



The Problems and Potential of China's Pharmaceutical Industry

By Roger Bate and Karen Porter

China's pharmaceutical market has experienced significant growth in recent years, fueled by increasing wealth among its own population¹ as well as accelerating global demand for cheap, effective medicines to treat ailments ranging from high cholesterol to HIV/AIDS.² Along with India, China supplies more than 40 percent of the active pharmaceutical ingredients (API) used to make U.S. pharmaceuticals. The current financial crisis, and the limited resources and tighter budgets it has engendered, may accelerate the trend. Yet, China is dogged by a history of poor-quality pharmaceuticals that have killed hundreds and sickened thousands of its own citizens and people across the globe. The government has begun to tighten its laws, but enforcement remains weak, and official obfuscation is rampant. While any retaliatory protectionist measures in the United States would be counterproductive, China and its international partners would gain from improving the frequency and technical sophistication of inspections, the prosecution of perpetrators, and the culture of self-policing within China's pharmaceutical industry.

China boasts the world's ninth largest pharmaceutical market—and one of the most rapidly growing. In 2007, total output was valued at RMB 667.9 billion (more than \$86 billion); its growth rate has averaged around 17 percent over the last few decades, according to Chinese government figures.³ Aid agencies aspiring to treat as many patients as possible and pharmaceutical companies in quest of the least expensive inputs—that is, labor, clinical trials, and API—have all looked to producers in or partnerships with China.⁴ From 1998 to 2007, China's pharmaceutical export trade increased from \$3.4 billion to \$24.6 billion;⁵ currently, more than 40 percent of API used by U.S. manufacturers is imported from India and China, a number that is expected to double within the next fifteen years.⁶ China remains an important supplier

of artemisinin, a vital component of the best anti-malarial drugs, and its Academy of Military Medicine helped develop artemether-lumefantrine, considered the most effective antimalarial drug on the market.⁷ Many Chinese producers operate in state-of-the-art production facilities and supply the U.S. market with high-quality products.

Key points in this Outlook:

- China is a major hub for the world's pharmaceutical industry, making deadly lapses in quality a concern everywhere, including the United States.
- Chinese government inattention fosters drug counterfeiting.
- However, China's drug regulator is ramping up quality standards and enforcement.
- International partnerships in both the public and private sector are helping to improve Chinese drug quality standards.

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Yet, China is also plagued by worrying incidents—in some cases deadly ones—of poor drug quality. Although most incidents have happened within China, between November 2007 and May 2008, ninety-five Americans died from heparin believed to have been “deliberately contaminated” in China.⁸ Melamine-laced milk powder sickened over 294,000 babies (and killed at least six) in China⁹ and led to dozens of product recalls across the globe. In January 2009, counterfeit diabetes drugs led to two deaths and the hospitalization of nine others in the Chinese province of Xinjiang.¹⁰

While these pharmaceutical production problems are not exclusive to China,¹¹ they have tarnished its reputation abroad.¹² Fears have been exacerbated by Beijing’s failure to acknowledge quality shortcomings quickly. During the Chinese milk scandal, nearly a year elapsed between the first complaints and official action:

Parents began complaining to Sanlu as early as last December [2007], and by June [2008] the company knew its products were tainted with melamine. . . . Doctors raised the alarm in blogs and online posts and reported their concerns to the General Administration of Quality Supervision, Inspection and Quarantine. But the quality watchdog, which had exempted Sanlu and several other well-known dairy companies from government inspection, did nothing.¹³

The identity of the company remained unknown until September 11, 2008, when a Chinese journalist, frustrated by the government’s inaction, revealed it in a blog post. Nearly three months later, officials announced that five times more children had taken ill than originally reported.¹⁴ When Zhao Lianhai, a former employee of the Chinese Food Safety Board whose son was sickened by the tainted milk, tried to hold a press conference to lobby for more compensation for the victims, Beijing authorities told him that negotiation was possible—but only if he stopped publicizing the scandal.¹⁵ In another instance, when the deadly additive diethylene glycol was discovered in Chinese-produced toothpaste in Panama in 2007, China defended its manufacturers at first by saying that the substance was commonly used as a thickening agent and caused no health problems among Chinese consumers.¹⁶

