NTRODUCTION

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The Asia-Pacific is arguably the most diverse region in the world. Home to deep-rooted cultural traditions and all the world's major religions, the Asia-Pacific also encompasses a wide array of political systems governing countries both large and small, wealthy and poor, rapidly growing and stagnant. Health-care systems in the region, also diverse, face challenges common around the globe: safeguarding public health, expanding health-care coverage, and improving quality while controlling costs and balancing government and market roles in the health sector.

Pharmaceuticals and their regulation play an increasingly important and often contentious role in the health-care systems of the Asia-Pacific. For example, drug expenditures account for an extraordinarily high percentage of total health expenditures in China, while India and a few other countries host thriving domestic pharmaceutical industries of global importance. At the same time, controversy surrounds patents, trade-related aspects of intellectual property (TRIPS), and pharmaceutical pricing within bilateral trade agreements (Australia-United States, Republic of Korea-United States). Nations throughout the region struggle to regulate drugs appropriately, from patents to evidencebased purchasing (for example, the Australian government's Pharmaceuticals Benefit Scheme) and direct-to-consumer advertising. Meanwhile, strong traditions of indigenous medicine are becoming integrated into broader health-care systems, and new policies that separate drug prescription from dispensation are rewriting the professional roles of physicians and pharmacists. Throughout the Asia-Pacific, effective pharmaceutical prescription and use will be central to controlling infectious diseases both old and emerging, protecting the efficacy of antibiotics around the world, and treating the growing burden of chronic disease.

This book seeks to explore these issues in detail, using a multidisciplinary approach. Each contributor focuses on a specific area of expertise, while touching on two overarching questions. First, what institutional forces are driving pharmaceutical use, industry trends, and medical policies in the Asia-Pacific? Second, what lessons can the economies of the Asia-Pacific learn from one another and from other regions to improve pharmaceutical policies? The first section of the book features chapters on pharmaceutical policy in seven health-care systems of the Asia-Pacific: South Korea, Japan, Thailand, Taiwan, Australia, India, and China. The second section focuses on the cross-cutting themes of prescribing cultures and access versus innovation. Taken as a whole, the contributors aim to provide an evidence base for policies even as they acknowledge the historical and cultural contexts that distinguish them.

The book targets several audiences. Policymakers will find it a useful reference not only for understanding other nations' domestic health-care systems but also for learning about U.S. policy toward Asia. In addition, the book explores potential policy solutions to the global dilemma of how to provide incentives for innovation—especially in the creation of drugs to treat neglected diseases—while ensuring access to life-saving medicines. Researchers will find the collection useful for defining what we know and what we need to know about pharmaceutical policy in this region and for examining these issues from multiple perspectives. For government analysts and nongovernmental organizations investing in global health, the book seeks to show how the process of research and producing "evidence" can and should be policy based. Industry insiders will find the analyses useful for putting market developments in a broader context. Finally, professors and students will find the book an important resource in the learning process.

The chapters assembled here analyze the forces that have shaped industry development, regulatory structures, and other policy decisions to date, as well as the likely trajectories and uncertainties ahead for this region. Using pharmaceutical policy as a window into the economic trade-offs, political compromises, cultural legacies, and historical institutions that shape health-care systems, the book facilitates cross-country comparisons of policymaking processes and industry structures. It also illustrates how cultural legacies shape and are shaped by the forces of globalization, and thus may be of interest to social scientists beyond the confines of pharmaceutical and health policy.

Because no single volume can provide a comprehensive overview of all aspects of pharmaceutical policy in the Asia-Pacific, the most populous region in the world, we have chosen a select group of economies from northeast, southeast, and south Asia, as well as Oceania, which vary in per capita income, health-system structure, and approach to pharmaceutical industry development, procurement, and regulation. In addition to the seven systems highlighted individually, Anita Wagner and Dennis Ross-Degnan provide an extended example from the Philippines in chapter 18. As F. M. Scherer notes in the book's conclusion, the covered jurisdictions were "home to some 2.6 billion individual human beings in the year 2000, or 42.8 percent of the world's population." A cluster of six chapters—chapter 9 by Yiyong Yang, chapter 10 by Mingzhi Li and Kai Reimers, chapter 11 by Qiang Sun and Qingyue Meng, chapter 12 by Yanfen Huang and Yiyong Yang, chapter 13 by Wei Wilson Zhang and Xue Liu, and chapter 14 by Michael A. Santoro and Caitlin M. Liu-provides a case study of Chinese pharmaceutical policy, ranging from domestic industry structure and distribution channels to prescribing incentives, price regulation, product safety, and the relationship to overall health-sector reforms.

At least two central themes emerge in the chapters that follow: first, the crucial role that differences in "prescribing cultures" and policies play in delineating the functions of prescribing and dispensing medications; second, the perennial balancing act of providing access to medications and incentives

for innovation. In this introduction, I provide an overview of these two key themes, which cut across the different contributions in the book. I then offer a brief description of the seven selected health-care systems and a preview of the main arguments presented in each chapter.

Prescribing Cultures and Physician Dispensing

The physician-patient dyad lies at the heart of medical care. Economists often conceptualize this as one example of a "principal-agent relationship," in which the patient (principal) "hires" the medical-care provider (agent) to supply expertise such as diagnosis and treatment. Providers may be able to exploit their superior information for profit. The asymmetry of information between patient and provider is often compounded by differences in social status and power as well as the feelings of urgency and discomfort (or even incapacity and defenselessness) associated with illness.

Health-care systems differ in the incentives and assumptions that govern the physician-patient relationship, including use of pharmaceuticals. In many herbal medicine traditions, for example, doctors prepare, prescribe, and dispense drugs to their patients. This tradition seems alien to practitioners of other systems, especially Western systems of biomedicine, in which pharmaceutical firms produce medications, physicians prescribe them, and pharmacists dispense them to patients.¹

Economic theory suggests some possible advantages of integrating prescription with dispensation. First, fixed costs (patient search and travel costs, provider diagnosis costs) may imply less expense when a single provider both diagnoses and treats the patient. In economic models such as that of Wolinsky (1993), the fixed costs of search and diagnosis imply the advantage of integration, all else equal.² Second, even if another provider treats a given diagnosis more efficiently, there may be nontrivial costs associated with accurately communicating the diagnosis and its nuances. Third, if barriers to timely, accurate feedback between diagnosis and treatment hamper the development of appropriate human capital in each skill set, then integrating diagnosis and treatment provides better incentives for improving their quality over time, compared with separating them.

