

SECTION 3: CHINA'S HEALTHCARE INDUSTRY, DRUG SAFETY, AND MARKET ACCESS FOR U.S. MEDICAL GOODS AND SERVICES

Introduction

The healthcare sector has played a marginal role in U.S.-China relations, but that is beginning to change. China has become the world's top producer of active pharmaceutical ingredients (APIs) and inert substances, as well as a significant exporter of medical products.¹ U.S. drug companies and distributors are sourcing a large share of ingredients and finished drugs from China and selling them in the United States. Concurrently, China is experiencing a major demographic and epidemiologic transition, challenging the nation's health care system. China's median age will exceed that of the United States within this decade, and the proportion aged 65 and above is projected to increase from 9 percent in 2013 to 25 percent by 2040, totaling 300 million.*² An older and wealthier population, with a rising incidence of non-communicable diseases, is seeking more frequent and better-quality treatment.³ U.S. companies that market drugs, medical devices, and healthcare services consequently view China as an important opportunity.⁴

To explore these issues, the Commission held a hearing in April 2014 on China's healthcare sector, drug safety, and the U.S.-China trade in medical products. Among the witnesses were Christopher J. Hickey, the U.S. Food and Drug Administration's (FDA) country director for the People's Republic of China; Rod Hunter, senior vice president for international affairs at PhRMA; and Karen Eggleston, fellow and director of the Asia Health Policy Program at the Shorenstein Asia-Pacific Research Center of Stanford University. The hearing built on the Commission's past work on healthcare, in particular the April 2010 commissioned report *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients*, authored by NSD Bio Group, LLC.⁵

The Commission determined that the Chinese government is stepping up efforts to fix the country's troubled healthcare system. In addition to promoting structural reforms, it invested over \$371 billion between 2009 and 2012, much of which has gone toward expanding public health insurance and building healthcare facilities in small towns and rural areas.⁶ The government is also taking preliminary steps to improve regulation of pharmaceutical production. Important measures include updating good manufacturing practices (GMP) legislation in 2011 and consolidating separate reg-

*The U.S. over-65 population is 14 percent. United States Census Bureau, "Quickfacts," <http://quickfacts.census.gov/qfd/states/00000.html>.

ulatory agencies into the China Food and Drug Administration (CFDA) in 2013.⁷

However, not all of China's healthcare reforms have succeeded, and serious problems remain. The government operates the largest hospitals and health insurers, thereby competing against the private sector and creating conflicts between government ownership and regulatory functions. Beijing also intervenes heavy-handedly in the healthcare market by controlling prices for drugs and devices, setting distorted fee schedules for medical providers, and determining which drugs are eligible for reimbursements from government-run insurers. Meanwhile, underfunded hospitals and doctors solicit bribes and overprescribe costly drugs and treatments to compensate for strict curbs on fees. Escalating costs, as well as rising utilization, are driving healthcare spending. Some frustrated patients have even taken violent action against doctors and nurses. Central directives to address these issues are often poorly designed or implemented unevenly by local governments.⁸

The goal of promoting indigenous producers has also impeded efforts to develop a well-regulated pharmaceutical industry. Although some private Chinese companies are competing fairly, the government is subsidizing domestic firms while inducing technology transfer from foreign drug and device makers.⁹ At the same time, China has become one of the prime sources of counterfeit and substandard drugs and drug ingredients. Fragmented supply chains, competition based primarily on pricing, and weak enforcement of standards encourage producers to cut corners.¹⁰

As producer and consumer, China now plays a central role in the global healthcare sector. For the United States, this presents opportunities as well as risks. Outsourcing production to China may help U.S. drug makers lower production costs but can compromise the safety of U.S. consumers. Tainted heparin products that originated in China claimed at least 81 U.S. lives and many sick patients in 2007–2008.¹¹ Since then, the FDA has enhanced its efforts to monitor drug safety in China, at the border, and in the U.S. market. Congress has passed new bills, such as the Food and Drug Administration Safety and Innovation Act (FDASIA) (2012) and Drug Quality and Security Act (DQSA) (2013), to enhance the agency's legal authority and operational capabilities over drug imports. Still, in view of China's vast industry and weak domestic regulation, U.S. consumers remain at risk. As of late September 2014, the FDA had just one part-time and two full-time drug inspectors stationed in China.¹²

U.S. companies looking to sell goods and services in China's healthcare sector also face market access barriers. Onerous clinical trials in China can delay the marketing of U.S. drugs by up to eight years. Uneven access to reimbursement lists makes U.S. drugs less affordable for Chinese patients.¹³ U.S. device makers likewise suffer from a number of regulatory hurdles that impact data protection and competitiveness.¹⁴ A recent crackdown on foreign drug makers on bribery charges has raised broader questions about whether U.S. companies can operate ethically in an authoritarian state plagued by widespread corruption.¹⁵

China's Pharmaceutical Exports: Public Health Risks and Policy Responses

China's Position in the Global Drug Industry

U.S. reliance on foreign medical products has increased substantially in the 21st century. The number of drugs from foreign sources for sale in the U.S. market doubled between 2001 and 2008, and today represents 40 percent of the market. Import reliance is even starker for APIs—some 80 percent are now sourced from abroad.¹⁶ This trend is reflected in U.S. imports from China. According to Dr. Hickey, the total number of shipments of FDA-regulated products from China increased from approximately 1.3 million entry lines (food, drugs and devices) in 2007 to almost 5.2 million in 2013.*¹⁷ Dr. Allan Coukell, a drug safety expert at the Pew Charitable Trusts, testified that about 40 percent of APIs used in the United States are sourced from China and India. The United States imported over 100 million kilograms of pharmaceutical goods from China in 2013, a close to 200 percent increase over the past decade.¹⁸ Charles Bell, a health expert at Consumers Union, told the Commission: “Over the last decade or so, a lot of the sourcing of dietary supplements and vitamin ingredients has shifted to China, following the pattern set by the drug industry.”¹⁹

Product-specific data substantiates these claims. Import statistics gathered by the U.S. International Trade Commission demonstrate that, although volumes fluctuate over time, a substantial share of U.S. non-prescription painkillers such as ibuprofen, acetaminophen, and aspirin, originates in China (see Table 1). The increase in China's share of antibiotics imports is striking, as is the reliance on China for organic glands used for organotherapeutic purposes. According to Chinese government sources, China's volume of production for a range of drugs has increased substantially since 2005 (see Table 2).

Table 1: U.S. Imports of Select Pharmaceuticals, Drug Ingredients, and Vitamins †
(kilograms thousands)

<i>Volume of Total U.S. Imports (kilograms thousands)</i>				
	1998	2003	2008	2013
Ibuprofen	415	1,492	3,017	3,837
Acetaminophen	1,488	2,291	3,040	1,941
Aspirin	2,034	4,314	4,663	4,453
Glands/organs for organotherapeutic uses	—	—	3,758	3,699
Antibiotics	8,455	5,752	6,759	8,233
Vitamin C	12,405	21,601	36,251	33,006
Vitamin D	306	583	1,195	1,246

*In this context, a “line” is an FDA entry line, which represents each portion of a shipment that an importer lists as a separate item on an entry document. According to Dr. Hickey, 3.4 million entry lines in 2013 were medical devices and 25,000 were drugs and biologics.

† HTS codes used for this table are: Ibuprofen (2916391500), acetaminophen (2924296210), aspirin (2918221000), glands and other organs for organotherapeutic uses, dried, whether or not powdered (30019001), antibiotics (all 10-digit codes under HTS 2941), vitamin C and its derivatives (2936270000), vitamins D and their derivatives (2936295020).

Table 1: U.S. Imports of Select Pharmaceuticals, Drug Ingredients, and Vitamins †—Continued
(kilograms thousands)

<i>China's Share of U.S. Imports (%)</i>				
	1998	2003	2008	2013
Ibuprofen	0.1%	6.2%	73.4%	70.3%
Acetaminophen	48.5%	65.1%	41.9%	44.7%
Aspirin	37.0%	39.7%	31.8%	28.6%
Glands/organs for organotherapeutic uses	—	—	69.4%	57.9%
Antibiotics	39.4%	26.3%	51.0%	70.4%
Vitamin C	64.7%	86.4%	90.1%	89.9%
Vitamin D	0.3%	16.5%	53.6%	83.4%

Source: U.S. International Trade Commission.

Table 2: Selection of Top Pharmaceuticals Products Produced in China (by Volume)
(tons)

	Tons		Compound annual growth rate (%)
	2005	2013	
<i>Antibiotics</i>			
Amoxicillin	7,765	14,401	8.0%
Penicillin K	362	4,396	36.6%
Ceftriaxone Sodium	1,320	4,009	14.9%
<i>Antipyretics and Analgesics</i>			
Paracetamol	44,244	64,485	11.4%
Ibuprofen	2,437	5,795	11.4%
<i>Antiparasitics, Vitamins, and Minerals</i>			
Vitamin C	80,804	107,042	3.6%
Vitamin E Powder	12,562	40,133	15.6%
Vitamin A Powder	2,259	5,804	12.5%
Vitamin B12	704	1,789	12.4%
<i>Drugs for Central, Alimentary, and Respiratory Systems</i>			
Caffeine	9,630	14,349	5.1%
Taurine, 2-Aminoethanesulfonic acid	2,141	12,159	24.2%
Piracetam	2,096	2,947	4.3%
Sodium Bicarbonate for Injection	733	1,450	8.9%
<i>Fluid, Electrolyte & Acid Base Balance and Anaesthetics</i>			
Sodium Chloride for Injection	16,239	32,189	8.9%
Dicalcium Phosphate	972	21,638	47.4%
Potassium Chloride for Injection	396	2,156	23.6%
<i>Antiallergic Agents, Enzymes, and Other Biochemicals</i>			
Phenylalanine	122	1,894	40.9%
Thiopropine	710	1,361	8.5%
Leucine	529	1,004	8.3%
<i>Other Substances</i>			
Glucose	255,308	304,388	2.2%
Glucose for Injection	78,153	88,972	1.6%
Xylitol	8,644	34,345	18.8%
Microcrystalline Cellulose	2,036	3,159	5.6%
Fructose	57	1,328	48.3%

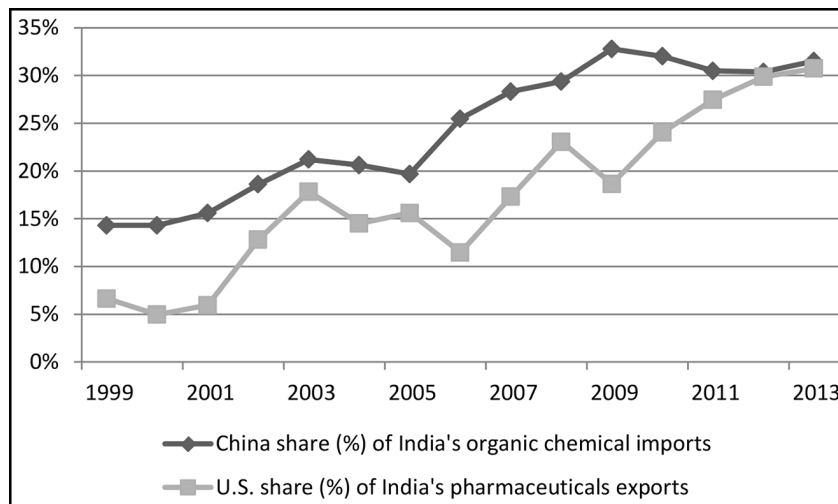
Source: China State Food and Drug Administration, via CEIC data.

The outsourcing of drug production to developing countries is not unique to China. U.S. and European drug makers today are manufacturing fewer small molecules in house and focusing instead on the higher-value development of biologics.* Much of their research and development (R&D) takes place in Boston, Geneva, and other “clusters of expertise.”²⁰ Producers across Asia have entered drug manufacturing, taking advantage of low labor costs, advances in transport and communications, and government policies that encourage value-added exports. India is now the preeminent supplier of generic drugs, serving as an export platform for U.S.-based multinationals, as well as Indian competitors.²¹ To regulate Indian drug exports to the United States more effectively, the FDA has established offices in New Delhi and Mumbai, and stationed one full-time medical products investigator in New Delhi.²²

However, China also occupies a distinctive position in global drug production. In contrast to India, its products tend to enter the value chain further upstream, or in a more preliminary stage—what experts call the “precursor supply chain.”²³ Precise evidence is hard to come by, but experts estimate that China is the top global manufacturer of APIs and drug dyes, binding agents, gel capsules, and other inert substances.²⁴ In a 2010 study of pharmaceutical executives by the consulting firm Axendia, 70 percent of respondents cited China as their top country source for pharmaceutical ingredients.²⁵ Research conducted at the Commission’s request by NSD Bio Group shows that the United States in 2008 was the top destination for China’s pharmaceutical raw material exports, with a 16.2 percent share. India ranked as China’s second-leading export destination.²⁶ Since India’s drug industry is export oriented, a substantial portion of Chinese-origin ingredients processed in India may be exported to the United States as part of finished drug products. Indian customs data show that China’s share of India’s organic chemical imports and the U.S. share of India’s drug exports have both risen over the past decade (see Figure 1).

*The bio/pharmaceutical industry discovers and develops both small molecule drugs (also referred to as New Chemical Entities or NCEs) and biomolecular drugs, also called biologics (also referred to as New Biological Entities or NBEs). While NCEs tend to be chemically synthesized and have a known structure, NBEs are complex mixtures that are not easily identified or characterized. Since the early 1980s, drug innovations for NCEs have leveled off while those for NBEs have increased. Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that have no other treatments available. U.S. Food and Drug Administration, “What Are ‘Biologics’ Questions and Answers.” <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm>; “Small Molecule Drugs versus Biomolecular Drugs (Biologics)” (James Samanen Consulting, 2014). <http://www.portfoliomangement-solutions.com/the-organization-of-pharmaceutical-rd/small-molecule-drugs-versus-biomolecular-drugs-biologics/>.

Figure 1: China Share of India's Organic Chemical Imports; U.S. Share of India's Drug Exports
(Share, %)



Source: India Ministry of Commerce and Industry, via CEIC.

China's Production of Counterfeit and Substandard Medicines

China is a prolific source of counterfeit and substandard medicines. Fake drug production is, of course, a global problem, not least in India.* Dr. Shaohong Jin, vice president of China's state-run National Institute for Food and Drug Control, maintains that the incidence of fake and substandard drugs in China has in fact declined: His tests of thousands of drug samples indicate that the share of failed drugs fell from 14 percent in 1998 to less than 5 percent in 2013.²⁷ However, there is alarming evidence that points in the other direction. In 2012, for example, Chinese authorities discovered 77 million gel capsules made from industrial waste.† Economist Ginger Zhe Jin told the Commission that fake drugs from China are making their way across the world. In a recent study, she sampled 1,437 drugs sold in 18 poor-to-middle-income countries. Drugs labeled "made in China" accounted for 6 percent of the total sample, but for 20 percent of the fake drugs in the sample.²⁸ The White House Office of National Drug Control Policy states that

*During a crackdown in May 2014, authorities in the United Kingdom seized millions of dollars worth of counterfeit and unlicensed medicines. Of these, 72 percent came from India and 11 percent from China. Margaret Davis, "Fake and Unlicensed Drugs Seized," *Press Association National Newswire*, May 22, 2014, via Factiva.

†Other prominent cases of drug safety lapses in China include: Xinfu Clindamycin Injections (2006); Qiqihar Counterfeit Armillarisin A Injections (2006); Shanghai Hualian Major Drug Production Quality Accident (2007); and Dalian Jingang Anti-Counterfeit Rabies Vaccines (2009). For an analysis of these cases, see NSD Bio Group LLC, *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients* (U.S.-China Economic and Security Review Commission, April 2010), pp. 35–40; Associated Press, "Tainted Drug Scandal: China Makes Arrests, Seizes 77 Million Capsules in Crackdown of Pills Made from Industrial Waste," April 23, 2012. http://www.huffingtonpost.com/2012/04/23/china-tainted-drugs_n_1444926.html.

China is among the countries producing precursor chemicals for the illicit narcotics trade.* Roger Bate, a counterfeit drug expert and Visiting Fellow at the American Enterprise Institute, says that China is “the largest manufacturer of fake drugs in the world.”²⁹

China has advantages in producing both legitimate and illegitimate drugs. The country’s large manufacturing industry and domestic consumer market facilitate economies of scale that lower costs. To promote goods for export, the Chinese government has for decades promoted foreign direct investment, along with loosely regulated special economic zones that move massive volumes of goods each day.³⁰ During the global financial crisis, the government provided generous export tax rebates to producers of active pharmaceutical ingredients, claiming that this would boost exports in “high value-added” industries.³¹

Protection of intellectual property is weak, which serves as a backdoor subsidy to Chinese companies that rely on piracy for profits. According to data from the World Customs Organization, collected from 121 countries in 2008, 65 percent of seized counterfeit shipments detected worldwide and 79 percent of counterfeits seized in the United States were shipped from mainland China. In the European Union, where sector-specific data is available, 6 percent of all seized counterfeits in 2008 were medicines.³²

China is a top producer of basic chemicals and agricultural products, which supply important drug ingredients to Chinese manufacturers. For example, over half of the global pig herd is based in China, providing a cheap and ready supply of porcine mucosate tissue for crude heparin, which is made into anticoagulant, or “blood thinner.” † China has overtaken the United States as the leader in global chemical shipments (see Figure 2). China’s exports of organic chemicals, the ones most commonly used in pharmaceuticals, grew from \$5.3 billion in 2004 to \$36.5 billion in 2013. Over the same period, the sales revenue of organic chemical producers in China increased from \$17 billion to \$241 billion. ‡³³

The agricultural and chemical industries are heavy polluters of air, water, and soil, and require commodity imports such as soybean feed and petrochemicals. In the interest of public health, domestic stability, and resource security, the Chinese government is taking measures to reform these industries.§ For the time being, though, many U.S. companies find it more expedient to source from China than to produce domestically in the United States.

