

# **ELEMENTS OF MEDICAL LAW**

**Second Edition**

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**CHARLES FOSTER**



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Every law book is woven from the ideas of thousands of people. The legislators and the judges do the main strands, and then everyone the writer talks to contributes something to the rest. All barristers spend a lot of their lives wandering into other people's rooms and asking them for their view on things. So I owe a lot to all my colleagues and opponents at the medical bar. Professor Tony Hope and Professor Mike Parker at Oxford have helped me to look at some of these problems through the eyes of clinical ethicists, and convinced me that promiscuous cross fertilisation between ethical theory and law is necessary to produce a medico-legal creature with enough hybrid vigour to deal with the exhausting and exciting challenges of medical advance.

Some parts of some sections appeared in some form in articles by me in the Solicitors Journal, the New Law Journal, Counsel magazine, Family Law and the Journal of Personal Injury Law. I am very grateful to the publishers for permission to reproduce parts of those articles.

No one could ask for a more congenial publisher than Lukas Claerhout: I am so grateful to him for his belief in this project.

Much of this book was written in David Monteath's house in southern Poland, in between episodes of misanthropic pacing. His hospitality and long suffering were crucial.

But Mary, a doctor who will never need any help from anyone in my corner of the law, bore the brunt of my moodiness and absence. This book is dedicated to her.



# PREFACE

This book stems from a number of convictions.

First: medical law is nothing like as difficult as practitioners in the field (like myself), pretend that it is. There are lots of intimidating and very good books on medical law which bristle with footnotes. Unless you are one of the cognoscenti, those books are unreadably thorough: you would never be able to sketch your own mental map of the subject from wandering through them. I reckon that there are just a few landmarks in the subject. Fix them, and you will be able to take your own line across country on most medical law matters.

Second: medical law is far and away the most fascinating corner of the law. It deals with life and before it, and death and after it. There's not much left. The cases which illuminate it are the most tragic and happy and colourful, as the medico-legally obsessed tabloids agree.

Third: medical law matters. It is bound to, given its scope. It says a lot about what society thinks is the essence of a human being. Other areas of law hint at this: medical law is forced to say it directly.

Fourth: medical law is utterly incoherent. It is a sort of philosophical pick and mix. If you are kind you put that down to pragmatism. If you are not you sometimes put it down to intellectual dishonesty and sometimes to downright sloppiness. The law is old, and too often gives old answers to new problems. Medicine is evolving fast, throwing down new philosophical gauntlets to the law as it does. The law is sometimes too tired to pick them up.

Fifth: it is possible for the law to be more coherent than it is. There are some principles which appear everywhere. They are mostly ethical: like a respect for human autonomy, and a realisation that autonomy has limits.

I have tried to give the co-ordinates of the main landmarks. The book should therefore be useful to anyone who wants to know something about the black-letter law; whether student, practising lawyer, doctor or interested layman. I have also dealt in more detail than a student's crammer would want with the difficult and controversial cases, asking what if any principles drove the judges concerned, and commenting on ethical and legal discordances with other cases. You can't just brush the case of the conjoined twins under the forensic carpet, commenting that hard cases make bad law, as if that were a reputable philosophical position. It will certainly come crawling back out at an embarrassing time if you do. Nor is it good enough to keep the case in a museum of legal monstrosities, to be peered at for entertainment outside working hours. Better to see where it comes from and where it is going. If you decide that the doctors who withdrew Tony Bland's feeding tube aren't murderers because the withdrawal was an omission, you can't object loudly, or at any rate honestly, if obviously murderous omissions go

unpunished. Better to look at whether there is a real distinction between acts and omissions, and if so or if not, what to do about it.

I have failed, of course, but at least I had a go.

The law is as I reckon it is in November 2006.