Official government data suggest that the percentage of substandard drugs circulating in China’s market is small. Between March and August 2006, the Chinese

State Food and Drug Administration (SFDA) screened 110,426 batches of antimalarial pharmaceutical drugs in mobile labs and found that only 2.8 percent contained counterfeit or substandard drugs. Zhong-Yuan Yang, the former head of the Guangzhou Municipal Institute for Drug Control, a division of the local SFDA, reports that approximately 0.5 percent of all medicines in China are counterfeit, depending on the sampling venue.¹⁷

But these figures differ markedly from other independent reports, do not differentiate between “counterfeit” and “substandard” drugs,¹⁸ and mask regional and product-specific differences.¹⁹ In 2002, the Shanghai Drug Administration Bureau found that 12.2 percent of the 14,980 drugs it inspected were below quality standards.²⁰ Jin Shaohong, director of China’s National Institute for the Control of Pharmaceutical and Biological Products, says that his research suggests that less than 10 percent of drugs are substandard.²¹ Gao Jingde, acclaimed by the Chinese media as China’s foremost leader in the fight against counterfeit and substandard medicine, claims that his own studies since 2004 have revealed that two-thirds of Chinese drugstores sell counterfeit medicine.²² Estimating the precise size of the problem is difficult, given the lack of reliable data. But with a pharmaceutical market valued at \$86 billion, even the most conservative estimates suggest that there is between \$450 million and \$7.2 billion worth of poor-quality drugs circulating in the country.²³

Given China’s role as an *exporter* of pharmaceuticals, the problem is worrying for the international community, too. Most exports to wealthy industrialized countries—which are monitored by pharmaceutical manufacturers policing their own supply chains and by strict drug regulatory authorities—appear to be of high quality. But data collected by European Union customs officials also show that China is among the world’s top four exporters of counterfeit pharmaceuticals. In 2005, China ranked third, with 6 percent of all drugs seized by European Union customs officials originating in the country. In 2006, that number shot up to 20 percent before falling to 4 percent in 2007. This may owe to reform in import-export requirements and manufacturing policy or, as many industry watchers believe, diversion from Asia through other countries with loose import-for-export restrictions and free trade zones, such as Dubai (both Switzerland and the United Arab Emirates saw significant increases in 2006–2007).²⁴ In March 2009, the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (MHRA) announced it had seized

approximately £500,000 (\$745,000) of counterfeit pharmaceuticals. “Enquiries suggest that the counterfeit medicines originated from China and were being delivered to various addresses in the Middlesbrough area,” MHRA head of enforcement Mick Deats said in a press release.²⁵ With more Americans opting to procure drugs directly from overseas, often by purchasing over the Internet, understanding the causes of the counterfeit and substandard problem in China—and what can be done to combat it—has never been more important.²⁶

Who Is to Blame?

John Newton, a senior investigator with Interpol, blames transnational Chinese gangs for the counterfeit anti-malarial drug trade in Southeast Asia.²⁷ But the Chinese government has long enabled pharmaceutical drug counterfeiting, even if it did not participate outright. The government has been hesitant to crack down on a black market that employs 3–5 million people, including pharmaceutical counterfeiters.²⁸ Many formerly state-owned enterprises have turned to counterfeiting as a substitute for the money they once received in subsidies from the state.²⁹

The People’s Liberation Army (PLA) has also participated in the drug trade. “Trucks with military license plates are seen bringing goods in and out of Puning’s pharmaceuticals market,” the *Washington Post* reported in 2002.³⁰ During an investigation into the producer and distributor of a counterfeit drug used to treat sexually transmitted diseases, an investigator was threatened and intimidated by thugs; a rogue element of the PLA was later determined to have manufactured the drug.³¹ Private investigators confirm that counterfeit pharmaceutical operations are still “tolerated by the Beijing regime.”³²

