This book is dedicated to my wife, Rebecca, and my children, Ryan, Matthew, and Lauren, for it is their love and support that brings a project like this to fruition. Also, for Mom and Dad—I wish you could have seen what I’ve accomplished.

—T. M. J.

To Joaquima and Lia, who permitted this endeavor at the expense of some family activities, and to Bill Helfand who introduced me to the pharmaceutical industry.

—A. I. W.
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Any book on today’s pharmaceutical industry establishes an ambitious set of goals, and the chapters that editors Tom Jacobsen and Albert Wertheimer include in this volume do offer a wide range of topics, from discovery and formulation to postapproval and legal issues. It is a “primer” unlike anything I have seen since the early part of the past decade. Its subject matter goes beyond its title and rewards readers with valuable insights into three major industry segments—the innovative, generic, and self-medication industries—by current and recently retired practitioners and academics, an excellent mix of authors.

Among manufacturing industries, the pharmaceutical industry is the most significantly dependent upon the state of legal and regulatory measures and the practices of governments, from clinical development and patenting to regulatory approval, promotion, and postmarketing surveillance. These controlling political factors are uniquely additive to the general worker’s health and safety as well as to the environmental laws and regulations that all manufacturers encounter. Many of these issues remain subject to review and frequent change. For example:

- The societal balance between the effectiveness of new drugs and the risks of adverse reactions reflected in the US Food and Drug Administration’s and international agencies’ decisions
- The scope of duration of patents, broadened internationally in recent years and lengthened in a number of developed countries
- The transparency and reporting of clinical trial results, generally toward greater transparency in reporting earlier trials more rapidly
- The ongoing debates about direct-to-consumer advertising of medicines in the United States and the growing urgency for better informed patients in Europe and Japan, especially in light of continuing restrictions of the access of patients in these regions to innovative medicines
- The regulatory boundaries set for prescription and over-the-counter medicines
• The trend toward the harmonization of technical documentation required for regu-
lar reviews not only among the original International Conference on 
Harmonisation (ICH) regions, but also beyond in Latin America and Southeast Asia

Globalization is a force that will continue to be a key element in the future of the 
pharmaceutical industry. Demands are placed on innovative companies to think globally in their marketing strategies, as most clearly evidenced by the AIDS “access-to-
medicines” discussions at the World Health Organization and the World Trade 
Organization. Developing countries, such as China and India, are expanding their capacities in generic medicines to supply global markets while also aiming to become forces for the development of innovative medicines. The rate of patenting is accelerating rapidly in China, India, Korea, Singapore, and in others such that they, too, are beginning to see that they cannot rely solely on a “commodity” generic industry to survive as pharmaceutical product providers. To paraphrase R. A. Mashelkar—a leader in India’s transition to a high-quality and innovative industry—in India, the issue is no longer “publish or perish” but “patent or perish.”

The industry faces many challenges today, a number of them not new in nature but occurring today in wider geographic scale:

• Demands by regulatory authorities for more clinical trial data resulting in regula-
tory delays
• Challenges to intellectual property
• Parallel importation
• Circulation of substandard and counterfeit medicines
• Price controls
• Challenges of doing business in countries where corruption is prevalent

These issues never die, and, with the expansion of the industry into the global mar-
ketplace, they will become a constant pull on the attention of scientists and managers in the industry.

However, as the industry is highly regulated and constantly challenged to address po-
litical, regulatory, and legal challenges, it is—as the editors and authors of this book demonstrate—uniquely positioned to improve the global health standards of society by saving lives and improving the quality of lives around the world through developing and marketing innovative products of chemical and biological science as well as high-quality generic and over-the-counter medicines. The industry has and will continue to adapt to changes in science and politics. Indeed, as a mentor said to me in my early days, the pharmaceutical industry treats political and regulatory challenges to its operations in the same way that an oyster treats a grain of sand that it ingests: it creates a pearl.

—Dr. Harvey E. Bale, Jr. 
Director General, International Federation of 
Pharmaceutical Manufacturers and Associations 
President, Pharmaceutical Security Institute
The idea for this book arose in 2004 during conversations with some new hires at a major pharmaceutical firm. The idea percolated during the following year until we, the editors, clearly decided that our assumption was a correct one. That assumption was that most people—even some who are employed in the pharmaceutical industry and in associated fields—often have a very limited and incomplete picture of the size, diversity, and activities of the necessary divisions or components in a contemporary pharmaceutical company.

We discovered that personnel in the manufacturing, quality assurance, or laboratory areas frequently knew almost nothing about their own company’s activities regarding marketing, legal, and regulatory activities. And, similarly, persons in the sales and marketing divisions seemed to have incomplete information about what goes on in clinical development, manufacturing, and the R&D laboratories. So, in 2005, the final concept for the book was born. The most difficult part was not in the writing or organization of the book but in locating colleagues who were willing and able to contribute chapters in the areas of their expertise and experience. The “willing” part was not difficult, but the “able” component proved to be a real challenge. Time after time, our friends and colleagues told us that their employers would not approve of their involvement. We finally succeeded by using persons who, in many cases, had previously been in the industry, due to recent retirement or a job change to academia or elsewhere.

We need to insert a few words of caution. The functions of nearly all pharmaceutical companies are very similar. They need a human resources capacity, a legal department to write contracts and other documents, persons to interface with the regulatory authorities, scientists, and many others. But that is where the similarity ends. Each firm is organized somewhat differently, often because of their history. You should consider what you read in this book more as a prototype or typical organization instead of an accurate description of any one company in the industry.

And lastly, we want to express our great gratitude to the generous friends and colleagues who freely share their knowledge and experience with you. If there are any
errors, we alone are responsible and apologize in advance. We hope that the book can be used by persons considering employment in the pharmaceutical industry and by those who want to learn more about “their industry” as well as students new to the industry.

After reading the book, you should understand how the industry does far more than merely synthesizing some white powder, compressing it into tablets, testing it on animals, and selling it. All comments from readers are welcome.
About the Editors

THOMAS M. JACOBSEN, PharmD, MS, RPh, has more than 15 years of industry experience in the areas of medical affairs, clinical research, regulatory affairs, microbiology, and analytical chemistry. In addition to his industry experience, Dr. Jacobsen has taught at the School of Pharmacy at Temple University and at the University of Pennsylvania. He completed his postdoctoral training at Temple University’s Schools of Medicine and Pharmacy in infectious diseases and pulmonary/critical care medicine. Dr. Jacobsen lives in suburban Philadelphia with his wife and three children.

ALBERT I. WERTHEIMER, PhD, MBA, is a professor at the School of Pharmacy at Temple University and director of its Pharmaceutical Health Services Research Center. He is a former director of outcomes research and management at Merck and Company and a former vice president of First Health Services, a pharmacy benefit management firm. Previously, he held academic positions at the State University of New York at Buffalo and at the University of Minnesota. Dr. Wertheimer has served as a consultant or invited lecturer in more than 50 countries, and he is the author or editor of 25 books and nearly 400 scientific or professional journal articles.
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