**Charles Foster,  
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**November 2006**

# CHAPTER 1

## LEGAL ISSUES BEFORE BIRTH

### THE LAW OF GENETICS

This is straightforward. There isn't any. Genetics has to borrow its law from other areas. It is therefore unsurprising that the law doesn't fit properly, looks odd, and rubs painfully in sensitive places. The law has failed to keep up with genetic advances. This is worrying, because whatever one thinks about the law which governs genetics, it matters. Everyone agrees: witness the hysteria over genetically modified crops, the almost universal horror at the idea of human reproductive cloning and the concerns about the use of DNA banks.

The problem is that genes and DNA are difficult to classify. English lawyers are tidy, conservative creatures who get upset if they cannot put concepts neatly into ancient pigeonholes. DNA confounds them. It is a physical substance: English lawyers tend to respond to that fact by saying that it should be governed by the law of property. It also bears information: English lawyers tend to react to that by saying that it should be governed by the law of confidentiality and/or intellectual property. Confidentiality and the law of property are two entirely different conceptual islands. There is little communication between them. The lawyers who practise on one island do not regard themselves as qualified to practise on the other. This has led to a dangerous incoherence in the law. The Human Genetics Commission has noted the need for legislation. The request is likely to be well down the list of any Government's legislative priorities, although the Human Tissue Act 2004, discussed in detail in Chapter 5, does remove some of the uncertainty about what can legitimately be done with DNA.<sup>1</sup>

#### Genetic confidentiality

The general law of confidentiality is considered in detail in Chapter 3. At the heart of the common law and the codifying statutes are two notions. They do not always stand easily together. First is the idea that the conscience of the discloser is a crucial determinant of whether a breach of confidence is actionable. In *R v Department of Health ex p Source Informatics Ltd*<sup>2</sup>, a case about pharmacists, Simon Brown LJ said, having reviewed a number of cases:

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<sup>1</sup> The Act applies to "material other than gametes which consists of or includes human cells": s. 53(1). Embryos are excluded: so are hair and nail from a living person.s. 53(2). Once DNA is extracted, it does not fall under the general provisions of the Act because it does not "consist of or include human cells." Thus the Act deals specifically with dealing with DNA in several sections: see in particular s. 45 and Schedule 4

<sup>2</sup> [2000] Lloyd's Rep. Med. 76

*“To my mind the one clear and consistent theme emerging from all these authorities is this: the confidant is placed under a duty of good faith to the confider and the touchstone by which to judge the scope of his duty and whether or not it has been fulfilled or breached is his own conscience, no more and no less. One asks, therefore, on the facts of this case: would a reasonable pharmacist’s conscience be troubled by the proposed use to be made of patients’ prescriptions? Would he think that by entering [the data collection agency’s] scheme he was breaking his customers’ confidence, making unconscientious use of the information they provide?”<sup>3</sup>*

In deciding what the conscience of a reasonable professional says, the courts always pay close attention to the disciplinary codes of the professional organisations. In the past the courts have tended to be more forgiving than the professional conduct committees. There are some signs that that is changing. Increasingly a disclosing doctor will be damned by the court if he would be damned by the GMC, and excused by the court if he would be excused by the GMC.

The other principle is that a breach of confidence will be actionable if the public interest in disclosure does not outweigh the public interest in maintaining confidence. The balancing of public interests is quintessentially a judicial activity. It presupposes an objective answer: where, objectively, does the public interest lie? That is in stark contrast to the partial subjectivity of the *Source Informatics* enquiry: “What should register in the conscience of the (admittedly reasonable) professional?” There is a lot less room for manoeuvre in the public interest balancing test than in the conscience test. Either something is in the public interest or it is not. But professionals can and very often do differ very materially but very reasonably over matters of conscience.