According to local anticounterfeiting expert Li Guorong, “Counterfeiting is now so huge [that] radical action would crash the economy overnight [and] even destabilize a government where counterfeit factories and warehouses are often owned by local military and political grandees.”³³

Gao Jingde says when pharmaceutical counterfeiting operations are discovered, authorities often impose fines as small as RMB 100–4,000 (\$15–580).³⁴ With the average individual income in China around \$5,370, this penalty is insignificant for even a small- to moderate-sized pharmaceutical company.

Information on good manufacturing practices (GMP) is scarce. American firms seeking to do business with a

Chinese manufacturing facility, for example, report being faced with the “Byzantine process” of searching newspapers and “unreliable government databases” in order to find information about the facility and any possible past violations.³⁵

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Meanwhile, the popularity of alternative medicines, self-medication, and holistic supplements in China has facilitated the distribution of counterfeits to consumers. Sold in simple packaging, at times even wrapped in paper, these alternative medicines have inured Chinese customers to pharmaceutical products that would instantly raise suspicion among Western consumers.³⁶ Until recently, counterfeiters took advantage of the loosely regulated food and supplement market and sold drugs under these labels to avoid prosecution for their products. In carefully crafted fine print, producers of copycat medicines (*shanzhai*) labeled their wares “nutritional products” rather than medicines, which moved them outside of the jurisdiction of drug regulators. While these producers could still be prosecuted by the Industry and Commerce Ministry, the medical severity of the problem was often obscured. Not until December 2008 did the SFDA issue a regulation banning pharmacies from selling medicine disguised as nutritional products.³⁷

Whither Reform?

Under pressure from its increasingly vocal population and its trade partners, China has taken some encouraging steps toward reforming its legal apparatus to combat poor-quality products. But these efforts have been hobbled by erratic implementation and even, at times, corruption at the highest levels of government. In 1998, the government established the State Drug Administration (SDA, later to become the SFDA), consolidating the duties of the Ministry of Health’s (MOH) Drug Administration Bureau, the State Pharmaceutical Administration Bureau, and the State Administration of Traditional Chinese Medicine. The SDA was to provide unified leadership and oversight to the thousands of health

departments at the provincial, county, and municipal levels. It was notably independent of the MOH.³⁸

During its first years of existence, the SDA/SFDA embraced a host of reforms. The 2001 revision of China's Drug Administration Law eliminated local product registration and quality standards for pharmaceuticals, creating a nationwide set of standards for drugs.³⁹ In 2004, the SFDA formally adopted a system for reporting and monitoring adverse drug reactions, connecting more than two hundred monitoring institutions that already existed in the provinces. In 2004, the head of the litigation department of Rouse & Co., an intellectual property (IP) law firm focused on East Asia, reported progress in curbing illegal pharmaceutical manufacturing through criminal prosecution of large-scale networks.⁴⁰

In 2006, in response to a spate of publicized counterfeit drug incidents, the Chinese government "launched a six-month national campaign to improve the policing of drug markets." At a national meeting in Beijing, SFDA officials urged provincial and local leaders to "enhance supervision of license applications, and the production, distribution and use of drugs, vaccines, and medical equipment." Drug companies found to give misleading information in their license applications would be denied licenses. (The rules previously had permitted a producer to obtain a license if three defects were found but corrected.⁴¹) Not only were they denied licenses, but they were also publicly named, a significant deterrent in a country that reveres reputation. Those with inadequate management, illegal production, or potential risks to drug safety would be "punished."⁴²