Conversely, separation may bring several advantages. First, integration implies a strong economic incentive for oversupplying profitable goods and services. This potentially severe supply-side "moral hazard" problem has also been referred to as "supplier-induced demand" (see, for example, Gruber and Owings 1996). Separation can remove this incentive. Second, separation subjects a diagnosis and treatment decision to two experts, who may check the safety and quality of each other's decisions. True, to err is human, but medical error can lead to tragedy. A monitoring role may justify additional costs even if we do not suspect either expert of any systematic bias or deficiency. The benefit of this role increases when there is reason to suspect substantial heterogeneity

in diagnosis skill, unobserved by patients, which a second expert's systematic review can rectify cost-effectively (such as by checking for drug interactions with decision-support tools). Third, patients may value different opinions, especially when a variety of appropriate treatments are available in which doctors have varying levels of expertise. Fourth, insofar as the two roles—diagnosing and managing disease on the one hand and preparing and dispensing medications on the other—require distinct skill sets, separating them may lead to greater safety, quality, and efficiency over time.

Economic theory clearly does not indicate that separation is inherently superior to integration. Given this theoretical ambiguity, relative efficiency is largely an empirical question. To date, few empirical studies have examined the relative benefits of separating versus integrating diagnosis and treatment; notable exceptions are Iizuka (2007) and Afendulis and Kessler (2007). As several chapters in this book illustrate in detail, Asia-Pacific systems with traditions of integration have attempted, to varying degrees, to separate prescribing from dispensing. Such policies include instituting a fee for prescribing (which South Korea later abolished); paying an extra fee for pharmacy dispensing (which in Japan in 2008 was linked to the prescription of generic drugs); closing inpatient pharmacies (South Korea); establishing formulas for regulating pharmaceutical retail prices (Japan); and bundling forms of provider payment, such as capitation and case-based payment (Thailand), which encourages providers to reduce drug spending along with overall spending.

The results show that although separation may bring benefits, it is not a silver bullet for reducing overall health-care spending, particularly as the capabilities—and costs—of medicine continue to expand. In some cases, the reforms were watered down, with so many loopholes that they appear to have had little substantial effect on behavior (as in Taiwan). In other cases, sweeping change succeeded but did not slow the pace of spending increases (South Korea). Generous but bundled case payments for inpatient episodes appear to complement separation policies.

Moreover, separation and pricing policies appear to affect the industrial organization of domestic pharmaceutical industries. Although one might think that branded pharmaceuticals have an advantage in offering price-cost markups to doctors, in many systems a large number of small-scale generic drug firms thrive by offering generous price-cost margins to hospitals and doctors. Such an industrial structure—with a large number of small-scale generic drug firms—suffers from its lack of economies of scale in research and development (R&D) for innovative drugs, and substantially complicates efforts to regulate quality and safety. Whether separation policies do in fact complement efforts to foster larger-scale, research-based pharmaceutical firms is an important area for further research.

Access and Innovation

Globalization affects virtually all segments of society, including health care. Pharmaceutical policies in particular are interlinked globally not only by multinational and domestic firms that sell to global markets, but also by pricing policies that spill over into international price comparisons and parallel trade (importing drugs from low-price economies to high-price ones; see Danzon 1997). Moreover, prices are a key determinant of pharmaceutical access and innovation, two goals that are often in conflict.

Producing innovative, research-based pharmaceuticals involves high R&D costs but low production costs for each pill or dose (Danzon 1997; Sloan and Hsieh 2007). This cost structure presents challenges in allocating the high R&D costs across products and users. Moreover, these joint sunk costs are increasingly global, so that their payment does not clearly fall to a single country or region. As Patricia Danzon (1997:11) notes, "it is the *global* nature of the sunk, joint costs of pharmaceuticals that makes the regulation of drug prices potentially more distortionary than the regulation of traditional utilities," another industry characterized by high fixed costs and low user-specific marginal costs.

Herein lies a fundamental dilemma. At a given point in time, it is efficient and equitable to provide access to therapeutically beneficial drugs to all patients for whom the benefit exceeds the low user-specific marginal cost. But maximizing access in this way is also myopic. Over time, it is efficient (and, many would argue, equitable) to invest in innovations that bring benefits to patients in the future. Indeed, without past innovation, there would be no current access. The dilemma arises because promoting innovation—dynamic efficiency—requires a price high enough to cover the joint sunk costs of R&D and some return on investment, whereas promoting access—static efficiency—requires a price low enough to cover only user-specific marginal costs. No pricing policy can achieve both goals simultaneously.

This access-versus-innovation dilemma is not an equity-versus-efficiency trade-off, even though some observers frame it as such. While one can argue that promoting access is efficient and promoting innovation is equitable, the reverse is equally true.³ The policy challenge is to design systems that promote appropriate access, constrain inappropriate access, and cooperate at the global level to stimulate innovation, particularly for drugs targeted at diseases that disproportionately afflict the poor (or "neglected" diseases).⁴ Several chapters in this book, especially in the final section on access and innovation (including chapter 19 by John H. Barton; chapter 20 by Henry G. Grabowski, David B. Ridley, and Jeffrey L. Moe; and the conclusion by F. M. Scherer), explore the contours of this debate and propose promising ways forward.

Compulsory licensing vividly illustrates the controversies that surround access and innovation. In chapter 4, Sauwakon Ratanawijitrasin describes Thailand's compulsory licensing policies, which have made access to life-saving drugs possible in her country. As F. M. Scherer notes in the conclusion, "I was

shocked to read, in chapter 4 (Ratanawijitrasin), that the U.S. government put Thailand on a priority watch list in 2007 for its compulsory licensing activities. A similar patent-linked action by the United States in 1991 led to proposed legislation in the Thai parliament precipitating a no-confidence vote and dissolution of the government. Will we Americans ever learn to let other governments make their own decisions freely, within the latitude allowed by international law?"

The United States figures prominently in other pharmaceutical policy controversies as well. U.S. health spending, at 15.3 percent of the gross domestic product (GDP) in 2006, far exceeds that of other regions; the closest economies in terms of percent of GDP allocated to health were Switzerland (11.3 percent), France (11.1 percent), and Germany (10.6 percent) (OECD Health Data 2008). The United States is also the largest market for pharmaceuticals in the world. U.S. policies shape innovation incentives, and U.S. policymakers thus have a special responsibility to promote access to the fruits of that innovation. Numerous chapters in this book focus on issues of importance for U.S. policymakers. For example, Grabowski and his colleagues discuss priority review vouchers, a new U.S. policy designed to promote R&D for drugs targeting neglected diseases. Scherer discusses drug exports to the U.S. market. And multiple chapters examine global public health problems that require multilateral solutions, from TRIPS to regulation of supply chains so that drug safety and quality are assured.

