BOOK REVIEW

MABEL TSUI*

RICHARD GOLDBERG, MEDICINAL PRODUCT LIABILITY AND REGULATION (HART PUBLISHING, OXFORD, 2013) 214PP

In December 2013, settlement was reached between approximately 100 Australian and New Zealand Thalidomide victims and the company which had acted as the Australian distributor of the infamous drug, thus putting to rest the possibility of litigation.[1] Around the same time, Thalidomide victims in the United Kingdom (UK) launched a similar bid for compensation against the manufacturer and distributor.[2] It is clear that despite a lengthy amount of time having passed ever since the thalidomide disaster commenced in 1962, the controversy over compensation continues. Indeed, the author of *Medicinal Product Liability and Regulation* (published before the announcement of the British legal claim), Professor Goldberg, notes that claims for resulting birth defects continue to emerge right into the present day. His prescient insight into the contemporary relevance of compensation for pharmaceutical injuries thus makes *Medicinal Product Liability and Regulation* a very relevant addition to the small body of scholarship that is available on this rather specific and complex issue.

Early on in the book, Goldberg seeks to examine the existing product liability regimes from a comparative law analysis, contrasting the strict liability regime found in the UK's *Consumer Protection Act 1987* against the compensation schemes found in Germany and Nordic states. He also makes the point that unlike the United States (US), the UK regime does not seek to distinguish pharmaceutical products from other general goods, but the nature of pharmaceutical products merit such a distinction, and it is on this foundation that much of the book appears to be based upon.

Another key theme throughout the text appears to Goldberg's championing of the US jurisprudence in this area, and a subtle plea for UK lawmakers to recognise the invaluable contribution that US law could make towards future reform. Due to the differences between the legal frameworks as well as culture of the US and the UK,

* PhD Candidate (Australian Consumer Law and pharmaceutical product liability claims), Faculty of Law, School of Law, QUT; member of the Health Law Research Centre and the Commercial and Property Law Research Centre.

1 Sarah Farnsworth, 'Thalidomide victims guaranteed care for the rest of their lives under Australian-first court settlement', *ABC News* (online), 2 December 2013 <http://www.abc.net.au/news/2013-12-02/thalidomide-victims-in-australia-get-multi-million-dollar-payout/5128298>.

2 'Thalidomide victims launch high court battle for compensation', *The Guardian* (online), 5 June 2014 <http://www.theguardian.com/society/2014/jun/05/thalidomide-victims-launch-high-court-battle>.

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the approach of the former cannot be directly adopted by the UK. Goldberg tackles this hurdle by continuing the comparative discussion throughout the chapters, highlighting the strengths of the US approach and using that to demonstrate the deficiencies in the UK law, thus ingeniously merging the two jurisdictions. The discussion takes the form of eight chapters: two introductory and the remaining six each focus on a specific topic in relation to medicinal product liability claims and regulation. A notable example of Goldberg's holistic and balanced approach is the first issue-specific chapter of the text, being chapter three. It aptly focuses on the issue of design, which is one of three types of defect associated with pharmaceuticals and is arguably also the most controversial type. On discussing the test for determining whether a design is "defective", Goldberg undertakes a detailed comparison between a test based on risk/utility (an approach favoured by current lawmakers in the US) and the UK consumer expectations test, to form a strong argument that risk/utility considerations are inevitable when it comes to pharmaceuticals.

With Goldberg's expertise on causation, as well as causation being one of the most difficult and controversial concepts in tort law generally, it is natural that the next issue addressed by Goldberg is causation. Chapter five is an extension of Goldberg's previous work on this topic and considers the difficulties of using epidemiological evidence in determining legal causation, again with a focus on the laws of the UK and US, as well as Australia and Canada. Chapter six then provides a different sort of comparative perspective on the issue of causation by discussing in detail the closest example to drugs: vaccines. In this chapter, Goldberg traces the history of the Measles, Mumps and Rubella (MMR) vaccine litigation in Europe and the United States, which had been triggered by the 1998 Wakefield hypothesis about the association between the vaccine and autism. Goldberg ends by noting that Andrew Wakefield's claims, which were published in *The Lancet*, were eventually discredited on the basis of fraud.

