BOOK REVIEWS

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Basara, L.R. and Montagne, M.
Searching for Magic Bullets: Orphan Drugs, Consumer Activism, and Pharmaceutical Development.
New York: Haworth Press, 1994, 266 pp., illustrations and appendices, $39.95 (hardcover), $14.95 (softcover).

Bleidt, B. and Montagne, M. (eds.)
Clinical Research in Pharmaceutical Development.
New York: Marcel Dekker, 1996, 384 pp., illustrations and appendices, $135.00 (hardcover).

TWO recent books by Michael Montagne and co-authors present valuable information to MAPS readers on the drug discovery, development, and approval process in the U.S., which has great implications for the future therapeutic use of psychedelic drugs.

Searching for Magic Bullets is written for the general public, and it reveals the quest of consumers, health professionals, and drug developers to find safer and faster methods of bringing new medications to the marketplace. The current U.S. drug development and approval process is explored, identifying its strengths and weaknesses, and describing mechanisms by which patients and consumer support groups evade this process as they search for new treatments.

The book is divided into three parts. The first five chapters outline the drug development and approval process, its historical background and modern problems and concerns with it. Illustrations of the process of drug discovery portray Dr. Robert Raffauf (co-author of *The Healing Forest*) in the field and in his laboratory.

The role of the FDA in approving new medications is described and recent changes in the approval process are detailed. The next three chapters provide a case study of the whole process by focusing on the development and approval of orphan drugs. The final three chapters describe how and why consumers evade the traditional system and process to seek alternative treatments from nontraditional sources. Information is provided on empowering both health consumers and professionals in searching for solutions to health problems.

Clinical Research in Pharmaceutical Development is a technical textbook and multidisciplinary resource that examines the role of the clinical research process in development and approval of new pharmaceutical agents. It provides both a theoretical foundation and practical application to the creation of novel drugs.

There are three sections, along with a keynote chapter by Albert Hofmann. The first section outlines, in three chapters, the U.S. drug development process, a briefer but more technical version of what is covered in *Searching for Magic Bullets*. The second section introduces in detail the clinical drug research process, and the planning, coordinating and monitoring of clinical trials in five information-packed chapters. It includes many useful forms and tools for documentation of clinical trial data. The third section consists of four chapters that discuss the social, ethical, legal and marketing aspects of clinical drug development.

The keynote chapter that leads off the book is a wonderful description of the role of both planned research and chance discovery in pharmaceutical development, portrayed by the 40-year career of Albert Hofmann. Dr. Hofmann is known to MAPS readers for his discovery of LSD and isolation of psilocybin, but he is also responsible for developing a wide variety of products for the Sandoz Pharmaceutical company, including one of their most popular products, *Hydergine*. His research developing innumerable compounds shows the true consequence of basic research: only a very small portion of the experimental products that are synthesized in the laboratory and come to a clinical trial prove to be therapeutically useful in humans.

Besides the insight provided by his amazing career, this chapter guides us through the drug discovery process along four paths.

(1) From the ancient sources of folk medicine and from the study of the active principles of medicinal plants.

(2) From modern biological research, from the investigation of substances with physiological activity.

(3) From the pharmacological screening of a very large number of synthetic compounds and natural materials.

(4) From the observed effects of drugs in the patient.

Yet, Dr. Hofmann points out that "today we can say of many drugs that we know how they act and in what way, but we are still quite unable to say why they act as they do. There are no known laws defining the relation between chemical constitution and pharmacological effects. All knowledge of the relations between chemical structure and pharmacological action is ultimately based on empirical data."

He also notes that "not only is it impossible to predict the biological activity of a substance from its chemical structure, it is also impossible to predict its activity in human beings from the pattern of activity demonstrated in laboratory animals."

Dr. Hofmann's remarks serve to show that pharmaceutical research does not and can not always proceed as rigidly along a planned approach as might appear from publications in scientific and technical journals, but that chance, or rather what Walpole called "serendipity" very often contributes much more to success and will probably continue to do so in the future. •

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