Policymakers and analysts in the United States and elsewhere often use Europe as a frame of reference (see, for example, Mossialos, Mrazek, and Walley 2004), but they may benefit from exploring the experiences of the Asia-Pacific as well. Indeed, pioneering work has been done in this region, as in the case of adopting economic evaluation in purchasing—for example, Australia's Pharmaceutical Benefits Scheme—and, more recently, in developing performance measures that include medicines, also in Australia, as noted in chapter 18 (Wagner and Ross-Degnan). Thailand has achieved the remarkable feat of offering universal health coverage despite relatively low per capita income.

For these and other topics examined in this book, we hope that the value of a comparative approach to health policy will be apparent and compelling.

Seven Health-care Systems of the Asia-Pacific

South Korea

South Korea's population of 49 million enjoys relatively good health. Life expectancy at birth is 79.1 years, exceeding the OECD average of 78.9 years. Korea's 27-year increase in longevity between 1960 and 2006 was the most rapid gain in life expectancy among OECD countries (OECD Health Data 2008). The three major causes of death are cardiovascular disease, cancer, and accidents. Korea's population is also rapidly aging, with the 65-or-older population expected to increase to more than 13 percent by 2020 (Kwon 2005).

Health spending absorbed 6.4 percent of Korea's GDP in 2006, and health spending per capita was \$1,480 (calculated based on purchasing-power parity). Public spending accounts for 55 percent of Korea's total health spending. Out-of-pocket payments account for 37 percent of total health spending, more than in most OECD countries (OECD Health Data 2008).

Korea has had universal coverage since 1989, through national health insurance and a government-managed Medicaid program. In July 2000, the nation's many health insurance programs were merged into a single insurer system to address inequity. Health-care expenditure has continually increased due to the requirements of an aging population, poor physician incentives for cost-effective care, and increasing demands for health care (Kwon 2005). Payment for services is chiefly on a fee-for-service basis.

The private sector dominates health-care delivery in Korea (fewer than 7 percent of hospitals are public; Kwon 2005). As in many Asian countries, hospitals have large outpatient departments, most clinicians are trained as specialists, there is little or no primary care gatekeeping, and large tertiary hospitals are overcrowded while smaller clinics and hospitals (often physicianowned) have lower occupancy. The number of doctors per capita in Korea doubled between 1990 and 2005, the fastest growth rate in the OECD (OECD Health Data 2008). Like Japan, Korea has a high number of beds per capita, and its inpatient length of stay is longer than that of most other OECD countries.

Korea implemented controversial reforms in 2000 to separate prescribing and dispensing, both to help reduce pharmaceutical spending and to correct distorted incentives for overuse (Kwon and Reich 2005; Kim and Prah Ruger 2008; Soonman Kwon, chapter 1, this volume). These reform objectives have only been partially realized. Korea's drug spending in 2006 absorbed 25.8 percent of total health spending, compared to the OECD average of 17.6 percent. But when compared in terms of per capita purchasing power parity, Korea's drug spending remains below the OECD average and less than half of that in the United States (OECD Health Data 2008).

Japan

Japan's population of 128 million enjoys the longest life expectancy in the world, which stood at 82.4 years in 2006. Mortality rates for heart disease are the lowest in the OECD. But smoking rates among males remain high, at 41 percent (the highest among OECD countries after Turkey, South Korea, and Greece; OECD Health Data 2008). As Hyoung-Sun Jeong and Jeremy Hurst note, "Japanese health status is, in most respects, the highest observed among OECD countries, but it is not clear to what extent this is due to the health system and to what extent due to other factors such as the Japanese culture, diet, or social conditions" (2004:4).

Japan devoted 8.2 percent of its GDP to health spending in 2005, slightly less than the OECD average of 8.9 percent. Health spending per capita was

\$2,474 (adjusted for purchasing power parity) and was growing slower than the OECD average. Public sources fund 82.7 percent of health spending, well above the OECD average of 73 percent (OECD Health Data 2008).

Japan achieves universal coverage through a social insurance system that includes separate funds for different population groups (employees of large firms and their dependents, retirees, the self-employed, residents of different regions, and so on). Insurance premiums are proportional to income.

The delivery system in Japan is pluralistic. Hospitals, mostly not-for-profit, include small, physician-owned facilities and large tertiary facilities that employ their own physicians. Recently, investor-owned hospitals have been permitted in specific localities. But they are not allowed to charge patients more than the regulated price and do not receive reimbursement from public health insurance (Ikegami and Campbell 2004). Japan has fewer physicians per capita than other OECD countries but the highest number of hospital beds and magnetic resonance imaging (MRI) units—40.1 units per million people, compared to an OECD average of 10.2 per million people in 2006 (OECD Health Data 2008).

The government regulates fees paid to health-care providers, and all citizens enjoy similar benefits (aside from some differences in the modest, capped copayments) regardless of their specific insurance plan or where they receive their care (Ikegami and Campbell, 1995 and 2004). A "free access" guarantee assures patients access to the hospital of their choice within their *iryo-ken*, a region that may encompass several municipalities but is smaller than a prefecture (Noguchi, Shimizutani, and Masuda 2008). Although reimbursement has traditionally been on a fee-for-service basis, payment for university hospitals, subacute care, and long-term care now features inclusive fees that are case-mix-adjusted but independent of actual interventions (Ikegami and Campbell 2004; Nomura and Nakayama 2005).

Relative economic stagnation and rapid population aging have put additional pressure on Japan's system. Public long-term-care insurance started in April 2000, with government subsidies financing about half of the long-term-care insurance benefits. Since October 2007 government subsidies, financed by general tax revenues, have paid for half of the health insurance benefits for those aged 75 and older (Ikegami and Campbell 2004). The introduction of a separate insurance program for this population has proved controversial.

Japan's health-care system has attracted international attention for its relative success in fostering good population health at modest cost. In the World Health Organization (WHO) ranking of health systems in 2000, Japan ranked tenth overall, with top-ten rankings in virtually all categories (level of health, responsiveness, fairness of financial contribution, spending, and so on). In many studies of high-income countries, such as the Health Care Quality Indicators Project focusing on twenty-three OECD countries, Japan is the only Asian country included. Japan is also the second-largest market for pharmaceuticals in the world, and therefore critical to that industry.

Thailand

Thailand is a middle-income country (per capita GDP of \$8,440 in 2005) with a population of more than 65 million and relatively fast economic growth. The infant mortality rate decreased from 31 per 1,000 live births in 1990 to 18.2 in 2004, and life expectancy rose from 68 to 70.5 years. HIV/AIDS is the leading cause of death, especially among the working-age population, followed by traffic accidents (WHO 2007; Hanvoravongchai and Hsiao 2007).

Total health expenditure accounts for 3.5 percent of GDP, which is relatively low when compared to that of nations with similar per capita incomes. The national health budget increased from 5.8 percent of total government expenditure in 1993 to 7.6 percent in 2004 (WHO 2007). Public spending accounts for more than 60 percent of health expenditure (Hanvoravongchai and Hsiao 2007).