The Chinese government budgeted RMB 3.7 billion (\$500 million) for food and drug supervision in 2006–2007, more than it spent in the previous seven years combined. The increased funding meant that 90 percent of provincial drug control departments and 60 percent of city ones were capable of conducting at least some full-scale drug tests.⁴³ In early 2006, the government brokered an agreement with Massachusetts-based Bruker Optics to buy more than three hundred near-infrared spectrometers, ranging in price from \$40,000 to \$100,000, for the SFDA's twenty-eight regional offices. The spectrometers would be used in portable labs in vans that would travel throughout China to screen for substandard drugs.⁴⁴

In November 2007, the SFDA announced that it would impose stiffer penalties—including heavy fines, life imprisonment, and the death penalty—in counterfeit drug cases that led to "very serious damage," regardless of

the value of drugs involved. Previously, a manufacturer could only be prosecuted based on the volume traded and price of any counterfeit product discovered—regardless of the harm it caused.⁴⁵ The new standard of "very serious damage," defined as "serious deformities," "grievous bodily harm" to more than three people, or "slight injury" to more than ten, significantly expanded the number of cases in which counterfeiters could be held liable.⁴⁶

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The government announced thirty-four new GMP standards (for a new total of 259) designed to tighten supervision over production and quality management. Whereas the original guidelines had focused almost exclusively on adequate production facilities, the new standards added requirements for staff, production processes, quality control, and documentation.⁴⁷ The government announced an export licensing and registration system for ten categories of drugs.⁴⁸ Beijing also established a network of 97,000 "drug safety coordinators" and 514,000 "information specialists,"⁴⁹ mandated qualification examinations and ongoing training for pharmacists, and issued a set of regulations to standardize nursing practices.⁵⁰

By December 2007, the agency reported stopping nine hundred counterfeit drug operations, shutting down three hundred drug and medical instrument manufacturers for inferior-quality products, and withdrawing 150 GMP certificates.⁵¹ Pharmaceutical companies in China, responding to the government's stricter and more closely enforced requirements, had withdrawn more than 7,300 drug registration applications, 24 percent of the total.⁵² Zheng Xiaoyu, the former head of the SFDA, was sentenced to death for taking bribes from eight pharmaceutical and medical equipment firms to approve their products,⁵³ and 279 other people were facing criminal charges.⁵⁴

In January 2008, the SFDA vowed to crack down on illegal online drug sales and enforce its supervision of internet drug distribution by creating an online system in which information gathered from inspections could be collected and evaluated.⁵⁵ One year later, the SFDA blacklisted twenty-five websites for publishing false

information or selling counterfeit drugs, and the State Administration of Traditional Chinese Medicine black-listed forty-six websites for selling fake herbal medicine.⁵⁶

And in March 2008, state councilor Hua Jianmin, secretary-general of the cabinet, announced that the SFDA would be put under the jurisdiction of the MOH as part of the cabinet restructuring plan to “monitor the country’s food and drug safety” better.⁵⁷ Shao Mingli, the head of the SFDA, applauded the plan as an efficient way to “further promote the role of the SFDA to oversee the nation’s drug safety in the process of production, circulation and use.” Some analysts, however, feared that the centralization of power could encourage corruption.⁵⁸

The Enforcement Problem

More can be done on the legal front. Parts of China’s IP regime remain inconsistent with its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights, a WTO dispute settlement panel ruled in January 2009. Chinese rules, for example, still permit counterfeit goods to be resold, rather than destroyed, after offending packaging or labeling is removed.⁵⁹ Criminal liability thresholds remain high, making prosecution difficult. According to a judicial interpretation announced in December 2004, a minimum of RMB 50,000 (\$7,400) in counterfeit product is required to initiate criminal prosecution. If there are two or more trademarks counterfeited in one factory or found in one raid, then the threshold can be lowered to RMB 30,000 (\$4,400). When a company discovers that one of its products has been counterfeited, it must launch its own investigation in order to determine the breadth of the problem. If the company cannot prove that the monetary amount involved exceeds \$7,400 or has caused “very serious damage,” defined as “serious deformities,” “grievous bodily harm” to more than three people, or “slight injury,” the case will not be tried in criminal court.⁶⁰ Even administrative courts may not accept the case. A company “would need to present a case gift-wrapped to the authorities to get them to accept it,” one U.S. government official with more than a decade of experience in IP enforcement in China says.⁶¹

