PREFACE

In some quarters, there continues to be scepticism over medical law's claim to be a distinctive area of legal scholarship, as opposed to a melting pot of tort, criminal, family and public law with some applied ethics thrown in for good measure. What is uncontroversial, on the other hand, is that some medico-legal questions have received much more academic commentary and analysis than others. Lawyers are often drawn to the complex issues that arise in malpractice litigation and in applications for judicial review, and it is easy to see why academics, as well as the general public, are fascinated by the complex and thorny ethical issues that arise at the beginning and end of life. Clashes between and autonomy and other values, such as beneficence or the public good, are played out in debates over the best way to solve the organ shortage. Medicines regulation, in contrast, has attracted comparatively little attention.

I do not mean to suggest that the regulation of medicines has been ignored altogether, although it is noteworthy that, within the UK, sociology journals are more likely than law journals to contain articles devoted to defects or gaps in the regulation of medicines. There are a number of scholarly works which explain the increasingly complex web of European Directives; indeed, given the impact of the EU on medicines regulation, it has clearly represented an important case study in the field of European law. There is also a burgeoning literature, much of it coming from the US, describing alarming, not to say shoddy or even downright illegal practices in the pharmaceutical industry.

At the risk of drastic over-simplification, analysis of medicines regulation tends to fall into one of two camps. Either it explains, describes and evaluates existing regulation, or it draws attention to the negative consequences of drug companies' relentless pursuit of profit. My purpose in this book is to try to steer a course between these two poles by concentrating on the way in which regulation shapes behaviour. It should not surprise anyone that a for-profit company, which is under a duty to maximise shareholder value, will strive to increase its profits within the rules that constrain its activities. Those rules are therefore critical, since both their content and their implementation will largely determine the limits of what the pharmaceutical industry can do, and therefore does, in its pursuit of the bottom line.

To take a concrete example: many commentators are critical of the fact that drug companies often seem to be more interested in developing 'me-too' drugs – that is, new versions of existing profitable medicines – than they are in discovering novel treatments for neglected diseases. In practice, however, castigating drug companies for acting in the best interests of their shareholders diverts attention away from the role that the law plays in *facilitating* and *encouraging*, albeit not

intentionally, the development of drugs that do not offer much, if any, improvement over existing and well-tolerated medicines. Rather than worrying about why drug companies do not behave more like charities, we should instead focus upon the regulatory framework which specifies the essential prerequisites for receiving a licence to market a new medicine. If it is only necessary to prove that a drug is safe and marginally more effective than nothing, then this is what clinical trials will set out to prove. There is no point in lamenting the fact that many new drugs offer no improvement over established medicines if such a requirement is absent from the criteria which must be satisfied before a marketing authorisation can be granted.

The pharmaceutical industry is a global one: a series of mergers towards the end of the twentieth century means that a handful of supranational companies are now responsible for developing and supplying almost all branded medicines worldwide. These companies are extraordinarily powerful, and countries which institute hostile regulatory regimes may find that important sources of employment and tax revenues simply move abroad. It would probably be impossible to institute a uniform global regulatory system, although attempts at harmonisation of certain aspects of the licensing process do exist. Nevertheless, while this book concentrates on the UK, and inevitably also the European legal framework, the way in which the development and supply of medicines is regulated in other parts of the world is also important. Clinical trials, for example, commonly cross national borders, taking place in many countries simultaneously. If a UK-based company is carrying out research in India, the Ukraine and Japan, for a medicine which it intends to market worldwide, whose rules should govern the conduct of those trials?

Although it is important not to ignore the global reach of the pharmaceutical industry, the UK offers an especially interesting site for investigation of what might be described as a clash of cultures between for-profit drug companies and state-run healthcare provision. At the time of writing, there is much greater private involvement in the supply of healthcare in other high-income countries than there is in the UK. In Australia and in most European countries, state funding for healthcare exists in tandem with private insurance, and reimbursement schemes are more common than Aneurin Bevan's vision of the NHS as a comprehensive healthcare system, free at the point of use. Of course, in the US, the healthcare system is thoroughly saturated with for-profit companies that provide health services, manage care and offer insurance schemes.

It seems likely that recent reforms to the NHS will give a greater role to private providers, but nevertheless the UK has a long and proud history of publicly funded and state-run healthcare provision. Obviously, the treatment we receive within the NHS is not limited to medicines, but equally they are an important aspect of the care which the NHS provides, and critically, they are developed and supplied by the private sector. Imagine that an orthopaedic surgeon working in the NHS develops a promising new way to treat torn knee cartilage. The surgeon's first step will not be to obtain a patent for his new technique and prevent anyone else from carrying out surgery in the same way for 20 years. Rather, the surgeon is likely to

seek to publish his results in a medical journal and discuss them with colleagues. In contrast to this public-service ethos, the development of a new medicine is treated as a private good, to be patented and profited from, even though, like the innovative surgeon's salary, it will be paid for by public funds.

