

Ethical Issues in Drug Research, Through a Glass Darkly

Michael J Parnham (1996). IOS Press: Amsterdam. 165pp. Hardback. Obtainable from the publishers, Van Diemenstraat 94, 1013 CN Amsterdam, The Netherlands; for UK and Ireland, 73 Limewalk, Headington, Oxford OX3 7AD, UK; or for the USA and Canada, PO Box 10558, Burke, VA 22009-0558, USA (ISBN 90 5199 279 3). Price £48 or US\$70.

The author of this book has spent many years in drug discovery, some of them as a researcher for an international pharmaceutical company. Although he has set out to concentrate on ethical issues, he covers a much wider field including scientific, political and economic factors which have shaped drug research in recent years. The author writes as a committed Christian and gives biblical explanations and justification for many of his conclusions. Since this reviewer was brought up in the non-conformist Christian tradition, the numerous scriptural references are mostly familiar, but it is unlikely that these will have much impact on non-Christian readers and may even have an adverse effect on those of other religions.

The book consists of seven chapters starting with a short but important general discussion of science in relation to social standards. This is followed by three chapters devoted to the philosophy and ethics of drug discovery and development. The following chapters, on 'Animal experimentation and toxicity' form the only part of the book directly concerned with animal welfare. Finally, there is a chapter looking at the future for new drugs.

The author starts from the premise, now widely recognized, that scientific research requires ethical justification and that there are doubts, particularly amongst young people, as to the moral virtue of many scientific advances. As a result of the success of drug discovery there is a danger that the benefits may be taken for granted or even forgotten. On the other hand we have come to assume that the next therapeutic breakthrough will be just around the corner. Public discussion of the issues helps to create an atmosphere of trust but there is also a need for expert assessment. This need is well illustrated by reference to aircraft safety, which is recognized as being of general concern, but can only be assured by experts. Current interest in herbal remedies is criticized as essentially non-progressive, relying on existing knowledge and preparations. The direct clinical trial of a completely new plant remedy would not be permitted in today's climate of safety-consciousness, without extensive toxicity testing on animals.

The chapter on animal experimentation adds little to current understanding of this contentious topic. The author reviews the history of changes in our attitude to animals concentrating very much on the Western world. In noting that Western drug research is traditionally based on animal experiments he advances the concept (also developed elsewhere in the book) that most modern 'breakthrough' drugs have come from countries with a direct or imported Christian tradition.

Conscience is presented as the overriding determinant in deciding the limits of animal experimentation, but for an individual and even a society, this will surely be shaped by history, custom and experience? Even within Christianity there are widely differing attitudes to the ethics of contraception, abortion, genetic manipulation and the eating of meat, so I find it difficult to see how conscience will lead to an acceptable consensus on animal experiments. Singer's contention that the lack of an evolutionary barrier between man and other animals

should inhibit animal research is rejected on the grounds that using the example of some animal (predatory) species could serve as a justification for the exploitation of other animals. Conversely, Paton's distinction between man and other species, based on our ability to communicate by the spoken and written word is also challenged on the grounds that the morality of communication is determined by its content rather than its existence. In the author's view conscience remains the overriding consideration.

In spite of a lack of convincing ethical argument this chapter does contain good practical advice. In particular, the questionnaire for research workers planning to carry out animal experiments (p 111) provides an essential checklist of questions which should be answered fully and honestly. It is relatively easy to justify animal experiments in drug research on grounds of the relief of human pain and suffering, but this is not obviously applicable to experiments driven by scientific curiosity for the advancement of biological knowledge.

There is a disappointing lack of discussion on the choice of animal models in drug research, particularly the justification of those causing more than minimal pain and distress.

In the chapter entitled 'How much toxicity is acceptable?' the author draws attention to the current view, largely shaped by the media, that the aim should be for absolute safety. In such a climate the public pays little attention to the statistical analysis of risk, and a single side-effect can receive greater emphasis than therapeutic benefit. Toxicity tests are not reviewed in any detail but the pertinent point is made that pharmacokinetic data should receive more attention in the assessment of the relevance of animal studies to man. Regulators should pay more attention to efficacy. Reduced toxicity without increased beneficial effect cannot, in the author's opinion, be a 'prime mover' in drug research. A system of peer review of new drugs by Manufacturers' Associations is suggested with the emphasis on efficacy and therapeutic need.

In looking to the future it is recognized that important advances depend on a leap forward in knowledge and understanding. Although market forces can hasten development they cannot guarantee therapeutic advance. Risks in researching new areas must be seen as challenges rather than obstacles to be avoided. A consensus involving national governments, the World Health Organisation and industry is required to decide the therapeutic areas in which new drugs are most urgently needed. A greater diversification of the industry's efforts should be made into areas in which human need is greatest. Few readers would disagree with these ideals, but their attainment demands major revisions in current relations between healthcare, governments and the pharmaceutical industry. Several sections of this book are devoted to a critical examination of the workings of the pharmaceutical industry. These will prove of interest to all those involved in drug research and development, but are not reviewed here as they have no direct relevance to animal welfare.

Although the book contains a wealth of ideas and information this reviewer found it surprisingly difficult to read. This is perhaps partly due to the author's desire to cover so many facets of each topic while leaving the reader still trying to grasp his main contentions. The three explanatory diagrams did nothing, in my view, to assist this process. There are several references to other publications at the end of each chapter together with the numerous scriptural references already mentioned.

John Sanford
Reading, UK