MEDICINE, PATIENTS AND THE LAW

MARGARET BRAZIER
& EMMA CAVE

IFTH EDITION

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Medicine, Patients and the Law

Fifth Edition

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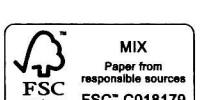

Preface

The pace of change in the National Health Service (NHS), Parliament and the law courts has not slowed down at all since our last edition in 2007. We have struggled to keep up. As we sought to complete the text at the start of 2011, the Health and Social Care Bill was published, heralding the most radical changes to the NHS since its foundation in 1948. It has proved a very exciting time to be writing about medical law. In 2010, the last ruling of the House of Lords, before it moved to the new Supreme Court, changed the face of assisted suicide. A number of cases prompted new debates about the role of the criminal law in cases of 'mercy killing'. The Human Fertilisation and Embryology Act 2008 amended the 1990 Act, dealing with past problems and creating new ones. The Health and Social Care Bill has prompted a reassessment of the interface between the various regulatory regimes in medicine. The fate of the Human Fertilisation and Embryology Authority and the Human Tissue Authority lies in the balance. Lord Justice Jackson's proposals for reform of clinical negligence claims are under consideration and legal aid for such claims looks set to be abolished. Both the Clinical Trials Directive and the Data Protection Directive are under review. We can only apologise to our readers for the number of times they will encounter the phrase 'at the time of writing'. We have tried to identify sources to guide the reader through this tumultuous period of medical law reform.

The first edition of this book was published in 1987. There was much less medical law to write about then, and in 2011 it often seems as though every chapter of the book could easily grow into a book in its own right. We cannot cover every key issue in the depth that we might wish to. We continue to hope that the work remains readable to a broad audience, and offers a picture of the way that law and medicine relate to each other that will engage the interest of students, lawyers, health professionals and the general public. We are all affected by how law regulates medicine. As before, we do not attempt to cover mental health law as such. To do so would double the length of the book. We do, in chapter 6, address complex and seemingly intractable questions about vulnerable patients, mental capacity and consent to treatment. We have merged chapters 11 (Family Planning) and 12 (Pregnancy and Childbirth) into one chapter entitled Contraception, Pregnancy and Childbirth. As medical care involves women and men, as both doctors and patients, we use the pronouns she and he interchangeably. We could not be comfortable with the 'old' legal

tradition of using only the male pronoun, and he/she (or s/he) seems intolerably clumsy.

We remain in debt to Professors Harry Street and Gerald Dworkin who were initially to have co-written this work with Margaret Brazier. Harry Street's untimely death, and Gerald Dworkin's many other commitments, prevented those original plans coming to fruition. We want to thank all our colleagues at Manchester, Leeds and elsewhere for their unstinting help and advice. Colleagues from the disciplines of law, bioethics and medicine have listened patiently as we tried out ideas on them, and advised us as the work progressed. We owe a particular debt over many years to Maureen Mulholland, Marie Fox, Jean McHale, Sara Fovargue, Suzanne Ost, John Harris and Charles Erin. Jean McHale and Hazel Biggs kindly advised on a number of issues relating to this new edition. We owe special thanks to Anne-Maree Farrell and Kirsty Keywood who have helped us immensely with materials and advice for chapters 6 and 8, and to Sarah Devaney, Neil Allen and Peter Gooderham who patiently read draft chapters for us. It was a great sorrow that Peter died so suddenly in February 2011. We are indebted to David Pickworth and Helen Moore for their invaluable advice on the practical implications of recent reforms. We also thank our students who often challenge our views and force us to think again on many issues. And we are especially grateful to Beverley Clough and Chantel Davies who prepared all the Tables for us. This edition could not have been written without the support and encouragement of our families, Rodney and Victoria Brazier, and Simon, Hannah and Tom Cave.

Any criticism of medical practice in this book is the result of academic endeavour and not personal experience. We are grateful for the care our families have received from general practice and NHS hospitals. We care passionately about the NHS. Were all care of the standard that we have received, this book would be shorter.

No book on this subject is ever wholly up to date. This book is (we trust) up to date to 7 February 2011.

