BOOK REVIEW

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EMILY JACKSON, LAW AND THE REGULATION OF MEDICINES (HART PUBLISHING, OXFORD, 2012) 302PP

In light of the increasing media reports about defective breast implants, the recent Thalidomide settlement in Victoria, and the Australian Vioxx litigation in 2010 and 2011, *Law and the Regulation of Medicines* is a timely addition to the scholarship on the intersection between law, pharmaceuticals and the broader area of medical science. Even though the author makes clear the book's focus is on UK and European law, the influences of these jurisdictions on Australian law are sufficiently significant that the book will be of interest and assistance to Australian legal practitioners and researchers.

Chapter one provides an appropriate introduction to the unique properties of medicine. Scientific terms, the types of medicines, as well as a general history of the regulation of medicines, set the tone and justification for a publication of this kind. Chapter two then looks at regulation of the clinical trials involved in establishing the safety and efficacy of a potential drug. An overview of the process is provided before legal and ethical issues such as consent, capacity and research ethics are discussed. The remainder of the chapter demonstrate how conflict of interests and profits may have a negative impact on the accuracy of the trials and raises legitimate concerns about the integrity of this side of scientific research.

A chapter that may be of particular interest to Australian practitioners and researchers specialising in consumer protection law is Chapter four, *Pharmacovigilance and Liability for Dangerous Drugs*. Here, Jackson addresses the difficult question of liability for side effects of drugs and the *Consumer Protection Act 1987* (UK), which implemented the 1985 European Directive on product liability. Given that Part VA of the Australian *Trade Practices Act 1974* (now Part 3-5 of the Australian Consumer Law) was also directly influenced by this Directive, this chapter provides both the history as well as information for a comparative analysis between the UK and the Australian statutory regimes.

As well as legal regulation, *Law and the Regulation of Medicines* also delves into matters associated with corporate social responsibility. Understandably, in an industry dealing with medicine and technology, there is a lot of scope for problems to emerge. Jackson focuses on two: marketing and advertising (chapter five); and global access to medicines, especially in developing countries (chapter seven). On the topic of marketing and advertising, an interesting (and concerning) aspect is the need to sell a new drug. Jackson observes that the first priority is to '"sell" the disease which it is intended to treat.'[1] Some specific examples are provided of how the industry 'sells' disease, including: Viagra and male sexual dysfunction; the depiction of *shyness* as a disease to enable sales of

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1 Emily Jackson, *Law and the Regulation of Medicines* (Hart Publishing, 2012) 132.

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anti-depressants; and hormone replacement therapy (HRT) as the saviour to the natural occurrence of menopause in women.[2] Jackson also delves into the problem of the pharmaceutical industry's gifts to, and financial influence over, medical practitioners as part of their marketing strategy. This is a problem that was of such alarm in the United States of America, that lawmakers passed the *Physician Payment Sunshine Act*[3] (included as part of the *Patient Protection and Affordable Care Act*, otherwise known as 'Obamacare') which requires disclosure of payments by pharmaceutical companies to medical practitioners.

As for global access to medicines, Jackson admits that this issue is not directly relevant to the domestic UK regulatory regime, but rightly points out that it is one of 'political importance' and highlights the question of medicines as a 'private or a public good.'[4] Certainly, the compulsory licensing scheme that falls under the *Trade Related Aspects of Intellectual Property Rights* (TRIPs) has always been a topic of political, legal and social importance. TRIPS attempts to balance the conflicting principles between the pharmaceutical industry's protection of intellectual property rights, and the right to health for citizens of developing nations. Jackson also looks at other initiatives in promoting health in low-income nations, including incentives to develop and supply treatments in such countries[5] and philanthropic measures. She concludes that investment in the promotion of public and global health and encouraging self-sufficiency in developing nations is preferable to the current environment where reliance by smaller nations on richer, western governments make them vulnerable to exploitation.

The final two chapters of the book are dedicated to looking at the 'future of medicines'. After alluding to one of the difficulty of medicines, being their unpredictable and unique interaction with each individual physiological makeup, chapter eight considers the possibility and implications of 'pharmacogentics'. This is where the genetic makeup of a patient will be analysed to predict their individual response or reaction to a specific drug or dosage.[6] Chapter nine looks at the concept of 'enhancement' where medicines are taken to 'improve upon or enhance normal functioning.'[7] In both chapters, Jackson raises legal and ethical concerns that are designed to provoke further thought into future regulation.

As the title makes clear, this publication is intended to provide a general introduction into the legal aspects of medicine and pharmaceuticals. Each chapter introduces a different issue about medicines and how the law affects each issue respectively. As is expected from a United Kingdom publication, Jackson focuses predominantly on UK law. However, the influence of UK law and its similarities to the laws of other common law jurisdictions (including Australia) means that practitioners, academics, law students, and policy makers will benefit from this text, whether it be for understanding regulation of medicines generally, the specifics of UK law, or undertaking a comparative law exercise. The author has

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2 Ibid 135-139.

3 Larry Husten, *Ray of Light for the Physician Payment Sunshine Act* (22 December 2011) Forbes <http://www.forbes.com/sites/larryhusten/2011/12/22/ray-of-light-for-the-physician-payment-sunshine-act/>

4 Jackson, above n 1 xv.

5 Ibid 198.

6 Ibid 212.

7 Ibid 235.

encapsulated the issues admirably in a book which is able to provide sufficiently detailed information about a complex topic in a timely manner.