

Regulatory Learning and Its Discontents in China:
Promise and Tragedy at the State Food and Drug Administration¹

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Throughout the reform era, China's reformers have actively considered international practices in domestic reforms. Whereas China's leaders have far from adopted wholesale westernization, they have nonetheless become bolder in adopting international practices. The trend toward convergence hit a high note during the administration of Premier Zhu Rongji (1998–2003) with China's re-accession into the World Trade Organization in 2001. Since then, as the results from a recent Chicago Council on Global Affairs survey of public attitudes suggest, China has become a poster child for globalization.²

The Zhu Rongji administration also stood out for remodeling various Chinese government agencies to structurally resemble American counterparts. In restructuring the People's Bank of China, the central bank, for example, the Chinese leadership replaced the PBOC's 32 provincial-level branches with nine regional branches to look, structurally, like the US Federal Reserve.

Another area that drew the central leadership's attention was regulation of the pharmaceutical industry and the promotion of drug safety. Here again, the Chinese reformers' model was the US Food and Drug Administration (FDA). The United States has had the world's strongest pharmaceutical industry and the US FDA is well known for setting the standard in drug regulation. In survey after survey, the FDA, along with the FAA (Federal Aviation Administration), have received positive performance ratings and are ranked as the top institutions the American public have come to trust.³ Chinese reformers hoped that the move to emulate the US FDA would help provide the regulatory environment for the upgrading of China's own drug industry.

In 1998, China's own State Drug Administration (SDA) was born. In 2003, the SDA

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² 'The United States and the Rise of China and India: Results of a 2006 Multination Survey of Public Opinion', Chicago: Chicago Council on Global Affairs, 2006.

³ See, for example, The Pew Research Center for the People and the Press, 'Performance and Purpose: Constituents Rate Government Agencies', April 12, 2000, <at <http://people-press.org/reports/display.php3?PageID=224>>.

was also given oversight over food safety regulation and became the State Food and Drug Administration (SFDA). Chinese officials have not been shy in suggesting the SFDA is modeled upon the US FDA and have used SFDA, the abbreviation of the agency's name in English translation, as the agency's web name (<www.SFDA.gov.cn>).

Yet the SFDA has turned out to be no US FDA at all. In this paper, I provide an overview of the SFDA's first decade and describe how the SFDA has failed to live up its promise so far. In particular, I discuss the SFDA's pursuit of much-needed reforms of the drug regulatory system and how each of these reforms has been riddled with corruption. In July 2007, Zheng Xiaoyu (郑筱萸), the first SFDA commissioner until June 2005, was executed for bribe-taking and dereliction of duty. The SFDA's vicissitudes in its first decade thus offer a striking case for explicating the challenges of regulatory globalization in the Chinese context.

The Politics of Institution Building

Historically a regulatory state has tended to be associated with the expansion of markets and social transformation. It is now generally recognized that a modern regulatory state is essential to help overcome certain problems of coordination and collective action, and thus maintain market order.⁴

As China has made the transition from plan to market, most industrial ministries inherited from the pre-reform central planning era have been eliminated, while a long list of regulatory commissions, administrations, and bureaus have been established or reinforced. In addition to the regulatory commissions for banking, insurance, and securities, the list of regulatory agencies also include the State Environmental Protection Administration, the General Administration of Industry and Commerce, the General Administration of Quality Supervision, Inspection and Quarantine, the State Intellectual Property Office (formerly the State Patent Bureau), the State Administration of Press and Publications (National Copyright Administration), the State Food and Drug Administration, and the State Administration of Workplace Safety. Working alongside the powerful National Development and Reform Commission as well as government ministries such as the Ministries of Finance, Construction, Land, and Resources, the regulatory agencies are charged with the enforcement of state laws to protect the rights of consumers, workers, investors, and the state, as the case may be.

For the regulatory agencies to function well as modern regulators, they must be designed properly, in order to focus on the intended mission and be equipped with the appropriate resources (personnel and funds, as well as sufficient enforcement authority) to carry out that mission. In reality, regulatory agencies as organizations must contend with internal conflicts and cope with external pressures.⁵ Good agency design may help mitigate these internal and external complexities and motivate the agency to fulfill its mission, but that is only part of the story.

A review of Chinese regulatory developments in the reform era suggests that the regulatory institutions are often born with serious congenital flaws. The effects of these flaws are magnified by a volatile socio-psychological environment that has made many officials incapable of resisting the urge to seek self-enrichment at the expense of public interest. As a result the regulatory agencies have not only found it difficult to be effective regulators but have succumbed to widespread corruption. A history of Chinese regulatory developments in

⁴ Karl Polanyi, *The Great Transformation*, Boston: Beacon, 1957; Cass Sunstein, *After the Rights Revolution*. Cambridge, Mass.: Harvard University Press, 1990.

⁵ For comparative perspective on these issues, see, for example, John Huber and Charles Shipan, *Deliberate Discretion?: The Institutional Foundations of Bureaucratic Autonomy*, Cambridge: Cambridge University Press, 2002.

the reform era is thus a history of the struggle to cope with and overcome the various institutional flaws and to curb regulatory corruption.

The vicissitudes at the SFDA have sadly become Exhibit A for understanding the challenges of regulatory institution building in China. When China's leaders decided to strengthen regulation of the pharmaceutical industry and promote drug safety by establishing a drug regulator modeled after the US FDA, their goal was both clear and lofty. The leadership they installed at the SFDA also seemed determined to carry out the reforms needed.

To understand how the reforms at the SFDA went awry, we can begin with the role of Zheng Xiaoyu, the SFDA's founding commissioner until June 2005. The career and rise of Zheng Xiaoyu offers us an excellent vantage point for understanding the problems that have plagued the SFDA and the Chinese pharmaceutical industry, as well as the SFDA's continuing challenges to become a modern regulator.

Born in 1944 in Fujian Province, Zheng Xiaoyu graduated in 1968 from the Biology Department of the Shanghai-based Fudan University, one of China's best. Upon his graduation, Zheng was offered a job in neighboring Zhejiang province. For the next decade after his graduation, Zheng served as a technician at the state-owned Hangzhou First Pharmaceutical Factory, which was renamed the Hangzhou Minsheng Pharmaceutical Co. (杭州民生制药厂) in the reform era. With the reforms, Zheng's talents began to shine and he rose steadily through the ranks to become the company's managing director and party secretary at Hangzhou Minsheng.

Not content with the world of enterprise management, Zheng sought a move into the world of rank and political privilege. In early 1991, Zheng moved from the business world to the Zhejiang provincial Federation of Labor Unions and became, successively, its vice chairman and chairman. Though the Labor Union was hardly at the center of political influence in China, Zheng's post as Labor Union chairman placed his name on the nomenclatura list and got him ready for further promotions.

When the central leadership searched for someone with subnational experience to head the State Pharmaceutical Administration (SPA), Zheng looked like a candidate with the right qualifications for the job. He had a good college education, possessed the right bureaucratic rank for appointment to the SPA, and had extensive experience in the pharmaceutical industry in a province well known for its strengths in the pharmaceutical industry.

