Introduction

Health and Development in Late Industrial States

Market Menagerie uses an industrial lens to analyze technological advances in the health sector of industrializing nations today. These nations are often termed "late" or even "late, late" industrial economies. A multifaceted conceptualization of their developmental states and market variety is vital, for it can better configure their industrial policies in the provision of health-related products and processes.

Why "market menagerie"? A "menagerie" was an enclosure that housed exotic varieties of birds and animals for royal pomp and pleasure, seen as early, it is said, as 3500 BC in Egypt and from the eighth century onward in parts of Europe. Such exotica for royal amusement displayed the court's power because they were not only difficult to obtain but expensive to retain. Unlike zoological gardens (zoos), which appeared later and often had science and education as goals, early menageries displayed variety but were rarely studied systematically.

"Development" similarly is a menagerie that houses many institutional varieties—especially of states and markets. However, scholars very often pose development as mediated through "the" market, as if there were only one of that species, while those who advocate state intervention similarly discuss "the" state versus "the" market. Neither approach captures the ever-changing varieties of markets that developmental states may have to structure and rein

in, and choices that they must make as they plan. Let us push the metaphor further. Early menageries tended to be more for royal pomp and pleasure than for the populace's enjoyment. Markets too risk becoming exclusive and exclusionary rather than catering to more universal or democratic ideals. The less we study their variety, the less we know about how they might be differently planned. Phrased differently, the task is to make the menagerie rather more like a zoological garden: to open it up and to look more closely at species variety and the geographic context in which species thrive. We can then consider what developmental states can or cannot do and whether market failure assists us in considering when the state should regulate.

Although nation-states and local states fail often, especially in the face of rapid technological advance, this book attempts a more sympathetic retheorizing of states attending to the market menagerie. Even when dysfunctional or outright malevolent, and despite its limitations and contradictions, the state (and its governments) is inevitably the most important planning institution in these economies. Theorizing sector cases rich in industrial capabilities—in pharmaceuticals, biotech, and vaccines—allows us an especially nuanced context for the industrializing world today, comprising markets, democracy, participation, employment, and health politics. Seen as such, the health sector is a story about planning citizen and democratic entitlements and, in India's case, the special context of religious, labor, language, and other spatial and political discriminations woven into the idea of the nation. Universalism in India has special weight for which a simple cosmopolitanism or multiculturalism will not do. In another sense, the growth of urban life sciences has everything to do with economic development strategies and with urban restructuring, the rise of industry megaprojects and private hospitals, and the pressures on land and investments. In yet another sense, science and technologies change; not surprisingly, therefore, so does the health sector. The state often decides both the politics of entitlements and the urban transformation, but it simultaneously plays a crucial role in technological advance that places bounds on state actions. Much if not most of this occurs outside voting cycles and insidiously changes urban landscapes. Therefore, how should we think about the state, its contingent influence, and the markets that drive the health sector? The concern here is with both the process and the outcomes of health distribution, although studying the evolution of outcomes over 50 years may make them more comprehensible, and a focus not exclusively on the

nation-state may make the urban contradictions that manifest themselves more visible. In this era of "national" health reform and "global" governance, we must be able to grapple with this peculiar contrast of advancing life-science concentrations amid health deprivation. How do policy and the state (with several governments that have come and gone) actually mediate in the health sector over time, and how does technological advance make this mediation more contingent?

Technological advance in specific sectors acts as the kernel of immense economic transformation precisely because it imposes sizable learning challenges for industrializing countries and the social changes to see them through. The health sector's advances represent a crucial economic and physical transformation of national and urban economies from Bangalore, India, and Turku, Finland, to Cambridge, Massachusetts, and Cambridge, England. The sector comprises not only pharmaceuticals and biotech firms but also myriad other research, production, demand, and delivery organizations and infrastructure. Visualize cities that have distributed diagnostic labs, hospitals, clinics, university labs, other R&D units, insurance firms, computation-intensive buildings, medical equipment firms, biohazard containment zones, and industrial recycling. These often exist despite health access being far from an assured right.

