pursuing a previously highly-paid career<sup>51</sup>. The courts, in such cases, are required to make decisions concerning lost future potential, which can be itself akin to crystal ball gazing: would the pursuer, but for the debilitating accident, have got that promotion? The approach has been clarified by the Court of Appeal, which was called on to assess how likely the plaintiff was to become world kick-boxing champion<sup>52</sup>.

For non-patrimonial loss, quantification effectively comes down to a judicial tariff which, through the medium of awards made in previous cases, allows one to specify what the loss of an arm is worth – because the courts have said, in previous cases, that it is worth £x. Proper quantification of loss is something of an arcane science, although a number of specialist works exist which are intended to simplify the practitioner's job<sup>53</sup>. As a general rule, damages in England tend to be somewhat higher than those in Scotland. Even there, damages for pain and suffering tend to be less than patrimonial loss, particularly when compared to long term loss of wages and care costs. In the case of death, no payments for pain and suffering prior to death can be recovered, although the next of kin may recover damages for loss of society and loss of support. It can therefore be seen that, in purely financial terms, death of a patient is less expensive than permanent injury to one. Damages elsewhere, most notably in the jurisdictions of the United States, tend to be very significantly higher again (and may also admit of exemplary or punitive damages). This gives potential pursuers an incentive to “forum-shop” so as to ground the claim in a higher-awarding jurisdiction. The rules covering

choice of jurisdiction are found in the discipline of Private International Law, and are outwith the scope of this thesis.

One particular area of note concerns the claimant whose prognosis is uncertain and may deteriorate in future. The traditional approach to damages involved a once and for all assessment of loss at the end of the trial. If it were more likely than not that you would suffer from the complication later in life, you could recover in full on the basis that the complication would occur. If it did not, in fact, occur, you were over-compensated. Conversely, if it were less than a fifty per cent risk you could not recover, and if the complication manifested then you were unable to come back for more damages and were left under-compensated. This was felt to be unfair both to pursuers and defenders, and the rules were changed by statute. In terms of the Administration of Justice Act 1982<sup>54</sup>, it is now possible to seek provisional damages where there is a risk that the pursuer will at some point in the future develop a serious disease or suffer a serious deterioration. If the risk is realised in future, the pursuer is free to re-apply to the court for a further tranche of damages. In practice, the section has predominantly been used for the most serious (but less than likely) potential complications, such as the development of asbestos-related mesothelioma, or development of epilepsy following certain head injuries. The courts have been reluctant to use this power for complications which, on the evidence, are more likely to manifest than not, such complications still being assumed to happen and enjoying full compensation after trial<sup>55</sup>.

Structured settlements are a separate concept, and are effectively done by agreement between the defender and pursuer. Under a structured settlement, payments are staggered over a long period. This typically happens where the injury has resulted in the pursuer requiring long term, ongoing care. While voluntary in nature, structured settlements were placed on a statutory footing by the Finance Acts 1995 and 1996 (which exempt payments under a structured settlement from liability for Income Tax) and the Damages Act 1996 Section 6, which allows central government to guarantee payments under a structured settlement made by NHS bodies. NHS Guidance recommends consideration of structured settlements in any case where damages are likely to exceed £250,000<sup>56</sup>, a threshold which tends to restrict their use to cases of obstetric accidents at birth<sup>57</sup>. In essence, the pursuer is awarded a certain annual sum for life instead of a lump sum. Either the defending body self-funds the payments, in which case it carries the financial risk of the pursuer living longer than anticipated (but also benefits if the pursuer dies sooner than expected), or else it purchases an annuity on the financial markets, in which case the risk is passed on to the annuity provider<sup>58</sup>.



In assessing damages, notice should be taken of Section 2(4) of the Law Reform (Personal Injuries) Act 1948, which provides that the existence of (free) NHS facilities is to be disregarded in awarding damages. Thus, the fact that the victim will be treated free of cost on the NHS is irrelevant and does not preclude a claim for private medical costs. Conversely, however, Section 5 of the Administration of Justice Act 1982 provides that savings made by being maintained in hospital are relevant to lost earnings claims.

Finally, there are certain peculiarities relating to the damages which can be awarded for specific types of action. For convenience, these are noted in the discussions of the types of actions *infra*.

### 3: Other remedies:

This section will restrict itself to discussing remedies of relevance to the medico-legal field. As we have seen, the most important remedy is the award of damages but other remedies can be and are sought in medical litigation.

Firstly, there is the remedy of interdict or injunction. This is a remedy whereby the court prohibits someone from doing the specified action. If the person interdicted proceeds with the prohibited act after the court order has been duly served on them, they commit a contempt of court and, if an individual, can reasonably expect a custodial punishment. Interdict or injunction may be sought as an interim measure and is often used to secure the status quo pending the substantive outcome of a legal dispute. Interim orders are granted on the basis of "balance of convenience". They may be granted *ex parte* (i.e. without the person you are seeking the order against being notified of the hearing in advance, and without their being present or represented in court). However, it is possible to lodge a *caveat* in court, the effect of which is that you must be given the opportunity to be heard before the order is granted. Most public authorities maintain permanent caveats as a matter of course. An interim injunction or interdict may be recalled, modified or made permanent following the outcome of the contested proceedings.

Interdicts or injunctions are negative in the sense that they can only be used to prevent something or prevent it continuing. It is not competent to use these orders to force someone to take positive steps. If you want the court to order someone to do something, the correct remedy to seek is that of mandamus or specific implement. Both of these are discretionary remedies in that they are not available as of right (as most

remedies are); even if you prove everything you have set out to prove, the court retains a discretion whether or not to grant the remedy. The courts will not, for instance, order anyone to comply with a contract of employment as this is incompatible with the abolition of forced labour. As with interdict or injunction, failure to comply with the court's order once it has been duly served constitutes a contempt of court. Interdict and interim interdict may not be sought against the Crown<sup>59</sup>.

If the legality of something is in question, the remedy most often sought is that of declarator or declaration. In essence, the court announces that something (such as a proposed course of action or a policy) is or is not lawful. Declarators are also used in other areas to do such thing as declare that someone who has been missing for a long time is dead, or to clarify the status of someone.

Finally, a few other remedies exist which are occasionally found useful in the medical field. Thus, gaps in the Scots law relating to incapacity (prior to the Adults with Incapacity (Scotland) Act 2000) were plugged by resurrecting the ancient remedy of appointing a tutor-dative. Similar defects in English law following the inadvertent abolition of the *parens patriae* jurisdiction were overcome by the discovery of an "inherent jurisdiction" of the court to achieve much the same end (i.e. the power to make declarations as to the legality of proposed medical interventions on people who are incapable of giving or withholding consent themselves). Exceptional equitable remedies such as this are unpredictable but occasionally useful. In Scots law, if all else fails it is possible to petition the Court of Session for that court to invoke the *Nobile Officium*<sup>60</sup>, which may occasionally be utilised to provide an exceptional remedy<sup>61</sup>.

#### 4: Costs and expenses:

Litigation is not cheap. It costs approximately £1,500 per hour to conduct a proof hearing in the Court of Session<sup>62</sup>. According to figures published in 1978, only some 30-40% of medical negligence claims actually succeed<sup>63</sup>. More recent figures suggest a figure of around 25% to 30%<sup>64</sup>, while a (1998) statement by the Government puts the figure at only 17%<sup>65</sup>. Few private individuals have the resources to fund legal action on the scale required in the medical sphere, particularly given the low success rate. The general rule in adversarial proceedings is that the winner must pay the expenses of the loser. Thus, the prospective litigant is looking not just at their own costs, but also at those of their opponent over which they have no control. There are controls over excessive legal expenditure in the form of taxation – legal expenses and outlays cannot be recovered through the court system until the accounts have been inspected and

approved (“taxed”) by the independent Accountant of Court. However, that will not stop the bill being extremely high, just indicate that it is reasonable in being so high. In England and Wales, excessive costs can be controlled by means of a wasted costs hearing<sup>66</sup>.

The costs of litigation would constitute an absolute barrier to justice for most people (and accordingly result in litigation failing badly on the *overall fairness* evaluation criterion, which incorporates issues of accessibility. The main solution for most litigants lies in the legal aid scheme. Without going into details<sup>67</sup>, the legal aid scheme provides a number of ways in which public funds are used to fund legal representation (and its ancillaries, such as payment for expert witnesses) for those who cannot afford it themselves and where the interests of justice so require. Legal Aid is therefore both means-tested (i.e. people earning more than the threshold level, or having savings above a certain amount are not eligible) and subject to a claim satisfying the *probabilis causa* (“probable cause”) test. The financial thresholds are such that around 60% of the population are eligible for legal aid for civil proceedings<sup>68</sup>. In 1998, the Legal Aid bill for medical negligence cases came to £27 million<sup>69</sup>. From the point of view of defenders, one of the most significant aspects of the scheme is that it reverses the normal rules on expenses following success. If someone in receipt of legal aid (typically described in court papers as “AB (assisted person)”) successfully sues you, then you have to pay your own expenses and reimburse the Legal Aid Board for their contributions. However, if you successfully defend the claim of the assisted person, then while you do not have to pay the costs of the pursuer or Legal Aid Board, you do not get to recover your own expenses either but must simply absorb these. Consequently, it is not cost-effective to defend an action raised by a legally-aided party where the costs of defending the action are likely to be greater than the sum sued for. Even if you successfully defend an action which was seeking say £15,000, if your own expenses came to £20,000 (which is not unlikely) then the defence has been uneconomic.

There is particular step which defenders can take to safeguard their positions as regards expenses, the use of the “tender” or “payment-in”. This is a mechanism whereby a formal offer in settlement is made in the course of litigation. If the pursuer or claimant rejects the sum offered but ultimately fails to win more damages than the amount offered (the existence of a tender is not made known to the judge awarding damages), then the pursuer is liable to meet the defender’s expenses from the point where the tender was lodged onwards. Rejecting a reasonable offer may also have implications for the continued availability of legal aid<sup>70</sup>. A variation on the theme, known as a *Williamson tender*<sup>71</sup>, relates to the apportionment of liability between different defenders. If there

are multiple pursuers, a separate tender or payment-in must be made in respect of each pursuer or claimant<sup>72</sup>.

An alternative route for would-be claimants who cannot afford to raise an action but who also cannot get legal aid is the use of conditional fee, or “no win-no fee” arrangements whereby lawyers accept a case on a speculative basis, as introduced by the Court and Legal Services Act 1990, section 58. In most US jurisdictions contingency fees consist of the lawyers taking a portion (typically around a third) of the damages ultimately awarded (if any), and accepting the risk of not getting paid if the claim is ultimately unsuccessful. Such arrangements are currently unlawful in the UK, although the restricted form of conditional fees which has been instituted permits the solicitors acting under a no win-no fee arrangement receive an enhanced fee (typically double) if the action succeeds, rather than a proportion of the damages awarded. It has been suggested that the introduction of such arrangements represents a sea-change in the way legal services will have to be provided<sup>73</sup>. The problem with such arrangements is that they require the lawyers to be prepared to accept the financial risks associated with losing the case, which may prevent some potential litigants from finding a lawyer prepared to take their case if it is particularly difficult or likely to be very expensive (i.e. most medical litigation). It does, however, offer another avenue for those whose financial standing makes them ineligible for Legal Aid.

Finally, something should be said concerning the overall costs of litigation. In its evidence to the Lord Chancellor’s review of civil justice, the National Consumer Council estimated that 85 pence of every pound awarded in compensation was used up by costs<sup>74</sup>.

#### **IV: The Legal Context of the Doctor-Patient Relationship:**

##### **A: Constitutional Law:**

In the broadest sense, any doctor-patient relationship takes place against a background of wider socio-economic and legal relationships. At its most basic, these are the notions of liberal capitalism and constitutional monarchy which, in effect, describe the legal make-up of the United Kingdom. More specifically, this legal framework creates a series of rights and duties within which individuals have to work, and it is with these rights and duties that we are concerned<sup>75</sup>.

Doctors in the UK have unique privileges only insofar as conferred by statute. Thus, only a registered medical practitioner may prescribe certain drugs, or issue certain statutory certificates relating to illness. Such areas, while they definitely affect the powers of doctors, and the rights of patients who consult them, are not generally the subject of litigation. Subject to certain minor alterations, therefore, doctors are subject to the same common law as everyone else.

The legal nexus of a doctor-patient relationship will vary according to circumstances. There may be a contract between the doctor and the patient, as in the case of private medicine, or there may be no contract, as in the case of NHS treatment. The patient may have consented to treatment, in some way or another; or there may be no consent, as in the case of emergencies or where the patient is deemed to be legally incapable of giving consent. It is thus not easy to place a specific legal tag on the relationship. The only constant feature is that the doctor, as is any other person, is under a duty not to harm the patient by acts which it is reasonably foreseeable are likely to injure them<sup>76</sup>.

#### **B: Private Law:**

Private law is the law regulating the rights and duties of persons *inter se*. "Persons" here means juristic persons, which can include corporate bodies such as health authorities. It is accepted that corporate bodies and (under statute) the Crown<sup>77</sup> may sue and be sued in their own right for the enforcement or breach of private law rights. Doctors and others in the health care team may be sued (and sue) as private individuals. What, then, are the rights and duties which private law imputes into medical situations?

The doctor-patient relationship is regulated almost entirely by the common law, subject to certain minor amendments<sup>78</sup>. At common law, a doctor has no duty to treat a patient. This was true historically, and remained true even after *Donoghue v Stevenson*<sup>79</sup> drastically expanded the nature of liability for negligent injury. In that case, Lord Atkin based his judgement on the so-called "neighbour principle":

"The rule that you are to love your neighbour becomes in law: You must not injure your neighbour, and the lawyer's question: Who is my neighbour? receives a restricted reply. You must take reasonable care to avoid acts and omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law, is my neighbour? The answer seems to be persons who are so closely and directly affected by my act that I ought

reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question." <sup>80</sup>

The Biblical answer to the question "who is my neighbour" received the parable of the Good Samaritan as a reply<sup>81</sup>. Would Lord Atkin's principle impose a duty on the Levite who passed by? A reading of the above passage, in its Biblical context, would suggest that it would. It would seem reasonably foreseeable that a man lying bleeding by the roadside would suffer from the failure of a passer-by to assist him. As it turns out, however, the common law imposes no duty of care on passers-by to act in such circumstances. Since the common law treats doctors like everyone else, by logical extension there is no common law obligation on doctors to treat someone not already a patient, even in emergencies. Thus, it would appear that a hospital casualty unit which closed its doors and refused to admit any more patients would incur no liability under this area of the common law<sup>82</sup>, although it may be liable on other grounds discussed later. Indeed, it has been suggested that,

"The law almost discourages the Good Samaritan. For if the doctor comes to the sick man's aid he undertakes a duty to him and will be liable if his skill fails him." <sup>83</sup>

It was against this background of a duty of care imposed on doctors (and the consequent possibility of substantial damages being awarded against the doctor) acting in such circumstances that a number of US states enacted so-called "Good Samaritan" legislation, designed to remove this disincentive for doctors to undertake emergency treatment of passers-by<sup>84</sup>. These have been criticised as unnecessary and insulting<sup>85</sup>. There is no comparable legislation in the UK; in general, a doctor has no duty to treat the man in the street, but if he chooses to do so, he is under a duty not to act negligently and may be held liable in damages if he is. In fact, "Good Samaritan" legislation appears to be unique to the United States; it has been noted that many continental jurisdictions have reacted in the opposite way, by making it an offence for a doctor to fail to act in such emergency situations instead of removing (or limiting) his liability<sup>86</sup>.

However, it is misleading to say that there is no duty at all on a doctor to act. Firstly, if a doctor has undertaken to treat a patient, he is obliged to continue treating that patient until either the patient wishes to, or agrees to, end the relationship, or else the patient's care is taken over by another competent doctor, or the patient dies. Failure on the part of a doctor to continue treatment until one of these conditions is satisfied is known as abandonment. The only British case in point here is *Barnett v Kensington & Chelsea*

*HMC*<sup>87</sup>, but the principle is well-established in the U.S.<sup>88</sup>, and would appear to be equally actionable in the British courts. This view is supported by the speech of Lord Keith in *Airedale NHS Trust v Bland*<sup>89</sup>.

The second exception to the general rule that doctors have no duty to treat relates to general practitioners within the NHS, whose contract of service obliges them to treat any emergency arising within their own practice area, and, if no other doctor is available, within the entire area of their Health Authority. There are a number of limitations on this duty; but for present purposes, the question is whether a person (not one of the doctor's existing patients) could rely on the doctor's contract with the authority to establish that the doctor owed him a duty of care. There appear to be no decided cases on this point; in the only case where the issue was raised, the doctor's lawyers conceded that the creation of the NHS had created a legal duty to the public on the terms of the contract of service<sup>90</sup>. A further point to consider is that the "contractual" relationship between the GP and the health authority has been classified by the House of Lords as being founded in public law under the relevant statutes, although it grants private law rights to the doctor<sup>91</sup>. This would tend to suggest that the GP "contract" is a public law creation which inadvertently creates private law rights. If these extend to imposing a duty of care on GPs, this would tend to support Brazier's analysis. It is interesting to note that some commentators see no difficulty in establishing a duty of care in such circumstances:

"The essential problem is not in establishing a duty to attend but in proving that in not attending the doctor was in breach of duty. General practitioners must be allowed some discretion in determining which calls to respond to."<sup>92</sup>

In Scotland, the position is much clearer, since it is well established in Scots Law that a contract can readily confer rights on a third party not party to the contract, *i.e.* it can create a *ius quaesitum tertio*. Under this rule of law, the third party or *tertius* will have title to sue if he belongs to a particular class of persons named or referred to in the contract, and where it can be shown that the object of the contract was clearly to advance the interests of that class of persons. A contract intended to confer benefits on the general public will not confer title to sue on anyone, however<sup>93</sup>. On the basis that emergency patients within a defined area constitute a sufficiently-defined class of persons to be granted a *ius quaesitum tertio* by the GP contract, this provision should impose a duty of care on all Scottish GPs within their practice areas.

But if no duty is incumbent on the individual doctor (except as noted above), are any duties incumbent on the NHS itself? As noted above, the NHS is an organ of state, and

as such is susceptible to public law forms of action - and in particular to judicial review of administrative action. This is considered next; but in the private law context, it has been held that it is at least arguable that the ambulance service owes people a duty to provide a prompt service and to provide treatment en route to hospital<sup>94</sup>.

### **C: Public law:**

In a judicial review, the courts scrutinise the activities of public and administrative bodies to ensure that they act "reasonably", *i.e.* not contrary to the precepts of natural justice<sup>95</sup>, and that they act within the law, *i.e.* that they exercise duties incumbent on them under statute and do not exceed their jurisdiction. The classic description of the purposes of judicial review is taken from the judgement in *Associated Provincial Picture Houses v Wednesbury Corporation*<sup>96</sup>. This held that in questions of policy decisions, the court will overturn such a decision only if it is so unreasonable that no reasonable body could have made it. It should be noted then that judicial review is not an appeal from the original decision-making body; the courts have consistently refused to substitute their own decision for that of the body in question<sup>97</sup>, and are only concerned with questions of procedural fairness and legality. The traditional grounds for judicial review have recently been expanded by the courts to include fundamental error of fact and "proportionality", a concept applied by the European Court of Human Rights; this is considered *infra* in the context of the functions of litigation in controlling other regulatory bodies. Secondly, judicial review is a discretionary remedy: the leave of the court is required before an action can proceed<sup>98</sup>, and before this happens the applicant must generally show

1. sufficient interest in the policy decision to be reviewed, and
2. that any other remedies available (such as appeal) have been exhausted, unless it would be unreasonable to do so in the circumstances of the case.

This leads to an interesting procedural difficulty encountered in such cases: it has been held (in the House of Lords) that as a general rule, a person seeking to overturn the decisions of a public body must use the procedure for judicial review, rather than any private law procedures<sup>99</sup>, unless the case is in reality concerned with private rights (*e.g.* an action for negligence) and doesn't raise any public law issues<sup>100</sup>.

Judicial review is the mechanism by which the courts (and through them, the citizen) ensure that public sector bodies adhere to their statutory functions, and act reasonably in their conduct in furtherance of these functions. Two examples will be given to show the uses to which public law remedies have been put in the medical context.



The first concerns the duty, or otherwise, of the National Health Service (as opposed to individual doctors) to treat people. While this thesis is not examining mechanisms within the NHS to regulate itself, it is still necessary to consider the courts' approach to the NHS as this is the main provider of health care in the country and provides the largest number of examples of litigation being used as a regulatory tool. In *R v St Mary's Hospital Ethical Committee ex p. Harriott*<sup>101</sup> the court held that where treatment was refused on non-medical grounds, this could be reviewed. In this case the applicant failed to show that the decision was either procedurally unfair or itself unlawful, but the judge indicated that refusal to treat on, for example, grounds of race would be illegal. It is therefore authority for the proposition that the right to NHS treatment is legally enforceable.

The second line of authority concerns a series of unsuccessful judicial review applicants. In essence, all these cases revolve around the National Health Service Act 1977. This imposes a duty on the Secretary of State to provide a "comprehensive health service"<sup>102</sup> and to provide, to such extent as he considers necessary to meet all reasonable requirements, such services as hospitals, medical and ambulance services<sup>103</sup>. The cases were concerned with the question of whether this "duty" was justiciable.

The cases all revolved around patients denied treatment which had been deemed to be medically necessary, on the basis of lack of sufficient resources (usually availability of trained nursing staff) to conduct the treatment. The answer is that overall allocation of resources to the NHS by Parliament is completely non-justiciable<sup>104</sup> and that individual patients may not sue the Secretary of State for damages. It has been suggested, however, that in extreme cases (e.g. deliberately subverting the health service), even this would be susceptible to judicial review<sup>105</sup>.

The situation is little different as regards decision-making delegated to Health Authorities. There is a line of judicial decisions here: firstly the High Court held that decisions as regards resource allocation by authorities were non-justiciable<sup>106</sup>, then the Court of Appeal in the same case said these decisions were justiciable, but that the courts would not interfere unless the decision were "Wednesbury unreasonable", and finally the High Court held that this rule applied even in life-threatening situations.<sup>107</sup> Furthermore, it was suggested that in future the courts would not (and should not be asked) to intervene unless there was at least *prima facie* evidence of unreasonableness. Thus, while the right to seek review has broadened somewhat, this broadening has been accompanied by increasingly stricter rules regarding the appropriateness of exercising this right.

In the context of regulating medicine, what emerges is a very clear "hands-off" approach by the courts. In a sense, then, the provision of NHS services is effectively unregulated by litigation, being controlled in the first place by the parliamentary accountability of the Secretary of State for Health, and in the second place by the administrative machinery of the NHS itself. This "hands-off" approach has been severely criticised by several commentators<sup>108</sup>.

The point made here is not that the courts should take it on themselves to make resource allocation decisions; they should not, and all the judges concerned conceded this. The criticism concerns the degree of scrutiny which the court actually exercises. In *R v Cambridge HA ex p. B*<sup>109</sup>, Laws J at first instance set aside the decision of the Health Authority on the basis of failure to take all relevant factors into consideration, stating that the authority "...must do more than toll the bell of tight resources... They must explain the priorities that have led them to decline to fund the treatment."<sup>110</sup> However, his decision was overturned on appeal, the court holding that there was no need for the authority to justify its budget allocation decisions<sup>111</sup>.

Lastly, while technically not arising in a public law action, the Court of Appeal has recently held that public bodies given specific statutory responsibilities can seek injunctions to prevent interference with the performance of those duties, and that such injunctions will be granted if it is "just and convenient to do so".<sup>112</sup>

### **E: Hybrid situations:**

The most widely-discussed case involving the use of private law procedures to address what was clearly a public law matter occurred in the much-discussed case of *Gillick v West Norfolk and Wisbech AHA*<sup>113</sup>. This case essentially decided (1) the legality of providing contraceptive advice and services to under-16s, and (2) whether or not such advice and services could be provided without the knowledge and/or consent of the girl's parents. The case also provides a clear example of litigation affecting medical practice: both the DHSS (as was) guidelines and the GMC's ethical guidelines (the "Blue Book") relating to contraceptive services were amended after each stage of the judgement, which went ultimately to the House of Lords.

*Gillick* involved a challenge to a policy decision (to provide contraceptive services to under-16s) by a Health Authority. As indicated above<sup>114</sup>, a person seeking to impugn and overturn the decision of a public authority must normally use judicial review procedures, but *Gillick* saw a challenge to such a decision reviewed by the courts under

ordinary private law procedures. The procedure in question was an action by Mrs Gillick for a declaration that (1) the DHSS advice was unlawful, and (2) that the AHA would not give contraceptive advice to her children while they were under 16 without her own knowledge and consent. The case also shows an interesting interaction between the civil and criminal law, although it was conceded at an early stage that if the declarator Number (1) were granted, then Number (2) would be irrelevant since parental consent could not legitimate conduct which was *de iure* illegal. Ultimately Mrs Gillick lost, a majority of the House of Lords holding that, provided certain conditions were adhered to, a doctor could lawfully prescribe contraceptives to under-16s, without either a violation of the criminal law or needing parental consent. This case is also authority for the right of minors to consent to treatment generally, and as such it has significantly affected medical practice.

How were private law proceedings used in what looks like a public law case? This was extensively discussed in two leading articles<sup>115</sup>. Lord Fraser allowed the action because it had begun before the decision in *O'Reilly v Mackman*<sup>116</sup>. Lord Scarman felt firstly that it fell into the exception created by Lord Diplock in that case whereby private law proceedings were competent if the invalidity of the public body's decision (*i.e.* a public law issue) arose as a collateral feature of infringement of private law rights, and secondly there was no objection to the use of private law procedure by the defendant, although judicial review would have been competent. Lord Bridge, however, doubted the competence of judicial review in this case, given the non-statutory and advisory nature of the circular in question, but accepted that Mrs Gillick had sufficient *locus standi* to bring the present action. Lastly, it should be noted that Lord Scarman also held that it was competent for the court, in a civil action such as this, to grant a declaration which would obviously influence the criminal law. This power cannot technically be exercised by the supreme Scottish civil court, the Court of Session, as declarators of that court only relate to civil law consequences of the action.<sup>117</sup>

It should also be emphasised that the *Gillick* ruling applied solely to England and Wales. In Scotland, without any clear legal justification, the practice had also developed of providing contraceptives to under-16s. However, matters in Scotland have been placed on a statutory footing and are therefore considered in Chapter 6 *infra*.

## **F: Contractual Liability and Medicine:**

There was far greater scope for a breach of contract action in medicine prior to the inception of the National Health Service. Up to that point, the majority of medical

consultations were private in nature, which therefore meant the existence of a valid contract between the doctor and whoever paid his fees. In spite of this commonplace nature of the exercise, doubts remain in England as to the precise moment when the contract comes in to existence. In Scots law, by contrast, a valid contract requires only offer and acceptance, which is readily shown or inferred from the fact of the doctor actually treating the patient.

If liability is to be based *ex contractu* it then becomes vitally important to determine what exactly was contracted for. In this context, the case of *Thake v Maurice*<sup>118</sup> is relevant. The plaintiff paid for a vasectomy, which reversed itself naturally. At first instance, it was held that the doctor had undertaken to sterilise the plaintiff and, having failed to do so, was liable for breach of contract. On appeal, the court held that the surgeon had not given an absolute undertaking to sterilise the patient; he had merely undertaken to perform the operation with due care. This case reiterated the point that a clause will be inferred into any such contract to the effect that the treatment contracted-for will be carried out with due care. Such an implied clause is in keeping with the general common law of contracts<sup>119</sup>. Thus, negligent performance of the contract will give rise to an action for breach of contract, as well as an action for the tort or delict of negligence. The test for negligence (discussed *infra*) being identical in either case, there is no particular advantage for either the contract or tort/delict action in the event of negligent performance, apart from procedural points such as different periods of prescription and limitation. But *Thake v Maurice*, while holding that there is no implied "success clause" in medical contracts, does leave it open for the doctor explicitly to warrant success. The courts will only uphold such a clause if it makes it absolutely clear that success is actually warranted. While there is no British case applying such a ruling (apart from *Thake* at first instance), a number of Canadian cosmetic surgeons have been held liable under this heading<sup>120</sup>. On the other hand, while success is not warranted, neither may the doctor reduce his liability by contract<sup>121</sup>.

Of course, contractual liability is only of interest to the private patient, and despite its recent growth, private medicine is still very much in the minority in the UK today. It could be argued that a contract exists between an NHS patient and doctor as a result of the patient requesting, and the doctor agreeing to, his or her inclusion on the GP's list of patients. Consideration, from the English viewpoint, is provided by the fact that the doctor's payment is on the basis of capitation, *i.e.* he gets more money the more patients he has on the list. However, the NHS doctor is acting on the basis of the relevant statutes, and the House of Lords has held that performing a service in pursuance of a statutory obligation precludes the consensual element necessary in a contract<sup>122</sup>. It is

implicit in the Court of Appeal's judgement in *Hotson v East Berkshire HA*<sup>123</sup> that there is no contract between a GP and his or her patient. The practical results are the same in either case, so to a large extent the existence or not of a contract between an NHS doctor and patient is irrelevant, at least as far as negligence is concerned. There remain procedural differences between the two actions, most notably in terms of prescription or limitation, and in an action for breach of contract it is unnecessary to prove loss (although this would be necessary in order to win more than nominal damages<sup>124</sup>). Given the substantive similarities between the actions, the procedural distinctions are effectively pleading points which are for the doctor's legal advisers to worry about, not for the doctor.

## **V: Medical negligence:**

### **A: The basis of negligence liability:**

In the foregoing discussion, we have seen that perhaps the only constant feature of the doctor-patient relationship is the existence of a duty of care between the doctor and the patient being treated. It is at this juncture that the law most closely becomes involved in determining the quality of medical treatment required of a doctor as a matter of legal entitlement rather than contractual agreement or general rights against the State through the mechanism of the NHS. The discussion which follows is, for that reason, somewhat extended.

The legal foundation for the legal duty imposed on a doctor to take reasonable care is now regarded as being the judgement in *Donoghue v Stevenson*<sup>125</sup> - you are under a duty not to harm others by acts which it is reasonably foreseeable would cause harm. In a sense, classifying an action for breach of this duty as a negligence action is something of a misnomer, since the action also extends to liability for intentional acts; intentionality is no defence<sup>126</sup>. In Scots law, the test is one of *damnum iniuria datum*, i.e. harm caused by a wrongful act<sup>127</sup>. Such wrongfulness may be intentional or negligent, so intentionality is, if anything, even less of a defence in Scotland.

However, the notions of tortious or delictual liability extend much further back than 1932. The first recorded malpractice action, for instance, was brought against a surgeon in 1374<sup>128</sup>. However, early cases invariably proceeded on the basis of breach of contractual obligation. Clear decisions showing that liability for defective medical practice can arise independently of contract came somewhat more recently: *Pippin v*

*Sheppard*<sup>129</sup> held that a patient had a right of action against a negligent doctor irrespective of contractual relationships, a decision followed in Scotland in *Edgar v Lamont*<sup>130</sup>.

A related point concerns the doctor's liability to the patient where the patient is being examined for the benefit of a third party. The most common example would be medical examinations conducted on behalf of a potential or actual employer of the patient. In such a case, it would seem clear that *Edgar v Lamont* does not apply, and that the doctor obviously owes a contractual duty to the employer. But does he also owe a duty to the patient to inform him of the results if, for example, he diagnoses a potentially-serious but treatable affliction? The issue has never been addressed by a British court, but an American court has held that the patient in such cases would reasonably expect to be informed of any significant findings; a duty of care therefore exists between the doctor and patient in addition to the contractual duty to the employer<sup>131</sup>. This would appear to be in line with the general ambit of the duty of care, and some commentators have expressed the view that an English court would find this reasoning "persuasive"<sup>132</sup>.

#### **B: Ambit of the Duty of Care:**

This point leads us nicely to the first major issue in negligence cases: who owes the patient a duty of care? Put another way, who can the patient sue if things go wrong? As we have seen, the principal duty of care is incumbent on the doctor who treats the patient, and the doctor-patient relationship probably comes into existence by the patient's presence on the doctor's list. But modern medicine is frequently characterised by the need for whole teams of doctors and allied professionals to cooperate in the patient's care regime - to say nothing of the attendant care by nursing and non-medical ancillary staff. From the prospective litigant's perspective, this raises two issues. Firstly, can institutions such as hospitals, or the NHS itself, be directly liable to their patients? Secondly, what duty of care do the individuals working within these institutions themselves owe to a patient? A related question concerns identifying *to whom* a duty of care may be owed. Does it, for instance, arise in the context of advising the next of kin of a deceased patient what happened? In keeping with the general approach of restricting the scope of liability for informational issues, the courts have held that no such duty of care arises<sup>133</sup>. The general approach to the existence of a duty of care consists of considering three issues: foreseeability of loss resulting if the duty is breached, whether it is fair, just and reasonable for a duty to be imposed, and whether there be sufficient proximity between the parties<sup>134</sup>. In advising relatives of the cause of death, a

doctor may have close contact with the relatives, but unless they are his patients this closeness still lacks the requisite proximity to give rise to a duty of care.

Historically, hospitals were established as charitable or institutional organisations which had no contractual liability to their patients<sup>135</sup>. *Evans v Liverpool Corporation*<sup>136</sup> held that there could be no vicarious liability for delicts committed by doctors since their employers did not exercise control over them. It was initially held in *Hillyer v Governors of St Bartholomew's Hospital*<sup>137</sup> that there was no vicarious liability for the delicts of their employees, but on appeal this decision was reversed; it was further held that there could be vicarious liability for the actions of doctors, but only in respect of their administrative duties. But Hillyer also held that the hospital itself had a duty of care to ensure that its staff were competent and that adequate resources were available.

In any case, the formulation of vicarious liability applied in cases such as these is vulnerable to a number of criticisms. Vicarious liability, as an exception to the normal fault-based concept of negligence liability, is often justified on the basis *Qui sensit commodum debet sentire et onus*, "he who obtained an advantage ought to bear the disadvantage as well";<sup>138</sup> the concept of justice thus can be seen to play a role here, as judges occasionally explicitly acknowledge<sup>139</sup>. Similarly, the "deterrence" theory holds that vicarious liability gives organisations an incentive to take care in minimising the torts or delicts of their employees, and to take care in selecting staff; this too has found judicial support<sup>140</sup>. The distinction formerly made, which was crucial in delimiting vicarious liability for doctors' actions, was between contracts of service (*locatio operarum*) where vicarious liability applies, and contracts for services (*locatio operis faciendi*) where it does not<sup>141</sup>. Later cases emphasised that there must be an element of control before an employer could be vicariously liable<sup>142</sup>. It is this element of control which is said to be lacking in the medical sphere: doctors are granted clinical autonomy beyond their employers' ability to interfere (except in very unusual circumstances), and these employers are in any event unlikely nowadays to be medically qualified to be able to exercise control even if they wanted to.

The strange dichotomy between non-liability for doctors' actions, and liability for those of others in their professional capacities, was weakened in *Gold v Essex County Council*<sup>143</sup> which held that the employer was vicariously liable for the acts of a radiographer, and removed in *Cassidy v Ministry of Health*<sup>144</sup>, which applied vicarious liability to all employees and all activities carried out in the course of that employment.<sup>145</sup> In *Roe v Ministry of Health*<sup>146</sup> the court went further and found the hospital vicariously liable for

the actions of a part-time anaesthetist who also engaged in private practice - exactly the sort of person who, on the old reading of the law, would have been deemed to be an independent contractor. The present approach is to look at various factors in combination with each other, rather than any one conclusive test. Key factors include the parties' intentions, duration of contract and method of payment, freedom of selection of employees, and ownership of the tools or equipment used<sup>147</sup>. However, a more recent trend has been to suggest that the hospital or health authority may itself be liable, not vicariously for the delicts of its employees, but directly for breach of its own duty of care to its patients. Thus in *Wilsher v Essex AHA*<sup>148</sup> the then Vice Chancellor (Sir Nicholas Browne-Wilkinson) said

“...a health authority which so conducts its hospitals that it fails to provide the doctors of sufficient skill and experience to give the minimum treatment offered at the hospital may be directly liable in negligence to the patient.”

This case held that the inexperience of staff was no defence to an action of negligence - if the doctors were insufficiently experienced to meet the requisite standard of care, then they were still liable. A number of cases have been raised on this basis<sup>149</sup>, and while they have generally failed on evidential grounds, the existence of a direct duty to patients by hospitals seems to be widely accepted by the courts. This is in accordance with the general law of negligence<sup>150</sup>. In a sense, this is the corollary to the resources cases mentioned above<sup>151</sup>: these cases held that failure to provide a service due to resource limitations was not, in general, actionable; *Wilsher* makes the point that if you do offer the service, then resource constraints are no justification for failing to meet the requisite standard of care. As a final point, there is no vicarious liability for the acts of a fellow employee, even a subordinate. Consequently, a consultant is not liable for the actions of registrars under his direction<sup>152</sup>.

### **C: Nature of the Duty of Care and the Standard of Care:**

The basic elements of liability for negligent acts or omissions is, essentially, as follows:

- “1: There must be a duty of care owed by the defender to the pursuer.
- 2: There must be a breach of the duty.
- 3: The breach must cause loss.”<sup>153</sup>

Having established that the doctor (and through him the hospital or health authority) owes his patient a duty of care, it is now necessary to consider in which circumstances a



doctor will be in breach of that duty. In layman's terms, when is a doctor deemed to be negligent?

As noted above, the classic exposition as regards liability for negligent acts is Lord Atkin's "neighbour principle" in *Donoghue v Stevenson*<sup>154</sup>. This attributes liability for acts which the "reasonable man" would foresee could cause harm. However, the reasonable man is not a doctor, and will therefore have at best a very limited idea of what, in the context of medical care, is or is not likely to cause harm. How, then, do the courts assess the liability of those who profess specialised knowledge? This point was raised in *Hunter v Hanley*<sup>155</sup>; Lord President Clyde held, in a widely-quoted judgement, that:

"The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proven guilty of such failure as no ordinary doctor of ordinary skill would have been guilty of if acting with ordinary care."

This test, then, is a specialised application of the general rule in *Donoghue v Stevenson*, except that instead of basing liability on the "reasonable man", it is based on that of the "reasonable doctor" - or lawyer, or any other person being sued on the basis of specialist (usually professional) knowledge. The judgement in *Hunter v Hanley* was quoted verbatim and applied in England in the case of *Bolam v Friern Hospital Management Committee*<sup>156</sup>, and subsequently approved by the House of Lords<sup>157</sup>. It is accordingly known as the "*Bolam* test". In determining what constitutes medical negligence, it is necessary to show (1) that a usual and normal course of treatment exists; (2) that it was not followed; and (3) that the course of treatment actually adopted is one of such a nature that no professional person would have chosen it when acting with ordinary care<sup>158</sup>. To provide an adequate description of medical malpractice law, it is necessary to provide a gloss on all of these points.

First and foremost, the test obviously places heavy reliance on medical expert evidence both as to normal practice and on the acceptability of the course actually adopted. Since both sides are free to lead their own expert witnesses, a "trial by experts" is not uncommon in this field<sup>159</sup>. The problem is compounded by the fact that "... a man is not negligent... merely because there is a body of opinion who would take a contrary view."<sup>160</sup> Or, as Lord Denning put it, "...Mere differences of opinion are not, per se, actionable."<sup>161</sup> The courts have been consistently reluctant to get involved in debates between different bodies of medical opinion as to which is correct<sup>162</sup>. The practical upshot of this is that, even if the pursuer finds experts willing to testify on his or her

behalf, if the defender also finds such experts then the doctor will have acted in accordance with a respectable body of medical opinion, and the claim will fail. There may be serious practical difficulties in finding experts prepared to testify on behalf of patients. On the other hand, the courts have, on occasion, been prepared to apply commonsense notions to the problem at hand and, if they conclude that the issue does not raise a technical medical question at all, may decide the case on the basis of their own common sense, rather than the expert testimony led before them. Thus, a doctor's bad handwriting will attract liability even if it is no worse than most doctors' <sup>163</sup>.

A few more points need to be made about the duty of care. Firstly, while it is clear that clinical judgements are susceptible to legal review<sup>164</sup>, it remains true that adherence to accepted standards will seldom be challenged by the courts. This approach is somewhat more deferential to the medical profession than to others, where it has been held that evidence as to trade practice alone is not conclusive for the defender if there is evidence justifying a finding that this practice is unsafe<sup>165</sup>. There is, however, some authority in medical cases to the effect that, if necessary, judges will overrule accepted medical practice. The most striking example of this is in *Smith v Tunbridge Wells HA*<sup>166</sup> in which the judge, Morland J., effectively held that evidence as to standard practice from "the greatest of experts" in the field in question was insufficient to prove that the converse view was

"...not only the generally accepted proper practice, but was also the only reasonable and responsible standard of care to be expected from a consultant in [the doctor's] position faced with the plaintiff's situation" <sup>167</sup>

This case, and the others making similar judgements as to the correctness of accepted medical practice, concerned information disclosure; they are considered in greater detail below. As yet, there appear to be no cases where a doctor has successfully been sued over a clinical matter (treatment or diagnosis) where he followed accepted medical practice.<sup>168</sup> However, the Court of Appeal has indicated that

"It is not enough for a defendant to call a number of doctors to say that what he had done or not done was in accord with accepted clinical practice. It is necessary for the judge consider that evidence and decide whether that clinical practice puts the patient unnecessarily at risk" <sup>169</sup>

In practice, however, the effect of this seems merely to be that the courts are withholding to themselves jurisdictional grounds to challenge medical decisions which they have no

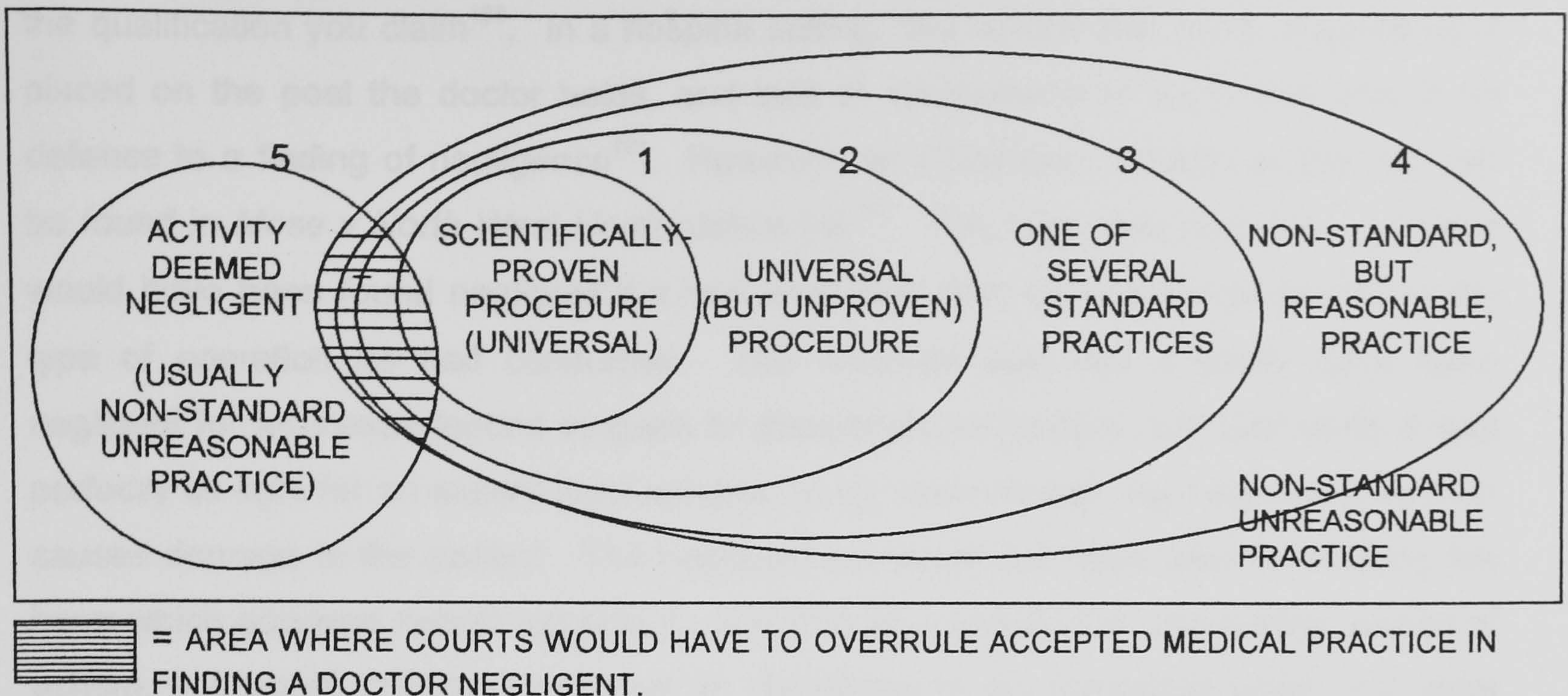
intention of exercising; even respectable evidence that what the defendant did was a course of action which no responsible doctor would have undertaken, rather than simply saying that they would have acted differently, is still not sufficient to discredit the defendant's experts who support him.

The second factor in a successful professional negligence claim is that you must show that the treatment did not follow any accepted practice. There are three problem issues here. Firstly, even if you show that the doctor departed from normal practice, this does not in itself show negligence; it does not even place an evidential burden on the doctor to justify his departure from that practice<sup>170</sup>. The evidential burden remains at all times on the pursuer to show all these aspects (*i.e.* accepted practice, departure therefrom, and unreasonableness of course actually adopted). Secondly, it may be difficult to find out exactly what has happened. The Access to Health Records Act 1990 was passed to give patients access to their own medical records. The 1990 Act was not retrospective, although the new access rights under the Data Protection Act 1998 are<sup>171</sup>, which may help to alleviate some of the problems claimants have experienced in this field. The problem is exacerbated somewhat by the fact that it is unclear whether a doctor is under a duty of *ex post facto* disclosure to tell a patient what has actually happened to him, although he probably is<sup>172</sup>.

The third problem with departure from accepted practice is, however, rather more fundamental: supposing there *is* no accepted practice? It has been claimed that for 90% of medical conditions, there is either no specific remedy, or else that the efficacy of the normally-adopted treatment is unknown<sup>173</sup>. There appears to be no case law on this situation, or at least no decided cases where the point was argued. On general principles, it would seem that if the treatment is so radical and innovative that no other doctor would have undertaken it, then liability would follow. Of course, the causation problem in such a case might be insuperable, and in any case it should be noted that such an approach *simpliciter* would discourage doctors from trying a new and untried therapy for a novel disease. The action could still fail on the basis that for an action to succeed, the duty of care breached must be fair and reasonable as a matter of public policy<sup>174</sup>.

This also relates to the third aspect of the claim, that you must show that the course adopted is of such a nature that no professional person would have chosen it when acting with ordinary care. Given the relatively fragile scientific base of medicine, and the huge degree of variation in treatment, we can graphically display medical practice as shown in figure 5.1:

FIGURE 5.1: COMPARISON OF LEGAL TESTS AND MEDICAL KNOWLEDGE



It can thus be seen that most findings of negligence relate to activities which are far from the core of good medical practice. In deciding where, on this diagram, a given intervention would lie, the courts are naturally reliant on medical evidence. However, it should be noted that the judges still decide, ultimately, on whether an activity is negligent. Thus, sets 1 to 4 above are medical decisions; set 5 is a legal one. This point is occasionally noted by judges: Lord Scarman once observed that "The law imposes the duty of care, but the standard of care is a matter of medical judgement."<sup>175</sup> Having heard medical evidence on the standard of care (sets 1-4), the judge determines whether this constitutes a breach of the duty of care, *i.e.* whether the pursuer's claim fits into set 5.

Some comments are needed on assessing the standard of care. The standard by which a doctor's acts are judged is by what was the prevailing knowledge at that time. The clearest example of this is where a misfortune occurs as a result of a risk which could not have been discovered at the time due to the limitations of scientific and technical knowledge, as happened in *Roe v Ministry of Health*<sup>176</sup>; in the words of Lord Denning, "We must not look at the 1947 accident with 1954 spectacles."<sup>177</sup> The rationale is that a person should not be held liable for following a course of action which is only subsequently shown to be wrong. The converse is also true, however, and a doctor who adopts an unorthodox course of treatment will incur no liability if it is subsequently shown to be correct<sup>178</sup>.

Lastly, the standard of care by which a doctor is judged is that of his own speciality<sup>179</sup>. This is again a refinement of the neighbour principle: for "reasonable man" we now substitute "reasonable consultant" or "reasonable specialist"; the test remains the same.

If you hold yourself out as being qualified, then you will be judged by the standards of the qualification you claim<sup>180</sup>. In a hospital setting, this means that much importance is placed on the post the doctor holds, and lack of competence to be in that post is no defence to a finding of negligence<sup>181</sup>. However, an interesting corollary to this rule can be found in *Mose v North West Hertfordshire HA*<sup>182</sup>. This case was held that a surgeon would have been found negligent if it had been held that he was *inexperienced* in the type of operation he had conducted. The rationale was that it would have been negligent for an inexperienced surgeon to attempt the procedure, but apparently it was perfectly all right for an experienced surgeon to try, even though (as happened) he then causes damage to the patient. The negligent act would not have been in causing the harm which occurred (which appears to have occurred as a result of an acceptable course of action), but would instead have been in attempting to do something which you were unqualified to do. This is in effect a new limb of negligence, in that it is reasonably foreseeable that you will cause harm by attempting something intrinsically beyond your skill - even if you follow a course of action which is identical to one which an appropriate specialist would have followed.

#### **D: Criticisms of the *Bolam* Test:**

The *Bolam* test has been subjected to intense, and increasing, criticism. As we have seen, it appears to place medical evidence on a pedestal which no other class of evidence

enjoys. That deference is criticised as follows:

“The standard test of medical negligence was set down in 1957... This test has a number of practical implications. If the conduct in question did not fall below the minimum standard of the reasonably competent practitioner in that field of practice at that time then it does not constitute negligence. If the conduct in question, even if it reflects a minority view of how practice should be conducted and even if there is a body of opinion who would take a contrary view, was within a reputable minority view then it does not constitute negligence.

... In medical cases the courts go further [than in cases involving other professions] and defer to the medical witnesses by allowing them to determine whether the conduct in question conformed with the standard of care required by law. The effect is that it is the medical profession rather than the judges which sets the legal standard of care in practice.”<sup>183</sup>

More fundamentally, Goldrein and de Haas blame it for a fundamental distortion of the entire structure of medical tort:

“... when seeking to establish liability for negligence in an accident claim:

- There has to be balanced (broadly speaking) the risk of injury to the proposed plaintiff against precautions to reduce the risk to be taken by the proposed defendant.
- ‘General and approved practice’, where relevant, can be invoked to help guide the court as to how that balance is to be struck

...Such analysis in the context of medical negligence has been clouded by ‘*The Bolam Test*’... What in fact does *Bolam* achieve? Surely it has two consequences:

Firstly, it merges into one confused and unsatisfactory test, the three entirely separate avenues of analysis otherwise known to the tort lawyer:

- a risk,
- b precautions, and
- c where should the balance be struck.

Secondly, it makes judges subconsciously believe that they exercise judgment on the central issue - *where the balance should be struck?* - as lawyers rather than as laymen.”<sup>184</sup>

A 1997 decision of the House of Lords, *Bolitho v City and Hackney Health Authority*<sup>185</sup>, raised the question of whether the *Bolam* test was applicable to questions of causation (causation itself is considered *infra*), as historically it was felt that its applicability was restricted to the question of duty of care and standard of care. In the leading judgement, Lord Browne-Wilkinson held that *Bolam* was indeed relevant in deciding issues of causation where the central question to be decided was what should have been done. However, he also emphasised that the courts ultimately retain the task of assessing whether the body of medical opinion led before the court is a reasonable one, and ultimately the court can overrule even unanimous medical opinion if that opinion is not capable of withstanding logical analysis. This is in line with the courts’ approach to expert evidence generally<sup>186</sup>. Opinion is split as to the effect of *Bolitho*. Thus, Davies suggests that;

“...if this case represents any real change at all it is that the courts are being more explicit in publicising their rare and residual power to question medical practice. The slight change is more cultural than substantive.”<sup>187</sup>

Whereas Brazier and Miola argue that

*“Bolitho has already made a difference. Bolitho has been applied by the Court of Appeal to uphold a judgement against a defendant general practitioner. In Marriott v West Midlands Health Authority<sup>188</sup> the judges concluded that the expert opinion advanced in the doctor’s favour was not defensible. Most importantly Bolitho has been decided at a time when other developments also point to a revolution in the way medical malpractice is judged.”<sup>189</sup>*

The emerging evolution of this area of law is taken into account in the conclusions *infra*.

### **E: Causation:**

It is not enough to show that a duty of care exists, and was breached by the doctor. For an action to succeed it is necessary to show that the loss you suffered was caused by that breach of duty, *i.e.* it was the *causa causans* of the injury, and not just a *causa sine qua non*. This is, in fact, often one of the most difficult parts of an action for malpractice:

*“It is generally held that a causal connection between the wrongdoer’s conduct (or the event for which he is responsible) and the resulting harm is a precondition of his liability to pay compensation. Establishing the causal connection between medical negligence and the injury complained of is probably the most difficult task in medical malpractice litigation (as indeed in many negligence actions).”<sup>190</sup>*

The reasons underlying the tests used for establishing this causal connection have been criticised as having more to do with public policy aimed at controlling potential liability than with juristic logic<sup>191</sup>. The following discussion will focus on the general principles actually applied by Scottish and English courts, and the variations on these principles used in medical cases.

To start with, it is clear that the doctor is not liable simply because he has failed to make you better:

*“There is no absolute liability to cure, not even if the patient’s post-operative condition is worse than before, though such facts may raise a prima facie case of negligence.”<sup>192</sup>*

To suggest that a *prima facie* case of negligence is raised in such circumstances is to start with the most favourable (to the patient) interpretation of events. The basic premise of causation is that you are only liable for the harm caused by your wrongful actions. This can be described as the “but-for” premise: you are liable for harm which would have not occurred but for your negligence. In trying to decide whether act A has caused injury B, the choice should be made on a common sense basis<sup>193</sup>.

Causation is easily seen to be lacking in *Barnett v Chelsea & Kensington HMC*<sup>194</sup> in which a night watchman who had been poisoned received no treatment from the hospital. There was a duty of care, and a clear breach of that duty. But the evidence was that even prompt and skilled treatment could not have prevented the death of the watchman; therefore the doctor’s negligence in no way caused or exacerbated the injury, and so no damages were recoverable. Most cases, however, are not so easily disposed of. In a large number of malpractice claims, the negligence complained of will have arisen in the course of treating some underlying injury or illness. How is the court to decide whether it was the negligence which caused the deterioration, or the underlying illness?

The general rule of delict is that if the breach of duty by the defender “materially contributed” to the injury suffered by the pursuer, then the defender is 100% liable for the loss or injury sustained. A material contribution means anything other than completely peripheral matters covered by the maxim *de minimis non curat lex* - the law is not concerned with trivialities. Anything which had more than a *de minimis* contribution to the accident will therefore render the defender liable in full damages. This applies even if the defender were only liable to the extent of, say, 10% responsibility for the harm: he will have to pay all the damages unless he cites the person responsible for the 90% contribution as a co-defender<sup>195</sup> or argues contributory negligence by the pursuer. If the issue is whether harm was caused by a negligent or non-negligent cause, then there is no apportionment and the entire case will hinge on which cause is deemed to have been responsible. In these cases, the “but-for” test is largely inapplicable, and the issue is again one of material contribution, where even a minority culpable cause (*i.e.* one caused by breach of duty of care) will render the defender wholly liable in damages. What is of particular importance is that this also applies to factors which serve to increase the risk of harm being caused by a non-actionable cause, such as underlying disease. If the pursuer succeeds in showing that the negligence complained-of materially increases the risk of suffering harm from the other cause, and if this harm materialises, then he will succeed in his action<sup>196</sup>. From



this, it would seem that if a patient suffers an injury which could have been caused either by negligent treatment or by an underlying condition, then on the “*McGhee Principle*” he would be able to recover damages.