Yet Zheng didn't just wait for the appointment. After all, the possession of the right qualifications is no guarantee of promotion in the world of Chinese politics, particularly because national leaders can choose from a long list of potential candidates. Instead, Zheng actively lobbied for his appointment, armed with an "activities" fund contributed by his friends in the pharmaceutical industry, especially Zhejiang-based firms.⁶ For these firms, it was an investment that would ultimately repay itself many times.

The State Pharmaceutical Administration, then subordinated to the State Economic and Trade Commission, was not a modern drug regulator. Instead, as a legacy agency from the era of central planning, it primarily acted as the central government's steward of the pharmaceutical industry and was considered the mother-in-law of China's leading pharmaceutical enterprises. As such, the SPA's mission included the formulation and implementation of policies on and strategies for pharmaceutical industry development, including participation in adjusting total output, responsibility for supervision of the finances and assets of state-owned firms directly under the SPA, and promotion of medical research

⁶ 赵何娟, '郑筱萸腐败路线图', 第一财经日报, April 10, 2007, <<http://finance.sina.com.cn/g/20070410/02353485549.shtml>>.

and new product development. Nonetheless the SPA had also gradually acquired certain regulatory functions that would fall under the rubric of a modern drug regulator, including supervision of production and operation of pharmaceutical products, the right to approve licenses for the production and sale of medical devices, and the setting and implementation of national standards for medical devices, materials, machinery, and packaging.⁷

Yet the SPA's regulatory authority overlapped with that of the Ministry of Health. The Ministry of Health's main functions include the supervision of food, drug, and bio-medical products, as well as bio-materials and medical equipment. It also oversaw the State Administration of Traditional Chinese Medicine. The Ministry of Health's Drug Administration Bureau (药政管理局 DAB), in particular, had the authority to set and implement laws and regulations on drugs and biomedical products and to set the standards for the same. It also had the key power to approve drugs and biomedical products and to issue licenses for the production, sale, and in-hospital manufacture of drugs and biomedical products.⁸

As is to be expected, the SPA and the Ministry of Health's overlapping regulatory authority was a source of constant friction. Because the Ministry of Health enjoyed a higher bureaucratic ranking than the SPA, it was natural for Zheng to feel somewhat overshadowed by the Ministry of Health.

The regulatory fragmentation, coupled with the burgeoning but "chaotic" pharmaceutical industry, cried out for rationalization. Zheng Xiaoyu, as director-general of the SPA, wrote or authorized various reports, based on trips abroad, advocating reforms of the drug regulatory system.⁹ The model that continually evoked admiration among Chinese regulators and industry was the United States, with its FDA overseeing the world's largest and most innovative pharmaceutical industry. In January 1997, the CCP Central Committee and State Council's decision on health reform and development called for "active exploration of drug administration reforms and gradually form a unified, authoritative, and efficient management system."¹⁰

In accordance with the above objective and as part of the sweeping government reorganization and rationalization in spring 1998, incoming Chinese premier Zhu Rongji chose to merge the regulatory functions over drugs (the DAB; and part of the State Administration of Traditional Chinese Medicine) and medical devices (SPA) under one roof in a newly constituted State Drug Administration (国家药品监督管理局, SDA).¹¹ Because the SPA (and Zheng Xiaoyu) boasted a vice-ministerial rank and thus outranked the Ministry of Health's Drug Administration Bureau headed by Shao Mingli (邵明立), it was natural that Zheng Xiaoyu was appointed the new Commissioner and party secretary of the newly constituted SDA while Shao was appointed Deputy Commissioner.¹² Zheng continued in these positions after the SDA took over responsibility for food safety regulation to become the SFDA in 2003. When Zheng retired in June 2005, Shao Mingli was his successor.

Zheng Xiaoyu was not only an advocate for the administrative reorganization that

⁷ 中国政府机构明录 (1996), 上卷. Beijing: Xinhua Chubanshe, 1996, pp. 25–27.

⁸ 中国政府机构明录 (1996), 上卷. Beijing: Xinhua Chubanshe, 1996, pp. 209–215.

⁹ 刘薇 郭爱娣, '药监历经改革权力扩大', 京华时报, March 8, 2007, <<http://finance.sina.com.cn/g/20070308/07533387009.shtml>>.

¹⁰ '中共中央、国务院关于卫生改革与发展的决定', January 15, 1997, at <<http://www.china.com.cn/chinese/zhuanti/yg/933900.htm>>.

¹¹ For an overview of the 1998 reforms, see Dali Yang, *Remaking the Chinese Leviathan*, Stanford: Stanford University Press, 2004, pp. 37–58.

¹² I have followed the official SFDA translation by using the word "commissioner." Chinese and foreign media reports have generally translated Zheng's post as director but this makes it difficult to distinguish his position from those held by the directors of the various bureaus within the SFDA.

created the SDA but also a forceful Commissioner. Partly because the SDA is a newly-constituted administration, Zheng had more leeway to shape it, especially because the Chinese SDA was a stand-alone agency in contrast to the US FDA, which is within the Department of Health and Human Services. Like the enterprise manager that he once was, Zheng put his stamp on the SDA by placing trusted lieutenants in key positions. During the transition to the SDA in 1998, Zheng first appointed Cao Wenzhuang, his former secretary and the former director of the SPA Labor and Personnel Bureau, to serve as the SDA Personnel Bureau Director, as well as head of the SDA General Office. The appointment of Cao Wenzhuang helped Zheng Xiaoyu to take firm control over personnel appointments in the SDA. In 2002, Zheng moved Cao Wenzhuang to direct the Drug Registration Bureau, the heart of the SDA. Another of Zheng's former secretaries, Hao Heping (郝和平), previously the deputy director of the Bureau of Medical Devices Administration (械政), assumed the directorship of the Bureau of Medical Devices at the SDA. Zheng thus had his two former secretaries control the two most important regulatory bureaus in the SDA.

The commissioners and deputy commissioners oversee work in different areas. Not surprisingly, Zheng Xiaoyu took on drug registration and approval—the core of any drug administration, even though his operational background in the pharmaceutical industry suggested that he would have been especially suited to assume oversight of production safety supervision (安全监管). In contrast, he put Shao Mingli, who had dealt with drug approval at the Ministry of Health, to oversee production safety supervision. After Zheng fell from power, some insiders noted that Zheng placed his own people in the key posts on drug and medical devices registration and industry legislation, where they reported only to Zheng. They commented, “Those deputy commissioners who didn’t come from the former SPA were almost idle,” and “The first deputy commissioner Shao Mingli was always excluded from the circle of real decision makers.”¹³

Zheng Xiaoyu’s Reform Initiatives

With these personnel appointments and other maneuvers, Zheng Xiaoyu took firm command of the SDA as its first commissioner and pursued an aggressive reform agenda. The reform initiatives launched during Zheng’s tenure included the nationalization of standards for drugs, the reform of drug registration, as well as the promotion and adoption of good practices for manufacturing (GMP), research (GLP), and sales (GSP). Had this agenda been realized, it would have had an enormously positive impact on the development of China’s pharmaceutical industry. As it transpired, however, every one of the major reform initiatives launched on Zheng’s watch went awry. An examination of how this happened helps to illuminate the promise and pitfalls of efforts to quickly spread regulatory norms globally.