Thailand recently became one of the few developing countries to achieve universal health coverage. The system features multiple insurance plans. The Civil Service Medical Benefits Scheme covers government employees and their dependents (about six million people). It is financed by taxes, and pays for pharmaceuticals on a per item basis. Similar benefit packages are also available for the employees of public enterprises (i.e., industrial firms rather than government agencies). The Social Security Scheme covers private business employees—a category that comprises about eight million people—and is financed by contributions from employees, employers, and the government. Payment to contracted hospitals is made on a capitation basis (with additional payments based on utilization). Pharmaceuticals are included in the overall per person payment (Ratanawijitrasin 2005).

The 30 Baht Health Insurance Scheme is the largest insurance program in Thailand, covering approximately 48.4 million people, or 76.6 percent of the insured population. According to the National Health Security Act, anyone who is not covered under the other two public schemes is eligible under this one, which is funded by general taxes (Ratanawijitrasin 2005). The 30 Baht Scheme requires all beneficiaries to register with a local contracting unit for primary care, an innovative channeling of funds intended to promote primary care and fundamentally change how public hospitals are financed (Hughes and Leethongdee 2007). The scheme employs capitation and diagnostic-related groups (DRGs) as its main payment methods. Payment for drugs is included in the capitation and DRG rates (Ratanawijitrasin 2005).

In addition to these three schemes, private insurance companies offer a multitude of health insurance policies, covering approximately 1.5 million people and generally paying on a fee-for-service basis (Ratanawijitrasin 2005).

At present, these schemes cover services and pharmaceuticals given by hospitals—both private and government-owned—and government-owned health centers. A small number of privately owned clinics are eligible for payment under health insurance within pilot projects managed by public insurers. Drugstores and

physician clinics are generally excluded from insurance payment, so their clients pay out of pocket (Ratanawijitrasin 2005). Many public doctors also work in the private sector for extra income (Hanvoravongchai and Hsiao 2007).

Taiwan

Taiwan, with a population of almost 23 million, enjoys comparatively high life expectancy (77.8 years). Like many middle- and high-income economies of the Asia-Pacific, Taiwan has experienced an epidemiological transition—with the burden of disease from infectious diseases declining and the burden attributable to noncommunicable diseases such as heart disease and cancer increasing over the past several decades—and now faces relatively rapid population aging.

Taiwan spends about 5.5 percent of GDP on health and since 1995 has had a compulsory universal health insurance scheme financed through premiums and taxes. Most services require a modest copayment, with an annual cap of 10 percent of average income; low-income households, veterans, and some other vulnerable groups are exempt from copayments (Cheng 2003).

Taiwan's health-care system includes both public and private hospitals, with the latter more numerous. The majority of physicians work in hospitals on a salary basis; the remainder practice fee-for-service primary care in their own clinics. Private clinic doctors do not have hospital admitting privileges, and there is no referral system. Patients can freely choose among providers.

The social insurance program traditionally paid providers on a fee-for-service basis at a uniform rate. More recently, to address growing financing pressures, Taiwan's authorities introduced bundled payments for some hospital services and global budgets for separate components of health spending, as well as increased premiums and some copayments (Cheng 2003; Chee-Ruey Hsieh, chapter 5, this volume). The health insurance system has enjoyed a high public satisfaction rate.

Providers in Taiwan traditionally earned a large share of their revenue from dispensing medications, but reforms since 1997 have sought to separate prescription from dispensation, with mixed results. Pharmaceutical regulation has also figured prominently in general cost-containment efforts (Hsieh, chapter 5).

Australia

Australia is a high-income, highly urban economy with a population of 20.6 million in 2006. Life expectancy is 78 years for men and 83 years for women. Leading causes of death are heart disease, stroke, and cancer. Morbidity and mortality rates are higher among people living in rural areas than in urban ones and especially among indigenous Australians. The population is aging, with 12.8 percent of the population aged 65 and over (Healy, Sharman, and Lokuge 2006).

Australia spends 9.7 percent of GDP on health, representing \$3,652 per capita in terms of purchasing power parity, slightly above the OECD average. Since 1984, Australian Medicare has provided unlimited subsidized access to the

doctor of choice for out-of-hospital care, subsidized prescription drugs, and free public hospital care. Financing (about 68 percent public) comes from general taxation, a small insurance levy, private insurance, and out-of-pocket payments. The Medicare levy is 1.5 percent of taxable income above a certain income threshold, with an additional 1 percent surcharge for high-income earners who choose not to buy private insurance (Healy, Sharman, and Lokuge 2006).

The private sector delivers most of the primary and specialist medical care and runs private hospitals. The public sector provides some primary health care and includes public hospitals and public health programs. The majority of doctors in Australia are engaged in private practice. Additionally, private health insurance funds are heavily subsidized by a tax rebate on premiums. Private hospitals are traditionally smaller than public ones, deal with a more limited range of cases, rarely offer emergency services, and undertake a substantial amount of elective surgery. More than two-thirds of all private hospital beds are owned by large for-profit chains and by the Catholic Church (Healy, Sharman, and Lokuge 2006).

Doctors can choose to "bulk-bill" Australia's Medicare program, charging no more than the Medicare rebate and receiving payment from Medicare directly; there is no out-of-pocket cost for the patient. Patients must pay the difference if the doctor charges more than the rebate. Free treatment under Medicare at a public hospital is provided by doctors nominated by the hospital. Treatment as a private patient allows a choice of doctor. For patients in private hospitals, Medicare pays 75 percent of the schedule fee for medical services. Private health insurance covers spending that is not covered by Medicare, such as treatment and accommodation as private patients in hospitals; the gap between the Medicare benefit and fees charged for inpatients; and charges for ancillary services. Primary medical care provided by doctors is not covered by private insurance (Healy, Sharman, and Lokuge 2006).

Australia's Pharmaceutical Benefits Scheme has aimed, since 1948, to provide "timely access to the medicines that Australians need, at a cost individuals and the community can afford." Patients make a copayment for drugs depending on income. The scheme is an international pioneer in adopting economic evaluation in benefit decisions (Healy, Sharman, and Lokuge 2006).

India

India is the second most populous country in the world, with 1.1 billion people diverse in ethnicity, religion, and language. Although a rapidly developing economy, poverty persists, and there are large regional variations in income. For example, residents of New Delhi—the richest city in India—have an average per capita income of \$532, which is more than double that of the rest of the country (Das and Hammer 2007a and 2007b).

According to the WHO, communicable diseases account for 38 percent of India's disease burden. Maternal and child-health issues, such as malnutrition,

are prevalent. Noncommunicable diseases have also become major health problems, accounting for 53 percent of all deaths in people between the ages of 30 and 59. There are significant differences in health outcomes between rich and poor. Many factors account for this difference, such as nutrition, education, hygiene, and quality of health care (Das and Hammer 2007a).