Indeed, the greatest problem remains weak enforcement. Under Article 34 of the Drug Administration Law, “drug manufacturers, drug distributors and medical institutions” are technically required to “purchase drugs from pharmaceutical enterprises . . . qualified for production or distribution,” with the exception of the

domestically produced “crude drugs,” which are unrefined drugs derived from natural sources.⁶² (The unregulated herbal supplement market remains another problem, though this is not exclusive to China.) While the SFDA claims to conduct unannounced inspections of drug manufacturers and organize nationwide quality testing, results are not easily accessible. “There are still not uniform requirements for disclosure of problems,” Scott Gottlieb, an AEI resident fellow and former deputy commissioner for medical and scientific affairs at the U.S. Food and Drug Administration (FDA), warns. “Reporting of findings is often selective and based sometimes on political considerations.”⁶³

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Local authorities often ignore proper protocol when cracking down on substandard producers, jeopardizing legal proceedings. In June 2008, two Kaifeng-based pharmaceutical companies, Henan Yisheng Pharmacy Co. Ltd. and Liaoning Yisheng Biopharmaceuticals Co. Ltd., announced that they were appealing the decision of Kaifeng’s Municipal Food and Drug Administration (MFDA) to confiscate their products, arguing that the agency’s methods were illegal and may have undermined the integrity of test results. The dispute began in September 2006, when an inspection team from the local agency found rabies vaccines and human rabies immunoglobulin produced by Liaoning Yisheng stored in a residential apartment. Testing of the vaccines revealed that they were substandard. But the company argued that the inspection team’s methods were faulty: four hours after confiscation, they put them into a competitor’s cold storage facilities, which “clearly would affect the result of tests done on the products.” According to a news account, “It is likely that the case probably consists of both sides breaking regulations. Clues can be found in the court’s ruling that the local drug administration’s methods were ‘basically legal,’ which is quite ambiguous, and the company’s failure to say whether Liaoning

Yisheng's vaccine storage site in Henan is GMP-certified."⁶⁴ SFDA officials are accused of accepting bribes from pharmaceutical companies in exchange for approving untested or substandard medicines or for issuing production licenses and other certificates.⁶⁵

Because of the difficulty of initiating criminal prosecution, many companies opt to address IP infringement through China's administrative system, in which the rights holder files a complaint with the local administrative office rather than through the civil or criminal court system. But this system can be confusing, with jurisdiction diffused throughout several government agencies and offices. While China's State Intellectual Property Office has now been given the authority for coordinating IP protection policy throughout China, it is not involved in criminal prosecution. It is unclear that it has the resources to coordinate efforts throughout China's diverse jurisdictions and regions.⁶⁶

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The drug quality problem varies widely from region to region. In its annual report on IP, the U.S. Trade Representative identified Guangdong province as a "relatively difficult place to criminally prosecute counterfeiters" of health products, with Shenzhen, Guangzhou, and Dongguan labeled as particularly difficult spots.⁶⁷ According to a well-placed senior U.S. official involved with IP issues in China, companies generally try to use courts in major cities like Shanghai and Beijing because enforcement is better than in rural areas, where local protectionism often thrives.⁶⁸

What Can Be Done

Gather and Disseminate Information. One of the problems in China—as elsewhere in much of the world—is the lack of reliable information on the extent and impact of substandard and counterfeit drugs on the market. One of the most-cited statistics in the literature on the impact of counterfeit and substandard drugs—that nearly 200,000 died in China from fake drugs in 2001—is sourced to a 2002 report in the *San Francisco Examiner*, which

indicated that 192,000 people died.⁶⁹ In 2007, however, several University of Oxford researchers revised their prior citation of the statistic, noting that a Beijing professor had brought it to their attention that the *Shenzhen Evening News* story used by the *Examiner* had been incorrectly translated. The article did not refer to counterfeit drugs but claimed that 192,000 people died of drug-induced diseases from the irrational use of drugs in 2001.⁷⁰