The Conversion to National Standards

The replacement of local with national standards was a much needed reform. It would have been impossible to have a unified drug regulatory regime if each provincial unit in China could set its own pharmaceutical standards and keep them secret as they had done to that point. It was thus natural that Zheng Xiaoyu put the promotion of national standards high on his reform agenda shortly after the SDA was formed.

In 1999, Zheng Xiaoyu decided to recentralize the right to approve new drugs in the national drug administration. To sort out the local standards, the SDA itself set up a temporary office in the Drug Registration Bureau to assess whether the locally approved

¹³ 罗昌平 张映光, ‘郑筱萸罪与罚’, 财经, April 18, 2007, <<http://finance.sina.com.cn/g/20070418/11223513657.shtml>>.

drugs met the national standards as set forth by the Chinese Pharmacopoeia Commission (药典委员会), which reports to the SDA.¹⁴

Whereas the replacement of local with national standards greatly enhanced the SDA's power of approvals, the process for the re-registration of existing drugs was not one welcomed by the pharmaceutical firms or local drug administrations. It was well known that various local administrations had adopted lower standards to make it easier for firms within their jurisdictions to secure drug approvals and accelerate production. If the SDA firmly adhered to the more rigorous national standards (国标), it would have to revoke many drug approvals that were based on local standards. This would in turn cause many pharmaceutical firms to suspend production and alienate most local authorities.

In practice, the SDA re-certification of drug approvals based on local standards faced a major logistical obstacle. The entire SDA headquarters had only a modest authorized staff size of 120 (though supplemented by temps or others on secondment). Simply put, unlike the U.S. FDA, which once enlisted the help of the National Science Foundation to help it deal with the backlogs of drug applications, the State Drug Administration, even if it could have mobilized the entire headquarters staff, simply did not have the personnel to do a good job of vetting the local drug licenses in a reasonable time period.¹⁵ In fact, the special office for the upgrade to national standards had a staff of less than twenty.

Rather than holding the local drug licenses to the more rigorous national standards, however, what transpired in the review process amounted to an abdication of responsibility by the SDA. Faced with intense lobbying by firms and local administrations, the SDA eventually offered national status to existing local drug approvals. In one three month period, the Drug Registration Bureau certified 147,900 locally registered drugs as meeting national standards.¹⁶ Rather than elevating existing drug approvals to the rigors of national standards, the review process essentially devalued the drug approval standards to the pre-existing local standards. Eventually, prosecutors would charge Zheng Xiaoyu and Cao Wenzhuang for lowering drug approval standards, endangering the public, and lowering the credibility of a government agency.¹⁷

The re-certification process also turned into a rent-seeking process. Some pharmaceutical companies simply would not have met the national standards (that necessitated experiments and trials) but nonetheless obtained drug approvals with faked data and bribes to the Drug Registration staff.¹⁸ Most remarkably, some members of the Pharmacopoeia Commission turned the re-certification into a lucrative venture for themselves. Prior to the re-certification, the local standards were not public information. In the process of converting to national standards, local administrations were required to submit their local standards, including confidential information regarding production processes (生产工艺) and quality specifications (质量标准) to the Pharmacopoeia Commission. The

¹⁴ The website for the Chinese Pharmacopoeia Commission is at <http://www.chp.org.cn/>

¹⁵ For a history of U.S. FDA, see Philip Hiltz, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation*. New York: Knopf, 2003.

¹⁶ 李欣悦, '药监局原药品注册司长曹文庄被控受贿 200 万', 新京报, May 21, 2007, <<http://news.sina.com.cn/c/1/2007-05-21/044213034442.shtml>>. For details on the investigation into the Cao Wenzhuang case, see 吴珊, '一抓住刘玉辉 曹文庄就蔫了', 新京报, December 25, 2007, <<http://www.thebeijingnews.com/news/deep/2007/12-25/011@072955.htm>>.

¹⁷ 李欣悦, '药监局原药品注册司长曹文庄被控受贿 200 万', 新京报, May 21, 2007, <<http://news.sina.com.cn/c/1/2007-05-21/044213034442.shtml>>.

¹⁸ 孙晨, '郑筱萸双规激荡药监新政 药监局内部凸显大换班', 中国经营报, <<http://finance.sina.com.cn/g/20070108/16063226153.shtml>>.

Pharmacopoeia Commission should have kept all this information confidential but a company based in Jilin province obtained the entire package of local production processes and quality specifications by bribing Wang Guorong (王国荣), executive vice secretary general of the Pharmacopoeia Commission, and others, to the order of 8 million yuan. After obtaining this cache of information, the firm selected over 100 injection products and bribed personnel at the Jilin provincial drug administration into giving the company back-dated (pre-1996) approvals for these products. Equipped with the back-dated local approvals and supporting materials, the company was able to convert the local approvals into national approvals (药品批准文号) for over 200 products, even though the company had not done research on these drug products on its own.¹⁹

Drug Registration

In light of how the conversion to national drug standards was handled, it comes as no surprise that drug registration and approval would continue to fall short. Before we discuss the problems that afflicted drug registration and approval, however, it is useful to note that government regulation of drug prices in China has created powerful incentives for drug makers. More specifically, the National Development and Reform Commission, in its efforts to placate public complaints about rising medical costs, has intervened vigorously to cap the prices for commonly used drugs. To get around the NDRC's drug price caps, a drug maker must work hard to secure approvals for new drugs for which the drug maker is more at liberty to set the price. Meanwhile, the SFDA worked with a broad definition of new drugs, and drug manufacturers generally could secure approval of new drugs that are essentially old drugs in new formulations, for example, by making tablets into injections or by adding innocuous new ingredients. In essence, the SFDA became the institutional gatekeeper for getting around the NDRC's price controls.

Once the pharmaceutical standards were “nationalized” and the authority to approve new drugs centralized in the SFDA, the SFDA essentially became a rent-collecting machine under Zheng Xiaoyu. Cao Wenzhuang, as director of the Drug Registration Bureau, wielded enormous power over the pharmaceutical companies. In the absence of well designed processes, the regulators had much discretion. For drug companies, their livelihood all depended on whether or not Cao gave approval to their new drug applications and how fast the approvals were given. To get the approvals speedily, the companies would seek to bribe Cao. Likewise, Zheng Xiaoyu's oversight over the Drug Registration Bureau offered him much influence. Both Zheng and Cao were later found to have taken bribes for approving drug registrations.

