

## Book Reviews

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***The Price of Global Health: Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation***, Ed Schoonveld (Gower Publishing Limited, Surrey, UK), 2015, 455 pp., \$120.27 (Hardcover).

Ed Schoonveld, one of the leading experts in global pharmaceutical pricing on behalf of pharmaceutical industry, addresses the challenging issues of finding balance in drug pricing strategies between patient access to medicines and profit generation by pharmaceutical companies, gently referred to as funding of innovation. Over the last few years public outcry about the sky-rocketing prices of new drugs, and biotechnology products in particular, has reached unprecedented scale, healthcare budget pressures have mounted up in ever more strained national economical environments, governments established firmer hold on price control.

Having agreed to prepare this book review on the drug pricing topic, I looked forward to a comprehensive compendium on all aspects of drug pricing problems and challenges in the context of growing initiatives in Global Health defined as “*the area of study, research and practice that places a priority on improving health and achieving equity in health for all people worldwide*” [9]. I was planning to learn from researchers experiences and to acquire new aspiration to implement more studies in pharmaceutical pricing in my own country.

In this brief review, I critically look at “The Price of Global Health”, wondering about such questions as:

- Are the interests of funding of innovation and of access to medicines as the Global Health priority fairly balanced in the book?
- Are the proposed strategies aimed at meeting the Global Health priorities? Could the Global Health agenda of access to medicines for all be achieved through the proposed drug pricing strategies?
- Are there better, alternative strategies for drug pricing, really tailored to improve health and lives of all people worldwide bearing in mind health justice principles?

### **Brief description of the book and its author**

This is the second edition of “The Price of Global Health: drug pricing strategies to balance patient access and the funding of innovation” by Ed Schoonveld, first edition (2011), which was described as “*the pharmaceutical pricing strategy process . . . of critical importance to pharmaceutical company executives and other leaders and professionals in commercialization and drug development, including marketing, business development, market access and pricing, clinical development, drug discovery, regulatory affairs, health outcomes, market research and public affairs*” [2].

The author worked as head of Global Market Access and Pricing functions for many pharmaceutical companies, including Wyeth, Lilly and BMS, and as a consulting leader in Cambridge/IMS and others. The author graciously acknowledges the ZS Associates team and colleagues who have enthusiastically supported him in finalizing the first edition and “*for their support and suggestions to further build*

on the first edition and incorporate updates on the many changes that have occurred in the global marketplace.” ZS Associates, as described on the main page of their website, “is one of the world’s largest business services firms specializing in transforming sales and marketing from an art to a science. . . . help clients gain market share at lower cost . . . by creating data-driven strategies that they can implement rapidly and by taking on sales and marketing operations to make them more competitive. . . . across consumer products, energy, high-tech, insurance, medical products and services, pharmaceuticals and other industries.” [18].

This second edition includes new chapters on oncology, orphan drugs, payer values and negotiations; country specific sections describing country statistics and health system approaches to drug pricing, insurance, reimbursement, etc (US, UK, Germany, France, and other); new illustrations, event analysis and implications on the pharmaceutical industry.

The book consists of five parts (from A to E) and 31 chapters, with a surprisingly short list of references (58 references totally for a book of 455 pages) and index. It is illustrated with 103 colored figures and 21 tables, but unfortunately just a few of them have references to the sources of data, presented in a figure or a table. This makes the book less useful; its information value is compromised.

### **Are the interests of funding of innovation and of access to medicines as the Global Health priority fairly balanced in the book?**

The goal of this book, as the author describes it, is to present “*an in-depth but straightforward exploration of the pricing process and its implications. The book is designed to help a wide range of audiences gain a better understanding of this complex and emotionally charged field*”.

It is a pity to me that the Global Health priorities of health and equity in health for all escaped from this goal.

The author presents his volume to consumers, legislators, pharmaceutical company leaders and market access and pricing professionals. Although the author mentions consumers on the first place among the target audiences, this does not reflect claimed global health-oriented approaches of proposed strategies. The language, used by the author, speaks for itself: consumers are supposed “*to better appreciate how pharmaceutical prices are determined and what factors influence the process*”.