Introduction

The law's relationship with medicine has become a highly publicised affair. Rarely a day passes without media coverage of some new controversy surrounding medical practice, or medical ethics. Cases relating to the rights and responsibilities of doctors and patients feature regularly in the Law Reports. The medical profession finds itself in the limelight. One day the doctor is hailed as a saviour. The next she is condemned as authoritarian or uncaring. Advances in medical science, extending life at one end and bringing new hope to the childless at the other, have given rise to intricate problems of law and ethics. At every level of medical practice, law plays a role. Doctors cannot escape the reach of the law. For many medical practitioners, the rise in the number of malpractice claims is their main concern. Despite legislation designed to tackle a perceived 'compensation culture', doctors still fear an epidemic of US proportions. Some refuse to risk an apology or even to explain what went wrong, lest their careers and reputations suffer should the patient choose to litigate. Patients still find the pursuit of any grievance frustrating. Despite significant reforms of the civil justice system, litigation is expensive and slow. In 2011, people also seek a greater say in their own treatment. Patients are no longer prepared to be patient. The extent to which patients have a right to determine their own treatment is a question for the law. How far patients who claim rights are also subject to responsibilities is increasingly debated.

It is not only the narrow question of our own health needs that concerns people today. Many of the recent scientific developments are themselves controversial. Research on embryos, 'saviour siblings', human cloning, organ retention – all excite controversy. Older controversy about abortion and euthanasia gets no less difficult with time. The purpose of this book, then, is to examine how medical practice is regulated, to analyse the rights and responsibilities of doctors and patients, to look at the provision of compensation for medical wrongdoing or error, and to explore the framework of legal rules governing those delicate questions of life and death when medicine, morals and the law overlap. It is easy to perceive law's relationship with medicine as one of conflict, mirroring conflict between doctors and their patients. We suggest that this is a 'false' conflict. What the medical profession, patients and the public need is for:

- the medical profession to be properly regulated;

- where possible, the rights and obligations of patients, doctors and other health professionals to be clearly defined;
- there to be an adequate, fair and rational system of compensation for patients suffering injury;
- there to be effective means of investigating medical accidents and errors;
- the law (together with professional guidelines) to offer comprehensive guidance on those areas of medical practice of moral and ethical sensitivity.

Sources of law

In contrast to most European countries, the law of England is not to be found neatly encapsulated in any Code. The task of the non-lawyer seeking to establish her rights, or ascertain his duties is far from easy. The law relating to medical practice is to be discovered from a variety of sources. Parliament has enacted a number of statutes governing medical practice. The regulation of medical practice and the disciplining of the defaulting doctor have traditionally been entrusted by Act of Parliament to the General Medical Council (GMC), by virtue of the Medical Act 1983. That Act has already been substantially amended, and further reforms altering the powers of the GMC are planned. The organisation of the health service has been governed by a series of statutes on the National Health Service, now consolidated in the National Health Service Act 2006, which will require significant amendment if the Health and Social Care Bill 2011 survives the Parliamentary process. The Medicines Act 1968 is concerned with the safety of drugs. A number of other Acts of Parliament, such as the Abortion Act 1967 and the Human Fertilisation and Embryology Act 1990 (as amended), the Human Tissue Act 2004 and the Mental Capacity Act 2005, are crucially relevant to questions about medicine, patients and the law. An Act of Parliament can create only a general framework of legal rules. Acts of Parliament, therefore, commonly empower government ministers to make subsidiary regulations known as statutory instruments. These regulations may determine crucial questions. For example, most of the duties of GPs within the NHS are dealt with by regulations and not by Acts of Parliament.

It is impossible today to understand the legal rules governing the practice of medicine without reference to European law. In matters within the jurisdiction of the Treaty of Rome and subsequent treaties, notably the Treaty of Amsterdam, the EU is empowered to make laws affecting all member states. This may be by way of regulations which immediately and directly become law in the UK, or by way of directives which oblige the UK government to introduce an appropriate Act of Parliament to give effect to the directive. In 1985, a Community directive on liability for unsafe products resulted in the Consumer Protection Act 1987 which, as we shall see in chapter 9, introduced strict liability for defective drugs. The Data Protection Directive is considered in chapter 4. The Clinical Trials Directive, promulgated in April 2001, obliged the UK to introduce reforms of the law governing medical research. This was done by way of a new set of regulations – the Medicines for Human Use (Clinical Trials) Regulations 2004. At the time of writing both the Clinical Trials

Directive and the Data Protection Directive are under review. New scientific innovations and pressure to facilitate medical research provide strong incentives for reform. Provisions of the EU treaties themselves may be invoked to make a case for greater rights for patients. This is how Diane Blood won her case to be allowed to be inseminated with her dead husband's sperm abroad.