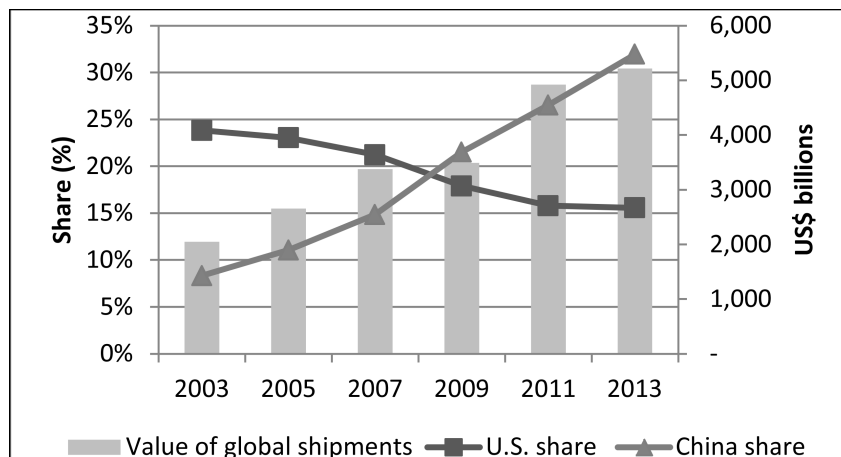
*The White House Office of National Drug Control Policy states: “Global efforts to prevent the diversion of methamphetamine precursors have made significant progress. This is a complex effort, requiring cooperation of the countries that produce these precursor chemicals—principally India, China, and Germany.” *Controlling Precursor Chemicals* (Washington, DC: The White House). <http://www.whitehouse.gov/ondcp/precursor-chemicals>.

† For more information, see U.S. Economic and Security Review Commission, *2013 Annual Report to Congress*, Chapter 1, Section 4.

‡ Export data denominated in current U.S. dollars. Sales revenue data in current renminbi, converted to U.S. dollars based on historic exchange rates (year-end 2004 and year-end 2013).

§ For more information on environmental issues in China, see U.S. Economic and Security Review Commission, *2014 Annual Report to Congress*, Chapter 1, Section 4.

Figure 2: Global Chemical Shipments, 2003–2013: China vs. the United States
(US\$ billions)



Source: American Chemistry Council. <http://www.americanchemistry.com/Jobs/EconomicStatistics/Industry-Profile/Global-Business-of-Chemistry>.

Detecting Harmful Drugs in a Complex Industry

Regulating China's vast drug industry is difficult. Production is extremely fragmented, with some 4,000 manufacturers of pharmaceutical products, about 400,000 retail pharmacy shops, and according to Chinese customs data, about 29,000 firms involved in exporting medical products.³⁴ Since most suppliers in China sell to other businesses downstream instead of directly to the consumer, they are easily missed by regulators. According to Dr. Hickey:

In China, whether they're manufacturers of active pharmaceutical ingredients or, for instance, workshops that do the rendering that creates crude heparin that goes into heparin, those kinds of sites are not accustomed to being inspected as much as let's say [generic drug producer] Ranbaxy in India. So there's less familiarity perhaps with how our inspections work and what our inspection regime is.³⁵

Criminals in China resort to a variety of ruses to avoid detection. According to Dr. Coukell, China hosts many "show and shadow factories," where the factory of record is not the actual origin of an active ingredient.³⁶ Packaging may also take place at a different location from production. Chinese counterfeiters sometimes claim on packages that the drug is "made in India," so that when quality issues are detected, Indian rather than Chinese producers are blamed. Dr. Bate's fieldwork has revealed that manifests at ports are frequently inaccurate, helping fake drugs from China to go undetected when they are unloaded in other parts of the world, particularly at transit ports.³⁷

While China has its fair share of outright criminal operations, many harmful products stem from *semi-legitimate* producers. Examples include licensed chemical producers who supply pharma-

ceutical ingredients that they are not licensed to produce; illegal producers that are owned by companies selling into the legitimate supply chain; and firms that produce legitimate products during the day shift and grey market products during a secret night shift. Suppliers may also adjust the level of quality based on the standards and detection capability of the customer and export market to minimize compliance costs.³⁸

When producers of harmful drugs are identified, it is hard to prove liability. In theory, experts distinguish “substandard” from “counterfeit” drugs; in practice, the distinction is blurred, since companies can claim that they unwittingly corrupted their products. Ingredients may contain residues of toxins, which could originate either from the production facilities themselves (e.g., trace elements of one production line spill over to another) or from a prior stage in the value chain (e.g., agrochemical residues). Moreover, companies may be caught unaware if contamination or counterfeiting was committed by their upstream suppliers.³⁹

When a harmful product reaches the end consumer, its effects vary widely. Most pernicious are cases where an incorrect formula of active ingredients is used. That is what occurred with tainted heparin in 2007–2008: the culprits used an extremely harmful substitute ingredient that was not detected by standard laboratory tests (see textbox). Other illegitimate products commonly seen in the market exert a subtler impact:

- *No active ingredients*: In this case, the patient thinks he/she is receiving effective medication and so foregoes corrective treatment until it is too late. This problem has arisen, for instance, with anti-malarial drugs sold in Africa;⁴⁰
- *Insufficient dosage*: In this case, the patient may develop resistance to the particular drug, making the patient less responsive to subsequent treatments. This problem is compounded among large populations since increasing resistance makes specific legitimate drugs, or even entire classes of them, useless;⁴¹
- *Trace amounts of dangerous substances*: Examples include heavy metals such as lead or cadmium that have been found in China’s contaminated soils. In this case, the damage to the user is cumulative, raising the probability of cancer and chronic degenerative illness. Similar problems arise with food imports from China;*
- *False packaging*: This can affect the quality of drugs in storage and processing, mislead users about ingredients and effects, and in the case of counterfeits, do grievous damage to the reputation of the real company.⁴²

Another challenge for regulators is to identify which types of drug products are most liable to be corrupted. Counterfeiters operate on a risk-return basis. The mimicking of higher-end products

* Over half of herbal dietary supplements tested in a Congressional investigation in 2010 contained trace amounts of lead and other contaminants. While the levels of heavy metals did not exceed levels that the investigators thought were dangerous, in 16 of 40 samples, the pesticide residues exceeded legal limits. U.S.-China Economic and Security Review Commission, *Hearing on China’s Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Charles Bell, April 3, 2014.

(e.g., a brand-name drug by a leading U.S. pharmaceutical company) offers a higher return but also a higher risk of detection, since the affected companies can afford superior supply chain monitoring. The faking of lower-end products, such as “made in India” generics, offers lower returns but also a lower risk of detection.⁴³ As Dr. Jin argued, any investment in enforcement by drug makers themselves has to be seen relative to the final consumer price of the drug. If margins are low or the cost of supervision cannot be passed on to the consumer, companies may lack the willingness or capability to properly monitor their supply chains.⁴⁴ According to Dr. Coukell, the likelihood of an active ingredient coming from China is higher in the case of a generic than a brand-name drug.⁴⁵

Counterfeiters often prefer to produce “lifestyle” drugs rather than the better regulated “lifesaving” drugs. Weight-loss pills, antihair loss agents, virility and muscle enhancing drugs, and other non-essential medical products have proliferated in recent years, as has the demand for vitamins and botanicals. According to Mr. Bell, the United States spends an estimated \$32 billion a year on dietary supplements, and six in ten Americans reportedly take dietary supplements on a regular basis. Since lifestyle drugs are rarely prescribed by doctors and pharmacists, consumers are more indiscriminately exposed than in the case of lifesaving drugs. Key facilitators of lifestyle drug sales—and other over-the-counter medications—are online pharmacies, which afford buyers privacy, choice, and convenience, but also make it difficult to certify the quality of the product and the integrity of the seller.⁴⁶ Chinese wholesalers, for instance, have set up websites that claim to be based in Canada.⁴⁷

The dangers of fake lifestyle drugs became apparent in a 2009 case involving a Texas emergency room doctor, who nearly died from tainted weight-loss pills he had purchased on eBay. The blue capsules were loaded with sibutramine, a prescription drug the FDA had warned was linked to heart attacks and strokes and subsequently pulled off the market. The FDA launched a long-term investigation. According to a May 2014 report, the FDA linked the fake pills to a Chinese national, Shengyang Zhou, who had sold them into the United States through a middleman. An agent from the FDA’s Office of Criminal Investigations, posing as a potential client, met with Zhou in Bangkok in 2010. The agent discovered that Zhou had made millions of dollars selling counterfeit drugs that he produced in a small factory operation in Southwest China. He had traveled frequently to the United States, purchasing real drugs that he used as a template to make authentic-appearing fakes.⁴⁸

Lessons from the Heparin Case

Between January 2007 and May 2008, at least 81 Americans died after taking contaminated heparin, a blood-thinning agent. Many other patients suffered from acute symptoms, such as breathing difficulties, plunging blood pressure, nausea, and ex-

Lessons from the Heparin Case—Continued

cessive sweating. Baxter International, Inc., the U.S. company selling the product, relied on a long and complex supply chain for the active ingredient that led back to China. Somewhere in that upstream supply chain, someone deliberately substituted over-sulfated chondroitin sulfate, a counterfeit and toxic ingredient, for crude heparin.⁴⁹

The case exposed troubling gaps in drug supply chain monitoring. Baxter began receiving heparin from a new Chinese plant in 2004. Wisconsin-based Scientific Protein Laboratories (SPL) was the API supplier to Baxter. But SPL had a joint U.S.-Chinese branch, Changzhou Scientific Laboratories (CZSPL), which purified pigs' intestines to make heparin. Baxter did not conduct its own audit of the heparin supplier CZSPL plant until 2007, relying instead on an earlier assessment by a different company. The FDA approved the plant as a supplier for Baxter without conducting a pre-approval inspection, in part because the agency confused the plant with another site in its database.⁵⁰ To make matters worse, CZSPL was licensed as a chemical manufacturer in China, not a pharmaceutical manufacturer, exempting it from the GMP standards enforced by China's State Food and Drug Administration (SFDA).⁵¹

The FDA and the U.S. National Institutes of Health eventually found suspect samples from six companies associated with the contamination over a period of several years.⁵² In March 2008, the FDA inspected the CZSPL facility in China for the first time. It found numerous violations of GMP standards, including scratched tanks with "unidentified material" sticking to their interiors and missing records for some sources of raw heparin.⁵³ Even at this stage, the Chinese government denied Baxter access to upstream workshops and consolidators, and refused the FDA access to two upstream consolidators of heparin as well.⁵⁴

The legal ramifications of the case proved costly for the U.S. pharmaceutical company but had minimal impact on China's heparin exporters. The victims of the contaminated product filed hundreds of lawsuits against Baxter. In the first decision in June 2011, a jury in Cook County, Illinois, awarded \$625,000 to the estate of a 63-year-old Chicago area man, Steven Johansen. The award was for the pain and suffering over a five-day period.⁵⁵ Chinese authorities acknowledged that heparin produced in China contained harmful ingredients but never accepted that the contaminated drug caused the deaths associated with Baxter's products in the United States.⁵⁶ China's heparin exporters appear to have recovered quickly from the scandal: the volume of annual exports fell to 65,087 kilograms in 2008, but has averaged 107,560 kilograms per year since then.⁵⁷

Drug Safety Regulation in China

The first line of defense for guaranteeing the safety of Chinese medical products is the Chinese government itself. The spread of

counterfeit and substandard drugs, however, indicates that Chinese regulators do not adequately meet their obligations. The evident failure to guarantee the safety of domestic drugs has compelled Chinese consumers to buy from abroad. According to Mr. Hunter: “[Because] of the weakness of the regulatory system, [Chinese] people don’t have the same assurance that Chinese-company-produced pharmaceuticals are of the same quality, even if it’s the same molecule.”⁵⁸

China only began to build an FDA-type regulatory system in the late 1990s. As Mr. Hunter acknowledged:

*One of the challenges that China has is building the state capacity of a modern regulatory state. Our experience [in the United States] is a relatively recent one of the last several decades that we’ve built an FDA capacity to the extent that it [is] now. China has to do this all within a period of a decade. [The CFDA] is not very well-resourced, either in terms of numbers of people or financially.*⁵⁹

Several capacity-building efforts are already underway. Since a Memorandum of Agreement was signed between the then-SFDA and the U.S. Department of Health and Human Services (HHS) in December 2007, U.S. regulators and corporations have lent support to China’s efforts.⁶⁰ Areas of progress include:

- *Bureaucratic consolidation:* China in 2013 reorganized disparate government agencies into the CFDA to better coordinate regulatory efforts. The FDA’s China Office has encouraged the CFDA to participate in the International Medical Devices Regulatory Forum, an important multilateral venue. The FDA’s Center for Devices and Radiological Health now meets regularly with its CFDA counterparts under the auspices of the Forum.⁶¹
- *New legislation:* China updated its GMP legislation under the “Good Manufacturing Practices for Pharmaceutical Products (2010 Revision),” which took effect in March 2011. The legislation was a coordinated effort by the then SFDA, the National Development and Reform Commission (NDRC), the Ministry of Industry and Information Technology (MIIT) and the Ministry of Health (MOH). According to Dr. Hickey, the Chinese regulators incorporated and implemented some of the U.S. FDA’s suggestions.⁶² The new GMP requires the manufacturers of sterile drugs to acquire the new GMP certificate by year-end 2013, and other drug manufacturers to be licensed by December 2015. Those who fail to meet the requirements face rejection of their new drug registration applications, and in the case of a pending registration application, suspension of the approval process.⁶³
- *Upgrading record-keeping systems:* At the 2009 Joint Commission on Commerce and Trade (JCCT) talks between the United States and China, China agreed to strengthen its oversight and enforcement of APIs and counterfeit pharmaceuticals by establishing a Drug Master File system; enforcing record-keeping requirements for companies that manufacture and sell APIs; and regulating unregistered Chinese companies adver-

tising and marketing APIs at foreign trade shows and on the Internet.⁶⁴

- *Personnel training*: The FDA is training CFDA regulators. For example, an expert from FDA's China Office recently instructed over 1,000 Chinese inspectors on how to conduct inspections based on the new GMP standards China enacted in 2011.⁶⁵
- *Joint enforcement and information sharing*: The FDA has held formal monthly meetings with its Chinese counterparts since 2008. The two sides discuss strategy and regulatory issues, collaboration and joint capacity building, and emerging issues of bilateral concern. Informal communication also takes place on a day-to-day basis. In addition, CFDA inspectors now regularly observe FDA inspections in China, and since 2012, the FDA's Office of Criminal Investigations has worked closely with CFDA to strengthen U.S.-China collaboration in the fight against Internet-based illegal distribution of falsified, counterfeit, and adulterated goods. In December 2013, Hong Kong, U.S., and European authorities jointly raided 700 counterfeit websites worldwide.⁶⁶ The Customs Administration of China also announced in 2012 its intention to carry out a global operation, in conjunction with the World Customs Organization, to combat illicit drugs and chemical substances being transported by post and express carrier.⁶⁷

It is questionable, however, whether these efforts will tangibly improve drug regulation in China. First, the new GMP standards may not be well adapted to China. According to one industry journal, cash-strapped drug manufacturers, lacking in technical support and intrinsic capacity, have adopted a "wait-and-see attitude" toward the new legislation, or worse yet, abandoned plans to apply for the new GMP certificate by the 2015 deadline.⁶⁸ For similar reasons, the CFDA has had difficulty enforcing record-keeping requirements and regulating unregistered Chinese companies advertising and marketing APIs overseas.⁶⁹ The FDA also informed the Commission that China has made slow progress in implementing its 2009 JCCT commitments:

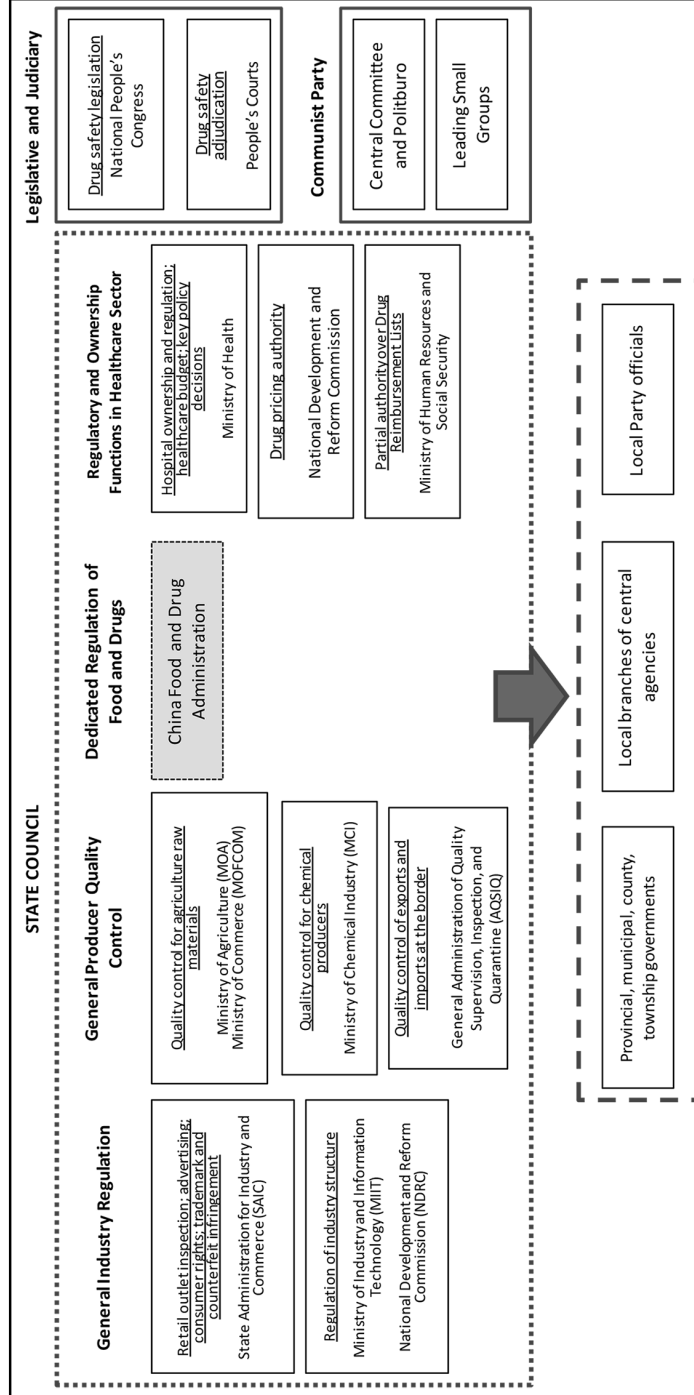
While the China Food and Drug Administration aims to establish a Drug Master File system, it has not done so to date. Through China's current implementation of new requirements for Good Manufacturing Practices for drugs, it is in the early stages of implementing the commitment to enforce requirements for record keeping. . . . China has not yet made significant strides in regulating unregistered Chinese companies that advertise and market APIs at foreign trade shows or on the Internet.⁷⁰

