

The \$800 Million Pill. The Truth Behind the Cost of New Drugs. By Merrill Goozner; University of California Press, Berkeley, California; 2004; ISBN 0-520-23945-8; \$24.95 (hardcover); 297 pp.

Books addressing the “what is wrong with the pharmaceutical industry” (e.g., 1, 2) have become a cottage industry lately. One of these books with a catchy title is *The \$800 Million Pill. The Truth Behind the Cost of New Drugs* by Merrill Goozner, a journalist, and a former Chief Economics Correspondent at the Chicago Tribune. After reading several of these books and numerous articles on the pharmaceutical industry on the pages of psychiatric, general medical journals and newspapers, I hoped that this book, written by a journalist and not by yet another physician, would provide me with a bit fresher, different look at the problems with the pharmaceutical industry.

In the Introduction to his book the author starts with the story of Amgen, Inc., a fabled biotechnology company. According to the author, every start-up biotechnology company wants to be another Amgen. Yet Amgen’s spectacular success (especially on Wall Street) and revenues came from just two drugs, which are “artificial versions of naturally occurring enzymes that had been identified and isolated well before the company began developing them”—Epogen (recombinant-engineered version of erythropoietin) and Neupogen (an artificial version of granulocyte colony-stimulating factor). Mr. Goozner points out that Amgen’s labs were notoriously unproductive in the decade after its first drugs were approved, and focused frequently on modified versions of their previous products or better “me-too” drugs. The author then poses two basic questions, which he tries to answer in his book: Where do new drugs come from? And what do they really cost to invent? The rest of the introduction makes points about the biotechnology industry being developed mostly by scientists trying to get rich using the patents they took out on their government-funded inventions; and about the extraordinary profits of the pharmaceutical industry.

The bulk of the book mostly reviews examples of drugs whose development started outside of the industry. The first part, Biohype, consists of three chapters. The first chapter details the mentioned development of Epogen, an interesting story of a true researcher who spent his life developing this medicine and all the intrigues surrounding its introduction to the market by Amgen. The second chapter illustrates how the companies use the development of orphan drugs to yet another huge profit. Chapter three focuses on the human genome and how the industry again got into using the information obtained in public-funded research.

The second part, Directed Research, focuses in four chapters (“A public-private partnership”; “The divorce”; “Break-through”; “The failed Crusade?”) on the government’s role in fostering basic science and the early steps of the drug innovation process, how taxpayers-funded directed research played a leading role in the battle against some of the nation’s most pressing health care problems, namely AIDS and cancer, and

that pharmaceutical and biotechnology companies also played a critical role in bringing those new drugs to the market (p. 206).

The third part, Big Pharma, first attempts to answer the question of whether the steps companies play in bringing an innovative drug to the market demand the extraordinary sums the industry spends on research and development (p. 206) in two chapters (“Me Too!”; “The \$800 Million Pill”). The answer to this question is fairly clear, no, it is not worth the money the industry spends. Especially in view of the repeated stories on the development of almost undistinguishable me-too drugs (e.g., Prilosec and Nexium), and in view of the indiscriminate, inappropriate and incorrect prescribing by many physicians, very frequently under heavy and constant marketing pressure by numerous company representatives, advertising, dinners and other venues. The last chapter, “The future of drug innovation,” is probably the most interesting one for a fairly informed reader as it makes some suggestions for the solution of the presented problems. The author first makes the point that “much of the risk in drug innovation has been borne by the public and nonprofit sectors” (p. 249) and not by the most profiting pharmaceutical industry. He then suggests that Congress should create an independent institute on clinical practice within the National Institutes of Health whose major purpose would be to conduct clinical trials that compare existing medicines. He further suggests that this institute should also become a primary sponsor of clinical trials designed to look for new uses for old drugs (p. 251) (as pointed out, generic companies have no interest in this research). According to Mr. Goozner, this institute should also look at the lessons learned from AIDS treatment trials and study the effect of drug combinations. Finally, the institute could also serve as an objective source of information about the true economic value of new medicines (p. 252). The author makes several other recommendations, such as that new drugs should be required to be tested not only against placebo but also against existing effective therapies (an important requirement in view of the recent CATIE study results on treatment of schizophrenia – 3); that Congress should redress the loopholes in patent laws of new medicines; and that we need to study new medication for diseases prevalent in the developing world (malaria, leishmaniasis, etc). Mr. Goozner ends by suggesting that unless “the government helps the pharmaceutical industry by reforming its drug approval process in a manner that fosters innovation, the prognosis for the industry is grim” (p. 259). After reading this and other texts, one must agree with this grim prediction.