The lack of fit between the private and public good models of healthcare provision is an important theme that emerges in several different contexts in this book. One particular point of pressure is the moment at which a medicine's chemical formulation moves from being a trade secret, protected by patent law, to being part of the publicly available 'knowledge commons'. Deciding to grant manufacturers 20 years of patent protection enables them to recoup their costs and make a profit, but it inevitably does so at the expense of making medicines available cheaply more quickly. Of course, in theory the patent system also protects public health by creating an incentive towards innovation. In practice, however, because it is possible to patent medicines which do not represent a 'step-change' for patients, patents incentivise the development of profitable medicines, and these are not always necessarily especially innovative.

The chief purpose of this book is to tell the 'story' of a medicine's journey through the regulatory system in the UK. First, it is necessary to define what a medicine is, and what it is not, and this means contemplating where alternative and complementary medicines might fit within the regulatory scheme. Next, the medicine must successfully complete the various phases of clinical trials in order to gather evidence sufficient for it to be granted a marketing authorisation. Once a medicine is licensed for use, it continues to be monitored, and if safety problems emerge, litigation is possible. After licensing, the medicine's manufacturer will market its new product, to both prescribers and consumers, and decisions must be taken within the NHS about its affordability.

While the UK's regulatory regime is this book's principal focus, it quickly became apparent that a book on medicines regulation which ignored global access to medicines would fail to address an issue of growing political importance, and one where the question of whether medicines should be treated as a private or a public good comes into particularly stark focus. As a result, the chapter on the funding of medicines within the UK is followed by one which addresses global access to medicines and vaccines.

Two further specific challenges exist to the future of medicines regulation, and these are dealt with separately in the final two chapters. First, it is possible that pharmacogenetics might end the blockbuster model of drug development, whereby medicines are developed for the population as a whole. Genetic testing could enable medicines to be targeted much more specifically to subgroups of the population in whom they are likely to be safe and effective, and while this could have obvious health benefits for patients who receive effective treatment more quickly, by shrinking the potential market for new medicines, it also raises a number of distinctive issues. What will happen to people with rare genotypes for whom it will not be profitable to develop medicines? Unlike genetic testing that can identify future susceptibility to disease, pharmacogenetic testing might reveal that

someone will be largely untreatable in the future. Routine pre-prescription genetic testing might also raise new confidentiality issues, and although patients would have the right to refuse testing, this might decrease their access to medicines.

Second, we normally think of medicines as something we take when we are ill, to restore us to health or to alleviate our symptoms. Of course there have always been exceptions to this: the contraceptive pill is a good example of a medicine which is intended to improve quality of life by enabling women to control their fertility. The development of more medicines which are intended to enhance well-being or performance, rather than treat disease, has led to interest in whether we might be entering a new era of cosmetic pharmacology, in which taking medicines may be a lifestyle choice, rather than a public health good. Does enhancement medication raise any special ethical issues – is it cheating, for example, and should it be routinely available within the NHS?

Throughout, I hope to demonstrate that law and regulation are important 'actors' in the development and supply of medicines. This is not to anthropomorphise law, rather it is to argue that those responsible for the content of the regulatory regime, and the way in which it is administered, play a crucial role in shaping the development, supply and marketing of medicines. If we believe that drug companies devote too much energy to developing new treatments for obesity and male-pattern baldness, and not enough to finding cures for sleeping sickness and dengue fever, we should acknowledge that the regulatory framework may help to create or sustain incentives towards the former, and disincentives towards the latter. If we are concerned about the indirect marketing of medicines to consumers, through disease awareness campaigns for example, then attention should be paid to the existence of easily exploitable loopholes in regulations which are supposed to restrict the advertising of medicines.

In sum, we all benefit from the wide availability of safe and effective medicines, which may be facilitated by creating the background conditions in which the pharmaceutical industry can flourish and be productive. At the same time, the pursuit of profit will sometimes be in tension with the promotion of public health. We need to be alive not only to the intended but also to the unintended consequences of regulation, and to the understandable tendency of large multi-national companies to seek out and exploit any potentially profitable loopholes and cracks in the regulatory regime. We should not be surprised that for-profit companies are motivated by the pursuit of profit, rather our focus should be on the role of regulation in shaping and influencing the way the medicines industry works. This is not to say that regulation is the only relevant factor, nor that changing the status quo will always be easy, or even possible. Rather, what I hope this book will demonstrate is that regulating the development and supply of medicines is not only a complex and challenging task, but also one that should be of central importance to anyone interested in the promotion of public health and the fair and equitable distribution of healthcare resources.