India spends about 5 percent of its GDP on health. Of this, the government contributes 18 percent, and 82 percent comes from out-of-pocket payments (WHO National Health Account, 2005). Public-sector services are financed through taxes and other revenue. India's public health-care expenditure is among the bottom 20 percent of countries (Peters et al. 2002).

India's health-care delivery system consists of private providers and public central, state, and local hospitals and first-responder primary health centers. Visits to private providers constitute 82 percent of all visits. There is no medical insurance scheme, except for the free service in the public health system; thus, families incur high out-of-pocket costs in the private system (Das and Hammer 2007a).

Despite India's low GDP per capita, Indian residents visit the doctor more frequently than Americans do (Banerjee et al. 2004), and the poor visit doctors more than the rich (Das and Hammer 2007a).

The World Bank has described the public health-care sector in India as underfunded and not large enough to meet current health needs (Peters et al. 2002). The system is overly centralized, bureaucratic, inflexible, and poorly managed. It is widely perceived to provide poor treatment and also suffers from high absentee rates among public-sector providers (Das and Hammer 2007b).

At the same time, many private providers are unlicensed (Deshpande et al.). There are also a large number of traditional health practitioners. Incentives in the public and private sectors do not promote high-quality care. For example, according to one study, providers ask patients only 22 percent of the questions that a qualified provider should ask to provide appropriate diagnosis and treatment for a specific disease—26 percent for tuberculosis and 18 percent for diarrhea (Das and Hammer 2007a and 2007b).

China

With over 1.3 billion people, China is the most populous country in the world. Life expectancy has increased to 73.2 years from 50 in the 1960s and 65 in the 1970s. Health improvements vary greatly by income and geographic location. Among those covered by the Maternal and Child Health Surveillance System in 2003, for example, maternal mortality was 73 per 10,000 live births among the poorest fifth, compared to 17 per 10,000 live births in the richest fifth (Wagstaff and Lindelow 2008).

China spends about 5.6 percent of GDP on health, comparable to economies of similar per capita GDP. But until recently, the majority of spending was made up of private out-of-pocket payments, and only 20 percent was spent in rural areas, where most of the population still lives (Evans and Xu 2008).

Before economic reform, universal affordable basic health care had been provided in rural areas by the Cooperative Medical System (CMS), a government insurance scheme for government employees and teachers. In urban areas, employees and their dependents received their health care through firm-based schemes. CMS covered 90 percent of the rural population in the late 1970s (Yip and Hsiao 2008). As a result of rural economic reform in 1979, CMS disappeared, and 90 percent of peasants became uninsured. In urban areas, a social health insurance scheme financed by employer and employee contributions replaced the previous government and worker schemes, but only formal employees, not their dependents or migrant workers, were eligible (Yip and Hsiao 2008; Eggleston 2008). In 2006 only 27 percent of urban residents received coverage under the scheme (Ministry of Labor and Social Security 2007).

Under this system, the average cost of a single inpatient episode represented 60 percent of annual household per capita consumption (Wagstaff and Lindelow 2008). The cost of health care led to the impoverishment of 5.2 percent of households, or 67.5 million people, disproportionately in rural areas (Evans and Xu 2008). Out-of-pocket payments have been common even for preventive public health services (Wagstaff and Lindelow 2008). Such access barriers have contributed to the problem of oversupply in China's health-care delivery system. Bed occupancy rates (60 percent) and the number of cases per bed per year are the second lowest of the OECD countries, behind Turkey and Japan, respectively (Wagstaff and Lindelow 2008).

Recently, under the Chinese government's broader goal of a "harmonious society," health has become a high priority. In 2003 a medical assistance safety net scheme was implemented to further assist specific vulnerable groups. Between 2006 and 2007, the central government's health budget rose 87 percent (Yip and Hsiao 2008). The government put in place social insurance programs designed to fill the gaps in coverage—the New CMS (NCMS) in rural areas and a pilot program for other urban residents—with a goal of achieving universal basic coverage by 2010 (Yiyong Yang, chapter 9, this volume). Over the next several years, in order to provide universal basic coverage, the Chinese government has committed to triple government funding for health care by 1 to 1.5 percent of GDP.

The NCMS aims to protect rural residents against catastrophic health expenses and impoverishment. Benefit packages vary by county, with copayments ranging from 30 to 80 percent of charges; counties cover different inpatient and outpatient services, but all programs must be voluntary and cover some expenses for catastrophic illness. The NCMS has increased health-care utilization but has apparently not reduced out-of-pocket spending (Evans and Xu 2008; Wagstaff and Lindelow 2008). And because the benefits coverage of the new insurance scheme for urban residents is limited, its effect on out-of-pocket payments has likewise been constrained. Providers are paid mostly on a fee-for-service basis according to a government-set fee schedule, with low fees for basic services and higher fees for high-tech diagnostic procedures and for dispensing pharmaceuticals. Hospitals and clinics derive substantial income from drug

sales to their patients (Sun et al. 2008). A few localities have experimented with different forms of provider payment, including global budgets, diagnosis-related groups, and capitation payments.

In urban areas, consumers prefer large tertiary hospitals over primary care physicians, although the government has recently tried to promote community health centers. Reforms announced in April 2009 call for prescribing and dispensing of drugs to be separated, for an essential drug list to be established, and for drug production and distribution systems to be improved. Broader reforms are also in store, which will increase government financing, expand social insurance toward universal coverage, improve public health services, reform public hospitals, and encourage private investments in the health sector.

Overview of the Book

The first section of the book features analysis of the pharmaceutical policies of seven health-care systems of the Asia-Pacific. Chapter 1, by Soonman Kwon, provides an overview of pharmaceutical policy in South Korea, focusing on the contentious pharmaceutical reform of 2000. Previously, physicians and pharmacists both prescribed and dispensed drugs in Korea, but the reform mandated that the two tasks be separated. The goal was to change providers' economic incentives by eliminating their profit from dispensing drugs—up to that point a major source of their income. When the president and civic groups succeeded in quickly setting the reform agenda, the medical profession was unable to block it. But a series of nationwide physician strikes forced the government to modify critical elements of the reform package and to raise medical fees substantially. Kwon argues that the reform resulted in little behavioral change among physicians and smaller net social benefits than expected, primarily because it failed to provide physicians with a financial incentive to prescribe in a cost-effective manner. Recently, the Korean government has implemented several policy measures for pharmaceutical cost containment. These include price negotiation between the National Health Insurance Corporation and pharmaceutical manufacturers, and economic evaluation for positive listing of reimbursable drugs. Until it finds a way to change the prescribing behavior of physicians, however, Kwon concludes that the South Korean government will probably fail to contain rapidly increasing pharmaceutical expenditures.