It is with a deep sense of irony and sadness that I write the above. For the SDA had started with a system of expert review panels to mitigate corruption in the approval process and Zheng Xiaoyu was himself behind the expert review panel. In December 1998, the first group of 591 national drug evaluation experts (国家药品审评专家) were elected to form China's national expert bank for drug evaluation. The move was hailed as a major measure of corruption prevention. According to the original design, a drug maker would first make an application for a new drug to the provincial drug administration and, following the initial review by the provincial drug administration, pass the file on to the SFDA national headquarters. The SFDA would then convene a panel of experts, comprised of seven to eight experts randomly chosen from the bank of national drug evaluation experts, to review the

¹⁹ 王强, ‘药监设租之祸’, 商务周刊, January 22, 2007, <<http://finance.sina.com.cn/g/20070122/15553270240.shtml>>.

case, in particular with a technical review of the clinical trial data, and then provide technical evaluations.

Yet the expert review system failed to make a dent on corruption during Zheng Xiaoyu's tenure as commissioner. According to Huang Jun (黄峻), an expert who had participated in the drug application reviews, each time the experts chosen would gather at a hotel and be shown the application materials. Since the experts did not visit the applying firm's production facilities, they had no way to know if the application was faked. Sometimes, even when the experts' assessment was not very favorable and they had issued reservations, their assessment was used as reference only. The SFDA official could go to someone else for a different and more favorable opinion and could even discard the negative opinion. Such discretion meant that the experts' opinion had relatively little impact on the outcomes of drug applications.²⁰ The situation was made even worse because, according to Ba Denian (巴德年), a member of the Medicine and Health Group of the Chinese People's Political Consultative Conference, some of the experts took bribes from the pharmaceutical firms.²¹

In 2004, the SFDA processed 10,009 applications for new drug approvals. To process these applications, the SFDA would have had to go through and decide on more than 38 applications each business day. This would be an impossible job to perform adequately for the small staff at the Drug Registration Bureau in light of the size and complexity of each of the applications. In effect, the Drug Registration Bureau processed the applications like an assembly line. Even in 2006 (the year Zheng retired), when the situation had become more routine at the SFDA, the SFDA approved 1,426 applications for new drug clinical trials, 1,803 applications for the production of new drugs, and 5,958 applications for the production of drugs on state standards (generics).²² In contrast, in a fairly typical year, the US FDA, whose Center for Drug Evaluation and Research had a staff of more than 1,700, approved 78 new drugs and 321 generic versions of already-marketed drugs in 2002.²³

With the likes of Cao Wenzhuang, the SDA (SFDA) became a magnet for lobbyists and mediators. Various companies emerged near the SDA (SFDA) headquarters that touted their identities as drug registration agents or purveyors of medical information. They were supposed to help pharmaceutical companies to prepare the complex applications that were needed to comply with the regulations and procedures for new drug applications or for the approval of medical devices. Yet it was understood that some of these entities had "special access" to help acquire approvals for new drugs or medical devices (新药批号或药械使用批文). In their quest for profits, pharmaceutical companies paid handsome sums for such special access.²⁴ In the words of one pharmaceutical company executive, "[If you] go to them, [you'll] have to bring money. Money quickens the approval process; [you're made] to wait if you don't bring money. [They] won't say [you're] not qualified, or that there's a need

²⁰ 刘薇, '政协委员钟南山: 郑筱萸案源于监督缺失', March 8, 2007, 京华时报, <<http://news.sina.com.cn/c/2007-03-08/021811361410s.shtml>>.

²¹ 刘薇, "政协委员钟南山: 郑筱萸案源于监督缺失" March 8, 2007, 京华时报, <<http://news.sina.com.cn/c/2007-03-08/021811361410s.shtml>>.

²² State Food and Drug Administration, '2006年统计数据年报', 2007年10月11日, at <<http://www.sfda.gov.cn/WS01/CL0108/25441.html>>.

²³ This data is quoted from <<http://www.fda.gov/opacom/factsheets/justthefacts/3cder.pdf>>. For discussion of FDA staff size and drug approvals, see Daniel Carpenter, Michael Chernew, Dean Smith, and Mark Fendrick, "Approval Times For New Drugs: Does The Source Of Funding For FDA Staff Matter?," Health Affairs, December 13, 2003, pp. W3/618-624 <<http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.618v1.pdf>>

²⁴ 罗昌平 张映光, '郑筱萸罪与罚', 财经, April 18, 2007, <<http://finance.sina.com.cn/g/20070418/11223513657.shtml>>.

for additional materials. Anyway, [you] just have to wait and wait.”²⁵ Money became the essential lubricant for smoothing the approval process.

The corruption that infested the drug approval process went far beyond using money to speed up approvals. Some pharmaceutical companies even purchased the application materials and passed drugs from established manufacturers as their own samples to go with the applications, to secure approvals and thus the right to manufacture the drugs.²⁶ Because of the rampant issuance of new drug approvals, many firms had the approvals but would not go to the length of producing the drugs. In fact, there was a virtually open market for drug approvals (licences), with some firms transferring some approvals, for a profit, to others to produce.²⁷

Indeed, as the whistle-blower Gao Chun and others found out, it was not simply the pharmaceutical companies that committed outright fraud in the process of drug registration and production. Most remarkably, some of the personnel working at the drug registration bureau sold copies of application documents supplied by legitimate companies, including foreign companies, to other Chinese pharmaceutical companies, who then used dressed-up versions of these documents to get similar drug approvals.²⁸ Some of the drug registrants (新药注册专员), including both retired drug administration staff in the provinces and in the SDA (SFDA) and even staff still working at the SFDA, made huge sums in the process.²⁹ When a company can quickly secure approval for a new drug using someone else’s documents, what incentive is left for China’s own pharmaceutical companies to invest in research and development?

The Forced March to GMP Compliance

With the formation of SDA in 1998, Zheng Xiaoyu also made the promotion of Good Manufacturing Practices (GMP) a key mission of the SDA. GMP, which governs the documentation of the manufacturing process and the certification of all manufacturing and testing equipment, is a set of industry standards designed to ensure the quality of the manufacturing process for foods and pharmaceutical products. Like the nationalization of drug standards, the adoption of GMP, which has spread worldwide in both developed and developing economies, is a highly desirable goal for China’s pharmaceutical industry. It is, nonetheless, a technical and highly complex, as well as costly process, and thus demands substantial regulatory capacity.

Initially GMP certification was centralized in the SDA, but was voluntary for drug manufacturers. This made sense because the SDA had a small staff and it was impossible for the SDA staff to undertake a lot of certifications at any one time. From 1999 to 2002, about 1,000 pharmaceutical firms passed GMP certification.

Then Zheng Xiaoyu was seized with the idea of industry-wide GMP-compliance. In August 2001, Zheng, in his desire to upgrade the profile of China’s pharmaceutical industry and that of the SDA (SFDA), decided to mandate all drug manufacturers to become GMP-

²⁵ Quoted in 仇玉平, ‘药监新政使医药行业走出信任危机阴影’, 法制与新闻, August 6, 2007, <<http://news.sina.com.cn/c/2007-08-06/113013603509.shtml>>.