Translation of health-related jargon requires a highly specialized Chinese vocabulary, which staff at even many major newspapers lack. The government can help by tracking counterfeit incidents and reporting results publicly. It can facilitate this process by coordinating efforts of the many departments involved in combating counterfeiting, a process it has already begun with the establishment of an interagency task force.⁷¹ It should consider proposals to consolidate IP cases in one office.

Promote Consistent, Unbiased Enforcement. China must attract and train civil servants with technical expertise, inculcate an ethical approach in which truth supersedes loyalty, and encourage its pharmaceutical industry to develop a rigorous culture of self-policing and accountability to the public.

International partnerships can help, as Beijing acknowledges. The SFDA's formulation of policies to improve drug safety, effectiveness, and quality control in recent years has been "based on its national conditions and learning from international advanced experience."⁷² At the opening of the U.S. FDA's office in Beijing, Shao Mingli said that enhancing cooperation was "the only choice. . . . Along with economic globalization, drug safety has become an issue that crosses the borders of individual countries."⁷³

The United States and China can build on a long history of technical exchanges stretching back to the late 1980s. The FDA is a participant in the Medical Device Task Force on the U.S.-China Joint Commission on Commerce and Trade Pharmaceutical and Medical Devices Subgroup, with annual meetings in Washington and Beijing. "Collaboration with SFDA and presentations at major device conferences in China have helped hundreds of China-based firms understand, and thus better comply with U.S. FDA medical device regulations," says Murray Lumpkin, deputy commissioner for international and special programs at the FDA.⁷⁴ Since 2007, drug regulatory authorities in China and the United States have participated in a series of meetings designed to enhance supervision over the export and

import of active pharmaceutical ingredients. China has also signed agreements and memoranda of understanding with authorities in the European Union, Australia, Brazil, Canada, Cuba, France, Italy, Singapore, South Korea, Thailand, and the United Kingdom.

If the drive for profits has sometimes led officials in China to pursue poor policies,⁷⁵ it may also spur reform from within the private sector. Partnerships between Chinese producers and Western companies can be lucrative for both parties. “China’s underdeveloped economy holds great promise for companies like Pfizer that see cost effective production capacity in its factories and work force as well as the tremendous sales potential in its markets,” David J. Clark wrote in 2003 after spending a year working with Pfizer’s Corporate Security Division.⁷⁶ “We have developed very good working relationships with the authorities” there, says a security executive for one major pharmaceutical company.⁷⁷ In 2004, for example, the Shanghai MFDA signed a memorandum of understanding with Pfizer to train staff to detect and respond to pharmaceutical counterfeiting.⁷⁸

Because companies’ primary incentive is to target counterfeiters of their own high-value products, non-governmental organizations also have an essential role to play.⁷⁹ In October 2007, U.S. Pharmacopeia opened a joint facility in Zhangjiang Hi-Tech Park in Shanghai. The facility’s staff provides assistance to companies looking for technical, product, and service information.⁸⁰

Between 2005 and 2006, the FDA, Peking University, and the nonprofit International Society for Pharmaceutical Engineering cosponsored a training program on U.S. pharmaceutical regulation and guidelines, including current GMP, inspection regimens, and testing methods. Ten percent of participants were SFDA officials. In July 2006, the university announced a new graduate program in international pharmaceutical engineering management designed in close collaboration with the FDA.⁸¹

