PRESCRIBING CULTURES AND PHARMACEUTICAL POLICY IN THE ASIA-PACIFIC

Edited by Karen Eggleston



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Karen Eggleston Stanford, CA June 2009

Editor's Note: In August 2009, as this book was going to press, John H. Barton—a contributor to this volume and longtime Stanford law professor—passed away. Professor Barton devoted his academic career to the examination of questions at the intersection of science and the law, and his chapter in this book explains how the global pharmaceutical market fails to meet global medical needs. We mourn the passing of our brilliant and distinguished colleague.

FOREWORD

Michael R. Reich

The pharmaceutical sector—one of the most conflict-ridden areas of any health system—promises great benefits and also poses enormous risks. This book examines how pharmaceuticals play, in editor Karen Eggleston's words, an "often contentious role in the health-care systems of the Asia-Pacific." Indeed, this is an understatement. Conflicts abound over public policies, industry strategies, payment mechanisms, professional associations, and dispensing practices—to name just a few of the regional controversies covered in this excellent book. While many of the authors are economists, they recognize that an analysis of pharmaceutical policy must address politics as well. Each chapter covers important aspects of the pharmaceutical sector's political economy, which in turn captures many of the core conflicts affecting health systems. Taken as a whole, the book points to three key lessons.

First, the pharmaceutical sector needs to be viewed within the context of a national health system. This book covers eight major health systems of the Asia-Pacific, ranging from poor (India) to rich (Japan), including countries with universal coverage (Taiwan, South Korea, and Japan), countries with highly regulated markets (Japan), and others with chaotic regulation (China). The two most populous countries in the world (India and China) have huge regional variation within their borders. Yet all of these countries are struggling with how to make the pharmaceutical sector contribute in positive ways to the ultimate goals of their health systems. It is helpful to think about three ultimate goals for a health system: the *health status* of the population, citizens' satisfaction with the system, and the capacity to provide financial risk protection to individuals (Roberts et al. 2004:24). Each of these goals is deeply influenced by the role of pharmaceuticals in the health system, including which products are available, where they are available, at what cost to individuals and to the system, who provides them and under what conditions, the quality of the products, and what patients know about the products. Questions about access to pharmaceuticals are addressed in each of the various—in fact, very different—health systems studied in this book. In short, national context matters.

A second lesson is that certain conflicts emerge in all kinds of national health systems and must be confronted by those societies. Such conflicts take various forms, and the solutions vary as well. Comparing national trends can help advance our understanding of contested issues. This book is structured around two basic conflicts: (1) the trade-offs of separation versus integration in the dispensing and prescribing of pharmaceuticals, and (2) tension between promoting innovation versus access to pharmaceuticals. The first conflict is

especially important in Asia because of its long cultural tradition of medical practitioners who both prescribe and dispense, a practice that became embedded in modern health systems and payment and reimbursement policies. This book provides a long-needed analysis of how different Asian countries are struggling with the separation of dispensing from prescribing and what kinds of results (both intended and unintended) are being achieved by system reform. Meanwhile, the tension between emphasizing innovation versus access is examined in several chapters, which go on to propose policies that may be able to achieve both goals. This tension represents a topic of hot debate on today's global health policy agenda—especially when asking how to promote the development of new medicines (and devices and diagnostics) for conditions that affect poor people in poor countries where market incentives are insufficient to stimulate private research efforts (Frost and Reich 2008).