However, consideration of the medical cases shows that this is seldom the case. There are two primary constraints on the *McGhee Principle* as applied in this area. Firstly, the principle does not remove all the evidential hurdles in the pursuer’s path: while *McGhee* sets out circumstances whereby a *causa sine qua non* may be elevated to the status of *causa causans*, it is still necessary for the pursuer to prove causation at least to the extent of proving that the breach of duty of care was a *causa sine qua non*. A modern interpretation of *Barnett* would be that the failure to treat was not shown to have even such a *de minimis* effect on the ultimate harm, but the rule is better seen in *Kay’s Tutor v Ayrshire & Arran Health Board*<sup>197</sup>. A unanimous Inner House and unanimous House of Lords overruled the Lord Ordinary and denied recovery following a dispute over causation, negligence having been admitted. A massive overdose of penicillin was administered to a two year-old with meningitis, who was later found to be profoundly deaf. Medical evidence was that meningitis could (and often did) cause deafness; there was no evidence at all as to whether a penicillin overdose could cause it. The House of Lords held that reliance on the *McGhee* principle was only possible if there was evidence to make the breach of duty of care a *causa sine qua non*. If such evidence were lacking, then *McGhee* could not create it.

Insofar as *Kay’s Tutor* proceeded on the narrow evidential point that the effect of the overdose had at best a *de minimis* effect in causing the subsequent blindness, it is nothing more than a tragic illustration of the general rule. However, the later case of *Wilsher v Essex AHA*<sup>198</sup> held that where the breach of duty resulted in circumstances which could give rise to the injury actually suffered, it was still not open to the plaintiff to rely on *McGhee* to exclude the possibility that one of several other possible causes had not been responsible. Insofar as the evidence was split as to whether or not the negligent act was capable of causing the injury, it would have been possible to exclude *McGhee* on the same basis as in *Kay’s Tutor*, namely lack of evidence making the negligent act even a *causa sine qua non*. The judgements, however, do not proceed on this basis.

In analysing the judgements given in the three cases of *Wardlaw*<sup>199</sup>, *McGhee*<sup>200</sup> and *Wilsher*<sup>201</sup>, there is a problem in that much of what is said seems to be internally contradictory. In *Wardlaw*, the House of Lords overruled the lower courts who had

applied an inversion of the normal rules of evidence, *i.e.* they had said that it was for the employer to disprove causation where the breach of duty was in failing to take measures designed to prevent the injury which occurred<sup>202</sup>. The real test was whether the pursuer could prove, on the balance of probabilities, that the breach of duty caused or materially contributed to his injury. The question was not to find the most probable source of the defender's illness, if other factors have a material contribution. The inconsistency is that the court went on to hold that the evidence was sufficient to warrant an inference that the breach of duty had made a material contribution to the injury. This was notwithstanding the finding that the dust caused by breach of duty was a minority factor. Since a presumption of causal connection is sufficient to win an action, the effect is that the defender will be liable unless he can displace this presumption; in other words, the onus is then on the defender to disprove causation, in practice if not in strict theory.

In some ways, *McGhee* is almost indistinguishable from *Wardlaw*, the main difference being that in *Wardlaw* medical evidence was clear that the pursuer's illness could only have been caused by silica dust from his workplace, whereas in *McGhee* the scientific knowledge of the disease was insufficient to do more than highlight factors which tended to increase or decrease its occurrence. However, since the evidence was that the defender's negligence materially increased the risk of the injury occurring, this was sufficient to amount to a material contribution to the injury, and so liability followed. Again, *McGhee* was concerned with cumulative factors, which were not present in *Wilsher* (the choice there being between wholly discrete causes; ultimately, *Wilsher* was sent for retrial because there were insufficient findings in fact to justify a decision either way without inverting the onus of proof). This would again give scope for not applying *McGhee* in *Wilsher*. In *Wilsher*, either the negligent act caused the injury or it didn't; and if it didn't, it had no impact or effect on the factor which actually caused it. The judgement in *Wilsher* (by Lord Bridge, the other four Law Lords concurring) actually proceeds in part on this basis, Lord Bridge adopting part of the dissenting Court of Appeal judgement by Sir Nicholas Browne-Wilkinson VC that

"A failure to take preventive measures against one out of five possible causes is no evidence as to which of those five caused the injury."<sup>203</sup>

However, in so holding he ignores a highly pertinent statement by Lord Kilbrandon:

"When you find it proved (a) that the defenders knew that to take the precaution reduces the risk, chance, possibility or probability of the

contracting of a disease, (b) that the precaution has not been taken, and (c) that the disease has supervened, it is difficult to see how those defenders can demand more by way of proof of the probability that the failure caused or contributed to the physical breakdown." <sup>204</sup>

*Wilsher* has done little to clarify the law on causation, either in medical cases or generally. It appears that *Wilsher* creates a specific departure from the normal tests of causation used in negligence actions and applies a much stricter test of actual proof of agency in medical negligence cases. If this is true<sup>205</sup> then there is one rule for the doctors and one for everyone else: *Wardlaw* and *McGhee* were decided explicitly to assist pursuers facing otherwise insurmountable problems with the evidence, and at the same time to ensure that employers (as the defenders were) could not escape liability just because there was limited scientific knowledge about the risks they exposed their employees to. That these considerations do not apply to pursuers seeking to hold doctors accountable for their mistakes may be an indication of the courts' unwillingness to regulate the medical profession in any systematic way.

Another medical peculiarity concerning causation arose in *Bolitho v City and Hackney Health Authority*<sup>206</sup>. Causation, in general, proceeds on the "but-for" basis: but for your negligence, I would not have suffered the injury I suffered. In *Bolitho*, the issue revolved on the following points: but for the negligence of the attending doctor (actually the non-attending doctor, which was admitted to be negligent), the patient would have received medical treatment. However, the treatment which (hypothetically) would have been given is treatment according to the *Bolam* standard. If, at that stage, it would have been reasonable (*per Bolam*) for the attending doctor not to have given a particular life-saving course of treatment, then the plaintiff will have failed to prove causation. Had the doctor attended and followed a reasonable course of action, the injury would still have been suffered. Viewed in this light, there is little difference between *Bolitho* and *Barnett*. The difference is in the subtle point that an equally respectable body of medical opinion would have treated on attending, thus averting the injury. Under normal rules of causation, this question would fall to be determined by asking the purely factual question of whether those who would, but for their negligence, have attended the patient, have carried out the treatment. By applying the *Bolam* test to this question (i.e. by asking whether a reasonable body of medical opinion would have withheld the treatment, rather than whether those who should have treated would have done so), *Bolam* has been extended into a new area. Yet again, the rules for medical negligence appear to be different from those applicable elsewhere.

A final point on causation concerns loss of a chance of recovering from illness or injury: supposing the negligence complained-of did not cause harm, but merely deprived the pursuer a chance at being healed or cured? The normal rules of recovery prevent the courts awarding proportionate damages based on the chance of recovery which has been lost (e.g. awarding 50% of the damages normally awarded if there were only a 50% chance of effecting a cure)<sup>207</sup>. Note that in the reverse situation, where you sue for possible future complications, there is the possibility of seeking provisional damages, referred to *supra*, which reduces the likelihood of either seriously over- or under-compensating a patient<sup>208</sup>. However, when the incident complained-of has robbed a person of a chance of recovery, then the complications have already arisen and the crystal ball-gazing conducted by the courts is the retrospective one of whether, with proper treatment, the injury or illness could have been cured or avoided. The courts in such a case decide the issue purely on the basis of balance of probabilities: if proper treatment would have afforded a greater than 50% chance of success, you are entitled to full damages<sup>209</sup>; if the chance would have been less than 50%, you get nothing.<sup>210</sup> It was pointed out in the Court of Appeal that this would render doctors immune from suit for failing to treat in any case where the chances of success were less than 50%<sup>211</sup>, but this reasoning failed to persuade the House of Lords.

It is worth noting in relation to “lost chance” cases that proportionate damages are payable under claims for breach of contract. Thus, for example, a solicitor negligently handling a case which had a 60% chance of success would have to pay compensation amounting to 60% of the damages which could have been won<sup>212</sup>. Thus, private patients suing under contract have a chance of recovering damages which their counterparts treated (or not treated) on the NHS are denied. This would seem to be out of keeping with the series of decisions noted earlier extending the liability of health authorities for their employees, and the law would seem to be in need of reform. The House of Lords left open the wider question of whether a less than 50% chance could ever found an action in tort; the general consensus seems to be that it could, but only in unusual circumstance<sup>213</sup>.

As noted above, deterioration in the patient may raise a *prima facie* case of negligence. The patient must still positively prove causation. However, the courts may be willing to infer certain facts in the absence of evidence in such cases; once you have established *prima facie* negligence, all you have to do is bring it home to the defender<sup>214</sup>; however, notwithstanding Professor Walker’s comments above, it seems improbable that simple deterioration in a patient’s condition would raise the inference of negligence in medical

cases, since so many ill people deteriorate even with the best possible medical care. A stricter form of inferred negligence arises under the doctrine of *res ipsa loquitur* - literally, that things speak for themselves. Initially this meant simply that the defender was obliged to explain what had happened. The current rule is that, if *res ipsa loquitur* applies, then the facts raise such an inference of negligence that the defender is obliged to explain how the event could have happened. In the absence of such an explanation, the court will find for the pursuer<sup>215</sup>. *Res ipsa loquitur* applies as follows:

"When the thing is shown to be under the management of the defendant or his servants and the accident is such as in the ordinary course of things does not happen if those who have the management use proper care, it affords reasonable evidence, in the absence of explanation by the defendants, that the accident arose from want of care."<sup>216</sup>

The classic example of *res ipsa loquitur* is when, for instance, a barrel falls out of the defendant's warehouse and lands on the plaintiff<sup>217</sup>. It follows that since deterioration can occur in medical cases without want of care, that the doctrine has limited applicability to medical cases. Thus, even leaving a swab in a patient will not necessarily always raise a presumption of negligence<sup>218</sup>. The leading description of how *res ipsa loquitur* applies in a medical case is surprisingly by Lord Denning<sup>219</sup>:

"If the plaintiff had to prove that some particular doctor or nurse was negligent, he would not be able to do it. But he was not put to that impossible task: he says, 'I went into hospital to be cured of two stiff fingers. I have come out with four stiff fingers and the hand is useless. That should not have happened if due care had been used. Explain it, if you can.' I am quite clearly of the opinion that that raises a *prima facie* case against the hospital authorities... They have nowhere explained how it could have happened without negligence... They have not therefore displaced the *prima facie* case against them and are liable in damages to the plaintiff."<sup>220</sup>

Of course, having raised the presumption of negligence against the defendant is not the same as saying the plaintiff has won, and if the defendant is able to adduce evidence either disproving negligence<sup>221</sup> or else suggesting a non-negligent explanation which was as likely to have been the cause of injury as negligence<sup>222</sup>, then the presumption will have been rebutted and, barring further evidence, the plaintiff will be unable to recover. Another possible reason for the relative scarcity of *res ipsa loquitur* in the decided cases

is that the maxim generally only applies where there is informational asymmetry in the case, *i.e.* the defender knows what happened and the pursuer doesn't<sup>223</sup>. The doctrine of *res ipsa loquitur* was considerably expanded by the American courts in the 1970s, which was one factor in the "malpractice crisis" there - to the extent that 10 states have legislation barring or restricting the application of the rule in medical cases<sup>224</sup>. The considerably more restricted version of the doctrine applied in British courts is another factor suggesting that fears of an impending malpractice crisis in the UK are unfounded.

## VI: Patient Consent to Treatment:

You go to see a doctor. The doctor gives you an injection. *Quid iuris?* On the bald facts as outlined here, the doctor has committed an assault and may be liable to both criminal and civil sanctions at the patient's behest. If a doctor invades your bodily integrity then, in the absence of other factors, he is committing an assault<sup>225</sup>. The civil law of assault does not require *mens rea* to be present in order to establish guilt/liability<sup>226</sup>. Consequently, good intentions (the opposite of *mens rea*) do not constitute a defence to an action for assault. This is true even of medical treatment given without consent<sup>227</sup>; the classic quote on this is by Cardozo J:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent, commits an assault."<sup>228</sup>

In this context, the language of autonomy (*i.e.* the right to decide what happens to your own body) features largely in Anglo-American judgements. This is shown in the most explicit terms in the judgement of Butler-Sloss LJ in *R v Collins and Others ex parte S*<sup>229</sup>, where she stated that

"Even when his or her own life depends on receiving medical treatment, an adult of sound mind is entitled to refuse it. This reflects the autonomy of each individual and the right of self determination."<sup>230</sup>

The quality of information to be given is considered below in the context of medical negligence. For the purposes of assault liability, however, the view expressed in *Chatterton v Gerson*<sup>231</sup> that, in order for "consent" given by a patient to bar an action for assault, the patient must be "informed in broad terms of the nature of the procedure which is intended" remains true. Given the broad general consent forms routinely used

in the NHS<sup>232</sup>, the practical upshot of this is that, unless the consent was either for a totally different treatment altogether (e.g. a hysterectomy conducted instead of minor gynaecological surgery<sup>233</sup>) or was obtained by fraud or misrepresentation<sup>234</sup>, then no action for assault will lie and the aggrieved patient must sue instead in negligence. Consent obtained by duress is of no validity, and the same holds true for a withdrawal of consent<sup>235</sup>. Treatment of someone who has mental sufficient mental capacity and refuses treatment will, however, be actionable: *B v An NHS Trust*<sup>236</sup>. This case lays down an important set of procedural guidelines to be followed in cases where an apparently-competent patient refuses life-saving or life-continuing treatment<sup>237</sup>.

### **A: Where Consent Cannot Be Given:**

As seen above, a doctor must secure his or her patient's consent before treating them in order to avoid liability for battery or assault. However, there are three areas where it may be problematic to obtain consent from the patient himself before embarking on treatment. These are children, the mentally incompetent, and in cases of emergency. The related issue of whether soldiers and prisoners, for instance, are capable of giving a genuinely voluntary consent is more a question of the quality (as opposed to the existence) of consent, and is discussed under the heading of negligence. It should be noted, however, that a "consent" which is extorted is generally wholly void.<sup>238</sup>

#### 1: Emergencies:

As we have seen, there may not be any duty incumbent on a doctor to treat a patient in an emergency situation. But if the doctor acts the Good Samaritan, will he be liable simply for failing to have secured the (unconscious) patient's consent first? There are two alternative possibilities here. The first consists of the "classic" emergency, where the patient's entry into medical care may well be in an ambulance while unconscious. In the second situation, the patient is undergoing surgery (which he or she has consented to) when the surgeon discovers an unrelated life-threatening condition which was previously unknown.

The law appears to be that in a genuine emergency, the surgeon is permitted to take immediate action. One older case justified such intervention on the grounds of "tacit consent", *i.e.* that if the patient could have seen what the surgeon could see, then she would have consented to the further treatment<sup>239</sup>. This idea found some recent support in the Court of Appeal, which took the general notion that normal everyday contact is inactionable and extended it as applying to emergency treatment<sup>240</sup>. This approach was

criticised by Butler-Sloss LJ (as she then was) in the Appeal Court stage of *Re F (mental patient: sterilisation)*<sup>241</sup>; she preferred to justify the intervention on the grounds of public policy. Lord Goff in the House of Lords preferred to justify it by permitting a defence of necessity<sup>242</sup>. Brazier makes the point that the distinction has significant evidential implications, since if consent is implied then, following *Freeman v Home Office*<sup>243</sup> it is for the patient alleging lack of consent to prove that they did not do so; if intervention is based on a defence of necessity, then it is for the surgeon to prove the defence<sup>244</sup>. The upshot, however, is that if the action is both necessary and cannot be reasonably delayed, then no liability will follow<sup>245</sup>. The specific problems raised by the issue of whether or not to give life-saving blood transfusions to a devout Jehovah's Witness who is unconscious have not been addressed by the British courts. The issue was raised in a Canadian case, which found the emergency transfusions to be unlawful and awarded substantial damages<sup>246</sup>.

The foregoing principles apply equally to "discovered" emergencies, *i.e.* emergencies arising in the course of other medical treatment. "Discovered" emergencies differ in only two respects. Firstly, within the NHS the standard consent form for surgery specifically authorises the surgeon to carry out any additional procedure if it is necessary for the patient's best interests and can be justified for medical reasons<sup>247</sup>. Again, the legal effect of this part of the form has not been tested in court. As regards Jehovah's Witnesses, the next part of the form specifically requests the patient to advise of any procedures which he or she does not wish carried out. If this part of the form is given effect, it would in practice bar the doctor from giving emergency transfusions if the patient had previously stated such opposition. If they had not, when specifically asked to do so on the form, there may be a presumption that the patient, despite being a Jehovah's Witness, did not in fact object to the use of blood products.

## 2: Children:

This section is exclusively concerned with England, since the law in Scotland has been placed on a statutory footing and is therefore considered in Chapter 6. Although the age of majority in Britain is eighteen<sup>248</sup>, in general the crucial age for medical purposes is sixteen. At 16, a person is presumed capable of consenting to treatment on their own behalf (and at best their parents have a very limited right to consent for them<sup>249</sup>) and has the right to be registered with a GP<sup>250</sup>. For children under 16, however, the situation is somewhat more complicated. The *Gillick* case<sup>251</sup> was principally concerned with the right (or otherwise) of children under 16 to receive contraceptive advice and treatment. More generally, it establishes that



"Provided the patient, whether a boy or a girl, is capable of understanding what is proposed and of expressing his or her own wishes, I see no good reason for holding that he or she lacks the capacity to express them validly and effectively and to authorise the medical make the examination or give the treatment which he advises."<sup>252</sup>

Lord Scarman referred to the fact that

"...parental right yields to the child's right to make his own decisions when he reaches sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision."<sup>253</sup>

Thus, if a child under 16 is capable of understanding the treatment proposed, he or she may validly consent without the parents being involved. If the child fails to satisfy the *Gillick* test for competence, then it is for the parent (or person with parental authority) to make the decision for the child.

In terms of regulation, then, the upshot of the *Gillick* case is to impose on doctors a duty to satisfy themselves of the child's competence before accepting their consent as valid (and additionally, in the case of contraception, for the doctor to be satisfied that the girl will have, or continue having, sexual relationships regardless of contraception, plus certain other criteria<sup>254</sup>).

Two problem areas remained unresolved by *Gillick*. First, what if the parents of a "*Gillick*-incompetent" child withhold consent to treatment where such treatment is in the child's best interests? In *Re J (a minor)(medical treatment)*<sup>255</sup>, the court held that parental rights, and particularly those exercised by the courts under their inherent jurisdiction, must be exercised solely in the best interests of the child. Thus, where the parents object to treatment which is necessary, the court can overrule their objection and consent on the child's behalf<sup>256</sup>.

Secondly, can a parent overrule the objections of a child who is under 16 but competent? *Gillick* held that the child's consent overrules parental objections; is the converse true? The issue arose in the case of *Re R (a minor)(wardship: medical treatment)*<sup>257</sup>. This case concerned a 15 year-old who suffered from a psychotic disorder of a fluctuating nature. During apparently lucid intervals, when she appeared to be

*Gillick* competent, she refused to consent to being given anti-psychotic medicaments. In his judgement, Lord Donaldson MR held that *Gillick* did not apply, and that while a competent child could of her own volition consent to treatment, this did not remove the right of the parent (or the court, acting *in loco parentis*) to override a refusal to consent<sup>258</sup>. This directly contradicts statements in *Gillick* to the effect that a competent child patient acquires the right to decide whether to accept *or refuse* treatment. Lord Scarman, for instance, specifically stated that

“... the parental right to determine whether *or not* their minor child below the age of 16 will have medical treatment terminates if and when the child achieves a sufficient understanding to enable him or her to understand fully what is proposed.”<sup>259</sup>

In *Re R*, Farquharson and Staughton LLJ reached the same result as Lord Donaldson MR by adhering to *Gillick* by holding that, looked at in the wider context, the girl R was not, in fact, *Gillick* competent at all. This meant that the court was empowered to give its consent on her behalf, without having to override an otherwise-valid refusal by a competent patient - which the courts in general will not do: it is a consistent feature that competent persons have the right to be wrong, and a court will not (Lord Donaldson apart) substitute its own decision just because it disagrees with the patient<sup>260</sup>. The position of allowing competent refusal to be overridden has been criticised as illogical<sup>261</sup>.

### 3: The Mentally Incompetent Patient:

This thesis is primarily concerned with adult, competent patients. However, it will be necessary here briefly to describe the ways in which the presumption of competence may be rebutted. This section in effect asks when and in what circumstances a doctor is or is not entitled to take the consent (or refusal) of an adult patient at face value. As with children, Scots law on this topic has been placed on a statutory basis and is considered in Chapter 6.

The law presumes that at 16 a person is fully competent (as regards medical treatment<sup>262</sup>), although this presumption too may be rebutted. Until recently there was no authoritative legal test for incompetence<sup>263</sup>, and until fairly recently there were no judicial guidelines on this point at all. While *Gillick supra* established a general test of competence in under-16s, there is no suggestion that the converse is true, *i.e.* that failure to understand the general nature and purpose of what is intended rebuts the

presumption of adult competence. However, as will be seen, it may be that this is the actual situation. The problem is compounded by the fact that, even in cases relating to authorising treatment for incompetent patients, the issue of competence itself is seldom, if ever, actually addressed. Until recently the courts had inquired into the person's capacity in only one case; the case formulated no general rules<sup>264</sup>.

Capacity is not a binary concept, which persons either have or not. Thus, in *The Estate of Park*<sup>265</sup> it was held that Mr Park had had sufficient capacity to marry, but insufficient capacity to make a valid will. It follows from this that any test of capacity must be flexible. The classic work by Roth, Meizel and Lidz lists five possible such tests, but most illuminatingly they note that

"It has been our experience that competency is presumed as long as a patient modulates his or her behaviour, talks in a comprehensible way, remembers what he or she has been told, dresses and acts so as to appear to be in meaningful communication with the environment, and has not been declared legally incompetent."<sup>266</sup>

Thus, if a person appears reasonable, competence will be presumed. However, one of the factors which a doctor will take into account in deciding how "reasonable" a patient is whether or not the patient actually consents to the treatment the doctor is proposing. As seen above, a consent will vitiate assault, *i.e.* be legally valid, if the patient is "informed in broad terms of the nature of the procedure which is intended"<sup>267</sup>. It has been argued that from this it follows that the legal test of capacity is that the patient must simply be capable of understanding the general nature and purpose of an intervention<sup>268</sup>. The issue of capacity was central in the case of *Re W (a minor) (medical treatment)*<sup>269</sup>. The Court of Appeal, however, failed to clarify the tests which they were applying in finding W competent (before overruling her refusal to consent). The case does, however, establish that *Gillick* does not establish a universal test of competency applicable to adults as well as children, notwithstanding claims to the contrary.<sup>270</sup>

Guidelines on adult tests of competency can be found in the decision in *Re C (adult: refusal of treatment)*<sup>271</sup>. Thorpe J came down on the side of actual understanding, rather than merely being capable of understanding, the nature, purposes and effects of the treatment in question. The approach of Thorpe J was followed more recently in *Re JT (adult: refusal of medical treatment)*<sup>272</sup>. The court in that case applied the tests of considering whether the patient understood the information given as to the purpose and

nature of the treatment, whether she believed that information, and whether she realised the consequences of refusing treatment. Interestingly the patient in question was detained under the Mental Health Act 1983, but the fact that the patient was suffering from a degree of mental disability justifying her compulsory detention created no presumption of incompetence to make decisions concerning treatment<sup>273</sup>. Most recently, *B v An NHS Trust*<sup>274</sup> lays down a series of procedural steps to be followed before a patient's refusal to consent should be overruled; this involves medical opinions (on the basis of the test established in *Re MB*<sup>275</sup>: inability to comprehend the information, and in particular the consequences of refusal, or inability to use the information and weigh it in the balance) with the presumption of capacity emphasised and resort to court only in cases where difficulties cannot be resolved even after bringing in independent experts).

In *Re F*<sup>276</sup>, the House of Lords held that no court had jurisdiction to give or withhold consent to an operation (in this case therapeutic sterilisation); however, the court did have jurisdiction to declare an operation lawful notwithstanding the absence of consent. To be lawful, the operation should be in the patient's best interests - either lifesaving, or necessary to ensure improvement or prevent deterioration in the patient's health (including mental health), and in accordance with a responsible body of medical opinion. The test for determining the "best interests" was the standard *Bolam* test<sup>277</sup>, notwithstanding that test's origin as a means of measuring professional competence.

Precisely why "best interests" and professional competence should have been rationalised in this way is unclear. In any event, leaving the issue to the doctors, as the court in *Re F* does, cannot be regarded as effective scrutiny of the medical profession in this area - a point which even some judges have expressed misgivings about<sup>278</sup>. However, the application of the *Bolam* test to "best interests" was criticised in *SL v SL*<sup>279</sup>. At first instance<sup>280</sup>, the High Court (Wall J) held that as two possible courses of treatment were lawful, *per* the *Bolam* test, it was for the mother and doctors to decide between them which course to follow. This was reversed by the Court of Appeal; Thorpe LJ holding that *Bolam* "has no contribution to make to this second and determinative stage of the judicial decision." [i.e. best interests]<sup>281</sup>. Similarly, in the same case Lady Butler-Sloss P reiterated her view that it "...falls to the judge to decide whether to accept or reject the expert medical opinion that an operation is, or is not, in the best interests of a patient"<sup>282</sup>. The procedure to be followed in cases where the patient may lack capacity were laid down in detail by the Court of Appeal in *St George's Healthcare NHS Trust v S*<sup>283</sup>. In terms of this procedure it is not always necessary to apply to the court (although it appears to be necessary to notify the Official Solicitor), so notwithstanding the

assertion of judicial control in *SL v SL*<sup>284</sup>, the *Bolam* test will still tend to exert a strong influence on the outcome.

### **B: Consent to treatment and negligence liability:**

As has been discussed above, the doctor must secure his patient's consent before treating or examining him or her (or else be within one of the recognised exceptions to that rule) to avoid liability for assault. For such consent to be effective in avoiding assault liability, the patient must be "informed in broad terms of the nature of the procedure which is intended"<sup>285</sup>. This, however, is far from the end of the matter, since there still exists, quite apart from liability for assault, the possibility of raising an action in negligence. *Chatterton v Gerson*<sup>286</sup> saw a judicial policy decision that cases of alleged inadequacy as to information and warnings are more properly argued in negligence than assault, and this has been a characteristic of judicial decisions in this field<sup>287</sup>. From the patient's point of view, the key point in all this is that a lesser degree of non-disclosure may still give rise to an action in negligence, even though an assault action fails.

The basic principle underlying such actions is that the doctor, in failing to provide relevant information (usually regarding the risks or side-effects) about the proposed intervention, breached his duty of care to the patient - specifically, his duty to inform the patient prior to obtaining his consent, and is consequently liable in damages. However, since judicial policy has restricted the use of assault actions in these cases, it follows that the aggrieved patient must pass the normal hurdles present in any negligence action - namely, the existence and subsequent breach of the duty of care, and causation.

The existence of a duty on the doctor to inform his patients of attendant risks is implicit in *Chatterton v Gerson*, and is relatively uncontentious nowadays. Problems arise, however, in trying to delimit the ambit of this duty of care, and, more specifically, in deciding whether it has or has not been breached. Traditionally, English law (but not Scots) decided the issue on the basis of normal medical practice; *Bolam v Friern HMC* was itself concerned with failure to disclose, as well as with negligence in the actual treatment. On this basis, a doctor would only be liable for having failed to disclose information which no reasonable doctor using ordinary skill would have failed to disclose. However, this is subject to the criticism that giving a patient sufficient information to make an informed choice as to treatment options is not really a medical decision at all, and that consequently liability for non-disclosure of information should not be decided on the same basis as liability for negligence in diagnosis and treatment. This criticism gave

rise, in a number of overseas jurisdictions, to what has become known as the "doctrine of informed consent"<sup>288</sup>. "Informed consent" actually embodies a number of distinct themes and is not a unitary concept<sup>289</sup>; its key features are as follows:

"The principle of informed consent requires that health professionals, before any diagnostic or therapeutic procedure is carried out which may have a reasonable possibility of harm to the patient, explain to the patient what is involved in order to secure the understanding of the patient to proceed."<sup>290</sup>

Crucially, respect for patient autonomy meant that the test of how much information should be given was set by the court, not by the medical profession<sup>291</sup>. The alternative test created in *Canterbury v Spence*<sup>292</sup> (and subsequently adopted by around one-third of US jurisdictions<sup>293</sup>) was to apply a "prudent patient" test: what would a "prudent patient" in the plaintiff's shoes want to know? A similar test has been applied by the Supreme Court of Canada<sup>294</sup>. "Informed consent" applies a new test for establishing breach of duty of care; but in order for a claim to succeed, the patient must still show causation.

Causation in information negligence cases proceeds on the traditional "but-for" basis. In this context, what it amounts to is showing that not only was the doctor negligent in not informing you of the risks, but also that if you had been so informed, you would have refused to undergo the treatment. The courts are reluctant to accept evidence to this effect at face value, and so a further test is usually applied in assessing the plaintiff's testimony<sup>295</sup>. It follows that if you can prove you would have refused to consent had you been properly informed, the doctor will be liable for any injury resulting from the procedure – even ones you were warned of – as you wouldn't have been exposed to any risks if fully informed<sup>296</sup>

In *Sidaway v Board of Governors of the Bethlem Royal and the Maudsley Hospitals*<sup>297</sup>, the House of Lords resoundingly rejected informed consent in English law (Lord Scarman dissenting). The exact content of the decision in *Sidaway* is unclear, as there are four separate judgements, not all consistent with each other. This has caused some disagreement among commentators as to the true extent of the judgement<sup>298</sup>. While there are indications in the judgements in the case that the *Bolam* test should be modified in certain respects in information disclosure cases, subsequent English cases have given it a restrictive interpretation<sup>299</sup>, and the current law seems to be an almost-blanket application of an unmodified *Bolam* test. Only a few cases have found accepted medical practice concerning disclosure insufficient in law<sup>300</sup>. These decisions were at

first instance; the Court of Appeal has displayed a tendency of overturning High Court judges' attempts at utilising *Sidaway* loopholes<sup>301</sup>.

In Scotland, the starting point was that unlike *Bolam, Hunter v Hanley*<sup>302</sup> only ever applied a professional standards test to diagnosis and treatment, not to disclosure. Consequently, it was at least theoretically possible for a Scottish court, even after *Sidaway*, to reach a different conclusion. However, in *Moyes v Lothian Health Board*<sup>303</sup> Lord Caplan, facing the issue head-on, held that *Sidaway* applied an unmodified *Bolam* test – and proceeded to do the same himself.

“...I can read nothing in the majority view which suggests that the extent and quality of warning to be given by a doctor to the patient should not in the last resort be governed by medical criteria.”<sup>304</sup>

In *Goorkani v Tayside Health Board*<sup>305</sup>, the pursuer failed on the grounds of lack of causation to recover damages for the infertility he suffered (an undisclosed side-effect of the treatment) as the judge was not satisfied that he would have refused the treatment even if informed. However, he still recovered £2500 damages for the shock and distress of finding out about the infertility without prior warning. This illustrates at least one way in which the courts are increasingly intervening, within the constraints imposed by *Sidaway*, to provide a remedy in cases of information negligence<sup>306</sup>.

The upshot of the decided cases on consent in Britain leads to the conclusion that the courts are unwilling to apply different standards to a doctor's duty to take reasonable care in diagnosis and treatment (which are specifically medical technical skills), and his duty to inform his patient and get their consent, which is arguably not a technical decision at all. Certainly fears that informed consent could be used as a tool to expand the negligence liability of physicians<sup>307</sup> appear to be misplaced<sup>308</sup>. Informed consent itself can be criticised for imposing an objective standard rather than asking what the actual subjective patient would want<sup>309</sup>.

Another drawback is that most “informed consent” tests continue to recognise an exception to the normal rules known as “therapeutic privilege”. This exception means that if certain information would be harmful to the patient, then the doctor is entitled to withhold that information. Therapeutic privilege (which has been described as “vastly overused” in practice<sup>310</sup>) is determined on the basis of professional practice; but, as has been noted,

“In taking it upon himself to determine what will be most beneficial or least harmful to this patient, the physician is not simply making ill-founded medical judgements which might someday be confirmed by psychiatric research. He is making moral evaluations of the most basic and problematic kind.”<sup>311</sup>

The upshot of these rules would seem to indicate that, unless and until *Sidaway* is overruled or medical practice changes so much as to render it obsolete, that the negligence action for inadequate counselling and information disclosure is destined to remain very much an underdeveloped and unsatisfactory area of medical law; indeed, it has been argued that for an action to succeed, there would have to be sufficiently poor information as to be susceptible to an assault action<sup>312</sup>. Nor can informed consent be advocated as a suitable route forward, although continental-style patient-based "materiality of risks" tests have much to commend them<sup>313</sup>. The courts' current regulation of this issue has been seriously unbalanced in favour of doctors.

## **VII: Confidentiality and verbal injury:**

### **A: Basic rules of confidentiality:**

The law of confidentiality is relatively underdeveloped in both Scotland and England; a number of the problems inherent in this field became apparent in the litigation surrounding Peter Wright's book *Spycatcher*<sup>314</sup>. The problems in this area of the law have led both the Law Commission<sup>315</sup> and the Scottish Law Commission<sup>316</sup> to suggest major statutory amendments to the common law. At the time of writing, neither proposal has been the subject of legislation. It should be recalled, however, that the implementation of the Data Protection Act 1998 and Human Rights Act 1998 (both considered in Chapter 6 *infra*) have had a major impact on the law as it relates to privacy and disclosure of information. Most of the recent cases involving breach of confidence have also argued breach of data protection rules, and are accordingly considered in Chapter 6 *infra*; the following discussion concerns the preceding common law position.

However, in spite of the complexity of the law in this area, it will be dealt with relatively briefly since the major regulatory actor here is not the courts, but rather the GMC. The reasons for the GMC's primacy here are twofold: firstly, the GMC imposes a greater duty of confidentiality on a doctor than the law does<sup>317</sup>. Secondly, as will be seen below, the law of confidentiality in medical matters is largely only useful proactively, *i.e.* to obtain an injunction or interdict preventing a threatened breach of confidence from arising; if



breach of confidence has occurred, it can prove exceedingly difficult to actually win substantive damages. This alone can act as a major disincentive to litigation, and may partly explain the relative paucity of cases in this field. The fact that Legal Aid is not available for actions of "verbal injury" may also have an impact. However, there is considerable interdependence between law and ethics in this area: *X v Y*<sup>318</sup> and *W v Edgell*<sup>319</sup> both considered the GMC's guidance to doctors on confidentiality in reaching a decision, and the GMC correspondingly accepts that there is no ethical breach of the duty of confidentiality where such breach is required by law<sup>320</sup>.

The medical duty of confidentiality has its origins in the Hippocratic Oath. The important question is how this ethical obligation, repeated in some form in all the modern variations of the Hippocratic Oath<sup>321</sup> translates into law.

The answer to this question is complicated by the slightly unusual historical origins of the action for breach of confidence. The Scottish Law Commission are of the opinion that early cases on the point in Scotland, while looking delictual in character, were in fact based on breach of common law copyright<sup>322</sup>. The Commission accepted the existence of a delictual duty here, but could reach no firm conclusion as to whether this arose as a result of a prior relationship of confidentiality between the parties, or could arise circumstantially<sup>323</sup>. The Commission's proposals favour the latter approach<sup>324</sup>, but since in the medical sphere there clearly is a pre-existing relationship of confidentiality, we can conveniently ignore this problem.

In England, the case law begins with the equitable presumption that "he who has received information in confidence shall not take advantage of it."<sup>325</sup> Equitable remedies, in particular the injunction, were available; following Lord Cairns' Act of 1858 damages could be awarded by the Chancery courts, as well as the equitable remedy of accounting for profits. However, in the medical sphere there will seldom be any profits to account for. The courts have also entertained actions for breach of confidence based on an implied contractual term<sup>326</sup>, which has led to some uncertainty as to the courts' jurisdictional base. The courts have been prepared to intervene irrespective of, and occasionally acknowledging, this uncertainty<sup>327</sup>. The duality of approach was summarised by Lord Keith in the *Spycatcher* case as follows:

"The obligation may be imposed by an express or implied term in a contract, but it may also exist independently of any contract on the basis of an equitable principle of confidence."<sup>328</sup>

This was based on a general principle that an invasion of personal privacy may be sufficiently serious to justify the law's intervention<sup>329</sup> and may therefore extend to third parties. Lord Keith quoted with approval the following:

"...in common with other professional men, for instance a priest... and there are of course others, the doctor is under a duty not to disclose (voluntarily) without the consent of his patient, information which he, the doctor, has gained in his professional capacity... save in very exceptional circumstances."<sup>330</sup>

Much more recently, it has been held that confidentiality can arise even in the absence of *any* pre-existing relationship between the parties, as when a reporter sees a supermodel entering a drug rehabilitation clinic<sup>331</sup>, although this case was post-Human Rights Act and so this development (which has been severely criticised as doing damage to the law of confidentiality<sup>332</sup>) is considered in more detail in Chapter 6. It is however clear that, whatever the legal genesis of the action, the law will act to uphold confidentiality, and that such confidentiality definitely extends to the doctor-patient relationship. The question then becomes, in what circumstances does the law permit this obligation to be breached?

#### **B: Exceptions to the Duty of Confidentiality:**

At one extreme, Kattow, writing from a German perspective, has argued for an absolute defence of medical confidentiality without any exceptions whatsoever<sup>333</sup>, claiming that legally-imposed disclosure risks turning doctors into political informers. However, it is clear that this is not the law in Britain. In its ethical guidance to doctors, the GMC allows exceptions to the rule of confidentiality in a number of circumstances including patient consent, sharing with other members of the health care team, where required by law or, most problematically, where disclosure is in the public interest. Some of these points require comment.

While it would seem unobjectionable that other health care professionals involved in a patient's care should have access to their health records, problems arise when non-professionals have such access - such as health service managers<sup>334</sup>. This has led to the creation of "Caldicott Guardians"<sup>335</sup> who are responsible for ensuring that medical information in the NHS is not misused; Caldicott Guardians are typically the medical director, or a similarly high-ranking clinician, of the NHS body in question.

Secondly, doctors enjoy no legal privilege entitling them to refuse to give evidence<sup>336</sup>, unlike lawyers<sup>337</sup>. There are also a large number of statutes require disclosure. These cover a huge variety of areas ranging from notification of infectious diseases<sup>338</sup> to informing the authorities of possible terrorist involvement<sup>339</sup>. As a statutory requirement, disclosure under this heading gives rise to no particular legal problems, but some may find the inroads made into the sanctity of the doctor-patient relationship to be excessive.

The most problematic area, however, remains the public interest exception - which in general only permits, rather than requires, the doctor to breach confidentiality<sup>340</sup>. In these cases, it is therefore the doctor who decides whether or not to breach the patient's confidences. What is the law's reaction if he does so?

Historically, judges equivocated between regarding the doctor who informed the police of a patient's crime as having acted cruelly<sup>341</sup> and holding that the investigation of serious crime always entitled a doctor to breach confidence<sup>342</sup> on the basis that since "there is no equity in the disclosure of iniquity"<sup>343</sup>, equitable remedies could not be sought in such cases. The case of *Lion Laboratories Ltd v Evans*<sup>344</sup> held that the public interest defence was not limited to situations of disclosing criminal activities if it were "vital in the public interest to publish a part of his confidential information"<sup>345</sup>. This overruled (or denied the existence of) the so-called "iniquity rule".

Two cases show the extent of the current exception to confidentiality in the public interest<sup>346</sup>. Firstly, *X v Y*<sup>347</sup> saw Rose J performing, in his own words, either "a balancing exercise, or an exercise in judicial judgement, or both"<sup>348</sup> in deciding whether or not to allow a newspaper to identify two GPs who were HIV-positive. The newspaper had acquired the information through a breach of confidence by Health Authority staff, with the newspaper's active collusion. Rose J held that there was a public as well as a private interest in the maintenance of medical confidentiality, and went on to find that this outweighed the public interests in freedom of the press and of actually learning who the affected doctors were. He consequently granted a permanent injunction against publication. More recently, the ongoing litigation in *H v Associated Newspapers Ltd*.<sup>349</sup>, also involving a healthcare worker, H, who is HIV positive, also challenged the legality of a proposed "look-back" exercise by which the health authority proposed to notify H's patients that they had been exposed to an infection risk. The Court of Appeal upheld a prohibition on publication of details which would allow H to be identified, but ordered him to make available to the health authority such records as might reasonably be required for the look-back exercise, if that exercise is carried out (the legality of this was remitted back to the High Court and at time of writing had not been determined). The disclosure

of these records was explicitly on the basis that they were not to be further disclosed or any action taken on the basis of them until the issue had been determined.

*W v Edgell*<sup>350</sup> is perhaps more typical of the sort of predicament which may face a doctor contemplating breaching confidentiality in the public interest. Dr Edgell, the defendant, was asked to prepare a psychiatric report on W with a view to having W transferred out of a secure hospital. The report was unfavourable. Without W's consent, Dr Edgell forwarded it to the Secretary of State and hence to the Tribunal deciding the issue. The Court of Appeal refused the claim, but disagreed with Scott J at first instance that W's private interest was the main issue to be balanced: it was the competing elements of the public interest which mattered. Dr Edgell had acted entirely properly since he had disclosed the information to the appropriate authorities, and not for instance sold it to a newspaper<sup>351</sup>.

### **C: Damages for Breach of Confidence:**

There are a number of problems regarding damages for breach of confidence which, again, are related to the complicated history of the action. This area of the law largely developed around breach of commercial confidentiality, and assumed that there would be some form of economic loss flowing from the harm suffered (and some corresponding gain by another person), for instance the value of a trade secret. This also allows damages to be quantified and profits to be accounted for (or an action for unjustified enrichment to succeed). Thus, in the *Spycatcher* case, Times Newspapers were found to have acted in breach of confidence, and consequently had to account for profits.

However, in most cases of breach of medical confidence there will be no such profit to account for, and no measurable economic loss. Can the patient recover damages for hurt feelings and embarrassment? In *W v Edgell*, Scott J followed *Bliss v South East Thames RHA*<sup>352</sup> in holding such damages to be not recoverable. This led the Law Commission to recommend a change in the law allowing such recovery<sup>353</sup>. However, in *Campbell v MGN Ltd*<sup>354</sup>, damages were awarded for hurt feelings, although the case did not involve a doctor-patient relationship; as noted above this case has been criticised as seriously distorting the pre-existing law of confidentiality. In Scotland, there is also no clear authority on the question of damages. The Scottish Law Commission were of the opinion that they were recoverable, but recommended clarifying legislation<sup>355</sup>.

## D: Verbal injury actions as a way of upholding confidentiality:

A complicating factor in Scotland relates to the co-existence in Scots law of three separate delicts arising from verbal injury. Scots law draws no distinction between (written) libel and (verbal) slander; both are treated under the delict of defamation, which protects "fame, reputation and honour"<sup>356</sup>. This follows the *Lex Aquilia* and allows damages where these arise due to loss of reputation wrongfully caused. However, since *veritas* (truth, or, in English terminology, justification) is a complete defence to such actions<sup>357</sup>, they are accordingly of very limited use in the medical sphere where the harm alleged will usually involve disclosure of true facts. Of course, the existence of the law of defamation imposes an additional duty on the doctor to ensure that the information he discloses is, in fact, true. The *Lex Aquilia*, like English law, requires loss to follow from the defamation before damages are payable. However, Scots law also follows the Roman *actio injuriarum* in allowing action for insult or affront (*contumelia*). Such an action lies for insult irrespective of loss caused thereby, which raise the possibility of winning substantial damages purely for hurt feelings. Again, though, since truth is a defence under the *actio injuriarum* it also has limited applicability here.

But there is another variety of verbal injury action which avoids this restriction. This is the action for *convicium*, based on a Praetorian edict<sup>358</sup> against bringing others into "hatred, ridicule or contempt". There is, however a lively debate among academics over whether such an action for *convicium* is actually part of Scots law<sup>359</sup>. The case of *Steele v Scottish Daily Record*<sup>360</sup> was decided on the basis of *convicium* at first instance, although the issue was not raised on appeal (Counsel having agreed to treat it as a case of verbal injury). The following discussion will assume that the action is competent in Scots law. Its importance here is that it appears that in *convicium*, the maxim *veritas convicium non excusat* applies, so that the truth of the offending statement is no defence<sup>361</sup>. This means if a doctor (whether in breach of confidence or not, and irrespective of justification) divulges information which causes insult or affront to the patient, then an action for *convicium* will lie and damages will be recoverable. Precisely what defences would succeed in avoiding liability in *convicium* is unclear, since by the nature of the delict the communication must be intended to bring the subject of it into ridicule or contempt. From the doctor's point of view, lack of malice is likely to prove an effective defence if the action falls within those categories which would also be covered by the public interest defence in a corresponding breach of confidence case. From the patient's perspective, while this approach would deny a remedy in certain situations, it still has the advantage that if there is no public interest justifying the publication, it would

be far easier to recover damages for *convicium* than for breach of confidence. Secondly, the *convicium* action can succeed without the necessity of having to show the existence of a duty of confidentiality and breach thereof. This may have relevance for disclosure by non-medical personnel having access to medical records. Non-medical personnel are not bound by GMC rules on confidentiality, so it would be highly appropriate for the law to provide a mechanism whereby the victims of such "leaks" could seek redress, and at the same time deter people from making such breaches of confidence in the first place. The *convicium* action could provide such a mechanism.

#### **E: Confidentiality: Special cases:**

The two prime examples here are children and the mentally incompetent. Do they enjoy the same right to confidentiality as the competent adult does? Secondly, does the obligation of confidentiality extend beyond the patient's death?

As regards children, the law seems to be based on an interpretation of *Gillick v West Norfolk and Wisbech AHA*<sup>362</sup>. If this interpretation is correct, then a duty of confidentiality arises between the doctor and child patient if the child has sufficient understanding of the nature of a confidential relationship to acquire the capacity to enter into one<sup>363</sup>. This may not necessarily be the same capacity as that required to consent to examination and treatment<sup>364</sup>. If the child has this requisite capacity, then the duty of confidentiality exists and will be breached if the child's parents are informed. Conversely, if the child is deemed incompetent, then it follows that there is no duty of confidentiality. Problems could arise if the child is incompetent as regards consenting to the treatment in question but competent to form a confidential relationship with the doctor. In such circumstances, the doctor could face an action for breach of confidence from the child patient, as well as possible disciplinary sanctions<sup>365</sup> (action by the parents would only be competent if parental rights have been infringed, which would not be the case here<sup>366</sup>). An action by the child would seem to lie in any case where the breach of confidence could not be justified as for an adult patient<sup>367</sup>, although the chances of success in such an action are probably not high<sup>368</sup>. In any case, a breach of confidence action is only competent where there is a duty of confidentiality, so the doctor's main defence to such an action would say that, in his professional judgement, the minor was incompetent and therefore owed no such duty. Following *Gillick*, it would be hard for a court to deny the logic of this, so to all intents and purposes there is likely to be no chance of a successful breach of confidence action by a minor patient in these circumstances, and child patients are left only with the uncertain protection afforded by medical ethics.

As regards incompetent adults, however, this approach means that there is no legal bar on a doctor disclosing details of a patient who is incompetent, as they are by definition incapable of entering into a confidential relationship. Of course, in the case of adults there is a legal presumption of competence, so if taken to court the divulging doctor would still have to prove his patient's incompetence in order to justify his breach of confidence (or, more accurately, to deny the existence of a duty of confidentiality). However, this analysis (if followed by a court) could still provide no redress for the patient, simply because of his incompetence. This would leave the disciplinary sanctions of the GMC as the only protection for the confidentiality of incompetent patients, and, powerful though these sanctions may be, it would be a highly inappropriate stance for the law to adopt. And for this reason it is submitted that a British court would find this reason unsatisfactory, and instead apply a different approach. This could, for instance, regard the duty of confidentiality as arising automatically in the doctor-patient relationship. In the case of young (*i.e.* Gillick-incompetent) children, there would be an exception requiring the doctor to disclose the information to the parents or guardian. Indeed, since the overriding factor is the child's best interests, there will very often be a positive duty to disclose, particularly with very young children.

The problem issue in this field typically concerns girls under 16 seeking contraceptive advice and treatment, but being worried that the doctor will tell her parents. If the "best interests" test specifically takes into account the fear and embarrassment such a girl will experience, then even a doctor concluding his patient was *Gillick*-incompetent would not have *carte blanche* to inform the girl's parents that she had sought contraceptive or other advice or treatment. This approach could be extended to mentally-incompetent adults, the main difference being that here, there is no-one *in loco parentis* to whom the doctor is entitled to disclose facts about the patient.

As regards the dead, the ethical situation is clear: the WHO Declaration of Geneva<sup>369</sup> states clearly that "I will respect the secrets which are confided in me, even after the patient has died." This is repeated in the GMC *Blue Book*, which states that:

"The fact of a patient's death does not, *of itself* release a doctor from the obligation to maintain confidentiality." <sup>370</sup>

Such ethical constraints reflect the furore caused by incidents like that when Lord Moran, physician to Winston Churchill, published his memoirs which included details of the

wartime Prime Minister's medical history<sup>371</sup>. But the law does not impose such rigorous safeguards. While there seems to be no decided authority for this view, there are two lines of reasoning indicating it. Firstly, by statute<sup>372</sup> a dead person cannot be defamed; by process of analogy this could extend to actions for breach of confidence, since in such an action the estate itself suffers no harm which it is entitled to recover. Secondly, it could be argued that death of the patient ends the relationship of confidentiality, since there is now no-one to whom the doctor can owe the duty; clearly, he owes no duty to the estate or descendants of the deceased, and for an action of positive breach of confidence to succeed, the court would have to be convinced that the duty was owed to society in general, or else that, having acquired the status of confidentiality through being disclosed in the context of such a relationship, the mere termination of that relationship (which may not have been due to the death of the patient) does not of itself change the character of the information so received, which should continue to be protected. An analogy with the situation whereby an ex-employee is not entitled to use confidential information despite no longer being in a relationship of confidentiality may be drawn<sup>373</sup>. However, the problem of damages remains insuperable, and even if such an action were theoretically possible, for all practical purposes it would serve no useful function.

#### **F: Telling relatives:**

It is common practice for doctors to consult with the relatives of patients, particularly those diagnosed as having a terminal illness. The precise legal justification for this is unclear, and may be non-existent. It is arguable (if implausible) that a doctor sued for breach of confidence having discussed a patient's medical affairs with his relatives could plead some form of the public interest defence, in that discussions with relatives are a socially-acceptable, indeed socially highly-approved course of action, and that it would be inappropriate for the courts to reach a decision which tended to inhibit it. More plausibly, it may instead be that the patient's consent to such disclosure is implied or presumed. However, this may simply not be the case; as Newdick says, "The question is very delicate..."<sup>374</sup>.

The pressures on a doctor faced with this problem are conflicting. The law provides scant grounds for justifying disclosure to relatives<sup>375</sup>. However, the GMC's rule 81 (c) provides that

"If, in particular circumstances, the doctor believes it undesirable on medical grounds to seek the patient's consent, information regarding the patient's



health may sometimes be given in confidence to a close relative or person in a similar relationship to the patient."<sup>376</sup>

This would seem to suggest that the doctor is under no obligation to tell relatives, but that if he does in accordance with the above guidance, he won't face disciplinary proceedings - whatever stance the law takes on this<sup>377</sup>. However, the Health Services Commissioner<sup>378</sup> criticised a hospital precisely because it failed to inform the relatives of a patient about his terminal cancer<sup>379</sup>, notwithstanding the fact that such notification may have been unlawful. This shows clearly how different regulatory actors can both interact and conflict over a given issue, possibly partly due to insufficient understanding of what the other parts of the regulatory picture are doing.

A much more pointed discussion focuses on the circumstances where a doctor may find it necessary to breach a patient's confidence in order to avert harm to another person. This has most recently arisen in the context of HIV and AIDS, but the same principles apply to other infectious diseases<sup>380</sup>, dangerous psychiatric patients<sup>381</sup>, and patients who are dangerously unfit for certain activities such as driving. May the doctor tell the patient's partner/the police/the public health authorities/the DVLC? And if he does not, will he face a court action from the person who suffered as a result of his failure to do so?

It is necessary to distinguish cases where there is a clear risk to an identifiable person, and cases where the risk is to a class of persons or the public at large. Apart from the old (and discredited<sup>382</sup>) case of *Holgate v Lancashire Mental Hospitals Board*<sup>383</sup> there is no British authority directly in point. In *W v Edgell*, W claimed that his dangerousness didn't justify Dr Edgell breaching confidentiality in telling the appropriate authorities, but failed in court. On this basis, if a patient (a bus driver, say) has epilepsy but intends to keep driving the doctor might be justified in telling DVLC (but not the bus passengers<sup>384</sup>). But it is one thing to say a doctor is justified in breaching confidence, another to say he will be liable in damages for failing to exercise that option. In cases where there is no readily identifiable prospective victim, it seems that any action would fail purely on the general principles of lack of foreseeability or lack of duty of care.

If there is an identifiable victim likely to be hurt if the doctor doesn't act, this points towards a duty to inform - particularly if that victim is another patient of the doctor's. Ethically, the GMC advocates securing the patient's consent to partner notification, but notes that if such consent is not forthcoming then

“...there are grounds for such a disclosure only where there is a serious and identifiable risk to a specific individual who, if not so informed, would be exposed to infection.”<sup>385</sup>

The GMC also imposes a duty on doctors to “whistle-blow” on any infected colleagues. Whether the law would similarly impose a duty on doctors to notify partners in such circumstances is unclear, but it is submitted that it would, and that a partner infected following a doctor’s refusal to notify him or her could recover damages. The reason for this conclusion is this: in accordance with the general rules of tort or delict, the doctor owes a duty of care to those whom he can reasonably foresee will be harmed by his act or, here, his omission. In the case of the partner of an HIV+ patient, it is readily foreseeable that they will be exposed to harm, notwithstanding that the harm is inflicted by a third party. The issue then becomes a balance of competing interests: the interests of the patient in his continued privacy, coupled with the general rule that there is no liability for the acts of third parties<sup>386</sup>, weighed against the partner’s right not to become infected. The complication introduced by liability for third party actions is effectively now one of causation and foreseeability rather than a rigid policy<sup>387</sup>, and it has been held that liability for third party actions exists if it is the likelihood of exactly that kind of action which the defender was under a duty to prevent<sup>388</sup> - which is exactly the case here. So we are left with the straight weighing of whether the patient’s right of confidentiality is sufficient to defeat the partner’s right not to be infected. The result of this balancing exercise is unclear, which in itself is an indication that the civil law is lacking somewhat in its regulation of this area through lack of sufficiently-clear rules.

## **VIII: Regulation of ethico-legal controversies:**

### **A: Introduction:**

The foregoing discussion presents only the briefest outline of the case law as it has affected the doctor-patient relationship. The subtleties and problems inherent in any of these have, for the sake of brevity and direct relevance, largely been either omitted or only briefly alluded to.

The remaining problem areas with regard to regulating doctors’ conduct relate to issues of ethical controversy such as modern reproductive medicine, abortion, selective non-treatment of neonates, physician-assisted suicide, euthanasia, and withholding life-sustaining treatment. The problematic issues of points as yet unanswered by the law, and the extremely complex (and occasionally vitriolic) ethical arguments are not

addressed except insofar as these issues have direct bearing on the resolution of the matter under discussion. While ethical and moral considerations doubtless weigh heavily on individual doctors and others making decisions in these cases, they cannot be regarded as part of the regulatory framework, and are consequently outwith the scope of this thesis. However, it is important to realise that certain ideas run through a number of the cases, in particular a desire to "do the right thing". Consequently it is necessary to be sensitive to the ethical considerations in these areas<sup>389</sup>.