The book gives an overview of drug market access and pricing discipline. “*It describes the main issues and challenges for payers, drug industry and other stakeholders and discusses some of the most commonly used approaches in the field.*”

The author starts with defining “*the new buzzword in the pharmaceutical industry*” – market access:

*“Market access is the discipline that addresses any financially based consideration or hurdle to drug prescribing and use, whether imposed by public or private third-party payers, or experienced as a consequence of patient affordability.”*

Surprisingly, in the context of Global Health, the word access in this book refers to pharmaceutical products reaching payers (access to money of products [pharmaceutical companies]) and not patients in need of treatment having access to effective and safe medicines, as per WHO definition of the access to medicines as part of the right to health:

*“Access to essential medicines as part of the right to the highest attainable standard of health (“the right to health”) is well-founded in international law. The right to health first emerged as a social right in the World Health Organization (WHO) Constitution (1946) [4] and in the Universal*

*Declaration of Human Rights (1948) [14]. The binding International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966 [8] details the progressive realization of the right to health through four concrete steps, including access to health facilities, goods and services [16].*

To me, the market access definition by the book author in its objective and description stands in contradiction with the WHO definitions and objectives and the Millennium Development Goals [15].

The facts prove that the costs to Global Health of drug company profits are enormous, and that the profits are generated at the expense of the most vulnerable populations of the world – people of developing countries. They suffer from unethical behaviours of pharmaceutical industry in testing their new products on people who will never benefit from them, in preventing poor countries from developing their own manufacture of generic essential medicines, in refusing to market life-saving medicines in poor countries [10].

Ironically, the picture on the cover pages – the coins spilling out of the open capsule – illustrate the market access definition of the author.

Thus it seems that the book is more focused on the interests of funding of innovation rather than on those of the Global Health with its access to medicines priority.

**Are the proposed strategies aimed at meeting the Global Health priorities? Could the Global Health agenda of access to medicines for all be achieved through proposed drug pricing strategies?**

The author proposes developing a Global Pricing strategy and presents two reasons for maintaining the strategy fairly strict – to consistently support the global marketing strategy and to closely manage prices between countries and over a drug’s life cycle to avoid a negative impact on company profits.

Starting with “*customer price elasticity of demand*” and referring to “*the micro-economics laws of supply and demand that drive optimal price*”, the author explains complications, created in this field by “*the third-party payers such as insurance companies*” and “*why governments deem it necessary to exert control over its marketing and pricing practices*”, clearly emphasizing that his book works for the opposite.

Advocating for “*a broader set of activities . . . as part of market access*”, the author refers to the well-known pharmaceutical companies’ techniques in their drug promotion campaigns [12], such as including their products in clinical treatment guidelines, “*as they are frequently agreed upon and published, for example, in the US for hypertension, by the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure*”, and extends his market access definition to health technology assessments and health economic evaluations because these are used for reimbursement decision making.

The author separates his definition of market access from marketing authorisation by regulatory authorities (FDA) and “*the ability to reach patients in developing countries or even the ability for the sales force to speak to physicians*”, thus creating even more confusion between two terminologies: drug promotion and market access, which seem to be essentially the same.

The book creates an impression of a textbook or guideline of marketing practices for pharmaceutical company managers. The author states under the heading of industry cost structure “*the cost of development of a new drug was estimated to be in excess of \$1.3 billion in 2006 (DiMasi, 2007) [6]. Given the past steep growth curve in the cost of drug development, today’s average cost of drug development is probably much higher than \$1.3 billion dollars.*”

This is the first in ten industry myths, described and debunked by Professor Peter C. Gøtzsche, the Director of the Nordic Cochrane Centre and the co-founder of the Cochrane Collaboration in his ground-breaking book “Deadly Medicines and Organised Crime. How big pharma has corrupted healthcare” [7].