The EU must not be confused with the European Convention on Human Rights. That Convention is a separate treaty to which the UK is a party. The Convention seeks to establish the rights of the individual and directly addresses questions such as rights to life, to privacy, and to found a family. The Human Rights Act 1998 renders rights granted by the Convention enforceable against public authorities in the United Kingdom. As we shall see, the Act has transformed areas of medical law and, as a living instrument, that potential does not diminish with time.

Conventions, statutes and statutory regulations alone, be they British or European legislation, by no means paint the whole picture of English medical law. Much of English law remains judge-made: the common law of England. Decisions (judgments handed down by the courts) form precedents for determining later disputes and define the rights and duties of doctors and patients in areas untouched by statute. The common law largely governs questions of compensation for medical accidents, the patient's right to determine her own treatment, parents' rights to control medical treatment of their children and, as we shall see, several other vital matters.

We deal with English law. The common law is not confined to England. Decisions of courts in the USA, Canada and elsewhere are mentioned from time to time. Such judgments do not bind an English court. They can be useful as examples, or warnings, showing us how the same basic principles of law have developed elsewhere. Finally, it must be remembered that for the lawyer, Scotland counts as a foreign country. Scotland maintains its own independent legal system and, post-devolution, enjoys the power to legislate independently on most issues relating to medical care. Scotland has, for example, enacted its own Human Tissue (Scotland) Act 2006. On many of the questions dealt with in this book, English and Scottish law coincides. Occasionally, the law in England and Scotland diverges. We confine ourselves to stating the law as it applies in England and Wales. The problems of law and medicine embodied in the book are common to the UK as a whole.

Part I

Part I of this book begins by seeking to examine the overall framework of medicine today. How does the law seek to ensure that patients are treated by competent, qualified doctors practising ethical medicine? Does the GMC, which for over a century and a half has regulated the medical profession, meet patients' needs? What rights do we enjoy in the context of health care and how has the Human Rights Act 1998 affected medical law? Law can, at best, only set basic standards of behaviour. So we explore some of the ethical principles and dilemmas in modern medicine. Then in the final chapter of this first Part,

we examine that critical component of any doctor–patient relationship, the necessity for trust and confidence. Can we be assured that our doctors will respect our privacy so that we can feel confident enough to be wholly frank with them? In what exceptional circumstances should that duty of confidence be breached to fulfil some more pressing responsibility to others?

Part II

In this Part, we examine what remedies the law affords a patient dissatisfied with the medical care which he or she has received. A patient may feel that he has not been fully consulted or properly counselled about the nature and risks of treatment. He may have agreed to treatment and ended up worse, not better. Consequently the patient may seek compensation from the courts. Or he may simply want an investigation of what went wrong, and to ensure that his experience is not suffered by others. It is the rise in litigation that has caused so much anxiety among doctors.

The law relating to medical errors, often described as medical malpractice, operates on two basic principles. (1) The patient must agree to treatment. (2) Treatment must be carried out with proper skill and care on the part of all the members of the medical profession involved. Any doctor who operated on or injected, or even touched, an adult patient against her will might commit a battery, a trespass against the patient's person. A doctor who was shown to have exercised inadequate care of his patient, to have fallen below the required standard of competence, would be liable to compensate the patient for any harm he caused her in the tort of negligence. In short, to obtain compensation, the patient must show that the doctor was at fault. And if she sues for negligence, she must show that the doctor's 'fault' caused her injury. Three overwhelming problems are inherent in these two simple statements.

First, how do courts staffed by lawyer-judges determine when a doctor is at fault? We shall see that the judges in England used to defer largely to the views of the doctors. Recent case law suggests judges are now more ready to scrutinise medical practice. Establishing what constitutes good practice will still cause the court some difficulty. The courts remain dependent on expert evidence and a clash of eminent medical opinions is not unusual.