Proceeding chronologically, medical involvement with life arises first in the course of counselling and examining potential parents, then with assisting conception in any of a large number of ways<sup>390</sup> or else by assisting with or arranging what can be non-medical forms of assistance, such as surrogacy or AID; facing a claim for the pregnancy arising at all following a failed sterilisation or abortion, or the mother's refusal to have an abortion; considering whether to carry out an abortion; being faced with a maternal-foetal conflict in the event of complications or refusal of the mother to accept treatment intended to help the foetus; assisting with the birth itself; deciding whether to perform lifesaving surgery (or even commonplace treatment) or not if the child is born handicapped; facing liability to the parents or the child if the child is born handicapped as a result of alleged negligence on the doctor's part; facing liability to the child either because of prenatal injury which has resulted in the child being born with some defect which, but for the injury it wouldn't have had, or because of a claim that the child should not have been born at all; deciding, after birth, whether continued treatment is justified; overruling parental objections to treating the child; deciding whether to examine and treat the child without the consent of the parents, and whether to inform the parents of that decision and approach; owing the normal duty of care to patients (and occasionally non-patients) throughout their adult lives, including making decisions as to that patient's entitlement to both therapeutic and non-therapeutic treatment; and finally, being party to decisions at the end of life as to withholding<sup>391</sup> or ceasing life-sustaining treatment, and possibly even assisting with the patient's suicide, accelerating their death in order to alleviate pain or even killing them. A number of these acts, particularly the last two, remain criminal offences in the UK and were considered in Chapter 3. It should be noted that almost any of the others could also give rise to criminal proceedings in certain circumstances.

These issues give rise to a host of ethical problems which need not concern us here, although the ethical considerations do affect the decisions reached. In a field such as this, which is almost completely novel, ethical considerations probably have more impact

on the final decision than the general body of law. The scope of medical ethics as espoused by the GMC as a regulatory tool are discussed in Chapter 6; the regulatory power of philosophical medical ethics *in abstracto* is impossible to gauge and has to be regarded as an extant but unquantifiable background feature which is outwith the scope of this work. Ethical issues aside, however, the extant law in these areas can be described relatively succinctly.

We have already seen, in the foregoing discussion, how the law has been used in contentious areas such as the provision of contraceptive advice and treatment to under-16s. The discussion which follows proceeds by looking at matters chronologically, starting with injury suffered prior to birth, proceeding to consider matters relating to assisted conception, and concludes by considering end of life situations.

### **B: Pre-birth injuries:**

This area can be dealt with relatively briefly. It is now established that English common law allows an action by a child for injuries suffered prior to birth, notwithstanding the child's pre-natal lack of legal personality<sup>392</sup>. Any such English cases are liable to be rare, since it is now over 20 years since the passage of the Congenital Disabilities (Civil Liability) Act 1976, but the rule is likely to be strongly influential in Scotland, where the 1976 Act doesn't apply<sup>393</sup>. In the first place, the English rule was partly based on Roman law<sup>394</sup>, and Roman law is still a valid source of Scots law in the absence of other authority<sup>395</sup>. Secondly, it was the very fact that the Scottish Law Commission were of the opinion that such a right existed at common law that led to the 1976 Act not being extended to Scotland<sup>396</sup>.

In either country the child must be born alive to have any right of action<sup>397</sup>. On the basis that there won't be any more claims under English common law it is unnecessary to discuss this, and the 1976 Act is discussed in Chapter 6. The Scottish courts reached a similar view of the law in the case of *Hamilton v Fife Health Board*<sup>398</sup> where the court held that the child who suffered from pre-natal injury was not a "person" while in utero, and thus enjoyed no rights at that time. However, on being born alive the child became a person in law, and the harm done was only suffered at that point (non-persons not being capable of suffering a legal harm). Damages were accordingly held to be recoverable. Whether the mother's actions can be imputed to the child as contributory negligence remains open to question. A more contentious issue concerns cases where a child is born which has been so seriously damaged before birth that the essence of its claim is that it should never have been allowed to be born. The English courts have

rejected such a claim for "wrongful life"<sup>399</sup>, and it is unlikely that a Scottish court would depart from this. However, that is not to say that the parents would not have a claim for the birth of such a child; the courts have rejected the argument that the mother of such a disabled foetus should have an abortion, and that her failure to do so is a *novus actus interveniens*<sup>400</sup>.

### **C: Medically-assisted conception:**

Moving forward, the issue has arisen of whether doctors may treat pregnant women without their consent in the interests of the unborn child. Some of the applicable case-law in this area has already been considered in the context of patient consent *supra*.

It is clear that parental wishes are insufficient to deny medical care to a child once born<sup>401</sup>, but in such a case the only rights of the parent which are violated are their rights *qua* parents - which exist in the interests of the child, not of the parents. In the case of a child *in utero*, non-consensual treatment clearly involves violating the bodily integrity of the mother – bodily integrity which the law is generally presumed to uphold. Yet in *Re S (adult: refusal of treatment)*<sup>402</sup> the court authorised a caesarean section against the express wishes of the mother. The ethics of this appear questionable<sup>403</sup>, since the authorisation was done in the face of a refusal by a patient who was not seen to lack capacity to consent to the procedure or not. As was discussed *supra*, the law proceeds on the basis that an adult is presumed to have full mental capacity and as such is free to consent to or refuse treatment for any reason unless that presumption is displaced (which appears not to have been the case in *Re S*). Lord Donaldson MR's dictum in the case was based on the rights of the foetus, and was reached in the face of authority just considered that a child is not a person in the eyes of the law (and is consequently incapable of having any rights vest in it) until born alive<sup>404</sup>.

Most of the cases in this area proceeded on the basis that the pregnant woman actually lacked capacity to make the decision herself, and accordingly the courts could proceed to authorise the treatment on her behalf (presumably on the basis of a substituted judgement test, although this is seldom articulated<sup>405</sup>). It is clear that here, as in many other problem areas of medical law, the doctor's course is not to do as he sees fit, but to petition the court. If the court decides that the proposed intervention (or whatever) is unlawful, then the doctor will learn this before exposing himself to a claim for damages, and it is better for the patient not to have the unlawful treatment inflicted on him or her than to suffer it and then try to seek damages after the event. "Prevention is better than

cure" is as true of medico-legal controversy as of medical treatment. And if the court decides that a given course is lawful, they will generally merely authorise the doctor to do it, not order him to<sup>406</sup>. As Lord Denning once said, there were no conceivable situations where the court

"...should ever require a medical practitioner to adopt a course of treatment which in the *bona fide* clinical judgement of that practitioner is contraindicated as not being in the best interests of the patient."<sup>407</sup>

Consequently, the decision remains the doctor's, unless the treatment has been found to be unlawful. Whether it is appropriate for doctors to be making such decisions, and whether the courts can be said to be exercising proper control of the medical profession in making such declarations, is open to question - but that is the law. The problems inherent in the courts' approach to problems of this nature are discussed in the final part of this chapter. Consistent with the judicial approach which refuses to order doctors to do anything, so too the courts have refused to accept the costs of medically-assisted reproduction or surrogacy as recoverable damages in cases of negligently-inflicted sterilisation<sup>408</sup>.

Assistance at the birth is a routine medical intervention (assuming the mother consents to that treatment) and is governed by the normal rules of negligence; the main difference is that any negligence which leaves the child alive but permanently injured will tend to result in far higher awards of damages than most other cases<sup>409</sup>. As to failing to treat a new-born infant, this is covered more by the criminal law<sup>410</sup>. The issue of treating children over parental objections was raised in *Re S (a minor) (medical treatment)*<sup>411</sup>. This followed the pattern mentioned above, the doctors going to court for permission (which was granted) to give a blood transfusion to the child of two devoted Jehovah's Witnesses, the parents objecting to the transfusion on religious grounds. The issue of treating a child on the basis of the child's own consent has already been dealt with, as have the duties of care and confidentiality required in the context of "ordinary" medical care, and the circumstances whereby a patient can challenge a decision not to treat him due to resource shortages.

Where the decision not to treat is not based on resource limitations, there may be more chance of successfully challenging the decision. In *R v St Mary's Hospital Ethical Committee ex p Harriott*<sup>412</sup>, it was held that any decision not to treat someone on non-medical grounds was susceptible to judicial review. However the courts, it will be remembered, apply the "*Wednesbury*" standard to judicial review, which means a

decision not to treat will be upheld unless it is so unreasonable that no reasonable doctor or health authority could have made it; the judgement noted that a policy refusing treatment to Jews or members of ethnic minorities would definitely be unreasonable. This applies even in cases concerning life-saving treatment, which takes us to the final area.

#### **D: End of life decisions:**

There are two principle areas where the law has been utilised in challenging (or clarifying the legality of) medical decisions which will ultimately result in the death of the patient. The first concerns decisions to discontinue treatment which is of no clinical benefit to the patient, usually because the patient is in a persistent vegetative state. The second concerns decisions to withhold or discontinue treatment (usually on resource grounds) which could benefit the person.

The decisions concerning cessation of life-continuing treatment have already been considered<sup>413</sup>. In essence, a declaration by the High Court (in England and Wales) will preclude prosecution, or a declarator by the Court of Session will entitle a doctor to the protection of the Lord Advocate's binding policy statement not to prosecute in such cases. The familiar pattern of seeking advance clearance from the courts can again be seen in this approach. The courts have recently drawn attention to the fact that there are currently two sets of guidance on PVS, not entirely consonant with each other, and suggested that it was time the guidelines on the existence of PVS were reviewed<sup>414</sup>. Judicial suggestions on medical practice of this type are exceedingly rare.

In the case of discontinuance of therapeutic treatment, or a decision not to offer it in the first place, this issue has been considered in the discussion of judicial review cases and NHS statutory duties *supra*. The issue also arose in *R v Cambridge HA ex p B*<sup>415</sup>, another case concerning resource allocation, in the context of treatment which was lifesaving but very expensive and arguably experimental in nature. The decision not to offer the treatment was upheld by the courts, principally because it was not so unreasonable that no reasonable health authority, properly directing itself, would never have reached it. However, there was also some more general discussion of what a health authority had to do by way of justification of such decisions; the decision was defended principally on economic grounds. Yet the discussion of utilitarian values and resources was not initially a factor in the case; the original decision not to offer further treatment to the child having been taken on purely clinical grounds<sup>416</sup>; the court failed to pay any attention to the clinical aspects and decided the case purely on the basis of

resources. This was notwithstanding clear-cut evidence that at least one respectable body of medical opinion would not have given the treatment irrespective of costs. If nothing else, the case shows the courts' unwillingness to interfere with decisions reached on whether to treat or not, whether the reasons for doing so are clinical or not.

A more pointed issue confronted the courts in the case of *Re A (Children) (conjoined twins: medical treatment) (no. 2)*<sup>417</sup>, the so-called conjoined twins case. Here, an operation to separate Siamese twins, Mary and Jodie, would inevitably result in the death of one of them, Mary. However, the uncontroverted medical evidence was that if not separated, both twins would die within at best a few months. The hospital petitioned the court for a declaration that it could carry out the operation, notwithstanding that it would inevitably kill Mary. This raised issues of family law and criminal law. In the family law context, the court clearly found little difficulty in balancing the competing interests of the two twins. Mary was bound to die. Jodie could be saved. Her interests in having the operation performed clearly outweighed those of Mary. The criminal law aspects of the case are less clear, but ultimately the Court of Appeal was prepared to hold that the operation would not be murder, notwithstanding that it incorporated all the ingredients of that crime (although Walker LJ's judgement indicates that the *bona fide* exercise of clinical judgement which will inevitably result in death cannot co-exist with the *mens rea* of murder). Having toyed with the idea of deciding that the issue of the conflict between Mary and Jodie's rights was too complex for a court to decide, the Court ultimately found that it could not, in all conscience, avoid the issue and so proceeded to carry out the balancing exercise described and issued its decision accordingly. While the facts of this case are highly unusual and singular, the court's decision does go somewhat further than any previous decisions in terms of the court's power to declare proposed actions lawful.

Getting the court's sanction before stopping treatment (or, as in *Re A (Children)* carrying out treatment with such drastic consequences) is important because having done so, the doctor will also be immune from criminal liability<sup>418</sup>. Medical opinion is important even where the patient dies as a result of the doctor's actions. In terms of *R v Adomako*<sup>419</sup>, discussed in Chapter 3 *supra*, a charge of manslaughter by criminal negligence must first satisfy the normal civil test of negligence before considering whether the negligence was gross as to amount to a crime; consequently, such medical testimony will be a prerequisite to a verdict of manslaughter<sup>420</sup>; this again shows the interplay between the different spheres.



In summary, while these areas are of pressing ethical importance, and often highlight the need for law reform or the creation of a suitable forum for deciding these issues in a sensitive and appropriate way, from the point of view of the doctor, the mechanism exists whereby he can apply to court for a suitable declaration, and, in effect, let the court sort out the competing and conflicting interests at stake. Such is the level of the law's regulation as it affects the doctor; all the doctor need know is which areas of decision-making fall into those categories where prior judicial approval would be advisable.

### **IX: Litigation and other regulatory bodies:**

As mentioned at the outset, the justiciability of other regulatory bodies' decisions is principally considered in the discussion of those other bodies. However, a few general comments are included here for completeness.

To start with, the nature of the regulatory bodies selected for inclusion in this thesis means that they are all susceptible to judicial review actions, at least in relation to their public law functions. This category encompasses virtually all the regulatory tasks carried out by those bodies. To this generalisation there are a few exceptions. Firstly, the superior courts are themselves not susceptible to judicial review, which (as explained above) is the mechanism whereby the superior courts ensure lower courts and tribunals and administrative bodies carry out their allotted functions properly. Secondly, the lower criminal courts in Scotland are also not susceptible to judicial review *per se*, although equivalent procedures allowing decisions to be reviewed by the High Court of Justiciary (which is staffed as the same judges as the Court of Session) do exist.

To recap briefly, the actions of a body can be challenged on judicial review on the basis of illegality, irrationality or procedural impropriety<sup>421</sup>. The grounds for quashing a decision also extend to the adequacy of reasoning and supporting facts, i.e. taking into account irrelevant considerations, failing to take account of relevant and material considerations, or if there is no proper basis in fact to support a decision requiring a factual basis<sup>422</sup>.

This level of scrutiny is applicable across the regulatory framework. The distinction between policy issues and other matters has recently been revisited by the House of Lords, albeit in a non-medical context<sup>423</sup>. The case in question suggests that proportionality<sup>424</sup> should be considered as a separate ground of judicial review at common law, as should straightforward misunderstanding or ignorance of an established

and relevant fact<sup>425</sup>. This expansion was considered in the case which was brought under the Human Rights Act 1998, but the expansion of judicial review jurisdiction was not, according to their Lordships, driven by that Act but was simply a development of the common law.

The volume of judicial review cases of regulatory bodies is significantly reduced because as will be seen in subsequent chapters, many of the statutes under which these other bodies have been established include an appeal to the courts or, in some cases, to the Judicial Committee of the Privy Council, and are therefore considered under the aegis of the mechanism in question rather than here. However, judicial review is still important firstly because it allows review of the decision by someone other than the person being regulated. Most statutory appeals are only available to the individual practitioner who is being subjected to the regulator's discipline, whereas anyone who can show sufficient title and interest to sue can raise a judicial review. This could, at least in theory, include a patient aggrieved at the perceived leniency or inaction of a regulator towards a doctor who is allegedly in breach of the rules of the regulator in question.

Judicial review can also be used as an alternative to statutory appeals by those regulated, particularly where the statutory appeal would not provide an adequate remedy (which is a prerequisite in any case, judicial review in general not being available where an alternative remedy exists). It has, for example, been used to challenge an alleged breach of natural justice by the regulatory mechanism<sup>426</sup>. It is also the appropriate way for someone aggrieved by a proposed course of action to challenge that proposal before it has been carried out<sup>427</sup>.

### **X: The effects of medical litigation:**

This section will seek to assess, in necessarily general terms, the effects of civil litigation in achieving its assigned regulatory functions, *viz.* the provision of a system of redress for those who suffer due to a failure to adhere to acceptable standards, setting and upholding standards, provision of a system of investigation into whether standards are being adhered to, the airing of grievances, punishing failure to adhere to standards, facilitating good medical practice, and regulating the regulatory system.

The effects of civil litigation in terms of medical regulation will also be assessed by looking at three "target" groups in terms of the different aspects of regulatory task being undertaken. These groups are the regulated themselves (*i.e.* doctors), the regulators (*i.e.* those operating other parts of the regulatory bureaucracy), and those who stand to

benefit from the regulation, *i.e.* the general public as being actual or potential patients of the doctors.

## **A: Effects on doctors:**

### 1: Personal injury actions:

The most prevalent form of medical litigation is, as seen, the action for personal injury. The effects of personal injury actions on doctors are, on one level, far less marked than previously. Until January 1990, NHS hospital doctors were required by their contract of employment to carry professional liability insurance. This requirement is imposed on many other professionals, such as solicitors, by their statutory regulatory body rather than their employers; the fact that this was an NHS requirement means there is no requirement for doctors in private practice to have any form of indemnity insurance. Since 1990, NHS indemnity<sup>428</sup> has meant that the NHS will now directly pick up the financial liability of any NHS hospital doctor. From the doctor's perspective, there was little change since in the event that damages were awarded against them, it simply means that instead of one third party (the insurer, typically one of the medical defence organisations) paying the damages and costs, another third party (the employing part of the NHS) picks it up instead. It is extremely rare in the UK for a doctor ever to have to meet an award personally (in contrast to the situation in the US<sup>429</sup>). Given how large the damages which can be awarded are relative to the personal wealth of the individual doctor, such a situation benefits both doctors (who do not face the prospect of personal bankruptcy) and patients (who can be reassured that if they win, someone will be able to pay the compensation in question).

NHS indemnity only extends only to NHS hospital doctors, and does not apply to general practitioners or to private medical practice (including any private practice done by NHS hospital doctors). In these other sectors, the doctors are likely to carry insurance for self protection, rather than under compulsion. However, there is no guarantee that a patient injured by a private practitioner will be able to recover damages in full, which could be considered to be an extremely unsatisfactory situation.

There are, however, implications to personal injury actions beyond the financial. The doctor who is being sued for negligence may regard this as a serious slur on his or her professionalism. While there is no formal mechanism currently in place whereby anyone tracks negligence actions against specific doctors, or takes any form of action where the court has held that a doctor failed to meet the requisite standard of care, such conduct

may (exceptionally) attract the attention of the GMC or other regulators<sup>430</sup>. And the personal impact of litigation should not be underestimated. One US study analysed the impact of being sued for malpractice. The results have been summarised as follows:

“Thirty-nine per cent of physicians admitted to four or five symptoms suggestive of a major depression; 20 per cent acknowledged another group of symptoms including anger, change of mood, tension, frustration and the like; 8 per cent noted the onset of physical illness, of which 2 per cent had a myocardial infarction; 8 per cent noted the aggravation of a previously diagnosed illness; 18.8 per cent felt a loss of nerve in a clinical situation; 14 per cent felt less self-confident... 56.5 per cent said they and their families had suffered as a result of the suit... This degree of emotional damage is unacceptable but the worst part is that 75 per cent of the physicians experiencing this emotional trauma were later acquitted by the courts. So it is the litigation process which is so very damaging to physicians.”<sup>431</sup>

The situation in the UK has not, so far as this writer has been able to ascertain, been studied, although similar effects were noted in a study of doctors who had been the subject of complaints<sup>432</sup>. There is, however, at least one suggestion that doctors in the UK have been driven to the verge of suicide by the stress of being sued<sup>433</sup>. In addition, the doctor being sued will require to attend court if matters proceed that far, and will have had to spend time reviewing matters with lawyers and expert witnesses. This is a time-consuming process, and probably contributes to the stress generated. The number of doctors facing this stressful experience be underestimated: almost one third of the 3,500 doctors who responded to a survey by the magazine *General Practitioner* had faced a claim for negligence<sup>434</sup>. While this was a self-selecting sample, it seems that some 37% of consultants and senior registrars in the NHS were sued at least once in 1996<sup>435</sup>, which suggests that the survey respondents were not unrepresentative.

The action for personal injury is, however, also argued to have beneficial effects too. In particular, it is often argued (usually in response to suggestions that medical malpractice actions should be abolished altogether in favour of so-called “no fault” compensation schemes) that tort and delict serve a useful purpose in upholding the accountability of individual doctors. The argument runs that the possibility of being sued, with the attendant adverse publicity this generates, deters the doctor from acting negligently and thus serves to enhance the overall standard of medical practice, particularly diagnosis<sup>436</sup>.

There are, however, a number of difficulties inherent in this theory. As we have seen, a doctor found to have been negligent in this country is highly unlikely to face any personal financial repercussions, in marked contrast to the US situation where the possibility is a real one. The introduction of NHS indemnity represented a major shift in policy, however, and doctors covered no longer have to worry even about premiums. Some suggested that this would also mean doctors stopped complaining about the current tort system.<sup>437</sup>

A major problem with the deterrent theory lies in assessing the actual deterrent effect exerted. The problem has been described as follows:

“One of the difficulties... has been the diffuse nature of the information flows generated by negligence claims. Tort actions for medical negligence tend to be brought by single plaintiffs against single defendants or a small group of defendants united on an *ad hoc* basis by their involvement with the care of the individual victim of an adverse event. The overwhelming majority of cases where negligence is admitted are settled privately between the parties and there is no public statement about the outcome. Claim databases, if they exist at all, are the property of insurers...

On the other hand, the value to the public of such data is equally clear. To the extent that tort claims signal the presence of sub-standard medical care, information on the frequency and severity of such claims can contribute to the effective monitoring of quality in the health care sector. Given that such data, once collected, could be disseminated at very low cost, it seems that it is socially beneficial for private databases to be made public. However, this misses the point that the information would not be collected by insurers if it were to be made public, as it would no longer lead to any private return.”<sup>438</sup>

In essence, the cases which actually go to court are a small minority representing the most borderline issues; the serious breaches of standards are handled privately and not subject to detailed analysis which is available to the public (or indeed, to much of the regulatory system either) and so there is no feedback loop to the doctor in question. There is no mechanism within the system of civil litigation itself intended to create a deterrent effect, only the fear factor inherent in the possibility of being sued. Such fear of litigation may provoke better medical behaviour, but equally it may result in interventions which are arguably inappropriate.

Finally, therefore, mention should be made of the concept of “defensive medicine.” This

expression is normally used to describe the situation whereby a doctor carries out a procedure for the principal reason of avoiding subsequent civil liability rather than because (absent the threat of litigation) it is clinically indicated. The arguments for and against have been put as follows:

“It is suggested that a doctor, aware of the risks of litigation arising from the performance of a particular medical procedure, will have that risk in mind rather than the primary concern, the health and welfare of patients. There is ample evidence that in the USA, the cost of insurance has meant that fewer doctors are willing to practise certain ‘well litigated’ areas of medical practice, such as gynaecology. The shadow of litigation may also have a detrimental effect on the development of innovative forms of treatment.

There are those, however, who believe that the practice of defensive medicine, if it really exists at all, is actually only evidence of a correctly cautious approach to the practice of medicine. The individual patient, the arguments goes, cannot suffer unduly in a regime of ‘careful’ medicine. If the doctor has an awareness of the prospect of litigation, this may lead to a clearer understanding of the need for the patient to be fully and accurately informed of the need for surgery, the risks involved in it and the alternative forms of treatment that might be available. In response to this it is contended that to have such a ‘cautious’ approach to each patient would be practically impossible and economically disastrous. Modern medicine exists in a society where resources are limited, the population is ageing and the demands on the health-care system as a whole difficult to withstand. To devote such time to each patient would invariably mean that there was less time for someone else. To have a clinical regime based on the chances of being sued could ultimately destroy the system.”<sup>439</sup>

As has been seen above, the tests for clinical negligence are set by accepted medical practice. Against this background, fears of defensive medicine appear unfounded. If the medical profession itself continues to adhere to a practice which does not require every conceivable diagnostic test to be carried out at the first suspicion of a problem, then the doctor who follows this practice will not, under the current tests, be held to have been negligent. It may be that much of the fear concerning misplaced defensive medicine is based on the American experience, where lay juries will sometimes award damages even where there is no clear medical evidence of any negligence<sup>440</sup> and defensive medicine is estimated to cost between 15 and 35 per cent to the cost of medical care<sup>441</sup>. Certainly there seems to be no clear evidence that defensive medicine

is a problem in the UK<sup>442</sup>, and one study in particular concluded that any UK “malpractice crisis” concerned “the difficulties facing patients and their relatives bringing a claim against doctors.”<sup>443</sup>

## 2: Other civil litigation:

Other forms of civil litigation tend not to be addressed to the actions of specific doctors, so the effects of such actions are, from the individual perspective, less marked. The effects of the *Gillick* case<sup>444</sup>, for example, were pervasive and, until the decision was reversed by the House of Lords, resulted in a nationwide change in medical practice. Other cases are more limited; the cases on authorising treatment without consent or on withholding treatment, for example, lay down a generally-applicable framework for doctors operating in these fields to adhere to if faced with that sort of problem. Provided the appropriate clearance has been secured in advance, the doctor will not face subsequent civil or criminal sanction for following the course of action duly authorised. Litigation based on resource decisions could (if they ever succeed) result in resources being made available to allow the doctor to carry out some procedure which that doctor has already decided is clinically indicated (recalling that the courts will not, as a rule, order doctors to do something clinically contraindicated), which may facilitate good medical practice in such cases.

### **B: Effects on other regulators:**

We have already seen that the main way the civil law operates to control other regulatory mechanisms is through the judicial review action. In essence, this means that in carrying out their functions these other bodies are obliged by the courts to act reasonably, in accordance with the rules of natural justice, and on a correct understanding of their legal powers and duties. Decisions will be struck down if they breach any of these precepts, or cannot be justified on the evidence which the body had available. More recently, fundamental error of fact has become a separate ground for review, as has proportionality: if the decision in question involves infringing the rights of someone and that infringement is disproportionate to the result being sought, the decision will be struck down.

The courts do not, as a rule, substitute their own view on the subject under scrutiny for that of the original decision-making body. Instead, the matter is remitted back to the body in the expectation that it will then revisit the issue, hopefully this time avoiding the errors which vitiated the previous decision. There is, however, an important area where

the courts will not interfere with the original decision-maker: this relates to the areas of policy (or “expediency”) judgements which have been delegated to the body in question. If the decision in question properly falls into the area of policy, where the body will typically be taking decisions on the basis of the “public interest”, then so long as the body has behaved reasonably and justified its decision by reference to the correct law and facts, then the courts will not interfere<sup>445</sup>. This exclusion from the scope of review is clearly seen in the cases relating to resource allocation, such decisions clearly falling into the “policy” sphere and accordingly only being subjected to a very low degree of scrutiny. What this means in practice is that the courts are happy to let bodies entrusted by Parliament with a particular regulatory task to get on with it. By the same token, if a body has a discretion given to it, then it is expected to exercise that discretion itself. Thus both improper delegation of decision-making powers and fettering of discretion (for example, by slavish adherence to a rigid policy) will provide grounds for striking down a decision.

A recent example of a number of these principles can be seen in the case of *R v Human Fertilisation and Embryology Authority ex parte (1) Assisted Reproduction and Gynaecology Centre (2) H*<sup>446</sup>. There was conflicting medical research on how many eggs should be implanted in a given IVF cycle. This led to judicial review of the HFEA, alleging that its decision to forbid a particular course of treatment was irrational or that it had fettered its discretion. The application failed, Ouseley J holding that “irrationality” required the applicant to demonstrate that there were features present in the case which took it outwith the scope of the range of reasonable responses open to the decision-maker. Conflicting academic research merely showed that two points of view existed. For the court to attempt to adjudicate between competing academic theories was to become involved in scrutiny of the merits of the decision - far beyond what was required to ensure that the decision was lawful. Specific allegations of fettering discretion were not made out on the facts.

The rarely-utilised action for implement of statutory duty provides an alternative route<sup>447</sup> to much the same end, although if the statutory duty in question is generally-formulated, it will not be susceptible to review<sup>448</sup>.

### **C: Effects on patients and the public:**

The patient who embarks on litigation in the medical sphere has, as we have seen, embarked on a long and uncertain journey; it is necessary to consider why. Thus, while Brazier suggests that



“For the patient for whom the doctor’s mistake resulted in disability or death, money is poor compensation. Finding out why things went wrong may be more important to the patient and the family.”<sup>449</sup>

Goldrein and de Haas comment that

“It is frequently said that the client does not want money, but only to find out what went wrong and if appropriate, an apology. Medical negligence litigation is a curious route to achieve that result. If the client only wants to find out what went wrong and an apology, then more vigorous use of the hospital complaints procedure is a more compelling route. It is certainly cheaper than an adverse order as to costs.”<sup>450</sup>

For present purposes, it will be assumed that the patient actually wants the remedy which they ask the court for. In most cases, that will be financial compensation.

We saw earlier that success rates in malpractice cases are exceptionally low, the most recent figure being that only 13% of claims actually succeed<sup>451</sup>. For the remaining 87%, the effect of civil litigation is that having embarked on a long, stressful and possibly expensive process, they get nothing at all. The 13% who recover in this forensic lottery receive potentially huge sums, but only if they have actually suffered a genuinely serious and permanent disability. And even among the winners, the costs of the present system seriously deplete the amount recovered, since the rules on recovery of expenses seldom allow for recovery of all costs incurred. Indeed, this factor led Allsop and Mulcahy to suggest that

“The fact that in claims under £5000 the costs of the action came to 131 per cent of the value of the settlements suggests either that claimants are receiving bad advice from their lawyers or that the recovery of damages is not their primary aim.”<sup>452</sup>

This point may or may not be true; certainly, a recent survey by the Law Society indicated that client satisfaction with their solicitor was lower for medical accidents than for other areas<sup>453</sup>. Similarly, in terms of dissatisfied patients wanting their “day in court”, a prediction that the (New Zealand) Medical Practitioners’ Disciplinary Committee was going to be busy following the abolition of malpractice actions in that jurisdiction appears to have been correct<sup>454</sup>. However, one cannot exclude unrelated factors as being

behind the increase in complaints to the statutory regulator. Such increases have also been recorded in the UK despite the continuing right of access to the courts<sup>455</sup>.

However, the (theoretical) deterrent effect of civil litigation referred to above is of more general significance; if the theory has any validity, then the tort/delict systems benefit everyone by driving up standards across the board simply by their existence. However, as we have seen above, the actual deterrent effect of legal action in the UK may be minimal. If that is the case, then a system which fails to compensate most victims of medical accidents is bereft of any countervailing benefits.

## **XI: Summary and conclusions**

### **A: Purpose:**

As stated *supra*, there are a number of purposes apparent in the forms of civil litigation available to dissatisfied parties or those seeking guidance on their proposed actions, falling generally into the categories of giving financial redress to the victims of failure to adhere to standards, upholding patient autonomy (at least in theory), and protecting both patients and doctors by providing a framework allowing the legality of actions to be tested. Critics of the current system might suggest that the main effects are, however, the reduction of doctors' liability and the maintenance of professional autonomy, although it may also serve to punish wrongdoers. The system of civil litigation is such that it is reasonable to ascribe all eight regulatory tasks to it, albeit in differing degrees.

### **B: Mechanism:**

With the exception of certain forms of contempt of court (which is more akin to the criminal law than the civil law), the civil courts are a reactive form of regulation and require someone to initiate legal proceedings before anything else can happen. However, once that action has been initiated the court system does provide tools intended to allow the parties to the action to locate, secure and bring to the court the evidence and witnesses which those parties believe will be helpful to their case. While the courts adopt an interventionist stance in some situations (most obviously in cases relating to child welfare), for most actions the civil courts still essentially follow the "umpire" role described *supra*.

Assuming that there is no extra-judicial settlement of the action, matters will proceed to

court. Each side is then entitled to lead its own evidence, so far as admissible and so far as they have complied with applicable procedural rules. Having heard the evidence and legal submissions, the judge reaches a decision. He or she then issues a judgement which, on one level, is the end of the court's necessary involvement in the dispute. The nature of the decrees which the court can issue at the end of the case has already been considered; the effect of court decrees can be summarised as being able to clarify what the respective rights and duties of the parties to the action are, *vis a vis* each other.

There are a number of ways in which court orders can be enforced, but in the context of medical regulation these are largely irrelevant since most of the players in this area against whom court orders are issued will tend to obey the court's ruling without the need for coercive measures. For present purposes, suffice to say that there are ways of ensuring compliance, most of which involve the party in whose favour the order has been granted coming back to court in the event of the other party's failure to obtemper the decree. The courts themselves do not monitor compliance with their own decrees, although in some cases they will set future dates at which parties are required to appear to explain themselves.

### **C: Effect:**

The effects civil litigation are obvious insofar as at the end of the process there is a decision by the court. In adversarial proceedings such as a malpractice action, it is easy to regard this as meaning that there is a winner and a loser. The effect of the court action in such circumstances is that the previously disputed (or unclear) rights and duties of the parties to the litigation are laid down explicitly by the court. There are also cost and expenses issues beyond the question of whose opinion of the law, and whose version of the facts (if either) the court has decided to uphold, which will occasionally mean that the apparent "winner" can end up being more out of pocket than the "loser". The system also has the side effect of engendering high stress levels among those who are sued while at the same time producing a far lower success rate for those who sue than other areas of civil litigation. This is coupled with the extremely high overheads associated with litigation as a method of redressing harm.

What is far harder to assess is the wider effect of the system of civil litigation and the tests which it applies on the general practice of medicine (and the activities of the other medical regulators). Indeed, what evidence there is seems to indicate that civil litigation (specifically, the action for medical negligence) has at best a marginal effect on clinical

behaviour, a fact which reinforces calls (principally driven by other perceived deficiencies of the malpractice action) to abolish the malpractice action and replace it with some form of “no-fault” compensation scheme.

The ability to take legal action against (and in particular, to seek judicial review of) other regulators is not so easily disposed of, however. Displacing the supervisory jurisdiction of the superior courts would entail a major shift in the constitutional norms of the UK. There appears to be no support whatsoever for such a shift; indeed, most commentators in this area argue for more penetrating judicial review, rather than less. These calls in themselves suggest that judicial review in its current (and, it has to be said, recently extended) basis is inadequate in controlling the actions of administrative bodies. It may instead be that the current judicial review action is not good at teasing out reasons behind decisions, rather than being deficient in being able to examine the legality of decisions. If so, this is a criticism which can be applied to civil litigation generally: adversarial proceedings, whatever they may achieve, are not a good way to get at the reasons behind something.

#### **D: Comparison with Core Evaluation Criteria:**

In Chapters 1 and 2, we identified seven core evaluation criteria. Civil litigation will now be assessed against each of these in turn.

##### 1: Visibility:

Civil litigation exists for the sole purpose of allowing the rule of law to be enforced by everyone. This purpose is highly visible: virtually everyone who has had their rights (as they perceive them) transgressed knows that, in theory at least, they can sue the transgressor. Precisely which rights the law (as opposed to the aggrieved individual) will recognise, and the practical difficulties of enforcing these rights, may not be so well known, but there is a highly visible legal profession (much of it advertising free first interviews) which *is* aware of these drawbacks and which can readily appraise the lay client of these facts. Less visible are the purposes underlying some of the judicial decisions on where liability falls and the tests to be applied in answering that question, which have been criticised as unduly favourable to doctors.

The mechanisms of civil litigation are highly visible. The substantive content of the civil law is also visible, if (like criminal law) somewhat opaque to the non-specialist and difficult for the layperson to access. Judicial decisions, particularly from the higher

courts (which enjoy a virtual monopoly on medical cases), tend to be accompanied by written judgements which are increasingly available on the Internet to people who would not generally frequent law libraries (traditionally the only depository of the law as laid down in judicial decisions).

Again similar to the criminal law, the effects of civil litigation are visible in terms of the outcome on the parties to the case, but virtually impossible to identify, far less measure, in terms of their impact more generally. In terms of publicity, few civil cases receive the publicity accorded to criminal trials (particularly those involving serious crimes) and only civil cases involving celebrities or cases whose outcome is likely to involve very large numbers of people tend to be mentioned in the mass media. However, this does not appear to detract from public awareness of, and ability to find out about, civil litigation.

Overall, civil litigation is considered to be acceptable in terms of visibility, and appears to be moving in the direction of even greater visibility and accessibility to information concerning decisions.

## 2: Accountability:

This chapter has as its focus the approach of the civil (or common) law to medical regulation. The common law, by definition, has been shaped (arguably, created) by judges, and it is the accountability of these judges which we are presently concerned with.

The judges who make all the key decisions concerning the subject matter of this chapter are, as respects the parties affected by those decisions, not accountable for their decisions. The reasons for this are identical to those applicable to judicial accountability for criminal law determinations, *i.e.* that being able to hold a judge accountable for his or her decisions is unlikely to satisfy the requirement for impartiality in decision-makers. As with the criminal law, the only accountability of a judge at first instance lies in the ability of the appellate courts to overrule (and criticise) lower courts. The civil law fairs better than the criminal law since in civil litigation whichever party is dissatisfied with the original decision can appeal against it (or at the very least seek leave to appeal), in contrast to the victim of crime who cannot appeal against an acquittal.

For these reasons, and again recognising the difficulty in reconciling judicial accountability with judicial independence, it is concluded that civil litigation is adequately accountable.

### 3: Overall Fairness:

As explained in Chapter 2, the category of overall fairness incorporates a number of aspects including impartiality, accessibility, and speed of decision-making.

Firstly, as regards impartiality, it is clear that the rules on judicial independence and the common law rule *nemo iudex in sua causa*, i.e. that no-one should be judge in their own cause, ensure that the decision maker in civil litigation will be structurally independent of the parties to the dispute. Civil litigation therefore satisfies the “impartiality” limb of this criterion.

As regards accessibility, the problem here is mostly connected to the extremely high cost of litigation. While legal aid provides a safety net for those on low incomes, there are substantial numbers who are wealthy enough so as to be ineligible for legal aid but who cannot afford the costs of litigation. Conditional fee arrangements have provided a major improvement in court accessibility for these people, but these arrangements still require someone to be persuaded to accept the risk of paying the costs of the action if it fails. Given the very low success rate for malpractice actions, this risk would seem very real. Civil litigation therefore fails to satisfy the “accessibility” limb of this section.

In terms of speed, the laws of prescription and limitation are designed to strike a balance between ensuring cases are brought timeously (both to spare defenders indefinite uncertainty and to ensure cases are brought while the evidence is still fresh) and not denying access to the courts where the interests of justice so require. In theory this should provide a reasonably prompt introduction to the process of litigating a claim, but as we have seen the practice is that many medical claims are not found to be attributable to negligence for some time, or else are injuries to people under the age of legal capacity, and so the limitation clock does not always even start ticking for some time after the incident. And even where the time limits for raising actions have passed, medical cases often raise issues allowing the courts to permit late actions to be raised.

Once embarked on the process of litigation, progress becomes even slower (apparently notwithstanding recent changes in the rules intended to speed the process up) and medical cases routinely take years to come to any sort of conclusion. Appeal proceedings lengthen the process even more, although only a minority of cases are appealed. Accordingly, for the majority of actions the system of civil litigation does not satisfy the requirement of speed. A qualification should be entered here in relation to

judicial review actions, which often proceed very quickly indeed (even in Scotland, where there is no technical time limit on raising judicial review proceedings). However, these actions represent too small a proportion of civil cases to save the system overall from being deemed to fail this aspect.

In terms of fairness generally, while the courts are generally taken to be the epitome of impartial decision making, it is necessary to qualify this statement in relation to medical cases. The judiciary, despite recent re-assertions of their ability to overrule medical evidence, appear too willing to accept it without question. This is in stark contrast to the healthy scepticism applied to other evidence led before the courts. In particular, there appears to be no way to challenge whether a practice accepted by a responsible body of medical opinion is rightly held, and even a very small group can amount to a “body” of opinion. In addition, professional standards tests are applied in areas where what is at issue is not principally a question of medical practice. A regulatory deficit has been identified in a large number of areas where dissatisfied parties have unsuccessfully sought redress through the courts in areas such as judicial review of non-treatment decisions. Criticism can be levelled at the use of a professional standards test in consent cases, at unrealistic applications of causation tests in malpractice actions, inadequate control of non-consensual treatment, inadequate safeguards for confidentiality, and general excess deferentiality to medical witnesses. For this reason, and despite the courts’ institutionally designed impartiality, they are deemed not to satisfy the “general fairness” limb of this criterion. And in failing to satisfy both the overall aspects of fairness, as well as most of its constituent elements, it is therefore concluded that civil litigation fails the standard of overall fairness as a whole.

#### 4: Effectiveness:

The effectiveness of the civil courts can be considered in a number of different ways. At one level, the courts are highly effective in that the civil law has mechanisms in place to allow those who wish the scope of their rights and duties to be clarified to have them clarified. Unless the courts have to decline jurisdiction for some reason, every case pursued by a party will (eventually) reach a conclusion and a decision will be handed down. As between the parties to the litigation, and in relation to the subject matter of the dispute, the courts are very effective (even if one might quibble with the way in which that effectiveness is actually applied in particular cases.)

On a different level, however, one can consider instead the wider effectiveness of the civil law in terms of its purposes. These were identified in particular as including giving

financial redress to the victims of failure to adhere to standards, upholding patient autonomy, and providing a framework allowing the legality of actions to be tested, but with elements of all other regulatory tasks to some extent. For present purposes, we are concerned particularly with the regulatory tasks which go beyond the impact of a particular case on the parties.

In terms of setting standards, the courts can be regarded as completely ineffective, having in all but name delegated this task to the medical profession itself. The courts do, however, uphold the standard thus set: doctors who fail to meet the standard will be held to have been negligent, and (assuming causation is shown) compensation awarded accordingly. However, whether this can be said to be an effective way of upholding standards is a different question, and the immense difficulties faced by pursuers in medical cases suggest that the standard of medical practice is not effectively upheld by the courts. In the wider context, the courts have no formal remit and any deterrent effect which the prospect of being sued may have on medical practice is difficult to quantify. The existence of “defensive medicine” (if such there be) indicates that the civil courts can effect a change in medical conduct, albeit inadvertently. However, the system of litigation means that there is no ongoing monitoring of the situation by the court, no follow-up to ensure that identified shortcomings have been redressed. Nor is there any formal system of feedback whereby the courts’ views on what constitutes an acceptable standard is made known to the wider medical profession, although informal channels do provide this. Given these shortcomings, it appears that the civil courts do not effectively perform the function of upholding standards of medical practice.

Civil litigation plays at best a minimal role in facilitating medical practice, usually in the context of authorising doctors to do something clinically indicated but legally uncertain. It does so effectively by providing a framework for health professionals to follow when faced with such a situation.

Perhaps the main function of the civil courts in medical matters is the provision of a system of redress for those who have suffered due to a failure to adhere to standards, yet it is in this respect that the civil courts are most heavily criticised by commentators. Embarking on civil litigation is not seen as an effective way of providing redress: most victims of medical mishaps do not even seek to use this route, only a small minority of those who do so succeed in recovering anything, and most of the money which goes into the system is taken up by operating costs rather than going to the person who is to be compensated. Yet in terms of this framework, these are all shortcomings in relation to other evaluation criteria rather than the *effectiveness* of civil litigation in being able to



award compensation. Assuming the problems caused by shortcomings falling within other criteria are overcome, then the civil courts will, with a high degree of effectiveness, award compensation. Nonetheless, the cumulative effect of these other problems is such as to frustrate what might better be regarded as the *potential* (rather than actual) effectiveness of the civil courts in awarding compensation.

Similarly, while the route may be a long and expensive one, civil litigation does provide an effective means to permit grievances to be aired and disputes resolved. Indeed, we have seen the frequent suggestion that the wish to have their “day in court”, rather than the recovery of compensation, is the main motivation for many of those who embark on medical litigation. The system of investigation is effective so far as it goes, but is only restricted to the particulars of the specific case in question. In addition, the system of adversarial proceedings is not really intended as an investigative tool, and there are considerable shortcomings in using it to this end. The system of investigation is therefore deemed effective but capable of significant improvement.

Punishment of wrongdoers is at best a peripheral purpose for systems of civil litigation which do not recognise punitive damages. Insofar as this is a purpose of the civil courts in the UK at all, it is one which is ineffective in that it will almost never be the individual doctor being sued who actually has to meet the bill at the end of the day. The stress of being sued affects “guilty” and “innocent” doctors equally, and cannot be said to be effective either, while the punishment of adverse publicity will only affect doctors whose conduct was arguably defensible and the action not settled quietly, out of court.

Lastly, the civil courts have a role to play in regulating other regulatory bodies. As we have seen, the courts have observed a distinction between policy and operational matters, and have refused to intervene (beyond a fairly superficial level) on policy matters. However, this is regarded as permitting the other regulators to do their job (rather than the courts seeking to do it for them) and is not seen as a regulatory failure, although a higher degree of scrutiny could be applied without doing damage to that principle. Accordingly, the courts seem to be effective in regulating other regulators, although there is certainly room for improvement.

Overall, the courts are effective at all the main regulatory functions they are tasked with, with the notable exceptions of setting and upholding standards of medical practice. There is room for significant improvement in the functions of investigating mishaps and regulating other regulators, and the compensation function is rendered ineffectual by other failures.

### 5: Efficiency:

As we have seen, civil litigation is very expensive and an estimated 85% of the sums awarded in compensation are taken up in costs<sup>456</sup>, a figure rising to 131% in claims under £5000<sup>457</sup>. This can only be regarded as a staggeringly inefficient way of compensating people, and the civil courts are accordingly deemed to fail this evaluation criterion.

However, that is purely in relation to medical malpractice actions which, while they may be the most numerous type of medical litigation, are not the only ones. It is harder to assess the efficiency of the courts in relation to other types of actions, since there is rarely a damages award to provide a benchmark of what the action was actually worth to the parties. However, this is also true of many criminal cases, and the criticisms of criminal court management made in Chapter 4 are equally valid to all types of civil court proceedings. For this reason, it is concluded that civil litigation is inefficient for all types of actions – but the inefficiencies in the compensation function, particularly when compared to the relative costs of “no-fault” compensation systems, are the most marked.

### 6: Avoidance of undue influence with good medical practice:

In a widely-quoted dictum, Lord Denning once compared the medical malpractice action to someone coming at the doctor with a knife<sup>458</sup>, an approach to medical malpractice cases which inspired McLean to suggest that

“The interests of the community then are seen by Lord Denning not as being the facilitation of compensation in the event of damage as a result of medical intervention, but rather as being that medical practice should be interfered with as little as possible.”<sup>459</sup>

This point appears to be generally applicable: courts in the UK seem excessively keen to avoid any expansion of the existing grounds of civil liability so far as the medical profession is concerned. This can be seen clearly in the judgements in *Sidaway v Board of Governors of the Royal Bethlem Hospital*, considered *supra*. Given the deferential approach the courts have adopted in relation to medical evidence of what medical practice should consist of, it seems that there is little prospect of a malpractice crisis occurring in the UK, nor of doctors being driven to otherwise unnecessary

defensive medicine. For this reason the civil courts pass the test of not unduly interfering with good medical practice, although the stress associated with the process arguably interferes unduly with good medical personnel. The situation might be somewhat different in relation to the courts' (occasional) refusal to authorise treatment of people who refuse consent, but given our starting premise of what good medical practice is, such refusals are actually preventing medical treatment from taking place which would fall outwith our definition of "good" medical treatment.

Finally, however, mention should be made of the cost implications of civil litigation. Money spent on compensating the victims of medical mishaps (or indeed, money spent seeking declarators or on any other court action) is money which is not being spent on patient care. Accordingly, the existence of an inefficient system of patient compensation in itself has an adverse impact on patient care overall. However, as this is more a function of the realities of resource limitations rather than the inefficiencies of the courts, it is concluded for present purposes that the civil courts satisfy this evaluation criterion.

#### 7: Respect for patient autonomy:

In some respects, the corpus of medical law involves one long dialogue with the language of autonomy. This, however, is not to say that the civil law adequately respects the autonomy of those within its jurisdiction.

The key here lies in the law relating to consent to treatment, since it is in the free expression of consent that the autonomous individual agrees to the course of treatment being proposed. But as we have seen, this law is highly defective in allowing the medical profession rather than the individual patient decide how much information the patient receives before the consent is deemed valid in law. It also allows the refusal of treatment of autonomous individuals to be overridden in some instances, most notably in the case of pregnant women. A system of law which fails to protect the autonomy of any person or group, particularly a group which is more vulnerable than most, can be classed as deficient. Laws which only protect the autonomy of people or groups who are capable of protecting their own interests are of no use, or worse still serve only the purpose of propaganda.

Insofar as the civil law allows doctors to withhold information from patients who could reasonably be expected to have wanted to know it or to lie to patients in the face of direct questions so as to secure a so-called "consent", the civil law is flawed in its

protection of patient autonomy against medical paternalism. Insofar as the civil law authorises intrusive treatment of individuals recognised as having mental capacity against their wishes, it actively participates in the destruction of those individuals' autonomy. Accordingly, civil litigation is deemed not to satisfy this evaluation criterion.

### **E: Conclusions:**

Civil litigation and the civil law are perhaps the most pervasive of the regulatory mechanisms. Anyone (in theory) can institute legal proceedings, and anyone can be sued. This pervasiveness is reflected in the fact that civil litigation can play a part (admittedly in some cases a peripheral one) in all eight regulatory functions.

However, closer scrutiny reveals that the civil law's role is more limited than one might imagine. While recourse to the civil courts is a remedy known to virtually everyone, and while the courts you can raise proceedings in are themselves accountable higher up the appeal hierarchy, it has to be said that the courts themselves stack the deck unfairly in favour of the medical profession. This assumes one has reached court in the first place, having overcome access difficulties and delays along the way, coupled with investigative tools which are not really designed to discover the truth of the situation.

If these hurdles are overcome, the civil courts are effective in relation to the cases before them but have at best a peripheral impact in the wider world, and exert virtually no effect at all in setting or upholding standards. In cases where compensation is awarded, very often more money is absorbed by the system itself than is paid out in compensation. And while the system does not interfere with doctors doing what they should be doing, neither does it stop them from doing what their patients (if properly informed) would *not* want them to do.

Certain functions of civil litigation, such as the supervisory judicial review jurisdiction, could only be changed by altering the constitutional makeup of the UK, and in these areas it appears certain that the current system (possibly with some tinkering) will remain in place for the foreseeable future.

Other aspects, however, are not set in constitutional tablets of stone and are prime candidates for reform. The medical malpractice action is one such, and calls for reform in this area have provoked the government into serious consideration of alternatives, including "no-fault" compensation<sup>460</sup>. While many of the defects in the current system may be insurmountable, or only capable of being resolved by means of injecting more

cash than is likely in the foreseeable future, many of the worst failings of the current system could be cured or substantially alleviated by the introduction of a well thought-out no fault compensation scheme.

**Chapter 4 notes:**

- <sup>1</sup> G. Williams & B.A. Hepple, *Foundations of the Law of Tort* (2<sup>nd</sup> ed, 1984), 2
- <sup>2</sup> Collins *Dictionary of the English Language*, (2<sup>nd</sup> ed. 1986)
- <sup>3</sup> JAC Thomas, "Roman Law" in JDM Derrett (ed.), *An Introduction to Legal Systems* (1968) 22.  
For a contrasting approach which was resistant to state involvement in essentially private disputes, cf. H. MacAleavy's chapter on Chinese law in the same book, esp. at 115-6.
- <sup>4</sup> OF Robinson, TD Fergus & WM Gordon, *An Introduction to European Legal History* (1985) 2
- <sup>5</sup> For an analysis of the development of English law with particular reference to medical cases, see DJ Gee, "The English medical witness - why so late?" *Med Sci Law* (1993) Vol 33 No 1, 11-20
- <sup>6</sup> Now regulated by the Criminal Procedure (Scotland) Act 1996
- <sup>7</sup> On the relationship between civil liability and the CICB, see Trindade, "Intentional Torts: Some thoughts on assault and battery" (1982) 2 OJLS 211
- <sup>8</sup> G. Williams & B.A. Hepple, *op. cit.*, pp 27-28.
- <sup>9</sup> D.M. Walker, *The Scottish Legal System*, (5<sup>th</sup> ed. 1981), 456-7.
- <sup>10</sup> D.M. Walker, *The Law of Civil Remedies in Scotland* (1974), 14.
- <sup>11</sup> Although it should be noted that not all monetary compensation is strictly classified as "damages", e.g. in English restitution cases. Statutory compensation payments are also not damages: *Hall Bros. S.S. Co. v Young* [1939] 1 KB 748. Nonetheless, "damages" is used here in the broader sense of money which a court orders a defender or defendant to pay to the pursuer or plaintiff.
- <sup>12</sup> I. Kennedy & A. Grubb, *Medical Law: Text and Materials*, (1<sup>st</sup> ed 1989), 3.
- <sup>13</sup> I. Kennedy & A. Grubb, *Medical Law: Text with Materials*, (2<sup>nd</sup> ed 1994), 3. All subsequent references to Kennedy & Grubb are, unless otherwise indicated, to this edition.
- <sup>14</sup> 1983 SLT 397
- <sup>15</sup> For a historical background, see JM Evans, *de Smith's Judicial Review of Administrative Action* (4<sup>th</sup> ed. 1980), Appendix 1.
- <sup>16</sup> *Brown v Hamilton DC*, *supra cit.*
- <sup>17</sup> *per West v Scottish Prison Service* 1992 SCLR 504
- <sup>18</sup> *SL v SL* (2000) 2 FLR 389; [2000] 3 WLR 1288; (2000) 55 BMLR 105
- <sup>19</sup> In terms of the Scotland Act 1998
- <sup>20</sup> See *R v Governor of Brockhill Prison ex parte Evans*, [2000] 4 All ER 15; [2000] 3 WLR 843 (HL)
- <sup>21</sup> A statutory exception to this rule can be found in Section 102 of the Scotland Act 1998 whereby a court striking down an Act of the Scottish Parliament as *ultra vires* may modify the retrospective nature of the ruling
- <sup>22</sup> Ten years: 1973 Act, Section 1(1)
- <sup>23</sup> 1973 Act Section 6 and Schedule 1
- <sup>24</sup> 1980 Act Section 2 (tort), Section 5 (simple contract).
- <sup>25</sup> 1973 Act Section 17; 1980 Act Section 11
- <sup>26</sup> 1973 Act, Sections 11(3) and 22(4); 1980 Act Sections 11 and 14

<sup>27</sup> 1980 Act Section 33

<sup>28</sup> But cf *Steeds v Peverel Management Services Ltd.* [2001] EWCA Civ 419, where it was held equitable to allow a claim which was 49 days out of time to proceed as there was no prejudice to the defendants and the fault of the solicitors should not automatically be attributed to the claimant.

<sup>29</sup> 1973 Act Section 17(2); this provision only applies to someone not in the custody of one or other parent; 1980 Act Section 28

<sup>30</sup> Discussed in M Brazier, *Medicine, patients and the law* (2<sup>nd</sup> ed., 1992), 147

<sup>31</sup> *Miller v National Coal Board* 1960 SC 376

<sup>32</sup> *Thomson v Glasgow Corporation* 1962 SC (HL) 36 at 52

<sup>33</sup> *Lee v South West Thames RHA* [1985] 2 All ER 385

<sup>34</sup> Referred to as a “third party haver”

<sup>35</sup> Section 1

<sup>36</sup> Section 33 (for parties to the action) or Section 34 (for non-party havers)

<sup>37</sup> See, for example, *Dunning v United Liverpool Hospitals’ Board of Governors* [1973] 2 All ER 454

<sup>38</sup> Section 7

<sup>39</sup> But cf *Smith v Tunbridge Wells HA* [1994] 5 Med LR 334, where the doctor being sued gave evidence to the effect that he regarded himself as being in breach of his legal duties.