According to Dr. Bate, China's GMP legislation does not clearly define at what point in the supply chain manufacturers are obliged to comply. A process may be GMP-certified based solely on final process in final location, without compliance by earlier suppliers.⁷¹ Dr. Jin told the Commission that dietary supplement facilities are subject only to voluntary GMP standards.⁷²

Second, in China's fragmented and authoritarian political structure, conflicts of interest frequently contribute to regulatory failure. At the central level, this is illustrated by the uncertain status of China's food and drug regulator, the CFDA. The CFDA's predecessor, the State Food and Drug Administration (SFDA), was one of the U.S.-type regulatory bodies that the Chinese government created in the 1990s.⁷³ Revelations of corruption, however, resulted in the execution of the head of the SFDA in 2007 and placement of the agency under the supervision of the MOH in 2008.⁷⁴ A Product Quality and Food Safety Leading Small Group was set up the same year to coordinate government agencies in addressing major issues related to product quality and drug safety.⁷⁵ The creation in 2013 of the CFDA—a ministerial-level agency directly answerable to the State Council—signaled a reversion to the earlier policy of having an independent food and drug regulator. Yet it left many bureaucratic dilemmas unresolved. For instance, the scores of pharmaceutical producers in China that are registered as “chemical producers” are answerable to the Ministry of Chemical Industry. The same goes for ingredients sourced from the agriculture sector, which are monitored by the Ministry of Agriculture and Ministry of Commerce. In regard to drug exports and imports, the CFDA has usurped some functions of the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ), but the AQSIQ is still a ministerial-level department that reserves the right to inspect production facilities (see Figure 3).⁷⁶

In addition to infighting among agencies, drug regulators in China are too decentralized. There are about 400 CFDA staff in Beijing, compared to approximately 200,000 local food and drug regulators in 31 provinces, 2,321 counties, and 339 municipalities.⁷⁷ Because some localities (e.g., Shanghai municipality) are better able to enforce GMP standards, counterfeiters may migrate to other jurisdictions that are less vigilant.⁷⁸ Where local regulators are underpaid and overloaded with applications, they become susceptible to bribes from drug producers seeking expedited approvals.⁷⁹

Figure 3: Overview of Chinese Government Agencies Involved in Drug Regulation



Because regulators rely on local governments for funding, their work may be compromised by vested interests, or face capacity constraints. Fiscal decentralization policies enacted in 1994 have left local governments with limited taxation and borrowing authority but an inordinate share of government spending on public services. According to a World Bank study, governments at the county level accounted for half of healthcare expenditures in China in 2007.⁸⁰ Recent changes to the Party cadre evaluation system have introduced novel performance metrics that emphasize local welfare;* yet the overarching concern of cadres is to collect taxes and fees to meet spending obligations.† There is thus an incentive to support rather than punish local drug and chemical enterprises that boost the economy and generate tax revenue.⁸¹ In Shanxi province, for example, the China Centers for Disease Control and Prevention in 2010 appointed a private entrepreneur to head up their Biological Product Distribution Center and allowed his own company (not licensed to handle vaccines) to monopolize vaccine distribution in the province.⁸² If a safety lapse occurs, cadres come under greater pressure to maintain social stability. Yet in such cases, there is still an incentive either to cover up the incident or to “pass the buck,” since the cadres wish to remain in favor with the higher-ranking officials who determine their career advancement.⁸³

The tendency of local governments to shirk responsibility is apparent in cases of epidemic outbreaks. According to Dr. Yanzhong Huang of the Council on Foreign Relations, China has made significant strides in terms of disease surveillance and risk communication since the severe acute respiratory syndrome (SARS) outbreak ‡ a decade ago. But communication between local and central authorities is not always smooth. After the H7N9 outbreak § in 2013, the Shanghai municipal government and the Shanghai Cen-

* Since the 11th Five-Year Plan (2006–2010), the Chinese government has adjusted the cadre evaluation system to incorporate more qualitative performance metrics, such as energy efficiency and environmental governance. Alex L. Wang, “The Search for Sustainable Legitimacy: Environmental Law and Bureaucracy in China,” *Harvard Environmental Law Review* 37 (2013): 36–440.

† In a groundbreaking study, the political scientist Victor Shih and his colleagues find “no evidence that strong growth performance was rewarded with higher party ranks at any of the post-reform party congresses. Instead, factional ties with various top leaders, educational qualifications, and *provincial revenue collection* [emphasis added] played substantial roles in elite ranking, suggesting that promotion systems served the immediate needs of the regime and its leaders, rather than encompassing goals such as economic growth.” Victor Shih, Christopher Adolph, and Mingxing Liu, “Getting Ahead in the Communist Party: Explaining the Advancement of Central Committee Members in China,” *American Political Science Review* 106:1 (2012): 166–187.

‡ The U.S. Centers for Disease Control and Prevention define SARS as follows: “Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a coronavirus, called SARS-associated coronavirus (SARS-CoV). SARS was first reported in Asia in February 2003. The illness spread to more than two dozen countries in North America, South America, Europe, and Asia before the SARS global outbreak of 2003 was contained. Since 2004, there have not been any known cases of SARS reported anywhere in the world. The content in this Web site was developed for the 2003 SARS epidemic.” U.S. Centers for Disease Control, “Severe Acute Respiratory Syndrome (SARS).” <http://www.cdc.gov/sars/>.

§ The U.S. Centers for Disease Control and Prevention defines H7N9 as follows: “H7N9 is the designation for one subtype of influenza viruses that is sometimes found in birds, but that does not normally infect humans. Like all influenza A viruses, there also are different strains of H7N9 ... While H7N9 viruses had never before been detected in people, from March 31 through April 30, 2013, China reported more than 126 cases of human infection with this new H7N9 virus ... Most of these infections are believed to result from exposure to infected poultry or contaminated environments, as H7N9 viruses have also been found in poultry in China. While some mild illnesses in human H7N9 cases have been seen, most patients have had severe respiratory illness, with about one-third resulting in death.” U.S. Centers for Disease Control, “H7N9: Frequently Asked Questions.” <http://www.cdc.gov/flu/avianflu/h7n9-faq.htm>; and U.S. Centers for Disease Control, “Avian Influenza A (H7N9) Virus.” <http://www.cdc.gov/flu/avianflu/h7n9-virus.htm>.

ter for Disease Control and Prevention (CDC) were able to identify a novel type of flu virus but waited two weeks before communicating with the central CDC in Beijing. During the hand, foot, and mouth disease outbreak in 2008, the Anhui provincial government waited two weeks to communicate the problem and send samples of the virus to the central CDC.⁸⁴ Local CDCs in sensitive border regions and minority areas, such as Xinjiang Autonomous Region and Yunnan Province, are reluctant to divulge information on infectious diseases.⁸⁵

Even where the government has acted decisively to combat counterfeiting, it has done so via sporadic crackdowns. After scandals involving tainted pharmaceutical, milk, and pork products were revealed in 2007, a nationwide counterfeit food and drug sweep went after scores of producers, and lasted until around 2009.⁸⁶ The recurrence of food and drug safety incidents since then, however, suggests that these law enforcement efforts came up short.

Inconsistent enforcement is compounded by shortcomings in China's legal system. As the U.S. Trade Representative's annual report on China's World Trade Organization (WTO) compliance details, China has a history of weak enforcement against counterfeiting and intellectual property theft.⁸⁷ In 2009, China's Supreme People's Court issued a new judicial interpretation that raised the penalties—including lengthy jail sentences—for manufacturers of counterfeits in cases where their products cause severe harm to public health.⁸⁸ Although it is difficult to assess the application of this specific law, a study of China's 2009 Food Safety Law, conducted by John Balzano of Yale University Law School, suggests potential pitfalls. Disputes invoking the Food Safety Law are frequently dismissed by the courts because a product's origin is difficult to trace or its specific defects are obscure. More often than not, reported cases are against retailers of food products rather than the counterfeiters themselves, because of the lack of access to evidence or in-depth discovery procedures. Among the tort cases studied by Dr. Balzano, none of those allowed in court involved death or serious injury, presumably because such cases would be politically sensitive. In none of the tort cases were punitive damages awarded.⁸⁹

These judicial procedures are emblematic of the absence of checks and balances in China's political system. Dr. Jin argued that local governments "have an incentive to try to minimize the exposure of [drug safety] problems, and the whistleblowers or even sometimes the victims have been discouraged, harassed, or jailed for merely exposing the problem."⁹⁰

According to Dr. Bate, private investigators in China avoid publicity and contact with foreigners for fear of being punished by the government.⁹¹ Mr. Bell said he felt "some obligation to speak out for the right of Chinese civil society to do what we're doing here [in the United States]. You need to have watchdogs, and you need to have whistleblowers."⁹²

U.S. Regulation of Drug Imports from China

Safety lapses in the pharmaceutical industry have become a global concern. In the United States, the 2007–2008 heparin scandal drew wider attention to the issue. Several hearings on drug safety have since been held in Congress, including by the House Energy

& Commerce Committee (April 2008 and March 2014) and the Senate Committee for Health, Education, Labor, and Pensions (September 2011). A landmark report issued by the Institutes of Medicine of the National Academies in 2013 called for tougher standards and regulations to avert an impending crisis.⁹³ Finding concrete solutions at the international level, however, has been difficult. There is disagreement on whether “counterfeit” should be defined merely as a product that violates intellectual property rights—a definition preferred by major pharmaceutical companies—or also incorporate broader concepts of public health. Although drug safety is an issue that affects patients in all countries, some governments view anticounterfeit efforts foremost as a threat to affordable generic drugs or to the growth of their domestic pharmaceutical industries.⁹⁴

In this context, the U.S. FDA, U.S. companies, and regulators elsewhere have begun to tackle drug safety on numerous fronts. In addition to supporting Chinese regulatory authorities, the FDA relies on two “layers of defense”: its inspectors on the ground in China and its regulators back in the United States.

The FDA’s Work in China

Based on a bilateral agreement signed in December 2007, the FDA now operates three field offices (Beijing, Shanghai, Guangzhou) in China. The U.S. agency has been working with the Chinese government to train local regulators and to share information. Drug inspections carried out by the FDA in China averaged 79 per year in 2011 to 2013, compared to 19 inspections in 2007. In fiscal year 2013, the FDA’s China office received \$10 million in additional federal funding and was authorized to increase its staff size from 13 people (eight U.S. civil servants and five Chinese staff) to 27 people, which includes nine additional drug inspectors.⁹⁵

Given China’s vast drug industry, these measures are only preliminary steps. According to Dr. Hickey’s testimony, the FDA currently has just one part-time and two full-time drug inspectors based in China. Even the increase in staff size proposed in fiscal year 2013 proved difficult to implement due to China’s reluctance to grant the necessary work visas. Although the FDA notified the Chinese government as early as February 2012 of its intention to hire more inspectors, China delayed issuing the visas.⁹⁶ The FDA told the Commission in September 2014:

There are currently two visa applications pending with the Chinese Government for staff members who were hired for the FDA China Office in FY 2012 and FY 2013. In discussions connected with the December 2013 visit to Beijing by Vice President Joe Biden, the Chinese Government assured FDA that it would begin granting visas for an increased number of U.S. food and drug CSOs [Consumer Safety Officers] stationed in China. These new FDA staff, however, have still not received visas.⁹⁷

Limited in terms of manpower, the FDA also faces restricted access to Chinese manufacturing sites. Said Dr. Hickey:

When we’re operating overseas, whether it’s in China or India or anywhere else, we don’t have the same authority

*to enter a premises that we do in the United States. ... As a result, in the vast majority of cases when we're doing inspections in China or in India or elsewhere, we are notifying firms in advance and working to schedule those inspections in advance. ... We do reserve the right, and we have, in a handful of cases, done inspections unannounced as we would in the United States.*⁹⁸

Changes in U.S. Product Safety Regulation

The FDA issued a landmark report in 2011 on improving U.S. supply chain security, titled *Pathway to Global Product Safety and Quality*. The report signaled a shift away from the frequency of inspections toward *risk-based* surveillance.⁹⁹ A program called PREDICT forms the foundation of this new surveillance system. It collects data on individual producers—including those registered in China—from a variety of federal agencies, corporations, and foreign governments to calculate a customized risk score for every line in an entry. PREDICT score calculations are based on numerical weights, which factor in inherent risk, data anomaly, and data quality rules as well as the compliance history of firms and products associated with the line. Application of rules results in the generation of a cumulative score for a specific line. The higher the score, the greater the identified risk and likelihood that the product will be put on import alert and detained at the border. Each line receives a percentile rank based on all other lines screened over the past 30 days.¹⁰⁰

PREDICT does not assign risk based on specific countries where the FDA carries out field assignments. However, a substantial number of FDA import alerts are specific to a country or area. For China, as of September 24, 2014, there were nine country-wide import alerts for particular products. According to Dr. Hickey, an exporter that has been placed under import alert usually stops sending products to the United States, because such an exporter is unwilling to meet the extensive requirements for readmission.¹⁰¹

In 2012–2013, Congress also passed two pieces of legislation that significantly enhance the FDA's legal authority and operational capability. The first is the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012. Under this law, the FDA has the following rights:

- To administratively detain drugs, meaning the FDA has the authority to halt the movement of drugs while investigating and determining the appropriate response. Products may also be refused admission into the U.S. market, unless the importer is able to demonstrate that the product is in compliance with relevant laws and regulations. Dr. Hickey has argued that this new authority better enables the FDA to better prevent “port shopping,” as well as to refuse exports from a Chinese manufacturing site that “delays, limits, or refuses inspection.”*¹⁰²
- To make explicit that industry compliance with GMP standards includes managing upstream risks, which would also include inputs sourced from China. FDASIA also requires drug

*Port shopping refers to the practice of selecting ports that are understaffed or otherwise ill-equipped to conduct rigorous inspections.

importers to register with the FDA, and adhere to Good Importer Practices (GIP). The FDA has indicated that it expects to propose a GIP rule by April 2015, and finalize it by January 2017.¹⁰³

- To share confidential information with other foreign regulators; enter into agreements to recognize inspections by foreign regulators that are capable of conducting inspections that meet U.S. standards; and use the results of these foreign inspections as evidence of compliance with U.S. law.¹⁰⁴
- To collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and bio-similar biological products.¹⁰⁵ According to Dr. Hickey, these user fee acts have greatly enhanced the FDA's ability to carry out risk-based assessments.¹⁰⁶

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, further supports the FDA's mandate. Title II of DQSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The new "track and trace" system will enable verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the drug supply chain, and facilitate faster recalls of drug products. Dr. Coukell explained that, four years from now, every package of prescription drugs in the United States will have a unique serial number that can be checked against a database. Faking a serial number requires far greater skill than faking packaging.¹⁰⁷

In spite of these legislative and regulatory improvements, unsafe drugs are still entering the United States from China. Risk-based surveillance represents an innovative step, but may not suffice to offset the low frequency of inspections at the border and overseas. A 2010 report by the Government Accountability Office reported that the FDA inspected fewer than 11 percent of the plants on its own list of high-priority sites.¹⁰⁸ Moreover, according to Dr. Bate, the laboratory tests currently required by the FDA and U.S. Pharmacopeia are insufficient to uncover trace amounts of harmful residues. Until recently, so-called "rapid dye tests" were only able to detect products that contained no active ingredients, not ones that contained inadequate levels of ingredients, which can be just as harmful.¹⁰⁹

Dietary supplements remain under-regulated as well. Mr. Bell told the Commission that, among the 465 adulterated drugs and supplements recalled in the United States between January 2004 and December 2012, over half were dietary supplements. His research demonstrates, however, that the FDA has done a poor job taking dangerous supplements off the market.¹¹⁰

Actors at the local level in the United States also share the blame for lapses in drug safety. In its 2011 study "After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs," Pew Charitable Trusts found that many safety lapses occur through the redistribution of drugs among small wholesalers, national and regional wholesalers, and hospitals and pharmacies.¹¹¹ Individual states retain the power to grant licenses to

intermediaries between manufacturers and retailers. In states where regulation is lax, individuals with little or no pharmaceutical qualifications are able to set up drug wholesale businesses, usually online. Some states previously were reluctant to implement “e-pedigree”^{*} systems, suggesting that nationwide adoption of unique serial numbers in the coming years will not be easy.¹¹²

Industry self-regulation is on the increase, led by Rx360, a non-profit consortium that includes the largest U.S. drug manufacturers and suppliers. The consortium is developing a shared audit program and disseminates risk information to its members.¹¹³ Even so, Dr. Bate alleges that 90 percent of Chinese drug substances bought by Western purchasers are only audited *after* purchase. U.S. and European pharmaceutical companies are misinformed about the identity of the manufacturing site of 39 percent of the drug substances they purchase from China. A mere 6 percent of suppliers in China provide impurity profiles[†] to their U.S. customers. U.S. companies frequently fail to verify the GMP certifications of new suppliers before entering into contracts, and background checks on suppliers-of-suppliers are even rarer.¹¹⁴ When a safety lapse does occur, companies may delay a recall out of fear that it will damage their reputation, even though a delay can lead to heavier losses once the problem is exposed.¹¹⁵

Drug safety experts also question whether the right lessons have been learned from the heparin incident. As Dr. Coukell acknowledged:

*Heparin was a wake-up: All of a sudden, we realized we had risks that we weren't thinking about, we weren't aware of, we needed to make some changes. . . . So if that was the sort of level of awareness of branded pharma at that stage, it's reasonable to assume that there are companies that are less sophisticated, that are store brands, that have less skin in the game, that just have not taken those steps now, and have frankly less incentive to do so.*¹¹⁶

China's Healthcare Challenges and Reforms

China's Healthcare Market Potential

Alongside its role as a pharmaceutical exporter, China is also becoming a major healthcare market. China's healthcare spending, public and private, amounted to \$357 billion in 2011.¹¹⁷ That is still far from the \$2.8 trillion spent in the United States in 2012,¹¹⁸ but China could catch up with the U.S. market sooner than ex-

^{*}An electronic pedigree is an e-document that provides data on the history of a particular batch of a drug. It satisfies the requirement for a 'drug pedigree' while using a convenient electronic form.