A third lesson is that health systems around the world are struggling to contain costs and that this often generates conflicts over policy. Many pharmaceutical policy reforms described in this book were adopted by governments seeking to contain rising health-care costs, as discussed in the chapters on Japan, South Korea, Taiwan, China, and Australia. The government goal of cost containment often leads to a focus on pharmaceuticals, which frequently represents the largest area of government spending after health workers and is thus a politically attractive target. This focus then leads to policies that use listing and pricing decisions as mechanisms to control costs and that promote the economic analysis of new medicines. Author Hans Löfgren notes that in Australia in the early 1960s, "drugs formed the largest single item of government expenditure under national health benefits, and costs became a political concern." Australia subsequently became the first country to adopt mandatory cost-effectiveness analysis for all medicines listed on the public reimbursement formulary. In Thailand, as described by Sauwakon Ratanawijitrasin, the government adopted all sorts of policies in its pursuit of cost containment—what she calls "multiple policies, one aim." The government has adopted policies for procurement, production, pricing, payment, and patents, with varying results (including some unintended consequences)—a theme that appears in other chapters as well. This and other chapters demonstrate that problems arise in both market-oriented and state-based efforts to address the policy dilemmas around cost containment; there is no simple fix.

This book makes a special contribution to our understanding of the pharmaceutical sector in China through the six chapters of analysis devoted to this country. Qiang Sun and Qingyue Meng underscore the importance of medicine in the Chinese health system, citing the fact that in 2005, China spent 4.7 percent of its gross domestic prodct (GDP) on health care—of which 44 percent was for pharmaceuticals, with about half of total health costs paid by individuals out of pocket. China's health policymakers are now focused on cost containment, which depends critically on what happens in the pharmaceutical

sector. The government has shifted back and forth in its pricing policies on medicines (indeed, it has introduced nine different policies since 2000 and is preparing yet another one). But cost control is not the only elusive goal in China. As Mingzhi Li and Kai Reimers report, "Many researchers and industry analysts now ascribe the overall chaos of China's health-care sector to the government's rapid opening of the industry to market forces without the establishment of sufficient and enforceable regulations." This chaos includes high prices, poor quality, counterfeit medicines, official kickbacks to hospitals and secret kickbacks to doctors, ineffective regulation, lax drug approval, and more. Michael A. Santoro and Caitlin M. Liu report that in May 2007, China executed the former director of the China State Food and Drug Administration for receiving "\$850,000 in bribes to facilitate the approval of myriad new drugs, including some that contained substandard or counterfeit ingredients." China's ineffective regulations continue to have global consequences through an increasingly connected network of medicines and food products. As Santoro and Liu write:

Perhaps the most significant regulatory gap concerns chemical companies, which are neither certified nor inspected by Chinese drug regulators. Chemical companies from China supply active ingredients and, in some cases, finished products to drug manufacturers and distributors worldwide. There are approximately 80,000 chemical companies in China, and no one knows how many of these are involved in manufacturing drug ingredients.

Globalization is galloping forward, with Chinese producers pushing the pace at breakneck speed. More and more, our safety depends on China's ability to get its regulatory act together, especially since it is increasingly difficult to determine the production source of many medicines and food products. The crisis resulting from contaminated infant formula and milk products made by Chinese firms (reported in September 2008) highlights the risks of lax Chinese regulation combined with high global connectedness (Yardley and Barboza 2008). We all depend on the Chinese government to effectively regulate its producers and markets.

In conclusion, this book contributes to our knowledge of how the pharmaceutical sector operates in the Asia-Pacific—including public policies, industrial strategy, and market issues. The countries discussed offer many different political and economic contexts, as governments, companies, and societies struggle with the many contentious questions raised by pharmaceutical products. The book contains nuggets of wisdom for academics as well as policymakers. I hope that similar studies can be conducted for other parts of the world—such as Latin America, Sub-Saharan Africa, and the Middle East. Each region shares certain structural and cultural traits that would bear regional analysis and cross-national comparisons. At the same time, regional studies

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like this one can help lead us toward a more general understanding of how to address the problems at the heart of the pharmaceutical sector—the promises of better health and cost-effective care, compounded by the risks of economic costs, adverse health effects, and fraudulent claims. Neither a market-based system nor a state-based system alone can provide the right mix of constraints and incentives, hence the need for cross-sectoral approaches and public-private interactions.

Michael R. Reich Brookline, MA October 1, 2008

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