<sup>40</sup> This can be seen clearly in the case of *Whitehouse v Jordan*, considered *infra*

<sup>41</sup> As happened at first instance in *Kay’s Tutor v Ayrshire and Arran Health Board*, considered *infra*

<sup>42</sup> Following *Osman v UK* [1999] 1 FLR 193

<sup>43</sup> Failure to wear a seatbelt usually results in a finding of 25% contributory negligence: *J (a child) v Wilkins* [2001] 1 PIQR P12

<sup>44</sup> The “last opportunity” rule – see *British Columbia Electric Co. v Loach* [1916] 1 AC 719 – criticised in *Davies v Swan Motor Co.* [1949] 2 KB 291, esp. *per* Denning LJ at 321

<sup>45</sup> Section 1(4)

<sup>46</sup> *Hall v Brooklands Auto Racing Co.* [1933] 1 KB 205

<sup>47</sup> *Per* Lord Kilbrandon in *McCaig v Langan* 1964 SLT 121 at 124

<sup>48</sup> *Briody v St Helens and Knowsley Health Authority* [2002] 2 WLR 394; [2001] 2 FLR 1048

<sup>49</sup> B Manuel, “What may happen if there is no change in the UK system?” in J Wall (ed.), *Compensation and accountability: keeping the balance* (1992), 92-3

<sup>50</sup> *Rose v Ford* [1937] AC 826; *Balfour v Beardmore & Co* 1956 SLT 205

<sup>51</sup> See e.g. the £1,032,000 awarded to a permanently brain-damaged engineer in *Aboul-Hosn v Trustees of the Italian Hospital*, July 1987, unreported, referred to in M Brazier *op. cit.*, 161

<sup>52</sup> *Langford v Hebran and Another* [2001] EWCA CIV 36, [2001] All ER (D) 169, analysed by J Benson, 2001 NLJ 598

<sup>53</sup> See, for example, D Kemp, M Kemp and R Havery, *The quantum of damages* (4<sup>th</sup> ed., 1982, with cumulative supplement) and A Paton, *McEwan and Paton on damages for personal injuries in Scotland* (2<sup>nd</sup> ed., 1989), the standard practitioners’ works on the subject in England and Scotland respectively.

<sup>54</sup> Section 12(2)(b)

<sup>55</sup> See e.g. *Prentice v William Thynne* 1989 SLT 336

<sup>56</sup> NHSE Guidance Note FDL (96) 34 (29 July 1996)

<sup>57</sup> See S Ashcroft, "NHS structured settlements" in Law Society of Scotland Update papers, *Medical Negligence* (1997)

<sup>58</sup> *Ibid.*

<sup>59</sup> *McDonald v Secretary of State for Scotland* 1994 SLT 692

<sup>60</sup> *i.e.* the Court of Session's "extraordinary equitable power to do justice in case of necessity or strong expediency, where ordinary procedure would provide no remedy." - DM Walker, *The Scottish Legal System, op. cit.*, 189.

<sup>61</sup> *Ferguson, Pet'r* 1965 SC 16; and see Wade and Bradley, *Constitutional and Administrative Law*, 5th ed. 673-4.

<sup>62</sup> A proof hearing is the part in the procedure where witnesses and other evidence is actually led before the court. Figures: R. Conway, "Litigation in context", handout for Diploma in Legal Practice, Glasgow University 1996.

<sup>63</sup> Royal Commission on Civil Liability and Compensation for Personal Injury (The Pearson Commission), *Report*, Cmnd. 7054, 1978

<sup>64</sup> P Fenn and C Whelan, "Medical litigation: trends, causes, consequences" in R Dingwall, *op. cit.*, 8

<sup>65</sup> *Hansard*, 24 March 1998, cols. 165-166

<sup>66</sup> The functions of these are described by Rose LJ in *Re Freudiana Holdings Ltd.*, unreported, Times, 4 December 1995

<sup>67</sup> For a detailed account of the legal aid system as applied to medical cases, see J Elder, *Who cares about the health victim?* (1998), Chapter 6

<sup>68</sup> P Fenn and C Whelan, "Medical litigation: trends, causes, consequences" in R Dingwall *op. cit.*, 15

<sup>69</sup> JK Mason and RA McCall Smith, *Law and medical ethics* (5<sup>th</sup> ed., 1999), 219fn

<sup>70</sup> P Fenn and C Whelan, *loc. cit.*, 16

<sup>71</sup> Following *Williamson v McPherson* 1915 SC 438

<sup>72</sup> *McNeill v National Coal Board* 1966 SC 72

<sup>73</sup> I Goldrein and M de Haas, *Medical negligence: cost effective case management* (1997), ix

<sup>74</sup> Times, 5 August 1986

<sup>75</sup> "Rights and duties" being used in a non-technical sense, since Scots law historically did not recognise the concept of "duty of care": see Black, "A historical survey of delictual liability in Scotland for personal injuries and death", (1975) 8 CILJSA 46, 189, 316; (1976) 9 CILJSA 57. The expression has, however, entered into Scots law and is used throughout this thesis

<sup>76</sup> *per Donoghue v Stevenson* 1932 SC(HL) 31; [1932] AC 562.

<sup>77</sup> Crown Proceedings Act 1947

<sup>78</sup> e.g. the Congenital Disabilities (Civil Liability) Act 1976

<sup>79</sup> *Supra cit.*



<sup>80</sup> 1932 SC(HL) at 34; [1932] AC at 580.

<sup>81</sup> Luke X, 30.

<sup>82</sup> *Barnett v Chelsea & Kensington HMC* [1969] 1 QB 428, discussed further below.

<sup>83</sup> M. Brazier, *op. cit.*, 118.

<sup>84</sup> See, for instance, "Negligence - Medical Malpractice - Criticism of Good Samaritan Statutes" 42 Ore.L.Rev. 328 (1963).

<sup>85</sup> E.D. Shapiro, in C. Wood (ed.), *The Influence of Litigation on Medical Practice*, 1977, 10

<sup>86</sup> *Id.*

<sup>87</sup> *Supra*: the case is discussed further below.

<sup>88</sup> See, e.g. *Burnett v Layman* 133 Tenn. 323, 181 S.W. 157 (1915), where the patient being operated on by a surgeon suddenly began to haemorrhage; the physician thereupon announced that he was no surgeon, told the patient to find a surgeon, and left the operating theatre - making no effort to help the bleeding patient. This was held to be abandonment.

<sup>89</sup> [1993] 1 All ER 821, [1993] 12 BMLR 64.

<sup>90</sup> *Barnes v Crabtree*, Unreported, Times, 1 & 2 November 1955

<sup>91</sup> *Roy v Kensington & Chelsea FPC* [1992] 1 AC 624

<sup>92</sup> RWM Dias, *Clerk & Lindsell on Torts* (16th ed. 1989) 629n

<sup>93</sup> *Finnie v Glasgow & SW Railway* (1857) 3 Macq. 75, *per* Lords Cranworth and Wensleydale.

<sup>94</sup> *Kent v Griffiths and Others* [1999] 2 Lloyds Rep Med 58 (CA)

<sup>95</sup> Lord Morris of Borth-y-Gest noted that "Natural justice is but fairness writ large and juridically": *Furnell v Whangarti High Schools Board* [1973] AC 660 at 679

<sup>96</sup> [1948] 1 KB 223

<sup>97</sup> But see *Secretary of State for Education v Tameside Metropolitan BC* [1976] 3 All ER 665, discussed in I. Harden and N. Lewis, *The Noble Lie*, (1986) p207, where the court came close to doing just that.

<sup>98</sup> In Scotland, there is no requirement to seek leave to apply; see Rules of the Court of Session 1994 (SI 1994/1443) Chapter 58

<sup>99</sup> *O'Reilly v Mackman* [1983] AC 237; [1982] 3 All ER 1124. This case has been criticised as "creating a British version of one of the elements that Dicey so detested in *droit administratif* ...[i.e.] it has created an administrative court without the consent of Parliament.": Harden & Lewis, *op. cit.*, 213, and see L. Blom-Cooper, [1982] P.L. 250, 260.

<sup>100</sup> *Davy v Spelthorne BC* [1983] AC 237; [1982] 3 All ER 278, [1983] 3 WLR 742.

<sup>101</sup> [1988] 1 FLR 512

<sup>102</sup> Section 1

<sup>103</sup> Section 3

<sup>104</sup> *R v Secretary of State for Social services ex p. Hincks* (1980) 1 BMLR 93

<sup>105</sup> M. Brazier, *op. cit.*, 22

<sup>106</sup> *R v Central Birmingham Health Authority ex p. Walker* (1987) 3 BMLR 32

<sup>107</sup> *R v Central Birmingham HA ex p. Collier*, 6 January 1988, unreported; Lexis transcript available; and see *R v Cambridge HA ex p. B*, *infra*.

- <sup>108</sup> D Longley, *op. cit.*, 81; I. Harden & N. Lewis, *op. cit.*, 213
- <sup>109</sup> [1995] 2 All ER 129 (CA; unreported at 1st instance)
- <sup>110</sup> Quoted by Sir Thomas Bingham MR at 137
- <sup>111</sup> *Supra cit.*; for an overview of recent developments in this field, see K Syrett, "Of resources, rationality and rights: emerging trends in the judicial review of allocative decisions" [2000] 1 Web JCL, accessible at [www.webjcli.ncl.ac.uk/2000/issue1/syrett1.html](http://www.webjcli.ncl.ac.uk/2000/issue1/syrett1.html) (accessed 16 November 2000)
- <sup>112</sup> *Broadmoor Special Hospital v Robinson* [2000] QB 775 per Lord Woolf MR at 795
- <sup>113</sup> [1984] 1 All ER 365; [1985] 1 All ER 533; [1985] 3 All ER 402
- <sup>114</sup> *O'Reilly v Mackman*, *supra cit.*
- <sup>115</sup> Jolowicz [1986] CLJ, and Harlow (1986) 49 MLR 768.
- <sup>116</sup> See fn 99; the significance of this was that *O'Reilly* held that public authority decisions had to be challenged by means of judicial review and not through private law actions.
- <sup>117</sup> *Law Hospital NHS Trust v Lord Advocate and Another* (1996) 2 FLR 407; (1998) 39 BMLR 166; the practical impact of this is minimal due to the Lord Advocate's published policy not to prosecute if Court of Session authorisation has been granted: see 1996 JLSS 401-2
- <sup>118</sup> [1984] 2 All ER 513, [1986] 1 All ER 497; and see also *Eyre v Measday* [1986] 1 All ER 488
- <sup>119</sup> *Shiells & Thorne v Blackburn* (1789) 1 Hy BI 159
- <sup>120</sup> *Sullivan v O'Connor* (1973) 296 NE 2d 183; *LaFleur v Cornelis* (1979) 28 NBR (2d) 569
- <sup>121</sup> Unfair Contract Terms Act 1977, s.2(1)
- <sup>122</sup> *Pfizer Corporation v Ministry of Health* [1965] AC 512, [1965] 1 All ER 450; and see also *Appleby v Sleep* [1968] 2 All ER 265
- <sup>123</sup> [1987] AC 750, [1987] 2 All ER 909, [1987] 3 WLR 232
- <sup>124</sup> *Hotson v East Berkshire HA*, *supra cit.*.
- <sup>125</sup> 1932 SC (HL) 31
- <sup>126</sup> *Williams v Humphrey* (1975) Times 12 February 1975
- <sup>127</sup> See Black, *loc cit.*, fn 75
- <sup>128</sup> *Morton's Case* (1374) YB 46 Edw III fol. 6 pl. 11
- <sup>129</sup> (1882) 11 Price 400
- <sup>130</sup> 1914 SC 277
- <sup>131</sup> *Green v Walker* (1990) F 2d 291
- <sup>132</sup> Kennedy & Grubb, *op. cit.*, 75
- <sup>133</sup> *Powell v Boladz* [1998] Lloyds LR Med 117
- <sup>134</sup> *Caparo Industries plc v Dickman* [1990] 2 AC 605
- <sup>135</sup> *Latter v Braddell* (1881) 50 LJQB 448
- <sup>136</sup> [1906] 1 KB 160
- <sup>137</sup> 1907 unreported, reversed on this point on appeal [1909] 2 KB 820
- <sup>138</sup> Alternatively, *qui facit per alium facit per se*, "he who does something through another does it himself."
- <sup>139</sup> *Duncan v Findlater* 1839 M&R 911
- <sup>140</sup> *Morgans v Launchbury* [1973] AC 127, [1972] 2 All ER 606

<sup>141</sup> *Duncan v Findlater*, *supra cit.*

<sup>142</sup> Hillyer, *op cit.*; *Ready-Mixed Concrete v Ministry of Pensions and National Insurance* [1968] 2 QB 497

<sup>143</sup> [1942] 2 KB 820

<sup>144</sup> [1951] 1 All ER 574; in Scotland, liability for resident doctors was established in *McDonald v Glasgow Western Hospitals Board* 1954 SC 453

<sup>145</sup> Activities outwith the scope of employment, where the employee goes off "On a frolic of his own" do not attract vicarious liability: *Joel v Morison* (1834) 6 C. & P. 501. This is unlikely to arise often in the case of medicine except where NHS doctors treat private patients in NHS facilities.

<sup>146</sup> [1954] 2 QB 66

<sup>147</sup> *Short v J & W Henderson* 1946 SC (HL) 24

<sup>148</sup> [1988] 1 All ER 891

<sup>149</sup> *Hyde v Tameside AHA*, Times, 16 April 1981; *Gravestock v Lewisham Group HMC*, Times, 27 May 1955; *Gauntlett v Northampton HA*, unreported, CA 12 December 1985; *Bull & Wakeham v Devon HA* [1993] 4 Med LR 117. Nor is the doctor's illness any excuse - *Nickolls v Ministry of Health*, Times, 4 February 1955.

<sup>150</sup> e.g. *Nettleship v Weston* [1971] 2 QB 691, [1971] 3 All ER 581 - a learner driver was expected to show the same standard of care as the reasonably skilled and experienced motorist.

<sup>151</sup> *ex p Hincks*, *ex p Harriet*, *ex p Walker* etc. - see *supra*

<sup>152</sup> *Rosen v Edgar* (1986) 293 BMJ 552

<sup>153</sup> W.J. Stewart, *Delict*, 39

<sup>154</sup> *Supra cit*

<sup>155</sup> 1955 SC 200

<sup>156</sup> [1957] 2 All ER 118

<sup>157</sup> In *Whitehouse v Jordan supra* as regards treatment, *Maynard v West Midlands RHA* [1984] 1 WLR 246 as regards diagnosis. *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871, [1985] 1 All ER 643 largely applied it to information disclosure, considered *infra*.

<sup>158</sup> *Per* Lord President Clyde in *Hunter v Hanley supra cit.*

<sup>159</sup> A good example being *Whitehouse v Jordan* [1980] 1 All ER 650, [1981] 1 WLR 246

<sup>160</sup> *Bolam, supra cit.*, at 587-8

<sup>161</sup> *Hucks v Cole*, Times, 9 May 1968; [1993] 4 Med LR 393

<sup>162</sup> See e.g. *Bolitho & Ors v City & Hackney HA* [1993] 4 Med LR 381

<sup>163</sup> *Prendergast v Sam & Dee Ltd* [1989] 1 Med LR 36; for further examples of this approach, see C. Newdick *Who Should We Treat?* (1995) 84-86.

<sup>164</sup> *Whitehouse v Jordan supra cit.*, Lord Edmund-Davies specifically overruling a statement to the contrary by Lord Denning

<sup>165</sup> *Cavanagh v Ulster Weaving Co.* [1960] AC 145; and in *Clarke v Adams* (1950) Sol. J. 599, a standard warning approved by the Chartered Society of Physiotherapists was held to be inadequate.

<sup>166</sup> [1994] 5 Med LR 334

<sup>167</sup> At 339

<sup>168</sup> The judge at first instance in *Maynard v West Midlands RHA* being overturned by the House of Lords, which casts doubt on the dicta in *Hucks v Cole supra*. For a critique of the courts' unwillingness to query evidence as to accepted practice, see Newdick *op cit* pp84-94

<sup>169</sup> *Bolitho v City & Hackney HA supra* per Farquharson LJ

<sup>170</sup> *Wilsher, op. cit.*, overruling dicta to the contrary in *Clark v MacLennan* [1983] 1 All ER 416; but *cf Landau v Werner* (1961) 105 Sol J 1008, where the doctor (a psychiatrist) was held liable after he failed to justify his departure from accepted medical practice.

<sup>171</sup> The 1990 Act has, for most purposes, been superseded by the Data Protection Act 1998, discussed in Chapter 6.

<sup>172</sup> *Lee v South West Thames AHA supra cit.* at 428; *Naylor v Preston AHA* [1987] 2 All ER 353, both *per* Sir John Donaldson MR.

<sup>173</sup> Pickering, "Therapeutics: art or science?" (1979) 242 JAMA 649, 653

<sup>174</sup> *Caparo Industries plc v Dickman supra cit.*

<sup>175</sup> In *Sidaway* (dissenting) ; [1985] 2 WLR 480

<sup>176</sup> [1954] 2 KB 66

<sup>177</sup> At 84; note, however, that strict liability for defective products would hold a manufacturer liable even in these circumstances, unless the strict liability regime permitted the "development risks" defence, as the UK currently does: Consumer Protection Act 1987 s.4 (1) (e)

<sup>178</sup> *Per* Lord Caplan, *obiter*, in *Moyes v Lothian Health Board* [1990] 1 Med LR 463

<sup>179</sup> *Maynard v West Midlands RHA* [1985] 1 All ER 635, [1984] 1 WLR 634

<sup>180</sup> *Ruddock v Lowe* (1865) 5 F&F 519

<sup>181</sup> *Wilsher v Essex AHA, supra cit.*

<sup>182</sup> Unreported, Court of Appeal, 26 November 1987

<sup>183</sup> P Fenn and C Whelan, *loc. cit.*, 12; references omitted.

<sup>184</sup> I Goldrein and M de Haas, *op. cit.*, 57-58; and see their Chapter 5 generally for a sustained critique.

<sup>185</sup> [1998] AC 232

<sup>186</sup> See e.g. *Edward Wong Finance Co Ltd. v Johnson Stokes and Master* [1984] AC 296, considered by Lord Browne-Wilkinson in the course of his judgement.

<sup>187</sup> M Davies, *Textbook on medical law* (2<sup>nd</sup> ed., 1996), 98-9

<sup>188</sup> [1999] Lloyd's Rep. Med. 23

<sup>189</sup> M Brazier and J Miola, "Bye-bye Bolam: a medical litigation revolution" [2000] Med. L. Rev. 85 at 99

<sup>190</sup> D. Giesen, *International Medical Malpractice Law* (1988) 163 (footnotes omitted)

<sup>191</sup> Stewart, *op. cit.*, 50; and see references cited in Giesen, *ibid.*, at 164-5, 170-176

<sup>192</sup> DM Walker, *Law of Delict in Scotland* (2nd ed 1981), 1059

<sup>193</sup> *Yorkshire Dale SS Co. v M.O.W.T.* [1942] AC 691, 706

<sup>194</sup> *Supra cit.*

<sup>195</sup> *Wardlaw v Bonnington Castings* 1956 SC (HL) 26

<sup>196</sup> *McGhee v National Coal Board* 1973 SC (HL) 37

<sup>197</sup> 1987 SLT 577

<sup>198</sup> [1988] 1 All ER 871

<sup>199</sup> 1956 SC (HL) 26

<sup>200</sup> 1973 SC (HL) 37

<sup>201</sup> *Supra cit*

<sup>202</sup> Based on a passage from the Court of Appeal in *Vyner v Waldenberg Brothers* [1946] KB 50

<sup>203</sup> [1986] 1 All ER 801 at 835

<sup>204</sup> [1972] 3 All ER at 1016

<sup>205</sup> cf *Fitzgerald v Lane* [1987] 3 WLR 249, applying *McGhee* to non-medical cases of factual uncertainty.

<sup>206</sup> [1993] 4 Med LR 381

<sup>207</sup> *Kenyon v Bell* 1953 SC 125 disapproving *Chaplin v Hicks* [1911] 2 KB 786

<sup>208</sup> cf the remarks of Lord Scarman in *Lim Poh Choo v Camden & Islington AHA* [1980] AC174 at 182-3

<sup>209</sup> *Mitchell v Hounslow & Spelthorne HA* (1984) 1 Lancet 579

<sup>210</sup> *Hotson v East Berkshire AHA* [1987] AC 750

<sup>211</sup> [1987] 2 WLR at 294, per Sir John Donaldson MR

<sup>212</sup> *Kitchen v Royal Air Force Association* [1958] 1 WLR 563; *Gascoine v Ian Sherridan & Co.* [1994] 5 Med LR 437

<sup>213</sup> See *Dias op. cit.* 647; *Brazier op. cit.* 133-134; *Giesen op. cit.* §119

<sup>214</sup> *Inglis v LMS Railway Co.* 1941 SC 551

<sup>215</sup> *Byrne v Boodle* (1863) 2 H&C 772, 159 ER 299

<sup>216</sup> *Scott v London & St Katherine Docks* (1865) 3 H&C 596, 159 ER 655; and for Scotland see *Devine v Colvilles* 1969 SC(HL) 67

<sup>217</sup> *Scott v London & St Katherine Docks, supra cit*

<sup>218</sup> *Mahon v Osborne* [1939] 2 KB 14; but cf *Cooper v Nevill* [1961] EA 63: the Privy Council applied the doctrine to difficult emergency surgery but held that in an emergency, such a mistake was not necessarily negligent.

<sup>219</sup> Surprising, because Lord Denning's pronouncements were frequently among the most deferential of all judgements in favour of the medical profession; see SAM McLean, "Negligence - a dagger at the doctor's back?" in P Robson & P Watchman, *Justice, Lord Denning and the Constitution* (1981)

<sup>220</sup> *Cassidy v Ministry of Health* [1951] 2 KB 343, [1951] 1 All ER 574

<sup>221</sup> *Roe v Ministry of Health, supra*

<sup>222</sup> *Howard v Wessex RHA* [1994] 5 Med LR 57

<sup>223</sup> *Delaney v South Mead HA*, unreported, Ct of Appeal 9 June 1992; the Court was doubtful as to the applicability of the maxim where all the evidence had been adduced.

<sup>224</sup> Farrow, Johnson, Jost & Schwarz, *Health Law* (2<sup>nd</sup> ed., 1991), 311.

- <sup>225</sup> Or, perhaps, a battery: see Chapter 3 *supra* and WVH Rogers, *Winfield & Jolowicz on Tort*, (14<sup>th</sup> ed 1994), 58-63
- <sup>226</sup> *Reid v Mitchell* (1885) 12 R. 1129; in England, civil battery must be "hostile" to be actionable, although what constitutes hostility is open to debate: *Wilson v Pringle* [1987] QB 237
- <sup>227</sup> *Thomson v Devon* (1889) 15 Sh. Ct. Rep. 209
- <sup>228</sup> *Schloendorff v Society of New York Hospital* (1914) 211 NY 125 at 125
- <sup>229</sup> (1998) 2 FLR 728
- <sup>230</sup> Official Transcript, page 10
- <sup>231</sup> [1981] 3 WLR 1003
- <sup>232</sup> Samples of which are shown in Brazier, *op. cit.*, p76, and Kennedy & Grubb, *op. cit.*, pp95-6
- <sup>233</sup> *Devi v West Midlands AHA* [1980] 7 CL 44
- <sup>234</sup> Lord Denning would allow even "therapeutic lies" to be inactionable - *Hatcher v Black*, Times, 2 July 1954.
- <sup>235</sup> *Centre for Reproductive Medicine v U* [2002] EWCA Civ 565
- <sup>236</sup> [2002] All ER (D) 362 (Mar) (another decision by Dame Butler-Sloss P); the damages awarded in this case were a nominal £100 as the patient, Ms B, was more interested in establishing her right to have the life-sustaining treatment stopped
- <sup>237</sup> Summarised by R. Stein and F. Swaine, "*Ms B v An NHS Trust: the patient's right to choose*" 2002 NLJ 642
- <sup>238</sup> *Adamson v Martin* 1916 SC 319
- <sup>239</sup> *Beatty v Illingworth* (1896) BMJ 21 November, p.1525
- <sup>240</sup> *Wilson v Pringle, supra cit.*
- <sup>241</sup> [1990] 2 AC 1; sub nom *F v West Berkshire Health Authority* [1989] 2 All ER 545
- <sup>242</sup> (1989) 4 BMLR 1
- <sup>243</sup> [1984] 2 WLR 130
- <sup>244</sup> M. Brazier, *op. cit.*, p.91
- <sup>245</sup> *per Neill LJ in Re F, supra cit.*
- <sup>246</sup> *Malette v Shulman* (1988) 63 OR (2d) 243
- <sup>247</sup> NHS Consent Form para. 3; see note 230, *supra*.
- <sup>248</sup> Family Law Reform Act 1969; Age of Majority (Scotland) Act 1969.
- <sup>249</sup> Family Law Reform Act 1969 s.8
- <sup>250</sup> NHS (General Medical Services) Regulations 1992 (SI 1992/635), Regulation 2
- <sup>251</sup> *Supra cit*
- <sup>252</sup> *Per Lord Fraser*, [1985] 3 All ER 402
- <sup>253</sup> *Ibid*, at 422
- <sup>254</sup> *i.e.* that the girl cannot be persuaded to tell her parents, that lack of contraception is likely to harm her physical or mental health, and that it is in her best interests to receive such contraceptive advice and treatment; *per Lord Fraser* at 413.
- <sup>255</sup> [1993] 1 FLR 376

- <sup>256</sup> But only consent to treatment, not order it: *Re J (a minor)(wardship: medical treatment)* [1993] Fam. 15, [1992] 4 All ER 614
- <sup>257</sup> [1992] Fam. 11, (1991) 7 BMLR 147
- <sup>258</sup> An approach he followed in *Re W (a minor)(medical treatment)* [1992] 4 All ER 627
- <sup>259</sup> [1985] 3 All ER at 423; emphasis added.
- <sup>260</sup> e.g. Lord Donaldson MR himself said, in *Re T (Adult: refusal of treatment)* [1992] 4 All ER 649 that “[a patient’s] right of choice is not limited to decisions which others might regard as sensible. It exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent...”
- <sup>261</sup> e.g. Brazier notes that “legal principles which result in a mother having no say as to whether her teenage daughter agrees to an abortion, no right even to know of the operation, but being able to require that same daughter to undergo abortion against her will, are odd in the extreme.”; Brazier, *op. cit.*, 346.
- <sup>262</sup> Although it should be noted that in English law, the concurrent right of a parent to consent on a child’s behalf does not seem to terminate until the child reaches 18.
- <sup>263</sup> Cf the Adults with Incapacity (Scotland) Act 2000, which establishes such a test in Section 1.
- <sup>264</sup> *Re D* [1976] 1 All ER 326
- <sup>265</sup> [1954] P. 112
- <sup>266</sup> L. Roth, A. Meizel & C. Lidz, “Tests of competency to consent to treatment” (1977) 134 Am J. Psychiatry 279
- <sup>267</sup> *Chatterton v Gerson* [1981] 3 WLR 1003
- <sup>268</sup> M Brazier, *op. cit.*, p101
- <sup>269</sup> [1992] 4 All ER 627, (1992) 9 BMLR 22
- <sup>270</sup> See e.g. Kennedy & Grubb, *op. cit.*, p148.
- <sup>271</sup> [1994] 1 WLR 290, [1993] NLJR 1642
- <sup>272</sup> (1998) 1 FLR 48
- <sup>273</sup> There is also a separate system of compulsory treatment under the mental health legislation; this is considered in Chapter 6 *infra*
- <sup>274</sup> *Supra cit.*
- <sup>275</sup> *Re MB (medical treatment)* [1997] 2 FLR 426
- <sup>276</sup> *Supra cit.*
- <sup>277</sup> At 1064
- <sup>278</sup> e.g. the comments by Lord Mustill in *Airedale NHS Trust v Bland* [1993] 1 All ER 821 at 898 that “...the decision is ethical, not medical, and there is no reason in logic why on such a decision the opinions of doctors should be decisive.”
- <sup>279</sup> (2000) 2 FLR 389; [2000] 3 WLR 1288; (2000) 55 BMLR 105
- <sup>280</sup> Reported as *Re SL (adult patient) (medical treatment)* [2000] 1 FCR 361 and *Re S (sterilisation: patient’s best interests)* [2000] 1 FLR 465
- <sup>281</sup> *Supra cit.*, paragraph 7
- <sup>282</sup> *Supra cit.*, transcript page 7, referring to *Re A (medical treatment: male sterilisation)* [2000] 1 FCR 193, 200

<sup>283</sup> [1998] 3 All ER 673

<sup>284</sup> *Supra cit.*

<sup>285</sup> *Chatterton v Gerson, supra cit.*

<sup>286</sup> *Supra cit*

<sup>287</sup> e.g. *Hills v Potter* [1983] 3 All ER 716, *Sidaway v Governors of the Royal Bethlem and the Maudsley Hospitals supra cit.*

<sup>288</sup> The literature on the topic is extensive; see SAM McLean, *A Patient's Right to Know*, (1989) and bibliography therein for a list

<sup>289</sup> J Katz, "Informed consent - a fairy tale? Law's vision" (1977) 39 U Pitt L Rev 137, 137-8

<sup>290</sup> Kirby J., "Informed consent - what does it mean?" 1983 J Med Ethics 69

<sup>291</sup> *Per Canterbury v Spence* (1972) 464 F 2d 772, the landmark US case on informed consent.

<sup>292</sup> *Supra cit*

<sup>293</sup> Although at least 37 States now allow recovery, under some test or other, for information negligence: Giesen, *op. cit.*, §597n

<sup>294</sup> *Reibl v Hughes* (1980) 114 DLR (3d) 1

<sup>295</sup> *Smith v Barking, Havering and Brentwood HA* (1989), [1994] 5 Med LR 285; but cf the "innate honesty" of the plaintiff in *McAllister v Lewisham & N. Southwark HA* [1994] 5 Med LR 343

<sup>296</sup> *Moyes v Lothian Health Board* [1990] 1 Med LR 463, 1990 SLT 444

<sup>297</sup> [1985] 1 AC 871

<sup>298</sup> cf Brazier, *op cit.* 63-64 and McLean *op. cit.* 111

<sup>299</sup> *Blyth v Bloomsbury AHA* [1993] 4 Med LR 151; *Gold v Haringey HA* [1987] 2 All ER 885, *Palmer v Eadie* (unreported, Ct of Appeal 18 May 1987)

<sup>300</sup> *Smith v Tunbridge Wells HA supra cit.*; *McAllister v Lewisham & N Southwark HA supra cit.*

<sup>301</sup> See all three cases mentioned in Note 299, *supra*.

<sup>302</sup> 1955 SC 200

<sup>303</sup> *Supra cit*

<sup>304</sup> 1990 SLT 444 at 449

<sup>305</sup> [1991] 3 Med LR 33

<sup>306</sup> For an equivalent English case see *Smith v Barking, Havering and Brentwood HA, supra cit.*

<sup>307</sup> Noted in an article which several of the judges in *Sidaway* relied on: G Robertson, "Informed consent to medical treatment" 1981 LQR 102

<sup>308</sup> Law & Polan comment that "The informed consent rule has never been a significant factor in malpractice litigation.": *Pain and Profit: the politics of malpractice*, (1978) 113

<sup>309</sup> e.g. by Lord Diplock (dissenting) in *Sidaway* at [1985] 1 AC 894-5; and see K McK Norrie, "The scope of informed consent in negligence" (1983) 32 ICLQ 235

<sup>310</sup> Presidential Commission for the Study of Ethical Problems in Medicine, *Making Health Care Decisions* (1982)

<sup>311</sup> A Buchanan, "Medical paternalism" (1977-78) 7 Philosophy & Public Affairs 340, 381

<sup>312</sup> SAM McLean, *op. cit.*, 92



<sup>313</sup> Giesen *op. cit.* §§590-601 provides an overview of how these are applied in several jurisdictions.

<sup>314</sup> *Attorney-General v The Observer Ltd. & Ors.; A-G v Times Newspapers & Ors.* [1988] 3 WLR 3 WLR 776; and see *Lord Advocate v The Scotsman Publications Ltd* 1988 SLT 490, Times July 7 1989 (HL) for an equivalent Scottish case.

<sup>315</sup> Law Commission Report No 110, *Breach of Confidence* (Cmnd. 8388/1981)

<sup>316</sup> SLC Report No 90, *Breach of Confidence*

<sup>317</sup> J Jacobs, "Confidentiality: the dangers of anything weaker than the medical ethic" (1982) *J Med Ethics* 18

<sup>318</sup> [1988] 2 All ER 648

<sup>319</sup> [1990] 1 All ER 835

<sup>320</sup> Whether under statute or ordered by a court: *GMC Professional Conduct: Fitness to Practice* (1991) 18

<sup>321</sup> See JK Mason & SA McCall Smith, *op. cit.*, Appendices, for a selection of these modern codes.

<sup>322</sup> Abolished by the Copyright Act 1911, s.31; SLC Report No 90, p.8

<sup>323</sup> *Brown's Trs. v Hay* (1895) 25 R 1112; *Roxburgh v Seven Seas Engineering Ltd* 1980 SLT (Notes) 49

<sup>324</sup> SLC, *loc cit.*, p.55

<sup>325</sup> *Seager v Copydex Ltd.* [1967] 2 All ER 415 at 417, *per* Lord Denning

<sup>326</sup> *Thomas Marshall (Exporters) Ltd v Guinle* [1979] Ch 227

<sup>327</sup> *Morison v Moat* (1851) 68 ER 492

<sup>328</sup> *A-G v Observer Ltd & Ors.*, *supra cit.*

<sup>329</sup> *Argyll v Argyll* [1967] Ch 302

<sup>330</sup> *Hunter v Mann* [1974] QB 767, 772 *per* Boreham J.

<sup>331</sup> *Campbell v MGN Ltd.* [2002] EWHC 499 (QBD)

<sup>332</sup> B Mahendra, "Confidentiality confounded" 2002 NLJ 573; for overviews of recent developments in this area, see R Dadak, "Privacy update" 2000 Sol. J. 355 and A Mackenzie, "Privacy – a new right in UK law?" 2002 SLT (News) 98

<sup>333</sup> MH Kattow, "Medical confidentiality: an absolute and intransigent obligation" *J Med Ethics* 1986, 12, 117-122

<sup>334</sup> See C Newdick, *op. cit.* 304-7 for a discussion of this problem

<sup>335</sup> Following the recommendations of the Caldicott Committee

<sup>336</sup> *Hunter v Mann supra cit.*

<sup>337</sup> *Duchess of Kingston's Case* (1776) 20 State Trials 355; *C v C* [1946] 1 All ER 562

<sup>338</sup> Public Health (Control of Disease) Act 1984; see Chapter 6 *infra*

<sup>339</sup> Prevention of Terrorism (Temporary Provisions) Act 1989

<sup>340</sup> cf the American position as shown in *Tarasoff v Regents of the University of California* (1976) 551 P 2d 334, where a psychiatrist was effectively held liable for failing to breach confidentiality in respect of a dangerous psychiatric patient.

- <sup>341</sup> *Kitson v Playfair* (1896) Times 28 March 1896; the crime here was illegal abortion.
- <sup>342</sup> *Initial Services Ltd v Putterill* [1968] 1 QB 396, per Lord Denning MR at 405
- <sup>343</sup> *Gartside v Outram* (1857) 26 LJ Ch 113
- <sup>344</sup> [1984] 2 All ER 413
- <sup>345</sup> *Ibid*, 433, per Griffiths LJ
- <sup>346</sup> Note that "public interest" is not the same as "of interest to the public": *BSC v Granada Television Ltd* [1981] 1 All ER 417, per Lord Wilberforce at 455
- <sup>347</sup> [1988] 2 All ER 648, (1987) 3 BMLR 1
- <sup>348</sup> *Ibid*.
- <sup>349</sup> Sub nom *H (A healthcare worker) v N (A health authority)* [2002] EWCA Civ 195
- <sup>350</sup> [1990] 1 All ER 835, (1989) 4 BMLR 96
- <sup>351</sup> Which Bingham LJ considered would clearly have given rise to an action for breach of confidence.
- <sup>352</sup> [1987] ICR 700
- <sup>353</sup> Law Commission *loc cit* paras 6.5 and 6.114; the issue of damages was not discussed by the Court of Appeal.
- <sup>354</sup> *Supra cit*.
- <sup>355</sup> Scottish Law Commission, *op. cit*.
- <sup>356</sup> Stair, *Inst. I*, 9,4
- <sup>357</sup> At common law; now regulated by the Defamation Act 1952 s.5; and see the Rehabilitation of Offenders Act 1974, s.8
- <sup>358</sup> Digest 47, 10, 15
- <sup>359</sup> Those supporting its inclusion in Scots law include Walker, *op. cit.*, 846-850; "Verbal injury: defamation or convicium?" 1970 JQ 157 and Stewart, *op. cit.*, §§ 8.24-8.25. Those denying its inclusion include K McK Norrie, "Hurts to character honour and reputation" 1985 JR 163 and Clive, Ware & McKain, *Scots Law for Journalists*, (5th ed. 1988) 204.
- <sup>360</sup> 1970 SLT 53
- <sup>361</sup> Again, the authorities are equally split on this point, see note 359 *supra*
- <sup>362</sup> *Supra cit*.
- <sup>363</sup> Kennedy & Grubb *op cit*. 640-642
- <sup>364</sup> Following *In the Estate of Park*, *supra cit.*, although Mason and McCall Smith *op. cit.* 203 consider that entitlement to consent to treatment automatically creates an entitlement to confidentiality, and vice versa.
- <sup>365</sup> See *GMC v Browne*, Times, 6 & 8 March 1971, and chapter 6 generally
- <sup>366</sup> *F v Wirral MBC* [1991] Fam. 69
- <sup>367</sup> *Re C (a minor) (evidence: confidential information)* (1991) 7 BMLR 138
- <sup>368</sup> Brazier, *op. cit.* 340
- <sup>369</sup> Amended Sydney 1968; see Mason & McCall Smith *op. cit.* for the full text.
- <sup>370</sup> GMC, *op. cit.*, para 91; emphasis added.

- <sup>371</sup> Lord Moran, *Winston Churchill: the struggle for survival 1944-1965* (1966); for a critical view of Moran's role in shaping the NHS, see D Gould, *Examining Doctors*, 81-2, 86-7, 102
- <sup>372</sup> Law Reform (Miscellaneous Provisions) Act s.1(1), a proviso excluding defamation actions from the reversal of the common law maxim *actio personalis moritur cum persona*. In Scotland, *Broom v Ritchie* (1904) 6 F 942 held that no action for defamation lay at the hands of the deceased's personal representatives unless it reflected on them.
- <sup>373</sup> *Printers & Finishers v Holloway* [1965] 1 WLR 1
- <sup>374</sup> Newdick, *op. cit.*, 266-7
- <sup>375</sup> Except, following *W v Edgell*, where such disclosure was necessary to protect the health of those relatives.
- <sup>376</sup> GMC, *op. cit.*
- <sup>377</sup> But note that in *W v Edgell, supra*, Bingham LJ described the GMC's description of the obligation of confidentiality as accurately stating the general law as it stands; whether a court would similarly find the exception for relatives similarly persuasive is open to question.
- <sup>378</sup> An NHS regulatory official, usually referred to as the ombudsman
- <sup>379</sup> Health Service Commissioner's Annual Report for 1988-89, para 50, cited in Newdick *op. cit.* 267
- <sup>380</sup> e.g. *Gammill v United States* (1984) 727 F 2d 950; the situation is heavily regulated by statute; see Chapter 6 *infra*
- <sup>381</sup> *Holgate v Lancashire Mental Hospitals Board* [1937] 4 All ER 19; *Tarasoff v Regents of the University of California* (1976) 131 Cal Rptr 14
- <sup>382</sup> *per* Lord Diplock in *Home Office v Dorset Yacht Co Ltd* [1970] AC 1004, where he specifically reserved his opinion on it.
- <sup>383</sup> *Supra cit*
- <sup>384</sup> *Per* the New Zealand case of *Duncan v Medical Practitioners' Disciplinary Committee* [1986] 1 NZLR 513
- <sup>385</sup> GMC, *HIV infection and AIDS: The ethical considerations* (1993) para 19
- <sup>386</sup> *Weld-Blundell v Stephens* [1920] AC 956
- <sup>387</sup> *The Oropesa* [1943] 1 All ER 214
- <sup>388</sup> *Maloco (Smith) v Littlewoods* 1987 SLT 425
- <sup>389</sup> See in particular E Pellegrino & D Thomasma, *A Philosophical Basis of Medical Practice* (1981) for a comprehensive attempt at constructing an ethical framework within which to reach decisions on such matters.
- <sup>390</sup> See for instance Warnock Report (Cmnd 9314/1984) paras 2.1-2.4, B Dickens "Reproduction law and medical consent" (1985) 35 Toronto Law J 255 at 280, A Capron, "Alternative birth technologies: legal challenges" (1987) UC Davis L Rev for lists of the possibilities
- <sup>391</sup> M Langford, "Who should get the kidney machine?" J Med Ethics 1992, 18, 12-17
- <sup>392</sup> *Barton v Islington HA, and de Martell v Merton & Sutton HA* [1992] 3 All ER 833, overruling *Walker v Great Northern Ry. Co. of Ireland* (1890) 28 LR Ir. 69
- <sup>393</sup> Except for parts applied to Scotland by the Consumer Protection Act 1987 s.6

<sup>394</sup> Digest 1, 5, 7

<sup>395</sup> *Sloan's Dairies v Glasgow Corporation* 1977 SC 223

<sup>396</sup> Basing its conclusion on the authorities reviewed in *Elliot v Joicey* 1935 SC (HL) 57 and *Montreal Tramways v Leveille* (1933) 4 DLR 337

<sup>397</sup> 1976 Act s 1(2)

<sup>398</sup> [1993] 4 Med LR 201

<sup>399</sup> *McKay v Essex AHA* [1982] QB 1166; such claims are now statute-barred in England.

<sup>400</sup> *Emeh v Kensington, Chelsea & Fulham AHA* [1985] 3 All ER 1044

<sup>401</sup> *Re S (a minor) (medical treatment)* [1993] 1 FLR 376

<sup>402</sup> [1992] 4 All ER 671; [1993] Fam. 123

<sup>403</sup> See, in particular, the discussion of a number of similar cases and a critique of the underlying reasoning in SAM McLean, *Old law, new medicine: medical ethics and human rights* (1999), Chapter 3

<sup>404</sup> *Re F (in utero)* [1988] 2 All ER 193 and *Hamilton v Fife Health Board supra cit.*

<sup>405</sup> See, for example, the cases cited by Butler-Sloss LJ in *Re MB supra cit.*

<sup>406</sup> e.g. *Airedale NHS Trust v Bland*; the decision was, in effect, a declaration that it would not be unlawful (or actionable) for the doctors to discontinue feeding; the House of Lords did not order the doctors to desist.

<sup>407</sup> *Re J (a minor) (wardship: medical treatment)* [1992] 2 FLR 165 at 172

<sup>408</sup> *Briody v St Helens and Knowsley Health Authority, supra cit.*

<sup>409</sup> See Nelson-Jones & Burton, *Medical Negligence Case Law*, 154-5

<sup>410</sup> *R v Arthur* (1981) 12 BMLR 1; see Chapter 3 *supra*

<sup>411</sup> [1993] 1 FLR 376

<sup>412</sup> [1988] 1 FLR 512

<sup>413</sup> *Airedale NHS Trust v Bland, supra cit.*; *Law Hospital NHS Trust v Lord Advocate and Another, supra cit.*

<sup>414</sup> *NHS Trust A v H*, Times, 17 May 2001

<sup>415</sup> [1995] 2 All ER 129

<sup>416</sup> See D Price, "Lessons for health care rationing from the case of child B" (1996) BMJ 312, 167

<sup>417</sup> [2001] 1 FLR 267

<sup>418</sup> *R v Bingley Magistrate's Court ex p Morrow* (1994) Times, 28 April

<sup>419</sup> [1994] 5 Med LR 277

<sup>420</sup> But cf *R v Adams, supra*, which held that evidence of what other doctors did was irrelevant in a charge of murder or attempted murder not due to breach of duty.

<sup>421</sup> *Per Council of Civil Service Unions v Minister of State for the Civil Service* [1985] AC 374

<sup>422</sup> *Wordie Property Co Ltd v Secretary of State for Scotland* 1984 SLT 345 per Lord President Emslie at 347-8

<sup>423</sup> *R v SSETR ex parte Holding and Barnes plc and others* [2001] UKHL 23, [2001] 2 WLR 1389, [2001] 2 All ER 929

<sup>424</sup> A concept of the European Court of Human Rights considered in Chapter 6 *infra*

<sup>425</sup> *Per* Lord Slynn at para. 53

<sup>426</sup> See, for example, *R v GMC ex p Gee, R v Professional Conduct Committee of the GMC ex p. Gee* [1986] 1 WLR 226 (QBD); [1986] 1 WLR 1247 (CA).

<sup>427</sup> See, for example, *Tehrani v United Kingdom Central Council for Nursing, Midwifery and Health Visiting* (2001) IRLR 208, considered in more detail in Chapter 6 *infra*

<sup>428</sup> Department of Health, *Claims of medical negligence against NHS Hospital and Community Doctors and Dentists* (1989) HC (89) 34

<sup>429</sup> B Manuel, *loc. cit.*, at 92-3

<sup>430</sup> See Chapter 5 *infra*

<sup>431</sup> B Manuel, *loc. cit.*, 94-5, referring to SC Charles, "Malpractice suits: their effect on doctors, patients and families" *J Med Assoc. Ga.*, 76: 171, 1987

<sup>432</sup> Reported by J Allsop & L Mulcahy, *Regulating medical work: formal and informal controls* (1996), 191-3

<sup>433</sup> See "Trust me, I'm a doctor", *Times*, 8 May 2001

<sup>434</sup> Reported in *The Times*, 8 May 2001

<sup>435</sup> JK Mason and RA McCall Smith, *op. cit.*, 215

<sup>436</sup> JK Mason and RA McCall Smith, *op. cit.*, 217, referring to PM Danzon, *Medical Malpractice* (1985) esp. Chapter 1

<sup>437</sup> Reported by M Brazier, *op. cit.*, 219

<sup>438</sup> P Fenn and R Dingwall, "The tort system and information: some comparisons between the UK and US" in R Dingwall and P Fenn (eds.), *Quality and regulation in health care: international experiences* (1992), 11

<sup>439</sup> M Davies, *op. cit.*, 60

<sup>440</sup> B Manuel, *loc. cit.*, 101

<sup>441</sup> *Id.*

<sup>442</sup> MA Jones and AE Morris, "Defensive medicine: myths and facts" (1989) 5 *Journal of the Medical Defence Union* 40

<sup>443</sup> C Ham *et al.*, *Medical negligence: compensation and accountability* (1988), 5

<sup>444</sup> *Gillick v West Norfolk & Wisbech AHA, supra cit.*

<sup>445</sup> The principle has most recently been restated in *R v SSETR ex p Holding & Barnes Ltd, supra cit*

<sup>446</sup> [2001] EWHC Admin 317 (QBD Administrative Court 25 April 2001)

<sup>447</sup> For a rare example, see *LaFarge Redlands Aggregates Ltd. v The Scottish Ministers*, 2000 SLT 1361

<sup>448</sup> According to the resource allocation cases considered *supra*; see fn 110 *supra*

<sup>449</sup> M Brazier, *op. cit.*, 8

<sup>450</sup> I Goldrein and M de Haas, *op. cit.*, 5

<sup>451</sup> Government statement, *Hansard*, 24 March 1998, cols. 165-166

<sup>452</sup> J Allsop and L Mulcahy, *op. cit.*, 164

<sup>453</sup> Law Society, *Client views: clients' experiences of using a solicitor for personal matters* (2001)

<sup>454</sup> C James, "Professional accountability in New Zealand 1974-1991: doctor, patient and advocate" in J Wall (ed.), *op. cit.*, 11

<sup>455</sup> For example, the 50% increase in complaints to the GMC in 2000 as compared to 1999: Times, 15 February 2001

<sup>456</sup> According to the National Consumer Council; see note 74 *supra*

<sup>457</sup> J Allsop and L Mulcahy, *op. cit.*, 164

<sup>458</sup> *Hatcher v Black supra cit*

<sup>459</sup> SAM McLean, *loc. cit.*, 104

<sup>460</sup> C Dyer, "UK considers new compensation plan for NHS" BMJ 2001; 323: 66 (14 July 2001)

## Chapter 5: Statutory Regulatory Bodies

### I: Introduction and Scope:

This chapter analyses the statutory regulatory bodies which have been established by law to perform regulatory tasks in the field of health care. A number of bodies have been established for a variety of purposes. Closer scrutiny of the category, however, served to exclude all but one statutory regulatory body. The exception is the General Medical Council (GMC). The GMC is included here because: it is established by legislation; it performs (or seeks to perform) specific regulatory functions; the regulatory functions undertaken involve an element of discretion as to what is acceptable; its jurisdiction extends to medical conduct universally; and its determinations have legally-binding effect on those being regulated.

However, before proceeding to consider the GMC, it is necessary to consider the roles and remits of other bodies created by or under statute. The main bodies omitted from detailed examination in this Chapter, and the reasons for their exclusion, are as follows:

- The Information Commissioner (IC): the IC is an official tasked with regulatory and supervisory functions under the Data Protection Act 1998 and Freedom of Information Act 2000. However, she is not included in this section because the effects of the legislation she is responsible for apply by force of law without her intervention, and the duties created by the legislation are enforceable in the ordinary courts without need for her intervention. This is in marked contrast to the GMC, which is entrusted with policy discretion as to what is or is not acceptable. The IC's role is limited to enforcing standards laid down in the legislation itself whether by initiating court action or through the system of assessments (which can be regarded as a system of alternative dispute resolution). Accordingly, the Data Protection Act 1998 and Freedom of Information Act 2000 are considered in Chapter 6 *infra*.
- The Mental Health Act Commission (and Mental Welfare Commission for Scotland): these bodies are established in terms of the Mental Health Act 1983 and Mental Health (Scotland) Act 1984 respectively<sup>1</sup>. The remit of these bodies is limited to overseeing the treatment of persons compulsorily detained under mental health legislation. Given this limited scope, and the fact that the Mental Health Act Commission has explicitly indicated that its role is essentially one of

review and advice rather than an inspectorate role<sup>2</sup>, they are considered to fall outwith the scope of this thesis. In addition, the facilities within which people are detained are exclusively NHS facilities, and therefore the bodies principally responsible for overseeing such detention can reasonably be regarded as NHS regulatory systems, and are accordingly outwith the scope of this thesis.

- The National Audit Office and Audit Commission/Audit Commission for Scotland: these bodies are established to oversee the financial management of government agencies. Again, given their limited remit they are outwith the scope of this thesis.
- Assorted advisory bodies. There are many bodies established to review current practice in healthcare, provide guidance and assistance or carry out similar functions. However, the functions performed are purely advisory in nature. As described in Chapter 2, the only bodies included for study within this thesis are those which fulfil an identifiable regulatory function. Advisory bodies do not fulfil any of these roles, and for this reason are accordingly not included.
- The National Clinical Assessment Authority, the Commission for Health Improvement (CHI) and a variety of other bodies which, while they have a clear remit in terms of regulating the standard of care, are purely NHS internal bodies.
- The Human Fertilisation and Embryology Authority (HFEA): This is established in terms of the Human Fertilisation and Embryology Act 1990, section 5. The functions of the HFEA are, to quote itself,

“...to regulate, by means of a licensing system, any research or treatment which involves the creation, keeping and use of human embryos outside the body, or the storage or donation of human eggs and sperm. It must also maintain a Code of Practice giving guidance about the proper conduct of the licensed activities.”<sup>3</sup>

In fact, even this short description of the HFEA’s jurisdiction was briefly questioned: in the case of *R (on application of Quintavalle) v Secretary of State for Health*, the court at first instance<sup>4</sup> held that organisms created by CNR (the technique commonly known as “cloning”) were not embryos within the Act’s definition, and so were not covered at all by the statutory regime. The decision



was rapidly reversed by the Court of Appeal<sup>5</sup>, but not before Parliament had (even more rapidly) passed the Human Reproductive Cloning Act 2001, making it illegal to place an embryo created by CNR in a woman. For purposes of this thesis, however, it is sufficient to note that the role of the HFEA is narrowly confined to those involved in areas of embryology and infertility treatment. As such, most doctors are outwith the scope of influence of its activities. Since this thesis only seeks to analyse the impact of what could be called “universal” regulatory systems, the HFEA is not considered in any more detail.

- The Unrelated Live Transplant Regulatory Authority (ULTRA): This is established under the Human Organ Transplants (Unrelated Persons) Regulations 1989<sup>6</sup>, themselves made under the Human Organ Transplants Act 1989<sup>7</sup>. This legislation was passed as an emergency response to a scandal involving “kidneys for sale”, an activity which brought down the weight of the GMC’s disciplinary sanctions<sup>8</sup>. The Act’s principle effect is to outlaw commercial dealings in human organs, and as such is a form of direct statutory regulation of the type considered in Chapter 6. Section 2(1) of the Act creates two offences relating to removing or transplanting organs from a live donor to an unrelated recipient. Section 2(3) of the Act disapplies the prohibition if the Authority created under the Act is satisfied as to certain conditions.

The conditions laid down in the Regulations are, in essence, that the doctor has caused the matter to be referred to ULTRA for its consideration of the matter, that the person whose organ it is proposed to remove has given their free and informed consent to the procedure, and that there is no inducement given or to be given which would fall foul of the prohibition found in Section 1 of the Act.

It can be seen that, in terms of structure and function, ULTRA fulfils most of the criteria for inclusion in this Chapter as a statutory regulatory body. However, given the extremely narrow remit which ULTRA has, and (as with the HFEA) given that the overwhelming majority of doctors have no involvement in the area of medical practice covered by ULTRA (and will accordingly be unaffected by its existence, even theoretically), it is not proposed to examine it in any greater detail.

- The National Care Standards Commission: this is established under the Care Standards Act 2000, and has jurisdiction only in England and Wales. Its purpose is to residential care homes, and private and voluntary health care providers. The

regulation of residential care homes is by way of replacement of a function previously carried out by local social services departments, but the regulation and inspection of private/voluntary health care providers is completely new. However, it has been excluded from detailed study for exactly the same reason as NHS bodies are excluded, namely lack of universality of coverage. Most health care provision is carried out under the auspices of the NHS and is therefore outwith the jurisdiction of the new Commission. However, in creating for the first time a standards regulator for the private medical sector, this legislation does represent a significant improvement in the regulatory landscape.

Having excluded from the scope of this thesis all the other bodies which could potentially have been covered by the description of “statutory regulatory body”, the remainder of this chapter will consider the position of the sole remaining contender, the General Medical Council.

## **II: History and purpose of the General Medical Council:**

The GMC (in its original guise as the General Council of Medical Education and Registration) is one of the oldest bodies in the regulatory framework, having been established originally by the Medical Act 1858. It is not intended to provide an exhaustive description of the GMC here. Two relatively recent studies have analysed the history, structure and functions of the GMC<sup>9</sup>, and the cases dealt with by the GMC under its disciplinary powers<sup>10</sup>. Little would be gained by duplicating this research here. Instead, a very brief summary of the structures and powers of the GMC is given, followed by an analysis of its regulatory impact. In terms of nomenclature, Smith notes that while not technically designated as “the General Medical Council” until 1950, the body was known informally as the “General Medical Council” since 1859<sup>11</sup>. This chapter refers throughout to the GMC, although some comments relate to times when it was not officially so called.

The GMC was adopted as part of the overall regulatory landscape by Nye Bevan when he was instituting the NHS<sup>12</sup>. The subsequent history of the GMC has been often unsettled, and a doctors’ revolt at the GMC’s proposals to introduce annual membership fees would, if carried to its logical conclusion, have shut down the NHS<sup>13</sup>. Its more recent history has been no less turbulent, and an active debate over the future of the GMC is taking place at the time of writing<sup>14</sup>. The functions of the GMC when it was established in 1858 were fairly well summed up in its original corporate title – “The General Council for Medical Education and Registration”. In essence, the GMC (GCMER

as was) had responsibility for ensuring the medical schools provided an adequate standard of initial training for would-be doctors, and maintained a register of those who had gained the requisite qualifications.