Far from neglecting the "regulation" component of his book, and demonstrating the interconnectedness of regulation and liability, Goldberg delves into the defences to product liability by starting with whether regulatory compliance can and should act as a defence to product liability claims. Generally, he notes the administrative and evidentiary burdens associated with proving, or disproving regulatory compliance as a defence. Chapter eight is the final issue-specific chapter in the book and examines the development risk defence, which is just as controversial as the topic of pharmaceutical product liability generally and is indeed worthy of its own chapter.

The development risk defence appears in the European Product Liability Directive,[3] article 7(e) and is emulated in the UK and Australian laws which have domestically implemented the Directive. Article 7(e) provides that 'a producer shall not be liable if

[3] *Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States concerning Liability for Defective Products* [1985] OJ L 210/29.

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he proves … that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defence to be discovered'. Although the defence has been written about extremely comprehensively (possibly exhaustively), Goldberg's synthesis of the history, the notable *European Commission vs United Kingdom*[4] case which considered its interpretation, and the existing literature only serves to highlight the continuing controversy as to both the defence *per se*, and its hindrance to the otherwise strict liability nature of the European Directive.

Throughout this review, Australian readers may be wondering how a book which focuses mainly on European and American medicinal product liability and regulation be of relevance to Australian law. The reasons are threefold. The first is for law reform purposes; just as Goldberg wrote this book with the aim of demonstrating the value of US jurisprudence for UK and European audiences, so too might Australian lawmakers and judges may see and appreciate the value of US jurisprudence in this area of law. During Australian law reform efforts in the past, US law had been overlooked in favour of European developments. Had the thalidomide claims not settled, and given the dearth of Australian case law on pharmaceutical product liability, one would hope that Australian courts would refer to the law of comparative jurisdictions for insight and guidance. Secondly, on a related note, although the number of pharmaceutical product liability claims in Australia is far lower than those seen in the history of the US, there has been a noticeable increase in Australian pharmaceutical and medical device litigation, with Vioxx and a range of allegedly faulty medical devices making frequent appearances in the national media. This context necessitates an examination of how the four year old Australian Consumer Law, enacted in 2010, does or should operate with respect to such products. Finally, one must remember that it is the Part 3-5 safety defect provisions of the Australian Consumer Law (and its *Trade Practices Act 1974* (Cth) predecessor, Part VA) which implement the European Product Liability Directive into the domestic legal framework, much like the UK *Consumer Protection Act 1987*. Any work that discusses the interpretation and operation of the Directive and the UK legislation will be of direct relevance and interest to Australian law.

When Part VA of the *Trade Practices Act 1974* (Cth) was enacted in 1992, the Australian Attorney-General cautioned that any finding of a pharmaceutical or a vaccine as potentially defective due to associated adverse reactions had to be counterbalanced against potential benefits that such products conferred upon the wider community. Even back then, they were acutely aware of the uniqueness of pharmaceutical products compared to other consumer goods. Yet, like the UK, they refused to afford such products a tailored liability regime to reflect this uniqueness. Goldberg's book, *Medicinal Product Liability and Regulation* provides insight into how a distinct regime for pharmaceutical products could operate. As one of the few monographs on the topic of medicinal and pharmaceutical product liability, it is a valuable addition to the scholarly literature in this field. Given Goldberg's analysis of

[4] *Case C300/95* [1997] 3 CMLR 923.

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a wide range of topics in this controversial area, which spans across three jurisdictions, it is anticipated that this publication will be extremely useful for practitioners, academics, law students and those with a general interest in the area of product liability, pharmaceutical law or consumer protection generally.

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