²⁶ 罗昌平 张映光, ‘郑筱萸罪与罚’, 财经, April 18, 2007, <<http://finance.sina.com.cn/g/20070418/11223513657.shtml>>.

²⁷ 厉林, ‘国家药监局反思审批之乱’, 中国经营报, August 28, 2006, <<http://www.cb.com.cn/News/ShowNews.aspx?newsId=5145>>.

²⁸ Personal interview with a foreign pharmaceutical executive.

²⁹ 王刚, ‘他只是一个人在战斗’, 中国新闻周刊, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473728.shtml>>.

compliant by July 1, 2004. Those manufacturers that failed to achieve GMP compliance would essentially have to stop production and lose their business.

Zheng's forced march to GMP compliance immediately aroused vociferous complaints from the pharmaceutical companies that had yet to comply as well as the local authorities worried about firms in their jurisdictions not being able to become GMP-compliant and thus facing suspension of production.

Confronted with tremendous pressure from the localities and confronted with the possibility that he might have to eat his own words on the deadline for GMP compliance, Zheng relented. In 2003, the SFDA delegated the responsibility for GMP certification to the provincial-level drug administrations; the provincial-level administrations only needed to file the certifications with the SFDA headquarters for record (省局审批、国家备案的两级联审). As the delegation of GMP certification authority to the provinces was not accompanied by adequate training of staff in the provinces or the standardization of certification processes, it quickly led to the relaxation of standards for GMP compliance simply because the provincial administrations had strong incentives to let the firms in their own jurisdictions gain certification.

Not surprisingly, the delegation of GMP certification authority to the provinces dramatically accelerated the pace of GMP certification. In a year's time, the local food and drug administrations certified nearly 5,000 pharmaceutical firms for GMP compliance. By the deadline of July 1, 2004, some 6,000 pharmaceutical firms had been certified to be GMP compliant.³⁰ It was a contemporary version of China's Great Leap Forward in the pharmaceutical industry.

In practice, given the drive to undertake the GMP certification in a relatively short time period, the attention of regulators easily focused on improved equipment rather than management of manufacturing processes. Even in the best circumstances, the local drug administration often failed to crack down on local firms that were important to the local economy. Amid the campaign to certify pharmaceutical firms, GMP certification had become a mere formality as long as the applicant pharmaceutical firm possessed the right pieces of equipment and submitted the reams of data needed.

Most egregiously, it appears that the GMP certification process became a massive rent-seeking exercise for some local regulators and a giant sales opportunity for equipment makers and sellers. According to a survey by the Chinese Pharmaceutical Enterprise Management Association (中国医药企业管理协会) of 140-plus firms that passed GMP certification, the average cost to upgrade equipment and improve management to pass the GMP certification was 31 million yuan (about US\$3.7 million).³¹ This was a significant sum and a heavy financial burden, especially as many firms were starved of capital at that time and needed to borrow heavily from banks to keep operating. Many Chinese pharmaceutical firms continue to be saddled by the bank loans they took out to pass GMP certification.

Fraud was also not unusual, however, and there was little double-checking of data submitted. The SFDA had simply withdrawn from the actual certification process. Some pharmaceutical companies would systematically fake data needed for GMP certification by filling up the required forms for over half a year with fake data. With the right connections and perhaps money to lubricate the wheels of approval, they would become GMP certified

³⁰ 罗昌平 张映光, '郑筱萸罪与罚', 财经, April 18, 2007, <<http://finance.sina.com.cn/g/20070418/11223513657.shtml>>.

³¹ 何忠洲 蒋明倬, '一个部门损害的一个行业', 中国新闻周刊, March 19, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473733.shtml>>.

with little difficulty.³²

The SFDA did close some pharmaceutical firms for their failure to become GMP-certified. Yet Zheng clearly overstated the SFDA's regulatory prowess. One reporter estimated that Zheng's speeches and reports at the time implied that more than 4,000 firms had been closed but this was simply a gross exaggeration designed to falsely emphasize the significance of the reforms.³³ In fact, there were 6,984 pharmaceutical companies in China in 1998 and more than 6,600 as of early 2007. During that time, some of the firms were closed, others were merged, still others were new, and the suggestion that thousands of firms had to close as a result of the SFDA's drive to promote GMP certification was simply false.

Corruption, Whistle-blowing, and Disciplinary Failure

As noted earlier, the various reforms launched on Zheng Xiaoyu's watch became corrupted by bribery and rent-seeking. Much of the corruption involving SFDA officials occurred through their family members, many of whom also worked in the pharmaceutical industry. In connection with the trials of Zheng Xiaoyu, Cao Wenzhuang, Hao Heping, and others, the Chinese media has reported on some of the corrupt dealings, though they undoubtedly did not have the full story. For a short time, Zheng Xiaoyu's two defense lawyers released the key court documents connected with the case and thus revealed the major charges brought by the government.³⁴

Even a cursory review of the Zheng Xiaoyu case would help to illuminate how the personal failings of Zheng and his associates undermined the regulation of drug safety even as they took on the role of champions for regulatory reforms. Most of the bribes Zheng Xiaoyu took were for approval of new drug applications and collected through his wife Liu Naixue (刘耐雪) and son Zheng Hairong (郑海榕). Ultimately, Zheng was charged with taking bribes totaling 6.5 million yuan.

Zheng Xiaoyu's wife Liu Naixue accompanied Zheng from Zhejiang to Beijing and became a highly compensated employee at the Beijing Jinsaishi biotech company (北京金赛狮生物制药技术开发有限责任公司). In at least one case, Jinsaishi appeared to have gained access to a drug application by another company then pending (and stalled) at the drug administration.³⁵ It seems reasonable to speculate that Liu's influence helped Jinsaishi gain access to confidential information that it was not supposed to have and that the drug administration was not supposed to disclose. The indictment states that Zheng received more than one million yuan from the head of the Research Institute where Liu Naixue worked.³⁶

Zheng Hairong (郑海榕), Zheng Xiaoyu's son, also got into the medical industry. Hao Heping, director of the Bureau of Medial Devices, was instrumental in helping Zheng Hairong make profits from registering medical devices. In fact, under Hao Heping, it was relatively easy (and, relative to drug registration, relatively inexpensive) to obtain registration and approval for medical devices. Around Hao, besides Zheng Hairong, various other retired

³² 仇玉平, '药监新政使医药行业走出信任危机阴影', 法制与新闻, August 6, 2007, <<http://news.sina.com.cn/c/2007-08-06/113013603509.shtml>>.

³³ 何忠洲 蒋明倬, '一个部门损害的一个行业', 中国新闻周刊, March 19, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473733.shtml>>.

³⁴ '郑筱萸案行贿人曝光令人震惊', 中国金融网, July 23, 2007, at <<http://news.zgjr.com/News/2007723/News/092669132400.html>>.B

³⁵ 陈小莹, 沈玮, 左志坚, '亲友称郑筱萸落马与年幼时家庭贫困有关', 21 世纪经济报道, February 8, 2007, <<http://www.southcn.com/news/china/zgkx/200702080332.htm>>.