Debunking “*the outrageously false claim from industry that the high drug prices are a consequence of the high development cost*”, Peter says: “*A final blow to the myth that drug prices reflect the high research and development costs is: What can then be said about the much higher costs for sales promotion? [13] Those who pay for the drugs also pay for this extravagant marketing. If new drugs were as good as the industry wants us to believe they are, there wouldn’t be much need for pushing them and for bribing doctors into using them.*”

Professor Peter C. Gøtzsche brings an out-crying example of drugs “*monstrously expensive, e.g. \$600 000 a year for treating Gaucher’s disease [5], although all research and early development was done entirely by NIH-funded scientists [3].*”, and describes the real drug pricing mechanism and the working formula [7]:

“*Researchers have shown that the yearly cost per patient is inversely related to the prevalence of the disease. Italian researchers went a step further and developed a simple formula that fitted surprisingly well with the data they had for 17 cancer drugs [11]:*

$$\text{yearly cost per patient} = \text{€}2 \text{ million} \cdot e^{-0.004 \cdot \text{number of patients}} + \text{€}10 \text{ 000}$$

“*Thus, the annual cost per patient for a drug where there are 900 patients in Italy will be about € 60 000.*”

[I use here the references from Professor Peter C. Gøtzsche’s Book, direct citations.]

The author touches on ethical considerations and public policy, discussing profits versus right to healthcare, differential versus equity pricing, global trade (not Health) versus social policy, compulsory licensing, orphan and oncology drugs, risk sharing and managed entry agreements, pricing negotiations keeping his market access concept at the core.

Thus, it seems that the proposed strategies are aimed at meeting the Global trade rather than Health priorities and the Global Health agenda of access to medicines for all could not be achieved through proposed drug pricing strategies.

### **Are there better, alternative strategies for drug pricing, really tailored to improve health and lives of all people worldwide bearing in mind health justice principles?**

There are huge and glaring omissions in the book on pricing matters that influence global health such as the influence of donor organizations and the generic industry.

For example, it was shown that “a mechanism such as the Global Drug Facility can indeed secure lower prices for drugs that meet international quality-assurance standards than are available for unregulated drugs of unknown quality on the private market” [1], yet this is not covered by the book.

There is also almost nothing in the book about the special disease burdens of countries and regions, and certainly nothing about the successes of treatment and innovation in funding public health programs that have made inroads into some endemic tropical diseases as well as HIV/AIDS, which is an unfortunate omission. This is despite the fact, that it has been well documented that a right-to-health approach

to neglected diseases and populations ensures the benefit from rapid-impact interventions with immediate success. It is well known that powerful and cost-effective control tools are available as well as implementation strategies and there is good evidence that they bring the desired results.

It is a pity that Ed. Schoonveld did not tackle these important matters and did not include statements on the undoubted (partial) success of these donor ventures and generics in making drugs available to poor and in need at low cost.

The WHO identifies four factors on which the provision of access to medicines depends. Affordable prices are the second key factor along with the rational selection and use of medicines, sustainable financing, and reliable health and supply systems [17].

While the WHO, working with its mandate for affordable prices and developing drug pricing strategies in close collaboration with the Health Action International, postulates that this second factor – affordable prices – is the most affected by globalization, the author of the reviewed book seems to ignore this, and is quite inclusive in his description / definition of the market access and pricing.

Review Series on Pharmaceutical Pricing Policies and Interventions consisting of six working papers, developed by Health Action International (HAI) in collaboration with World Health Organisation (WHO), available at the HAI website (<http://www.haiweb.org/medicineprices/>) provides the most comprehensive health focused strategies for drug pricing and should be used in education on drug pricing and disseminated.

This is indeed a disappointment that none of these health-oriented strategies have been included in the reviewed book.

In conclusion I would like to finish this review citing once again Professor Peter C. Gøtzsche [7]:

*“We are jointly responsible for the complicated society we have created where we depend on each other and benefit from specialisation. But when drug companies charge copious amounts for their drugs, they make a mockery of their obligations towards the patients, the taxpayers, our mutual societal obligations, and our joint assets to such an extent that they put themselves outside society, just like street criminals do. It is theft.”*

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***Risky Rewards: How Company Bonuses Affect Safety***, Andrew Hopkins and Sarah Maslen (Ashgate Publishing Limited, Surrey, UK), 2015, 175 pp., £35, ISBN 978-1-4724-4984-9.