The Cost Card

Why has China put anticounterfeit laws on the books but enforced them poorly? One possible explanation is cost. Increased regulatory vigilance—and the improvements in GMP it demands—levies an effective tax on producers. In 2002, Bill Liang of China Healthcare Consulting estimated that improvements in GMP mandated by the SDA cost on average RMB 20–30 million per producer (\$2.4–3.6 million).⁸² He expected that more than half of the country’s six thousand pharmaceutical

manufacturers would be eliminated or acquired by 2004.⁸³ Producers, in turn, pass cost increases on to consumers. If not all producers are subject to the same regulatory scrutiny, those who adhere to GMP will find themselves frequently undercut by those who do not. “I know the distributors from the cities [of copycat medicine] were out to deceive me,” explains one pharmacist, “but if I refused to stock the copycat products, they would cut me off from all other supplies,” which would inevitably increase costs.⁸⁴

China must attract and train civil servants with technical expertise, inculcate an ethical approach in which truth supersedes loyalty, and encourage its pharmaceutical industry to develop a rigorous culture of self-policing and accountability to the public.

Even so, any increase in cost from improvements in GMP is more than offset by the thousands of lives saved from the scourge of substandard pharmaceuticals. If anything, the specter of increased costs underscores the importance of working with China to improve production standards, rather than adopting an across-the-board ban of Chinese goods, which would penalize the good along with the bad and drastically increase the cost of American drugs.

AEI interns Jack Bowman and Jessica Kokos worked with Mr. Bate and Ms. Porter to produce this Health Policy Outlook.

Notes

1. As China’s standard of living continues to improve, its per-capita consumption level of drugs is gradually rising, reaching RMB 332 (\$48) in 2006. (State Food and Drug Administration [SFDA], “Status Quo of Drug Supervision in China” [white paper, Information Office, State Council of the People’s Republic of China, July 2008], available at www.china.org.cn/government/whitepaper/node_7049495.htm [accessed April 16, 2009].)

2. In the United States, spending for prescription drugs—many produced in or with active pharmaceutical ingredients from China—hit \$216.7 billion in 2006, more than triple the

\$40.3 billion spent in 1990. (Kaiser Family Foundation, "Prescription Drug Trends," fact sheet, September 2008, available at www.kff.org/rxdrugs/upload/3057_07.pdf [accessed April 16, 2009].) The Global Fund to Fight AIDS, Tuberculosis and Malaria, an independent financing mechanism that receives funding from the U.S. government, the Bill & Melinda Gates Foundation, and other sources, estimates that 47 percent of its grants to developing countries (more than \$2.8 billion) have been used to procure medicines or health care products since 2003. In 2008 alone, the President's Emergency Plan for AIDS Relief allocated more than \$481 million for antiretroviral drugs, not including monies for central procurement and supply chain support. (Roger Bate and Karen Porter, "Quantity and Quality: An Rx for Efficient Drug Purchasing," *Health Policy Outlook* no. 8 (September 2008), available at www.aei.org/publication28642.)

3. SFDA, "Status Quo of Drug Supervision in China"; and Access China, "Executive Summary," *Chinese Pharmaceutical Industry* (Nanjing: Access China, 2006).

4. U.S. Department of Commerce, U.S. Commercial Service, "China: Pharmaceuticals," available at www.buyusa.gov/china/en/pharmaceuticals.html (accessed February 23, 2009).

5. SFDA, "Status Quo of Drug Supervision in China."

6. Marc Kaufman, "FDA Scrutiny Scant in India, China as Drugs Pour into U.S.," *Washington Post*, June 17, 2007.

7. Roger Bate, "On the Trail of a Cure: Reality and Rhetoric on Treating Malaria," *Health Policy Outlook* no. 4 (March 2007), available at www.aei.org/publication25834.

8. Roger Bate, "Stopping Killer Counterfeits," *Washington Post*, July 19, 2008, available at www.aei.org/publication28351.

9. "China to Sell Assets of Scandal-Hit Milk Company," Associated Press, February 14, 2009.

10. "Deadly Counterfeit Diabetes Drug Found Outside China's Xinjiang," *Xinhua*, February 5, 2009.