³⁶ '郑筱萸案行贿人曝光令人震惊', 中国金融网, July 23, 2007, at <<http://news.zgjr.com/News/2007723/News/092669132400.html>>.

SFDA officials set up or controlled registration agencies (注册代理公司). Hao dominated the approval process and overrode the technical assessments by experts.³⁷

For Zheng Hairong, however, it was much easier to collect money just by being the son of Zheng Xiaoyu. Between 2000 and 2006, Zheng Hairong was paid 730,000 yuan in salaries by a Guangdong company even though he never worked there. The same company also covered the costs of home decorations for Zheng Xiaoyu that were worth 250,000 yuan.³⁸ During his trial, Zheng Xiaoyu stated, “I have come to realize that the bosses of pharmaceutical companies took different approaches to bribe me. They gave stocks and money to my wife and son. I didn’t object but gave my tacit approval (予以默认). This was taking bribes.”³⁹

In his official capacity, Zheng Xiaoyu did pay some lip service to the need to combat corruption and fraud, especially in the early days of the SFDA. Yet the behavior of Zheng and his lieutenants obviously told a different story. Zheng’s relationship with the whistleblower Gao Chun (高纯), a pharmaceutical researcher responsible for research and new drug registration at the Hunan pharmaceutical company Yueyang Zhongxiang Kangshen (湖南岳阳中湘康神药业集团), reveals a striking portrait of personal willfulness and institutional arrogance at the SDA.

Between 1995 and 2003, Gao Chun visited the SDA (and its predecessor SPA) a total of 35 times. In 1995 Gao reported fraud at one Hunan pharmaceutical company directly to Zheng Xiaoyu. In 1999, Gao complained to the SDA that the Hunan provincial drug administration was shielding companies committing fraud. For nine years, Gao tried to blow the whistle on fraud at that company and others to Zheng Xiaoyu and other top SDA regulators, but Gao’s efforts had no effect on the behavior of either the firms or the regulators. Indeed, the SDA officials and staff grew increasingly dismissive of Gao, at one time even threatening him with custody. Frustrated that Zheng and other SDA officials were not taking action on his reports, Gao Chun sued the SDA for its failure to fulfill its administrative duties (行政不作为) at the Beijing First Intermediate Court in 2003.⁴⁰ Sadly for Gao, the court decided in 2004 that it had no jurisdiction over the case.

In contrast, some of the firms that committed fraud were downright ferocious in dealing with their critics. Zhang Zhijian(张志坚), then a pharmaceutical researcher at a Hainan pharmaceutical company, found this out the hard way. On March 20, 2006, Zhang reposted an essay written by someone else that mentioned corrupt dealings between Haikou Kangliyuan and SFDA officials including Cao Wenzhuang.⁴¹ A month later, Kangliyuan got the local police and prosecutors to have Zhang taken into custody on charges of defaming the reputation of a commercial enterprise (损害企业商业信誉). Had not Zheng Xiaoyu himself been taken into custody and put on trial, and had Kangliyuan not been among the firms that had bribed Zheng, Zhang Zhijian would most likely have continued to languish in custody. On February 6, 2007, the procuracy withdrew the lawsuit against Zhang Zhijian, saying that

³⁷ 丘敏 赵何娟, ‘郑筱萸之子办公司报父亲名号 受郝和平支持敛财’, 第一财经日报, February 7, 2007, <<http://finance.sina.com.cn/g/20070207/02423318579.shtml>>.

³⁸ ‘郑筱萸获极刑背后’, 中国经营报, July 14, 2007, at <<http://news.sina.com.cn/c/2007-07-14/152713446956.shtml>>.

³⁹ 杨昌平 张勇杰, ‘郑筱萸涉嫌受贿 640 万元案开庭审理’, 北京晚报, May 16, 2007, <<http://news.sina.com.cn/c/l/2007-05-16/144613003020.shtml>>.

⁴⁰ 王刚, ‘他只是一个人在战斗’, 中国新闻周刊, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473728.shtml>>; 李宗陶, ‘高纯: “郑筱萸, 你是天下第一贪”’, 人物周刊, February 11, 2007, at <<http://www.nanfangdaily.com.cn/rwzk/20070211/sz/200702280031.asp>>; 高纯, ‘我的中国梦’, accessed on March 16, 2007 at <<http://www.bokerb.com/logshow.asp?id=5439>>.

⁴¹ 康力元 (集团) 涉嫌巨额行贿 SFDA 曹文庄等, <<http://my.clubhi.com/bbs/661473/16/31253.html>>.

that “the evidence has changed.”⁴² For his ten-month ordeal, Zhang received state compensation of 24,000 yuan from the Longhua District Procuracy of Haikou city.⁴³

The Consequences and Implications of Regulatory Corruption

Even though Zheng was ultimately executed for bribery and dereliction of duty, some industry insiders nonetheless believed that the Chinese drug administration “underwent quite obvious reforms and made progress.”⁴⁴ Indeed, each of the reforms called for more strict and uniform regulation even though actual implementation fell short of the desired objectives. And the GMP certification did force most pharmaceutical companies to upgrade equipment, even if its effect on manufacturing processes was more limited. Yet where the regulators had no discipline and succumbed to venal temptations, every certification or approval process became an opportunity for rent-seeking and bribery, and therefore a potential safety hazard, with grave consequences.

First, in light of the large number of drugs approved, and because of the substantial corruption and outright fraud in the approval and GMP certification processes and the relatively small regulatory staff available to inspect and ensure drug safety, it is to be expected that safety issues would emerge. This is all the more the case because the SFDA has been criticized for having simply abandoned its regulatory duty beyond drug registration. It is thus no exaggeration to say that the SFDA on Zheng Xiaoyu’s watch had essentially approved various time bombs. It is only a matter of time before some of these time bombs would explode.

And explode they did. By the time of Zheng Xiaoyu’s retirement, China was confronted with a spate of major drug safety disasters, including the Qiqihaer No. 2 Pharmaceutical Factory case and the Xinfu case (‘齐二药’事件, ‘欣弗’事件). In each case, the problem came to light only after patients had suffered from serious adverse reactions and some had died.⁴⁵ These events focused attention on the SFDA and made the corruption cases at the SFDA especially egregious for putting lives in jeopardy.

Second, the proliferation of defective drug approvals has also been a major setback for the ambitions of China’s pharmaceutical industry. The proliferation of new drug approvals lowered the barriers to entry into the pharmaceutical industry. Seeing the ease with which one could obtain approvals to produce copies of existing drugs and make money, even some real estate developers decided to shift gears and get into the pharmaceutical industry, though their sole purpose for entering the industry was to make quick profits and they didn’t tend to have a long-term vision.⁴⁶ In the end, the lower regulatory barriers to entry served to drive down profit margins, especially because the “new” drugs being approved were typically versions of the existing drugs. This left the Chinese pharmaceutical industry in a vicious cycle. Precisely because it was easy to gain regulatory approval for “new” drugs, firms resorted to bribery and other means to get more and more versions of the same drug approved

⁴² 刘伟, ‘揭露郑筱萸网民张志坚: 中纪委让我放心讲真话’, 新京报, April 9, 2007, <<http://news.sina.com.cn/c/2007-04-09/011512728481.shtml>>.

