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Book Review of Michael D. Green, Bendectin and Birth Defects: The Challenges of Mass Toxic Substance Litigation

Erratum

The citation for this review is 8 *RISK* 91 (1997) in most commercial databases.

Michael D. Green, *Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* (University of Pennsylvania Press 1996). Acknowledgements, index, preface, selected bibliography. LC 95-42306; ISBN 0-8122-3257-7 [368 pp. \$29.95 Cloth. 1300 Blockley Hall, 418 Service Drive, Philadelphia PA 19104-6097.]

The drug industry is one of the most heavily regulated in the U.S. In determining whether to approve a particular drug, the Food and Drug Administration (FDA) must consider two factors. First, it must consider the safety of its citizens. It must next consider the public benefit which would be associated with the use of the drug in question. Professor Green's account of litigation over birth defects linked to a drug approved by the FDA captures readers' attention from the onset. Throughout, Green draws on our emotions as many are particularly sympathetic to injured children. While maintaining the reader's attention because of the subject matter, Green does not compromise the integrity of his description of the legal process in doing so.

After making us aware of the problem of birth defects, which Green links to the use of Bendectin by pregnant women, he gives a thoughtful account of the ensuing legal process, as well as an adequate scientific background for those who need it. Although parts of the book are more suitable for some than others, overall, readers need neither a legal nor scientific background to follow the process. Throughout the book, Green references legal terms, then follows with a short explanation. This enables non-lawyers to understand terms without boring those familiar with the law. There are, however, a few exceptions. While chapters 2, *Locating Bendectin Within the Mass Toxic Landscape*, and 4, *The Food and Drug Administration*, are designed for those who are not at all familiar with tort law, chapter 15, *Aggressive Procedure in Mass Toxic Substances Litigation*, may be hard to follow for one without a legal background. Green is sensitive to this, and but for these exceptions, the book should be accessible to all.

Safety is a priority, but readers begin to understand that some FDA oversights may be inevitable. To make what appears to be a safe and useful drug available as soon as possible, the FDA may err on the side of utility.

Of particular interest to me was Green's account of the litigation of the birth defects. It was the proverbial David and Goliath story. There were internal conflicts among the plaintiff's lawyers and their legal team was understaffed. The defendant was represented by a prestigious New York law firm with a plethora of resources. Furthermore, as this was the seminal Bendectin case, there were plenty of opportunities for mistakes.

In general, many participating lawyers were looking almost solely for a big payday. By and large, their conduct certainly raises ethical issues. Although it is not a matter of professional pride, the public definitely enjoys hearing about such conduct.

Overall, Green gives a thorough account of the vicissitudes of litigation. He neither bores lawyers nor alienates those unfamiliar with legal process. *Bendectin and Birth Defects* is an interesting read for those who enjoy reading a legal account with a scientific overlay.

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