[†]Various regulatory authorities such as the International Conference on Harmonization (ICH), the U.S. FDA, and the Canadian Drug and Health Agency (CDHA) are emphasizing purity requirements and the identification of impurities in APIs. The various sources of impurity in pharmaceutical products include reagents, heavy metals, ligands, catalysts, other materials like filter aids, and charcoal, as well as degraded end products obtained during and after manufacturing of bulk drugs. The different pharmacopoeias such as the British Pharmacopoeia, United States Pharmacopoeia, and Indian Pharmacopoeia are slowly incorporating limits to allowable levels of impurities present in APIs or formulations. Various methods are used to isolate and characterize impurities in pharmaceuticals. Kavita Pilaniya et al., "Recent Trends in the Impurity Profile of Pharmaceuticals," *Journal of Advanced Pharmaceutical Technology and Research* 1:3 (July–September 2010): 302.

pected. McKinsey & Company projects the country's healthcare spending to reach \$1 trillion in 2020.¹¹⁹ Benjamin Shobert, a healthcare consultant and member of the National Bureau of Asian Research, forecasts China's over-the-counter and branded generic market to expand from \$23 billion in 2010 to \$369 billion in 2020. That would make China the second-largest pharmaceutical market after the United States.¹²⁰

China's burgeoning healthcare market signals a transition to a mature economy. China's fertility rates have declined precipitously, owing not only to urbanization and rising incomes, but also to the lasting effects of the One-Child Policy. Average Chinese are living longer lives and are less prone than their grandparents to contract infectious diseases.¹²¹ China's healthcare system must now adjust to an aging demographic, which entails treatment of chronic diseases and provision of long-term care. A 2013 study, for example, showed that China in 2010 had more people living with Alzheimer's disease than any other country—and twice as many cases of dementia as the World Health Organization (WHO) thought.¹²² Over the next two decades, the WHO predicts the number of non-communicable diseases among Chinese over age 40 to rise substantially (see Table 3).¹²³

Table 3: Projected Cases of Non-Communicable Diseases in China, 2010–2030

(Cases millions)

	2010	2020	2030	Compound annual growth rate	
				2010–2020	2020–2030
Myocardial infarction	8.1	16.1	22.6	7.1%	3.4%
Stroke	8.2	21.4	31.8	10.1%	4.0%
COPDs	25.7	42.5	55.2	5.2%	2.6%
Lung Cancer	1.4	4.6	7.4	12.6%	4.9%
Diabetes Mellitus	36.2	52.1	64.3	3.7%	2.1%
Total	79.6	136.7	181.3	5.6%	2.9%

Source: Adapted from the World Bank, "Toward a Healthy and Harmonious Life in China" (2011), p. 2.

Urbanization and rising incomes are also spurring China's healthcare sector. Just half of China's population officially resides in cities, and given that urban residents currently spend twice as much on healthcare as rural residents, health spending will probably increase along with urbanization. China's economic growth is slowing but has created a middle-income class of some 300 million people. Household consumption growth, though low as a share of gross domestic product (GDP), is outpacing other large economies. At the same time, the healthcare sector is still underdeveloped relative to wealthier countries. The ratio of healthcare spending to GDP was 5.2 percent in 2013, compared to an Organization for Economic Cooperation and Development (OECD) average of 9.5 percent. As of 2012, China had 1.8 physicians per 1,000 people, a figure that ranged from 2 to 4.3 in OECD countries. Similarly,

there are only 3.7 hospital beds per 1,000 people—European Union countries average greater than six.¹²⁴

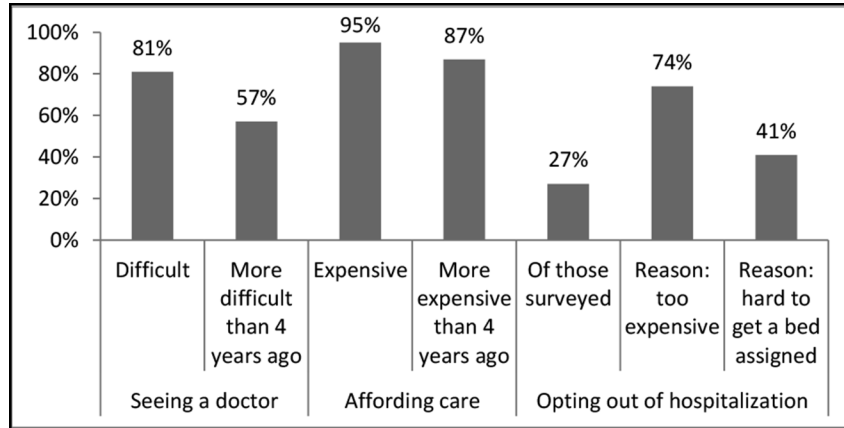
China's policy priorities appear to be aligning around healthcare. In 2009, the government released a long-awaited healthcare reform bill, the product of three years of deliberation by the senior party leadership. The bill sets out five ambitious goals: to extend basic government-subsidized health insurance; expand the population health benefit package; strengthen primary care; control the price of essential drugs at grassroots service providers; and reform government-owned hospitals.¹²⁵ Dr. Huang estimated that the Chinese government invested over \$371 billion in healthcare between 2009 and 2012, which accounted for 5.7 percent of total fiscal spending.¹²⁶ In China's 2014 central government budget, healthcare is among the fastest growing items, along with national defense and social security, and surpasses spending on science and technology.¹²⁷ Mr. Hunter told the Commission that the government's extension of public health insurance, attaining 95 percent of China's population in 2011, will help drive healthcare spending.¹²⁸ At the Third Plenum of the 18th Party Congress, held in November 2013, the government offered further suggestions for healthcare reform.*

Systemic Challenges: Unaffordable and Low-Quality Care

China's healthcare system still has many failings. One indicator of the system's own troubled health is the rapid rise in costs, which have consistently outpaced per capita income growth, making care less and less affordable. According to a 2008 estimate, the average treatment cost for an inpatient stay is equivalent to 60 percent of China's annual per capita income. Another study found that rising healthcare expenditures in the early years of the 21st century led to the impoverishment of 67.5 million people.¹²⁹ "Inaccessible and unaffordable healthcare" is perennially cited as a top concern in China's social surveys;¹³⁰ an October 2013 survey revealed that such sentiments have not changed much since the recent healthcare reforms were implemented (see Figure 4). Many ordinary patients choose either to forego treatment or to resort to traditional Chinese medicine, a cheaper alternative.

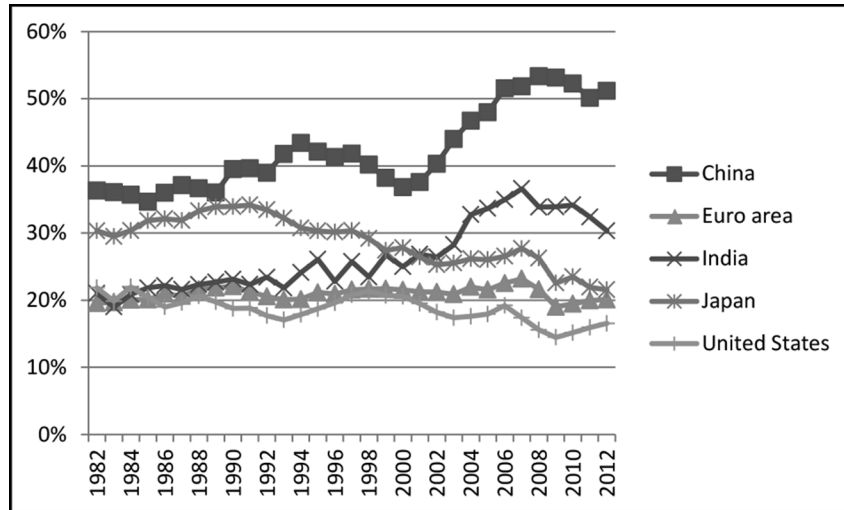
* Important policy suggestions set out in the Third Plenum Decision include: (1) integrate medical services across regions and rural and urban areas, especially at the grassroots level; (2) pay medical staff based on performance and skill, and allow physicians to practice in many locations; (3) allow private providers to be incorporated as designated locations for medical insurance and give priority to non-profit medical institutions; (4) reform the method of paying for medical insurance; (5) expand medical insurance to cover catastrophic diseases.

Figure 4: Public Opinion on Healthcare in China (October 2013)



Source: Horizon Research Consultancy Group, via Yanzhong Huang, "What Money Failed to Buy: The Limits of China's Healthcare Reform," Council on Foreign Relations, March 4, 2014.

Figure 5: Gross Savings Rates by Country



Source: World Bank.

High healthcare costs also damage China's economy. Households accumulate excessive savings to make up for rising costs, hampering growth (see Figure 5). As the workforce share of the population peaks and the ratio of retirees to workers increases, China can ill afford to finance exorbitant healthcare costs. Chinese workers, many of them single children, are forced to support not only themselves but also their dependents (see textbox, "China 'Getting Old before Getting Rich'"). Stated Dr. Huang:

So this is what I call the schizophrenic situation the Chinese government has to face: On the one hand, they have the incentive to lower the prices to rein in the rapid increase of healthcare costs. On the other hand, they have strong incentives to promote the healthcare industry. That means high healthcare costs because they say, “well, healthcare spending is only [5] percent of total GDP, but the world average is about 9 percent, so we still have a lot of room to improve.”¹³¹

China “Getting Old before Getting Rich”

China’s labor force is peaking and its “first demographic dividend” is ending. This may impact economic growth. Fewer workers will be forced to finance more dependents, while the government will have to divert more resources from capital spending (on items such as infrastructure) to current spending on healthcare. In a 2008 study of 40 countries, China is the only one in which retirees are funded almost entirely from labor income, due to a shortage of public retirement funds and non-monetary assets.¹³²

China’s life expectancy is primarily increasing among people aged 60 or older, who contribute little to productivity gains in the labor market. Due to the One-Child Policy, which was relaxed only recently,* many single adult children have to foot the medical bills of their parents and grandparents (representative of the “4–2–1” family structure). Changing social norms place additional strains on China’s healthcare market. Parents of migrants take care of their grandchildren in rural villages while their children work in the cities. In return, migrants earn higher wages and use surplus income to support their parents in old age. This “implicit social contract,” however, is falling apart due to the decline in filial piety values and the strains of the “4–2–1” family structure. Urbanization also weakens traditional problem-solving capacities in rural areas that facilitate care for the sick, elderly, and unemployed.¹³³

Higher costs have not translated into better quality or efficiency in delivering care. Academic studies show that, relative to Europe and the United States, China’s hospitals have low rates of staff productivity and are inefficient in terms of the time and cost required to cure illnesses. Smaller hospitals and local clinics have low bed occupancy rates.¹³⁴ China has more magnetic resonance imaging (MRI) machines per million people than middle-income countries like Thailand and Mexico; yet qualified staff is in short supply, especially at lower-level facilities.¹³⁵ While underproviding basic services, doctors routinely induce demand among wealthy and well-insured patients by over-prescribing expensive drugs and treatments, and prolonging inpatient stays. According to a 2010 es-

*As of this year, China will allow families in urban areas to have two children if one parent is a single child. Previously, both parents had to be single children to do this.

time, “supplier-induced demand” accounts for over 20 percent of China’s healthcare spending.*¹³⁶

Compounding subpar care at hospitals is deficient preventive care. China’s urban residents on average consume more calorie-rich diets and engage in less physical activity than 30 years ago.¹³⁷ According to the WHO, 61 percent of China’s adult males smoke.† About one in every seven Chinese has high blood pressure (hypertension),¹³⁸ and according to a nationwide survey released in September 2013, China accounts for one in three diabetes sufferers globally.¹³⁹ Based on a 2012 study by the U.S. National Institutes of Health, lung cancer accounts for a quarter of China’s cancer illnesses, with a much higher incidence than in the United States.¹⁴⁰ Meanwhile, mining, industry, and traffic accidents persist—China led the world with 275,983 traffic fatalities in 2010 (approximately twice the per capita rate as the United States, which had 32,788 fatalities).¹⁴¹

Equally taxing on health is the state of the environment. Drinking water is rendered unsafe by manure runoff, chemical residues, and other pollutants.¹⁴² According to an April 2013 study in a British medical journal, outdoor air pollution caused 1.2 million deaths in China in 2010, nearly 40 percent of the global total. In a March 2014 report, the World Bank projected that the environmental effects of urban sprawl will cost China \$300 billion a year in premature deaths, birth defects, and other health-related problems.¹⁴³ Where preventable illnesses do not result in death, they cause an increase in disability-adjusted life-years, which reduces a person’s ability to participate productively in society.

Infectious diseases in China have resurged as well. Stated Dr. Eggleston: “The nature of disease in China has changed from a primary burden of infectious disease to a disease burden dominated by chronic, non-communicable diseases . . . but with important lingering problems from endemic and reemerging infectious diseases such as hepatitis (a primary cause of liver cancer), multi-drug-resistant tuberculosis, and HIV/AIDS.”¹⁴⁴ A new strain of avian influenza (H7N9) resulted in 132 infections and 44 deaths in the spring of 2013, primarily in China.¹⁴⁵ Sexually transmitted diseases are spreading in border regions and major industrial centers where migrant laborers, female sex workers, and intravenous drug use are common.¹⁴⁶ Not least, the overuse of antibiotics in Chinese hospitals has reduced antimicrobial effectiveness,‡ posing a threat to global public health.¹⁴⁷

*Supplier-induced demand is not unique to China. The medical scholar Milton Roemer first proposed this hypothesis in 1961 from the observation that areas with greater hospital bed supply showed greater hospital use. The basic theory is that because doctors have more medical knowledge than their patients, patients depend on their doctors for treatment decisions, and doctors might exploit this situation by suggesting higher reimbursement procedures or by providing excessive care. A 1989 study, for example, demonstrated that Caesarean sections provided \$500 more in income to physicians than vaginal delivery. Kim Beomsoo, “Do Doctors Induce Demand?” *Pacific Economic Review* 15:4 (October 2010): 554–555. For a discussion of this problem in the United States, see Craig L. Garthwaite, “The Doctor Might See You Now: The Supply Side Effects of Public Health Insurance Expansions,” *American Economic Journal: Economic Policy* 4:3 (2012): 190–215.

† This figure is based on adjusted prevalence estimates for WHO member states. World Health Organization, *Report on the Global Tobacco Epidemic* (2013), p. 276.

‡ An antimicrobial is an agent that kills microorganisms or inhibits their growth.

Accounting for the Problems in China's Healthcare System

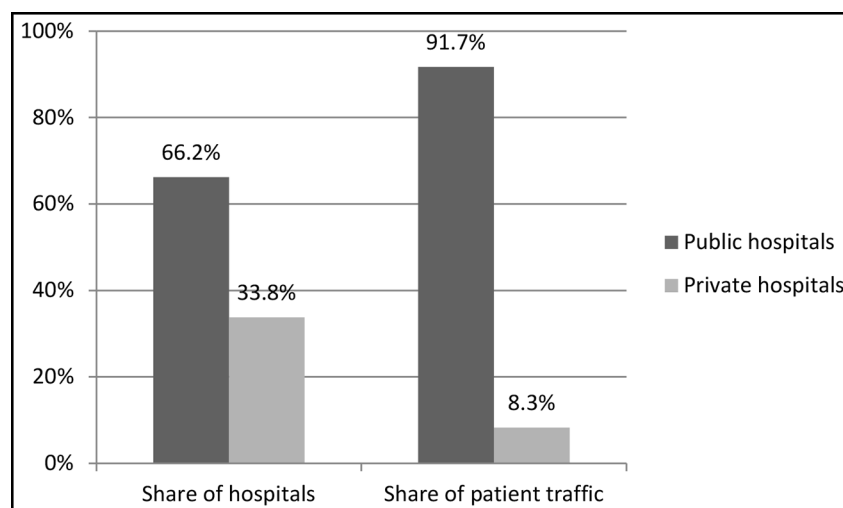
Why has China's healthcare system underperformed in terms of cost and delivery? Certainly, administering healthcare in a large developing country is challenging. Experts also disagree on what the ideal healthcare policy should look like. What is clear is that China's market reforms have not done enough to improve healthcare. Mao-era China (1949–1976) lacked modern medical infrastructure and qualified professionals, but basic care was affordable.¹⁴⁸ From 1960 to 1980, China's average life expectancy increased by 24 years, compared to a world average of 11 years.¹⁴⁹ Since then, a series of misguided policies has slowed down progress in public health indicators and made the healthcare system resistant to meaningful reform.