11. U.S. Food and Drug Administration (FDA), warning letter to Ranbaxy, September 16, 2008, available at www.fda.gov/foi/warning_letters/s6923c.htm (accessed April 16, 2009).

12. Li Fangchao, "China's Reputation at Risk, Says SFDA," *China Daily* (Beijing), July 9, 2007; Alexa Olesen, "China Battling Shoddy Food and Drugs amid Fears of Social Unrest, Tainted Image Abroad," Associated Press, July 9, 2007; and Carey Greenberg-Berger, "Chinese Poison Train Defeats FDA, the Prequel," *The Consumerist*, June 17, 2007, available at <http://consumerist.com/consumer/diethylene-glycol/chinese-poison-train-defeats-fdathe-prequel-269627.php> (accessed April 16, 2009).

13. Maureen Fan, "6 Chinese Infants Died in Milk Crisis," *Washington Post*, December 3, 2008.

14. *Ibid.*

15. Roger Bate, "China's Opportunity," *The American*, January 29, 2009, available at www.aei.org/publication29298.

16. Walt Bogdanich, "The Everyman Who Exposed Tainted Toothpaste," *New York Times*, October 1, 2007.

17. Jin Shaohong, "Mobile Labs for Detection of Counterfeit Drugs in China" (presentation, Third Global Forum on Pharmaceutical Anticounterfeiting, Prague, March 14, 2007); and Zhong-Yuan Yang (presentation, Pharmaceutical Sciences World Congress, March 25, 2007); both cited in U.S. Pharmacopeia (USP), "Matrix of Drug Quality Reports Affecting USAID-Assisted Countries," February 3, 2009, available at www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf (accessed April 16, 2009).

18. For a more in-depth discussion of this topic, see Roger Bate and Karen Porter, "IMPACT's Impact," *Health Policy Outlook* no. 1 (February 2009), available at www.aei.org/publication29297.

19. A 2001 market survey by Pfizer Corporate Security revealed that in seven major Chinese markets tested, 88 percent of purported Viagra products procured through locations other than hospitals were not genuine. (David J. Clark, "Product Counterfeiting in China and One American Company's Response" [Secretary of Defense Corporate Fellows Program, April 4, 2003], 7, available at www.ndu.edu/sdcfp/reports/2003reports/Pfizer2003.doc [accessed April 16, 2009].)

20. "Counterfeit Drugs in China: Shanghai Steps Up Drug Monitoring Systems," *PBI Asian Medical eNewsletter* 2, no. 12 (March 4, 2003), available at www.osdir.com/ml/file-systems.reiserfs.general/2003-03/msg00269.html (accessed April 16, 2009).

21. Jin Shaohong, personal communication with Mr. Bate, April 1, 2008.

22. Qiao Qi, "Two-Thirds of Chinese Drug Stores Sell Counterfeit Medicines, Says Investigator," *Epoch Times*, September 29, 2008.

23. This was calculated based on 0.5–8 percent of drugs substandard.

24. European Commission, Taxation and Customs Union, "Summary of Community Customs Activities on Counterfeit and Piracy," 2007 (available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf), 2006 (available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf), and 2005 (available at http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2005_en.pdf) (accessed April 16, 2009).

25. UK Medicines and Healthcare Products Regulatory Agency, "£500,000 Fake Drug Stash Seized in Undercover Operation," March 30, 2009, available at www.mhra.gov.uk/NewsCentre/Pressreleases/CON041483 (accessed April 16, 2009).

26. Paul Keckley and Laura Eselius, "2009 Survey of Health Care Consumers: Key Findings, Strategic Implications" (Deloitte Center for Health Solutions, Washington, DC, 2009), available at www.deloitte.com/dtt/cda/doc/content/us_chs_2009SurveyHealthConsumers_March2009.pdf (accessed April 16, 2009).
27. "Chinese Gangs 'Behind Fake Drugs,'" Daily International Pharma Alert, June 5, 2007.
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