These functions have undergone a degree of evolution since 1858, but these two original functions remain intact. The GMC's current statutory basis is the Medical Act 1983, as amended (hereafter referred to as "the Act"). The Long Title to the Act's original predecessor, the Medical Act 1858, states that it is

"An Act to regulate the Qualifications of Practitioners in Medicine and Surgery"

The specific duties imposed on the GMC are, in essence, a way of fleshing out this statement. Thus, when one scrutinises the Act for the specific ways in which the GMC regulates the qualifications of medicine and surgery, one finds the following duties:

- Section 2: the GMC has to keep a register of medical practitioners consisting of four categories of (fully) registered medical practitioners, plus a list of "medical practitioners with limited registration". It is inclusion on this list (or these lists; for simplicity, the registers will be referred to in the singular hereafter) which provides conclusive proof<sup>15</sup> of someone's status as a registered medical practitioner. Some of these advantages of this status can be found in the Act itself. Section 46 provides that only a registered medical practitioner can recover fees for medical services lawfully rendered; Section 47 provides that only a registered medical practitioner may be appointed as physician in the armed forces, prisons, mental institutions or other public establishments, and Section 48 states that any certificate requiring to be signed by a medical practitioner is only valid if the practitioner is registered. The details to be kept in the Register are described in Part IV of the Act (Sections 30 to 34). It is erasure from this Register, colloquially known as being "struck off", (discussed *infra*) which represents the most severe sanction in response to a doctor who has failed to meet or maintain the requisite standard of behaviour, practice, or health. Section 49 creates the offence of wilfully and falsely holding yourself out to be a doctor of medicine (or equivalent title) or being registered under the Act when you are not in fact so registered. This offence is punishable by a fine of Level Five on the standard scale<sup>16</sup>. However, fraudulent practice may also lead to other crimes being libelled such as assault, the defences mentioned in Chapter 3 not generally being available to fake practitioners. In one reported case, the offender was sentenced to five years' imprisonment<sup>17</sup>. Erasure from the Register is considered *infra*;

- Section 5: the Education Committee of the GMC (one of seven statutory committees the GMC is required to have by virtue of section 1),

“...shall have the general function of promoting high standards of medical education and coordinating all stages of medical education.”<sup>18</sup>;

and

- Section 35: the GMC has the power to provide advice to the medical profession on matters of medical ethics or professional conduct. To this has been added the power to advise on standards of professional performance<sup>19</sup>.

These purposes are as given in the GMC’s parent statute. However, it is also useful to consider the GMC’s own view as to its purpose, *i.e.* to identify the ends to which the GMC carries out these statutory functions.

The GMC’s current public consultation documents provide the most recent description of its own perceived purposes. The consultation document on the structure of the GMC<sup>20</sup> states unequivocally that

“While the structures for delivering the GMC’s functions need to change, the GMC’s role will remain the same: to protect the public.”<sup>21</sup>

While the theme of protecting the public is a recurring one in the GMC’s own literature, the only context in which the expression appears in the Act itself is in relation to the making of interim suspension orders. It was not until the Act was amended by the Medical (Professional Performance) Act 1995 that protection of the public explicitly became an objective for the disciplinary system. Arguably, the GMC was (prior to that amendment coming into force) merely applying its own interpretation of the law. The precise mechanisms by which the GMC undertakes its four tasks described comes next; whether the GMC’s assertion that its powers are “strong and effective” is considered thereafter. There is, additionally, a statutory provision<sup>22</sup> whereby the Privy Council is authorised to step in if it (the Privy Council) feels the GMC is not doing its job properly.

### **III: Mechanisms of the GMC:**

The GMC's main statutory powers are carried out through seven statutory committees, as described in Section 1 of the Act<sup>23</sup>. The Review Board for Overseas Qualified Practitioners, maintained by Section 28 of the Act, has a number of appellate functions in relation to doctors qualified outwith Britain and the EU. In addition, it is technically the Registrar of the GMC who is charged with the duty of maintaining the register<sup>24</sup> rather than the GMC corporately. The Registrar also has a number of specified functions to be carried out on behalf of the GMC, such as the obligation to notify persons affected by decisions of the Council or its committees as to the outcome of that decision<sup>25</sup>. The Registrar's functions may instead be carried out by a deputy or assistant<sup>26</sup>. As will be seen below, the preliminary screener also plays a key role in the disciplinary functions; this was a customary role which has found its way into the statutory framework<sup>27</sup>.

The functions and constitution of the GMC were analysed in detail by an independent Committee of Inquiry, the "Merrison Inquiry". In its report<sup>28</sup>, the committee endorsed the concept of professional self-regulation and accepted that the inter-relationship between the GMC's functions, particularly the connection between the standards of education needed to be placed on the register, and the rules on being entitled to remain on the register thereafter, meant that a single body should continue to be responsible for both aspects.

This observation goes to the heart of how the GMC operates. In terms of regulatory strategy, it has clearly opted for the compliance model by requiring the appropriate licensing of individuals (through their inclusion in the register) as a prerequisite to enjoying the advantages of membership of the profession. The GMC, through its statutory control of medical education and the qualifications entitling one to registration, controls the entry criteria for the medical profession. The same GMC controls the disciplinary mechanism through which someone who has become registered can be removed from the register. Lastly, the GMC has responsibility for publishing guidance on the standards to be achieved by registered medical practitioners, so it is able to establish (at least to some extent) the rules against which those brought before its disciplinary mechanisms will be judged. In keeping with Merrison, it is convenient to analyse the GMC's functions in terms of how one becomes registered, what one is expected to do (and not do) while registered, and how one stops being registered<sup>29</sup>.

## **A: Medical Education and Registration:**

These two aspects are heavily intertwined. Medical education is a necessary prerequisite to registration, while registration itself is dependent on previous education. Indeed, the nature of the previous education can determine the nature of the registration you receive.

The education remit of the GMC is entrusted to the Education Committee. Like the other statutory committees, the Education Committee enjoys a degree of independence from the main Council simply because the Act determines that it is the Committee, not the Council, which has the “general function of promoting high standards of medical education.”<sup>30</sup> The Education Committee also enjoys the unusual privilege of electing its own chairperson (unusual in that most committee chairs are appointed by the president of the Council<sup>31</sup>).

On paper, the powers of the GMC to regulate medical education are immense, although the statutory derivation is somewhat convoluted. Inclusion in the Register is conditional on one of three routes, in which the GMC exercises theoretical near-absolute control over two of them. In all cases, and irrespective of how a doctor became qualified or what qualifications he or she possesses, registration (including remaining on the Register after qualification) is conditional on payment of the appropriate fees<sup>32</sup>. The only exception to this is in relation to visiting EEC practitioners.<sup>33</sup>

### 1: Persons registered by virtue of European Law:

The first route to inclusion in the Register is that you are an EU national qualified elsewhere in the European Union, in which case European laws on freedom of movement of workers and mutual recognition of professional qualifications mean you are entitled to practise in the UK without further formality being required or permitted<sup>34</sup>. The GMC has no jurisdiction over the status of European qualifications, but the regulatory framework is maintained in that it enjoys powers to give effect to the equivalent to striking off or suspension if imposed by other EU regulatory authorities<sup>35</sup> and it may itself discipline medical practitioners practising in the UK under the auspices of other EU qualifications<sup>36</sup>. European legislation allowed persons to practise medicine as registered medical practitioners without GMC approval for the first time. The GMC was banned from requiring linguistic tests of EU-qualified doctors, something which apparently caused upset in the GMC at the time<sup>37</sup>.

## 2: Overseas-qualified doctors:

The second qualification route involves persons qualifying “overseas” (i.e. outwith the UK, but presumably other than EU nationals holding primary European qualifications); Part III of the Act lays out a detailed series of rules concerning this. The upshot of these rules is that you must either hold a qualification recognised as equivalent to UK registrable qualifications<sup>38</sup>, or else have an acceptable (but not recognised) overseas qualification and pass an exam (set under the auspices of the GMC)<sup>39</sup>. The mutual recognition rules are, apparently, an old relic of Empire<sup>40</sup>, and recognition has been steadily decreasing over the years. There are, as at November 2001, 24 recognised institutions; the GMC itself indicates that it is seeking to change the rules because it believes they are “unfair”.<sup>41</sup> Persons possessing a recognised overseas qualification, and who satisfy the same rules on work experience as domestically-qualified applicants, are entitled to full registration.

Conversely, the possession of an acceptable overseas qualification and passing the necessary exams only entitles the applicant to limited registration. Dealing with doctors qualifying overseas (but who did not qualify from a “recognised” institution) remains a significant part of the GMC’s workload. Candidates falling into this latter category are those who hold a primary medical qualification from any institution listed in the World Health Organisation’s Directory of Medical Schools, but which do not appear on the list of institutions “recognised” under Section 19. Such candidates require to satisfy the GMC (technically the Registrar) on five points, listed in Section 22(1) of the Act, *viz.* having been selected for employment in a UK hospital or other approved institution, holding an acceptable overseas qualification, knowledge of English, being of good character, and appropriate skills, knowledge and experience.

There are two main aspects to this which occupy the GMC’s time, the other three elements being (in effect) prerequisites. Existence of the acceptable overseas qualification is a necessary element but the GMC’s role is limited to checking its authenticity; the same is true of offers of employment. While in theory the requirement to be of “good character” could be actively examined by the GMC, in practice this seems to be limited to checking that the applicant has not been convicted of certain types of offence. An exception to the lack of active scrutiny of these matters by the GMC arises in that the Overseas Committee uses the requirement to be of good character as a means of exercising disciplinary powers over those having limited registration against whom charges of misconduct have been made; this is considered *infra*.

The GMC's main concern is with the tests applied under which linguistic and clinical ability are checked. Linguistic ability is measured according to the IELTS test series set by the British Council. The actual scores required vary depending on whether the applicant has passed the PLAB test (see below), on the basis that the PLAB

“...provides additional objective assessment of communication in a clinical context.”<sup>42</sup>

The Professional and Linguistic Assessment Board, or PLAB, was established following the passage of the Medical Act 1978, which replaced temporary registration with limited registration, although PLAB is not formally recognised by statute. Instead, successive Medical Acts have recognised the ability of the GMC to grant registration to those who satisfy the GMC (or its Registrar) as to certain issues; these issues are in effect delegated to the PLAB by the GMC. “Passing the PLAB”, as it is known, involves clinical problem solving exercises, in the form of a written exam (which, since it is in English, is the basis for saying it also assesses clinical English). Pass rates for the PLAB and its predecessor TRAB varied from 22% to 43% between 1975 and 1988<sup>43</sup>. While the PLAB itself does not enjoy formal statutory status, the Medical Act 1983 does provide a mechanism for appeals to be taken against adverse decisions in relation to overseas-qualified doctors. Section 28 of the Act continues in existence the Review Board for Overseas Qualified Practitioners. This Board has the power to hear appeals against decisions of the GMC in relation to overseas-qualified doctors (both those with “recognised” and “acceptable” qualifications). The Board itself consists of a chairman and deputy chairman appointed by the President on the recommendations of the councils for postgraduate education in England and Wales, Scotland and Northern Ireland; they may not be members of the Council. The other members (currently seven) are members of the Council, and must include one elected member, one appointed member, and one overseas-qualified doctor.<sup>44</sup> However, despite this elaborate machinery, the review of decisions which the Review Board can carry out is only advisory in nature. Ultimately, the President (or some other person appointed by the Council) retains the final say on whether to reverse or uphold the original decision; the only obligation incumbent upon them is to “have regard” to the Review Board’s opinion on the matter<sup>45</sup>.

Limited registration without passing the PLAB exam is possible if an overseas-qualified doctor is sponsored for postgraduate training by a small number of Royal Colleges or other postgraduate institutions<sup>46</sup>. These are subject to prior approval by the GMC which seeks to build quality assurance measures into its approval system; it is not intended to



be an alternative route for those who have failed the PLAB<sup>47</sup>. Sponsorship does not, however, exempt overseas doctors from the requirement to pass the IELTS linguistic proficiency test.

### 3: Registration following qualification in the UK:

The third, and most common, route to becoming fully registered involves registration by virtue of holding a primary United Kingdom qualification, passing a qualifying examination, and having the requisite experience<sup>48</sup>. There is no need for a person claiming full registration under the “domestic qualification” route to satisfy the GMC that they are of good character. “Qualifying exam” and a “primary United Kingdom qualification” are defined in Section 4; in essence, it means a medical degree awarded by any of the UK’s medical schools, plus a few other routes involving the Royal Colleges and similar bodies. The bodies able to award primary UK qualifications are also able to hold qualifying examinations.

The GMC exercises the most influence over the UK qualification route. In terms of Section 5, the Education Committee of the GMC shall determine the content both of the medical curriculum leading up to the award of primary qualifications, and also the standard of proficiency required to pass the qualifying examination. It is also allowed to determine the pattern of post-qualifying work experience necessary to move from provisional to full registration. The powers of the Education Committee are, on paper at least, impressive: visitors and inspectors can be appointed to monitor medical teaching and examinations respectively<sup>49</sup>. If the Committee feels that an institution is not maintaining the appropriate standards either in teaching or examining, it may make representations to the Privy Council which, if it sees fit, may direct that the qualification or examination no longer entitles recipients thereof to registration under the Act<sup>50</sup>. Revocation of the Order does not entitle such individuals to registration<sup>51</sup>. Similar powers exist allowing the Committee to appoint visitors to postgraduate training institutions, although there are no formal powers to withhold recognition of a particular institution<sup>52</sup>. This is because recognition of training institutions is done by the qualification-awarding bodies rather than the GMC itself<sup>53</sup>.

In reality, it would appear that the GMC does not utilise its formal statutory powers. The Education Committee itself has traditionally been composed of some of the most influential figures in the medical education community<sup>54</sup>. There are consequently internal and external politics involved in getting the Education Committee to use any of the powers theoretically available to it<sup>55</sup>. Indeed, Allsop and Mulcahy indicate that the GMC’s

activity in this area (such as it was) was ineffective<sup>56</sup>. This inactivity is illustrated by Stacey's revelation that between 1959 and 1982, none of the older UK universities was inspected by the GMC<sup>57</sup>. A limited inspection was conducted in 1982, but this only occurred following representations by the Presidents of three Royal Colleges<sup>58</sup>. Given that the GMC acted following these representations, it could be argued that the GMC's inactivity in other areas is an indication that matters are proceeding properly without the need for intervention. Stacey herself is sceptical about such claims, noting that the survey of education showed that "the study of some subjects was honoured more in the breach than the observance."<sup>59</sup>

#### 4: Types of registration:

As noted above, the GMC's duty under Section 2 is to keep a register of medical practitioners consisting of four categories of (fully) registered medical practitioners, plus a list of "medical practitioners with limited registration". In addition, there is a category of "provisional registration" under Section 15.

In practical terms, the only real differences are between full registration, provisional registration and limited registration. Full registration can be achieved through a number of different routes; the other forms of registration are (all going well) merely steps on the way to becoming fully registered. There are additional forms of registration applicable to visiting EU nationals<sup>60</sup> and temporary full registration for visiting overseas specialists<sup>61</sup>. Both of these are subject to time limits<sup>62</sup>. Full, unlimited registration can be achieved by means of the domestic route, the EU route, and the two routes for overseas doctors.

Limited registration only applies to overseas doctors whose qualification is not "recognised" for purposes of Section 19. Limited registration only permits the person to act as though fully registered in relation to a particular (supervised) employment in a hospital or other approved institution<sup>63</sup>, selection for employment in such an institution being a prerequisite for limited registration<sup>64</sup>. Registration is specific to the post, so repeat applications may be necessary if short-term posts are all that is available. Registration can only last for a maximum (aggregate) period of five years.<sup>65</sup>

The satisfactory experience required of UK-qualified doctors, and those having a recognised overseas qualification, is experience of working in a resident medical capacity in one or more approved hospitals or other approved institutions. This work has to satisfy the requirements of an examining body, acquiring the experience appropriate for that body's area of practice involving at least two branches of medicine, and

satisfactory service<sup>66</sup>. Work experience is acquired before full registration through the category of “provisional registration”.<sup>67</sup> This is similar to limited registration in that it permits the person provisionally registered to act as a registered medical practitioner so far as is necessary for them to gain the experience required by Section 10. The main difference is that, unlike limited registration, provisional registration is neither post-specific nor time-limited.

## **B: Obligations of doctors:**

There are a number of duties incumbent on the doctor who wishes to remain registered. The first of these is straightforward: the duty<sup>68</sup> to pay an annual fee if you wish to remain on the Register<sup>69</sup>. Fees are payable in respect of being added to the Register, being retained on it and (in the event that you are removed from it for any reason) for restoration to it. No fee can be charged to visiting EEC practitioners<sup>70</sup>, although if such a person becomes established in the UK their entitlement to be registered as a visitor ceases and they would thereafter be obliged to pay the fee like anyone else.

More significantly, the GMC also has the power to issue “advice for members of the medical profession on standards of professional conduct or on medical ethics”.<sup>71</sup> For a long time, the GMC has periodically produced the so-called “Blue Book”<sup>72</sup> describing those areas of conduct (or more accurately, misconduct) which are likely to attract the attention of the disciplinary procedures described *infra*. The Blue Book has, however, been described as a “best sins guide”<sup>73</sup> because in essence all it did was reiterate areas where a particular course of conduct had resulted in the GMC imposing disciplinary measures on a doctor. It made no attempt to lay down more general principles as a guide to future conduct beyond the very broadest (and least helpful) remarks. This approach has changed, and the Council does now produce a reasonably extensive list of guidance material for the benefit of the profession. The GMC has summarised the duties of the registered practitioner in 14 key principles<sup>74</sup>.

Detailed discussion of the content of the GMC’s guidance would effectively amount to a re-writing of *Good Medical Practice*<sup>75</sup> and so this has not been done. For present purposes what is important is to note that the obligations imposed on doctors do not end the moment the Registrar of the GMC enters his or her name on the Register without any provision or limitation.

The next section analyses the extent to which these ongoing obligations are enforceable, and enforced, by the GMC and how it goes about enforcing them.

## C: Disciplinary Functions of the GMC:

It is in the exercise of its disciplinary functions that the GMC most often comes into the public's attention. This particularly involves the powers under Section 36(1)(b), where a fully registered person is judged by the Professional Conduct Committee to have been guilty of "serious professional misconduct" (hereafter "SPM"), or where an allegation of SPM is made against such a person. The same procedures apply in relation to fully registered persons who have either been convicted in the British Islands of a criminal offence or (more recently) who "have been convicted elsewhere of an offence which, if committed in England and Wales, would constitute a criminal offence".<sup>76</sup> The GMC is a "public authority" for the purposes of Section 6 of the Human Rights Act 1998, and so the disciplinary functions of the GMC require to be compatible with the ECHR right to a fair trial<sup>77</sup>. While the impact of the Human Rights Act is principally considered in Chapter 7 *infra*, it is convenient to note the impact which cases brought under that Act have had on the GMC's functions at the appropriate part of the discussion.

### 1: Preliminary screening procedures:

In the early days of the GMC, disciplinary matters were dealt with by the full Council, a situation only amended by the creation of a separate disciplinary committee in terms of the Medical Act 1950<sup>78</sup>. This, of course, potentially raised the problem of cluttering up the Council meetings with manifestly ill-founded allegations of the sort described by Pyke-Lees:

"...one patient stated that 'I was definitely of sound mind before, during and after death', complained principally of the actions of doctors after that event, and signed himself 'the late' so-and-so."<sup>79</sup>

To avoid this problem, a screening procedure has always existed. Initially this function was carried out by the Branch Councils for England, Ireland and Scotland, but was taken over by the President in 1889<sup>80</sup>. This screening power does not feature in the statutory scheme of things but is instead a creation of the GMC itself. The potential power this placed in the hands of the preliminary screener (who was always the President of the Council until 1988<sup>81</sup>) should not be underestimated. The formal delegation of power to the President was

"... to withhold obviously unfit cases of complaint from reference to the General Council."<sup>82</sup>

However, the decision as to what constituted “obviously unfit” was that of the preliminary screener alone. A conservative approach could render the rest of the disciplinary mechanism nugatory by screening out all or almost all complaints. An actual example of this approach has been given, described as follows:

“Some hint of the narrow way in which these powers could be defined, even into the 1950s, is given in a summary history of the GMC written by MR Draper, a former registrar. Writing in the 1982 *GMC Annual Reports*, he comments on the central role of past presidents in disciplinary proceedings. He says they often acted alone in deciding which cases went forward. He reports that Sir David Campbell (President from 1950 to 1961) thought that the abuse of a professional confidence could never amount to ‘infamous conduct’, that the non-*bona fide* prescribing of dangerous drugs should be dealt with by the Home Office, not the GMC, and that the Council should ‘take no cognisance of findings of the Medical Service Committee [the tribunal dealing with complaints against family practitioners] that a doctor had failed to visit and treat patients.’ Draper also comments that the complainants could be told that they must pay the legal costs of presenting a complaint, which was likely to deter all but the most ‘wealthy or determined’.”<sup>83</sup>

Clearly leaving such power in the hands of a single, largely unaccountable, individual was open to criticism. While decisions of the preliminary screener are susceptible to judicial review<sup>84</sup>, this would only apply in the most extreme circumstances. Accordingly, the rules were changed in 1990 so that the decision of the preliminary screener must have the concurrence of a lay member of the Council<sup>85</sup>. Commenting on these provisions, Smith notes that

“From the point of view of accountability, these non-public filtering processes are of crucial importance, *a fortiori*, since the proportion of cases screened out is so large. The Council does, however, seem to be demonstrating a recent and commendable tendency to disclose its activities in this area to a greater extent and in greater detail than in the past.”<sup>86</sup>

More recently, the Privy Council has held (admittedly in a dental case involving a similar, but not identical system) that the preliminary screener should not subsequently be involved in either the PPC or PCC stages of any disciplinary action<sup>87</sup>.

## 2: Preliminary Proceedings Committee and Interim Orders Committee

Assuming the preliminary screener does not reject the complaint as unfounded, the allegation is then passed onto the Preliminary Proceedings Committee (hereafter the "PPC"). Criminal convictions of registered medical practitioners also come to the PPC, with the exception of convictions resulting in absolute or conditional discharge and minor motoring offences<sup>88</sup>.

The PPC presently consists of seven members, including two lay members. It sits *in camera*, except in cases which appear to call for immediate action. Such cases should now, however, be referred to the Interim Orders Committee (IOC). A challenge to the practice of the PPC sitting *in camera* was rejected by the Privy Council, which held that disclosing notes of such deliberations would seriously inhibit freedom of discussion and be contrary to the public interest<sup>89</sup>. The main function of the PPC is found in Section 42(2) of the Act. The PPC itself can decide to discontinue proceedings, either with or without issuing advice or a warning to the doctor in question; it can refer the doctor to the health procedures described *infra*, or refer the matter to a hearing before the Professional Conduct Committee (hereafter the "PCC"). Interestingly, it does not appear to be competent for the PPC to refer a matter to the Committee on Professional Practice. Despite the creation in 2000 of the IOC, it appears to remain competent for the PPC to suspend a doctor's registration or make it subject to conditions, and to do so forthwith. Any such immediate action requires the PPC (or any other committee of the GMC having the power to make such an order) to afford the doctor in question the opportunity of appearing before the Committee in question and being heard on the question of immediate suspension or conditions<sup>90</sup>. The Committee is thereafter obliged to provide reasons explaining why, if it imposes immediate suspension, it came to the conclusion that this was a necessary and proportionate step to take<sup>91</sup>.

The significance of the Interim Orders Committee in this equation is that the IOC, which was created in 2000 by an amendment to the Act<sup>92</sup> is specifically tasked with the issue of deciding whether the allegations against a doctor are so serious as to warrant immediate action. The formal amendments to the Act itself create a new statutory committee of the GMC. However, there is no requirement for the other committees having the power to impose immediate suspension on a doctor referred to them<sup>93</sup> to pass the matter to the IOC for its consideration. This could, but for the GMC's internal handling of these matters, lead to a duplication of powers. The amendments creating the IOC also create additional powers allowing suspensions to be extended and continued; they also require

such extensions to be referred to the courts and therefore (in effect) create more extensive rights of appeal to the courts against such interim measures<sup>94</sup>.

For present purposes, however, the effects of these two committees are as follows: the PPC acts as a second stage screening mechanism, and the IOC serves to provide measures in cases of urgency where this is required (in terms of the statutory tests) for the protection of the public, in the public interest, or in the interests of the actual doctor<sup>95</sup>. It should be noted that these are alternative, rather than cumulative, grounds for action and it is competent for the IOC to make an order even when not all three elements are present<sup>96</sup>. Suspension has the effect that the registered person is, for the duration of the suspension, to be treated as not registered<sup>97</sup>. If conditions are applied to a person's registration, failure to comply with those conditions may in itself result in the person's registration being suspended or the person being struck off the register<sup>98</sup>.

### 3: The Professional Conduct Committee:

The Professional Conduct Committee, or PCC, exercises the ultimate power of the GMC to remove a fully registered person from the register<sup>99</sup>. Its powers are found in Section 36. It has jurisdiction under that section in respect of three areas:

- Conviction in the British Islands<sup>100</sup> of a criminal offence or conviction elsewhere of an offence which would, if committed in England and Wales, be a criminal offence.
- Committing some act or omission which amounts to "serious professional misconduct"; or
- Breaching conditions attached to registration by the PCC or other statutory committee of the GMC able to attach conditions to registration.

Technically there are no specific powers to discipline those who practise while their registration is suspended. However, as noted, the effect of suspension is that you are treated as though unregistered. The Act is silent on the subject disciplining those who are suspended. However, any medical practice by someone whose registration is suspended will be tantamount to practice by an unregistered person and so potentially amounts to a criminal offence. Unqualified practice (which practice while suspended is equivalent to) is also grounds for the PCC to strike someone off the register, notwithstanding that they shouldn't have been there (or are treated as not being there) in the first place<sup>101</sup>.

The PCC procedures are akin to a criminal court, and Smith identifies increasing similarity to the forensic model as an ongoing trend<sup>102</sup>. The jurisdiction and procedures are fully described by Smith<sup>103</sup> and are not examined in detail here. The main features are that the PCC sits in open session with (typically) a full contingent of lawyers advising Council, committee, and the doctor whose conduct is under scrutiny<sup>104</sup>. Evidence is given on oath and the evidential standard is the same as that in criminal proceedings, i.e. proof beyond reasonable doubt. The onus of proof lies on the GMC to prove that the doctor has been guilty of serious professional misconduct, although it is not open to a doctor convicted of an offence in the British Islands to dispute the fact of that conviction<sup>105</sup>. In such cases, the proceedings before the PPC are purely to determine the response of the GMC to the conviction.

Sanctions available to the PCC are erasing the person accused from the register, suspending that registration for up to 12 months, or placing conditions on that registration for up to three years.<sup>106</sup> The Committee can alternatively find the allegations not proven, can admonish the doctor, or can continue deliberations for such period as the Committee sees fit. This latter appears to have been particularly common prior to the introduction of formal health procedures, as it permitted the PCC to monitor a doctor's rehabilitation. Matters can be referred to the Health Committee or Committee on Professional Practice, and in particularly serious cases the Committee can suspend registration forthwith. It is only this latter sanction which requires the doctor to stop practising during the course of the procedures. The varying sanctions are ranked by Smith as indicating a range of opinions of the committee to the conduct, ranging from "concern" to "gravest concern".<sup>107</sup> There is an appeal against any decision of the PCC to the Judicial Committee of the Privy Council<sup>108</sup>, considered *infra*. While erasure is the most severe (non-interim) sanction available to the PCC, it is important to note that it is possible for a person "struck off" to apply for re-admission to the Register<sup>109</sup>. This previously required ten months to have expired either from being struck off, or from a previous unsuccessful application to be so restored. Following criticism, however, the period was extended<sup>110</sup> so that now at least five years must have elapsed before you can apply for re-admission after being struck off, or twelve months elapse following a previous unsuccessful application for re-admission. In addition the PCC may require such an applicant to satisfy the committee as to the person's good character, professional competence or health before restoring them<sup>111</sup>. After a second (or more) unsuccessful application for re-admission the PCC may suspend the right to re-apply indefinitely<sup>112</sup>, although this suspension is itself subject to application for review after three years<sup>113</sup> and an appeal against such a suspension order lies to the Privy Council<sup>114</sup>.



Most of the litigation involving the GMC has revolved around the concept of “serious professional misconduct” which justifies the imposition of disciplinary measures absent a criminal conviction. The expression “serious professional misconduct” replaces the expression found in the original legislation, “infamous conduct in any professional respect”<sup>115</sup>. Again, it is not intended to review that body of case law here<sup>116</sup>. For present purposes, the key issue is the current operative definition applied by the PCC in its daily working (and also repeated in its published advice to the profession):

“Conduct connected with his profession in which [the doctor] concerned has fallen short, by omission or commission, of the standards of conduct expected amongst [doctors], and that such falling short as is established should be serious”<sup>117</sup>

One important point to take from the definition is that the conduct must be “serious”. The Privy Council (in a dental appeal dealing with an identical statutory formulation) has held that this requires a two-stage approach by the PCC: firstly whether the conduct has fallen short of the standards expected, and secondly whether this failure is serious enough to justify an adverse finding<sup>118</sup>. It is not necessary for the conduct to be directly connected to actual medical practice, although there does have to be some connection to medical practice. Thus, for example, a doctor acting as chief executive of a hospital, may be found guilty of serious professional misconduct even where the misconduct was more of a managerial failure than one related to his practice of medicine<sup>119</sup>.

Finally, as noted in Chapter 4, the decisions of the PCC (and indeed, of the GMC generally) are susceptible to judicial review, and as a public authority the GMC is bound by the terms of the Human Rights Act 1998. The main implication of this is that the sanction imposed by the PCC must be proportionate to the offence<sup>120</sup>. However, it is not necessary (except perhaps in exceptional cases) for the PCC to give reasons for its decisions on matters of fact<sup>121</sup>.

#### 4: Health Procedures:

Health procedures were introduced in 1980, under amendments brought in by the Health Act 1978. However, the formal procedures of the Health Committee are intended to act only as a backstop, and the intention behind the procedures introduced is to deal with as many health referrals as possible in an informal way<sup>122</sup>. The informality is introduced by the use of a preliminary screener for health, whose functions are akin to those of the preliminary screener already mentioned. The health screener’s job is really to enlist the doctor in appreciating that the doctor may have a problem. The majority of referrals to

the health screener are for alcohol or drug misuse or mental illness – all conditions which might make it more difficult for the person affected to realise that they are affected. The health screener is generally a psychiatrist. A lay screener has also been added to the health screening procedures<sup>123</sup>. The general thrust of the health screener's activity is to encourage self-help supported by local action.

The PPC and PCC can refer matters to the Health Committee if it appears to those other committees that there is an issue relating to the doctor's fitness to practise as a consequence of physical or mental health problems. Indeed, the courts have held that while not strictly mandatory, such referral should be made by the PCC as soon as the issue emerges<sup>124</sup>.

The formal procedures of the Health Committee itself are, in large measure, only there for those cases where the doctor refuses to cooperate, either with the initial medical examination itself or with the treatment or restrictions on activity proposed following this examination<sup>125</sup>. The procedures, while formal, lack the quasi-criminal trappings of PCC procedure<sup>126</sup>. The jurisdiction of the Health Committee extends to cases where the doctor's fitness to practise is seriously impaired by reason of physical or mental condition<sup>127</sup>. The Committee may suspend registration for up to one year, or impose conditions for up to three years. Failure to comply with conditions may in itself result in suspension<sup>128</sup>. The wording of Section 37 requires the Health Committee to make a judgement as to the fitness to practise of the doctor in question, and this judgement is presumably to be made on the basis of evidence led before it. However, the doctor who refuses to be medically examined will still have no cause for complaint if the Committee then decides that he or she is unfit, on the basis of old information.<sup>129</sup> This avoids doctors from using what would otherwise be a fairly serious loophole in the system.

The deliberations of the Health Committee take place *in camera* which, given the subject matter of its jurisdiction, is perhaps unsurprising. However, it has been suggested that the approach lacks openness:

“One of the difficulties with referring a case to the Health Committee, from the point of view of public accountability, is that, because that Committee's proceedings are conducted in private, the public does not know what transpires during the proceedings. It would be useful in this regard, while not unnecessarily infringing the confidentiality of Health Committee proceedings, if the GMC's *Minutes* recorded the dispositions of the Health Committee in cases which have

been referred from the PCC, to enable the public to see that the case has been effectively disposed of.”<sup>130</sup>

There is, however, a degree of interaction between the (*in camera*) Health Committee and the (open to the public) PCC. Thus, while a large proportion of the Health Committee’s work consists of doctors who are addicted to drugs or alcohol<sup>131</sup>, if the doctor has received a criminal conviction in relation to these matters then it is the PCC which has jurisdiction, although it may subsequently refer the matter to the Health Committee.<sup>132</sup> Furthermore, failure by the doctor to observe the limitations of any conditions attached to his or her registration by the Committee may result in the doctor being suspended. Continuing to practise while suspended may, as noted above, constitute grounds for the PCC exercising its disciplinary powers to strike a doctor off.

This supportive approach has, however, been criticised as a mechanism whereby the “medicalisation” of deviance allows a greater number of doctors to be treated as sick rather than as bad, and consequently have the GMC response removed from the public’s knowledge<sup>133</sup>.

##### 5: Professional Performance Procedures:

Historically, the GMC was not formally concerned with standards of medical practice. Assuming a doctor was correctly registered and did not commit any offence or act amounting to serious professional misconduct, the fact that he or she was not very good (or even competent) would only attract the GMC’s attention if the poor performance was attributable to health problems. As the GMC itself put matters, it is only concerned with errors of diagnosis or treatment where the doctor’s conduct is such as to raise a question of serious professional misconduct<sup>134</sup>. This approach was subject to severe criticism, including a private member’s bill introduced into Parliament seeking to introduce a two-tier discipline system<sup>135</sup>. The upshot of this activity was the passage of the Medical (Professional Performance) Act 1995 which, for the first time, gave the GMC a formal role in monitoring and evaluating the professional practice of doctors.

This Act created another two statutory committees: the Assessment Referral Committee and the Committee on Professional Performance. The Assessment Referral Committee serves the same general function as the PPC (but in relation to handling complaints about professional performance<sup>136</sup>). The Committee on Professional Performance has jurisdiction where the standard of professional performance of a fully registered person is found to have been seriously deficient<sup>137</sup>. In the first case involving the professional

performance procedures to have reached the Privy Council, it was held that the “seriously deficient” performance has to be in relation to the subject matter of the complaint, emphasising that the procedure remains complaint-driven and is therefore essentially reactive<sup>138</sup>. The sanctions available are the same as those of the Health Committee, i.e. suspension for up to one year, conditional registration for up to three years. The practitioner who continues in practice in violation of conditions imposed by the committee can be suspended, and as with other provisions the doctor who continues in practice can be struck off by the PCC.

The GMC has defined the new procedures as follows:

“‘Seriously deficient performance’ is a new idea. We have defined it as ‘a departure from good professional practice, whether or not it is covered by specific GMC guidance, sufficiently serious to call into question a doctor’s registration’. This means that we will question your registration if we believe that you are, repeatedly or persistently, not meeting the professional standards appropriate to the work you are doing - especially if you might be putting patients at risk. This could include failure to follow the guidance in our booklet *Good Medical Practice*”<sup>139</sup>

In terms of the procedure adopted by the GMC, referral to the Committee only occurs as a result of non-cooperation with the (non-statutory) assessment procedure by which the GMC seeks to get a view of the doctor’s ability. This involves a GMC member acting as case co-ordinator, and the establishment of an assessment panel consisting of two appropriate specialists and a lay person. Even the fact that an assessment is taking place is kept confidential. A report is then sent to the GMC listing any improvements required<sup>140</sup>. The procedures, while generally welcomed as better than the previous regulatory gap, have been subject to criticism:

“Taking a lay perspective, Stacey is concerned that they will be too complex and difficult to understand; decisions will still be taken in private; and there will be no appeal against a decision not to pursue a case. Nor is there any obligation to tell complainants what has happened, or allow them to put their concerns... Robinson has made much the same points but is also concerned with the delays involved in dealing with a deficient doctor. If a doctor has a complaint against her or him going through other NHS complaint procedures or the courts, any GMC action has to wait until these are completed. She has suggested that these actions may take years and meanwhile the doctor concerned continues to

practise. She is also sceptical that a short period of training (at taxpayers' expense) can remedy deficient performance.

From the perspective of the medical profession, concerns have also been expressed. Not surprisingly, these centre on the impact of widening the net of surveillance. Some commentators are concerned about the large number of people involved in the procedures and the consequent threat to the doctor's privacy. They also draw attention to the problems of maintaining the confidentiality of patients and doctors and the need for a fair and unbiased consideration of the issues.<sup>141</sup>

Having seen the mechanisms by which the GMC seeks to regulate the medical profession, the next section considers the effects which this actually has on medical practice.

#### **IV: Effect of GMC regulation:**

In terms of measuring the actual effect which the GMC exerts on professional practice, it is salutary to note some points flagged up by Smith in the course of his GMC-specific analysis:

“...great caution must be exercised in analysing the sanctions imposed by the GMC's Committees owing to the multivariate nature of the influences which affect the decision-making carried out in imposing sanctions. Simplistic correlational analyses based upon inadequate or imprecise data may create confusion and disclose misleading trends resulting in misunderstanding of the issues involved and perhaps ill-founded criticism. In addition, because of the complexity of the circumstances involved in individual cases, and especially those which involve protracted and frequent appearances before the Council, the analysis of sanctions can often fail to reflect the full range of subtle and varied factors which influence Committees in arriving at their decisions.”<sup>142</sup>

Having said that, both Smith and the other commentators whose comments have informed the analysis in this section have all had a lot to say about the efficacy (or otherwise) of the GMC's interventions. On a positive note, Smith himself notes the very low rates of recidivism among those struck off and then restored to the Register<sup>143</sup>. However, the summary of his overall study is less flattering. The positive aspects he identifies include the overall effectiveness in terms of specific deterrence, the fairness surrounding procedures, the lack of impact on the public purse and the increasing lay

involvement. However, his conclusion is that the whole jurisdiction was inadequately considered at the GMC's inception and has retained these flaws throughout<sup>144</sup>.

Stacey's study, conducted with the benefit of inside information (albeit as a lay member) is equally critical, concluding that the GMC is not adequately fulfilling its obligations to the state, in large measure due to its failure to address shortcomings in medical education<sup>145</sup>, its inability (at that time) to deal with continuing competence, and its tendency to favour the profession rather than the public<sup>146</sup>.

Allsop and Mulcahy, in the course of a study of the GMC which attempted to place it more in the context of the overall regulatory system (including NHS mechanisms and informal controls which are outwith the scope of this thesis), note that the GMC follows a prosecutory/disciplinary model of regulation which is, however, dependent on complaints being made. As a body, the GMC's complaints procedures are too little-known for this to be a common occurrence. The mechanisms themselves are lacking in public accountability, particularly at the screening stages and in relation to the health procedures. They highlight a reliance by the GMC in passing matters back to NHS regulatory mechanisms if possible, notwithstanding that these mechanisms do not dovetail properly with the GMC's procedures and jurisdiction. There is an unwillingness to hear complaints while litigation is pending. The threshold for serious professional misconduct is too high, and the whole mechanism fails to pay adequate attention to the person complaining<sup>147</sup>.

Lastly, in terms of critiques of the GMC, the report of the Inquiry into the Bristol Royal Infirmary<sup>148</sup> examined at some length the failure of the GMC to prevent the deaths of a number of paediatric patients, and indeed considered whether the rules of the GMC applicable at the time (1984-1995) actually contributed to the ongoing problem. The Inquiry's final report made a large number of findings (many of them, it has to be said, based on evidence from the then president of the GMC, Sir Donald Irvine, to the Inquiry) that the protection of patients by the GMC was, at that time in any case, highly deficient in a number of respects.

The main defects in the GMC's protective functions at that time, as highlighted by the Inquiry, were as follows:

- GMC regulation was regarded as a means of coping with exceptional misconduct, not a way to improve standards generally<sup>149</sup>

- No emphasis was placed on areas such as consent which the GMC considered to be the exclusive preserve of the civil courts<sup>150</sup>
- Guidance against making disparaging comments about colleagues was widely perceived in such a way as to discourage doctors from raising legitimate concerns about the performance or conduct of colleagues, particularly at the start of the period 1984-1995, coupled with the fact that (also initially), there was no professional guidance at all from the GMC indicating that doctors had any ethical obligation to raise concerns affecting patient safety with anybody<sup>151</sup>
- The functions of the GMC were not properly co-ordinated with other regulators<sup>152</sup>
- The GMC was perceived by many as being more interested in protecting doctors than in protecting patients<sup>153</sup>
- The threshold of “serious” professional misconduct was too high, which, coupled with the high burden of proof in proceedings before the PCC, left the public inadequately protected due to the difficulty of removing a doctor from the register on the basis of his or her unsatisfactory practice<sup>154</sup>
- The entire regulatory approach of the GMC at that time was reactive and complaint-driven, rather than proactive<sup>155</sup>; and
- The GMC was unable to enforce clinical standards (which it was not, in any event, responsible for setting in the first place)<sup>156</sup>

It should be remembered that these comments were in relation to the GMC’s approach to these areas within the 1984-1995 timeframe considered by the Inquiry, and that the Inquiry itself also heard much evidence of a changed culture and improved procedures within the GMC. The extent to which these improvements in policy are reflected in practice is much harder to assess.

To summarise these comments, both from Bristol and elsewhere, it appears that the GMC is reasonably effective as a guardian of standards of conduct and the ability of doctors to practice as a result of health problems, albeit the supervision is purely reactive and the sanctions seem to be biased against doctors who offend against professional esteem rather than those who offend or harm patients. The professional practice jurisdiction has not been subject to detailed analysis since its inception<sup>157</sup>, but the comments made above suggest that the procedures (possibly for good reason) are insufficiently clear to the public. Overall, in spite of recent improvements, there is still much that could be done to improve.

## **V: Summary:**

### **A: Purpose of the GMC:**

The purpose of the GMC is clear enough in terms of both its parent statute and the GMC's own statements: it regulates the qualifications necessary to become a registered medical practitioner, maintains a register of those who continue to be eligible for this status, and takes action against those alleged not to be fit or eligible for continued inclusion. In so doing, the GMC asserts that its main purpose is to protect the public. However, it appears that its practices tend to be driven more by considerations of protecting the profession itself.

### **B: Mechanisms of the GMC:**

The GMC acts formally through its statutory committees. These have power to restrict or suspend registration (and with it to remove the privileges attached to registration) and, in the case of the PCC, have the power to remove a doctor from the register altogether.

Most of the work, however, is done on an informal basis, away from any public scrutiny. Thus, the systems of utilising screeners (both for conduct and health referrals) and the *in camera* nature of proceedings before certain key committees mean that it is very hard to analyse fully what the GMC does.

### **C: Effects of the GMC:**

As we have seen, the GMC has an acceptably low level of recidivists so it is, on one level at least, effective. However, the reactive nature of the GMC's procedures make any attempt at estimating how much conduct which would attract the GMC's sanctions (if the GMC knew of the conduct in question) impossible to gauge. The deliberately informal and confidential nature of much (if not most) of the work done similarly makes full analysis impossible. Perhaps the best testament of the GMC's effects is, however, a form of peer review: as noted above, doctors registered in the UK are held in high esteem across the world by medical colleagues. Such esteem would not, it is submitted, continue if the GMC's powers did not exert a genuine influence in securing and maintaining the highest professional standards.



## **VI: Comparison with Core Evaluation Criteria:**

In Chapters 1 and 2, we identified seven core criteria against which each segment of the medical regulatory framework would be measured. The workings of the GMC will now be assessed against each of the evaluation criteria in turn.

### **A: Visibility:**

The purposes for which the GMC exists are generally highly visible in terms of legislative declarations and the GMC's own pronouncements. What is less clear is the workings of the mechanisms by which these actually translate into practice.

The mechanisms of the GMC are a mixture of highly visible and deliberately opaque. The nature of the formal decision-making bodies and officials and criteria for decision-making within these mechanisms, particularly in relation to the actions of the PCC, are conducted in the glare of full publicity and are regularly reported in the national media. However, the preceding decisions to proceed to the PCC are almost impossible to analyse and question. The PCC's lack of fully reasoned decisions is also worthy of particular criticism.

The effects of the GMC are highly visible in many respects, and completely invisible in others. PCC proceedings being conducted in public are, of course, very visible – but virtually everything prior to the PCC is kept a secret. As with the criminal law, the effects of the GMC are probably best seen by their absence than their presence. Most doctors appear to be behaving appropriately, but it is impossible to tell if this is the result of general compliance to the rules or merely lack of discovery of improper or substandard conduct. Again, this can be criticised.

Overall, the GMC is considered to be unacceptable in terms of visibility, in spite of recent reforms in the direction of more openness.

### **B: Accountability:**

“Accountability”, in the context of a self-regulatory system, is a concept which needs to be handled with care. The majority of the GMC's members are, by law, elected by the profession and so are accountable to the profession for their actions. However, where accountability is for policing that same group, this is not necessarily a good thing. It is not unreasonable to postulate that doctors may (perhaps subconsciously) display a bias

in favour of colleagues who are facing disciplinary proceedings; some of the studies suggested a degree of bias in the GMC's mechanisms which favoured protecting the profession. Thus, while having an elected majority may make the GMC more accountable to the profession, it could have an adverse impact on the fairness of its proceedings. However, there does not appear to be a direct link between this potential bias and the elected nature of the majority of the Council. Appointed medical members (of whom there are a considerable number) could equally display such bias in favour of medical colleagues.

It is, however, in terms of accountability to the general public that the GMC scores most poorly. All the commentators have criticised the GMC on this score. Too many things happen which are done away from public scrutiny. Giving lay screeners a veto over decisions not to proceed further with complaints is a welcome step forward, but since the screening decision then proceeds to another secret interim committee (on which the minority lay members have no veto) the procedure is still inadequate. While accepting that there are legitimate grounds for protecting confidentiality in some circumstances, there appears to be no good reason for not requiring these secret procedures to produce appropriately anonymised accounts of what they have done. The lack of feedback to the complainant is another shortcoming in this area.

Overall, therefore, it is concluded that the GMC fails to satisfy the criterion of accountability.

### **C: Overall Fairness:**

In the context of the PCC, this section adopts the comments of Smith:

“Members of the PCC attempt to act fairly when dealing with cases in terms of allowing opposing interests equal priority, and permitting both sides to state their case...

Aspects of proceedings which may still be seen as unfair include the problem of the GMC dealing with cases involving disputed theories of medicine prior to the resolution of the question in the professional scientific and medical community; the failure in some cases to give practitioners sufficient notice of charges (particularly where many and complex allegations are involved); the failure to give clear and unequivocal notification to some practitioners of conditions imposed on their registration; the failure of Committees to give reasoned decisions; the imposition of numerous consecutive directions for postponement or suspension;

problems associated with imposing conditions on the registration of practitioners which are unclear or unworkable; the inability of suspended practitioners, on occasion, to supply the names of referees owing to their being out of touch with colleagues while suspended; the problem of immediate suspension being under-used and inconsistently imposed in some cases; and the fact that some practitioners are unaware of ways in which to satisfy Committees of their good conduct on applications for restoration.<sup>158</sup>

There is, however, another aspect to fairness: fairness to those who make complaints to the GMC about a doctor. Such a complainer may be advised if it is proposed to take a case to the PCC, but will not always be advised as to what has happened prior to that stage. The prior stages also do not give the complainer an opportunity to put his or her case across, proceeding purely on the basis of written statements of complaint. However, these are largely attributable to the prior failure in terms of accountability and visibility. Accordingly, it is concluded that the GMC does satisfy the test of overall fairness.

#### **D: Effectiveness:**

We have already seen that the practical effects of the GMC are, in some respects, unquantifiable. This section is therefore concerned only with the quantifiable effects. From what we can observe, does the GMC do what it sets out to achieve?

The answer here would appear to be yes: the GMC has mechanisms in place to describe what is or is not acceptable conduct, how to determine if someone has committed unacceptable conduct if they dispute the allegation, and a system of means of disposal aimed partly at punishing the doctor and deterring him/her and others from any future wrongdoing, but principally to prevent the doctor from being able to cause any more damage (be it physical harm to patients or harm to the profession's image). The reactive nature of these procedures remains a problem, although the current proposals for revalidation by doctors may address this problem. For a reactive system, the GMC does what it does well enough to maintain standards.

In general, therefore, it is considered that the GMC is sufficiently effective.

#### **E: Efficiency:**

Quasi-criminal procedures such as that used by the PCC are expensive. Local health resolutions are inexpensive. Both have the same objective in mind, i.e. ensuring that those who are on the register are fit to practice medicine. The more informal procedures referred to above can be criticised on other counts, but they are clearly more efficient (assuming they work and therefore reflect the lower cost base in terms of productive efficiency) than formal ones involving committees sitting for days on end in London with full supporting cast of lawyers and support staff. In addition, the GMC is self-funding (or at least, and in the face of the 1970s professional revolt), funded by contributions from its membership. It therefore makes no drain on the public purse.

Accordingly, it is felt that the GMC is efficient.

#### **F: Avoidance of undue influence with good medical practice:**

One of the main reasons that advocates of professional self-regulation argue for its retention is the perceived need to avoid having an external body interfering with what they perceive as being the profession's own affairs. Against this background, it would be surprising if the GMC were to be found to interfere unduly with its own members' practice of medicine. While criticisms of the GMC are widespread, this is not one of them.

Accordingly, it is felt that the GMC satisfies the criterion of avoidance of interference with good medical practice.

#### **G: Respect for patient autonomy:**

Respect for patient autonomy is, in fact, one of the areas on which the GMC issues guidance to the medical profession. Having said that, it is unfortunate that in some respects the disciplinary functions of the GMC fail to follow its own advice. In particular, the fact that so many procedures are followed without any reference to the patient (assuming for these purposes that it is a patient or former patient of the doctor who has made the complaint) cannot genuinely be said to be treating that patient as an end in his or her own right. However, this is again a failure provoked by the preceding failures in accountability and visibility.

Accordingly, it is therefore concluded that the GMC does adequately respect patient autonomy.

#### **VII: Conclusions and Postscript:**

The GMC clearly has a central role to play in the regulation of the medical profession; that, indeed, is its *raison d'être*. In carrying out these functions it has an series of formal mechanisms and an array of disciplinary sanctions at its disposal. It has an equally large array of informal mechanisms supplementing and underpinning the statutory schemes. Given that overall standards of the medical profession in the UK appear high, it could be said to be doing its job.

However, the detailed analysis of the mechanisms, and the ways in which they are deployed, highlight a number of weaknesses in the current scheme. Indeed, it is very hard to be sure to what extent the GMC's mechanisms contribute to the standard of medical practice in general, and how much could be attributed to peer pressure and review, employer scrutiny and informal controls such as decisions not to appoint doctors known (through informal channels) to be less than top performers. One can point to the fact that the GMC has only exercised any formal control over standards of practice for the last six of its 143 years, with no appreciable (or at least quantifiable) improvement in standards, as indicating that perhaps the GMC's powers are really only of particular use in relation to the "bad apples", and make no real difference to the ordinary practitioner. This in itself is not a bad thing; the criminal law, for example, performs a similar function.

However, for the body which is given the key statutory responsibility for medical regulation to take a late, and still reactive, approach to standards of practice is not really a solid foundation on which to build the regulatory machinery of this country. Given that no other body regulates private practitioners, and given the difficulties in using the civil courts to enforce standards of care noted in Chapter 4 *supra*, this area was (until 1995) suffering from a major regulatory failure. Whether the professional performance procedures are adequate to fill this gap is still open to question, and it seems clear that more research should be done on this area. Possibly the GMC's proposals to introduce "revalidation" for all doctors wishing to practice medicine<sup>159</sup> will address the issue adequately<sup>160</sup>. For now, the main regulator of the medical profession cannot be said to be doing all it could.

This situation may change under new proposals before Parliament. The National Health Service Reform and Health Care Professions Bill 2002 includes, in Part 2, the establishment of a new body, the Council for the Regulation of Health Care Professionals<sup>161</sup>. This is intended to oversee the activities of various health care professions' regulatory bodies, including the GMC, to ensure that they act in the interests of patients rather than the profession<sup>162</sup>.

In some respects, the imposition of an external regulator (a sort of over-regulator) to a body which has been regarded as the epitome of state-sponsored self-regulation could be seen as weakening the principle of professional self-regulation. In one sense, this is true: the new proposals will allow the Council to investigate and report on the functions of the GMC<sup>163</sup> (and its counterparts for other health care professions, as well as making comparisons between the various regulatory bodies<sup>164</sup>), and, if it is “desirable to do so for the protection of members of the public”, direct these regulatory bodies (including the GMC) to make rules so as to achieve a particular effect<sup>165</sup>. It would also be able to investigate complaints about the regulatory bodies covered<sup>166</sup>, although the specifics of who would be able to complain and the matters to be included (and excluded) from such investigation are to be specified by statutory instrument<sup>167</sup>, making more specific comment impossible at this time. Lastly, the proposed Council would be able to appeal decisions of the GMC (and others) to the courts<sup>168</sup> if it feels disciplinary or competence matters have been treated unduly leniently<sup>169</sup> or in relation to decisions not to take such action or to restore someone to the register following previous disciplinary action<sup>170</sup>. All of these powers, if enacted and used, would mean that decisions concerning professional regulation were being taken by a body which, in the Department of Health's view at least, will be comprised of a majority of persons who speak for the interests of patients and the wider public<sup>171</sup>.

One alternative view is to regard the powers of this proposed new body as simply being an extension of the existing powers of scrutiny which exist (and which, in the main, have always existed) in relation to the GMC: oversight by the courts coupled with default powers vested in the Privy Council. The new proposals simply clarify and codify procedures which could have been effected through appropriate resort to the courts and/or the Privy Council (and subject to these bodies agreeing that the suggested intervention properly lay within their respective jurisdictions).

It is submitted that a better view is to consider what is currently being debated in Parliament as a radical departure from the past. This is not to say that what is proposed will detract from or dilute the principle of professional self-regulation. It is instead to say that these proposals recognise that the GMC (and its counterparts) forms part of the machinery of the state. It may be self-regulating and self-funding, but it is ultimately clothed with the power of government, and as such the modern democratic consensus requires it to be accountable to a wider constituency than its own membership. In this context, the GMC is being placed on exactly the same footing as other professions. As an example, solicitors in Scotland are subject to the disciplinary mechanisms of the Law Society of Scotland, the relevant professional regulatory body<sup>172</sup>. However, if someone

complains to the Law Society and is dissatisfied with the handling of their complaint, they have a further right of complaint to an impartial “over-regulator”, the Scottish Legal Services Ombudsman<sup>173</sup>. The ombudsman has certain rights in relation to investigations by the Law Society which do not exactly mirror the powers for the proposed Council, but the point is that professional self-regulation is not incompatible with external oversight. Indeed, the Scottish ombudsman himself saw no conflict between these two concepts. In his 1995 Annual Report, he expressed the following opinion:

“There appears no reason why self regulation should not work so long as the Law Society recognises that it needs to constantly review the way in which it and its members interface with the Public, so long as it is prepared to welcome constructive criticism and so long as its Client Relations & Complaints Office is provided with the resources that are necessary and changes are implemented to ensure that investigations are effectively controlled.”<sup>174</sup>

If the proposals currently going through Parliament are ultimately enacted (as is likely), there will be an external body able to intervene so as to provide a check on whether or not self regulation is working properly. Such a measure (if it lives up to its Department of Health description) can only improve the regulatory landscape, and as such is to be welcomed.