Most studies of pharmaceuticals and biotechnology, especially from an innovation standpoint, have been concerned almost exclusively with the supply side. Most analyses of the developmental state's role have similarly focused on health planning and have tended to take technological capability and firm-level constraints for granted. Three sets of questions therefore lie at the heart of this book: How can industrializing nations satisfy developmental mandates and promote access to medicines produced at home? What market varieties shape this access? What are the institutional implications for nation-states and urban and regional life-science growth paradigms today?

We cannot answer these questions even cursorily until we look at the sector's dynamics. Markets for health technologies have several unique characteristics, such as limited information and autonomous choice, blurred distinctions between producers and users (especially in clinician roles), risks of use, and particular cultural traits. Furthermore, in health technologies, neither patients nor health professionals but third-party payers (public and private alike) may be the buyers of the end products. As we will see, this collective aspect of consumption and demand shapes late industrial

technological advance and constrains how states can reconcile economic and social goals.

This book brings together three themes that are rarely aggregated in addressing health, industrial development, and developmental states: the building of industrial capabilities in late industrializers, the politics of their access, and their geography of production and redistribution. It situates these themes in terms of two concerns—*market varieties* and *market scales*—as challenges to the actions of developmental states and contributions to a new, developmental pragmatism. Therefore, this book is certainly not a health policy or health economics volume, although it analyzes the health industry. It is, however, very much about the health of development itself. As such, it should complement the interests of readers of health policy, those looking to understand its industrial context, as well as those in economic development and urban and regional planning who are concerned with the evolution of essential institutions, such as markets and states.

An author writes because of his or her certainty that something has been missed or wrapped up too quickly. I write because I am curious about what are termed "wicked" problems:[1] what can seem overwhelming, intractable problems that specialists rush to dissect and separate into individual strands. This dissection is satisfying to show off one's specialist tendencies, but it tends to shun the "wicked" character of the problem, which is a reflection of the real world. Rather than seek a straightforward industry and regional planning approach, or an economics-of-innovation approach, I have chosen to emphasize the multifaceted nature of the state's planning compass. My choice to bring several themes together stems from my desire to approach the future in an integrative theoretical manner and from my professional world that often collides with the dual realities of supply organizations, on the one hand, and access and demand politics, on the other. Theories of urban and regional planning and economic institutionalism urge reconstruction, not merely theoretical deconstruction.[2] I agree. They must not merely expose ideologies and generalizations about our world, but must also suggest new ways of approaching older problems and propose new conceptual possibilities for reconstruction and greater well-being. Therefore, in taking on states and markets, my task is partly to look within these institutions and partly to look beyond them to expand our debates. It is also essential that we move beyond complaining about our world, even if our kvetching is buttressed with thorough

social science research; rather, we must use deconstruction to reenvision our world when this is possible.

This book makes two essential points regarding developmental goals. First, it questions the common reading of development as market failure, but also development as production success. It therefore moves beyond the standard focus on market failures and public goods, emphasizing instead an evolutionary market variety and the wider institutional ecology that markets inhabit, which includes other institutions, such as states, firms, technical standards, intellectual property, insurance, and citizenship. Evolution of critical institutions such as markets and states need not mean evolving with no planning interventions (i.e., laissez-faire), but neither does it suggest full social control. What it does suggest is that state autonomy, power, and planning control are technologically and politically contingent. In exposing these contingencies, we can do better in redesigning the institutional scope of industry and health. Neither markets nor states possess absolute power, as we shall see in the forthcoming chapters.

Second, developmental states are practically synonymous with developmental nation-states. However, the abstract rhetoric of "national" health reform and "global" governance distracts us from important shifts occurring in subnational politics, rapidly advancing urban life-science concentrations, and intersecting scales of development and regulation. Therefore, the developmental agenda for states is to regulate in the face of technological evolution by managing the market menagerie, continually demarcating market bounds, health entitlements, and redistribution on multiple stages: international, national, and local.