The Government as Owner and Regulator

Private healthcare provision in China has moderately expanded since the government introduced market-oriented reforms in the 1980s. Every third provider in China today is in private hands (either for-profit or non-profit). In December 2010, China enacted new policies to encourage private investment in hospitals; for example, the approval process for opening new joint venture hospitals was shifted from central to provincial authorities.¹⁵⁰ The official target is for private hospitals to handle 20 percent of in-patient and outpatient traffic by 2015.¹⁵¹

Nonetheless, over 90 percent of China's patient traffic in 2010 went through public hospitals (see Figure 6). Private providers in China tend to be much smaller than public hospitals in terms of total assets, staff, beds, and equipment, and deal mainly with specialized cases, like skin disease and sexually transmitted diseases, rather than general acute cases.¹⁵²

Figure 6: Private vs. Public Hospitals: Share of Patient Traffic, 2010
(584 million hospital visits; 20,918 hospitals)



Source: Jing Ulrich et al., "Medicine for the Masses-China's Healthcare Reform: Progress and Future Steps," J.P. Morgan Hands-On China Report (J.P. Morgan, October 10, 2011), p. 3.

Dr. Eggleston, citing field research she conducted in Chinese hospitals, said that private and public providers both suffer from policy distortions in the healthcare system. Privatization in and of itself is not the solution.*¹⁵³ What is clear is that the playing field is not level; private providers confront a series of regulatory hurdles. Because they tend to be ranked lower in China's hospital accreditation system—over which local governments have considerable discretion—private providers have difficulty attracting the best doctors.† Since doctors are licensed to work only at one hospital, they prefer larger public providers, which offer greater incentives for career progression, as well as welfare benefits. Private providers frequently resort to hiring retired healthcare workers, which may undermine their service quality and reputation.¹⁵⁴ Patients are discouraged from seeking private care because many such providers are not under contract with government insurers.¹⁵⁵

Meanwhile, the 2009 healthcare reforms have done little to upgrade the public healthcare bureaucracy. Dr. Eggleston and her colleagues note that “Ministry of Health, military, and [state-owned] enterprise hospitals all provide similar services, increasing competition but also contributing to excess capacity and lack of coordinated care.”¹⁵⁶ The MOH exercises conflicting roles as regulator, manager, owner, and financier of state-owned healthcare providers.¹⁵⁷ According to Dr. Huang, MOH opposition was a key reason why pro-market measures were watered down in China's 2009 healthcare bill.¹⁵⁸ Beyond the MOH, regulation is divided into silos. For example, the CFDA issues drug approvals, but drug pricing authority rests with the NDRC, China's premier industrial planning body. Health insurance is administered separately by the MOH for rural areas and the Ministry of Human Resources & Social Security for urban areas.¹⁵⁹

Insurance Coverage and the Referral System

Before market reform, rural cooperatives (under the Cooperative Medical Scheme, or CMS) and urban work units bore most healthcare costs. Although this system extended privileges to party cadres and urban workers, most Chinese had access to basic treatment and preventive care. Market reforms, however, gradually dissolved cooperatives and work units, while failing to account for migrant workers who fell through the cracks. The result was a rapid in-

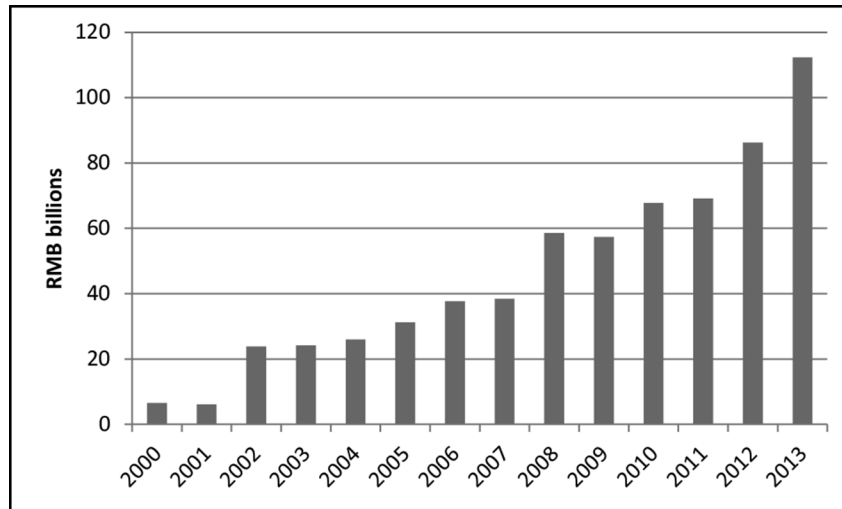
*A study carried out by Dr. Eggleston and her colleagues in Guangdong, one of China's wealthiest provinces, shows that private providers account for a disproportionate share of outpatient surgery, a niche market for patients seeking care at bargain prices. The same Guangdong study also finds that mortality rates—a common metric of quality—do not statistically differ between government and non-government hospitals of similar size, accreditation level, and patient mix. The scholars conclude that “changes in ownership type alone are unlikely to dramatically improve or harm overall quality.” Karen Eggleston et al., “Comparing Public and Private Hospitals in China: Evidence from Guangdong,” *BMC Health Services Research* 10:76 (2010): 1–11.

†According to Dr. Eggleston: “Chinese hospital accreditation began in 1989 with a system established by the Ministry of Health. This system defines three hospital grades (3, 2, and 1) based on infrastructure and administrative level and three within-grade levels (A, B, and C) based on evaluation by a committee established by the local health bureau. Since 2005, the hospital accreditation system rates hospitals according to a wider range of criteria, including ‘scientific management,’ patient safety, and service quality, and allows for rewards (e.g., government budgetary subsidies) and sanctions (e.g., fines or risk of closure) . . . The national accreditation guidelines give local governments considerable discretion in implementation, which limits comparability across regions. Many provinces do not include the private sector, and few include [township health centers] and village clinics.” Karen Eggleston et al., “Health Service Delivery in China: A Literature Review,” *Health Economics* 17 (2008): 160.

crease in out-of-pocket spending, which skewed delivery toward urban areas, the wealthy, and party cadres.*¹⁶⁰

Since the 1990s, the government has taken measures to improve coverage, primarily through government-run insurance programs. In 1998, the government introduced basic medical insurance for urban employees (UEBMI), based on payroll taxes paid by the employer and employee. The proceeds were divided into individual accounts for outpatient care and pooled risk accounts for inpatient and catastrophic needs. This was followed in 2004 by the introduction of a new CMS (NCMS) for rural residents, based on a small premium that is matched by the central and local government. A similar system of basic medical insurance was introduced for urban residents (URBMI) in 2007.¹⁶¹ Insurance coverage was ratcheted up under the 2009 healthcare spending plan. While the majority of Chinese was uninsured before 2008, about 95 percent are covered by government insurance plans today. The bulk is enrolled in the rural NCMS, which counted nearly a billion members by 2010.¹⁶² Expanded coverage is reflected as well in the value of total health insurance premiums, which grew from virtually zero in the year 2000 to over RMB 100 billion (about \$17 billion) last year (see Figure 7).

Figure 7: Total Health Insurance Premiums in China
(current RMB billions)

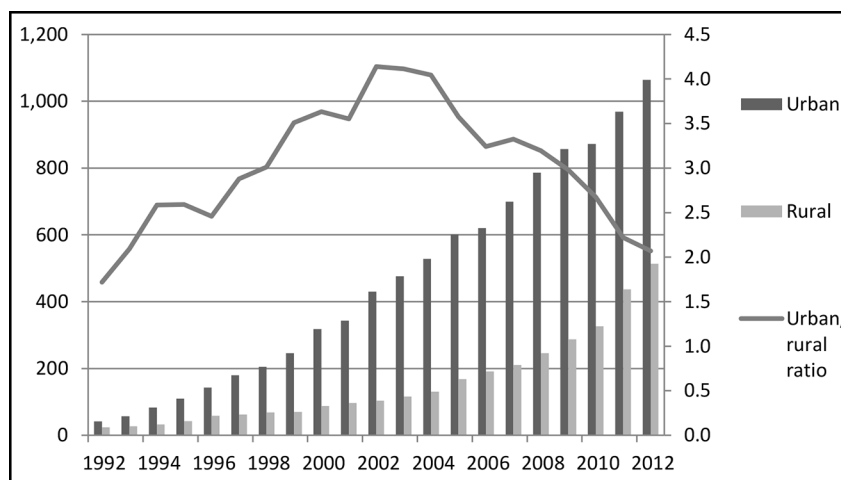


Source: China Insurance Regulatory Commission, via CEIC.

* Said Dr. Huang: "At the provincial level, the provincial leaders certainly have access to good healthcare for free. They have the Provincial People's Hospitals for each province. In some provinces, they also have the military hospitals that provide similar service. ... Despite the healthcare reform, there's still a percentage of basically what we call 'cadres,' the government officials [that] can access healthcare for free. ... There may be a couple million, eight million or so, of the government officials. They have free access to healthcare. But there's also a hierarchy in terms of what kind of services you have free access to." U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

Relative to other parts of the reform agenda, insurance coverage has had moderate success in increasing access and reducing costs. The share of private spending on healthcare has declined sharply, from a peak of 60 percent in 2001 to 35 percent in 2011. Reimbursement rates for inpatient treatment expenses increased from 50 percent in 2008 to 75 percent in 2013.¹⁶³ City dwellers a decade ago spent four times as much on healthcare as their rural counterparts; in 2012, they spent only twice as much (see Figure 8).^{*} At the National People's Congress meetings in March 2014, Premier Li Keqiang announced that the annual government subsidy for basic medical insurance premiums for the NCMS and URBMI would be raised again to RMB 320 (\$52) per capita, from RMB 120 (\$20) in 2010.¹⁶⁴

Figure 8: Per Capita Healthcare Spending in China
(in RMB)



Note: RMB in current prices.

Source: China National Bureau of Statistics, via CEIC data.

However, insurance expansion has not been a panacea. Said Dr. Huang:

The problem is that [the official coverage rate] includes 200 million migrant workers who are nominally covered in the countryside, but because they live and they work in the cities, they actually are not covered because their health insurance schemes so far are not portable. ... If you [dis]count these 200 million migrant workers, the actual coverage rate is about 87 percent.¹⁶⁵

Insurance coverage is also shallow. According to Dr. Eggleston, the NCMS and URBMI, which are voluntary government-sub-

^{*}Convergence between rural and urban spending power generally indicates a decline in rural-urban- inequality. In the healthcare sector, however, rural spending may be attributed to induced demand or high costs, so that convergence with urban spending levels is not necessarily a measure of success.

sitized programs, have lower premiums and less generous benefit packages than the mandatory and longer-standing insurance programs for urban employees and government workers. Some provinces are merging the NCMS and URBMI to widen risk pooling and thereby deepen benefit packages, but these reforms are at an early stage.¹⁶⁶ At present, according to Dr. Huang, most benefit packages fail to cover dental care and many of the effective medicines for treating non-communicable diseases.¹⁶⁷

Paradoxically, the expansion of insurance coverage has also compelled patients to seek too much inpatient care. The hospital bed utilization rate surged from 36 percent in 2003 to 88 percent in 2011, worsening the overcrowding at large hospitals.¹⁶⁸ A root cause is the absence of a functioning referral system. Before market reform, Communist China's healthcare system was built on a three-tiered hierarchy of government-run providers,* with separate systems for urban and rural areas. Local clinics, which focused on preventive care, were the first resort for the sick, who could only visit larger hospitals with an official doctor's referral. Although the basic three-tier system is still in place, patients can now choose to forego local providers in favor of larger hospitals, as long as they can afford the cost. This has reduced the use, quality, and reputation of local clinics.†

The bias of patients toward larger hospitals has also affected government efforts to build out local clinics. In the government's 2009–2011 healthcare budget, 71 percent of supplier-side spending went toward upgrading or constructing medical facilities, primarily in rural areas. The result was 2,000 new county hospitals (China has 2,859 counties); 29,000 new and 5,000 upgraded township hospitals; and thousands of clinics.¹⁶⁹ According to Dr. Huang, “the county hospital is extremely crowded, but at the township health center you stay an entire day and won't see that many people actually seeking care . . . despite the fact that the government has invested billions of dollars trying to strengthen the grassroots level healthcare institutions.”¹⁷⁰

Financing and Payment of Providers

On the supply-side of the healthcare sector, market reforms led to changes in the way China's providers are financed and paid. In the prereform period, central government funding, particularly in urban areas, was the primary source of provider income. Beginning in the 1980s, however, decentralization forced local governments to shoulder most of the funding burden, widening disparities between rich and poor regions. Overall subsidies were reduced as well; in 2009, the government health budget accounted for less than 10 percent of the actual costs of hospitals. The smaller pot of government funding was heavily skewed toward larger hospitals, even though

* In rural areas, the hierarchy is village clinics (tier-1), township health centers (tier-2), and county hospitals (tier-3). In urban areas, the hierarchy is urban health centers (tier-1), district hospitals (tier-2), and city hospitals (tier-3).

† Researchers from Stanford University conducted a study of 44 township health centers in 2005 to 2008. They found that rural health insurance “did not increase the overall number of patients served or the likelihood that a sick person would seek care at a township center.” Kimberly S. Babiarz et al., “China's New Cooperative Medical Scheme Improved Finances of Township Health Centers But Not the Number of Patients Served,” *Health Affairs* 31:5 (2012): 1065; Karen Eggleston et al., “Health Service Delivery in China: A Literature Review,” *Health Economics* 17 (2008): 151.

these facilities are less cost effective and prevention oriented than primary care units.¹⁷¹

While forced to generate their own revenue, healthcare providers in China have been squeezed by distorted fee schedules and price controls. The government, on one hand, has forced providers to offer essential treatments and drugs at below marginal cost; on the other hand, it has deregulated prices for costlier treatments and permitted hospitals. Hospitals not only prescribe their own drugs, but also charge markups on the drugs they sell. Providers thus have a perverse incentive to undersupply basic drugs and services, and oversupply costlier ones. Alternatively, they can raise the quantity of drugs and services provided to make up for the low prices of basic services. A 2010 study found that the average Chinese hospital depends on drug sales for 45 percent of its revenue, and for every four doctors employs one pharmacist. As Dr. Eggleston has noted, once patients choose to receive treatment at a certain provider, they have little choice about what goods and services they will consume, and rely on doctors to determine what is right for them.¹⁷² Over time, patients have come to expect drug prescriptions as part of their treatment. According to a 2008 study, China's spending on medicines accounts for 40 percent of total health expenditure, compared to 16 percent in OECD countries.¹⁷³

A further perverse incentive has to do with how government-run insurers pay providers. Because Chinese insurers use a "fee-for-services" system without adequate safeguards, providers are able to charge excessive fees retroactively, based on services rendered. Insurers in most advanced economies adopt sophisticated managed care systems to contain costs, such as diagnostic-related groups (pay providers based on prospective costs for a given treatment); capitation (pays providers a set amount for each enrolled person assigned to them, whether or not that person seeks care); or a fixed pool of funds (pay providers a fixed sum based on average case load, case mix, and other criteria).¹⁷⁴

Reforms have done little to alter costly incentives. Although government funding for healthcare has increased, only a small share of these funds has gone toward subsidizing the day-to-day operations of hospitals. Local governments, which contributed some three-quarters of the \$371 billion in investments in 2009–2012, have become reluctant to pick up the tab, especially in poor regions that are short of revenue. Vague directives from Beijing, which grant local authorities autonomy to experiment with healthcare reforms, have resulted in uneven implementation and regulatory uncertainty. Many providers pocket the funds from the government and use them as "seed money" to buy expensive equipment and ramp up capacity to offer specialized services. Recent data indicates that hospital revenue still depends heavily on drug revenue and expensive treatments.¹⁷⁵ Although pilot programs have tried out sophisticated payment systems, fee-for-services remains the norm.¹⁷⁶

The government is attempting to control drug prices by establishing an essential drugs formulary (the National Essential Drugs List, EDL) and forbidding markups. But this strategy has backfired. Government subsidies meant to compensate for the loss in drug revenue have been grossly insufficient, because policymakers

underestimated the hospitals' original markup rates, which in many cases exceeded the legal rate. Larger hospitals have used their political leverage to continue charging markups for lucrative drugs, while shirking MOH standards for prescribing a certain volume of essential drugs. The brunt of the reform has thus fallen on the already unpopular grassroots providers, who have responded to the no-markup policy by reducing their drug inventories, reinforcing the incentive of patients to seek care at larger providers.¹⁷⁷ According to Xiaoqing Lu Boynton, a China healthcare expert at Albright Stonebridge Group, forcing down drug prices has also caused shortages in drug production for domestic consumption. Chinese drug makers, many of them small private firms, do not see why they should produce drugs that offer scant profits.¹⁷⁸

The Medical Profession

A key reason why doctors overprescribe drugs and treatments is that they earn low base salaries. Doctors rely on fee-based revenue, and in many cases, are rewarded by hospital administrators based on the revenues they bring in rather than the efficacy of treatment. Bribes are another form of income. Said Ms. Boynton: "Patients who can afford bribery can get better care."¹⁷⁹

Only a small share of added government spending has gone toward raising medical workers' salaries. Hospital administrators, in turn, prefer to invest in physical assets, such as new machines. Since doctors cannot form independent unions, they lack bargaining power. Normally, they are licensed to work in just one hospital. According to Dr. Eggleston, the government hospital has to consent if its physician is going to go practice in a private hospital, "but then the government hospital manager doesn't necessarily have the incentive to let their best doctors do that."¹⁸⁰

Doctors in China are increasingly confronted by patients who are upset about the high cost and poor quality of care. According to Dr. Eggleston, patients have begun to disregard advice for taking drugs, assuming that profit-seeking is distorting the doctor's judgment.¹⁸¹ Worse yet, angry patients have resorted to violence. Murray Scott Tanner, a researcher at the Center for Naval Analysis, told the Commission that China's "medical disturbance" incidents, in which patients or their family members "violently beat, threaten, or curse medical personnel," increased from 10,248 in 2006 to 17,243 in 2010, and have "attracted the attention of party leaders and law enforcement officials."¹⁸² In 2006, the last year that MOH published statistics on hospital violence, attacks by patients or their relatives injured some 5,500 medical workers.¹⁸³ The government in March 2014 passed a new regulation requiring police, rather than in-house security services, to maintain the order and safety of hospitals.¹⁸⁴