## Chapter 5 notes:

- <sup>1</sup> The Mental Health Act Commission is technically a special health authority in terms of the National Health Service Act 1977 whose existence was continued by the Mental Health Act 1983 Act.
- <sup>2</sup> Mental Health Act Commission, *Fifth Biennial Report 1991-93* (1993)
- <sup>3</sup> HFEA, *Code of practice*, (2<sup>nd</sup> revision, 1995), 1
- <sup>4</sup> [2001] 4 All ER 1013
- <sup>5</sup> [2002] EWCA Civ 29; Times 25 January 2002
- <sup>6</sup> SI 1989 No 2480
- <sup>7</sup> Section 2(3)
- <sup>8</sup> See C Dyer, "GMC's decision on 'Kidneys for sale'" (1990) 300 BMJ 961
- <sup>9</sup> M Stacey, *Regulating British medicine: the General Medical Council* (1992)
- <sup>10</sup> RG Smith, *Medical discipline: the professional conduct jurisdiction of the General Medical Council 1858-1990* (1994)
- <sup>11</sup> *Ibid.*, 1, fn1
- <sup>12</sup> D Gould, *Examining doctors* (1991), 84-7
- <sup>13</sup> See M Brazier, *Medicine, patients and the law* (2<sup>nd</sup> ed., 1992) Chapter 4, esp. 36-7
- <sup>14</sup> The present consultation documents can be accessed on the GMC's website at [www.gmc-uk.org/consultation](http://www.gmc-uk.org/consultation) (accessed 11 September 2001). A summary of some of the criticisms currently levelled at the GMC is provided by R Smith, "The GMC: where now?", BMJ 2000; 320: 1356
- <sup>15</sup> Subject to correction where inclusion in the Register arose due to fraud or error: Section 39
- <sup>16</sup> Currently £5000: Criminal Justice Act 1991, Section 17
- <sup>17</sup> J Ironside, "Five year sentence for fake general practitioner", BMJ 1992; 304: 1652
- <sup>18</sup> Section 5(1)
- <sup>19</sup> Section 35 as amended by the Medical (Professional Performance) Act 1995
- <sup>20</sup> GMC, *Effective, inclusive and accountable: reform of the GMC's structure, constitution and governance* (2001)
- <sup>21</sup> At paragraph 4
- <sup>22</sup> Section 50
- <sup>23</sup> As amended by the Medical (Professional Performance) Act 1995 and the Medical Act 1983 (Amendment) Order 2000, SI 2000/1803
- <sup>24</sup> Medical Act 1983, Section 2
- <sup>25</sup> e.g. under Sections 39(2) or 42(5) of the Act
- <sup>26</sup> Schedule 1 Part II paragraph 16(3)
- <sup>27</sup> Schedule 4 Paragraph 5(2)
- <sup>28</sup> *Report of the Committee of Inquiry into the Regulation of the Medical Profession*, (1975), Cmnd. 6018



- <sup>29</sup> However, in its recent consultation document, *supra* n20), the GMC considers that it has four principal functions, *viz.* registration, regulating medical education, setting standards of practice, and considering complaints against doctors under the fitness to practice procedures.
- <sup>30</sup> Section 5(1)
- <sup>31</sup> Stacey, *op. cit.*, 95
- <sup>32</sup> Medical Act 1983 Section 32(2)
- <sup>33</sup> *Ibid.*, Section 32(5). Note that the nomenclature has not been changed despite the EEC being re-designated the European Union.
- <sup>34</sup> *Ibid.*, Section 3(b) and Schedule 2
- <sup>35</sup> *Ibid.*, Section 44
- <sup>36</sup> *Ibid.*, Section 45
- <sup>37</sup> Stacey, *op. cit.*, 136
- <sup>38</sup> Section 19
- <sup>39</sup> Section 22
- <sup>40</sup> Stacey, *op. cit.*, 131
- <sup>41</sup> GMC website: [www.gmc-uk.org/register/quals.htm](http://www.gmc-uk.org/register/quals.htm) (accessed 22 November 2001)
- <sup>42</sup> GMC website: <http://www.gmc-uk.org/register/register.htm> (accessed 22 November 2001)
- <sup>43</sup> *Ibid.*, 131, based on GMC Minutes and Official Reports.
- <sup>44</sup> Section 28(2)
- <sup>45</sup> Section 29(4)
- <sup>46</sup> For details, see [www.gmc-uk.org/register/noplabs.htm](http://www.gmc-uk.org/register/noplabs.htm) (accessed 22 November 2001)
- <sup>47</sup> *Id.*, para. 4
- <sup>48</sup> Section 3(a)
- <sup>49</sup> Sections 6 and 7
- <sup>50</sup> Section 9
- <sup>51</sup> Section 9(7)
- <sup>52</sup> Section 13
- <sup>53</sup> Section 11(4)
- <sup>54</sup> M Stacey, *op. cit.*, 103-6
- <sup>55</sup> *Ibid.*, esp. pp107-114
- <sup>56</sup> J Allsop and L Mulcahy, *Regulating Medical Work* (1996), 76
- <sup>57</sup> M Stacey, *op. cit.*, 111
- <sup>58</sup> *Id*
- <sup>59</sup> *Id*
- <sup>60</sup> Section 18
- <sup>61</sup> Section 27
- <sup>62</sup> 12 months for visiting overseas specialists (Section 27(2)); for visiting EU practitioners, the time limit depends on how long the visitor states he or she will be rendering medical services (Section 16(4)) and expires in any case if the visitor "becomes established in medical practice

in the United Kingdom (Section 18(5)(a)) or renders medical services (except in cases of urgency) other than as intimated in this declaration (Section 18(5)(b))

<sup>63</sup> Section 22(8)

<sup>64</sup> Section 22(1)(a)

<sup>65</sup> Section 22(3) and (5)

<sup>66</sup> Section 10(2) and (3)

<sup>67</sup> Section 15.

<sup>68</sup> Section 32(1)(a). The power to levy an annual retainer was originally contained in the Medical Act 1969.

<sup>69</sup> The opposition to the introduction of this measure is chronicled by M Stacey, *op. cit.*, chapter 5.

<sup>70</sup> Medical Act 1983 Section 32(5)

<sup>71</sup> Section 35

<sup>72</sup> GMC, *Professional conduct and discipline: fitness to practice*, published *inter alia* 1976, 1979, 1981, 1983, 1989, and 1991. For an analysis in the changing content of these, see M Stacey, *op. cit.*, 233-5

<sup>73</sup> D Gould, *op. cit.*, 109

<sup>74</sup> GMC, *The duties of a doctor* (1995); the principles are also found in *Good Medical Practice*, *infra cit.*

<sup>75</sup> GMC, *Good Medical Practice* (3<sup>rd</sup> ed., 2001)

<sup>76</sup> Section 36(1)(a) as amended by the Medical Act 1983 (Amendment) Order 2000, SI 2000 No.1803

<sup>77</sup> *Le Compte and Ors. v Belgium* [1981] 4 EHRR 1

<sup>78</sup> M Stacey, *op. cit.*, 139

<sup>79</sup> WK Pyke-Lees, *The centenary of the General Medical Council 1858-1958: the history and present work of the Council* (1958), 24, quoted by RG Smith *op. cit.*, 5

<sup>80</sup> RG Smith, *op. cit.*, 5-6

<sup>81</sup> RG Smith, *op. cit.*, 6

<sup>82</sup> GMC Minutes for 25 February 1889, quoted *id.*

<sup>83</sup> J Allsop and L Mulcahy, *op. cit.*, 80

<sup>84</sup> *R v GMC ex p Petch*, unreported, 17 June 1988 (QBD), 9 December 1988 (CA). The application failed to overturn the decision.

<sup>85</sup> GMC Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order in Council 1988, SI 1988 No 2255, Rule 4(5)

<sup>86</sup> RG Smith, *op. cit.*, 7

<sup>87</sup> *Preiss v General Dental Council* [2001] UKPC 36; (2001) IRLR 696

<sup>88</sup> *Per* GMC website, <http://www.gmc-uk.org/probdocs/complain.htm> (accessed 22 November 2001). The website has not been updated to reflect the changes, introduced in 2000, permitting the GMC to act where a doctor has been convicted of an offence outside the British Islands.

<sup>89</sup> *Roylance v GMC*, Privy Council 19 January 1999, unreported.

<sup>90</sup> Medical Act 1983 section 42(4) as amended.

- <sup>91</sup> *Madan v GMC* (2001) Lloyd's Rep Med 539
- <sup>92</sup> Medical Act 1983 (Amendment) Order 2000, SI 2000 No 1803
- <sup>93</sup> The PCC, Health Committee, and Committee on Professional Performance
- <sup>94</sup> Section 41A.
- <sup>95</sup> *Id.*
- <sup>96</sup> *R (on the application of X) v GMC*, [2001] EWHC Admin 447.
- <sup>97</sup> *Ibid.*, Sections 36(8), 36A(9), 37(8), 41A(11)
- <sup>98</sup> *Ibid.*, Section 36(2)
- <sup>99</sup> *Ibid.*, Section 36(1)(i)
- <sup>100</sup> The UK, Channel Islands and Isle of Man: Interpretation Act 1978, section 5 and Schedule 1
- <sup>101</sup> Stacey, *op. cit.*, 144-5
- <sup>102</sup> RG Smith, *op. cit.*, 59
- <sup>103</sup> *Ibid.*, Chapters 2 and 3
- <sup>104</sup> For an anecdotal description of cases being brought, see M Stacey *op. cit.*, Chapter 11
- <sup>105</sup> *R v GMC ex parte Spackman* [1943] AC 627 at 639 *per* Lord Wright
- <sup>106</sup> Medical Act 1983 section 36(1).
- <sup>107</sup> RG Smith, *op. cit.*, 140
- <sup>108</sup> Section 40
- <sup>109</sup> Section 41
- <sup>110</sup> Medical Act 1983 (Amendment) Order 2000, Article 9
- <sup>111</sup> Medical Act 1983 Section 41(5)
- <sup>112</sup> Section 41(5)
- <sup>113</sup> Section 41(8)
- <sup>114</sup> Sections 40(1)(d) and 41(7)
- <sup>115</sup> Medical Act 1858, section XXIX
- <sup>116</sup> For a summary of the evolution of the expression, see RG Smith *op cit* 33-37
- <sup>117</sup> Opinion of Lord Mackay of Drumadoon, quoted in *GMC Annual Report for 1992*, 14, and in Allsop and Mulcahy *op cit* 80
- <sup>118</sup> *Doughty v General Dental Council* [1987] 3 All ER 843
- <sup>119</sup> *Roylance v GMC (No. 2)* [1999] 3 WLR 541; (1999) Lloyd's Rep Med 139
- <sup>120</sup> *Anis-Uddin Manzur v General Medical Council* [2001] UKPC 55
- <sup>121</sup> *Gupta v GMC* [2001] UKPC 61
- <sup>122</sup> M Stacey *op cit* 166-7
- <sup>123</sup> *Ibid.*, 166 fn1
- <sup>124</sup> *Crompton v GMC* [1982] 1 All ER 35 at 38 *per* Lord Diplock
- <sup>125</sup> M Stacey, *op cit.*, 168
- <sup>126</sup> RG Smith *op cit*, 186-7
- <sup>127</sup> Section 37(1)
- <sup>128</sup> Section 37(2)
- <sup>129</sup> *Anjaneyelu v GMC* [2001] UKPC 60

- <sup>130</sup> RG Smith, *op. cit.*, 188
- <sup>131</sup> Allsop and Mulcahy, *op. cit.*, 88
- <sup>132</sup> RG Smith, *Ibid.*
- <sup>133</sup> Allsop and Mulcahy, *op. cit.*, 90
- <sup>134</sup> GMC *Professional conduct and discipline: fitness to practice* (1993), para 38
- <sup>135</sup> For accounts of the criticism and attempts at introducing reform, see RG Smith *op. cit.* 42-54; M Stacey *op. cit.* Chapter 13
- <sup>136</sup> This Committee's functions are not spelled out in the Act itself beyond an amendment to Schedule 4 allowing rules to be made allowing it to perform that function.
- <sup>137</sup> Section 36A(1)
- <sup>138</sup> *Krippendorf v GMC* [2001] Lloyd's Rep Med 9
- <sup>139</sup> GMC website [http://www.gmc-uk.org/probdocs/probdoc\\_frameset.htm](http://www.gmc-uk.org/probdocs/probdoc_frameset.htm) (accessed 6 December 2001)
- <sup>140</sup> The procedure is described *id*
- <sup>141</sup> Mulcahy and Allsop, *op. cit.*, 91-2, references omitted.
- <sup>142</sup> RG Smith, *op. cit.*, 123
- <sup>143</sup> *Ibid.*, 212
- <sup>144</sup> *Ibid.* 221
- <sup>145</sup> Education accounted for just one percent of GMC expenditure in 2001. Source: GMC News issue 11 (April 2002), 5
- <sup>146</sup> M Stacey, *op. cit.* 203-4
- <sup>147</sup> Allsop and Mulcahy, *op. cit.*, 84-6
- <sup>148</sup> Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary: *Final report*, 2001, available at [http://www.bristol-inquiry.org.uk/final\\_report](http://www.bristol-inquiry.org.uk/final_report) (accessed 1 September 2002)
- <sup>149</sup> *Ibid.*, Annex A para. 23
- <sup>150</sup> *Ibid.*, Annex A para. 27
- <sup>151</sup> *Ibid.*, Annex A paras 161-166
- <sup>152</sup> *Ibid.*, Annex A para. 84
- <sup>153</sup> *Ibid.*, Annex A para. 92
- <sup>154</sup> *Ibid.*, Annex A para. 109
- <sup>155</sup> *Ibid.*, Annex A paras 110-114
- <sup>156</sup> *Ibid.*, Annex A paras 295-301
- <sup>157</sup> But see P de Prez, "Self-regulation and paragons of virtue: the case of 'fitness to practice'" [2002] 10 Med.L.Rev. 29 at 32-33 for a brief critique of its value in protecting patients
- <sup>158</sup> RG Smith, *op. cit.*, 223-4
- <sup>159</sup> The proposals are summarised at <http://www.gmc-uk.org/revalidation/index.html> (accessed 7 December 2001)
- <sup>160</sup> The proposals have been condemned by the British Medical Association as a waste of time: L Beecham, "Revalidation proposals will waste time" *BMJ* 2001; 323: 70

- <sup>161</sup> The name has been criticised by the GMC on the grounds that the proposed body will not be responsible for regulating health care professionals, but instead for overseeing and coordinating the work done by the various bodies which *do* regulate the professionals themselves: GMC press release, "Modernising regulation in the health professions: comments by the General Medical Council", 28 September 2001
- <sup>162</sup> According to the Department of Health's Explanatory Notes to the Bill, para. 12
- <sup>163</sup> Clause 24(2)(a)
- <sup>164</sup> Clause 24(2)(b)
- <sup>165</sup> Clause 25(2)
- <sup>166</sup> Clause 26(1)
- <sup>167</sup> Clause 26(2)
- <sup>168</sup> Meaning the superior civil court of the UK jurisdiction where the individual would, if registered, be registered at an address within: Clause 27(5). The Act makes a number of changes to appeal jurisdictions, mostly removing appeal jurisdiction from the Privy Council and giving it to the courts referred to in Clause 27(5).
- <sup>169</sup> Clause 27(1)(c), (d), and (4)(a)
- <sup>170</sup> Clause 27(2)(a), (c), and (4)(b).
- <sup>171</sup> Explanatory Notes, *supra* fn149, para. 140
- <sup>172</sup> Solicitors (Scotland) Act 1980
- <sup>173</sup> Under the Law Reform (Miscellaneous Provisions) (Scotland) Act 1990, Section 34(1)
- <sup>174</sup> Scottish Legal Services Ombudsman, *Annual Report* (1995), para. 2

## Chapter 6: Direct Statutory Regulation:

### I: Introduction:

This chapter considers areas where Parliament has laid down the parameters of the conduct in question, and not delegated the matter to the courts (civil or criminal) or to some other actor such as a regulatory body. There remains a considerable overlap between this chapter and others, since much of the direct statutory regulation concerned will be enforceable in the courts at the behest of someone alleging a failure to adhere to Parliament's new standards. Sector-specific effects of legislation have already been considered within some of the preceding chapters; the present Chapter seeks to analyse the wider impact of legislative innovations.

As previously, considerations of both space and research methodology require some material to be excluded. It is worth noting that even a textbook intended to provide a comprehensive collection of medical statutes requires to exclude a huge volume of material from a book running to 400 pages<sup>1</sup>. So far as methodology is concerned, two main factors have served to reduce the scope of this Chapter. Firstly, the requirement that a regulatory measure have universal coverage excludes not only the huge body of law relating to the structures and functions of the NHS, but also a number of statutes which, while of theoretically general applicability, only really impact on a small number of practitioners working in particular specialities. A number of the more obvious examples of this type are mentioned in this Chapter for the sake of completeness, but are not subject to any analysis. Secondly, to avoid duplication, statutes whose impact has been considered in previous chapters are also excluded.

The main exception to the exception, however, arises in respect of statutes which affect the civil rights and obligations of individuals *vis-à-vis* their health care provider. The emphasis of Chapter 4 was on the role of the civil courts in regulating medical practice and so, underpinning that approach, there was an emphasis on the rules of the common law as laid down (or discovered) by the courts. The emphasis of this Chapter is to consider changes to the rights and duties of individuals or bodies following Parliamentary intervention, and so statutory variations to the previous common law position are considered within the ambit of this Chapter.

In the course of preparing this Chapter, it became apparent that the statutes included fell into two categories, and the chapter's structure reflects this. The first group of statutes considered represent limited interventions by Parliament, typically in response to a particular area of controversy which had reached prominent public attention. A selection

of the more prominent statutes falling into this group is given, but the limited scope of these measures precludes them from being subjected to any detailed analysis. The second group are statutes which (at least arguably) change the entire legal landscape. Only two statutes appear to have created such a widespread impact: the Human Rights Act 1998 (hereafter "HRA") and the Data Protection Act 1998 (hereafter "DPA").

## **II: Subject-specific Statutory Interventions:**

As noted above, this section is in effect a list of areas where Parliament has seen fit to legislate on a particular area so as to vary pre-existing civil rights (and occasionally to impose criminal sanctions). The list is not comprehensive, and no detailed analysis is offered on the impact of these measures. One reason for this lack of analysis is that the measures considered are generally binary in nature: previously you could do this, now you can't.

### **A: Assorted public health legislation:**

The main legislation consists of the Venereal Disease Act 1917 and the Public Health (Control of Diseases) Act 1984. This legislation concerns the potential compulsory detention and/or treatment of individuals suffering from any of a variety of "notifiable diseases". The specific diseases which are "notifiable" are contained in the Health (Infectious Diseases) Regulations 1985<sup>2</sup>. In essence, Parliament has determined that for the overall good of society, individuals suffering from these diseases forfeit their right to liberty and personal bodily integrity. Those having a notifiable disease also forfeit their right to confidentiality, since doctors are under a statutory obligation to advise the appropriate authorities if they diagnose such a disease in a patient. Neither HIV nor AIDS is notifiable, but they are subject to a slightly different regime under the AIDS (Control) Act 1987. It has, however, been argued that the current trends towards liberalism may result in this approach being challenged and, ultimately, changed<sup>3</sup>.

### **B: Human Tissue Act 1961:**

This is the legislation (amended by the Anatomy Act 1984 and Corneal Tissue Act 1986) by which Parliament sought to regulate the use which could be made of tissue or organs<sup>4</sup> removed from dead bodies. Recent scandals over organ retention have shown that this legislation is highly flawed. The Final Report of the Independent Review Group on Retention of Organs at Post-Mortem<sup>5</sup> stated that the 1961 Act should be replaced completely<sup>6</sup>.

It is understood that this recommendation has been accepted by the Scottish Executive. Similar recommendations were made by the parallel English inquiry<sup>7</sup>. Given that the legislation would appear to be due for repeal in the near future, its current form is not considered further here.

### **C: Abortion Act 1967:**

Most of the applicable parts of the Abortion Act 1967 were considered in Chapter 3. It is mentioned here simply as an example of the changes which Parliament can bring about, but which would be beyond the scope of judicial development to effect (not least because the 1967 Act was creating a statutory defence to what was, in England and Wales at any rate, a statutory offence). The knock-on effect of this change to the criminal law was also picked up on in Chapter 4: Parliament having removed the criminal sanctions attaching to therapeutic abortion, the courts proceeded to regard it as any other form of medical intervention, giving rise to civil liability for negligence in appropriate cases.

### **D: Congenital Disabilities (Civil Liability) Act 1976:**

This legislation, which applies only in England and Wales, was arguably unnecessary. The Act was intended to allow a child born with disabilities caused by someone's negligent action in relation to the child's parents, or to the mother in the course of pregnancy or the child itself in the course of birth, to bring an action in tort against the person whose negligence caused the disability. At the same time, the Act sought to exclude the possibility of a child suing its mother for such negligence (although the rule is modified slightly in relation to a woman driving while pregnant<sup>8</sup>), and also sought to rule out the possibility of so-called "wrongful life" actions<sup>9</sup>. As such, the Act represents a deliberate attempt by Parliament to change the common law rules of liability in such circumstances. The Act itself was subsequently amended to cover *ex utero* negligence arising (typically) out of IVF treatment<sup>10</sup>.

However, the courts have subsequently held that the Act in large measure simply reflected the pre-existing (but unstated) common law position, at least in relation to England and Wales. In the cases of *Barton v Islington HA and de Martell v Merton and Sutton HA*<sup>11</sup>, the court held that a child born disabled as a result of another's negligence could raise an action notwithstanding its pre-birth lack of legal personality. In *McKay v Essex AHA*<sup>12</sup>, the court held there was no right of action for "wrongful life" (i.e. a claim the essence of which was that the person on whose behalf the claim was being made should not have been born at all).



Some commentators have suggested that the 1976 Act inadvertently *creates* an action for “wrongful life”, at least in certain circumstances<sup>13</sup>. Another commentator has suggested that the Act’s supposed abolition of wrongful life actions is incomplete and that a common law action for wrongful life could be sustained notwithstanding the passing of the Act, in relation to injuries or disabilities arising without any negligence<sup>14</sup>. However, these comments fly in the face of the Court of Appeal’s opinions on the matter (albeit stated *obiter*<sup>15</sup>) and therefore appear not to reflect the Act as it is applied in practice.

#### **E: Vaccine Damage Payments Act 1979:**

In Chapter 4, a number of criticisms of fault-based compensation systems were noted, together with a final mention that so-called “no-fault” compensation generally meant more money going to compensate victims rather than going to overheads than in civil litigation.

However, the Vaccine Damage Payments Act 1979 establishes a “no-fault” compensation scheme, albeit in the limited area of persons who are severely injured by one of a specified number of vaccines against particular infectious diseases. The reasons for this sector-specific policy are described by Brazier as follows:

“Vaccine damage is a candidate for special treatment because of the distinction in social effect between vaccines and other drugs. Generally the benefit and risk of taking a drug rests with the individual patient alone. No one else suffers directly if he does not take the drug. No one else benefits directly if he does. With a vaccine the position is different. If a child is immunized against contagious disease, the child himself benefits from the immunity conferred and his friends and schoolfellows benefit from the elimination of the risk that he will pass that disease on to them. Consequently, vaccination of young children against tetanus, diphtheria, polio, measles and whooping cough is actively promoted by the Department of Health.”<sup>16</sup>

The scope of the scheme is limited to those who are severely disabled (meaning disablement to the extent of 80% or more, as measured under social security legislation tests<sup>17</sup>) as a result of vaccination for one of the specified diseases<sup>18</sup> and subject to certain other criteria such as place and time of vaccination<sup>19</sup>. The same principles apply to damage caused by vaccination of the mother<sup>20</sup>. The successful claimant is entitled to a one-off payment of a fixed sum, currently set at £100,000<sup>21</sup>.

The main reasons for excluding this Act from detailed examination were spelled out in Chapter 2: a “pure” no-fault compensation system does not (in the absence of additional features) fulfil any of the regulatory functions identified in Chapter 2. The scheme established by this legislation pays compensation following injury or harm occurring as a result of vaccination, and not (as with one of the identified regulatory tasks) because of any failure to adhere to standards.

#### **F: Mental Health Act 1983/Mental Health (Scotland) Act 1984:**

The mental health legislation under discussion here forms the core of an extremely large and complex area of the law. Aside from methodological considerations, space alone would preclude this thesis from including a detailed examination of mental health law.

Mental health legislation creates a highly-detailed legal code applicable to persons suffering from a “mental disorder”, and in particular to their reception, care and treatment and to the management of their affairs. Aspects of this include compulsory admission to hospital, procedures to be followed where the person is facing a criminal trial or has been convicted of an offence, rules regarding what forms of treatment may be given to such patients without their consent, and the established of mental health tribunals to hear appeals against (in particular) decisions concerning compulsory hospitalisation. While there are some distinctions between the Scottish legislation and its counterpart in England and Wales, particularly in relation to procedures which require to be referred to the courts, in general the two pieces of legislation address an identical problem and adopt similar solutions.

Clearly much of the activity under these Acts falls within our concept of regulation, and a number of distinct regulatory tasks are being carried out. However, this legislation is concerned with adults whose mental capacity is deemed to be impaired to the extent that overriding mechanisms are necessary either for the protection or well-being of the individual concerned, or else for the protection of the public. The main thrust of this thesis has been to consider the mechanisms which apply to adult patients of full capacity, and so the body of mental health law can be regarded as peripheral to the main body of rules under consideration.

Before moving on, however, it is useful to consider a few of the rules embodied in this legislation as examples of how legislation can be used to address complex issues surrounding the care and management of a difficult but vulnerable client group. Some of the responses embodied in the legislation are pragmatic responses to a real problem, but one can also see certain issues of policy surrounding the rules adopted. Thus, in

delimiting the scope of the (English) Mental Health Act 1983, we see in Section 1(3) the provision that mental disorder (which is, in effect, the triggering definition under mental health legislation) is not to be inferred or diagnosed as a result of the person's promiscuity or other immoral conduct, sexual deviancy or dependence on alcohol or drugs. While some of these other conditions may be felt to need a social response, Parliament was making it abundantly clear that the mental health legislation was not to be used for that purpose.

The general scheme of mental health legislation is, in very general terms, as follows<sup>22</sup>:

### 1: Compulsory detention:

Compulsory detention in a mental hospital is permitted for both assessment and treatment purposes. Compulsory admission to hospital for assessment is permitted under Section 2 of the Act, and can be done only where

- The individual to be detained suffers from a mental disorder;
- The nature or degree of the mental disorder warrants compulsory detention for assessment<sup>23</sup>;
- The individual's detention is either in the interests of his or her own health or safety or for the protection of others<sup>24</sup>; and
- The application for compulsory detention of the individual is based on the recommendations of two registered medical practitioners<sup>25</sup>.

The detention may initially be for only 28 days, although this can be extended in practice by subsequently making an application for admission for treatment. Compulsory admission for treatment is permitted under Section 3. This is subject to virtually identical terms, except that the individual's mental disorder must be of a type appropriate for treatment which will alleviate or prevent deterioration in his condition<sup>26</sup>, a term which the courts have interpreted broadly<sup>27</sup>. In addition, the treatment must be necessary for the patient's health and safety or the protection of others but cannot be provided unless the patient is compulsorily detained<sup>28</sup>. Again, two medical practitioners must support the application<sup>29</sup>.

Any compulsory detention of a person under the Act is subject to an appeal (technically an "application") to a Mental Health Review Tribunal, established under Section 65 of the Act. The Tribunal is authorised to review compulsory admissions, and if satisfied that the grounds under which admission was made do not apply or are not made out, may order the discharge of the patient<sup>30</sup>. This procedure has recently been found insufficient to meet

the requirements of the Human Rights Act 1998 and the provision declared incompatible with Article 5 of the European Convention of Human Rights by the Court of Appeal<sup>31</sup>. As a result, it is probable that aspects of the legislation will be amended in the near future.

There are, associated with the compulsory admission provisions, rules covering leave of absence from the hospital. Leave of absence could originally be granted for six months only<sup>32</sup>. This resulted in a practice growing up whereby patients were granted leave of absence and then recalled to hospital shortly before the six months expired, purely to allow the period of leave of absence to be renewed. This practice was declared unlawful by the courts<sup>33</sup>, which (at least in part) resulted in the procedures being changed by the Mental Health (Patients in the Community) Act 1995.

One regulatory gap which has become apparent in the current scope of the legislation is the situation of “informal patients”. These are persons who, while resident in the hospital already, were not formally admitted under the compulsory procedures because they did not object to going to hospital at the time when they were admitted. Informal patients are catered for by section 5 of the Act, which provides that the compulsory admissions procedures can be used even though the patient is already an in-patient in the hospital, and by Section 131, which covers “informal admission” of patients who are treated as in-patients in a hospital notwithstanding that the formal admission procedures have not been followed. In *R v Bournewood Community and Mental Health NHS Trust ex parte L*<sup>34</sup>, the House of Lords recognised that such patients are, in fact, detained in hospital but held that the detention and (non-consensual) treatment of such individuals was lawful on the common law basis of necessity. However, as such individuals do not benefit from the “second opinion” rules (on which see *infra*) or from supervision by the Mental Health Act Commission<sup>35</sup>, the “informal” treatment of this group of patients (which is far greater in number than those who are formally admitted<sup>36</sup>) is not really regulated by the Act at all and a regulatory deficit would appear to exist.

## 2: Consent to treatment:

In terms of the legislative scheme, compulsory hospitalisation occurs in two stages: firstly, the patient is admitted for assessment, and then they may be admitted for treatment. Given that the patient has had to be subjected to compulsory measures in order to get them into hospital at all, it is reasonably predictable that they may not be the most willing or co-operative patient and that the consent required in terms of both criminal and civil law may not be forthcoming.

It is at this point that policy issues enter into the picture. Having determined that a person is suffering from a mental disorder of a type or degree justifying their compulsory admission to hospital, the question then arises: to what extent does society, through mental health legislation, allow treatment of those who are unable or unwilling to consent to that treatment on their own behalf? There are two distinct elements here. Chapter 4 analysed how the common law deals with the patient unable to give consent. However, there are different considerations where someone actively refuses to consent. The criteria under which someone may be compulsorily admitted to hospital are not the same as the legal tests for capacity, and it is theoretically possible for someone to be admitted under mental health legislation who is legally competent to consent to treatment or not.

The approach adopted by the Act is essentially paternalistic, and subject to some minor exceptions, a patient detained under the Act may be treated even if incapable of consenting – and may also be treated even if they have refused consent, provided that a registered medical practitioner (not being the responsible medical officer, a doctor on whom certain duties are imposed under the Act) has certified that

“...having regard to the likelihood of [the treatment’s] alleviating or preventing a deterioration of his condition, the treatment should be given”<sup>37</sup>

There are some additional safeguards attached to this procedure in that before the doctor is permitted to make this certification, he or she must consult with two other people who have been involved in the patient’s care, one of whom must be a nurse, the other of whom must be neither a nurse nor a registered medical practitioner<sup>38</sup>. Curiously, in the case of detained patients who have consented to the treatment, the procedure is actually still more onerous than that which applies to patients in general, in that the doctor has to certify that the patient has understood the nature, purpose and likely effects of the treatment, and has consented to it<sup>39</sup>. The “second opinion” doctor should give adequate reasons for his opinion<sup>40</sup>; if this opinion is challenged in law, the doctors involved may be cross-examined even in judicial review proceedings<sup>41</sup>.

An exception to the rule permitting treatment without consent (or in the face of objection) is found in Section 57 of the Act. This states that treatment consisting of the surgical destruction of brain tissue (or of the functioning of brain tissue) can only be done with the consent of the patient (which again must be shown by means of a certificate by the doctor, backed by two non-doctors’ opinions, that the patient has understood the nature, purpose and likely effects of the treatment, and has consented to it)<sup>42</sup>. In essence, it appears that Parliament has decided that paternalism, even in relation to patients admitted under compulsion, has its limits. This limit is found in psychosurgery, and the state’s interest in

non-consensual treatment of those with mental disorders has been deemed to be insufficient to warrant subjecting people to irreversible brain surgery against their wishes. This, of course, may at the same time deprive those who are incapable of consenting from receiving treatment which may have cured them – precisely the sort of paternalistic intervention which Komrad argues is morally justifiable<sup>43</sup>. However, at least one Appeal Court judge has expressed the opinion that compulsory treatment of someone detained compulsorily but having capacity cannot be justified under heightened “human rights” scrutiny<sup>44</sup>. This is considered below<sup>45</sup>.

Mental health legislation encompasses other procedures in relation to patients who are not incarcerated, such as guardianship orders<sup>46</sup>, as well as after-care orders and the procedure for supervision orders introduced by the Mental Health (Patients in the Community) Act 1995. However, as it is the compulsory detention and treatment of individuals which represents the greatest intrusion on individual rights, it is not proposed to discuss these other aspects of the legislation.

#### **G: Age of Legal Capacity (Scotland) Act 1991 (and related legislation):**

As previously stated, this thesis is principally concerned with the treatment of adult patients with full capacity. This raises the question of when the law recognises someone as an adult. The age of majority in Britain is eighteen<sup>47</sup>, in itself a statutory innovation on the traditional age of 21. However, while 18 remains important in many contexts (e.g. the right to vote, and in relation to any number of age-restricted goods), its importance in the medical sphere is somewhat less marked. For most purposes in the medical context, 16 is far more important. It is at this age that the individual is presumed capable of consenting to treatment on their own behalf<sup>48</sup> and can register with a GP in their own name<sup>49</sup>.

In Scotland, the progressive reduction in the age at which persons are able to make decisions on their own behalf has gone a stage further. In terms of Section 2(4) of the Age of Legal Capacity (Scotland) Act 1991,

“A person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner<sup>50</sup> attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment.”

The 1991 Act was silent on the subject of concurrent parental rights to consent to a procedure which the child, having capacity, has refused to consent to. It was noted in Chapter 4 that in England and Wales the law seems to be that parents can overrule a competent refusal by a child<sup>51</sup>. Against this background, the 1991 Act has to be read alongside the provisions of the Children (Scotland) Act 1995. This later Act spells out the extent (and permissible uses) of parental rights and responsibilities, including the responsibility to act as the child's legal representative<sup>52</sup>. This is defined as

“...a reference to that person, in the interests of the child... acting in, or giving consent to, any transaction where the child is incapable of so acting or consenting on his own behalf.”<sup>53</sup>

From this it can be seen that in Scotland, parental rights cannot be exercised where the child has capacity to exercise that right on his or her own behalf. If there were any doubt that this was the case, the doubt has effectively been removed by Section 131A(1) of the Education (Scotland) Act 1980<sup>54</sup>, which provides that

“Nothing in this Act shall prejudice any capacity of a child enjoyed by virtue of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991...; and without prejudice to that generality, where under or by virtue of this Act a child is required to submit, or to be submitted, to any medical or dental examination, inspection or treatment but the child has the capacity mentioned in the said section 2(4), the examination, inspection or treatment shall only be carried out if the child consents.”

#### **H: Prohibition of Female Circumcision Act 1985:**

In terms of scope, this is one of the narrowest legislative interventions into medical law. It is also one of the shortest. The Act outlaws female circumcision, making it a criminal offence punishable by up to five years' imprisonment<sup>55</sup>. It is similarly punishable to “aid, abet, counsel or procure” someone else to perform such an operation on someone other than the procuring party<sup>56</sup>. It is not, on the face of it, unlawful to offer to perform such an operation, although the GMC has regarded such offers as justifying “striking off” doctors who do so<sup>57</sup>.

There are savings in Section 2 of the Act for necessary surgical operations carried out by registered medical practitioners or (in case of birth-related operations) by midwives. “Necessary” in this context means necessary for physical or mental health, disregarding the effect of custom or ritual in assessing mental health<sup>58</sup>.

## I: Surrogacy Arrangements Act 1985:

Surrogacy arrangements arise where a woman carries a child to term on behalf of someone else, and (if all goes to plan) to whom she will give the child on or shortly after birth. Modern IVF techniques mean that it is possible for the surrogate mother to carry a child to which she has no genetic relationship. The expression applies equally to the situation where the surrogate mother is also the genetic mother of the child who is to be given away to someone else (most commonly to a couple, the male partner of which is the father of the child – whether by artificial or natural means). The Surrogacy Arrangements Act 1985 was the only part of the 1984 Warnock Report<sup>59</sup> to receive a rapid legislative response. This may have been in response to a highly-publicised (and controversial) case involving a surrogacy arrangement which reached the courts relatively shortly after the report had made recommendations on that very subject<sup>60</sup>.

The 1985 Act outlaws commercial surrogacy, which is to say that it outlaws acting as an intermediary between the surrogate mother and the prospective social parents. It does not outlaw payments to the surrogate mother, nor criminalize the prospective parents for making or offering such payments. It is only the activities of intermediaries acting for gain which are outlawed by this Act<sup>61</sup>, although direct payments may potentially fall foul of other legislation<sup>62</sup>. Surrogacy arrangements are, by virtue of an amendment to the Act, expressly rendered unenforceable<sup>63</sup>.

While not enacted under the 1985 Act, it is worth pointing out one particular legislative clarification which is of particular relevance in this area. Section 27 of the Human Fertilisation and Embryology Act 1990<sup>64</sup> provides that, so far as the law of the UK is concerned, the legal mother of a child is the woman who bears the child, irrespective of genetic relationship (or lack thereof) to the child. This avoids any scope for an argument by the genetic mother that the surrogate was withholding the genetic mother's child from her without lawful authority.

Neither the Surrogacy Arrangements Act 1985 nor subsequent legislation actually outlaws surrogacy arrangements *per se*. Given the scope for commercial exploitation of poor but healthy women by (usually) wealthy couples, one might argue that this is a regulatory gap. It can equally be viewed as regulatory respect for the autonomous decision of a capable adult woman to allow others to benefit from the use of her womb for a while. For the purposes of this thesis, there is no regulatory gap because the rules specify unambiguously who the parents of any given child are, and (through the adoption legislation or the special procedure under the 1990 Act<sup>65</sup>) who is able to seek parental rights and responsibilities in respect of that child. A recent case indicated that, had the



case arisen after 2 October 2000, the claimant would have challenged sections 1 and 2 of this Act under the Human Rights Act<sup>66</sup>.

### **J: Human Organ Transplants Act 1989:**

This legislation provided the legislative background to the Unrelated Live Transplant Regulatory Authority (ULTRA), mentioned in Chapter 5. It is worth mentioning, in this context, a more general point concerning the material included within this Chapter. The 1989 Act creates a prohibition on live organ transplants except where the recipient of the organ is genetically related to the donor, or else where the transplant has been approved by ULTRA. In this respect, the (conditional) prohibition of unrelated live organ transplants can be regarded as the criminal sanction underpinning the functioning of ULTRA, rather than a legislative goal in itself. It would appear that legislation following this pattern does not really intend to outlaw the conduct in question, so much as seek to ensure that the conduct falls under the jurisdiction of the appropriate regulatory body. Legislation which renders conduct conditionally criminal in this way is not, barring relevant extraneous features, mentioned or discussed in this chapter.

For present purposes, however, it is also worth noting that the Human Organ Transplants Act 1989 also creates a free-standing and absolute prohibition on commercial dealings in human organs<sup>67</sup>, and also outlaws advertising services connected to commercial organ sales<sup>68</sup>.

### **K: Adults with Incapacity (Scotland) Act 2000:**

In Chapter 5, considerable time was devoted to discussions of the tests established (or not established) by the courts in relation to treatment decisions for adults deemed to be (or at least treated as) incapable of consenting to or refusing treatment. This thesis proceeds on a Britain-wide basis; had it proceeded on a purely Scottish basis, or if the 2000 Act had been passed by Westminster on a Britain-wide basis, almost all of that discussion would have been rendered superfluous. This legislation represents the first major piece of law-making by the devolved Scottish Parliament, and provides a complex and ambitious series of rules and procedures where previously there was a legal void<sup>69</sup>.

The Act itself is fairly large (89 sections and six schedules) backed by a number of statutory instruments<sup>70</sup>. It establishes a number of important procedures in relation to matters such as the appointment of persons with powers of attorney and a new category of persons having welfare powers of attorney, establishes a new regime for the management of the property of those with a mental incapacity, another new regime for the

appointment of guardians able to look after the affairs of such individuals (with related rules allowing for the making of specific intervention orders), all backed up by supervisory powers given to local social work authorities, the Mental Welfare Commission and the office of the Public Guardian, all with recourse to the civil courts in some circumstances. In particular, local authorities are obliged to seek authority from the court to intervene on behalf of the individual if it is necessary to do so in order to protect the property, financial affairs or personal welfare of the individual and it appears that no-one else will be seeking to apply<sup>71</sup>. For present purposes, however, attention will be focussed on only two aspects of this legislation: the tests for incapacity, and the rules authorising interventions in general and medical treatment in particular.

Incapacity is given a fairly straightforward definition:

“Incapable’ means incapable of –

- (a) acting; or
- (b) making decisions; or
- (c) communicating decisions; or
- (d) understanding decisions; or
- (e) retaining the memory of decisions,

as mentioned in any provision of this Act, by reason of mental disorder or of inability to communicate because of physical disability; but a person shall not fall within this definition by reason only of a lack or deficiency in a faculty of communication if that lack or deficiency can be made good by human or mechanical aid (whether of an interpretive nature or otherwise); and

‘incapacity’ shall be construed accordingly.”<sup>72</sup>

The Act specifically allows anyone directly affected by a decision that someone is incapable (including, most importantly, the adult himself or herself) to appeal that decision to the sheriff and thereafter to the Court of Session<sup>73</sup>.

The general principles underpinning any intervention in the affairs of an adult with an incapacity are spelled out in Section 1. The principles are that interventions should only take place if they will benefit the individual and the benefit cannot reasonably be otherwise achieved<sup>74</sup>; the intervention must be the least restrictive option<sup>75</sup>, and in deciding whether it should happen, account must be taken of the past and present wishes and feelings of the adult (so far as these can be ascertained), and of their nearest relative and primary carer, as well as any guardian or attorney or anyone appearing to have an interest in the adult’s welfare<sup>76</sup>. Anyone exercising any powers under the Act is also required to

encourage the adult to exercise whatever skills he or she has in relation to the matter in question, and encourage him or her to develop new skills<sup>77</sup>.

These general principles apply to medical treatment, but are bolstered by some specifics. Any proposed medical intervention must therefore accord with the general principles of individual benefit, minimum intervention and so on.

The rules relating specifically to medical interventions are found in Part 5 of the Act<sup>78</sup>. The general thrust of this Part is that the doctor who is primarily responsible is given authority “to do what is reasonable in the circumstances, in relation to the medical treatment<sup>79</sup>, to safeguard or promote the physical or mental health of the adult.”<sup>80</sup> This power only arises once the doctor has certified, in an approved form, that in his or her opinion the patient is incapable in relation to making a decision about the treatment in question<sup>81</sup>. From this it can be seen that the Act applies an issue-specific assessment of capacity.

There are a number of limitations and safeguards built into this general pattern. Thus, the general power to treat an incompetent adult does not extend to the use of force or detention unless immediately necessary and only for so long is necessary<sup>82</sup>, nor does it allow doctors to use the mechanism to place someone in hospital for compulsory treatment of mental disorder<sup>83</sup>, the procedure for which remains the Mental Health (Scotland) Act 1984. Some forms of treatment (in particular, those which cannot be carried out under mental health legislation without the patient’s consent) are excluded from the general authorisation<sup>84</sup>. If the doctor’s authority to treat the person is challenged, no treatment is authorised under this Act until the challenge is resolved<sup>85</sup>. There are provisions whereby disagreements between the doctor and other proxies<sup>86</sup> can be referred to what amounts to an independent medical referee<sup>87</sup>. Collusion is prevented by giving any person having an interest in the patient’s welfare a right to appeal the treatment decision to the Court of Session in cases where the doctor and proxies agree on the proposed course of action<sup>88</sup>. The general power to treat cannot be exercised where (to the knowledge of the doctor) there is a more specific power relating to the treatment granted to a proxy<sup>89</sup>, or where such a power is in the course of being applied for<sup>90</sup>. Nor can it be used to authorise treatment which is the subject of an interdict<sup>91</sup>.

There are particular restrictions on conducting research on persons incapable of consenting to it. Any such research has to satisfy the following conditions:

- the research cannot be carried out on persons having capacity
- the research is into the causes, diagnosis, treatment or care of the incapacity or the effects of treatment for it

- the research is likely to produce benefit to the patient (or others suffering from the same incapacity<sup>92</sup>)
- there is no or minimal risk to, or discomfort imposed on, the patient
- there are no indications of unwillingness to participate; and
- the research has been approved by the Ethics Committee (set up by the Act)<sup>93</sup>

It would appear that there is an appeal against the decision to carry out research, although the drafting is unclear. Section 52 states that any decision<sup>94</sup> taken for the purposes of Part 5 of the Act can be appealed to the sheriff by any person having an interest in the personal welfare of the incapable adult. However, this appeal is stated to be against “a decision... as to the medical *treatment* of the adult”<sup>95</sup>. This raises the question of whether research counts as treatment. “Treatment”, as we saw, is defined as including “any procedure or treatment designed to safeguard or promote physical or mental health.”<sup>96</sup> Given that some forms of medical research will not do this, then (at least arguably) decisions as to carrying out such research on the incapax could not be appealed against. Such research would, admittedly, be unlikely to find approval from the Ethics Committee, but there does appear to be a minor gap in the otherwise comprehensive system of safeguards built into this legislation.

#### **L: Freedom of Information Act 2000/Freedom of Information (Scotland) Act 2002:**

This legislation is closely connected to the provisions of the Data Protection Act 1998, and is therefore considered under that heading below.

#### **M: Human Reproductive Cloning Act 2001:**

This Act was mentioned briefly in Chapter 5, and its coverage here will be similarly brief. The Act was passed as an emergency legislative response to the decision at first instance in the case of *R (on application of Quintavalle) v Secretary of State for Health*<sup>97</sup>, which held that organisms created by “cloning” (technically called CNR) were not embryos within the Human Fertilisation and Embryology Act’s definition, and so were not covered by the statutory regime.

The Human Reproductive Cloning Act 2001 simply makes it illegal to place an embryo created by CNR (or indeed, by any other as yet unknown technique not involving fertilisation<sup>98</sup>) in a woman. The offence is punishable by up to ten years’ imprisonment<sup>99</sup>.

### **III: The Human Rights Act 1998:**

#### **A: Structure of the Act:**

The Human Rights Act 1998 (“HRA”) “gives further effect to”<sup>100</sup> the 1950 European Convention of Human Rights or, in popular terminology, “incorporates” it into the laws of the UK.

The HRA does not relate to the entire European Convention on Human Rights. Instead, only those parts found in Schedule 1 to the Act are covered. This consists of Articles 2-12, 14 and 16-18 of the Convention proper, Articles 1-3 of the First Protocol, and Articles 1 and 2 of the Sixth Protocol. These are known collectively as “Convention Rights”. Some controversy surrounded the government’s decision not to include Article 13, which confers the right to an effective remedy before the national authority. The official response to this was that the right to judicial remedies conferred by Section 8 of the Act was sufficient guarantee of a remedy<sup>101</sup>. This may not be entirely correct, as Section 8 empowers courts to grant “...such relief or remedy, or make such order... as it considers just and appropriate”<sup>102</sup> which is not necessarily the same as “effective”<sup>103</sup>.

It is useful to consider the effect of the Act in three distinct ways: the duty imposed on public authorities, the new interpretive approach, and the enforcement provisions. There are also other provisions of limited relevance to this thesis which are not be considered in detail. Thereafter the scope of the Convention rights will be considered, together with the impact or potential impact which these rights will have on the regulatory machinery.

So far as public authorities are concerned, the key provision in the Act is Section 6(1) which makes it unlawful for them to “act in a way which is incompatible with a Convention Right”. The only exception to this is where primary legislation makes it impossible for the public authority to do other than to violate these rights<sup>104</sup>. Such instances appear to be rare.

The expression “public authority” is partially defined by Section 6: Parliament (Westminster) is not a public authority, but the courts are. It seems clear that local authorities, the police, the army, and all the departments of central government will be covered. The National Health Service is also likely to be included, but it is unclear how far down the NHS structural hierarchy this will apply: it is not clear, for instance, whether the individual GP practice (or indeed, the individual GP) would count as a public authority. The definition also includes “any person certain of whose functions are functions of a

public nature”<sup>105</sup>, the so-called “Railtrack” clause. The hybrid public authorities caught by this section are only affected in relation to their public functions<sup>106</sup>.

More generally, all legislation and regulations must, in terms of Section 3, be read and given effect to (so far as is possible) in such a way as to be compatible with Convention Rights. This provision is retrospective<sup>107</sup>, and consequently any existing interpretations of the law, no matter how well established and authoritative, have to be revisited and changed if that interpretation violates Convention Rights. The provision has been held (by the House of Lords) to permit courts both to restrict the meaning of statutes, but also to allow them to supply additional provisions (or “read into” the legislation in question) in a way which would have been impermissible before the Act came into force<sup>108</sup>. Parliamentary sovereignty is preserved as Section 3 does not affect the validity of primary (i.e. Westminster) legislation, nor of subordinate legislation where the parent legislation makes it impossible for the subordinate legislation to be made compatible<sup>109</sup>. Section 2(1) additionally requires courts, when determining questions relating to Convention rights, to take into account decisions of the European Commission on Human Rights and European Court of Human Rights in Strasbourg. Within this two further complications arise. Strasbourg decisions emphasise that the Convention is a “living instrument” which has to be interpreted with evolving social notions of what is and is not acceptable<sup>110</sup>; activities which were human rights compliant ten or twenty years ago may not be so today. The Court has firmly rejected the “original intent” approach used by some conservative US Justices to interpret the US Constitution. However, the decisions of the Strasbourg bodies are not formally binding on the British Courts. When steering the Human Rights Bill through Parliament, the government indicated a desire to see the growth of an indigenous body of human rights law and the provisions of the Act should facilitate this. The judges have not been in agreement as to how strong an injunction Section 2(1) actually is<sup>111</sup>.

If primary legislation is found to be incompatible with a Convention Right, certain Superior Courts are empowered to make “declarations of incompatibility” which allow for a “fast track” procedure to amend the legislation<sup>112</sup>. This has no effect on the original legal proceedings. To date, only three declarations have been made<sup>113</sup>: one in relation to the Mental Health Act, discussed *supra*<sup>114</sup>, one in relation to certain provisions of the Consumer Credit Act 1974<sup>115</sup>, and most recently in respect of provisions whereby widows (but not widowers) were previously entitled to certain tax allowances<sup>116</sup>. In *R v A*<sup>117</sup>, the House of Lords emphasised that the declaration of incompatibility was only to be issued as a last resort, only if the most linguistically-strained re-interpretation of a provision still left it to be read as incompatible with a convention right.

The enforcement provisions allow the victim (or potential victim, considered below) of a breach of Convention Rights to bring proceedings in an appropriate Court or Tribunal. This means any court or tribunal able to grant the remedy being sought, with default jurisdiction falling on the Court of Session and High Court (in Scotland) or the High Court (in England and Wales). The courts are able to use all existing remedies against the offending public body including, where appropriate, awards of damages (subject to certain technical restrictions). However, it is also possible to raise Convention points in any legal proceedings whether by or against the public body. The only defence is to demonstrate that the activity was not a breach of the right in question, or else was done in unavoidable compliance with primary legislation. The Courts are themselves public bodies under the Act<sup>118</sup>, and are therefore bound to observe Convention Rights directly, even if not asked to do so.

Before Convention Rights can be relied on in Court, Section 7(1) of the Act requires the claimant to be a victim (or potential victim) of the unlawful act. "Victim" is defined in Section 7(7) by reference to Article 34 of the Convention (which is not actually included in the text of the Act). This means that a victim must:-

- be within the jurisdiction of a high contracting party (e.g. the UK);
- be a person (including legal person), non-governmental organisation or group of people. Public authorities, being regarded as part of the machinery of the state, do not count, and cannot themselves claim to be victims of human rights breaches;
- claim to be a victim of an alleged breach of human rights.

This last element precludes general interest litigation or litigation about hypothetical breaches. In *Amuur v France*<sup>119</sup>, "victim" was held to mean a person directly affected by the Act or the omission in question. It may be sufficient simply to show a reasonable likelihood of being directly affected<sup>120</sup>. It is not necessary to show actual prejudice - prejudice suffered goes to evaluation of "just satisfaction" rather than to status as a victim. Indirect victims of a breach (e.g. next of kin) may have standing. Status as a victim is not dissimilar to having title and interest to seek judicial review; being a victim itself automatically satisfies title and interest in terms of Section 7(4).

Section 8 of the Act provides that courts can grant any remedy in respect of a human rights case which they could grant in any other case. Accordingly, any court able to grant damages can award damages in human rights cases. However, the award of damages is restricted by Section 8(3) to cases where it is necessary to afford "just satisfaction" to the

victim, based on the principles of the European Court in applying Article 41 of the Convention (also unhelpfully omitted from the text of the Act). In providing “just satisfaction”, the Court has a number of options:

“In many cases the Court has found that the finding of a violation is in itself just satisfaction and in others that a token amount of money is sufficient. On the other hand, in some cases the Court awards substantial sums of money to successful applicants, including interest when the Government unduly delays payment. On occasion, the Court has ordered the return of unlawfully expropriated property to an applicant.”<sup>121</sup>

Damages can be awarded for both pecuniary and non-pecuniary loss<sup>122</sup>. For pecuniary loss, damages are awarded where the breach of Convention Rights has made a significant and financially quantifiable difference. Only actual direct losses are allowed - it will remain possible to challenge a claim on the basis of remoteness just as under other civil claims.

Finally, it is necessary to bring a human rights case within one year of the alleged breach, unless a shorter time limit is prescribed for the procedure in question<sup>123</sup>, although this can be extended if the court considers it equitable to do so<sup>124</sup>. Claims can, in general, only be brought in respect of violations of convention rights which occurred on or after 2 October 2000. However, in terms of Section 22(4), a victim can rely on convention rights in any legal proceedings brought by public authorities before 2 October 2000 (but not in appeals against such proceedings<sup>125</sup>).

### **C: Convention rights:**

There are, in accordance with the European Court’s approach to the Convention, three different types of Convention Rights. The three types of rights are *absolute*, *limited* and *qualified*. Absolute Rights admit of no limitations whatsoever. Limited Rights are similar except that there will be stated limitations. Thus the Article 5 right to liberty is an absolute right except for the series of exceptions listed within the Article. If the detention does not satisfy one of the (fairly closely defined) exceptions to the general principle then the detention will automatically be in violation of the Convention. Qualified Rights are easy to spot, typically consisting of two paragraphs. The first paragraph grants the impressive sounding rights or freedoms in question; the second paragraph, however, then proceeds to restrict or circumscribe the rights in some way. Rather than attempting to define these exceptions (as limited rights have the limitation defined), instead the qualified rights are subject to a series of tests which have to be satisfied before a breach can be justified.



Many of the Articles of particular relevance to the medical sphere are qualified rights. The tests against which infringement is assessed are a mixture of the express terms of the Convention, and the Court's approach to and interpretation of the Convention, broadly as follows:

- Is the interference prescribed by law?
- Does the interference pursue a legitimate aim?
- Is it necessary in a democratic society? (i.e. does it pursue a pressing social need?)
- Is it proportionate to the legitimate aims you are pursuing?
- Do you have relevant and sufficient reasons for the interference?

It is important to note that a failure on any of these points will mean that the *prima facie* infringement of the Article in question will be incapable of justification. All else being equal, a human rights claim should succeed in these circumstances.