⁴³ 杨燕生, ‘男子揭发郑筱萸被关押近 10 个月获国家赔偿’, 法制日报, July 23, 2007, <<http://news.sina.com.cn/c/2007-07-23/081613505986.shtml>>.

⁴⁴ 孙晨, ‘郑筱萸双规激荡药监新政 药监局内部凸显大换班’, 中国经营报, <<http://finance.sina.com.cn/g/20070108/16063226153.shtml>>.

⁴⁵ 王亦君, ‘专家态度: 药监部门不能认证后就当“甩手掌柜” 中国青年报’, August 7, 2006, <<http://news.sina.com.cn/o/2006-08-07/07289676745s.shtml>>.

⁴⁶ 蒋明倬 何忠洲, ‘谁来保证我们的药品安全’, 中国新闻周刊, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473735.shtml>>.

as “new drugs”. There was little incentive to become truly innovative.

There is a great irony in this state of affairs. To some extent, the regulators could mass approve large numbers of “new” drugs partly because they knew that these were copies of drugs that had already been tested in other countries. In the wry comment of one industry veteran, “If you really come up with a breakthrough drug, the SFDA may not dare to approve it [so quickly for fear of the safety implications].”⁴⁷

Third, the rampant corruption and regulatory failure in the SFDA were signs of the limited efficacy of China’s discipline and anti-corruption system. To be sure, Zheng and a substantial number of SFDA officials, as well as pharmaceutical entrepreneurs, have gone to jail and been executed in the case of Zheng, but the punishment occurred only after Zheng and his cronies had caused great harm over many years.

Zheng and his associates’ behavior would not have gone as far had there been more effective supervision. The SFDA is part of the State Council lineup but is ranked below the ministerial rank and doesn’t enjoy cabinet status. Part of the reason Zheng Xiaoyu rushed the various reforms was believed to be due to his desire to show quick results and thus to get the bureaucratic ranking of the SFDA and his own raised to the ministerial level like the other regulatory administrations.

While each of the regulatory administrations is overseen by one of the vice premiers or state councilors, the Chinese Communist Party and the Chinese Government monitor the ministries and administrations through a discipline and supervision system (the Central Discipline Inspection Commission and the Ministry of Supervision). Typically one of the deputy secretaries in each ministry or administration is to represent the CDIC/Ministry of Supervision. Yet in the past the discipline inspection person tended to become “captured” by the organization in which he or she was embedded. This was clearly the case at the SFDA, where the presence of Yang Baoxiang (杨宝祥), officially the team leader of the SFDA Discipline and Inspection Team and a member of the Party Group, was clearly ineffective in curbing the rampant corruption in the SFDA.

In recognition of the tendency toward capture, the CDIC began to introduce reforms to the discipline inspection system. In March 2006, Ms. Qu Shuhui (曲淑辉), formerly director of the Supervision Office of the Supreme People’s Court, was brought in to replace Yang Baoxiang. Yang Baoxiang was more like a member of the SFDA, Qu Shuhui’s reporting relationship was more oriented toward the CDIC. As an outsider, Qu became an effective player and reportedly played a significant role in the Zheng Xiaoyu case.⁴⁸ The arrest of some SFDA officials encouraged others to come forth as informers. In the first half of 2006, the Discipline Inspection team at the SFDA received 886 letters and visits from informers to report on cases of abuse of power and corruption and on problems of fraud and failure to comply with laws and regulations in drug research, registration application, and production.⁴⁹

The Quest for Regulatory Prowess in the Aftermath of Zheng Xiaoyu

On January 24, 2007, Premier Wen Jiabao convened a State Council executive

⁴⁷ 安库雷, ‘谁来监督药监局’, 人物周刊, February 11, 2007, <<http://www.nanfangdaily.com.cn/rwzk/20070211/sz/200702280032.asp>>.

⁴⁸ ‘国家药监局成腐败重灾区 中纪委整顿派驻机构’, 21 世纪经济报道, February 14, 2007, <<http://news.sina.com.cn/c/2007-02-14/104312316581.shtml>>.

⁴⁹ 蒋明倬 何忠洲, ‘谁来保证我们的药品安全’, 中国新闻周刊, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473735.shtml>>.

meeting (常务会议), attended by the vice premiers and State Councilors, to discuss the case of Zheng Xiaoyu. Most significantly, the meeting was also attended by the secretary and deputy secretary of CDIC, Wu Guanzheng and He Yong. The meeting came to the conclusion that this was a serious case of dereliction of duty and corruption. The SFDA had clearly become the poster child for regulatory corruption and incompetence in China. In the words of Vice Premier Wu Yi (吴仪), “The SFDA is a typical case and [the problems that afflicted it] may more or less exist in other government departments.”⁵⁰ At a time when the Chinese leadership sought to decrease the number of death penalties, Zheng became the first ministerial-level official to be executed since 2000 and only the fourth in the reform era.⁵¹

The arrest and trial of Zheng Xiaoyu and other SFDA officials as well as local drug administration officials did not solve the problems at the SFDA, but merely marked the beginning of a new phase. Now Commissioner Shao Mingli had to face up to the daunting challenge of cleaning up the mess at the SFDA. Not surprisingly, there was much soul-searching as well as personnel replacements within the SFDA. Besides rotations with the SFDA itself, key positions at the Drug Registration and Medical Devices bureaus went to outsiders, with Zhang Wei (张伟), formerly deputy director of the Beijing municipal FDA, taking over as director of the Drug Registration Bureau, and Wang Baoting (王宝亭), formerly deputy director of the Shandong provincial Health Bureau, assuming the directorship of the Medical Devices Bureau. Under great pressure, Shao Mingli launched intense study sessions among staffers to learn about and reflect on the purposes (For whom do we regulate? 为谁监管) and mechanisms (How to regulate? 怎样监管) of regulation.⁵² With much fanfare, the SFDA announced a list of eight prohibitions banning regulatory staff from various activities such as receiving gifts from drug firms.⁵³ In 2007, the SFDA severed links with 22 firms that were set up by ten SFDA affiliate units. SFDA staff gave up more than 3.5 million shares in drug stocks and more than 2.6 million yuan in gifts of cash and securities.⁵⁴

The SFDA has also introduced a series of institutional mechanisms designed to mitigate the incidence of corruption. These mechanisms include separation of regulatory duties (case acceptance, technical assessment, and administrative evaluation and approval), collective responsibility for administrative approval, enhancement of regulatory transparency including greater use of web-based processing, and the rotation of regulators within the SFDA.⁵⁵

Yet the Zheng Xiaoyu administration has left a massively-flawed legacy that cannot

⁵⁰ ‘郑筱萸的典型性腐败’, 中国新闻周刊, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473728.shtml>>.