Chapter 2, by Toshiaki Iizuka, focuses on the economics of pharmaceutical pricing and physician prescribing in Japan. The Japanese government regulates consumer prescription drug prices using a unique dynamic rule called Yakka Kijyun, which updates regulated retail prices based on the previous period's transaction prices. Other aspects of Japan's policies are not unique. For example, as in many regions of East Asia, Japan's separation of prescribing and dispensing has historically been weak. Indeed, at the end of 2007, 40 percent of all prescriptions were filled at hospital and clinic pharmacies.

Iizuka describes in detail recent empirical evidence of how physician prescribing is influenced by price-cost markups—the difference between the doctor's cost of purchasing a drug and the price at which he or she sells the drug to a patient. In particular, Iizuka discusses two of his recent studies that investigate the effect of pharmaceutical policy on physician prescribing. These studies provide compelling evidence that profit margins impact the prescribing behavior of Japanese physicians, in one case affecting the choice of hypertension drug and in the other influencing the choice between brand-name and generic drugs. At the same time, evidence suggests that Japanese doctors do care about the cost of the drug to the patient.

Iizuka's econometric estimates provide some of the first quantitative evidence on the extent to which the integration of prescribing and dispensing, common in many economies of the Asia-Pacific, distorts prescribing behavior. For example, he finds that the average doctor is willing to forgo one dollar of markup in exchange for a twenty-eight-cent reduction in patient cost. A counterfactual simulation suggests that expenditures on drugs are inflated by 10.6 percent due to overprescribing and by another 4.4 percent by the substitution of more expensive drugs that offer higher markups. Iizuka's chapter concludes with a brief discussion of recent changes in Japan's pharmaceutical policy, including a new prescription pad to promote generic substitution and new pricing rules to provide greater rewards for innovative or high-quality drugs.

In chapter 3, Naoko Tomita describes the political economy of separating prescribing from dispensing in Japan. She traces a long historical trajectory of efforts to separate the two tasks, from an 1874 Meiji government law through another law in the 1950s that generated strong protests from the Japan Medical Association to the manipulation of medical and pharmaceutical fee schedules since the mid-1970s. She describes the decision-making process behind health and pharmaceutical policy in Japan and discusses its relationship to the gradual separation of prescribing from dispensing and the continued growth of pharmaceutical expenditures despite strong attempts at cost containment.

The third economy covered is Thailand. In chapter 4, Sauwakon Ratanawijitrasin provides a comprehensive overview of the last three decades of Thai pharmaceutical policies, from now defunct budgeting rules to more recent procurement policies to the controversial issuing of compulsory licenses for seven pharmaceutical products. After briefly describing the Thai pharmaceutical sector, Ratanawijitrasin summarizes five key aspects of Thai government pharmaceutical policies: procurement, production, price, payment, and patents. She then analyzes the causes, contents, contexts, consequences, and controversies surrounding these policies. Arguing that Thailand enacted patent laws not for intellectual property protection but for international trade promotion, she notes that the government must strongly commit to investing in domestic industrial production if it is to benefit from its patent laws.

In chapter 5, Chee-Ruey Hsieh provides an overview of pharmaceutical policy in Taiwan, using drug policies to illustrate how policymakers in a rapidly growing economy with universal health insurance struggle to balance the short-run cost impacts and long-run health benefits of increasing health care. Hsieh first examines the evolution of pharmaceutical policy in Taiwan by focusing on three specific issues: reimbursement policy, the separation of prescribing and dispensing since 1997, and pharmaceutical innovation. Hsieh highlights the economic trade-offs associated with policies in each arena and the empirical evidence of their impacts. He then analyzes several options for reforming the pharmaceutical reimbursement policy in Taiwan and discusses the policy implications of his findings.

The fifth economy covered in the book—Australia—is actually a continent and a pioneer in pharmaceutical benefit coverage policies. Australia's government subsidizes more than 70 percent of all prescriptions through the Pharmaceutical Benefits Scheme (PBS). In chapter 6, Hans Löfgren describes the evolution of a half-century of pharmaceutical policy in Australia, identifying three phases: state dominance and decommodification (1951–1987), pluralist bargaining (1987-1996), and then the uneven advance of neoliberalism. Löfgren's account begins with the founding of the PBS and then covers the 1987–1999 Factor Scheme, which supported the expansion of drug production, exports, and R&D (the single largest program ever administered by the Australian Department of Industry). The chapter continues with a description of Australia's pioneering of cost-effectiveness analysis in pharmaceutical purchasing under the PBS, the systematic application of reference pricing, and the 1994-1995 adoption of the National Medicines Policy. It concludes with a discussion of the recent controversies surrounding pharmaceutical pricing within the Australia-United States Free Trade Agreement. Löfgren argues that although globalization and the reconfiguration of the international drug industry have made the pharmaceutical policy domain more fluid, regulatory issues are typically managed through cooperative exchange within relatively closed networks of core stakeholders in Australia. That subsidy arrangements were never devolved to regional government partly explains the PBS's capacity to effectively withstand lobbying against it.

Chapter 7, by Mark Johnston and Richard Zeckhauser, provides a conceptual framework for understanding how regulated insurance coverage, rather than direct drug price controls, can achieve regulators' equity and efficiency objectives while benefiting pharmaceutical firms and patients alike. Although Johnston and Zeckhauser focus on Australia's PBS as it operated in the 1980s, their analysis has broad relevance. Schemes with many similar features operate in several European countries as well as in Canada and New Zealand (Wright 2004), and developing and middle-income countries in the Asia-Pacific have shown interest in introducing elements of such a system.

The Johnston and Zeckhauser model draws on basic microeconomics and game theory to elucidate the interaction between regulators and pharmaceutical

firms in what the writers term "an ingenious price-contingent subsidy scheme," which turns deadweight loss (due to pricing above marginal cost) into consumer surplus. In the stylized model, the government offers pharmaceutical companies a per unit subsidy for selling their products at marginal cost. The subsidy is calibrated to enable the companies to recover what they would otherwise receive in monopoly profits. When two or more firms possess market power for a particular therapeutic use, the subsidy scheme creates a game—in effect a race—to determine who joins first and reaps most of the benefits. Properly constructed, the game transfers significant oligopoly profits to consumers.

Several key insights from the Johnston and Zeckhauser analysis—such as the use of the PBS to make transfers to pharmaceutical firms in return for agreeing to be regulated, and the regulators' role in achieving greater consumer surplus for patients—hold true in more complicated models of Australia's system, such as the five-stage game developed by Wright (2004).⁵ Although Australia no longer focuses exclusively on achieving low pharmaceutical prices, and has pioneered the use of cost-effectiveness analysis in benefits coverage since the early 1990s, the analytic framework developed in chapter 7 remains instructive for understanding the trade-offs facing government regulators in structuring pharmaceutical benefits for their citizens.