Proportionality is a key feature of this approach, and means simply that if an infringement of a Convention Right has occurred, then attempts to justify the breach must show that the violation was no more than was necessary to achieve the legitimate aim pursued. The measure employed (which infringes Convention Rights) must be proportionate to the aims sought to be realised: there must be a fair balance struck between interests of the community (as represented by the actions of the public authority) and the rights of the individual. Proportionality is also a general control test utilised by Strasbourg, and as such also has much in common with *Wednesbury*<sup>126</sup> unreasonableness. There are two potential domestic approaches to proportionality: the first is to consider that proportionality is for the public authority or officer entrusted with the operational decision to reach a view on. The court's function thereafter is to determine whether the decision maker's view on proportionality was a reasonable one. This approach was (in essence) adopted by the Court of Appeal in *R v Secretary of State for the Home Department ex parte Mahmood*<sup>127</sup>. The problem with this approach, however, is that the court (itself a public authority) could find itself putting a judicial seal of approval on a course of action which the court considered to be disproportionate, provided it was not what we might refer to as "*Wednesbury*-unreasonably-disproportionate". And since the European Court had already concluded that *Wednesbury* scrutiny was an insufficient safeguard for individual rights because the threshold for impugning decisions was too high<sup>128</sup>, it was arguable that regarding proportionality as just another aspect of decision-making to place under the *Wednesbury* microscope was failing to provide an adequate level of domestic scrutiny.

The second approach is that the court itself decides whether the action was proportionate without reference to what the original decision-maker actually thought. The problem is that in directly assessing whether a particular activity is or is not proportionate, the courts necessarily have to consider the merits of a decision – something which, on constitutional grounds, they consistently refused to do under common law judicial review. But the proportionality of an interference is impossible to measure without consideration of the merits of the decision being implemented, since the existence of a better (i.e. less intrusive) alternative will render the proposed option disproportionate. Ultimately, the House of Lords adopted the second approach in terms of proportionality review, disapproving (though not formally overruling) the Court of Appeal's approach in the process<sup>129</sup>.

A brief description of some of the more relevant Articles now follows.

### *Article 2: The Right To Life*

The question has arisen as to when “life” as protected by this Article actually begins. The issue has never been substantively addressed by the Court, but the Commission has had to issue opinions on the subject. The leading case is *Paton v UK*<sup>130</sup>, in which the Commission refused to apply the full safeguards of Article 2 to a foetus but, conscious of the lack of any consensus on the subject throughout Europe, declined to express a view on when life began or on what safeguards (if any) Article 2 conferred on a foetus.

Article 2 was intended from the outset to prohibit the lethal, involuntary “experiments” perpetrated by Nazi doctors during the Second World War, although a more explicit prohibition on such atrocities was rejected at the time the Convention was being drafted<sup>131</sup>. It was a Nazi decree which led to the only Commission decision on the applicability of Article 2 to medical interventions<sup>132</sup>. Commenting on this decision, Byk notes that

“...recalling that each case was special, it [the Commission] concluded that ‘the applicant has not submitted evidence that in his particular case a blood test would... create any danger to his life.’ This last remark has some bearing on an assessment, for example, of the effects of compulsory vaccination carried out despite contra-indications.”<sup>133</sup>

A challenge to a vaccination programme arose in *Association X v UK*<sup>134</sup>; the complaint was held admissible, but failed on its facts. Article 2 has also been used to argue for a state duty to warn of health risks and to monitor potentially harmful effects of state activity

(in the actual case, this was nuclear testing<sup>135</sup>). The case failed on the facts, but the reasoning and logic behind the application would seem to be sound. Article 2 issues were raised in a case involving compulsory treatment of a detained mental patient who had capacity relative to the treatment involved<sup>136</sup>. The argument here was that the patient was so vehemently opposed to the treatment that the forcible restraint involved in administering it could put a strain on his already weak heart. Ultimately, the Court of Appeal decision was on a preliminary point only and this aspect did not come up for decision, but Simon Brown LJ's opinion in the case suggests that it is just a matter of time before this comes to trial.

Lastly, it has been held that nothing in Article 2 prevents a hospital from withholding life-saving treatment from someone where this is in their best interests<sup>137</sup>. The Article imposes a positive obligation on the State to provide lifesaving treatment where this is in the patient's best interests, but not where the treatment would be futile<sup>138</sup>. At time of writing, there are no decided UK cases involving Article 2 where the patient has died in consequence of negligent medical treatment, the only case raised which sought damages under this point having been settled out of court<sup>139</sup>.

### *Article 3: Prohibition Of Torture*

This has been interpreted as creating a hierarchy (in a negative sense) of prohibited conduct. Torture is classed as the most serious kind of ill-treatment, whereas inhuman or degrading treatment is less severe than torture and may include certain physical assaults, inhuman detention conditions or corporal punishment. Article 3 may be violated as a result of either mental or physical suffering, or a combination of them. The Court has established a number of relevant criteria to assist in deciding if something amounts to torture or inhuman treatment<sup>140</sup>. The assessment will depend on a number of factors including location (a closed environment is subject to more intense scrutiny than an open one) duration, severity (and in particular, whether there are any lasting effects on the victim) and the vulnerability of the victim – what might be acceptable in relation to an adult with full mental capacity might not be acceptable in relation to a child or a frail elderly person.

Article 3 is one of the Articles under which the state has positive obligations. This has been interpreted as meaning that it is obliged to prevent breaches of the Article by one private individual against another - particularly in relation to children and other vulnerable persons. In particular, there is a duty to carry out an effective investigation into allegations of torture etc. and to provide explanations for injuries. This duty most commonly arises in relation to persons suffering otherwise unexplained injuries while in police custody, but the

same principle would apply to incidents occurring within a mental hospital or residential or nursing home. The state cannot, according to Strasbourg jurisprudence, delegate responsibility for investigation/protection to other bodies or individuals. It remains to be seen to what extent a health authority (for example) would be able to delegate its duties to a private nursing home.

Article 3 issues have arisen with particular force in relation to compulsory treatment of psychiatric patients. With regard to medical treatment given to such persons, the Court gave some guidelines in the case of *Herczegfalvy v. Austria*<sup>141</sup>:

“The Court considers that the position of inferiority and powerlessness which is typical of patients confined in psychiatric hospitals calls for increased vigilance in reviewing whether the Convention has been complied with. While it is for the medical authorities to decide, on the basis of the recognised rules of medical science, on the therapeutic methods to be used, if necessary by force, to preserve the physical and mental health of patients who are entirely incapable of deciding for themselves and for whom they are therefore responsible, such patients nevertheless remain under the protection of Article 3, whose requirements permit no derogation.

The established principles of medicine are admittedly in principle decisive in such cases; as a general rule, a measure which is a therapeutic necessity cannot be regarded as inhuman or degrading. The Court must nevertheless satisfy itself that the medical necessity has been convincingly shown to exist.”<sup>142</sup>

There is a Commission opinion to the effect that force-feeding a prisoner on hunger strike does not amount to a breach of Article 3, because it is motivated by the state’s obligations under Article 2 to protect life<sup>143</sup>. This has been criticised and described as “unlikely to be followed by a domestic court.”<sup>144</sup> In relation to consensual patients, there are at the very least indications from opinions of the European Commission that failure to treat someone in need may raise issues under Article 3. In *Tanko v Finland*<sup>145</sup>, the Commission stated that

“...lack of proper care in a case where someone is suffering from a serious illness could in certain circumstances amount to treatment contrary to Article 3.”

These “certain circumstances”, as the Commission put it, arose in the case of *D v UK*<sup>146</sup>. The government proposed to expel a convicted drug smuggler who had advanced AIDS and a poor prognosis to St Kitts. This was alleged to be a violation of Articles 2, 3 and 8

as the person would not continue to receive any treatment for their condition, and therefore was at real risk of dying in extremely distressing circumstances. The Court upheld the violation of Article 3, ruling that the discontinuation of treatment would amount to inhuman and degrading treatment. The absolute nature of the rights under Article 3 meant that the applicant was entitled to their protection notwithstanding his own reprehensible conduct.

Consent to treatment has arisen in the context of Article 3. In *X v Denmark*<sup>147</sup> the Commission considered a claim that a woman who had undergone consensual sterilisation had, in fact, been subjected without her knowledge or consent to an experimental procedure which therefore amounted to inhuman or degrading treatment. Ultimately it held that the claim was not made out, since the treatment was not properly to be classed as a medical experiment. The Commission also noted that for treatment to constitute inhuman or degrading treatment it has to reach the minimum level of severity such as to cause considerable physical or mental suffering. However, it did accept the principle that medical experimentation carried out without consent could, in some circumstances, fall foul of Article 3.

As with Article 2, it has been held that nothing in Article 3 prevents a hospital from withholding life-saving treatment from someone where this is in their best interests<sup>148</sup>. More controversially, it has also been held that Article 3 has no applicability to an insensate patient such as one who is in a Persistent Vegetative State<sup>149</sup>. The argument is that you cannot be degraded unless you are aware of your surroundings, but the logic of this has been severely criticised<sup>150</sup>.

#### *Article 5 : Right To Liberty And Security*

People have the right not to be arbitrarily arrested or detained, except where the detention is authorised by law and falls within one of the categories spelled out in the Article. The Article (which is subject to UK derogations relating to the situation in Northern Ireland and to the Crime, Terrorism and Security Act 2001) does not just apply to arrests for criminal matters, but covers all aspects of detention. In the medical context, the most relevant aspects of the Article are the fact that it includes detention for medical or psychiatric reasons.

The Court examined psychiatric detention in the leading case of *Winterwerp v The Netherlands*<sup>151</sup>, and established that to justify the compulsory detention of a patient under Article 5(1)(e), the following criteria have to be met:

- There must be a true mental disorder
- The existence of a mental disorder must be proved by medical evidence
- The mental disorder must be of a type and degree warranting compulsory detention
- The detention must only continue for as long as the mental disorder persists; and
- There must be regular reviews of the detention to reassess whether the criteria justifying detention continue to exist (and which can release the patient if they do not)

It was in respect of the last of these that the Mental Health Act 1983 was impugned<sup>152</sup>.

*Article 6 : Right To A Fair Trial:*

Article 6, it will be recalled, was used at the outset of this thesis to help identify the Core Evaluation Criteria against which the system of medical regulation is being measured. Article 6 has a wider scope than might be envisaged because of its applicability to civil matters as well as criminal ones. It covers all criminal and many civil cases, as well as cases heard by tribunals and some internal hearings or regulatory procedures (including, as we have seen, those of the GMC<sup>153</sup>). The additional safeguards apply only to criminal trials. These additional safeguards give anyone charged with a criminal offence a number of specific rights, including the right to be presumed innocent until proven guilty and to be given adequate time and facilities to prepare their defence. The emphasis on a public trial protects litigants against the administration of justice in secret with no public scrutiny. It should be noted that the test of what amounts to a criminal matter is an autonomous one, and the European Court will not necessarily be bound by domestic classifications of these matters<sup>154</sup>.

For the purposes of this thesis, the more important parts of Article 6 are the non-criminal ones. As we can see, the Article applies to the “determination of civil rights and obligations.” Civil rights and obligations are rights and obligations which exist under private law, although they may arise in a public law context where a public authority is involved with or has affected private rights. The concept of civil rights and obligations is also an autonomous one (heavily influenced by the Civilian law tradition), and therefore the definition in the Convention is not necessarily the same as that in UK law. Thus, for instance, the right to stand for elected office has been held to be an administrative law right, not a civil right, and so Article 6 was not applicable<sup>155</sup>. On the other hand, Article 6 has been held to cover matters including paternity proceedings<sup>156</sup>, commercial licences<sup>157</sup>,

Orights connected with land including planning decisions<sup>158</sup>, and certain social security benefits which are based on an insurance model<sup>159</sup>.

Article 6 is engaged where there is a dispute (“contestation” in the French version of the Convention) between parties as to the existence or extent of a right<sup>160</sup>. However, it also applies when a public authority makes a decision or takes a course of action which will ultimately be determinative of or for the civil right or obligation in question, even if the person affected had no enforceable right to the particular outcome being sought<sup>161</sup>. The decision to institute proceedings will not in itself engage Article 6 as this is a preparatory step, not a determinative one, and so Article 6 does not arise<sup>162</sup>; it would remain possible to challenge the decision to raise proceedings by way of judicial review, but this is based on the common law, not the Human Rights Act<sup>163</sup>.

Under the convention, anyone having their civil rights or obligations determined is entitled to the following safeguards (which also apply to criminal trials):

- the right of access to a body complying with Article 6<sup>164</sup>. The whole process needs to be considered. If the original decision is taken by a non-compliant administrative body (for example, a decision taken by an official in his or her office) the requirement is satisfied if that decision can be reviewed by a court or tribunal that does satisfy Article 6<sup>165</sup>. The right of access to a court or tribunal is not absolute, provided any restrictions on it do not impair the essence of the right, are for a legitimate purpose, and proportionate<sup>166</sup>. The level of appellate scrutiny required may vary.
- the right to a fair hearing, encapsulated in the notion that there should be “equality of arms”: one party should not be placed at a procedural disadvantage compared with the other<sup>167</sup>. This is particularly important in terms of access to information – both sides should, as a general rule, have access to the same documents and to everything that will be before the decision-maker<sup>168</sup>
- the right to a public hearing. Again, this is not necessary at the outset provided there is an appeal to a compliant body. While it is possible to exclude the public from some or all of the proceedings, the actual decision has to be pronounced in public.
- the right to a hearing within a reasonable time.
- the right to an independent and impartial tribunal. Judges and tribunal members must be free from outside pressures, and should be independent of the executive and of the parties. Independence must be such that a reasonably informed objective observer

would not conclude that there was any real possibility of bias. It was due to breach of this principle that temporary sheriffs were rendered unlawful by a decision of the High Court<sup>169</sup> (the temporary sheriffs were appointed without security of tenure by the Lord Advocate, who was also responsible for prosecuting offences before these same temporary sheriffs).

In terms of administrative bodies, many if not most operational decisions taken by the various arms of government (including the NHS) will rely on the rule mentioned above which states that Article 6 compliance can be secured through the appeal mechanism. To satisfy this test, the appellate body must have full jurisdiction to entertain the appeal, i.e. be able to cure whatever it is about the earlier administrative decision that is complained about. However, often the only real right of appeal (more accurately, right of review) is for the dissatisfied individual to seek a judicial review at common law or under restricted statutory grounds. Would this provide sufficient review to satisfy Article 6?

The issue arose initially in *County Properties v The Scottish Ministers*<sup>170</sup>, but was overtaken by the *Alconbury*<sup>171</sup> case leapfrogging directly to the House of Lords. The House of Lords unanimously upheld the Secretary of State's appeal, holding that the supervision of the courts was sufficient safeguard. This did not require the courts to sit in judgement over the policy decisions made by those to whom that responsibility had been given, as to do so would be both unnecessary and undemocratic<sup>172</sup>. However, the House did hold that proportionality review had become part of the judicial review armoury, although this was said not to be as a result of the passage of the Human Rights Act but merely another stage in the ongoing evolution of the common law.

#### *Article 8 : Right To Respect For Private And Family Life:*

Article 8 is one of the most wide-ranging of all the Convention articles, and covers everything from the right not to have your phone tapped<sup>173</sup> to the right not to be subjected to environmental pollution<sup>174</sup>. Article 8 also imposes positive obligations on the state<sup>175</sup>. In analysing Article 8, it is convenient to break it into the four component parts of private life, family life, home, and correspondence.

*Private life* was interpreted in *Niemitz v Germany*<sup>176</sup>, the European Court holding that the expression went beyond the "inner circle" in which the individual may live his or her own life as he or she chooses, but also extends to the right to establish and develop relationships with other people. The Court has also held that the right to privacy encompassed by Article 8 includes informational privacy such that holding files on someone which they are unable to refute constitutes an interference with Article 8<sup>177</sup>, and



that the right to respect for privacy imparts the concept of allowing individuals control over their personal details (and imposes a corresponding obligation on the state to ensure there are safeguards in place)<sup>178</sup>. This overlaps with the Data Protection Act, and is considered in more detail below.

The right to respect for private life includes protection of physical integrity: in *X v Austria*<sup>179</sup>, the Commission held that

“a compulsory medical intervention, even if it is of minor importance, must be considered an interference with this right.”

One area where private life is regularly infringed by state activities is the world of covert surveillance, mostly conducted by police and intelligence services. Such covert surveillance will involve a clear infringement on the right to privacy of the person under surveillance<sup>180</sup>, and so requires to be justified under Article 8(2). Such justification requires that the surveillance have a lawful basis, something the case of *Khan v UK*<sup>181</sup> held was lacking in the UK. With the Act due to come into force very shortly after this decision was issued, the Government rushed some emergency legislation through Parliament to ensure that a “lawful basis” was in place when the Act came into force, under which covert surveillance could be lawfully authorised<sup>182</sup>. Parallel legislation was also rushed through the Scottish Parliament at the same time<sup>183</sup>. It should be noted that certain medical regulatory bodies are authorised under this legislation to carry out covert surveillance; the British Pharmaceutical Society apparently makes extensive use of this power in supervising the activities of pharmacists<sup>184</sup>.

Finally, it would appear that Article 8 has now led to the creation of a common law enforceable right to privacy, something which was never previously recognised by the courts<sup>185</sup>. This right has recently been upheld by the Court of Appeal as justifying an injunction preventing a newspaper from disclosing the identity of a health care worker who had volunteered to his health authority that he was HIV-positive (including potentially-identifying information including the identity of his “employing” health authority), but did not necessarily prevent the health authority from conducting a “look-back” exercise to ascertain whether any of the health care worker’s former patients required to be offered an HIV test<sup>186</sup>.

*Family life* is entitled to respect under Article 8 irrespective of the legal status of the family – so families classed as “illegitimate” in domestic law are entitled to the same degree of protection as those classed as legitimate<sup>187</sup>. The protection extends beyond the traditional nuclear family, and if the hallmarks of family life can be seen, it seems that

even more distant relationships will be classed as giving rise to rights under this heading<sup>188</sup>. This clearly has a potential impact on the rules concerning child protection, adoption and fostering and (possibly) assisted fertility, although the right to marry and found a family (contained in Article 12 of the Convention) has been held not to extend to a duty on the state to assist in the activity. It remains to be seen whether state interference in reproductive technology (through the HFEA regulatory regime) will be able to be challenged under this heading. In *R v Human Fertilisation and Embryology Authority ex parte Assisted Reproduction and Gynaecology Centre and H*<sup>189</sup>, the High Court accepted that Articles 8 and 12 were engaged in the course of a judicial review of the HFEA's policy on egg implantation. However, the Court of Appeal in the case<sup>190</sup> doubted whether the applicants' convention rights were engaged at all.

*Home*, unsurprisingly, means where you live (even if your use of the home is unauthorised<sup>191</sup>). It might be thought to have limited relevance in the medical sphere, but has been used successfully in a resource-based case which would probably have been doomed at common law. In *R v North East Devon HA ex parte Coughlan*<sup>192</sup>, it was successfully argued that closing a nursing home in which the applicant lived (and had apparently been promised a "home for life") constituted a violation of her rights under Article 8, which could not be justified by reference to Article 8(2)<sup>193</sup>.

*Correspondence* similarly has limited relevance to the subject of medical regulation. Most of the issues debated in Strasbourg have related to interception of prisoners' mail<sup>194</sup>. However, it is recognised that the concept of "correspondence" includes telephone calls, including telephone calls made from the workplace<sup>195</sup>. This has provoked interest from the perspective of employee rights, and the practice of workplace telephone monitoring has also recently been put on a statutory basis<sup>196</sup>.

Looked at in the round, however, it is possible to see in Article 8 a general (if unstated) principle that says the Convention can be used as a means of upholding personal autonomy and dignity, and certainly it has been used to achieve that end<sup>197</sup>. Indeed, as Lord Bingham has recently commented,

"Article 8 is expressed in terms directed to protection of personal autonomy..."<sup>198</sup>

The case in which this was stated was the attempt by Diane Pretty to use the Act as a means of allowing her husband to assist in her suicide without fear of criminal prosecution. In the event, the House of Lords rejected her application, but the case is extremely informative from the perspective of how the various convention rights asserted were handled by the domestic court. The reasoning behind the decision is not without its

critics<sup>199</sup>, however, and the assertions of respect for autonomy in the judgements were not reflected in the actual decision, which was upheld by Strasbourg<sup>200</sup>.

### **III: Data Protection Act 1998:**

#### **A: Outline of the new rules:**

The Data Protection Act 1998 (hereafter “the Act” or “DPA 98”) gives effect in the UK to a European Union Directive on the free movement of personal data<sup>201</sup>. It completely replaces the Data Protection Act 1984 (DPA 84) and Access to Personal Files Act 1987 (including the Social Work and Housing Regulations made under that Act), and most of the Access to Health Records Act 1990 (which now only applies to access requests made in respect of persons who are deceased).

The Act creates a highly detailed code for the processing of personal data<sup>202</sup>, defined as data, whether stored electronically or in a relevant (manual) filing system, which relates to a living individual who can be identified from those data and/or other information in the possession of (or likely to come into the possession of) the data controller. Additional categories apply in the public sector<sup>203</sup>. Space precludes a full analysis of the rules<sup>204</sup>, but two key points to note are that the Act imposes an obligation on “data controllers” (i.e. the persons who determine the purposes for which data are processed) to comply with eight “data protection principles” in relation to the processing of personal data. “Processing” is very widely defined and covers almost everything – acquiring, disclosing, accessing, amending, deleting or even holding data. Stricter rules apply to “sensitive personal data”, i.e. information relating to racial/ethnic origin, political opinion, religious beliefs, trade union membership, physical/mental health, sexual life, and data about the commission or alleged commission of an offence or the disposal of criminal proceedings against someone. Everyone who processes personal data requires to have an entry (called a “notification”) in a public register maintained by the Information Commissioner (formerly the Data Protection Commissioner/Registrar)<sup>205</sup>. Processing personal data without a notification (if notification is required) is a criminal offence<sup>206</sup>.

The First Data Protection Principle requires processing to be fair and lawful, and in particular requires that at least one “Schedule 2 condition” (i.e. one of the conditions listed in Schedule 2 to the Act) is met. Schedule 2 conditions include matters such as where the processing is necessary to comply with legal obligations or to perform statutory functions, processing which is in the legitimate interests of the data controller or a third party (provided this does not result in unwarranted prejudice to the data subject), or processing to which the data subject has consented. For “sensitive personal data” it is also

necessary to satisfy a Schedule 3 condition; these are rather stricter than those in Schedule 2. Thus, consent under Schedule 3 must be “explicit”. The Information Commissioner’s view is that this consent must be “informed.” Whether the courts which have proved so resistant to the concept of “informed consent” in the medical treatment sphere are more receptive of it in the data protection arena remains to be seen.

For medical purposes, paragraph 8 is relevant. This covers processing for medical purposes undertaken either by a health professional or someone who, in the circumstances, owes a duty of confidentiality equivalent to that which would be owed by a health professional. Additional schedule 3 conditions have been made by regulation<sup>207</sup>. Lastly, the First Principle states that data is only to be treated as having been fairly obtained if certain particulars are made available to the data subject – what are known as Article 10 and Article 11 notices<sup>208</sup>. The contents of these notices are considered below. It is necessary to comply with these steps each time the data are processed.

Numerous exceptions exist to all of the above processing rules. Thus, Section 35 says information can be disclosed where this is necessary for the purposes of legal action. *Totalise plc v Motley Fool Ltd. and Another*<sup>209</sup> held that Section 35 permitted disclosure to be made irrespective of who the proceedings (which was held to include prospective proceedings) were between, i.e. it covered release of data in connection with legal proceedings not involving the data controller itself. The Court of Appeal decision<sup>210</sup> outlines when a party is entitled to resist disclosure and insist on the requesting party obtaining a court order before disclosure will be made. These circumstances include where the information is confidential or where its disclosure might infringe a legitimate interest of another. An additional complication arises because of the volume of subordinate legislation made under the Act – at least 20 SIs have been made, a significant proportion of which actually effect amendments to the principal statute in particular circumstances<sup>211</sup>.

It is now necessary to provide information up-front to data subjects. This arises because the First Principle states that data is only to be treated as having been obtained fairly if the data subject has, is provided with, or has made readily available, certain information concerning: who the data controller is, the nature of the processing (including any proposed disclosures of the information) and any other information required in the interests of fairness<sup>212</sup>. “Other information” may (and frequently will) require a statement advising the data subject of their right of access to the data.

Subject access rights under DPA 98 are significantly enhanced, and the right now extends to manual records. Under DPA 84, the right was essentially one of being able to request

a copy of the data held on you. Under DPA 98, this is extended to include the right to be told why the data is being processed, who it will be disclosed to, and any information held as to the source of the data<sup>213</sup>. The right is restricted insofar as complying would disclose personal data relating to someone else; data controllers receiving a subject access request are expected to carry out a series of tests and decide whether it is reasonable to contact the other parties and seek their consent (refusal of which, interestingly, is not decisive of whether this information should be disclosed) and have to make an assessment of reasonableness. Even if the decision is reached not to disclose the third party information, there is still an obligation to comply with as much of the request as possible without disclosing those parts of it. There is a tension between the obligation to advise as to the source of the data and the duty to protect third party information. This has led the Commissioner to publish a guidance note on the subject<sup>214</sup>. The guidance on subject access, however, does little more than rehearse the statutory tests and make reference to the ECtHR case of *Gaskin v UK*<sup>215</sup> on how to balance the conflicting interests. Unlike the Access to Personal Files Act 1987 and Access to Health Records Act 1990, subject access under DPA 98 is completely retrospective and applies irrespective of when the record was created. Requests must be complied with within 40 days of the latest of the following: proof that the person is, in fact, the data subject; being given sufficient information to allow you to locate the data, and receipt of the fee, if you decide to levy this. The maximum permissible fee is £10.00 (£2.00 for credit reference agencies)<sup>216</sup>. For medical records, the fee was £50.00 if you wanted a copy of a non-automated record<sup>217</sup>. Practitioners seeking copies of medical records (including X-rays, which are notoriously expensive) took especial note of this point, and as a result it seems that health service bodies were confronted with excessive numbers of speculative pre-litigation subject access requests. As a result of lobbying from these bodies, the government took the decision to extend indefinitely the transitional measure whereby access requests to medical records which involved copying non-automated records (such as X-ray pictures) were subject to a fee of £50.00 rather than £10.00<sup>218</sup>. Special tests for non-disclosure apply to social work/social services files and education records, and also to health records; the health rules are discussed *infra*

## **B: Interaction with Human Rights:**

Data Protection as a concept was originally driven by the perception of the Council of Europe that personal privacy was threatened by ability of organisations in the computer age (governmental or otherwise) to process and cross-reference previously unmanageable amounts of data about individuals. The whole thrust of data protection is to give the individual more control over what happens to their personal data - this is abundantly clear from the (very long) preamble to the Directive.

The Human Rights implications of data protection almost all arise in terms of Article 8 of the Convention. The right to privacy enshrined in Article 8(1) has, as we have seen, been held to incorporate the right to informational privacy, i.e. it imparts the concept of exercising control over the use to which your personal details are put, with a requirement for domestic legal systems to have adequate safeguards in place to protect informational privacy<sup>219</sup>. The interaction between Article 8 and DPA occurs in 2 ways. The first is in terms of the requirement that all processing be “fair and lawful”. For public authorities, processing of personal data will, in many (if not most<sup>220</sup>) circumstances engage Article 8. Accordingly it is necessary for the authority to justify its processing under Article 8(2), or else what is being done will be rendered unlawful by Section 6 of the Human Rights Act 1998. Once that happens, the processing itself will be unlawful and therefore in breach of the First Principle. The converse is also true: if an authority is processing in a way which engages Article 8, it will seek to justify this in terms of Article 8(2). This requires that the interference must have a lawful basis, have a legitimate purpose, and be proportionate to the objective pursued. If the processing is in breach of the DPA, then there will be no lawful basis for the interference and consequently what is being done will additionally breach the Human Rights Act. It follows from this that it is very hard for a public authority to breach one of these but not the other - the processing/interference with privacy stand or fall together. This could be seen in the case of Jacklyn Adeniji<sup>221</sup>. In an out-of-court settlement, £5,000 damages (plus an estimated £50,000 costs) were paid in respect of a breach of both the DPA 98 and Article 8. The damages were decided out of court, although the judge who approved the award (Garland J) recognised that this was a new area for the courts<sup>222</sup>.

There have been some decided cases which consider this interaction. The reasoning outlined above has been substantially applied by the courts in the small number of cases which have come up thus far: see, for example, the decision in *R v City of Wakefield Metropolitan Council and Anor. ex p. Robertson*<sup>223</sup>, which held that commercial sale of the electoral register without scope for an opt-out was in breach of the DPA and Article 8. There is also a decision of the Information Tribunal (National Security Appeals) in *Norman Baker MP v Home Secretary*<sup>224</sup> holding that issuing blanket exemptions to MI5 without a case-by-case consideration of the merits breached both provisions. In essence the tribunal, following a comprehensive review of both domestic and European authority, concluded that it should apply proportionality review to the decision Home Secretary’s decision to issue the exemption certificate being challenged.

### **C: Implications for medical records management:**

#### 1: Information and regulatory functions:

If an organisation handles sensitive personal data such as medical records, it is important to consider the impact of *A Health Authority v X and Others*<sup>225</sup>. The court in that case approached the matter from the direction of Article 8 ECHR (right to respect for private and family life) rather than DPA 98. Munby J held that disclosure of the records in question could be made, but only subject to a binding and transmissible duty of confidentiality being imposed on the recipients (and any subsequent recipients) thereof. This goes some way beyond what DPA 98 requires, the Act principally being concerned with the internal controls which exist within an organisation. Munby J's decision was subsequently upheld by the Court of Appeal<sup>226</sup>.

The case lays down that even where a particular disclosure is permissible, that does not remove the need for the disclosing body to attach safeguards to the disclosure, in particular to ensure that the tests of necessity and proportionality are met, and that confidentiality is safeguarded. The case arose out of care proceedings subject to specific English legislation, and wider extrapolation is problematic, but in many respects the ruling goes to the heart of medical regulation. In essence, the case involved a health authority investigating allegations that GPs whom it "employed" had not complied with their terms and conditions of service. In order to carry out this regulatory function properly, there would have to be a transfer of medical records to the health authority for investigation purposes. The doctors under investigation had sought the consent of the patients whose records were being asked for, but two patients refused this consent. The doctors accordingly asserted their duty of confidentiality to these patients as against the regulatory body.

Ultimately, the Court ordered disclosure but only subject to appropriate guarantees as to continuing confidentiality. A similar approach had been mandated for release of information to the GMC in the course of its regulatory functions<sup>227</sup>. The test was formulated by Thorpe LJ as follows:

"There is obviously a high public interest, analogous to the public interest in the due administration of criminal justice, in the proper administration of professional disciplinary hearings, particularly in the field of medicine... [I]n my opinion the objection to production fell to be decided in accordance with the principle... whether the public interest in effective disciplinary procedures for the investigation and eradication of medical malpractice outweighed the confidentiality of the records... A balance still had to be struck between competing interests. The balance came down in favour of production as it invariably does, save in exceptional cases."<sup>228</sup>

Accordingly, it seems that neither DPA nor Article 8 will prevent medical regulators from being able to process the information necessary for them to carry out their jobs, provided they attach appropriate safeguards to confidential information. This is not unlike the Schedule 3 condition whereby sensitive personal data may be processed for medical purposes either by a health professional or someone who, in the circumstances, owes a duty of confidentiality equivalent to that which would be owed by a health professional<sup>229</sup>.

## 2: Research implications:

Different considerations arise in relation to disclosure of personal data in connection with medical research. In *R v Department of Health ex parte Source Informatics Ltd. and others*<sup>230</sup>, the Court of Appeal held that the Directive (and by extension, DPA 98) did not have any applicability to the use of anonymised data. However, the Commissioner has expressed doubt as to how truly anonymous some data can ever be rendered. In addition, it should be remembered that the process of anonymising data will in itself constitute processing and will therefore have to comply with the Act.

It is also the case that much medical research can only be carried out using actual records. These may be “pseudonymised” (*i.e.* processed by reference to a non-personal unique identifier, typically a reference number), but so long as the researcher retains the key and is able to connect the pseudonymised record to a named individual, this will still fall within the definition of “personal data” and accordingly any processing of the records (and in particular, disclosure of them by the doctor to the researchers) requires to be justified according to the data protection principles and under Schedule 2 and 3 conditions. One simple option would be to seek the explicit consent of the individuals whose records are being sought, but the problem with this is that voluntary participation (particularly in relation to epidemiological research) generates immense problems with research methodology, and may in fact render the research statistically invalid. This issue has featured in the pages of the British Medical Journal on a number of occasions<sup>231</sup>, and has been of concern to researchers in varied fields such as cancer registries<sup>232</sup> and injury surveillance programmes<sup>233</sup>.

Such concerns are valid inasmuch as proper conduct of research requires the data protection position to be addressed, and compliance with all the rules will almost certainly involve the creation of legally-enforceable statements of the respective rights and duties of those involved. However, the concerns may be unfounded if they suggest that research cannot take place absent express consent. Successfully conducting research otherwise than by consent does require different Schedule 2 and 3 conditions; in particular, Schedule 3 can be satisfied by carrying out research only using medical professionals or



others bound by duties of confidentiality. It is still necessary to identify a Schedule 2 condition, but one could rely on consent more easily under this analysis since for Schedule 2 consent may be implied (although this may still create methodological problems). Research can continue without even an implied consent in circumstances where it is possible to identify an appropriate statutory duty imposed on one or other of the research partners. Most duties imposed in the health arena are couched in extremely wide terms, and in many cases it will be possible to structure the data sharing involved in research so as to be in compliance with these statutory obligations. Provided this is done using the minimum required datasets, will not cause any prejudice to the research subjects, is accompanied by appropriate safeguards (particularly in relation to data quality and security) and is of sufficient potential benefit to represent a proportionate interference with patients' rights, there is nothing in either DPA 98 or the Human Rights Act to prevent the research from taking place. This conclusion is backed by Section 33 of the Act, which provides that data processed for research purposes are not (for purposes of the Second Principle) to be treated as being processed in a manner incompatible with the purpose for which they were originally acquired. However, the draft Guidance on Use and Disclosure of Medical Data<sup>234</sup> does indicate that in the Commissioner's view disclosure to a cancer registry should proceed on the basis of implied consent. The situation may be clarified when the final version of the guidance is published<sup>235</sup>. In the meantime, these concerns led to the inclusion of Section 60 in the Health and Social Care Act 2002. This measure allows the Secretary of State to make regulations requiring persons to disclose patient information to other persons in certain circumstances; the measure was included at the behest of medical researchers. However, since the regulations to be made cannot require any processing to be carried out in a manner inconsistent with DPA 98<sup>236</sup>, it is far from clear that this measure actually does much to assist matters.

### 3: Individual rights:

Health records are subject to certain subject access peculiarities, under the Data Protection (Subject Access Modification) (Health) Order 2000<sup>237</sup>. In essence, this Order embodies the concept of "therapeutic privilege", accepted by the court in *Hatcher v Black*<sup>238</sup>, which says that a doctor need not tell the patient something if in the doctor's (purely subjective) opinion, it would be harmful to the patient to tell them it. Criticism of this was noted in Chapter 4, but the exemption is nonetheless repeated in the legislation. In the case of health information acquired other than from the data subject, there is a requirement to consult the "relevant health professional" on this subject prior to releasing (or not releasing) the data. In particular, therapeutic privilege cannot be claimed unless a health professional agrees. Interestingly, however, the health professional's views are not binding and if the health professional says not to disclose (or fails to respond within the

forty days) the data controller is still free to make up his/her own mind up on whether to disclose the information to the data subject or not.

The second main peculiarity in relation to medical subject access requests is that the identity of medical professionals mentioned in an individual's records are not regarded as third party personal data. In other words, provided the information in an individual's file identifies a member of the health care team whose presence there was due to them acting in a professional capacity, there is no bar to disclosing that data (*i.e.* the identity of the health care professional) to the data subject. This is in response to the case of *Gaskin v UK*<sup>239</sup>, where the refusal of professionals involved to having their identities disclosed was held to breach Article 8 ECHR<sup>240</sup>.

#### **D: Freedom of Information:**

Freedom of Information (FOI) has been given effect in the UK through both a (Westminster) Act of Parliament and an Act of the Scottish Parliament. While it is easy to think of the (Westminster) Freedom of Information Act 2000 (FOIA 2000) as an English measure, this is not the case: FOIA 2000 applies to all public authorities except those operating purely in Scotland. Thus, a request addressed to an Inland Revenue office in Scotland would be handled under the UK legislation, not the Scottish version. FOIA 2000 included a number of amendments to the DPA. Most of these were purely in relation to information held by UK/English public bodies, although the most visible effect was the change of name from Data Protection Commissioner to Information Commissioner, reflecting the fact that the Commissioner now has responsibility for policing FOI as well as data protection.

In essence, FOIA 2000 creates a statutory right to information held by a public authority, although most of the Act actually consists of limits on and exemptions to the right of access. An additional duty imposed on public authorities is to prepare "publication schemes" listing the information which the authority publishes voluntarily (as opposed to publication in response to a request under the legislation). The Holyrood version, the Freedom of Information (Scotland) Act 2002 (FOISA 2002) is structurally very similar to the UK legislation, the differences really being in relation to the detail<sup>241</sup>. For example, under FOIA 2000, information may be withheld if it would "prejudice" a particular protected interest. Under FOISA 2002, the test is one of "substantial prejudice". There will be a separate Scottish Information Commissioner (dealing only with Scottish FOI and not with data protection. Neither measure is fully in force yet, and the right of access to documents is unlikely to come into effect before 2004.

Perhaps the main impact of the FOI legislation will be that everyone in the regulatory framework (and a large proportion of those being regulated) will be under a new statutory duty requiring them to be more open about their affairs. In Chapter 4, we considered some of the (unsuccessful) attempts to litigate in relation to NHS resource decisions. In these cases, there was no requirement on the NHS body being challenged to justify the decision. However, FOI legislation could potentially strengthen the hand of anyone seeking to mount such a challenge in future by giving them access to internal deliberations (and financial details) which previously would have been kept from them. Thus informed, a challenge may be able to be more precisely-focused and accordingly have a greater chance of success.

#### **IV: Summary and Conclusions:**

##### **A: Purpose:**

As stated *supra*, there are a number of purposes apparent in the various statutory interventions which have been considered in this Chapter. In terms of the sector-specific measures considered in Part I, these appear to fall into two broad categories: major pieces of legislation intended to create a new legal framework for the area being legislated on (the Adults with Incapacity (Scotland) Act and the mental health legislation being examples of this), and smaller and highly specialised pieces of legislation which have typically been passed at speed as a rapid legislative response to a perceived pressing social problem which has arisen (the Human Reproductive Cloning Act 2001 being a good example).

In terms of the two main pieces of legislation considered, these both appear to fit into the former category. The Data Protection Act creates a self-contained and detailed system to control all use made of personal data. The Human Rights Act creates a system to allow an external source of law to permeate the entire legal system and be directly effective before the courts of this country.

The purpose of the Data Protection Act, at least on one level, is to transcribe the effects of the underlying Directive into the law of the United Kingdom. It is accordingly reasonable to consider the terms of the Directive to get some idea of the purpose of this measure. The Directive certainly provides a lot of material, the preamble running to some 79 paragraphs (rather more than the Directive proper). Running through the whole preamble, however, it is possible to discern a general desire to enhance the autonomy of the individual through a series of mechanisms designed to give the individual more

control over his or her own personal information. The Directive (and hence the Act) are therefore driven by a desire to increase the autonomy of the individual.

The Human Rights Act was intended by the Government to “Bring Rights Home”<sup>242</sup>, by which it was intended that anyone alleging failure by a public authority to respect the rights laid down in the Convention would be able to gain a remedy in the domestic courts. Most of the other provisions in the Act are, arguably, peripheral components intended to secure and safeguard that the actions of courts, other public authorities, and legislators were also consistent with the rights conferred. Again, one can discern a motive to increase the rights of the individual, and the move was expressly considered by the Government to be part of its modernising agenda.

The scope of these two interventions is such that it is reasonable to ascribe all eight regulatory tasks to them, albeit in differing degrees.

#### **B: Mechanism:**

The mechanisms in this Chapter are all the same: passing legislation through Parliament (or the Scottish Parliament, as the case may be).

Within that statement, however, and again confining remarks to the two main Acts examined, one can see a very different approach. With the Data Protection Act we see a detailed but self-contained code laid down, perhaps best regarded as being akin to mental health legislation. You are given the whole story in the Act and related subordinate legislation. The end result is large and complex, but it has no impact beyond its own defined boundaries (although in the case of data protection, the boundary is “all use of identifiable personal data”).

The Human Rights Act, on the other hand, is anything but self-contained. Even the Act itself directly refers to two Articles of the Convention which are not repeated in the text of the Act, and while the “incorporated” Articles are attached as a Schedule, closer scrutiny of the operative section reveals that you can equally permissibly refer to the French language version of the Convention, which is not repeated in the Schedule. The Human Rights Act by its very nature has the effect of altering, at least in theory, the entire legal system. All legislation requires to be interpreted according to a new rule of statutory interpretation, and the common law is now effectively all open to be overruled or distinguished on the basis that previously-binding authorities do not take account of Convention rights. The analogy to this is the European Communities Act 1972, which also required the courts to take account of a separate legal system and set of rules.

**C: Effect:**

The effects of the two main pieces of legislation included are hard to assess if only because neither measure has been in force for very long<sup>243</sup>.

The visible effects of the Human Rights Act can be seen in the court cases being raised and argued. According to research carried out by the former Home Office Human Rights Unit<sup>244</sup>, between 2 October 2000 and 12 March 2001, some 109 human rights cases came before the courts in England and Wales<sup>245</sup>. Of these, fifteen claims were upheld. This might be seen as a small proportion, but what is more interesting is that in 56 of the cases, the existence of the Human Rights Act affected the outcome, reasoning or procedure involved in the case. This would accord with the writer's own experience: the Act has made a massive difference to the activities of public authorities, but these changes have precluded the need for legal action and therefore have not been reflected in huge numbers of cases making findings of human rights violations. One possible reason for this is that many public authorities invested significant time and energy in ensuring compliance before the Act came into force<sup>246</sup>.

The Data Protection Act has also figured in very few decided cases, but in many ways its effects have been even more profound. In passing a law regulating how all use of personal data was to be carried out, Parliament has arguably given more power to the individual than ever before. In some ways, the response of organisations to this change has been to bombard individuals with information concerning possible uses that will be made of their personal details, possibly in the hope that no-one will ever read it all, but in the knowledge that having told the individual they can then use the information in the way described, barring an explicit objection. This can scarcely be seen as what Parliament had in mind, but it is true that the method of enhancing personal autonomy adopted by the Act has the potential of resulting in an exceedingly bureaucratic response. As with the Human Rights Act, Data Protection has also been the subject of extensive pre-commencement preparatory work (this time extending into the private and voluntary sectors); indeed, the transitional periods were intended specifically to allow records management systems to be brought into conformity with the Act before it started to bite. And again, this means (for the organisations which carried out preparations properly) that the effects of the Act will not be reflected in successful court action. In terms of decided cases, the only case which has gone to trial and awarded damages to a data subject involved a national newspaper rather than a public authority<sup>247</sup>.

**D: Comparison with Core Evaluation Criteria:**

In Chapters 1 and 2, we identified seven core criteria against which each segment of the medical regulatory framework would be measured. These will now be assessed against each of the evaluation criteria in turn.

### 1: Visibility:

Both mechanisms are highly visible – the Human Rights Act enjoying a major publicity campaign and enjoying a high (if usually negative) profile in the mass media, the Data Protection Act having provisions within it, the whole point of which is to advise individuals of their rights under the Act. Both measures are therefore deemed to be satisfactory in terms of visibility.

### 2: Accountability:

Legislation is made by Parliament, and Parliament is accountable directly to the electorate. Whether a government is likely to be voted out of office as a result of passing a particular piece of legislation may be doubtful, but since in theory the electorate *could* do this, this test is deemed to be satisfied in relation to primary legislation<sup>248</sup>. However, it is less clear that this is necessarily true in relation to subordinate legislation, particularly where this takes effect before it has been approved by Parliament. However, none of the legislation we are considering falls into that category.

One final complication in relation to accountability arises with respect to the DPA. This implements a European Directive; if Parliament had failed to legislate so as to give domestic effect to it, the Directive would have been directly effective against “emanations of the state”. It is also directly effective to the extent that the Act does not fully reflect the Directive<sup>249</sup>. This raises the issue of the accountability of the organs of the European Union, but that question is outwith the scope of this thesis.

### 3: Overall Fairness:

As explained in Chapter 2, the category of overall fairness incorporates a number of aspects including impartiality, accessibility, and speed of decision-making. In applying these criteria, it is important to consider the differences in approach mentioned above.

The DPA, for instance, has a mixture of internal controls (through the activities of the Information Commissioner) and external controls (by creating individual rights to seek a remedy through the normal civil courts). The external enforcement machinery is subject to the same comments regarding overall fairness as the civil courts generally, save that

unlike the courts' approach to medical law, there is no established tradition of deference to either party in disputes concerning data protection<sup>250</sup>. The internal regulation is also accompanied by safeguards allowing the targets of enforcement proceedings to appeal to the courts or the Information Tribunal. These mechanisms are deemed fair.

As far as the Human Rights Act is concerned, the only enforcement mechanism is recourse to the ordinary civil courts, again carrying over the comments made in Chapter 5, but also with the same caveat concerning lack of established deference in human rights cases. In the event, the courts have been criticised for adopting a very conservative approach to the Act<sup>251</sup>. However, there appears to be nothing inherently unfair in the courts applying a cautious attitude when dealing with this new area, and there have certainly been a number of cases representing major inroads into traditional legal attitudes and rules. Accordingly, external regulation of these measures by the courts is deemed to satisfy the criterion of overall fairness.

#### 4: Effectiveness:

At this stage, it is difficult to assess effectiveness. For the same reason it is hard to assess impact. In relation to the Human Rights Act, we have already considered whether the courts were obliged to provide an effective remedy where someone's rights were violated. It appears that the courts will do so, although the rule stating that compliance with primary legislation counts as a defence to a human rights claim does represent a dilution of the courts' power to guarantee the effectiveness of the remedy in all cases. Likewise, the fact that a declaration of incompatibility under Section 4 has no effect on the proceedings in which it is made can be criticised as leaving someone without a remedy in the domestic courts (but probably a sure-fire winner in Strasbourg, if they can wait three years for a decision). Another weakness has been the government's approach to Section 19. This section requires all legislation placed before Parliament to have a declaration of compatibility with Convention Rights. These have consisted of bland one-line comments saying, in essence, "I, the minister, think this complies". Again, this has been criticised as lacking rigour or transparency<sup>252</sup>. On the other hand, these comments are all in relation to aspects of the Act peripheral to giving the individual a remedy in the domestic courts for a breach of convention rights. For most people, the limitations just referred to will not preclude them from obtaining such a remedy, and so the Act is deemed to be effective (but capable of improvement).

With respect to the DPA, however, there is one major problem which leads to the opposite conclusion. There appears to be little in the Act to prevent a data controller from systematically abusing the data protection principles and then taking steps to comply only

at the point when an enforcement notice is about to take effect. Provided the unscrupulous data controller has duly notified (thereby avoiding committing a criminal offence), and provided their activities do not cause quantifiable loss to anyone (irrespective of how much inconvenience or distress they cause along the way), there is nothing either the Commissioner or the data subject can do. This major defect leads to the conclusion that the DPA, for all that it provides a framework built around individual informational autonomy, fails to provide fully effective tools for protecting this right.

#### 5: Efficiency:

As a regulatory tool in its own right, legislation is very efficient: Parliament passes an Act, which then rests on the statute book until Parliament takes it off again. Very efficient from Parliament's perspective.

However, we are more concerned with whether the legislation is efficient in terms of the impact it has on those affected versus the value of the rights supposedly enhanced by the legislation. Could the rights conferred have been given equivalent protection in a less resource-intensive way?

The answer to this is that, so far as the HRA is concerned, the Act is probably the least intensive way of securing the rights in question. This is not to understate the amount of work that has had to be done to prepare for the Act, merely to point out that a change in the legal landscape of this size could not possibly have been done without a major investment in effort across the public sector. And ultimately if someone's rights have been violated, it is plainly more efficient to have this decided by the domestic courts rather than, as previously, requiring the victim to "exhaust domestic remedies" by going to court in this country and losing, and then going to Strasbourg. The HRA is therefore deemed to be efficient.

The DPA, on the other hand, has a number of features which arguably impose bureaucratic burdens on data controllers but which confer no appreciable rights on anyone. The requirement to notify is an example: the entry which appears in the public register of data controllers is intended to allow data subjects to see what sort of things a data controller does with personal data. But the statements are necessarily high level and generalised comments which will provide the individual with very little idea of what will happen to their particular details. Particularly for large public sector bodies, the entry will cover so many possible activities as to be meaningless. The enforcement systems also have a huge number of potential notices which can be served on data controllers, yet these all seem to achieve objectives so similar that the system could have been



significantly streamlined with no loss of effect. And the overall complexity of the Act itself requires such an investment of time to make sense as to be inefficient in itself. The fact that operational observance of these rules requires organisations to familiarise a very large proportion of their staff with the rules simply underscores this problem. The DPA is therefore deemed to be inefficient.

#### 6: Avoidance of undue influence with good medical practice:

As we have seen, neither Act interferes with good medical practice, and both of them may actually enhance it. On the other hand, the DPA raises potential barriers to research which may be a problem, but given the definition of “good medical practice” which we adopted in Chapter 2, it is unlikely that research of this type would count. However, it is worth pointing out the potential difficulties, notwithstanding the fact that in accordance with the general methodology of this thesis both statutes are deemed to satisfy this criterion.

#### 7: Respect for patient autonomy:

We have seen that both these measures have concern for individual autonomy at their heart. It is therefore easy to conclude that both satisfy this criterion, although certain (generally minor or peripheral) issues have arisen where one could take issue with the outcome. Overall, however, both measures comply with this requirement.

### **E: Conclusions:**

It can be seen that Parliament has not been slow to use its powers to legislate both for the little issues and for the biggest issues of all. On a practical level, the legislative timetable is inevitably full or overcrowded, and there is a clear political element in determining which Bills actually go forward. The system of private members’ bills democratises the process a little<sup>253</sup>, but in large measure legislation is something proposed by the government of the day, and voted through by that government’s parliamentary majority<sup>254</sup>.

In terms of the measures we have considered briefly, the more thought-out and extensive measures appear to work well but are subject to ongoing refinement. The Acts which could be seen as “emergency responses” are more commonly found wanting, but given their typically-limited scope, this is seldom a major issue.

In terms of the two major pieces of legislation considered, both are measures which accord fully with the philosophical approach spelled out in Chapter 2 and to a large degree

satisfy the evaluation criteria. However, the mechanisms adopted to protect these rights are somewhat clumsy and may be ineffective, particularly in the case of the DPA. The government is currently reviewing the workings of the DPA, and it is to be hoped that some of the more obvious deficiencies can be rectified.

**Chapter 6 notes:**

<sup>1</sup> M Jones and A Morris, *Blackstone's Statutes on medical law* (2<sup>nd</sup> ed., 1999)

<sup>2</sup> SI 1985 No. 434

<sup>3</sup> M Brazier and J Harris, "Private health and public rights" (1996) 4 Med LR 17

<sup>4</sup> Neither expression having an adequate legal or medical definition; but see the comments of the Independent Review Group on the retention of organs at post mortem, *infra* fn5, at paragraph 47

<sup>5</sup> (2001); the Group was established in September 2000 by the then Scottish Executive Minister for Health. Its Final Report was published in November 2001

<sup>6</sup> At paragraph 27

<sup>7</sup> *Learning from Bristol: the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995* Cmnd 5207, 2001; and also the *Royal Liverpool Inquiry Report* HC 12-II (2001) (the "Alder Hey" inquiry)

<sup>8</sup> Section 2; the pregnant woman owes the same duty of care to her unborn child in relation to driving as she owes to everyone else.

<sup>9</sup> Discussed briefly in Chapter 5 *infra*

<sup>10</sup> Section 1A of the Act, inserted by the Human Fertilisation and Embryology Act 1990

<sup>11</sup> [1992] 3 All ER 833

<sup>12</sup> [1982] QB 1166

<sup>13</sup> I Kennedy and A Grubb, *Medical law: text with materials* (2<sup>nd</sup> ed., 1994), 976-7

<sup>14</sup> J Fortin, "Is the 'wrongful life' action really dead?" [1987] JSWL 306, quoted *ibid* 976

<sup>15</sup> In *McKay v Essex AHA*, *supra cit.*

<sup>16</sup> M Brazier, *Medicine, patients and the law* (2<sup>nd</sup> ed, 1992), 187

<sup>17</sup> Vaccine Damage Payments Act 1979, Section 1(4)

<sup>18</sup> Listed in Section 1(2); additional diseases can be added by statutory instrument

<sup>19</sup> Section 2.