On the one hand, the more decentralized the strategies for industrial and technological development become, the more necessary the nation-state is in reining in territories, in economic regulation, and in lowering regional inequalities. On the other hand, supranational globally harmonized standards (intellectual property rights or technical standards of trade, for example) push toward more uniform production, thus forcing nation-states and local states to attend to more customized production and regulation for domestic development needs. Economic plans and policies must combine the political economy of technological advance with federalism, public finance, and urban morphologies of design and distribution. An integrated economics approach, therefore, requires a more evolutionary, dynamic view of institutions and regulation because both "national" production and health care occur in

particular places and need local institutions. Complexity should not scare us; we should embrace it because more systematic understanding allows us to appreciate better why we collectively combine and choose some futures and let others go. Making plans, rather than controlling them, involves not only innovation and agility but also continuously changing course in light of necessary uncertainty. Theory poorly shows us how to do this. Therefore, I extend the discussions toward the end of the book to make some reasoned speculation about health in an industrial, technological age. More traditional health policy and industrial analysts may balk at this more philosophical extension of economics to new areas, metaphorical and literal. Without this engagement, however, I am convinced that we will continue to analyze our world in unhelpful disciplinary and analytic silos.

Finally, I highlight an important difference about access itself: many institutional economics and health economics volumes assume that the only issue at stake is affordability and "the poor." This book emphasizes that planning, regulation, and the state's roles must encompass both supply and broader concerns of affordability. My concern here, therefore, is with late industrial suppliers and their technological advance,[3] not with those nations that have industrialized (with or without a supply base) nor with "developing" countries. All countries need not have supply bases, but those that do—the focus of this book—are politically and economically distinct from "poor" or "developing" countries as categories.

Of course, development is not only for so-called developing countries. Industrialized countries do provide an important foil in later chapters for debating the timing and contradictions of technological advance. Even in the United States, important "developmental" goals have reemerged. The national health-reform debate has made world headlines, sharpened the focus of academics and the popular press, and pitted the country's advanced health technology supply against its large gap in access. It is therefore an excellent time for comparative health debates, judging from the number of books and scholarly articles and the surge in op-eds on health reform worldwide. Similarly, the global governance of health (AIDS, malaria, tuberculosis [TB]) and the growing number of cross-border epidemics and incidents of bioterrorism (swine flu, bird flu, TB, HIV/AIDS, and anthrax) have positioned health technologies as a crucial twenty-first-century issue. The fundamental challenges for nation-states are to wed technological advance to local institutional context, as well as international standardization pressures.

New influential groupings such as Brazil, Russia, India, China, and South Africa (BRICSA) already have almost half the world's population, a quarter of the world's land, and 20% to 25% of current economic output, and it is estimated that they will have over 60% of the world's gross domestic product (GDP) by 2050.[4] Most 2000–2008 increases in world output were from developing countries, with estimates of as much as half coming from the growing powers of Brazil, Russia, India, and China (BRICs) alone.[5] Trade among the BRICs now dwarfs some aspects of the trade between traditional North Atlantic and BRICs countries. China has now become India's second-largest trading partner, for example.[6] The institutional climate is doubly crucial because much of this economic surge has come from technology-intensive gains in several city-regions within the BRICs. India alone has 10 or more of the 30 fastest-growing urban regions in the world. These city-regions disproportionately add to the country's GDP and growth rates. The BRICSA countries require new approaches and scholarship in development debates on both industry and health fronts. Their immense size, growing economic power, politics of federalism, and technological advance are highly distinctive. India's growth-focused prospects look remarkably promising, but if one focuses on redistribution (and even more conservatively on per capita GDP based on historical growth rates), this future looks far less rosy.[7]

A point I will reiterate in the chapters ahead is that technological advance in the pharmaceutical and life-science industries can reinforce economic development and industry growth, but not necessarily positive health outcomes. Nevertheless, there are vital reasons to bridge more closely the spheres of the economy that can be self-reinforcing. After all, health policies can be powerful protectionist tools for industrial growth in generics and pricing, for example, while well-crafted industrial policies can boost health outcomes in drug safety and supply. A central task for states is to reconcile economic and social goals in their developmental agenda, something that no developmental state to date has arguably been fully able to do.