In his book Mr. Goozner demonstrates that the “inception of drugs which truly made a difference in recent years and which will make a difference in the twenty-first century can almost always be found in the vast biomedical enterprise funded by the federal government” (p. 8) He also points out that over the years, NIH-funded research played not only the key role in virtually all the basic scientific breakthroughs that underpin modern medicine but also a central role in the application of those findings to the search for many new therapies” (p. 8). Those are

probably the most important points of this book for an ordinary reader, as the role of the pharmaceutical industry with its main focus on huge profit is far better known.

From time to time we may come across a well-intentioned yet poorly written book whose message gets almost lost. This volume is an example of such a book. It presents a lot of well-known material with an attempt to synthesize it. Yet due to unnecessary attention to detail (e.g., the origin of names of pharmaceutical companies; the information where various researchers went to school; or who was married to a heavy contributor to the Democratic Party (see p. 183)) and lack of organization, the synthesis is lacking and the message almost gets killed. Maybe it is because the book is written like an investigative journalism article rather than a well-conceptualized book. Compared to a book, an investigative article, like a smaller portion of a huge meal, is always easier to swallow. Thus, keep your purse closed.

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Evidence-based Practice Manual. Research and Outcome Measures in Health and Human Services. Edited by Albert R. Roberts and Kenneth R. Yeager; New York, Oxford University Press; 2004; ISBN 0-19-516500-4; \$89.50 (hard cover); 1050 pp.

By now, every health care provider should be familiar with, at least, the concept of evidenced-based medicine, if not with the principles of it. There remains the gap, however, of how to effectively integrate the use of data, the collection of new data and the response to the new data in practice. Hoping to bridge this gap, the editors gathered chapters on practical tools, examples and inspirations into one tome. The editors explicitly intended the book as a reference to keep on the desk as opposed to using it as a textbook. That intent should serve as a warning: the book should not be read as a developing theme with a single focus. The chapters bounce around covering diverse subjects with a range of quality.

The 104 short chapters (averaging less than 9 pages apiece) are organized into ten different sections: 1) overview, 2) ethics and obtaining grant funding, 3) diagnosis, interventions, and outcome research, 4) epidemiology and public health research, 5) conceptualization, operationalization, and measurement, 6) assessment tools and measures, 7) program evaluation strategies, 8) examples of qualitative research, 9) examples of quantitative research, and 10) establishing, monitoring and maintaining quality, and operational improvement. After the chapters, there is an epilogue, Internet resource list and glossary.

To produce these chapters, the editors have assembled a vast array of mostly North American writers, many with academic social work affiliation. Although the introduction stresses that evidence-based practice is multidisciplinary, the orientation of the book is firmly tilted towards social workers (for example, there is a chapter entitled "Social Work Role in Disease Management"). I did find one chapter explicitly targeting clinical psychologists ("Developing Treatment Programs for Drug Courts and Evaluating Effectiveness") but not one oriented towards physicians or nurses. The editors justify this approach stating that there are differences between and within disciplines. These differences while enriching existing evidence-based practice, they contend do not facilitate collection and utilization of new knowledge in practice settings. More relevant, presented data show social workers lag other disciplines in awareness of such fundamental issues as practice guidelines for evidence-based practice.

The chapters include some very practical instruction on, for example, understanding focus groups, random digit dialing, grantsmanship, and applying for research grants. While the chapters will not make the reader an expert in the field, they will facilitate interaction with experts by covering key concepts and providing direction for obtaining more information. Less helpful was the chapter on secondary analysis of administrative databases. It included an example of its use but no discussion of the pitfalls, limitations and ways to appropriately use administrative databases. As the use of these databases is vital to the ongoing implementation of evidence-based practice, its deficiency is particularly glaring.

My favorite chapters dealt with the organization as the focus for evidence-based practice. The chapter entitled "Establishing Benchmark Programs within Addictions Treatment" very clearly laid out what the organization wanted to do, the obstacles encountered and ways that worked to overcome these obstacles. Rightly, the chapter stressed that it is a constant process, not just a one time process. These chapters on the organization included practical suggestions, examples of actual implementation, and tips for maintaining the process.

Evidence-based Practice Manual partially delivers on its promise to help bridge the gap between the principles of evidence-based medicine and its implementation by providing tools and offering practical guidance. It serves to inspire by presenting actual case studies of settings implementing evidence-based practice. It also contains, unfortunately, too many chapters that should have been weeded out. Some of the