<sup>20</sup> Section 1(3)

<sup>21</sup> Under the Vaccine Damage Payments Act 1979 Statutory Sum Order 2000, SI 2000 No 1983

<sup>22</sup> Statutory references hereafter are to the Mental Health Act 1983 unless otherwise specified; in general, there will be an equivalent section within the Mental Health (Scotland) Act 1984

<sup>23</sup> Section 2(2)(a)

<sup>24</sup> Section 2(2)(b)

<sup>25</sup> Section 2(3)

<sup>26</sup> Section 3(2)(b)

<sup>27</sup> *R v Canons Park Mental Health Review Tribunal ex parte A* [1995] QB 60, [1994] 2 All ER 659

<sup>28</sup> Section 3(2)(c)

<sup>29</sup> Section 3(3)

<sup>30</sup> Section 72

<sup>31</sup> *R (on the application of H) v Mental Health Review Tribunal, North and East London Region* [2001] EWCA Civ 415, [2001] 3 WLR 512. The Human Rights Act 1998 is considered *infra*

<sup>32</sup> Section 20 (in its original form)

<sup>33</sup> *R v Hallstrom ex parte W; R v Gardner ex parte L* [1986] 2 WLR 883

<sup>34</sup> [1998] 3 All ER 289, [1998] 3 WLR 107

- <sup>35</sup> A point made by Mason and McCall Smith, *Law and medical ethics* (5<sup>th</sup> ed., 1999), 510
- <sup>36</sup> *Ibid.*, 509
- <sup>37</sup> Section 58(3)(b)
- <sup>38</sup> Section 58(4)
- <sup>39</sup> Section 58(3)(a)
- <sup>40</sup> *R v Feggetter & Mental Health Act Commission ex parte Wooder* [2002] EWCA Civ 554
- <sup>41</sup> *R (on the application of Wilkinson) v Responsible Medical Officer, Broadmoor Hospital and Anor.* [2001] EWCA Civ 1545, [2002] Lloyds Rep Med 41
- <sup>42</sup> Section 57(2)(a) and (b)
- <sup>43</sup> MS Komrad, "A defence of medical paternalism: maximising patients' autonomy" 1983 J Med Ethics, 9, 38-44, esp. at 41-2
- <sup>44</sup> Simon Brown LJ in *v the Responsible Medical Officer, Broadmoor Hospital and Ors ex parte Wilkinson, supra cit.*, paras. 29-30
- <sup>45</sup> For an analysis of the decision, see D Hewitt, "An end to compulsory psychiatric treatment?" 2002 NLJ 194
- <sup>46</sup> Section 7
- <sup>47</sup> Family Law Reform Act 1969; Age of Majority (Scotland) Act 1969
- <sup>48</sup> Family Law Reform Act 1969, section 8
- <sup>49</sup> NHS (General Medical Services) Regulation 1992, SI 1992/635, Regulation 2
- <sup>50</sup> An expression which is not defined but presumably refers to a doctor registered under the Medical Act 1983, or a visiting EEC practitioner who would be entitled to be so registered.
- <sup>51</sup> *Re R (a minor) (wardship: medical treatment)* [1992] Fam. 11; (1991) 7 BMLR 147
- <sup>52</sup> Children (Scotland) Act 1995, Section 1(1)(d)
- <sup>53</sup> *Ibid.*, Section 15(5)(b)
- <sup>54</sup> Inserted by section 57, Standards in Scotland's Schools etc (Scotland) Act 2000
- <sup>55</sup> Prohibition of Female Circumcision Act 1985, Section 1(2)(a)
- <sup>56</sup> Section 1 (1)(b)
- <sup>57</sup> See Chapter 5 *supra*
- <sup>58</sup> Section 2(2)
- <sup>59</sup> Report of the Committee of Inquiry into Human Fertilization and Embryology, Cmnd. 9314 (1984)
- <sup>60</sup> *In re a Baby*, Times, 15 January 1985; see M Brazier, *op cit.*, 282-4
- <sup>61</sup> Surrogacy Arrangements Act 1985, Section 2
- <sup>62</sup> e.g. under the Adoption Act 1976, section 57, which prohibits making or receiving payments relating to consent to adoption; but see *re an adoption application (surrogacy)* [1987] 2 All ER 826
- <sup>63</sup> Section 1A, inserted by the Human Fertilisation and Embryology Act 1990, section 36(1)
- <sup>64</sup> Which was a rather later response to the Warnock Report, *supra* fn59
- <sup>65</sup> Human Fertilisation and Embryology Act 1990, Section 30
- <sup>66</sup> *Briody v St Helens and Knowsley Health Authority* [2002] 2 WLR 394; [2001] 2 FLR 1048
- <sup>67</sup> Human Organ Transplants Act 1989, section 1(1)
- <sup>68</sup> Section 1(2)

- <sup>69</sup> The Act had its genesis in a Scottish Law Commission draft bill entitled the “Incapable Adults Bill”. This was changed to “adults with incapacity” to reflect the bill’s (and Act’s) approach of regarding incapacity as being issue-specific rather than all-or-nothing.
- <sup>70</sup> Most of which are conveniently grouped as SSI 2001 numbers 75 to 82 inclusive
- <sup>71</sup> Section 53(3)
- <sup>72</sup> Adults with Incapacity (Scotland) Act 2000, section 6
- <sup>73</sup> Section 14
- <sup>74</sup> Section 1(2)
- <sup>75</sup> Section 1(3)
- <sup>76</sup> Section 1(4)
- <sup>77</sup> Section 1(5)
- <sup>78</sup> Sections 47 to 52
- <sup>79</sup> Defined as “any procedure or treatment designed to safeguard or promote physical or mental health.”: Section 47(4)
- <sup>80</sup> Section 47(2)
- <sup>81</sup> Section 47(1)
- <sup>82</sup> Section 47(7)(a)
- <sup>83</sup> Section 47(7)(c)
- <sup>84</sup> Section 48
- <sup>85</sup> Sections 47(9) and 50(7) and (8)
- <sup>86</sup> Used here to refer collectively to guardians, welfare attorneys or persons authorised under an intervention order. The expression is not found in the Act, but can be found in the draft Codes of Practice prepared by the Scottish Executive in terms of Section 13 of the Act. The draft codes can be accessed at [www.scotland.gov.uk/justice/incapacity](http://www.scotland.gov.uk/justice/incapacity) (accessed 27 February 2002)
- <sup>87</sup> Section 50(4)
- <sup>88</sup> Section 50(3)
- <sup>89</sup> Section 50(2)
- <sup>90</sup> Section 49
- <sup>91</sup> Sections 47(10), 49(3) and 50(8)
- <sup>92</sup> The rule providing for research from which the individual will not derive any benefit is an exception to the principle of individual benefit which, in terms of Section 1 of the Act, would otherwise preclude such research: see Section 51(2)
- <sup>93</sup> Section 51
- <sup>94</sup> Except decisions by doctors under Section 50, which have their own appeal route
- <sup>95</sup> Section 52, emphasis added
- <sup>96</sup> Section 47(4)
- <sup>97</sup> (2001) 4 All ER 1013, reversed by the Court of Appeal [2002] EWCA Civ 29; Times 25 January 2002
- <sup>98</sup> Human Reproductive Cloning Act 2001, Section 1(1)
- <sup>99</sup> Section 1(2)
- <sup>100</sup> The expression used in the Act’s long title

<sup>101</sup> The point was made by the Lord Chancellor, Lord Irvine of Lairg, during the Parliamentary debates surrounding the passage of the Human Rights Bill.

<sup>102</sup> Section 8(1)

<sup>103</sup> For conflicting approaches to this, cf *Wilson v First County Trust* [2001] 3 WLR 42 (CA) and *R v Lambert* [2001] 2 WLR 211 (HL)

<sup>104</sup> Section 6(2)(a); a similar defence exists if the act was in compliance with subordinate legislation which cannot be read so as to be compatible: section 6(2)(b)

<sup>105</sup> Section 6(3)(b)

<sup>106</sup> For an examination of some of the issues surrounding hybrid authorities in general, see D Oliver, "The frontiers of the state: public authorities and public functions under the Human Rights Act" 2000 PL 476. The definition has been considered in *R (Heather) v Leonard Cheshire Foundation* [2001] WL 606356, TLR 8 April 2002 (CA) and *Donoghue v Poplar Housing and Regeneration Community Association Ltd.* [2001] 3 WLR 183

<sup>107</sup> Section 3(2)(a)

<sup>108</sup> *R v A* [2001] 2 WLR 1546

<sup>109</sup> "Subordinate legislation" is defined in Section 21(1)

<sup>110</sup> See, for example, *Tyrer v United Kingdom* (1978) 2 EHRR 1

<sup>111</sup> For differing approaches, compare the remarks by Lord Slynn of Hadley in *R v SSETR ex parte Holding and Barnes plc*; *R v SSETR ex parte Alconbury Developments Ltd. and Others*; *R v SSETR ex parte Legal and General Assurance Society Ltd.*, [2001] UKHL 23, hereinafter collectively referred to as *Alconbury*, at para 26 with those of Lord Hoffmann at para 76 in the same case.

<sup>112</sup> Section 4

<sup>113</sup> Others were made at first instance but subsequently overturned on appeal

<sup>114</sup> *R (on the application of H) v Mental Health Review Tribunal, North and East London Region*, *supra cit.*

<sup>115</sup> *Wilson v First County Trust*, *supra cit.*

<sup>116</sup> *R (on the application of Wilkinson) v Commissioners of Inland Revenue* [2002] EWHC 182

Admin

<sup>117</sup> *Supra cit.*

<sup>118</sup> Section 6(3)(a)

<sup>119</sup> (1996) 22 EHRR 533

<sup>120</sup> *Halford v UK* (1997) 24 EHRR 523

<sup>121</sup> D Gomien, *Short guide to the European Convention on Human Rights* (2<sup>nd</sup> ed., 1998), 152

<sup>122</sup> The subject has been analysed in detail by the Law Commission and Scottish Law Commission, *Damages under the Human Rights Act, 2000*

<sup>123</sup> Section 7(5)

<sup>124</sup> *Id.*

<sup>125</sup> *R v Lambert*, *supra. cit.*

<sup>126</sup> Following *Associated Provincial Picture Houses v Wednesbury Corporation* [1948] 1 KB 223; see Chapter 4 *supra*

<sup>127</sup> [2001] 1 WLR 840

- <sup>128</sup> *Smith and Grady v UK* (2000) 29 EHRR 493
- <sup>129</sup> *R v Secretary of State for the Home Department ex parte Daly* [2001] 2 WLR 1622, [2001] 3 All ER 433
- <sup>130</sup> (1980) 3 EHRR 408
- <sup>131</sup> See C Byk, *Medical and biological progress and the European Convention on Human Rights* (1994), 33-5
- <sup>132</sup> *X v Austria*, 13 December 1979, unreported.
- <sup>133</sup> C Byk, *op. cit.*, 35
- <sup>134</sup> (1978) 14 DR 31
- <sup>135</sup> *LCB v UK* [1998] HRCOD 628
- <sup>136</sup> *R (on the application of Wilkinson v the Responsible Medical Officer, Broadmoor Hospital and Ors, op. cit.*
- <sup>137</sup> *A National Health Service Trust v D*, [2000] 2 FLR 677, (2000) 55 BMLR 19
- <sup>138</sup> *NHS Trust A v M* [2001] Lloyd's Rep Med. 28
- <sup>139</sup> Reported on <http://www.medneg.com/news/index.html> (News, April 2002) (accessed 19 September 2002)
- <sup>140</sup> *Ireland v UK* (1978) 2 EHRR 25
- <sup>141</sup> 24 September 1992, Series A no. 244, pp. 25-26
- <sup>142</sup> At Para 82
- <sup>143</sup> *X v Germany* (1985) 7 EHRR 152
- <sup>144</sup> J Gould and J Halford, "Implications of the Human Rights Act for health law", 2000 Legal Action 25 at 26
- <sup>145</sup> Application 923634/94, unreported
- <sup>146</sup> (1997) 24 EHRR 423
- <sup>147</sup> 2 March 1983, unreported
- <sup>148</sup> *A National Health Service Trust v D, supra cit*
- <sup>149</sup> *NHS Trust A v M, supra cit*
- <sup>150</sup> C Foster, "Switching off", 2001 Sol. J. 472 at 474
- <sup>151</sup> (1979) 2 EHRR 387
- <sup>152</sup> *R (on the application of H) v Mental Health Review Tribunal, North and East London Region, supra cit.*
- <sup>153</sup> See Chapter 5 *supra*
- <sup>154</sup> *Campbell & Fell v UK* (1984) 7 EHRR 165
- <sup>155</sup> *Pierre-Bloch v France* [1998] 26 EHRR 202
- <sup>156</sup> *Rasmussen v Denmark* (1984) 7 EHRR 371
- <sup>157</sup> *Bentham v the Netherlands* (1985) 8 EHRR 1
- <sup>158</sup> *Bryan v UK* [1995] 21 EHRR 342
- <sup>159</sup> *Schuler-Zgraggen v Switzerland* (1995) 21 EHRR 404
- <sup>160</sup> See K Meechan, "When is a dispute not a 'Dispute'" 2001 SLT (News) 95 for an analysis of this aspect
- <sup>161</sup> *Alconbury, supra cit.*
- <sup>162</sup> *Fayed v UK* (1994) 18 EHRR 393

- <sup>163</sup> *Avon County Council v Buscott and others* [1988] 1 All ER 841
- <sup>164</sup> *Golder v UK* (1975) 1 EHRR 524
- <sup>165</sup> *Albert and Le Compte v Belgium* (1983) 5 EHRR 533
- <sup>166</sup> *Ashingdane v UK* (1985) 7 EHRR 528
- <sup>167</sup> *Foucher v France* (1997) 25 EHRR 234
- <sup>168</sup> *McMichael v UK* (1995) 20 EHRR 205
- <sup>169</sup> *Starrs and Chalmers v Ruxton* 1999 SCCR 1052
- <sup>170</sup> 2000 SLT 965
- <sup>171</sup> *Supra cit.*
- <sup>172</sup> For an analysis of the judgements, see K Meechan, "Alconbury: democracy trumps human rights" 2001 SLT (News) 197
- <sup>173</sup> *Halford v UK supra cit*
- <sup>174</sup> *Lopez-Ostra v Spain* (1994) 20 EHRR 277
- <sup>175</sup> *Keegan v Ireland* (1994) 18 EHRR 542, paragraph 49
- <sup>176</sup> (1992) 16 EHRR 97
- <sup>177</sup> *Leander v Sweden* (1987) 9 EHRR 433
- <sup>178</sup> *Z v Finland* (1997) 25 EHRR 371
- <sup>179</sup> *Supra cit.*
- <sup>180</sup> *Klass and others v Germany* (1978) 2 EHRR 214
- <sup>181</sup> (2000) 31 EHRR 45
- <sup>182</sup> Regulation of Investigatory Powers Act 2000, Part II; for an analysis of the human rights issues surrounding other aspects of this legislation, see K Best and R McCusker, "The scrutiny of the electronic communications of businesses: striking the balance between the power to intercept and the right to privacy?" [2002] 1 Web JCLI
- <sup>183</sup> Regulation of Investigatory Powers (Scotland) Act 2000
- <sup>184</sup> Personal comment by an inspector from the Office of the Surveillance Commissioners
- <sup>185</sup> *Douglas & Ors. v Hello! Ltd* [2001] 2 WLR 992
- <sup>186</sup> *H (A healthcare worker) v Associated Newspapers Ltd. and Another* [2002] EWCA Civ 195
- <sup>187</sup> *Marckx v Belgium* (1979) 2 EHRR 330
- <sup>188</sup> e.g. *Boyle v UK* (1994) 19 EHRR 179, involving an uncle and nephew.
- <sup>189</sup> [2001] EWHC Admin 317 (Ousely J)
- <sup>190</sup> [2002] EWCA Civ 20 (Clarke LJ, Wall J)
- <sup>191</sup> *Buckley v UK* (1996) 23 EHRR 101
- <sup>192</sup> (1999) 2 CCLR 27
- <sup>193</sup> cf *R (on the application of Heather) v Leonard Cheshire Foundation, supra cit.*, where the applicant failed on very similar facts.
- <sup>194</sup> e.g. *Silver v UK* (1983) 5 EHRR 347
- <sup>195</sup> *Halford v UK, supra cit.*
- <sup>196</sup> Telecommunications (Lawful Business Practice) (Interception of Communications) Regulations 2000 (SI 2000/2699), made under the Regulation of Investigatory Powers Act 2000
- <sup>197</sup> e.g. *X and Y v Netherlands* (1985) 8 EHRR 235
- <sup>198</sup> *R (on the application of Pretty) v DPP*, [2002] 1 All ER 1



<sup>199</sup> See R English, "No rights to Last Rites", 2001 NLJ 1844

<sup>200</sup> *Pretty v UK*, ECtHR 29 April 2002, unreported

<sup>201</sup> Directive 95/46/EC

<sup>202</sup> Key definitions are found in Sections 1 and 2, miscellaneous definitions found in Section 70. However, the Act has so many other definitions scattered throughout it that there is an index to definitions contained in Section 71.

<sup>203</sup> As a result of amendments to the Act introduced by the Freedom of Information Act 2000

<sup>204</sup> For an analysis of the new rules, see K Meehan, "Data Protection – Time's Up" (2001) 145 Sol. J 952

<sup>205</sup> Section 17(2); subject to certain limited exceptions

<sup>206</sup> Section 21

<sup>207</sup> The Data Protection (Processing of Sensitive Personal Data) Order 2000, SI 2000/417

<sup>208</sup> Following the numbering from the EU Directive. The proper reference would be to the information required by Paragraph 2(3) of Part II of Schedule 1 to the Act. They are also known as subject information notices.

<sup>209</sup> (2001) 4 EMLR 750, [2002] 1 WLR 1235

<sup>210</sup> [2001] EWCA Civ 1897

<sup>211</sup> Space precludes a full listing – this can be found on the Lord Chancellor's website at [www.lcd.gov.uk/ccpd/dpsubleg.htm](http://www.lcd.gov.uk/ccpd/dpsubleg.htm); the majority of them can be found in the 2000 series of statutory instruments grouped from numbers 183 to 191 and 413 to 419

<sup>212</sup> Paragraph 2, Schedule 1 Part II

<sup>213</sup> Section 7

<sup>214</sup> Available on her website at [www.dataprotection.gov.uk](http://www.dataprotection.gov.uk); there is a lot of valuable guidance material on a number of subjects on the site, although it can be slow

<sup>215</sup> (1989) 12 EHRR 36

<sup>216</sup> Data Protection (Subject access)(Fees and miscellaneous provisions) Regulations 2000, SI 2000/191

<sup>217</sup> *Id.*

<sup>218</sup> The change was effected by the Data Protection (Subject access)(Fees and miscellaneous provisions)(Amendment) Regulations 2001, SI 2001/3223

<sup>219</sup> *Z v Finland*, *supra cit.*

<sup>220</sup> Not every collection of personal data engages Article 8: see *Friedl v Austria* (1995) 21 EHRR 83. Most processing will, however.

<sup>221</sup> Unreported; *Independent* 17 October 2001; Letter to the editor, 2001 Sol. J. 975.

<sup>222</sup> As the claim was by a minor, the settlement required judicial approval

<sup>223</sup> [2002] 2 WLR 889

<sup>224</sup> 1 October 2001 unreported (but available on the Lord Chancellor's website, [www.lcd.gov.uk/foi/inftrib.htm](http://www.lcd.gov.uk/foi/inftrib.htm))

<sup>225</sup> [2001] 7 Lloyds Rep Med 349

<sup>226</sup> 21 December 2001, unreported

<sup>227</sup> *Re A (Disclosure of medical records to the GMC)* [1998] 2 FLR 641

<sup>228</sup> Paragraphs 19-20

<sup>229</sup> Schedule 3 paragraph 8

<sup>230</sup> [2000] 2 WLR 940

<sup>231</sup> J Strobl *et al.*, "Data protection legislation: interpretation and barriers to research" *BMJ* 2000; 321: 890-2

<sup>232</sup> P Brown, "Cancer registries fear imminent collapse" *BMJ* 2000; 321: 849

<sup>233</sup> See the series of papers under the feature "Injury surveillance programmes, ethics, and the Data Protection Act" *BMJ* 1999; 319: 372-5

<sup>234</sup> Information Commissioner, first draft, May 2001

<sup>235</sup> The Commissioner's office was still accepting comments on the draft as late as January 2002, so publication is probably some way off: personal communication, Office of the Information Commissioner, December 2001

<sup>236</sup> Section 60(6)

<sup>237</sup> SI 2000 No. 413

<sup>238</sup> 1954, *Times* 2 July 1954; see Chapter 4 *supra*

<sup>239</sup> *Supra cit.*

<sup>240</sup> Equivalent exceptions apply to education and social work/social services records

<sup>241</sup> For a comparative analysis of the UK Act and the original consultation draft of the Scottish Bill, see K Meechan, "Freedom of information – north and south of the Tweed" [2001] *JLGL* 114

<sup>242</sup> The Green and White Papers preceding the Human Rights Act were entitled "Bringing Rights Home" and "Rights Brought Home" respectively

<sup>243</sup> Or, in the case of the DPA, it has been in force subject to transitional arrangements substantially restricting its effects.

<sup>244</sup> Human Rights Act Statistics, available at [www.homeoffice.gov.uk/hract/statistics.htm](http://www.homeoffice.gov.uk/hract/statistics.htm) (accessed 16 May 2001)

<sup>245</sup> Between May 1999 and October 2000, approximately 800 human rights challenges were raised in the Scottish Courts. Almost all failed: Crown Office representative, personal communication.

<sup>246</sup> K Meechan, "The Human Rights Act – Public authority preparations" [2001] *JLGL* 56; S Coope and L Lane, *Public authorities and the Human Rights Act: an exploratory study* (2001)

<sup>247</sup> *Campbell v Mirror Group Newspapers Ltd.* [2002] *EWHC* 499 (QB)

<sup>248</sup> Which, notwithstanding Section 21 of the Human Rights Act 1998, is intended in this context to include Acts of the Scottish Parliament

<sup>249</sup> See *R v City of Wakefield Metropolitan Council and Anor. ex p. Robertson*, *supra cit.*

<sup>250</sup> In fact, of all the cases referring to DPA 98, the data subject has only lost one.

<sup>251</sup> J Welch, "Human rights: one year on" 2001 *Sol. J.* 876

<sup>252</sup> *Id.*; and see in particular J Wadham, "The Human Rights Act: one year on" [2001] *EHRLR* 620 at 623-5

<sup>253</sup> The Abortion Act 1967, to take a relevant example, was a private member's bill introduced at a time when the government was unwilling to be seen introducing legislation on this subject

<sup>254</sup> The last minority administration being in 1978, barring a brief period at the end of John Major's administration in 1996-7 when it depended on Ulster Unionists' support to retain a majority in Parliament. The Scottish Parliament, on the other hand, has no overall majority and the administration in Scotland is a coalition between Labour and the Liberal Democrats.

## **Chapter 7: Summary and Conclusions:**

### **I: Introduction:**

Chapter 2 outlined how this thesis would seek to analyse the regulatory structures applicable to medical practice in Britain.

We have seen, in Chapters 3 to 6, how the four main regulatory mechanisms (criminal law, civil law, statutory regulatory body and direct statutory intervention) have actually worked out in practice. Each of these systems has been measured against the core evaluation criteria set out in Chapter 2, and various shortcomings (as well as a number of desirable features and strengths) have been highlighted through this comparison. However, at this point all we have are a series of analyses which are sector-specific and (aside from areas of overlapping concern) there is no cross-referencing between the different regulatory mechanisms. The working hypothesis set out in Chapter 1 was designed to test the possibility that the objectives pursued by the different regulatory mechanisms might, in some respects, be mutually incompatible. This Chapter sets out to answer that question.

This Chapter will revisit the regulatory tasks which were identified in Chapter 2, and, against the detailed examinations just considered, will seek to draw together the disparate strands of regulation in order to identify overlaps in jurisdiction as well as any regulatory gaps in the current system. It will then proceed to compare this broader picture against the core evaluation criteria, to see which of these are satisfied by the overall regulatory system, and which are not. Finally, it will answer the question posed at the outset in the working hypothesis: does the present system of regulation of medical practice in Great Britain provide adequate safeguards for the interests of patients, doctors and the State?

### **II: The regulatory tasks revisited:**

For the purposes of this thesis, “regulation” was defined in terms of eight activities covering the setting and maintaining of standards, facilitation of medical practice, provision of systems for redress, airing of grievances and investigation, punishment of malefactors and regulation of the system itself.

Setting of standards of medical practice was done by means of all four regulatory approaches, to a greater or lesser extent. For present purposes, we are mainly concerned with standards of clinical behaviour. The criminal law sets the baseline for acceptable behaviour in a non-clinical environment. However, before conduct could reach this level it required firstly to be below the level of conduct deemed acceptable in terms of civil liability. This in turn leads to consideration of how the civil standard is reached, and it is here that the first real regulatory gap can be found. As demonstrated in Chapter 4, the civil courts have, to all intents and purposes, delegated determination of the standard of medical practice to the medical profession. However, in contrast to the delegation of functions to the GMC by Parliament, this *de facto* delegation of the standard-setting function has taken place under the scope of judicial development of the common law. Since judges are, almost by definition, unaccountable, the practical upshot of this is that the delegation has taken place in a way which results in neither the courts nor the medical profession being accountable for the decision. Academic commentators in particular have been vociferous in their criticisms of medical law as developed by the courts (particularly the “*Bolam*” test, and its uncritical application to judicial scrutiny of a wide range of medical activities<sup>1</sup>). The main thrust of the criticism is that what should be a legal decision is instead treated by the courts as a medical one<sup>2</sup>. The nature of the test is that if a body of medical opinion regards something as acceptable, then the courts will follow suit - even if those holding this opinion are an unpopular minority. This amounts to standard setting by lowest common denominator. Regulation by direct statutory intervention has really only been to legalise or, more commonly, to criminalise, particular specified interventions and as such has done nothing to reverse this state of affairs. The GMC’s approach to standard-setting has been constrained historically by its reluctance to intervene in matters of clinical judgement unless the standard fell so far below the standard set by the civil courts as to amount to professional misconduct. Recent legislative changes have given the GMC powers in relation to standard setting, through the creation of the professional performance procedures<sup>3</sup>. However, even these procedures are based on a preceding breach of the civil standard. The GMC’s own guidance refers to conduct “repeatedly or persistently not meeting the professional standards appropriate to the work you are doing”<sup>4</sup>, a formulation referring to “professional standards” which sounds very much like the *Bolam* test. The GMC powers in this area are also principally reactive, something which tends to militate against a standard-setting role, but this is true of most standard-setting interventions. Indeed, the GMC’s own guidance on various subjects represents one of the few proactive attempts at setting standards emerging from the formal regulatory machinery. It seems, therefore, that standards are set, not by the formal systems of regulation, but by bodies and mechanisms which are outwith (or on the

periphery of) the formal regulatory machinery: the BMA, the Royal Colleges, ultimately the developing practice of medicine itself. As these new practices and approaches become widespread, or as old practices become discredited, the changes are ultimately reflected in the formal regulatory machinery<sup>5</sup>. But in general, it appears that the formal system does little in itself to set the standards of acceptable medical practice in the first place.

In terms of upholding standards, three out of the four regulatory approaches contribute something. In this respect, the criminal law has at once the most important and least important role: it is the most important because the jurisdiction of other regulators (and in particular, the requirement for doctors to register with the GMC) is safeguarded by attaching criminal sanctions to non-compliance. It is the least important because the standards of other mechanisms (notably those of the GMC and/or the civil courts) have been breached already before malpractice becomes a criminal matter. Direct statutory regulation has very little to do with upholding standards. Parliamentary intervention in this area has tended towards extending the powers of other regulators rather than intervening directly, although as has been seen the Human Rights Act 1998 could theoretically be used as a vehicle for driving up standards in certain circumstances. The civil law's role is similarly limited, the professional standards test meaning that the civil courts are, in effect, upholding the standards set (informally) by the profession itself. The civil law is also useful (if somewhat flawed) in being able to force decision-makers in the public sector to act reasonably and stay within their allotted responsibilities; it is less useful in determining between conflicting professional views as to the merits or demerits of something, and (in general) refuses to do so. While the civil law may well exercise the function of upholding standards, it lacks any formal mechanism to enable it to do so systematically. The GMC, particularly since it was given power to review professional competence, has an explicit role in upholding standards of medical practice. The reactive nature of this power, while it has a negative impact on the role of the GMC in setting standards, is appropriate to the function of upholding standards since it is an allegation of deficient performance which triggers the performance procedures. However, since the GMC will only act under its performance procedures in respect of conduct which is "seriously deficient"<sup>6</sup>, this leaves medical performance which is deficient (but not seriously so) effectively unregulated. It is possible that the GMC's proposed "revalidation procedures"<sup>7</sup> will redress this regulatory deficit, although it is also fair to say that these proposals appear simply to be a formalisation of the system of medical audit<sup>8</sup>. As such, it would appear that the standards of medical practice are upheld by informal mechanisms (medical audit, informal peer review and peer pressure, and the general cultural norms which imbue the medical profession<sup>9</sup>) rather than by any formal

mechanism. It is too early to say whether formalising aspects of this under the revalidation system will plug the regulatory gap, but for the present it appears that there is a clear regulatory gap in this area.

Facilitation of medical practice is mostly done through the legislation under which the National Health Service is established and funded which, while of immense importance to the provision of health care in Britain, is not part of the regulatory machinery being assessed by this thesis. Nor can the passage of the Human Rights Act 1998 be said to have altered this much, although the Data Protection Act 1998 has the potential to revolutionise aspects of medical care through the positive requirement to inform the "data subject" (i.e. the patient) of the purposes for which their personal data are to be processed. The criminal law has an even smaller role in this area, being restricted to ensuring that those who lack formal medical qualifications require to advise their prospective patients of this fact. The civil law does facilitate good medical practice in certain limited areas, by providing a framework under which those who wish to undertake interventions which are beneficial but difficult to justify on conventional grounds can seek approval from the court prior to the intervention proceeding. In Scotland, of course, the legislative framework created by the Adults with Incapacity (Scotland) Act 2000 creates an alternative framework by means of direct statutory regulation, although the courts retain a role in adjudicating in cases of difficulty. Again, however, the court's function is essentially the negative one of not interfering with good medical practice (and arguably not interfering enough with less good medical practice). The GMC's positive facilitation of good medical practice comes in the form of its role in supervising medical education. By creating a framework under which an adequate number of educated and trained professionals are able to come through the system, the GMC clearly has a vital role to play. Another positive aspect of the GMC's work can be seen in the health and performance procedures whereby a doctor having difficulties is, in effect, mentored and may be required to undertake re-training in a particular area before being allowed to resume practice in that specialisation. However, in relation to the majority of doctors it is fair to say that the formal regulatory machinery ceases to have any role in facilitating good medical practice the moment the doctor becomes fully registered and another regulatory gap appears to exist.

The provision of systems to allow redress for those who suffer due to a failure to adhere to standards is an easier regulatory task to identify since the only part of the regulatory machine concerned with compensation is civil litigation<sup>10</sup>. The shortcomings of the civil courts in addressing this matter were discussed in detail in Chapter 4: only around 13% of medical negligence claims actually succeed<sup>11</sup>. What is not clear from this bald

statistic is the reason the other 87% of cases fail. It is entirely possible that the reason for failure is attributable to the fact that the claim was unmeritorious to start with, or was due to poor legal representation. However, there do appear to be a number of aspects to civil litigation which make the medical claimant's task more difficult than that of the person suing in respect of any other form of personal injury. There are in addition barriers to access to the courts which may well mean that there is a volume of meritorious claims which do not even get to court, although this may well be offset against the number of claims which are settled before court proceedings are commenced and so do not show up in the statistics. Paradoxically, however, the fact that some 13% of people who go to court come away with damages of some sort indicates that this regulatory task is being fulfilled, albeit it is being fulfilled imperfectly and there is significant scope for improvement.

The foregoing analyses have indicated that there are numerous channels which the aggrieved patient can potentially choose to pursue, although the outcomes vary widely. The Human Rights Act 1998 has seen Parliament create a large number of new rights in relation to which persons can raise proceedings. However, as the channel for pursuing such claims is through the ordinary civil courts, no new channel for pursuing complaints has been created. This is in contrast to the Data Protection Act 1998, which allows anyone who feels their rights under the Act have been breached to request the information Commissioner to make an "assessment" of the processing complained of<sup>12</sup>. On receipt of such a request, the Commissioner is given fairly extensive powers of investigation<sup>13</sup>. In terms of the criminal law, the individual's right to complain is largely restricted to making a complaint to the police, with the decision to institute proceedings being taken by an external agency (as a rule in Scotland and a practical upshot of the procedures in England and Wales). The criminal law's role as a channel for complaint and dispute resolution is therefore highly circumscribed; rules on admissibility of evidence and the burden of proof underscore these limitations in respect of this function. The same is true, albeit to a lesser extent (given the broader jurisdiction) of complaints to the GMC: decisions to take proceedings or not are taken by the GMC, not the aggrieved individual. The confidential nature of the health or performance procedures removes the complaining patient from the frame altogether. The GMC cannot therefore be seen as an adequate channel for complaint and dispute resolution. Lastly, the civil courts have been subject to widely differing views on whether patients resort to civil litigation as a means of getting at the truth of an incident and getting an apology, or whether the motive is really (as it purports to be) to get financial compensation for the adverse outcome. Certainly, Goldrein and de Haas<sup>14</sup> have observed the drawbacks of using civil litigation for this purpose. However, this observation has to be considered

against the fact that we have identified the lack of alternative avenues for such a complaint to go down. While Goldrein and de Haas themselves recommend that "...more vigorous use of the hospital complaints procedure is a more compelling route"<sup>15</sup>, it should be noted that this is an NHS-specific mechanism and therefore not applicable to medical complaints more generally. While civil litigation *can* be used as a mechanism to make complaints and investigate allegations of failure to attain standards of care (both pre-trial discovery and the fact that in a defended case the defending health authority or doctor will seek to adduce evidence that what happened was in conformity with a responsible body of medical opinion will result in airing of facts and circumstances which might not otherwise have come to light), the onus of proof remains on the pursuer/plaintiff and the adversarial nature of proceedings severely restrict the possibilities of using civil litigation as a truth-finding exercise. It does, however, fare better as a complaints mechanism in circumstances where a person is challenging the decision of a public body. In these cases, particularly with the addition of the Human Rights Act, the judicial review courts are increasingly requiring public bodies to provide proper explanations for their decisions, and are also increasingly prepared to scrutinise the merits of those decisions. At present, however, it appears that the formal regulatory machinery fails to provide any truly adequate channels for airing grievances and resolving disputes.

At first blush, the provision of systems of investigation might appear to be the same function as the provision of channels for airing grievances and resolving disputes. However, there is an important distinction here in that this regulatory function does not require the input of the person making the complaint but can be an abstract system of quality monitoring. The Data Protection Act 1998 allows the Information Commissioner to carry out assessments of data processing with a view to ascertaining whether the provisions of that Act are being adhered to. The Commissioner has the power to initiate an assessment of her own volition, but staffing shortages mean that in practical terms her remit is a purely reactive one. This only slightly diminishes the importance of this part of her functions. The civil law can (in theory at least) be used by anyone asserting a civil claim, but its usefulness as an investigatory system is also severely restricted by the adversarial nature of the proceedings. While the court can order disclosure of documents and other evidence in the course of civil proceedings, it cannot (in general) require a party to appear instead of conceding the case and has no independent jurisdiction to make inquiry into matters of its own volition. The main value of the civil courts in this context is in relation to ensuring that the other statutory regulators carry out their allotted functions and exercise the discretion vested in them in a responsible and informed manner. Most of the system of investigation, however, falls to be done by the



other two regulators, the criminal courts and GMC (for purposes of this thesis the police are treated as adjuncts of the criminal courts in terms of their investigatory powers). Clearly, a full police investigation into allegations of crime (particularly serious crime) has immense power to uncover evidence even in the face of uncooperative witnesses and issues such as patient confidentiality. While these powers are (rightly) subject to a number of checks and balances, the overall effect of the crime detection community is to provide a highly effective system of investigation into allegations of conduct falling foul of the standards of the criminal law. For present purposes, however, the practical effects of this are diminished by the extremely limited scope for criminal investigations into clinical activity. This is not to advocate more police scrutiny of doctors, but rather to make the point that for more routine investigations into sub-standard treatment, we have to look elsewhere for an effective mechanism. This takes us to the GMC. On this issue, the GMC scores fairly well. While the GMC may not enjoy statutory rights to require records to be produced to it (unlike many other regulators), it has the jurisdictional advantage of being able to take effective action against a doctor who does not voluntarily provide the information sought or who refuses, for example, to submit to a medical examination. The practical upshot of this is that while the GMC may not be able to get to the bottom of an allegation of misconduct, it is able to protect the public anyway. While on a theoretical level we might prefer to find the truth of a situation, on a practical level the upshot of such an investigation is to determine what further steps are necessary to fulfil one or more of the other regulatory tasks. Discovering the truth is not, in general, an end in itself for the regulatory machinery.

Moving to the punishment of malefactors, it is possible to take a broader or narrower view of what "punishment" means. On the narrow view, it could be taken to refer purely to those measures which are specifically intended to be punitive in nature. However, this analysis will adopt a broader approach by considering measures which, from the subjective view of the recipient, appear to have a punitive effect. The distinction is clearly seen when considering the effects of civil litigation. In Britain, there is no scope for awarding punitive or exemplary damages and damages are supposed to be purely for purposes of restitution or compensation. However, the entire theory of the deterrent effect which civil litigation has on standards of practice presupposes that an adverse outcome for the doctor being sued also has a punitive effect. But while being sued is a very unpleasant experience for a doctor, this is true irrespective of the outcome of the litigation, so it is very hard to classify this as being an appropriate regulatory function. Statutory interventions are never targeted specifically against particular malefactors, and so as a regulatory tool legislation does not in itself punish those who fail to meet standards. It is, however, possible to consider specific criminalisation statutes (such as

the Human Reproductive Cloning Act 2001) as being aimed at the punishment of those who embark on the conduct in question once the statute in question has come into force. The GMC's disciplinary procedures are, as we saw, principally intended to protect the public. However, in many cases where the serious professional misconduct is completely unrelated to the doctor's medical activities, it is the reputation of the medical profession rather than the well-being of patients which appears to be being protected. In such circumstances where there is no suggestion that there is any issue of public safety involved, what is happening is clearly a punitive process. This is explicitly recognised in the Privy Council's review of GMC sanctions, which must be proportionate to the seriousness of the offence rather than (for example) being the sanction required to protect the public<sup>16</sup>. The GMC therefore fulfils the regulatory function of punishing those who do not adhere to the relevant standards of behaviour. Lastly, punishment is the stock in trade of the criminal law. The criminal courts also therefore fulfil this function, albeit to a lesser extent given how significantly (in the clinical context) a doctor's conduct has to depart from the norm before it will amount to criminal behaviour. However, given that conviction may trigger the GMC's disciplinary mechanisms, the combination of factors means that this regulatory task is adequately fulfilled.

The foregoing analysis of regulatory tasks has identified that of the preceding seven tasks, there is a regulatory gap in four of them. This in itself would tend to suggest that there is a failure in the regulation of the regulatory system. However, it remains important to consider the cause of this apparent failure: is there a complete regulatory void, or is the failure due to imperfect performance of one of the regulators?

Some of the regulators are easily removed from the frame. Thus, the GMC has absolutely no jurisdiction over anyone but its own members, and so cannot play a part in the wider regulation of the system. Legislative intervention, on the other hand, is arguably driven by Parliament's perception that the existing regulatory framework is in some way deficient, with the ensuing legislation being intended to remedy the defect or omission. In this respect, Parliament is the ultimate guarantor of the regulatory system. However, in operational terms what tends to happen is not so much ensuring that the regulatory system is fulfilling its allotted functions (although parliamentary inquiries may do this on an ad-hoc basis) but rather consists of redefining the functions and roles of the other regulators (or indeed, of establishing or abolishing a particular regulatory mechanism). There are exceptions, such as the National Health Service Reform and Health Care Professions Act 2002. This includes, in Part 2, the establishment of a new body, the Council for the Regulation of Health Care Professionals, which (once established) will have a clearly-defined role in ensuring that the GMC is carrying out its

functions adequately. Such a body would fulfil the task of regulating the regulatory machinery, viz. the GMC and other statutory regulatory bodies, but the mechanism adopted would be another statutory regulatory body rather than direct statutory regulation *per se*. The specific legislation considered in Chapter 6 may have the incidental effect of making the other regulatory mechanisms more open to scrutiny, but this is (in general) not an end in itself. In this regard, none of these recent legislative innovations fulfils this regulatory task. The criminal law performs a limited role in this area, mostly in relation to offences such as wilful neglect of duty for officers employed in other regulatory mechanisms. The criminal law is also, as we have seen, used as the mechanism to give other regulators teeth. However, most regulatory failures take place without any criminal offence being committed, and the criminal law cannot be seen as fulfilling the function of policing the regulatory machinery. This leaves the civil courts. As was shown in Chapter 4, the civil courts (through the judicial review jurisdiction<sup>17</sup>) have the power to scrutinise the activities of those who perform public functions. Mostly, however, this is the supreme courts' jurisdiction to ensure that those to whom Parliament has entrusted a discretion are exercising that discretion in the way which the courts presume Parliament intended. The courts have no jurisdiction over Parliament<sup>18</sup>, and so any failures in regulatory activity flowing from primary legislation (or the lack of legislation, if there be a regulatory void) are beyond the ability of the civil courts to rectify. The courts have also traditionally taken the view that if Parliament has entrusted a discretionary judgement to someone, it is not for the courts to impose their own views in place of the proper decision-maker. While the Human Rights Act 1998 has either caused or been co-incidental with an expansion of the judicial review jurisdiction to the extent that some inroads have been made into this principle<sup>19</sup>, this expansion has been cautious and the courts remain highly reluctant to interfere with the views of administrative decision-makers. This, of course, does not excuse the civil courts for their own regulatory failings in relation to the other tasks, but it is convenient for present purposes to separate out the supervisory jurisdiction from the adjudicatory jurisdiction. The supervisory jurisdiction is incapable of fashioning a regulatory mechanism where none exists, and it would be unfair to criticise the civil courts on this basis. Conversely, however, where there is a regulatory mechanism, the civil courts have provided a means of holding that regulator to account. The main problem is that given the limited nature of the regulatory system being considered in this thesis, the only part of the regulatory machinery being supervised is the GMC. No other part of the regulatory machinery considered within this thesis is subject to any real mechanism intended to ensure that the mechanism is doing its job. This has to be regarded as a major regulatory failure.

### **III: The core evaluation criteria:**

In this section, the different analyses of the regulatory mechanisms will be pulled together, and an assessment will be made as to how well they match up to the core evaluation criteria. However, in order to continue with the cross-sectional analysis being utilised in this chapter, each criterion will be considered in turn to evaluate how well the system as a whole matches up to it. This will provide the information based on which the final section of this Chapter will reconsider the working hypothesis.

When visibility is considered, the overall pattern seems to be that the regulatory systems themselves are adequately visible. The lack of visibility arises only in relation to the decisions as to whether formal proceedings (within the GMC or under the criminal law) are to proceed. There is, in particular, scope for improvement in terms of the openness of investigating and prosecuting authorities and why they reach decisions on investigation and prosecution.

In terms of accountability, at the highest level, responsibility for the passing of legislation, legislation which affects civil or criminal liability or which creates or removes a regulatory body, lies with Parliament. This is accountable to the general public through the normal mechanism of the general election, but this form of accountability is too remote to provide adequate safeguards in relation to a regulatory mechanism. The judicial aspects of the system are adequately (if poorly) accountable; however, the other aspects of the system are regarded as being deficient in this respect. The rights of victims are, however, not similarly protected, and while it is accepted that any move in the direction of victims' rights can impact adversely on the accused, it is suggested that adequate safeguards could be devised and improvements could be made in relation to victims' rights. The GMC, with its majority of elected members, would appear to be accountable to its own membership. It is, however, in terms of accountability to the general public that the GMC scores poorly. Too many things happen which are done away from public scrutiny, and even accepting that there are legitimate grounds for protecting confidentiality in some circumstances, there appears to be no good reason for not requiring these secret procedures to produce appropriately anonymised accounts of what they have done or to provide feedback to the complainant. The GMC fails to satisfy the criterion of accountability. Drawing these threads together, accountability fails in relation to the same invisible decision-makers criticised in the previous paragraph, coupled with a failure in accountability caused by lack of adequate feedback mechanisms keeping the complainant informed as to outcomes (and allowing them to challenge those responsible). Given that ultimately the only truly accountable part of the system is accountable only weakly, through parliamentary democracy, coupled with the

fact that so many functions are exercised by judges who are (in effect) necessarily unaccountable, it therefore appears that the system fails on this score.

Turning to overall fairness, it will be recalled that this incorporates a number of aspects including impartiality, accessibility, and speed of decision-making. A number of shortcomings were identified in relation to each of these aspects: the unduly biased approach of the civil courts, coupled with problems relating to costs, accessibility and delay were particular cause for concern, and there were some failings in relation to those who make complaints to the GMC about a doctor, although these were not so serious as to cause us to depart from the conclusion that the GMC does satisfy the test of overall fairness. When we look at these comments together, we find that the regulatory system as a whole is fair to those using it – but only just - and the unfairness is in relation to the only part of the system which the dissatisfied person can have resort to as of right (rather than at the will of a third party decision-maker). Indeed, the worst incidence of unfairness relates to the cost, delay and apparent evidential bias visible within the system of civil litigation. Any attempt to improve the impartiality, accessibility, speed of decision-making and overall fairness of the regulatory system would accordingly be well advised to focus its attention on the system of civil litigation.

It has already been seen that the practical effects of many regulatory interventions are, in some respects, unquantifiable and we are therefore concerned only with the quantifiable effects. From what can be observed, do the various regulatory mechanisms do what they set out to achieve? Certainly the criminal law appears to do its job, and for a reactive system the GMC is also tolerably effective. The legislative innovations considered are also, on the whole, effective subject to a caveat in relation to the defective enforcement provisions of the Data Protection Act 1998. The effectiveness of the civil courts, however, can be considered in a number of different ways. As between the parties to the litigation, the courts are very effective (even if one might quibble with the way in which that effectiveness is actually applied in particular cases). As has been seen, assuming the (many) problems caused by shortcomings falling within other criteria are overcome, then the civil courts will, with a high degree of effectiveness, award compensation – but only in a very small proportion of cases. Overall, the courts are effective at all the main regulatory functions they are tasked with, with the notable exceptions of setting and upholding standards of medical practice. There is room for significant improvement in the functions of investigating mishaps and regulating other regulators, and the compensation function is rendered ineffectual by other failures. Overall, it appears that the regulatory system is tolerably effective, although there are significant shortcomings in relation to all of its component parts. It should also be noted

that this assessment of effectiveness is in relation to the regulatory tasks undertaken by the constituent parts of the system. There is no attempt at assessing the regulatory gaps which this section is identifying. Where there is a clearly-identified regulatory gap, then the system as a whole is ineffective in relation to that failure, even if it has not been possible to localise the problem to one of our regulatory mechanisms. It may be that such a discovery points to the need for additional regulators to be created, or the jurisdiction or rules of an existing regulator to be changed in a way which that mechanism is incapable of doing unilaterally.

In assessing the efficiency of any regulatory mechanism, it is important to note that “most efficient” does not equate to “cheapest”. What we are concerned with here is the concept of *productive efficiency*<sup>20</sup>, a concept used by economists which explicitly relates the costs of a service to the quantity and quality of service provision. Thus, for a measure to satisfy this criterion, it is not necessary that it be the cheapest option, so long as higher costs are reflected in some form of improved performance. On this basis, both civil and criminal court organisation would appear inefficient and the fact that an estimated 85% of the sums awarded in compensation is taken up in costs<sup>21</sup> (131% in claims under £5000<sup>22</sup>) is itself a strong indicator of inefficiency on the civil courts’ part. The GMC’s use of informal processes is efficient, and it additionally makes no drain on the public purse. The Data Protection Act, on the other hand, has a number of features which arguably impose bureaucratic burdens on data controllers but which confer no appreciable rights on anyone. This Act is therefore deemed to be inefficient. Considering the overall effect of this, it would appear that, in the round, the regulatory system is not efficient and that much could be done to improve the efficiency of the system. The role of the courts in particular requires to be addressed.

Does the system interfere unduly with good medical practice? It is necessary to consider the definition of this adopted in Chapter 2: it means medical activity which is demonstrably of clinical benefit to the patient, and which is the course of treatment which, if the patient could be brought up to the level of knowledge concerning potential risks, benefits, alternatives and inherent uncertainties as the doctor treating him or her (or alternatively, of a “reasonable” doctor), the patient would have chosen for him- or herself. The criminal law patently does not, and the civil law (by relying so heavily on medical professional standards) does not either, although the stress of litigation on medical personnel being sued, and the diversion of resources from patient care into litigation expenses, are areas where there is scope for significant improvement. The (self-regulating) GMC, unsurprisingly, shows no signs of interfering unduly with its own members’ practice of medicine, nor do either the Human Rights Act or the Data

Protection Act. Overall, therefore, it would appear that nothing in the current regulatory framework unduly interferes with good medical practice (as we have defined that term), although there are some improvements which could be made in relation to civil litigation.

Both the Human Rights Act and the Data Protection Act have concern for individual autonomy at their heart. It is therefore easy to conclude that both satisfy this criterion. On the other hand, both the civil and criminal law uphold the principle of physical autonomy through the law of assault, but do so only poorly in the medical context. In terms of patients as victims of crime, the system substantially disempowers the victim, and this also shows a clear disregard of respect for patient autonomy. The civil law additionally protects individual personal autonomy through the law relating to consent to treatment, but this law is highly defective in allowing the medical profession to determine how much information the patient receives. The civil law also allows the refusal of treatment of autonomous individuals to be overridden in some instances, most notably in the case of pregnant women. Any shortcomings on the part of the GMC (which issues guidance on the subject of consent and autonomy) are better seen as a failure provoked by the preceding failures in accountability and visibility. But does the system overall respect patient autonomy adequately? The answer would seem to be no. Too many parts of the system fail to provide adequate protection for the rights of the individual, and even those that provide protection do so subject to caveats as to the extent of that protection. Procedural criminal law and substantive civil law would require amendment, and if we are serious about patient autonomy we would also want to look at the GMC's procedures.

#### **IV: Solution to Working Hypothesis:**

To recap Chapter 1, the working question underpinning this thesis is as follows:

“Does the present system of regulation of medical practice in Great Britain provide adequate safeguards for the interests of patients, doctors and the State?”

To answer this, it is necessary to provide a very brief summary of the two preceding sections of this Chapter, which between them have assessed the overall workings of the regulatory system across four mechanisms, eight regulatory functions and seven evaluation criteria.

The following things about the regulatory system as it currently stands have been identified in the foregoing analysis, measured against the list of regulatory tasks.

- Standards of medical practice are not set by any of the formal regulators, and are only gradually reflected by them
- These standards are only upheld by the formal regulators in the event of serious breaches, and then only on a reactive basis
- The regulatory system ceases to have any formal role in facilitating medical practice in accordance with these standards once a doctor is fully registered, except in relation to borderline cases
- The system for providing redress for those who suffer due to a failure to adhere to standards is deeply flawed
- There are very few channels which permit grievances to be aired and disputes resolved; most of those which do exist require an official to determine whether a complaint will be acted on or not or are expensive and/or hard to access
- Effective systems of investigation to inquire into whether standards are being adhered to or not only seem to exist in relation to allegations of serious criminal conduct, although this shortcoming does not necessarily prevent all regulators from being able to take action
- There are adequate systems for the punishment of those who fail to adhere to the standards, and
- There is virtually no regulation of the regulatory system itself to ensure that the above tasks are being carried out.

This is considering the current system against a hypothetical list of what a regulatory system *might* do (although this list is also arguably a description of that the system *should* do). In terms of assessing what the current system actually does, it is helpful to turn to the core evaluation criteria. The analysis here indicates that:

- Formal regulatory mechanisms are highly visible, although there are hidden preliminary stages
- Accountability for the system is largely confined to the electoral accountability of Parliament
- Most of the system is fair to those who are affected by it, with the exception of the system of civil litigation which is the only part the dissatisfied individual can access as of right.
- The system overall is effective at carrying out those regulatory tasks which it actually undertakes, although there are some exceptions
- The system is inefficient, although much of the inefficiency stems from the inefficiencies of the civil and criminal courts



- Nothing in the current regulatory system unduly interferes with good medical practice
- The system fails to accord proper respect to the autonomy of individual patients, particularly aggrieved ones.

Against this, the answer to the working hypothesis can only be given in the negative. Regulatory tasks are left undone, the overall regulatory system is unpoliced and scarcely accountable, the system is inefficient. From detailed analyses, it would appear that no-one's interests – those of doctors, patients, the wider public or the state – are well-served by this situation.

There are, of course, a number of positive aspects to these findings. Thus, while much of the process is not formalised (in particular, the setting and upholding of medical standards), this does not appear to have reflected adversely on those standards (although comparative study is impossible). None of the evaluation criteria are systematically ignored, and even those criteria which were not satisfied were not satisfied as a result of specific flaws rather than because the values reflected in those criteria are not respected by the system. And where it was possible to detect changes within the system, actual or pending, the trend of those changes was universally in a direction more in compliance with the evaluation criteria.

Perhaps surprisingly, given the disjointed and incrementalist approach which appears to have underlain all the changes to the system over the years, this thesis has not identified any instances of regulatory overlap. Where an incident or event can potentially attract the attentions of one or more regulator, this is because the attention is driven by a different regulatory function and does not represent any inefficient and unnecessary duplication of effort. The problem is not one of too much regulation. Neither, to be fair, is it one of too little regulation and it is not suggested that we immediately legislate to fill all the regulatory gaps just identified. The problem is more one of quality of regulation. The gaps which have emerged have done so because there appears to be no overarching theory of what we are trying to achieve. Ad-hoc solutions are proposed to particular problems. Regulatory systems are amended in ways which fail to consider the wider impact, and without any real thought as to the appropriate regulatory strategy. The effects of the measures adopted on the wider groups affected are not considered.

To conclude, therefore, it is worth briefly considering what factors would most easily improve the system so that the interests of doctors, patients and the state can be reconciled and adequately safeguarded.

Firstly, in terms of the regulatory gaps identified, there is a policy question to be addressed as to which of the unfulfilled regulatory tasks it would be desirable to formalise within the state apparatus. As we have seen, there is no formal mechanism for setting or (in the normal run of things) for upholding standards of medical treatment. This does not appear to have prevented the profession from setting its own standards quite successfully, and some at least would question the justification for imposing state regulation on medical practice. This has, however, increasingly happened within the confines of the NHS<sup>23</sup> which tends to remove any objection in principle to the state taking a hand in setting standards. In any case, the current revalidation proposals from the GMC may fill this regulatory gap without any further action being necessary.

Staying with the GMC for a moment, the Council for the Regulation of Health Care Professionals will at least have the potential of opening up certain internal procedures to external and independent scrutiny, which potentially removes some of the problems identified.

The biggest single improvement to the system, however, would be the removal of the civil courts from the system. The overwhelming majority of problems uncovered in the course of this thesis relate to difficulties in accessing the courts, the costs involved, delay in reaching a conclusion, and the fact that the forensic lottery is both unpleasant for doctors and loaded against patients. From the state's perspective it is an inefficient way of distributing resources to those who have a need for them, and the impact of litigation in diverting resources away from clinical care cannot be ignored. Some form of "no-fault" compensation system would appear to be a far more satisfactory approach. While some advocates of this argue that it would need to be accompanied by systems to maintain standards in the absence of litigation's deterrent effect, a quick glance at the foregoing summary shows that this is unnecessary. Civil litigation does not currently fulfil that regulatory task, and establishing a new body to do so once a "no-fault" system is established could in itself represent a regulatory duplication of the GMC's performance monitoring powers. The compensation-awarding body could in itself provide an outlet for certain grievances, and the activities of other regulators might become easier because the prospect of inadvertently prejudicing a civil court action would be removed. No-fault compensation is far from being a panacea; there are other, more deep-rooted problems in the current system. But this at least would be a tremendous step forward in removing the worst failings of the system as it stands.

**Chapter 7 notes:**

- <sup>1</sup> *Per Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582; see Chapter 4 *infra*
- <sup>2</sup> P Fenn and C Whelan, "Medical litigation: trends, causes, consequences" in R Dingwall (ed.), *Socio-legal aspects of medical practice* (1989), 12
- <sup>3</sup> Introduced by the Medical (Professional Performance) Act 1995
- <sup>4</sup> GMC website [http://www.gmc-uk.org/probdocs/probdoc\\_frameset.htm](http://www.gmc-uk.org/probdocs/probdoc_frameset.htm) (accessed 6 December 2001)
- <sup>5</sup> One study has suggested a very high success rate in ensuring conformity with such informal controls: M Rosenthal, *The incompetent doctor: behind closed doors* (1995)
- <sup>6</sup> Medical Act 1983 section 36A(1)
- <sup>7</sup> The proposals are summarised at <http://www.gmc-uk.org/revalidation/index.html> (accessed 7 December 2001)
- <sup>8</sup> Space precludes discussion of medical audit, a form of medical quality evaluation; a very recent and comprehensive review of published articles relating to medical audit can be found in Appendix XI of NICE, *Principles for Best Practice in Clinical Audit*, 2002, by R Baker *et al.*
- <sup>9</sup> M Rosenthal, *op. cit*
- <sup>10</sup> For completeness, mention should be made of the power of the criminal courts to make compensation orders following conviction; however, these are peripheral to the criminal law's main purposes and in any case appear to play little or no part in medical regulation.
- <sup>11</sup> Government statement, *Hansard*, 24 March 1998, cols. 165-166
- <sup>12</sup> Data Protection Act 1998, section 42.
- <sup>13</sup> Part V.
- <sup>14</sup> I Goldrein and M de Haas, *Medical negligence: cost effective case management* (1997), 5
- <sup>15</sup> *Id.*
- <sup>16</sup> *Anis-Uddin Manzur v General Medical Council* [2001] UKPC 55 (Privy Council 4 December 2001, unreported)
- <sup>17</sup> Subject to minor differences in jurisdiction between Scotland and England
- <sup>18</sup> The Westminster Parliament, at any rate. Acts of the Scottish Parliament can be struck down by the superior courts if outwith the legislative competence of the Scottish Parliament as conferred by the Scotland Act 1998.
- <sup>19</sup> *R v Secretary of State for the Home Department ex parte Daly* [2001] 2 WLR 1622, [2001] 3 All ER 433; *R v SSETR ex parte Holding and Barnes plc*; *R v SSETR ex parte Alconbury Developments Ltd. and Others*; *R v SSETR ex parte Legal and General Assurance Society Ltd.*, [2001] UKHL 23
- <sup>20</sup> W Bartlett & J Le Grand, "The theory of quasi-markets" in Le Grand & Bartlett (eds.) *Quasi-markets and social policy* (1993) 14-15
- <sup>21</sup> According to the National Consumer Council; see Chapter 4 *infra*
- <sup>22</sup> J Allsop and L Mulcahy, *Regulating medical work: formal and informal controls* (1996)
- <sup>23</sup> Most notably through the establishment of bodies such as the Commission for Health Improvement and the National Institute for Clinical Excellence

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