The authors examine a complex and timely topic which is suggested by their subtitle, “How Company Bonuses Affect Safety.” Their work has been inspired by their attempt to understand the apparent inexplicable behavior of persons within corporations who seemingly fail to attend to adequate risk management, at times with catastrophic sequelae. The precipitant for their work may have been the human and financial costs effected by two British Petroleum disasters, namely the Texas Refinery explosion of 2005 and the Gulf of Mexico well blow-out of 2010.

The premise of the authors’ overview and hypothetical underpinnings of the relationship between financial rewards and safety is an omnipresent concern – or, perhaps better said, should be a major concern – of the business community. The arguments of the authors focus related issues: Can financial inducements ever produce safe and effective business decisions at the same time that they reward individuals who promote productivity, financial growth and safe working conditions? Do financial or non-financial rewards necessarily produce short-cuts in safety that compromise short-term or long-term risk? Can systems be enacted which produce desired perpetual safe working conditions and similarly embrace a pro-active business agenda? These and other questions are implied and/or explicitly stated by the authors’ narrative.

The authors structure their book beginning with three chapters that explain the inspiration for the book and list both examples as well as questions, contradictions and solutions of the past. These chapters also introduce some basic hypotheses that have been studied or suggested by others. The following four chapters examine the issues with more detail, offering descriptive arguments with real world examples and examine the benefits and drawbacks of possible solutions. The last chapter summarizes ideas and offers concluding suggestions for using company bonuses with an outlook that incorporates strategies for avoiding major catastrophes. The entire outline of the book is logical and follows a well-laid out progression that provides descriptive content to the authors’ hypothetical.

The book is highly relevant and of interest to at least two groups of people: those who are in management of large, multinational corporations, and those who are interested in knowing more about how such companies conduct their businesses. Readers are offered distilled information about challenges confronted by corporations. They will also learn how major catastrophes, like the Gulf of Mexico oil well blow-out, can happen and what has and can be done to diminish or prevent such occurrences in the future. The material is also helpful to individual executives who work in smaller corporations as some of the alternative preventive mechanisms to minimize safety problems are also appropriate for any group business construction and analysis.

The book has some limitations. The number one problem is that the authors used data from 11 companies that were somewhat limited to mining and explorations of minerals, but do not allow us to know which companies they were discussing. This sampling bias presents a highly concentrated group of industries whose manifestations may or not be generalizable to a wider group of business enterprises. Separately, without adequate referencing of most materials (a notable absence throughout the book), the readers must rely on the authors' integrity and choice of examples without adequate substantiation of the dataset. From a scientific viewpoint, this is a missed opportunity.

In addition to the above, the writing style is often repetitive and, although the book is well organized, the authors put forth redundant arguments. This style does not assist the book's deductive argumentation that purports to assess and document a construct and then make reasonable hypotheticals for improvement. The general lack of clarifying tables and graphs to augment the narrative is also a drawback.

Towards the end of the book (page 160), the authors state: "At the end of the day, therefore, this study does not significantly advance our understanding of human motivation, since we have not been able to disentangle the effects of financial from other forms of motivation in a definitive way. What we do demonstrate is that bonus systems tap multiple motives, and we use these insights to suggest how bonus arrangements can be made to operate more effectively, particularly in relation to process safety." Importantly, the authors illuminate the uses and potential dangers of bonuses in large, multinational corporations. And, they also offer suggestions for more conscientious systems to assist the determination of bonuses for solitary and systemic major safety hazards over different time horizons. Understandably, the difficult and complex task of elucidating the behavioral underpinnings must await a future treatise. In other words, the work to understand the causation of how and why different kinds of bonuses may affect individuals and groups in this arena still leaves opportunity for further study. This book is a helpful and instructive addition to that subsequent research.

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