The health sector can consequently be seen as a triad consisting of a fragile web of three primary institutional dynamics: industrial production of technologies, medicines, and vaccines; the provision systems of health-care delivery, such as hospitals and clinics; and the consumption (demand) of health care through individual or collective buying systems. Instead of "a" market of supply and demand, health care is in fact a web of these three interlinked relationships (see Figure I.1).[8]

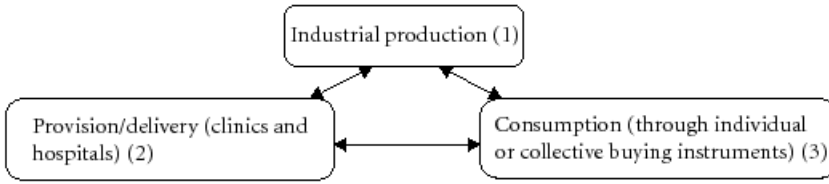

FIGURE I.1 Institutional triad of health care
SOURCE: Created by the author.

Indeed, despite the economic rhetoric that "institutions matter," "considering single institutions may be misleading and may altogether miss the genuine importance of institutions in the economy which is of a combinative nature."[9] This selective combinative nature and its tensions will be evident as we track the challenges to technological advance from 1950 to 2000.

Barbarians at the Gate: Late Industrial Supply

All democratic supplier countries face special challenges, even industrialized ones. For instance, U.S. President Barack Obama is attempting reforms in areas ranging from orthopedic procedures to diagnostic tests as costs spiral, the economy plummets, and employment-linked health benefits recede. Domestic politics can spur innovation policies, regulate health access, cap prices, or ration services. However, late industrializers are especially complex and presage the state of the world's economy and its health-care supply in the twenty-first century. Prime Minister Manmohan Singh of India has called health-care access a national priority (national emergency might have been closer to the truth); President Luiz Inacio Lula of Brazil walked a balancing act among strong social policies and family and community support for health care, organizational innovations, bold patent policies for HIV drugs, and a growing industrial and consumption base. It remains to be seen whether his successor, President Dilma Rousseff, can do the same. In general, not only must democratic industrializing supplier nations such as India, Brazil, South Africa, Nigeria, and Indonesia keep industrial momentum humming, but their health-care systems also must work triply hard: to provide healthy citizens (and they have many young ones) for this economic transformation, to manage the politics of redistribution and minimize unrest, and to boost the competitiveness of their health industries.[10] From generics to vaccines and from surgical instruments to

testing kits, this triad, especially in late industrializers, encompasses several subrelationships and lends itself to a noisy market menagerie at any time. Its coevolutionary elements indicate that several political economies can be conceptualised, but not all these institutional mixes necessarily complement each other in a well-working health system. Seeing the health sector in these terms is intended only as a broad heuristic to appreciate better how different types of planning and policy analysis tend to pick one or another realm. More important, this view reminds us that the three elements interact and constantly coevolve. Therefore, the goals of development plans, particularly when the goals may be both better supply and healthier populations, are never easy and are rarely simultaneously accomplished. In Chapter 8, for example, we will explore how several countries have emphasized some elements over time.

The health sector's several spheres of regulatory influence vie for state attention: competition policies, safety and efficacy policies, or access and equity policies may be peppered throughout the triad of production, delivery, and competition and may have no exact correspondence with them. After all, access and equity are important not only for consumption, but also for the design of delivery. Similarly, competition policies not only affect industrial production but also can, through increased competition, lower prices and increase access or improve quality (and thus safety). There is no comfortable equilibrium; constant state intervention and regulation are required. The heuristic of the triad cannot lead directly to policy prescriptions, but it can remind us of the complexity of development and regulation and thus make the prescriptions more palatable, as well as innovative. It also can make us less ideologically tied to particular institutions and national frames and more attuned to the necessity and challenges of local planning as an essential part of economic theory and practice.

The story of the Indian pharmaceutical and biotech sectors and the comparative questions I ask about other states in later chapters will repeatedly return to the varieties of market settings and development concerns in a single sector. The simple institutional triad can therefore be only a broad guide to analyzing market changes over time. This is neither a story of successful production states nor of how markets ruled supreme. It is a story of how markets evolved and developmental state learning and challenges grew. Indeed, technological advance (the production success of developmental East Asia, for instance) has exacerbated the challenges to demand for health care and its delivery. The forthcoming chapters and analysis will emphasize the menagerie of

markets in one country—India—for health technologies. How the nation-state unevenly governs these to fulfill its developmental task is at the heart of the book.

