Decision Making on the Efficacy and Safety of Drugs. Edited by JOSEPH D. COOPER. The Interdisciplinary Communication Associates, Inc., Washington, DC 20007. xiv + 188 pp. 15 × 22.5 cm. Price $5.50.

The regulation and use of prescription drugs have been in the headlines so often that we are in danger of assuming that the problems must have been solved by now. Nothing could be further from the truth, as the conference recorded in this unassuming paperback proves. Each of the speakers, representing a variety of disciplines, had something worthwhile to contribute, although the reader has to sift through the individual biases at times. This task is made easier by the editor's superbly written summaries at the beginning of each chapter and Dr. Lasagna's review at the close.

The FDA came in for most of the criticism, but the participants showed considerable sympathy for its problems. They brought out, for instance, the overreaction of the public to adverse effects of drugs and the tendency of congressional committees to hunt headlines instead of finding facts.

Representatives of the drug industry had one recurring complaint; it takes too long to get a new drug approved, and the participants made several suggestions for improving the approval mechanism. Everyone recommended more frequent use of committees of experts to advise the FDA, and deplored the fact that these committees had to be reconstituted following the change in administration.

In connection with appeals by industry, I must enter one gentle demurrer. Professor Cooper quoted me as having said in my book, "Medicines for Man," "All kinds of appeals are available to a drug company." I think he will find that on pages 256 and 257 I made the point explicitly that, although recourse to the courts was possible, drug companies had not usually availed themselves of it, presumably because it was expensive and the verdict was not likely to be in their favor. I suggested that in disputed cases, the FDA appoint a panel of experts under the chairmanship of a lawyer to hold hearings in which the various interested persons would present their cases. This is quite similar to the suggestion made by the lawyer-member of the conference, Mr. Kleinfeld.

Other problems discussed in the conference were: the need for a higher scientific stature for the FDA, the importance of molecular manipulation in producing new compounds, the significance of adverse reactions to a drug *versus* its therapeutic value and the need for determining why physicians prescribe drugs and of improving the prescribing process.

In summary, this book would repay reading by every pharmacist and physician in the country.

Reviewed by Harry F. Dowling
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Advances in Biochemical Engineering, Volume I. Edited by T. K. GHOSE and A. FIECHTER. Springer-Verlag New York Inc., 175 Fifth Ave., New York, NY 10010, 1971. vii + 194 pp. 16 × 23.5 cm. Price $13.90.

This is the first volume in a series of multiauthor books concerned with the engineering aspects of biotechnology. It will attempt to fill in previously neglected areas, with particular emphasis on the mathematical analysis of microbiological systems and bioprocesses.

Staff Review ■

Annual Drug Data Report, Volume I. Edited by R. J. PROUS. Medicamentos de Actualidad—Drugs of Today, Apartado de Correos 1641, Barcelona, Spain, 1971. xi + 544 pp. 17.5 × 25.5 cm. Price $45.00. (English)

As a new reference source for drug information, the first volume of "Annual Drug Data Report" is impressive. On a yearly basis, it will present information on more than 500 drugs, comprising those which have gained a place in clinical practice, drugs which are understudy or mentioned in the 600 biomedical journals and publications that will be scanned, and drugs to which a new nonproprietary name has been assigned.

Each drug is described in monograph style, providing various names, identity, properties, synthesis, actions, toxicity, manufacturers, and references. Dosage and preparations will be included for drugs in clinical practice.

Four indexes—chemical formula, pharmacological, manufacturer, and cross index of various names—are provided to facilitate locating information. The book is well designed, and, by using large type sizes, the book is easily read or scanned.

Staff Review ■

Introduction to Biopharmaceutics. By MILO GIBALDI. Lea & Febiger, Washington Square, Philadelphia, PA 19105. vii + 80 pp. 17.5 × 25.5 cm. Price $4.00.

The author has set out to provide a broad overview of many of the principles and concepts of biopharmaceutics that will be of value to those with a working interest in drugs, dosage forms, and therapeutics, but who have yet to be initiated into the subject. The fact that this contribution was published originally as a chapter in another text suggests an unusual degree of quality, and the author has certainly been successful in achieving his aim.

Following a concise discussion of relevant kinetics, the biological and physicochemical factors involved in drug absorption are presented in good detail. There follows a rather brief section that considers the relationship between GI absorption and the dosage form. Since it is here that there is most opportunity to effect changes in absorption, this material could have been expanded with advantage. The subsequent sections on drug distribution and elimination are dealt with in a most adequate manner. After a brief look to the future of biopharmaceutics, the author concludes with a useful appendix detailing the determination and application of the pharmacokinetic parameters for two hypothetical drugs, one rapidly absorbed, the other slowly absorbed. A necessary aspect of any introductory text is a comprehensive list of references that will permit further study by the stimulated novice. Such a person will have little difficulty in doing this, since reference is made to more than two hundred relevant published papers.

This is a well-written, informative, yet concise, text. While the biopharmaceutics "bible" has yet to be written, the appearance of this "pocketbook" will be of considerable use to those for whom it is designed.

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