

---

## BOOK REVIEW

---



Lisa Ruby Basara and Michael Montagne, *Searching for Magic Bullets: Orphan Drugs, Consumer Activism, and Pharmaceutical Development*. New York, London, and Norwood (Australia): Pharmaceutical Products Press (an imprint of The Haworth Press, Inc.) 1994. xvii + 266 pp., \$39.95 (hardcover), \$22.95 (softcover).

To best illustrate the controversial issues presented in this book, the authors state "it comes down to a fine line between the rights of individuals to make decisions for themselves versus the right of society to protect its members." The debate surrounding the FDA drug-approval process—assuring safe and effective drugs for life-threatening diseases in a timely manner—is the focal point of the book. The authors describe the drug development and approval processes and relate these processes to the discovery and development of orphan drugs. Arguments of both proponents and opponents of the current processes are presented to give the reader a better understanding of the dilemmas facing pharmaceutical manufacturers, the FDA and other government agencies, patients with life-threatening illnesses, and consumer (patient) advocacy groups. The authors use lay terminology and provide a glossary for terms that may need additional clarification, making the book suitable for both health-care professionals and consumers.

The authors have divided the information into three parts. The

first part, Chapters 1-5, describes the drug discovery and development process by manufacturers and the drug approval process of the FDA. An historical perspective of the evolution of drug regulation and the approval process assists in the understanding of why the process exists as it does today. The authors also provide a discussion of the marketing of drugs and the relationship between marketing and the approval process. Because the authors have translated the technical and regulatory information into a description that can be understood by a variety of audiences, these chapters would provide an excellent understanding for new pharmacy students of what they will be facing as they enter the profession.

Chapter 6-8 comprise the second part of the book, describing the development and approval processes as they relate to orphan drugs. The authors discuss the controversies associated with the approval and marketing of drugs to treat rare diseases or diseases for which it may not be profitable for manufacturers to invest research and development resources. One solution, the Orphan Drug Act, is described, including the impact of the regulation on research and development and on the treatment of patients with these rare disorders. The authors also present other possible solutions, including the development of biopharmaceutical products and the issues surrounding these products.

The final part of the book, Chapters 9-11, describes ways in which patients afflicted with rare diseases and diseases with no known cure circumvent the current health-care system in an attempt to seek and obtain alternative therapies for their conditions. These include underground drug distribution and consumer-buying groups, which provide alternative, and in many cases, unapproved products to treat conditions such as AIDS and cancer.

In addition to the excellent glossary of terms, the authors also provide a drug and disease information directory. This directory contains sources of information on orphan drugs and rare diseases, clinical trials of new drugs, volunteer health organizations, and general drug and disease information sources.

The search for "magic bullets" to target and treat specific diseases is a complex process that involves many individuals, groups, and organizations, from the discovery of a drug to its marketing. The information provided in this book allows consumers to ex-

amine the advantages and disadvantages of the current processes so that rational decisions can be made regarding the appropriate use of both approved and alternative therapies. Health-care professionals can also use the information to provide appropriate counseling on these therapies to patients and their families.

*Stephen W. Birdwell*  
*The Ohio State University*