There are also concerns about how genetic information might be used under the provisions of the sinister s. 60 of the Health and Social Care Act 2001. Section 60(1) provides that “*The Secretary of State may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed patient information for medical purposes as he considers necessary or expedient- (a) in the interests of improving patient care, or (b) in the public interest.*” This is potentially very scarily wide. It must be watched carefully. Lots of genetic information is thrown up incidentally in the course of routine genetic testing for specific conditions. Would regulations permitting that information to be held as part of a national database of epidemiological information about the incidence of particular damaging genetic traits be *ultra vires*? It is unlikely. And why stop at information about specific traits? Almost all genetic information is potentially medically significant. Do we really want the National Health Service, and anyone capable of hacking into its computers, to have access to information about ourselves which even we do not know? Is it ethical to hold potentially life-saving information about a patient and not disclose it? If the general answer to

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<sup>3</sup> At 82

that question is no, what about the patient's right not to know? The creation of a national genetic database, as is proposed in Iceland, has political connotations: if the state knows more about each citizen than the citizen knows, the relation between the individual and the state has shifted significantly. What on earth does Article 8 of the ECHR have to say about all this? Some of the answers to the ECHR question have been hinted at in contexts other than genetics, and are outlined in Chapter 3.

These are big issues. For lawyers there are lots of smaller but succulent bits and pieces in the pot of genetic confidentiality. By s. 170(b) of the Road Traffic Act 1988, for instance, where the driver or rider of a vehicle is alleged to be guilty of a road traffic offence, "*any other person shall if required.....give such information which it is in his power to give and may lead to the identification of the driver.*" Does this require a person who is a relative of a suspected driver to undergo genetic testing in order to confirm the suspect's identity? And what about the National Health Service (Venereal Diseases) Regulations 1974, which permit disclosure of information relating to "sexually transmitted diseases" where that disclosure is necessary to prevent the spread of the disease. Genetic diseases are obviously in one sense "sexually transmitted". Do the regulations permit a doctor to trumpet abroad the information that Mr. A is the carrier of a gene for a particular disease so that his chances of passing it on are reduced?

### **Gene therapy**

One's genes can sometimes be tinkered with so that they act in a helpful way towards disease. On its face there are no great difficulties with that. But what if (a) the process of tinkering incidentally alters your genetic makeup in a way which will be reflected in any offspring you produce; or (b) the tinkering is intended not to affect you but to alter your germ cells so as to create or eliminate characteristics in any offspring? One would have thought that the law would have least seen the potential problems. But it appears not to have done.

### **Intellectual property in genetic material**

The ethics of patenting genetics and genetic information are tricky. Obvious and important questions about human dignity and autonomy arise, but have featured little in the public debate. That debate has been rather crudely pragmatic. The biotechnology companies have pointed out that the potential benefits from gene research are colossal, but that this research is extremely expensive and simply will not happen unless the fruits of research can be protected by a patent. They have also relied on the observation that isolated genes do not occur naturally, and say that accordingly to patent a gene is not patenting nature. Opponents of this position have tended to assert that it is offensive to make money from human body parts. The rhetorical landscape is littered with slippery slopes and dubious parallels between gene sales and prostitution.

The law is summarised in Directive 98/44 EC, which has been implemented in the UK in The Patents Regulations 2000<sup>4</sup>, The Patents (Amendment) Rules 2001<sup>5</sup> and The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002<sup>6</sup>. It is complex, and gives little comfort to conservatives. There are predictable prohibitions on the patentability of processes for cloning human beings or modifying the germ line genetic identity of human beings, and also for modifying the genetic identity of animals where that modification causes suffering and where there is no likely substantial benefit to man or animal, but, that said, the tone of the rules is very much in favour of recognising intellectual property rights in genetic products. The simple discovery of an element of the human body is not patentable, and this includes the sequence of partial sequence of a gene<sup>7</sup>, but the force of this is hugely diminished by the provision that “*An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*”<sup>8</sup>