India is the sixth economy examined in this volume. In chapter 8, Chirantan Chatterjee discusses the evolution of India's patent regime and its implications for the development of India's pharmaceutical industry. Chatterjee traces the industry from its humble pre-1947 beginnings through the process patent period (between 1970 to 1995), when it rapidly developed, and into the era of strengthened intellectual property rights laws, during which India signed the WTO–TRIPs agreement and then implemented product patents in January 2005. He describes empirical studies of the impact that patent regime change had on firm innovation and concludes by comparing the development of India's thriving pharmaceutical industry with that of other countries, such as Japan, Italy, and South Korea.

In chapter 9, Yiyong Yang, director general of the Institute of Social Development Research in China's National Development and Reform Commission (NDRC), briefly summarizes the increasingly important role of the government in China's health sector. Public health subsidies will be increased significantly between 2009 and 2011 as China's reforms continue to unfold. New social insurance programs in rural and urban areas aim to achieve close to universal coverage within a few years, and the government recently announced a medical reform plan to restructure delivery and other aspects of the system in order to guarantee access to basic medical and health services for all Chinese by 2020. Yang describes how pharmaceutical reform fits in with this dynamic picture and argues that the reform should be open and transparent to be successful.

Chapter 10, by Mingzhi Li and Kai Reimers, presents an overview of the drug distribution and procurement process in China. The authors draw on an analytic framework and historical account that situate reforms within the broader debate

about how and why China chose to reform its health-care system the way it did during the transition from central planning to a market-based economy. As the authors note, critics of China's health sector reforms accuse the government of unleashing market forces in the absence of any effective regulatory framework, resulting in a chaotic and corrupt drug procurement process.

Each province (or province-level city) in China has discretion in implementing its own reforms, within the national guidelines. Li and Reimers present case studies of the centralized drug procurement processes in Beijing and Guangdong Province, paying specific attention to the stated goals and actual use of the e-commerce system. They find that although the centralized process is clearly technologically feasible and may have enhanced transactional efficiency, the e-commerce platforms are not used for their stated purpose: monitoring hospitals' compliance with drug procurement rules. Li and Reimers discuss how Oliver Williamson's model of transaction cost analysis applies to and illuminates the primary features of China's efforts to move drug procurement transactions into the e-commerce realm. They conclude that without significant and complementary reforms at both the macro- and micro- level of China's health sector, the centralized drug procurement process will likely continue to fall short of its intended goals.

In chapter 11, Qiang Sun and Qingyue Meng analyze key elements of China's pharmaceutical policy, especially the unintended (but predictable) consequences of physician incentives to prescribe according to profitability rather than clinical effectiveness. The authors also provide an overview of the domestic production and distribution sectors and describe how pharmaceutical policy reforms should be undertaken in conjunction with other reforms, especially those that pertain to hospital financing (to address the problematic system of medical care services supported by selling drugs). In addition to taking steps to remedy the perverse incentives of the current system, the government should, according to the authors, develop a monitoring and evaluation mechanism for pharmaceuticals, especially to monitor the availability of essential medicines in both rural and urban areas.

Yanfen Huang and Yiyong Yang analyze China's pharmaceutical price regulation policy in chapter 12. Citing NDRC documents, the authors describe the evolution of China's pharmaceutical pricing and current regulation policy. After assessing the effects of pharmaceutical price regulation and its associated problems, Huang and Yang offer policy suggestions for further reform. They recommend that China move away from pricing pharmaceuticals based on average social cost and instead consider economic evaluation and reference pricing. They also urge officials to establish an essential medicines system, which would strengthen the purchasing role of social insurance programs, and increase government fiscal support of the health sector.

Chapter 13, by Wei Wilson Zhang and Xue Liu, looks at China's pharmaceutical policy challenges from the perspective of the pharmaceutical industry. After a brief review of China's domestic industry structure and its

regulatory context, Zhang and Liu draw on their recent study of drug policy in a large metropolitan area in China to describe challenges to quality, expenditure control, and access. They then analyze pharmaceutical industry incentives and behavior in light of current industrial and regulatory structures and discuss implications for regulatory reform. These authors suggest that China's authorities should impose direct and immediate supervision of corporate behaviors by tightening regulatory standards; approving only bioequivalent generics; enforcing compliance with existing standards of production, distribution, and marketing; and fixing policy loopholes that allow superficial differentiation of drug products. Long-term policy, they suggest, could then focus on changing the industry's structure and promoting innovative products and R&D capacity.

Michael A. Santoro and Caitlin M. Liu also examine the complexity and ineffectiveness of drug regulation in chapter 14, the final China-specific essay in the book. In particular, they address the problem of adulterated and misbranded drugs manufactured in China. After discussing recent reforms in drug regulatory structure and evaluating their likely impact, the authors conclude that both China's regulatory system and the current bilateral efforts between China and the United States to provide further regulation are inadequate to assure drug safety and quality. Santoro and Liu propose reforms to make the pharmaceutical supply chain more transparent, hold responsible parties accountable, and improve safety for global consumers.

The second section of the book highlights cross-cutting themes of prescribing cultures and access versus incentives for innovation. Chapter 15, by Maarten Bode, explores the marketing of traditional Ayurvedic medicines in India. Bode describes the dual rhetoric of modernity and tradition that advertisers invoke for Ayurvedic products, using a case study of the most successful such product, Chavanprash, to show how the marketing claims measure up against the scientific evidence regarding its effectiveness and that of its primary ingredient. His account covers Ayurvedic medicines and the knowledge tradition they embody; the "bypassing" of Ayurvedic physicians (*vaidyas*); and the rational use of Ayurvedic medicines, including considerations of quality, effectiveness, and the possible policy role of modern pharmacology.

Such analyses speak directly to the "prescribing cultures" evoked in the title of our book. Traditional herbal or humoral medical traditions established a set of norms for health, medical care, payment for services, and expectations regarding the role of medicines in health care. Such norms have shaped the evolution of modern health-care systems in India, China, and elsewhere in the Asia-Pacific. Incorporating these traditions into the modern regulatory and industrial market structures and subjecting them to effectiveness (and cost-effectiveness) analyses present many distinctive challenges. Understanding how each society chooses to address these challenges and assessing the relative strengths of a variety of policy approaches can provide important insights for other nations. Here, again, the benefit of comparative analysis seems apparent.

In chapter 16, Karen Eggleston and Bong-Min Yang examine the integration of prescribing and dispensing in comparative perspective, drawing in particular from the history of medicine and pharmacy in South Korea. To explain the institution of physician dispensing, the authors, both economists, use theories of vertical integration and game theory to sketch a conceptual framework that emphasizes shared beliefs and internalized norms. The persistence of physician dispensing illustrates how the incentive structures of current health-care systems are embedded in institutions shaped by culture and history.