Low pay, limited mobility, and difficult work conditions have reduced the supply of good doctors. According to a prominent epidemiologist who has done fieldwork in China, the medical profession is looked down upon by aspiring professionals.¹⁸⁵ As Mr. Shobert observed, "A doctor that graduates in Beijing for the first couple of years will make less money than if he were driving a taxi-

* For more information, see Chapter 2, Section 3, "China's Domestic Stability."

cab.”¹⁸⁶ According to Dr. Huang, the competitiveness of entering medical studies in China is considerably lower than in the United States, because the country’s best minds find better job prospects elsewhere. The quality of medical education is also inferior: “If you meet someone from China who claims that he’s an M.D., don’t think that it’s the same M.D. you find here in the U.S. because usually these are the people who . . . receive five years of medical training, basically on the undergraduate level.”¹⁸⁷

Young Chinese who graduate with a medical degree are reluctant to work in the countryside, especially at the township and village levels. As part of its effort to improve primary care, the government is launching a number of pilot programs to incentivize physicians from large hospitals to practice in local clinics. However, since physicians earn their main income from fees instead of salaries, working with poorer patients in under-used local clinics is not very attractive. According to Ms. Boynton, even in cities, doctors are unhappy, and are looking to either move abroad if they have the qualifications or switch to the hospital administrator side of the system.¹⁸⁸

Market Access for U.S. Medical Goods and Services

Why U.S. Companies Do Business in China’s Healthcare Sector

Major U.S. companies are cognizant of the problems in China’s healthcare system. And yet, the China market is now central to U.S. business strategy. Biopharmaceutical products represent a growing net export from the United States to China, increasing by 28 percent every year for the last ten years to \$1.4 billion in 2013.¹⁸⁹ Pfizer, the largest U.S. pharmaceutical company, claims it is “the top multinational R&D-based biopharmaceutical company in China.” Its China subsidiary has cumulative investments of \$1 billion; business operations in over 300 Chinese cities; four state-of-the-art manufacturing facilities; and over 9,000 employees (business, R&D, production and other areas).¹⁹⁰ Mr. Hunter, speaking on behalf of PhRMA’s member companies, said he expects his members’ presence in China to “only strengthen in time.” This presence is no longer limited to production and sales: International drug makers are now bringing as much as \$8 billion per year in R&D investment to China.¹⁹¹ United Family Healthcare, the healthcare services division of the U.S. company Chindex International Inc., is China’s largest foreign-invested healthcare provider.¹⁹²

A variety of factors explain this turn to the China market. As Mr. Shobert observed, “[China] is no longer just an alternative geography where you can find a lower-cost supply partner. It’s also somewhere you can sell into.”¹⁹³ China’s healthcare boom is also occurring at a time when mature markets are losing luster. After decades of escalating costs, healthcare providers in Europe, Japan, and the United States are under pressure to make care affordable. Governments and households, still hurting from the 2009 financial crisis, are eager to reduce their debt burdens by cutting the cost of healthcare goods and services. In parallel, there has been a precipitous decline in pharmaceutical R&D productivity since the 1980s.¹⁹⁴ According to Bain & Company, pharmaceutical companies

will lose more than \$100 billion in patent protection by 2015, as key patents expire.¹⁹⁵

U.S. companies could turn to other developing markets, but most are smaller and present their own regulatory challenges. Mr. Hunter argued that China is faring better than India: “People have talked . . . about the challenges to the Chinese system, but if you were just to turn a little bit farther to the West, you’d find a country of a similar size that is vastly worse off.” India spends only 1.5 percent of GDP on healthcare. Because most Indians are uninsured, at least 70 percent of spending is out of pocket. Rural residents barely have access to care. All told, China’s healthcare sector “is decades or at least a decade ahead.”¹⁹⁶ An additional advantage of operating in China is that it has a large aging population compared with other emerging markets.

Witnesses told the Commission that the risk of intellectual property (IP) theft is not sufficient reason to avoid the China market. Mr. Hunter noted that India has pursued an aggressive policy to market generic drugs and rewrite the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Although patented drugs only account for 5 percent of the Chinese market, the figure is less than 1 percent in India.* China also helps U.S. pharmaceutical companies recoup R&D costs. Said Mr. Hunter: “If you don’t take your product to a market, you don’t work the patent in a market, and somebody else can use it. . . . It’s either you use it or lose it.” As for why U.S. drug makers would engage in R&D in China despite the risk of losing IP, Mr. Hunter pointed to China’s large pool of well-qualified scientists, and to the need to adapt U.S. drugs to Asia’s patient profiles.¹⁹⁷

Ralph Ives, executive vice president for global strategy and analysis at AdvaMed, acknowledged that IP theft is a concern in the medical device segment as well, especially when counterfeits do not perform like the original and put patient safety at risk. Yet such risks are mitigated by the innovation model of the medical device industry, which is different from pharmaceuticals. New medical devices come out about every 18 months, which reduces the incentive for counterfeit, since the fakes quickly become outdated. Higher value-added devices (e.g., implants) are usually sold in China through business-to-business transactions. That allows device makers to develop a direct relationship with doctors at hospitals, who themselves have an intrinsic interest in buying high-quality devices that are safe for their patients.¹⁹⁸

Closer analysis of market access issues, however, indicates that U.S. companies are incurring substantial risks by operating in China. Said Mr. Shobert:

In my [consulting] practice, we work pretty hard to get people to say no [to entering China], and that’s not because we’re fundamentally hostile to China, but simply [because]

*Stated Mr. Hunter: “India has had for some time a strong generics industry, and when it came time to implement its WTO obligations with TRIPS, the generics industry was very influential in the final drafting of the legislation that was passed in 2005, and it includes a series of provisions that undercut those commitments. We’ve seen in the case of India over the past two years either the disallowance or the attack in one form or another on the patents on some 15 products of which there are only 45 patented products in the market.”

*we want any new entrant to China to understand at the most basic level within their organization—and this goes all the way to the top, especially when you’re talking about compliance risk—selling into the healthcare economy in China is inherently a political act.*¹⁹⁹

China’s Medical Services Market

In contrast to drug and device makers, U.S. healthcare providers have yet to penetrate the Chinese market on a significant scale. They currently focus on delivering premium care to wealthy and privately insured patients in tier-1 cities like Shanghai and Shenzhen. But China’s need for high-tech facilities, as well as user-friendly spaces for the elderly, is raising demand for U.S. healthcare services. Given the current price pressures on drug makers, Bain & Company forecasts that hospitals will account for 40 percent of healthcare profit growth in China through 2020.²⁰⁰ Less than 2 percent of China’s senior population currently uses institution-based care, but more than 10 percent are willing to receive care in institutions.²⁰¹

Some promising projects are in progress. Medical device manufacturers across the world are vertically integrating into after-sales services, sometimes through in-house clinics. The U.S. company Chindex, for example, operates healthcare facilities across China, and also produces medical devices used in those facilities.²⁰² A Harvard-affiliated U.S. hospital, Brigham & Women’s, is reportedly exploring the “possibility of collaborating” with Evergrande Real Estate Group Ltd., a Chinese real estate company, to build a state-of-the-art hospital in China.²⁰³ In addition, the U.S. firm Henningson, Durham & Richardson signed an agreement with a Chinese company to jointly supply architectural planning and concept design for the proposed Beijing International Medical Center, a state-invested facility that aspires to become the largest healthcare education and research center in the world.²⁰⁴

Premier Li has also hinted that China will permit more “non-governmental capital” into the healthcare sector. In August 2014, the Ministry of Commerce and the National Health and Family Planning Commission announced a pilot program that will allow foreign investors in some parts of the country to set up new hospitals. The program will apply to Beijing, Tianjin, and Shanghai municipalities, as well as to the provinces of Jiangsu, Fujian, Guangdong, and Hainan. That followed a decision in July to let the German hospital operator Artemed Group establish China’s first hospital fully funded by foreign capital, based in the Shanghai Free Trade Zone.²⁰⁵

China's Medical Services Market—Continued

Despite these advances, it is uncertain whether foreign investors will be permitted to make full acquisitions of China's public hospitals. It may also prove difficult for U.S. companies to expand beyond the premium segment in the largest cities, if efforts to rein in healthcare costs put pressure on pricing and give preference to cheaper local providers. U.S.-style institution-based elderly care is too expensive for the mass of retirees and has been criticized by those who think the elderly should be cared for by their children, or at the very least receive community-based care.²⁰⁶

Corruption in the Chinese Healthcare System

The potential risks of operating in China were on display last year, when Chinese authorities began looking into allegations that the British drug maker GlaxoSmithKline (GSK) had funneled money through a local travel agency to pay bribes to doctors in return for prescribing its drugs. While the legal outcome dragged on, GSK reported that its third-quarter 2013 China sales fell 61 percent.²⁰⁷ In September 2014, a secret one-day trial was held in a Chinese court to adjudicate the case. GSK was fined nearly \$500 million, the highest fine on record against a foreign company. According to Xinhua, China's official news agency, the court also sentenced GSK's British former country manager and four other company managers to prison terms of up to four years. It suspended the sentences, however, allowing the defendants to avoid incarceration if they did not engage in further wrongdoing. GSK said in a statement that it "fully accepts the facts and evidence of the investigation, and the verdict of the Chinese judicial authorities."²⁰⁸

Other companies were targeted on bribery charges as well. The drug makers Sanofi (France), Bayer (Germany), AstraZeneca (United Kingdom—Sweden), and Eli Lilly and Company (United States), all reported visits from authorities to their China offices in August and September of 2013. Sanofi was accused of bribing over 500 Chinese doctors with \$277,600 in illicit payments.²⁰⁹ Nu Skin Enterprises, a listed U.S. company that develops personal care products and dietary supplements, was charged in January 2014 with operating an illegal pyramid scheme. The allegations were first lodged by *The People's Daily*, China's Party-run newspaper, which also accused Nu Skin of using direct-marketing methods "akin to brainwashing." Following publication of the report, China's State Administration for Industry and Commerce (SAIC) launched an investigation.²¹⁰

If a U.S. company had acted the way GSK did, it would likely have violated the U.S. Foreign Corrupt Practices Act, inviting substantial penalties in U.S. federal courts. In Ms. Boynton's opinion, the GSK case also signaled a sincere effort by the Chinese government to rein in escalating healthcare costs. The investigations put many foreign pharmaceutical companies in the spotlight but were not exclusively antiforeign. China National Pharmaceutical Group

Corporation (Sinopharm Group), China's largest state-owned drug distributor, was also targeted.²¹¹

Mr. Shobert, however, drew a negative conclusion from the GSK case. Although GSK did what it was accused of doing, the argument that the company behaved unethically is "convenient but not entirely accurate." He argued that bribery is a "reality of doing business" in China's healthcare sector:

*You pay this money to your doctor to be seen, and you pay that money to see a specialist, and you pay that money to jump to the front of the line. And you pay that money to get drugs that actually are high quality. Behind the scenes the same type of red envelope payments takes place between pharmaceutical sales representatives, dealers, [and] hospital administrators.*²¹²

Mr. Shobert further claimed that the GSK case is emblematic of aggressive tactics being taken by the Chinese government against foreign companies. The government not only seeks to benefit domestic companies, but also to promote the public perception that it is combating the escalation in healthcare costs. In 2012, the NDRC investigated four drug classes comprising over 500 different drugs, after which prices dropped by 17 percent. GSK reacted to the allegations in its case by agreeing to reduce its drug prices, as other foreign companies have done in response to the antimonopoly law.²¹³

These actions reflect the Chinese government's aggressive and prejudicial use of antitrust litigation. China's antimonopoly law, enacted in August 2007, is applied by the NDRC, the SAIC, and the Ministry of Commerce to hold companies accountable for anti-competitive agreements, abuse of a dominant position, or mergers that would lead to a dominant position. The law also calls for China to establish a review process to screen inward investment for national security implications.²¹⁴ The U.S. Trade Representative has complained that, even though the assets of state-owned enterprises account for 42 percent of the total assets of Chinese industrial enterprises, the market position of state-owned enterprises has been strengthened through administrative mergers that may not have been subject to review under the new antimonopoly law. At the same time, the law has been used as a pretext to block foreign investors, shielding selected Chinese domestic enterprises, even inefficient or monopolistic enterprises, from foreign competition.²¹⁵ The law has been applied with greater intensity in 2014, most recently against foreign automotive manufacturers.²¹⁶

Technology Transfer and Clinical Trials

Foreign drug makers are setting up state-of-the-art R&D facilities in China. This trend has coincided with government policies to spur innovation in the life sciences. In 2008, the Chinese government unveiled the New Drug Creation and Development Program, creating 20 incubator sites for life science innovation. The 12th Five-Year Plan (2011–2015) mandates that 4 percent of the country's GDP be derived specifically from the life science sector by 2015, and sets aside \$10 billion in funding. Said Mr. Shobert: "As

a result of China's goals, American companies have found they now must begin to allocate funding towards R&D directed specifically at bench science, product development and clinical trials completed in China." One example is Merck and Co.'s late 2011 announcement that it would be spending \$1.5 billion to improve its R&D capacity in China. Mr. Shobert argued that, just as China has conditioned market access on technology transfer in the renewable energy equipment sector, it is now doing so in life sciences, the next emerging industry.²¹⁷

In the near term, China is not expected to compete as a drug innovator. Only 9 percent of domestic pharmaceutical sales are attributed to non-generic brands. At \$150 billion, China's spending on drug R&D is only about one-third that of the United States.²¹⁸

Mr. Hunter told the Commission that his members are less concerned about China's state-led innovation efforts. He argued that it will be difficult for China to imitate the U.S. innovation system, which combines robust IP protection with synergistic relationships among the National Institutes of Health, U.S. universities, and pharmaceutical manufacturers. China's efforts to control drug pricing could also discourage capital-intensive drug innovation, and would have to be offset by substantial government subsidies. To the extent that China is innovating, it is doing so via its private sector; for example, the Chinese drug maker Tasly Phar. International Co. Ltd. has a cardiovascular product that is in phase III clinical trials in the United States.²¹⁹

Nonetheless, the Chinese government appears to be acquiring data from U.S. companies in ways that violate its WTO commitments. At the 2012 JCCT talks, China agreed to "define new chemical entities in a manner consistent with international research and development practices in order to ensure regulatory data of pharmaceutical products are protected against unfair commercial use and unauthorized disclosure."²²⁰ The impetus for this agreement stemmed from complaints that China is not providing six years of data protection to U.S. patent drugs, as is set forth in its WTO commitments. This problem is directly attributable to China's State Intellectual Property Office (SIPO), which uses a poorly defined phrase, "new chemical entity," that has allowed Chinese pharmaceutical manufacturers to receive approval from the CFDA before the six-year period of protection that China's IP laws establish.²²¹ The U.S. Trade Representative has also expressed concern with SIPO's interpretation of Article 26.3 and related provisions of China's Patent Law, which govern information disclosure requirements for pharmaceutical patent applications. SIPO: (1) requires the disclosure of more information than that sought by its counterparts in the United States; (2) requires all of this information be disclosed at the time of application, instead of permitting supplemental disclosure filings under appropriate circumstances; and (3) has retroactively applied the new standards in Article 26.3 to invalidate some older patents.²²²

A related concern is China's onerous clinical trial process. It takes an average of eight years for an existing U.S. patented drug to be re-patented in China, and therefore, to reach Chinese patients who could already be benefiting from innovative drugs available in the United States. For drugs that have a patent life of

around 15 years, this delay can substantially affect a drug maker's ability to recoup R&D costs. The Chinese government fails to compensate this loss by extending periods of market exclusivity. These delays are also damaging to China. For example, in the case of cancer, terminally ill patients may be denied access to state-of-the-art medications from the United States. Slow domestic clinical trials also hamper China's ability to participate in global R&D.²²³

Rather than simply registering a clinical trial with the government, U.S. drug makers must first apply for permission. This can be a drawn-out process, due to staffing limitations at the CFDA. Once clinical trials begin, they undergo the same process as a full approval; in contrast to most major economies that market U.S. drugs, China does not make adequate use of clinical trial data available for the same drug from the FDA.²²⁴ Chinese regulators have also been holding up or invalidating U.S. pharmaceutical patents by charging that the application contains insufficient information, without allowing companies to supplement information after the initial filing. At the 2013 JCCT talks, China "affirmed" that it would end this practice, and that it would "ensure that pharmaceutical inventions receive patent protection during examinations and re-examinations and before China's courts."²²⁵

According to Mr. Ives, clinical trials can delay the release of some U.S.-origin medical devices in China. FDA-approved products require re-approval by Chinese regulators, and the device has to be approved first by the FDA before it can begin the registration process in China. These regulatory hurdles could increase substantially under China's proposed amendment to the Medical Device Law, released in March 2014. The amendment could impose hundreds of new requirements on foreign device makers, including indigenous standards for serial number tracking.²²⁶

Distribution, Pricing, and Reimbursement

Once a U.S. drug or device hits the Chinese market, it faces further hurdles. To lower the cost of drugs, the MOH introduced a National Reimbursement Drug List (NRDL) in 2004, which designated 1,027 Western drugs eligible for reimbursement from state-run insurers and to be given preference by state-run hospitals.* In 2009, the same year that China greatly expanded health insurance coverage, an updated NRDL was published and supplemented by the Essential Drug List (EDL), a shorter compendium of generic drugs to be sold by grassroots providers at no markup.

The use of these lists has put U.S. drug makers in an uncomfortable position. While pricing and reimbursement lists are typically updated at least on an annual basis around the world, in China, the last update was in 2009. China's own laws dictate that updates should occur every two years. Effectively, all the U.S. drugs that have entered the market since then have not been eligible for reimbursement. Foreign drugs not on the lists can achieve moderate success in China, particularly for advanced treatments. Reimbursements can be negotiated individually with providers. But U.S. drug makers like Pfizer, Johnson & Johnson, and Merck derive signifi-

*These numbers exclude the traditional Chinese medicine products that account for over half of the NRDL.

cant sales from drugs that are on the lists.²²⁷ The drug list policy also harms Chinese patients who, in addition to not enjoying timely access to the latest drugs, may not get adequate reimbursement for them.