### **Questions relating to the ownership of gametes**

The 1990 Act has detailed provisions dealing with the use that can be made of sperm and eggs provided in the course of treatment governed by the Act<sup>9</sup>. Some of the litigation about these provisions has received a lot of media coverage. The classic example is the Diane Blood case, in which the English courts found that the Act did not entitle Diane Blood to use the sperm of her dead husband because he had not given the requisite written consent for its use<sup>10</sup>. There was public outrage there. It seemed very unfair to many. But rules were rules, said the court. The philosophy behind those rules is clear enough. Bequeathing genes to the next generation is a serious business. No-one should be made to reproduce against his or her will. Parliament had in mind many spectres when it approved the legislation. One was of a man being confronted by a son, of whom he had no knowledge, claiming an emotional relationship. That sort of confrontation, said Parliament, was good neither for the father nor the son. Another was of a child, or its mother, seeking some sort of financial contribution from a father who never knew he was a father. The European Court of Human Rights has shown itself very reluctant to query national solutions to the sort of dilemmas thrown up by the *Blood* case – most recently in its judgment in the case of Natalie Evans.\*

Outside the ambit of the 1990 Act, however, the position is much less clear. What happens, for example, if a woman removes semen from a condom used by her

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<sup>4</sup> SI 2000/2037

<sup>5</sup> SI 2001/1412

<sup>6</sup> SI 2002/247

<sup>7</sup> The 2000 Regulations, Schedule A2: Regulation 3(a)

<sup>8</sup> The 2000 Regulations, Schedule A2: Regulation 5

<sup>9</sup> Gametes are expressly excluded from the Human Tissue Act 2004: see s. 53

<sup>10</sup> *R v Human Fertilisation and Embryology Authority ex p Blood* [1997] 2 WLR 806: see too *U v W (Attorney-General Intervening)* [1997] 2 FLR 282

boyfriend and, knowing that he would object, inseminates herself with it? The simple answer is that we don't know. The difficulty arises from the English law's uncertainty about the ownership of body parts and body substances. The uncertainties relevant here have largely survived the Human Tissue Act 2004. The 2004 Act governs dealing with elements that consist of or include human cells. Semen certainly qualifies<sup>11</sup>. But what if the culpability relates to the use made of the gametes – not covered by the Act? If one considers first the criminal law possibilities, has the girlfriend committed any criminal offence at all? Even if the law would regard the semen as capable of constituting property (and there is a big debate about that, outlined in Chapter 5), can she sensibly be said to have stolen it? Has the boyfriend not abandoned it, in a way analogous to throwing an empty bottle into a dustbin? If so, it is not “property belonging to another”, within the meaning of the Theft Act 1968, and cannot be stolen. Probably the better position is that no offence has been committed.

The position in civil law is equally uncertain. Presumably, in order for the girlfriend to have “converted” the sperm to her own use (acted with it in a way inconsistent with the rights of the owner), one would have to assert not only that there was property in the sperm (facing the same difficulties as in the criminal law definition of property, discussed above), but also that the boyfriend had a continuing proprietary right (facing the same difficulties as in the criminal law definition of abandonment, discussed above). The law should be more pragmatic in its definition of property and abandonment. It should assert that there is property when to fail to do so would lead to an obviously unjust result, and conclude that there is no abandonment where the abandoner would decree that the abandoned material should not be used in the way that it has been. A proprietary right, in other words, should persist for as long as (a) nobody else has acquired better title; and (b) the original title holder wishes to assert his right, for purposes in accordance with the general policy of the law.

Answers to these criminal and civil questions will be needed sooner or later. An answer to the criminal question is needed for the same policy reasons which lie behind the 1990 Act: this mishandling of gametes is obviously undesirable and needs to be discouraged. An answer to the civil question is needed because, under the existing family law, a man propelled unknowingly and unwillingly into fatherhood in the self-insemination circumstances described above might well be saddled with financial liability for the child. Most people would think that this is wrong. The family legislation could be altered, but a re-draft would create some big problems of its own. It would be neater if the civil law entitled a man to bring an action for conversion of his semen - part of the damages for which would be any financial liability he shouldered under the Child Support legislation. He would no doubt want to annexe to this claim a plea for damages for breach of his right under Article 8 of the European Convention on Human Rights.

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<sup>11</sup> Section 53