Second, as liability, and the patient's right to compensation, is dependent on a finding of fault, doctors naturally feel that a judgment against them is a body blow to their career and their reputation. Yet a moment's reflection will remind the reader of all the mistakes she has made in her own job. A solicitor overlooking a vital piece of advice from a conference with a client can telephone the client and put things right when he has a chance to check what he has done. A carpenter can have a second go at fixing a door or a cupboard. An overtired, overstrained doctor may commit a momentary error which is irreversible. He is still a good doctor despite one mistake.

Finally, the doctor's fault must be shown to have caused the patient harm. In general, whether a patient is treated within the NHS or privately, the doctor

only undertakes to do his best. He does not guarantee a cure. The patient will have a legal remedy only if he can show that the doctor's carelessness or lack of skill caused him injury that he would not otherwise have suffered. So if you contract an infection and are prescribed antibiotics which a competent doctor should have appreciated were inappropriate for you or your condition, you can sue the doctor only if you can show either: (1) that the antibiotic prescribed caused you harm unrelated to your original sickness, for example, brought you out in a violent allergy; or (2) that the absence of appropriate treatment significantly delayed your recovery. And in both cases you must prove that had the doctor acted properly, the harm would have been avoided.

We shall see therefore that the law is a remedy only for more specific and serious grievances against a doctor. It is in any case an expensive and unwieldy weapon. Many patients have complaints, particularly about hospitals, which do not amount to actionable negligence. They complain about being kept waiting, inadequate visiting hours, or rudeness on the part of NHS staff. We shall look in this Part at extra-legal methods of pursuing complaints against a hospital or a doctor, and we consider if the whole system for compensating medical errors should be replaced by a no-fault compensation scheme. Nor do we limit our examination to faults alleged against medical practitioners. Many medical mishaps arise from the dangers inherent in certain drugs. We consider the liability of the drug companies and attempts by government to ensure that available medicines are safe.

Finally, we should say a word about legal 'language' today. The person who initiates a legal action, for example, the patient suing a doctor for battery or negligence, used to be referred to as the plaintiff. When Lord Woolf recommended radical reforms of the civil justice system, some of which are discussed in chapter 8, he also proposed that old-fashioned language should be changed into plain English. So today, the patient bringing a claim against a doctor is simply called the claimant. Where we discuss cases decided before 1999, we use the old term 'plaintiff'. Defendants, thankfully, remain just that, defendants.

Part III

The first two Parts of this book focus on the relationship of doctors and patients, both the framework of that relationship and how the law deals with conflict when a patient is dissatisfied with the care that he has received. Part III looks at the dramatic questions in medical law where what is at stake is not only what an individual patient may be entitled to, but also what society should allow. The range of questions addressed is broad. Others are omitted simply on grounds of space. We consider whether parents who find themselves with an unplanned child after receipt of negligent medical advice or treatment, should receive compensation to meet the cost of raising that child. What duties are owed to an unborn child, and should pregnant women continue to enjoy legal immunity from liability to their future children? We venture into the troubled waters of the reproductive technologies, seeking to explain and analyse the law governing such matters as the creation of 'saviour siblings', human

cloning, hybrid embryos. But we also attempt to address practical questions – how to define parental status, and access to information about gamete donors. Medical research, transplantation and the especial problems around the medical care of children are addressed. We end (appropriately) by examining laws relating to the end of life, and debates about euthanasia.

Law matters

Medical law has altered beyond recognition in the twenty years since the first edition of this book. No-one who reads a newspaper or watches television can be unaware of the sorts of questions which we address. On an almost weekly basis, new initiatives or new laws are proposed. Sometimes it seems as though the dizzying pace of reform reflects little thought about the whole picture. More attention is paid to policy and ethical debate than law. There is insufficient rigorous analysis of what the limits of the law's remit should be. One set of lawyers, doctors and patient groups address the adequacy (or inadequacy) of malpractice litigation. Ethicists, journalists and legal theorists join doctors and theologians in debating the grand moral dilemmas of medicine. Lay people tend not to get much of a chance to have their say until some controversy breaks, such as the scandals around poor standards of care at Mid-Staffordshire Foundation Trust. For all these reasons, this book seeks to concentrate more on law than ethics as such, and to attempt to locate our discussions of the law in a practical context. We hope that we can dispel the myth that law is 'boring'. We hope that our discussion may cast some light on what the role of the law should be in the context of modern medicine.

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