outlined at the start. He has seen so much of medicine at its best, of good drugs used with great care and understanding, that he sought to focus atention on those aspects of drug therapy which fell short of any reasonable ideals. Whilst wanting sincerely to understand the Author's concern, I was constantly thwarted by the many exaggerations or distortions which litter almost every page. I thought I would refer to just three.

In chapter I, entitled 'Lines of descent', the Author examines the development and commercial exploitation of the benzodiazepines. On page 11, the Author states 'By the end of the 1980s, the best estimates suggested that perhaps half a million people in Britain were more or less addicted to benzodiazepines'. The journalist's technique is interesting: who says the source of this opinion was 'the best'? He softens the statement further with the words 'perhaps' and 'more or less'. Again, on page 18 of the same chapter, after an introduction to the placebo effects of drugs, the Author says: 'One cannot be precise, but perhaps a third of all drugs are now prescribed mainly for their placebo effect . . .'. On what evidence is that conclusion made . . . equally of course, what evidence is there to say the Author is wrong! In Chapter 5, entitled 'A dose of regulation', the Author examines the development of the various regulatory bodies, following upon the thalidomide disaster of 1962. Notwithstanding the Author's emboldened opening quotation from Sir Derrick Dunlop, he goes on to detail the introduction of thalidomide in the UK by the Distillers Company in 1958, records Richard Crossman's involvement both as an opposition spokesman on health and subsequently the minister behind the introduction of the 1968 Medicines Act, and concludes 'it took until the early 1970s to set up the machinery for drug control'. Not a mention of the Dunlop Committee that worked so effectively between the thalidomide episode and the implementation of the Medicines Act's provisions. Of course, any admission that the Industry had effectively self-regulated itself would have sat uneasily on other remarks inferring that the Industry was totally incapable of self-regulation.

I was annoyed by the distortions and exaggerations contained in this book and because there are aspects of the Industry's operations which do require tighter control; and the regulatory bodies could be much more open and less secretive in their activities. The Author has some good ammunition, tossed away I believe in a book of low scholarship and journalistic excesses. In the end, the Author may have served his cause less than usefully.

P. S. J. SPENCER
UNIVERSITY OF WALES COLLEGE OF CARDIFF, UK

J. Pharm. Pharmacol. 1992, 44: 626

Book Review

Drug Biotechnology Regulation. Scientific Basis and Practices
Edited by Yuan-yuan H. Chiu and John K. Gueriguian
Published 1991 Marcel Dekker Inc., New York
592 pages
ISBN 0 8247 8420 0, $135 (USA and Canada), $155.25 (others)

In the 1980s, medicines derived from biotechnology became a reality. This book reviews the science, technology and regulation of biotechnologically derived products. The editors are a Supervisory Chemist and a Medical Officer working in the Center for Drug Evaluation and Research of the US Food and Drug Administration. The authors are drawn from industry, academia and regulatory authorities. Many of them are based in the USA and the book tends to reflect this with an emphasis on US regulations and procedures. The compilation of US regulations of biotechnology in the food, drug and agricultural areas, provided as an appendix, will be particularly useful to those attempting to unravel this complicated and evolving area. European and Japanese interests are not forgotten. There is a chapter by Fernand Sauer of the European Commission on European regulations and a chapter on Japanese requirements.

The first part uses the successful development of such products as recombinant human insulin, human growth hormone and hepatitis B vaccine to exemplify the application of biotechnology to medicinal product development. This is backed up by extensive reference to recent literature. Subject coverage is fairly comprehensive with sections on host/expression systems, fermentation and cell culture, purification and postbiosynthesis modification, product characterization, and pre-clinical and clinical development. Further information on the introduction of genetic material into mammalian cells, on potential viral contamination and on monoclonal antibody production would have been useful. There is very little repetition even though different authors are at times covering different aspects of the same subject. Although care has obviously been given to planning the sequence of chapters, the first part of the book does not always follow a natural progression. This is, no doubt, a consequence of the difficulty in producing a cohesive whole from the many individual contributions.

The second part, on future prospects, has interesting chapters on fungi and baculovirus expression systems, the potential for gene cloning in developing new antibiotics, new approaches to vaccine production and advances towards somatic cell gene therapy.

The sections dealing with regulations and guidelines provide a useful baseline of information. It is encouraging to see the similarity in approach that already exists amongst US, European and Japanese authorities in dealing with biotechnology products. A quirk of the US system is that a product may be defined as a drug or biologic and as a result be considered by different divisions under different laws. The US Orphan Drug Act with its period of exclusivity adds another dimension to the race to the market place.

It is inevitable, with regulations and guidelines in this field being produced so rapidly, that a book can only provide a snapshot in time. The authors emphasize the need to keep abreast of regulatory developments. The chapters by industrial contributors about their experiences with the registration of medicinal products derived from biotechnology give a favourable account of the interaction between manufacturers and the regulators. Understandably, the industrial contributors concentrate on their successes. It is clear from their contributions that many changes may be made to the production process from the start of product development to the submission of a Marketing Authorization. But it is the regulators that point out the valuable lesson that care must be taken to ensure that there is good clinical data on material representative of the product to be marketed and, therefore, that some changes in production may necessitate further clinical trials.

This is an interesting book for anyone working in the drug biotechnology field. It is not a beginners text as it assumes a good basic knowledge of biotechnology. I have no doubt that I will be dipping back into it for that useful piece of information or reference that I remember seeing.

GLENDA SILVESTER
MEDICINES CONTROL AGENCY, LONDON, UK
(The views and opinions expressed are personal and do not represent those of the MCA.)