A revised NRDL, due out in 2014, could place additional foreign drugs to the list. U.S. drug makers, however, will be forced to participate in reimbursement drug bidding, an opaque process that varies by region and often favors the lowest bidder, while giving less consideration to quality or to the costs incurred in developing and producing the drug.²²⁸

Widespread state ownership of pharmacies and providers has further hindered the introduction and distribution of U.S. products. Small clinics, for instance, are expected to sell only the essential drugs on the EDL, excluding foreign drugs deemed “non-essential.” According to Marc de Garidel, CEO of French drug maker Ipsen, doctors at public hospitals can be “paid by the state” to refuse foreign drug makers’ sales representatives.²²⁹ In light of these risks, foreign drug makers have come to rely heavily on local pharmaceutical distributors to navigate the process. Getting these companies involved, however, siphons off profits that could be pocketed by the drug makers themselves. Conflict of interest is magnified in the case of Sinopharm Group, a Hong Kong-listed, central state-owned enterprise that distributes medicines and runs retail pharmacy chains, but also researches, develops, and manufactures its own medicines.²³⁰

The medical device sector faces a series of regulatory hurdles as well. The Chinese government has required hospitals and clinics to acquire medical devices at the provincial level. Foreign medical devices are frequently subject to price ceilings or are prevented from competing in local tendering.²³¹ U.S. government and industry representatives have opposed these practices since they were first instituted by the NDRC in 2006. Although China at the 2012 JCCT talks vaguely committed to “taking into account comments from the United States on this issue,” its amended Medical Device Law, released this year, appears to make matters worse. Said Mr. Ives:

*It is expected that the revision to this law will impact all aspects of China’s regulatory system (clinical trials, testing, inspections, evaluations, re-registration, post-market surveillance, etc.). We have already seen more than 20 new requirements with significant impact to our industry over the past year, and expect to see hundreds more as the revision is implemented.*²³²

Of particular concern to the device industry is China’s implementation of Unique Device Identifiers (UDI), a bar code that will be required on all medical technology products. The ostensible purpose of UDI is to improve patient safety by allowing regulators to identify devices throughout distribution and use, akin to “track and trace” technology being adopted in the United States. But while the U.S. rule is based on international standards—in conjunction with the International Medical Devices Regulators’ Forum—Mr. Ives expressed concern that China is contemplating a “home grown” UDI system that would not be consistent with the global approach. U.S.

device companies would spend huge sums to comply with China's indigenous standards throughout the supply chain.²³³

Implications for the United States

Healthcare, still a marginal issue in U.S.-China relations, has the potential to become a positive and stabilizing force, at a time when bilateral disputes in other areas remain unresolved. The FDA is building constructive relationships with its Chinese counterparts, as pandemics and food and drug safety issues have forged a stronger partnership under duress. On the corporate side, the sheer size of China's market has compelled U.S. drug and device makers to do business there. Sourcing cheap ingredients is an important motive, but so are China's large pool of patients and its deepening role in developing drug products for the Asian market. Net exports of biopharmaceuticals to China can help remedy the bilateral trade imbalance. U.S. companies can help China to upgrade its pharmaceutical production and inform regulators on best practices.

U.S. policy and corporate interests could complement China's objective to make healthcare provision equitable and efficient. Policy documents and statements, such as the Third Plenum Decision, suggest that the new party leadership is indeed interested in modifying existing market structures and regulatory frameworks to bridge rural-urban gaps, realign incentives for medical professionals, and permit a larger number of foreign and private companies into emerging market niches, such as long-term care. Lower rates of precautionary saving could raise consumption among Chinese households, and with it, consumer demand for U.S. goods and services.

The reality, however, is that China's healthcare system is in dire need of repair. The reforms undertaken in 2009 introduced generous fiscal spending but could not remedy escalating costs and distorted incentives that have taken root over decades. In this difficult environment, U.S. drug and device companies are struggling to market their latest cutting-edge products and to move beyond the richest Chinese consumers in tier-1 cities. They also face ethical dilemmas when dealing with regulators, competitors, partners, or clients who view corruption and bribery as part of doing business.

U.S. drug and device companies have made some use of the JCCT to address market concerns in China, but appear hesitant to rely too much on government-to-government negotiations. An example is the WTO's Agreement on Government Procurement (GPA), which China has not signed, and which could potentially resolve the issues that U.S. companies face at the local level in China. Mr. Hunter said: "I am not sure going to USTR [U.S. Trade Representative] to complain about GPA is the most effective means, but we certainly engage with [China's Ministry of Health], the relevant ministries, and at the provincial level to urge expeditious updates of the reimbursement list to begin that complicated process."²³⁴ Referring to counterfeiting in the device industry, Mr. Ives said that "so far, [our members] have not wanted to pursue [remedies] through the USTR." Device makers have preferred to raise their concerns with the relevant Chinese authorities.²³⁵ These

statements raise questions about the role the U.S. government should and can play in resolving market access issues.

At greatest risk, perhaps, are U.S. consumers who continue to purchase China-origin drug products, in many cases unknowingly. The FDA has made significant efforts since the 2007–2008 heparin scandal to remedy this problem but still faces a series of obstacles. In China, increasing the number of drug inspectors has taken over two years, and inspections of API suppliers are infrequent. U.S. taxpayer funds are being used to train CFDA regulators, while the FDA has not been granted sufficient work visas or permission to conduct unannounced inspections of drug facilities. Back in the United States, the new authorities and capabilities afforded by FDASIA and DQSA will take time to be fully adopted. Drug regulation is challenged by uneven state-level oversight of wholesalers, infrequent inspections at the border, and loopholes with regard to ingredients, dietary supplements, and lifestyle drugs.

Conclusions

- China today is the world's largest producer of active pharmaceutical ingredients and inert substances. In a 2010 study of pharmaceutical executives by the consulting firm Axendia, 70 percent of respondents cited China as their top source country for pharmaceutical ingredients. China's rise as a pharmaceuticals exporter has coincided with growing reliance on drug and drug ingredient imports in the United States, which is estimated to be the top importer of China's pharmaceutical raw materials. These trends are worrying because China, by some estimates, is also the world's leading supplier of fake and substandard drugs. Tainted heparin, which contained ingredients sourced from China, claimed at least 81 lives in the United States in 2007–2008. More subtle risks of unsafe drugs include inadequate dosages of active ingredients, impure ingredients, and false packaging.
- Since 2007, the Food and Drug Administration (FDA) has taken important steps to improve drug safety regulation. In China, the FDA is expanding its team of drug inspectors, increasing the frequency of inspections, and working closely with its Chinese counterparts at the China Food and Drug Administration. In the United States, Congressional legislation has given the agency more authority to hold companies accountable for their supply chain safety, collect user fees from companies to finance regulatory efforts, seize unsafe products at the border, and track-and-trace products via serial numbers. The agency has also transitioned to an electronic, risk-based surveillance system known as PREDICT.
- There is much work to be done to improve drug safety in the United States. Regulating China's vast drug industry, especially the production of precursor chemicals by semi-legitimate companies, is a severe challenge. China's own drug safety regulation is fragmented and decentralized and lacks civil society monitoring. The FDA's China offices have had trouble securing work visas for new inspectors and conducting unannounced factory inspections.

- Alongside its role as a pharmaceutical producer, China is undergoing an epidemiologic and demographic transition that is fundamentally changing the country's demand for healthcare. Chronic and non-communicable diseases are on the rise, due to an aging population and to a worrying decline in public health, caused by pollution, poor diet, and other factors. A more affluent and urbanized population is seeking better quality care. Some experts estimate China's healthcare spending to increase from \$357 billion in 2011 to \$1 trillion in 2020, making China the second-largest market after the United States.
- At present, China's healthcare market is ill equipped to meet the rise in demand for care. Relative to wealthier countries, doctors and hospital beds are in short supply. Healthcare spending is only 5 percent of gross domestic product, compared to an average of 9 percent in Organization for Economic Cooperation and Development countries. To remedy this situation, the Chinese government launched ambitious healthcare reforms in 2009 that aim to extend basic government-subsidized health insurance, expand the population health benefit package, strengthen primary care by constructing new clinics, control the price of essential drugs, and reform government-owned hospitals. Fiscal spending to support these reforms totaled some \$371 billion in 2009–2012.
- Not all of China's healthcare reforms have succeeded, and serious problems remain. Expanded insurance coverage has had some success in reducing rural-urban gaps and out-of-pocket spending. But the insurance coverage of migrant workers is not portable, and coverage is limited for costlier drugs and treatments. The absence of a functioning referral system has led to overcrowding in large hospitals and underutilization of local providers.
- On the supply side, most of China's public funding increases for healthcare have gone toward brick-and-mortar investments and new machines, rather than increases in doctors' salaries. Prices and fees are subject to government interference, which incentivizes doctors to undersupply basic services and oversupply costly drugs and treatments. The net result is that hospitals are short of qualified staff and rely excessively on drug revenues, while healthcare spending is rising on the back of escalating costs rather than improvements in care. Private sector providers operate on an uneven playing field and have done little to improve overall delivery.
- U.S. companies that market drugs, medical devices, and healthcare services view China as an important opportunity, not only to source cheap inputs, but also to market goods and conduct research and development. An important impetus to focus resources on China is slowing demand and changing regulation in the United States, as well as a lack of other markets that match China in terms of market size and level of development.
- Market access for U.S. drug and device makers remains restricted. Companies are concerned about being targeted by China's recent anticorruption drive and indiscriminate use of its antimonopoly law, which ostensibly aim to lower healthcare costs

but serve to disadvantage foreign companies. China's process for approving new drugs leads to excessive data transfers. Loopholes in China's intellectual property laws allow local drug makers to reproduce U.S. patent drugs prematurely. Onerous clinical trials, combined with state interference in tendering, pricing, and reimbursement, cause delays of up to eight years for state-of-the-art U.S. drugs, and make these drugs prohibitively expensive for ordinary Chinese patients. U.S. device makers are concerned as well about proposed amendments to China's Medical Device Law, published in March 2014. The amendment could impose hundreds of new requirements on foreign device makers, including indigenous standards for serial number tracking.

ENDNOTES FOR SECTION 3

1. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.
2. Karen Eggleston et al., "Will Demographic Change Slow China's Rise?" *Journal of Asian Studies* 72:3 (August 2013): 505; data from World Bank, <http://data.worldbank.org/indicator/SP.POP.65UP.TO.ZS>.
3. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Karen Eggleston, April 3, 2014.
4. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ralph Ives, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Rod Hunter.
5. NSD Bio Group LLC, *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients* (U.S.-China Economic and Security Review Commission, April 2010).
6. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.
7. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
8. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Karen Eggleston, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014; and U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.
9. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ralph Ives, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Rod Hunter.
10. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ginger Zhe Jin.
11. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.
12. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Christopher J. Hickey, April 3, 2014; Uchenna Alexander (Congressional Affairs Specialist, Office of Legislation, U.S. Food and Drug Administration), e-mail to Commission staff, September 24, 2014.
13. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Rod Hunter, April 3, 2014.
14. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ralph Ives, April 3, 2014.
15. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Benjamin Shobert, April 3, 2014.
16. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.
17. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

18. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

19. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Charles Bell, April 3, 2014.

20. Ann Maruchek et al., "Product Safety and Security in the Global Supply Chain: Issues, Challenges, and Research Opportunities," *Journal of Operations Management* 29 (2011): 700–701; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

21. Heather Timmons, "A Pharmaceutical Future," *New York Times*, July 7, 2010, via Factiva.

22. U.S. Food and Drug Administration, "Global Engagement: U.S. Food and Drug Administration." <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM298578.pdf>; Uchenna Alexander (Congressional Affairs Specialist, Office of Legislation, U.S. Food and Drug Administration), e-mail to Commission staff, September 24, 2014.

23. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

24. NSD Bio Group LLC, *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients* (U.S.-China Economic and Security Review Commission, April 2010), p. 1; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

25. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

26. NSD Bio Group LLC, *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients* (U.S.-China Economic and Security Review Commission, April 2010), p. 16.

27. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

28. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.

29. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

30. Fred. C. Bergsten et al., *China's Rise: Challenges and Opportunities*. (Peterson Institute, 2008), pp. 106–109; Shankar Gopalakrishnan, "Negative Aspects of Special Economic Zones in China," *Economic and Political Weekly*, April 28, 2007. <http://farmwars.info/wp-content/uploads/2011/06/Negative-aspects-of-SEZ-in-China.pdf>.

31. Shuang Lewis, "China to Increase Tax Rebates on Anti-HIV and Insulin API Exports," *Global Insight Daily Analysis*, October 24, 2008, via Factiva; "China Raises Export Tax Rebates of Some Antibiotic APIs," *Interfax China Business Newswire*, June 9, 2009, via Factiva.

32. United Nations Office on Drugs and Crime, *The Globalization of Crime: A Transnational Organized Crime Threat Assessment* (Vienna, Austria: United Nations Office of Drugs and Crime), pp. 177–178.

33. Data from the China General Administration of Customs and the China National Bureau of Statistics, via CEIC.

34. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.

35. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

36. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

37. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014; Roger Bate, *Phake: The Deadly World*

of *Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), pp. 196–198.

38. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, oral and written testimony of Ginger Zhe Jin, April 3, 2014; Peter S. Goodman, "China's Killer Headache: Fake Pharmaceuticals," *Washington Post*, August 30, 2002; "Drug Piracy: A Wave of Counterfeit Medicines Washes Over Russia," *New York Times*, September 5, 2006, via Factiva; and Andrew Batson, "As China Reins in Piracy, Some Seek Faster Results," *Wall Street Journal*, November 27, 2006, via Factiva.

39. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

40. Ann Maruchek et al., "Product Safety and Security in the Global Supply Chain: Issues, Challenges, and Research Opportunities," *Journal of Operations Management* 29 (2011): 710; Agnes Binagwaho, Roger Bate et al., "Combating Substandard and Falsified Medicines: A View from Rwanda," *PLoS Med* 10:7 (2013): 1–3.

41. Lawrence O. Gostin, Gillian J. Buckley, and Patrick W. Kelley, "Stemming the Global Trade in Falsified and Substandard Medicines," *Journal of American Medical Association* 309:16 (April 24, 2013): 1693–1694.

42. Lawrence O. Gostin, Gillian J. Buckley, and Patrick W. Kelley, "Stemming the Global Trade in Falsified and Substandard Medicines," *Journal of American Medical Association* 309:16 (April 24, 2013): 1693–1694.

43. Nayanah Siva, "Tackling the Booming Trade in Counterfeit Drugs," *The Lancet* 376 (November 2010): 1726.

44. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.

45. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

46. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, oral and written testimony of Charles Bell, April 3, 2014; Roger Bate, *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade* (Washington, DC: American Enterprise Institute, 2008), pp. 8–24.

47. Jill Wechsler, "Campaign Mounts to Curb Counterfeit Drugs; Manufacturers and Regulators Struggle to Control Phony Versions of Crucial Medicines," *BioPharm International*, September 1, 2012, via Factiva.

48. Jon Swartz and Elizabeth Weise, "Online Buyer, Beware of Fakes," *USA Today*, May 1, 2014, via Factiva.

49. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

50. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

51. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), p. 13.

52. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), p. 13.

53. NBC News, "Heparin Probe Reveals Global Drug Market Perils," April 13, 2008. <http://www.nbcnews.com/id/24015019/#.UtgSFPRDvmc>.

54. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

55. "Nation's First Contaminated Chinese Heparin Case," China Weekly News via VerticalNews.com, June 21, 2011, via Factiva.

56. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), p. 14.

57. Data from China Administration of Customs, via CEIC.

58. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

59. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

60. NSD Bio Group LLC, *Potential Health & Safety Impacts from Pharmaceuticals and Supplements Containing Chinese-Sourced Raw Ingredients* (U.S.-China Economic and Security Review Commission, April 2010), p. 14.

61. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

62. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

63. Nadine He, "China Urges Pharmaceutical Manufacturers to Meet New GMP Standards," *ChemLinked*, January 17, 2013. <https://chemlinked.com/news/pharmaceutical/china-urges-pharmaceutical-manufacturers-meet-new-gmp-standards>.

64. U.S.-China Joint Committee on Commerce and Trade, "2009 Fact Sheet." <http://www.ustr.gov/about-us/press-office/fact-sheets/2009/october/us-china-joint-commission-commerce-and-trade>.

65. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

66. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014; Jon Swartz and Elizabeth Weise, "Online Buyer, Beware of Fakes," *USA Today*, May 1, 2014, via Factiva.

67. "Illicit Trade Report 2012" (Brussels, Belgium: World Customs Organization, 2013), p. 63.

68. Nadine He, "China Urges Pharmaceutical Manufacturers to Meet New GMP Standards," *ChemLinked*, January 17, 2013. <https://chemlinked.com/news/pharmaceutical/china-urges-pharmaceutical-manufacturers-meet-new-gmp-standards>.

69. Roger Bate (Visiting Scholar, American Enterprise Institute), e-mail to Commission staff, August 20, 2014.

70. Uchenna Alexander (Congressional Affairs Specialist, Office of Legislation, U.S. Food and Drug Administration), e-mail to Commission staff, September 24, 2014.

71. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

72. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.

73. Yanzhong Huang, *Governing Health in Contemporary China* (New York: Routledge, 2013), pp. 112–134; Margaret Pearson, "The Business of Governing Business in China: Institutions and Norms of the Emerging Regulatory State," *World Politics* 57:2 (January 2005): 296–322.

74. Vivian Wu, "Food, Drugs Fall under Health Ministry's Charge: Regulatory Agency Integrated under Reform," *South China Morning Post*, September 3, 2008, via Factiva.

75. Dali Yang, "Total Recall," *National Interest*, March 1, 2008, via Factiva; Yanzhong Huang, *Governing Health in Contemporary China* (New York: Routledge, 2013), pp. 112–134.