Today India is the world's tenth-largest industrial economy and one of the world's largest suppliers of vital medicines and vaccines. Médecins Sans Frontières (Doctors without Borders) today calls India the "Pharmacy to the World."[11] India has some of the world's most competitive generics suppliers, rapidly growing life-science concentrations, and a booming medical tourism industry, but also one of the highest populations without access to medicines, vaccines, and diagnostics. India's story is telling because it shows the tensions and political struggles to marry late industrialization and its benefits, with its poorly institutionalized and struggling links to employment and employment-linked health benefits—trends visible across South Asia, Latin America, West Asia, and Africa. To be sure, India has had its share of health successes, from declining infant and maternity mortality rates to a rise in immunization rates and a lower incidence of epidemics than earlier in the twentieth century.

Certainly, not all countries need to manufacture or innovate in health technologies.[12] Those that do manufacture or innovate, however, face considerable production challenges. Although several important traditional health systems exist in India, such as Ayurveda and Unani, and provide significant potential for health care, my analysis focuses primarily on "mainstream" drugs and biologics alone and the imperatives and dilemmas generated by industrial capabilities.[13]

The pharmaceutical industry has moved from older chemistry advances in discovery, categorization, and isolation of effective components of age-old drugs such as alkaloids, quinine, and morphine to the serendipitous discovery of organic synthesis clues arising from abundant industrial by-products such as coal tar to advances in pharmacology and chemotherapy.[14] Such advances have led to rapid growth and an avalanche of inevitable regulations. These have reorganized markets and public health priorities in safety, efficacy, pricing, and organizational forms in insurance, university-industry relationships, and public funding.

Firms in this domain of "synthetic" pharmaceuticals face certain types of technology: discovery of new drugs (product technology) and the development of viable production methods (process technology) and improvements to existing technologies. Industrial and laboratory technologies straddle multiple levels of sophistication, from simply importing and repackaging imported

medicines to locally producing bulk materials from raw materials (often local). Whether innovative in products, processes, or both, firms are inevitably constrained by low-cost competitors at one end and high-technology competitors at the other.

It is process technologies, however, that especially demonstrate the firm's crucial ability to develop a viable manufacturing method in making medicines. The firm needs to move from research laboratory to factory scale-up and eventual manufacture. The classic example, acetylsalicylic acid, was first synthesized in a laboratory in 1853 with acetyl chloride as an acetylating agent. However, it took more than 40 years for a large-scale production system with acetic anhydride as an acetylating agent to evolve. The result was Bayer's phenomenally successful drug aspirin. Similarly, fermentation process technologies revolutionized the industry and enabled lifesaving commercial penicillin production.

Two further types of manufacturing technologies are highly sensitive to scale economies: (1) bulk drugs (active pharmaceutical ingredients [APIs] in drugs) and (2) formulations (finished dosage forms, such as tablets, capsules, and ointments). Countries may specialize in or offshore formulations and the methods to store, transfer, and distribute therapeutics (packaging and storage technologies). Bulk drug producers can be of various types, generic or specialized suppliers. Although bulk drug production forms the primary source technology for pharmaceuticals, few countries today can manufacture bulk drugs from local raw materials. As health security becomes more urgent, so do these crucial industrial capabilities.

Biotechnologies that have revolutionized health products are "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[15] More generally, they are a field of applied biology with applications in medicine and are fundamentally based on process technologies in order to create proteins and cell- and tissue-culture engineering and/or use proteins, RNA molecules, and enzymes associated with specific genes and diseases.

In industrial biotechnologies a typical three-step process consists of preparation phases, fermentation phases, and recovery and purification phases. Biopharmaceuticals that use biotechnologies have similar stages. In contrast to synthetic pharmaceuticals, "biopharmaceuticals" involve simply the use of biological elements in drugs. The drug-development cycle for both synthetic and biological drugs is technologically complex and financially burdensome.