In chapter 17, the last chapter to focus on prescribing cultures, Siaw-Teng Liaw describes the efforts to promote quality use of medicines in Australia, one of the four goals of the Australian National Medicines Policy. Liaw summarizes a wide body of literature on the topic, comparing regulation and practice in Australia with those of other Asia-Pacific health-care systems. He argues that prescribing patterns flow from a complex interplay of intrinsic and extrinsic factors, including public institutions, the pharmaceutical industry, the health profession, and consumers, and can be improved through well-implemented e-prescribing and decision-support systems. His analysis provides a natural segue into the final section of the book, on balancing appropriate access to medicines with incentives for innovation in new drug discovery.

In Chapter 18, Anita Wagner and Dennis Ross-Degnan describe the potential for insurance systems to increase access to and appropriate use of medicines. The chapter begins with an illustration of activities undertaken in the Philippines by the Medicines and Insurance Coverage (MedIC) initiative of the WHO's Collaborating Center in Pharmaceutical Policy. The authors argue that governments in the Asia-Pacific region can design pharmaceutical coverage policies within their broader health-care coverage systems to address many of the supply- and demand-side factors that contribute to patients failing to obtain the medicines they need in a timely manner and at an affordable price. The MedIC initiative seeks to support the development, implementation, and evaluation of evidence-based medicine coverage policies in the Asia-Pacific, which in turn can contribute to individual health, household economic security, health-care system efficiency, and economic productivity.

Both the discovery and the availability of pharmaceuticals are shaped by medicines coverage, patent protection, and other policies balancing access with incentives for innovation. Chapter 19 by John H. Barton and chapter 20 by Henry G. Grabowski, David B. Ridley, and Jeffrey L. Moe concentrate on the incentives for the discovery of new drugs. Barton proposes a bold compromise to address the global market failure in pharmaceuticals. The current system provides many pharmaceuticals for the wealthiest nations and few to meet the needs of the poorest, which often cannot afford the products that have been developed. This disparity has led to substantial debate. Barton suggests that the United States and other wealthy nations support a compromise "international orphan drug" approach. Developed-world governments would promise to pay an adequate price for pharmaceuticals—rather than forcing prices down to the

level at which research is unprofitable—and to subsidize efforts to develop drugs for diseases found only in the developing world. All countries would cooperate to create an efficient generic market for drugs for the poorest nations, including for medicines that are still on-patent in the developed world. Developing countries would work with their higher-income counterparts to eliminate tax and customs barriers, strengthen controls on corruption and counterfeiting, and otherwise streamline the supply of drugs. Clearly, details of such a plan would need to be negotiated for it to be globally acceptable, and the nations of the Asia-Pacific would be critical to determining its fate.

As the largest pharmaceutical market in the world and the home to a considerable proportion of pharmaceutical industry R&D, the United States plays an extraordinarily important role in determining incentives for pharmaceutical innovation. In 2007, to stimulate research in diseases that affect the world's poorest citizens, the U.S. Congress created a novel program promoting "priority review vouchers." In chapter 20, the three Duke University professors upon whose proposal the legislation was based—Grabowski, Ridley, and Moe—discuss its evaluation and implementation. They estimate that the vouchers—which reward developers of drugs for neglected diseases with a voucher for priority FDA review of a different drug—could be worth hundreds of millions of dollars based on the time value of money associated with faster reviews, increases in effective patent life, and early-mover advantages vis-àvis competitors. The vouchers could therefore be a powerful stimulant for developing new drugs for neglected diseases, complementing other mechanisms such as public-private partnerships and advanced market commitment incentive programs. As was true for the Orphan Drug Act, Europe and Japan could pass their own variants of the concept, further fueling innovation for

In the conclusion, F. M. Scherer provides a critical overview of the contributions assembled in this book. As one indicator of industry dynamics and relative success in global terms, he presents data on economies' success in developing pharmaceutical manufacturing and in exporting to the United States. The forte of India (the sixteenth largest pharmaceutical importer to the United States) has been low-priced generic drugs. In Scherer's estimation, India's ethical drug producers are likely to continue making inroads into the U.S. market, despite the recent loss of generic sales advantages. Japan (the twelfth pharmaceutical importer to the United States) posted weak performance relative to its potential, possibly because of low standards for new drug product approval, fragmentation of innovative effort on minor local products, and reluctance to deal with FDA approval hurdles and establish extensive sales networks in the United States (also see Reich 1990).

Scherer comments on two overriding themes in the book: the dominant role that physicians play in dispensing medicines and the effect that various government price controls have on the pharmaceutical industry. He brings historical and comparative knowledge to bear in discussing many of the book's key themes: the distribution system and drug prices of China, drug price regulation in the Asia-Pacific region, global controversies over patent protection and compulsory licensing, and the challenges of regulating industries that have not developed scale economies. His conclusions suggest a broad agenda for future research and policy analysis, including how further study of pharmaceutical policies in the Asia-Pacific could make a significant contribution to U.S. policy deliberations.

Notes

- ¹ However, even in such systems, physicians can use renewing or adjusting prescriptions to stimulate additional patient visits, especially if paid on a feefor-service basis. This is one reason why physician drug budgets have been used to considerable effect in some European economies (Danzon 1997:24).
- ² Indeed, in Wolinsky (1993), whether reputation and customer search function to discipline providers depends on search-cum-diagnosis costs. For example, specialization is more likely when search-cum-diagnosis costs are smaller. In other words, if many experts locate next door to one another and all offer "free" diagnosis, this allows both shopping for treatment and associated consumer demand discipline on providers' prices and recommendation strategies. (In this model, specialization does not have to do with investing in diagnosis skills; it is a way to deal with information asymmetry and commitment not to defraud—because providers specializing in low-cost treatments have to refer patients to other providers for the high-cost treatments.) Moreover, in Wolinsky's model, a reputational equilibrium can be sustained only if search-cum-diagnosis costs are not too low (p. 391).
- ³ A whole range of pharmaceutical policies can be examined as case studies in difficult questions of ethics and distributional justice (Santoro and Gorrie 2005).
- ⁴ For an excellent concise overview of the "global drug gap," see Reich 2000.
- ⁵ Both Johnston and Zeckhauser (chapter 7, this volume) and Wright (2004) assume that pharmaceutical innovation is exogenous and pharmaceutical manufacturers are foreign firms. The observation that Australian regulators do take international prices into account when setting their own prices may indicate not an ignorance of the economic logic of the scheme as Wright suggests, but rather regulators' consideration of forces not included in the models (but discussed briefly in chapter 7), such as the credibility of property rights regimes and international relations with countries that are home to large research-based pharmaceutical firms.

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