76. APCO Worldwide, "Will China's Food Safety Law Make China's Food Safer?" April 2009. <http://www.apcoworldwide.com/content/contactus.aspx>; Vivian Wu, "Food, Drugs Fall under Health Ministry's Charge: Regulatory Agency Integrated under Reform," *South China Morning Post*, September 3, 2008, via Factiva; and Yanzhong Huang, *Governing Health in Contemporary China* (New York: Routledge, 2013), pp. 112–134.

77. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

78. Based on comments made by Dr. Christopher J. Hickey and other speakers at 50th Annual Meeting of the Drug Information Association, San Diego, California, June 18, 2014. <http://www.diahome.org/en-US/Flagship-Meetings/DIA2014/Meeting-Program/Find-Sessions-and-Presentations/Event-Details.aspx?productID=2972652&eventType=SESSION>.

79. Yanzhong Huang, *Governing Health in Contemporary China*. (New York: Routledge, 2013), p.124.

80. Christine Wong, "Toward Building Performance-Oriented Management in China: The Critical Role of Monitoring and Evaluation and the Long Road Ahead," *ECD Working Paper Series 27* (Washington, DC: World Bank, September 2012), p.6.

81. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.
82. Yanzhong Huang, *Governing Health in Contemporary China*. (New York: Routledge, 2013), p. 133.
83. Daniel Chinoy, "Black-Hearted Products: The Causes of China's Product Safety Problems," *Columbia East Asia Review* 2 (2009): 29–36.
84. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.
85. Information from a leading epidemiologist who briefed the Commission on August 19, 2014.
86. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), pp. 188–195.
87. U.S. Trade Representative, *2013 Report on China's WTO Compliance*, p. 4.
88. Shuang Lewis, "China Gets Heavy-Handed on Counterfeit Drugs," *IHS Global Insight Daily Analysis*, May 28, 2009, via Factiva.
89. John Balzano, "China's Food Safety Law: Administrative Innovation and Institutional Design in Comparative Perspective." *Asian-Pacific Law & Policy Journal* 13:2 (2012): 23–80.
90. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ginger Zhe Jin, April 3, 2014.
91. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), p. 183; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014;
92. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Charles Bell, April 3, 2014.
93. Lawrence O. Gostin, Gillian J. Buckley, and Patrick W. Kelley, "Stemming the Global Trade in Falsified and Substandard Medicines," *Journal of American Medical Association* 309:16 (April 24, 2013): 1693–1694.
94. Senate Finance Committee, *Hearing on Trade Enforcement*, testimony of Bart Peterson, June 25, 2014; Ann Capling and John Ravenhill, "Symposium: Australia–U.S. Economic Relations and the Regional Balance of Power Australia, the United States and the Trans-Pacific Partnership: Diverging Interests and Unintended Consequences," *Australian Journal of Political Science* 48:2 (2013): 184–196.
95. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
96. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
97. Uchenna Alexander (Congressional Affairs Specialist, Office of Legislation, U.S. Food and Drug Administration), e-mail to Commission staff, September 24, 2014.
98. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
99. Congressional-Executive Commission on China, *Food and Drug Safety, Public Health, and the Environment in China*, written testimony of Steven M. Solomon, May 22, 2013; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
100. Uchenna Alexander (Congressional Affairs Specialist, Office of Legislation, U.S. Food and Drug Administration), e-mail to Commission staff, September 24, 2014.
101. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.
102. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

103. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

104. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

105. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Christopher J. Hickey, April 3, 2014.

106. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

107. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

108. U.S. Government Accountability Office, *Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed*, GAO-10-960 (October 25, 2010).

109. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

110. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Charles Bell, April 3, 2014.

111. Pew Health Group, *After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs* (Washington, DC, 2011), p.14.

112. Suchira Ghosh, "RFID Act of 2006 and E-Pedigrees: Tackling the Problem of Counterfeit Drugs in the United States Wholesale Industry," *Michigan Telecommunications and Technology Law Review* 13:2 (2006-2007): 577-600; Roger Bate, *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade* (Washington, DC: American Enterprise Institute, 2008), pp. 25-38.

113. Rx360.org homepage. <http://www.rx-360.org/AboutRx360/tabid/55/Default.aspx>; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Allan Coukell, April 3, 2014.

114. Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines* (Washington, DC: The AEI Press, 2012), pp. 177-182; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Roger Bate, April 3, 2014.

115. Ann Maruchek et al., "Product Safety and Security in the Global Supply Chain: Issues, Challenges, and Research Opportunities," *Journal of Operations Management* 29 (2011): 716-717.

116. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Allan Coukell, April 3, 2014.

117. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

118. CMS, "National Health Expenditures 2012 Highlights." <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf>.

119. Franck Le Deu et al., "Health Care in China: Entering 'Uncharted Waters,'" McKinsey & Company (November 2012). http://www.mckinsey.com/insights/health_systems_and_services/health_care_in_china_entering_uncharted_waters.

120. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

121. Shanlian Hu et al., "Reform of How Health Care Is Paid for in China: Challenges and Opportunities," *Lancet* 372:9652 (2008): 1846.

122. Debora MacKenzie, "China's Alzheimer's Time Bomb Revealed," *New Scientist*, June 7, 2013. <http://www.newscientist.com/article/dn23673-chinas-alzheimers-time-bomb-revealed.html#.UzMLHPldXmc>.

123. The World Bank, "Toward a Healthy and Harmonious Life in China: Stemming the Tide of Non-Communicable Diseases" (2011), p. 2. http://www.worldbank.org/content/dam/Worldbank/document/NCD_report_en.pdf.

124. Jun Ma et al., *China: Themes and Strategy for 2014*, (Deutsche Bank, January 3, 2014), pp. 28-33.

125. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.
126. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014.
127. *Wall Street Journal*, "Beijing Plans to Spend \$2.45 Trillion This Year," March 5, 2014.
128. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.
129. Shanlian Hu et al., "Reform of How Health Care Is Paid for in China: Challenges and Opportunities," *Lancet* 372:9652 (2008): 1846–1847; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Karen Eggleston, April 3, 2014.
130. Karen Eggleston, "Healthcare for 1.3 Billion: China's Remarkable Work in Progress," *Miken Institute Review*, Second Quarter 2013.
131. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.
132. Qiulin Chen, Karen Eggleston, and Ling Li, "Demographic Change, Intergenerational Transfers, and the Challenges for Social Protection Systems in the People's Republic of China," in Park, Donghyun, Sang-Hyop Lee, and Andrew Mason, *Aging, Economic Growth, and Old-age Security in Asia* (Northampton, MA: Edward Elgar Publishing, 2012), pp. 161–202.
133. Karen Eggleston et al., "Will Demographic Change Slow China's Rise?" *Journal of Asian Studies* 72:3 (August 2013): 505–518.
134. Shanlian Hu et al., "Reform of How Health Care Is Paid for in China: Challenges and Opportunities," *Lancet* 372:9652 (2008): 1847–1848.
135. Karen Eggleston et al., "Health Service Delivery in China: A Literature Review," *Health Economics* 17 (2008): 151–152.
136. Christina Ho, "Health Reform and De Facto Federalism in China," *China: An International Journal* 8:1 (March 2010): 38–39.
137. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.
138. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.
139. Bloomberg, "China 'Catastrophe' Hits 114 Million as Diabetes Spreads," September 3, 2013. <http://www.bloomberg.com/news/2013-09-03/china-catastrophe-hits-114-million-as-diabetes-spreads.html>.
140. Yong-chuan Wang et al., "Comparison of Cancer Incidence between China and the USA," *Cancer Biol. Med.* 9:2 (June 2012): 128–132. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3643656/#:po=10.0000>; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.
141. *Global Status Report on Road Safety 2013: Supporting a Decade of Action* (Geneva, Switzerland: World Health Organization, 2013).
142. Mindi Schneider, *Feeding China's Pigs: Implications for the Environment, China's Smallholder Farmers and Food Security* (Institute for Agriculture and Trade Policy, May 2011), pp. 19–22.
143. *New York Times*, "Pollution Killed 7 Million People Worldwide in 2012, Report Finds," March 26, 2013. <http://www.nytimes.com/2014/03/26/world/pollution-killed-7-million-people-worldwide-in-2012-report-finds.html>; "Air Pollution Linked to 1.2 Million Premature Deaths in China," *New York Times*, April 1, 2013. <http://www.nytimes.com/2013/04/02/world/asia/air-pollution-linked-to-1-2-million-deaths-in-china.html? r=2&>.
144. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Karen Eggleston, April 3, 2014.
145. Centers for Disease Control and Prevention, "Avian Influenza A (H7N9) Virus." <http://www.cdc.gov/flu/avianflu/h7n9-virus.htm>.
146. Information from a leading epidemiologist who briefed the Commission on August 19, 2014.

147. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

148. Yanzhong Huang, *Governing Health in Contemporary China* (New York: Routledge, 2013), pp. 24–52; Zhe Dong and Michael R. Phillips, “Evolution of China's Health-Care System,” *Lancet* 372 (November 2008): 1715–1716.

149. Data from World Bank. <http://data.worldbank.org/indicator/SP.DYN.LE00.IN>.

150. Jing Ulrich et al., “Medicine for the Masses—China's Healthcare Reform: Progress and Future Steps,” *J.P. Morgan Hands-On China Report* (J.P. Morgan, October 10, 2011), p. 3.

151. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.

152. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Karen Eggleston, April 3, 2014.

153. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

154. Karen Eggleston and Winnie Yip, “Hospital Competition under Regulated Prices: Application to Urban Health Sector Reforms in China,” *International Journal of Health Care Finance and Economics* 4:1 (2004): 347–348.

155. Karen Eggleston et al., “Health Service Delivery in China: A Literature Review,” *Health Economics* 17 (2008): 159.

156. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

157. “Information from webinar presented April 20, 2012 by Double Helix, titled *Drug Policy Reform in China: Where Now and What Does It Mean for the Pharmaceutical Industry?*”

158. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014.

159. Shanlian Hu et al., “Reform of How Health Care Is Paid for in China: Challenges and Opportunities,” *Lancet* 372:9652 (2008): 1847–1848.

160. Zhe Dong and Michael R. Phillips, “Evolution of China's Health-Care System,” *Lancet* 372 (November 2008): 1715–1716.

161. Shanlian Hu et al., “Reform of How Health Care Is Paid for in China: Challenges and Opportunities,” *Lancet* 372:9652 (2008): 1847–1848; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Xiaoqing Lu Boynton, April 3, 2014.

162. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Xiaoqing Lu Boynton, April 3, 2014.

163. Karen Eggleston, “Health Care for 1.3 Billion: An Overview of China's Health System,” *Asia Health Policy Program Working Paper* 28 (January 2012): 17; Shan Juan, “Medical Reform Must Be Rational,” *China Daily*, March 10, 2014. http://www.chinadailyasia.com/news/2014-03/10/content_15123737.html.

164. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

165. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written and oral testimony of Karen Eggleston, April 3, 2014.

166. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

167. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014.

168. Jing Ulrich et al., “Medicine for the Masses—China's Healthcare Reform: Progress and Future Steps,” *J.P. Morgan Hands-On China Report* (J.P. Morgan, October 10, 2011), pp. 2–3.

169. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

170. Yuanli Liu, "Reforming China's Healthcare: For the People by the People?" *Lancet* 373 (January 2009): 282; Shanlian Hu et al., "Reform of How Health Care Is Paid for in China: Challenges and Opportunities," *Lancet* 372:9652 (2008): 1848; and Zhe Dong and Michael R. Phillips, "Evolution of China's Health-Care System," *Lancet* 372 (November 2008): 1715–1716.

171. Karen Eggleston and Winnie Yip, "Hospital Competition under Regulated Prices: Application to Urban Health Sector Reforms," *International Journal of Health Care Finance and Economics* 4:1 (2004): 343–344; Karen Eggleston et al., "Comparing Public and Private Hospitals in China: Evidence from Guangdong," *BMC Health Services Research* 10:76 (2010): 3; and U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014.

172. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ginger Zhe Jin, April 3, 2014.

173. Karen Eggleston et al., "Health Service Delivery in China: A Literature Review," *Health Economics* 17 (2008): 154–155.

174. Karen Eggleston et al., "Health Service Delivery in China: A Literature Review," *Health Economics* 17 (2008): 154–155.

175. Christina Ho, "Health Reform and De Facto Federalism in China," *China: An International Journal* 8:1 (March 2010): 38–53; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014.

176. Xiaoqing Lu Boynton, Olivia Ma, and Molly Claire Schmalzbach, *Key Issues in China's Health Care Reform: Payment System Reform and Health Technology Assessment* (Center for Strategic and International Studies, December 2012).

177. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Yanzhong Huang, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

178. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.

179. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.

180. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

181. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

182. U.S.-China Economic and Security Review Commission, *Hearing on Stability in China: Lessons from Tiananmen and Implications for the United States*, written testimony of Murray Scott Tanner, May 15, 2014.

183. Sharon LaFraniere, "Chinese Hospitals Are Battlegrounds of Discontent," *New York Times*, August 11, 2010. http://www.nytimes.com/2010/08/12/world/asia/12hospital.html?_r=0.

184. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.

185. Information from a leading epidemiologist who briefed the Commission on August 19, 2014.

186. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Benjamin Shobert, April 3, 2014.

187. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

188. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

189. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Rod Hunter, April 3, 2014.

190. Pfizer.com, "Pfizer in China." http://www.pfizer.com.cn/pfizer-china/about_pfizer_china_en.aspx.

191. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

192. United Family Healthcare, "About Us." <http://www.ufh.com.cn/en/about-us/>.

193. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Benjamin Shobert, April 3, 2014.

194. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

195. George Eliades et al., *Healthcare 2020* (New York: Bain & Company, 2012), p. 1.

196. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

197. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

198. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ralph Ives, April 3, 2014.

199. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Benjamin Shobert, April 3, 2014.

200. George Eliades et al., *Healthcare 2020* (New York: Bain & Company, 2012), p. 3.

201. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014.

202. United Family Healthcare, "About Us." <http://www.ufh.com.cn/en/about-us/>.

203. John Lauerman and Michael McDonald, "Harvard-Linked Hospital Eyes Expansion with China Billionaire," Bloomberg, February 17, 2014.

204. U.S. Department of Commerce, *Fact Sheet: 24th U.S.-China Joint Commission on Commerce and Trade (JCCT) Signings* (December 20, 2013). <http://www.commerce.gov/news/fact-sheets/2013/12/20/fact-sheet-24th-us-china-joint-commission-commerce-and-trade-jcct-signin>.

205. Fanfan Wang, "China to Allow Foreign Ownership of Hospitals," *Wall Street Journal*, August 27, 2014. <http://online.wsj.com/articles/china-to-allow-foreign-ownership-of-hospitals-1409133296>.

206. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Yanzhong Huang, April 3, 2014; U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Karen Eggleston, April 3, 2014.

207. Drew Armstrong, "China's Pharma Potential Diminished," *Bloomberg Businessweek*, November 14, 2013.

208. Keith Bradsher and Chris Buckley, "China Fines GlaxoSmithKline Nearly \$500 Million in Bribery Case," *New York Times*, September 19, 2014. http://www.nytimes.com/2014/09/20/business/international/gsk-china-fines.html?_r=0.

209. Reuters, "China Investigates France's Sanofi for Alleged Bribery: Xinhua," August 10, 2013, via Factiva; *China Economic Review*, "China Investigates Bayer for Alleged Wrongdoings," September 16, 2013. <http://www.chinaeconomicreview.com/china-investigates-bayer-alleged-wrongdoings>.

210. *Wall Street Journal*, "Communist Party Paper Alleges U.S. Company Is Operating Pyramid Scheme," January 16, 2014, via Factiva.

211. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Xiaoqing Lu Boynton, April 3, 2014.

212. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Benjamin Shobert, April 3, 2014.

213. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Benjamin Shobert, April 3, 2014.

214. Slaughter and May, "Competition Law in China," January 2014. <http://www.slaughterandmay.com/media/879862/competition-law-in-china.pdf>.

215. U.S. Trade Representative, *2013 USTR Report to Congress on China's WTO Compliance* (December 2013), pp. 69, 79.

216. Colum Murphy, "China Regulator Finds Evidence of Mercedes-Benz Monopolistic Behavior," *Wall Street Journal*, August 18, 2014. <http://www.marketwatch.com/story/china-regulator-finds-evidence-of-mercedes-benz-monopolistic-behavior-2014-08-18>.

217. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written and oral testimony of Benjamin Shobert, April 3, 2014.

218. Drew Armstrong, "China's Pharma Potential Diminished," *Bloomberg Businessweek*, November 14, 2013.

219. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

220. U.S. Department of Commerce, *Fact Sheet: 23rd U.S.-China Joint Commission on Commerce and Trade* (December 19, 2012).

221. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

222. U.S. Trade Representative, *2013 USTR Report to Congress on China's WTO Compliance* (December 2013), p. 108.

223. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

224. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

225. U.S. Trade Representative, *2013 USTR Report to Congress on China's WTO Compliance* (December 2013), p. 5.

226. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ralph Ives, April 3, 2014.

227. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014; IMS, *The 2009 Revision of the National Reimbursement Drug List* (Beijing: IMS Intelligence Applied, 2009).

228. Jing Ulrich et al., "Medicine for the Masses—China's Healthcare Reform: Progress and Future Steps," *J.P. Morgan Hands-On China Report* (J.P. Morgan, October 10, 2011), pp. 6–7; IMS, *The 2009 Revision of the National Reimbursement Drug List* (Beijing: IMS Intelligence Applied, 2009).

229. Drew Armstrong, "China's Pharma Potential Diminished," *Bloomberg Businessweek*, November 14, 2013.

230. See Sinopharm Group homepage. <http://www.sinopharm.com/p391.aspx>.

231. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ralph Ives, April 3, 2014.

232. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ralph Ives, April 3, 2014.

233. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, written testimony of Ralph Ives, April 3, 2014.

234. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Rod Hunter, April 3, 2014.

235. U.S.-China Economic and Security Review Commission, *Hearing on China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products*, testimony of Ralph Ives, April 3, 2014.