⁵¹ Joseph Kahn, ‘China Executes Former Food and Drug Regulator’, *New York Times*, July 11, 2007, <<http://www.nytimes.com/2007/07/11/business/worldbusiness/11execute-web.html>>.

⁵² While Shao Mingli has distanced himself from the Zheng Xiaoyu regime and been portrayed as a victim of Zheng’s dominance, it is an open question whether he was corruption-free during a period of massive bribery and rent-seeking at the SFDA. In private conversation, one Chinese reporter even suggested to me that Shao couldn’t possibly be.

⁵³ ‘食品药品监督管理局发布食品药品监管工作人员八禁令’, March 28, 2007, <http://www.gov.cn/gzdt/2007-03/28/content_564367.htm>.

⁵⁴ 曾利明, ‘国家药监局 07 年清退药企股票 350 多万股’, 中国新闻网, January 30, 2007, at <<http://news.sina.com.cn/c/2008-01-30/165514864034.shtml>>.

⁵⁵ 曾利明, ‘国家药监局 07 年清退药企股票 350 多万股’, 中国新闻网, January 30, 2007, at <<http://news.sina.com.cn/c/2008-01-30/165514864034.shtml>>.

be easily corrected. One statistic alone underscores the magnitude of the challenge. According to Zhang Wei of the SFDA Drug Registration Bureau, some 150,000 legacy approvals—the bulk of the existing drug registrations—were issued without adequate data from clinical trials and pharmaceutical evaluations.⁵⁶ In other words, the Chinese public has good reason not to trust the safety of most drugs manufactured by drug makers based in China.

As discussed earlier, many of the problems on Zheng Xiaoyu's watch arose when he set tough deadlines for various reforms but, lacking the resources to undertake the reforms at the SFDA headquarters, simply lowered the standards and thus defeated the goals of reform. Under Shao Mingli, there has been no campaign or forced march. Espousing the motto of "scientific regulation," which is a reference to General Secretary and President Hu Jintao's emphasis on the scientific outlook of development, the SFDA under Shao has taken a multi-pronged approach to drug regulation.

In drug registration, the pace of drug approvals at the SFDA has slowed down dramatically, to a virtual standstill as far as many drug firms are concerned, as the SFDA refocused its attention on quality rather than quantity. Numerous firms that had submitted drug approval applications voluntarily withdrew their applications for fear that their applications would not pass muster in light of the SFDA's newly-found emphasis on safety. According to one report, the number of withdrawn applications in the first half of 2007 amounted to 6,441 or 22 percent of the total.⁵⁷ To deal with the large number of legacy drug approvals, the SFDA announced in fall 2006 that all existing drug approvals would need to be re-evaluated and re-registered over time as they come up for renewal five years after the initial approval, with special emphasis on safety. It will be about 2011 by the time the SFDA will have re-examined all the drug approvals issued during the Zheng Xiaoyu era.

While the re-evaluation of existing drug approvals continues, the SFDA has stepped up initiatives to upgrade the overall regulatory environment for drug safety by amending the regulations on drug registration, GMP inspections, supervision of drug sales, and of drug advertising in 2007. It also issued new regulations on drug recalls.

Of particular import have been the SFDA's efforts to enhance post-drug-approval regulation. To begin with, central government budget allocation for food and drug regulation rose to 3.7 billion yuan in 2006–07, compared with about 2.85 billion for the 1998–2005 period. The funding increase has enabled the SFDA to upgrade facilities and equipment for analysis and detection.⁵⁸

Armed with more resources, the SFDA has turned to random inspections and onsite inspectors to keep pharmaceutical companies on their best behaviour, especially with respect to GMP-compliance. The dedicated onsite inspectors are first dispatched to drug manufacturers deemed to be of potentially high safety risks, including makers of blood products, vaccines, injected drugs, and certain special drugs. By the end of 2007, some 1,300 inspectors were already at work.⁵⁹ To mitigate the risk of the inspectors being bought off by the drug makers they are monitoring, the SFDA has devised a set of elaborate rules to ensure the inspectors do not take any payment or other forms of benefits from the drug makers. Moreover, the inspectors are to be rotated every two years, again to mitigate the possibilities

⁵⁶ 何忠洲 蒋明倬, '一个部门损害的一个行业', 中国新闻周刊, March 19, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473733.shtml>>.

⁵⁷ 苏永通 赵蕾 邓江波, '中国药监系统“刮骨疗毒”', 南方新闻网, August 17, 2007, at <http://www.china.com.cn/policy/txt/2007-08/17/content_8700292_3.htm>.

⁵⁸ 吕诺, '中央财政对食品药品监管两年投入 37 亿元', 新华网, January 31, 2008, <http://news.xinhuanet.com/newscenter/2008-01/31/content_7533998.htm>.

⁵⁹ '药监局约束派驻药企监督员行为 已派驻 1300 余名', January 1, 2008, <http://www.china.com.cn/policy/txt/2008-01/01/content_9464328.htm>.

of capture.⁶⁰ For certain classes of drugs (narcotic drugs and anti-psychotic drugs), a dedicated regulatory information network was set up to monitor the entire production and sales processes.⁶¹

Yet even random inspections have their limits. Software companies have produced software to help pharmaceutical companies cope with the stricter SFDA regulations and reportedly even provide periodic upgrades to the software. According to one pharmaceutical executive, such software can help pharmaceutical companies cook their data to deal with SFDA random inspections and are even designed to trick the software packages that the SFDA inspectors use to conduct the inspections.⁶² In this respect, the SFDA drive to conduct inspections may have only limited effect on the conduct of certain companies bent on deceit. Ultimately entrepreneurs must internalize the ethics and rules of the regulators before China's drug industry can truly clean up. Before that happens, however, what is needed is regulatory implementation with teeth that really bite.

Under tremendous pressure from the national leadership and the media, the SFDA has begun to show some backbone. During the 18-month drive in 2006–07 to improve drug regulation, the SFDA revoked 27 licences for the production of drugs and medical devices and cancelled 157 GMP certifications. The SFDA also cancelled 1,210 operational licenses for drug wholesalers or retailers and closed 1,719 that operated without a drug-sale license.⁶³ Drug recalls, some following the lead of the US FDA, have also become a well-accepted practice.

Whereas previously the Zheng Xiaoyu administration had tended to cave in to local and industry pressures and not uphold the policy aims and standards set earlier, the SFDA under Shao Mingli has chosen to stick to its guns. In one important area, the SFDA has displayed remarkable toughness. In 2004, the SFDA issued an order on promoting GMP compliance among producers of prepared herbal pieces (中药饮片). The order stipulated that all manufacturers of prepared herbal pieces must become GMP-compliant by January 1, 2008. By the end of 2007, however, only 300 of the 1,100 firms making herbal pieces had been certified to be GMP-compliant, while most others balked at the high costs of GMP certification and took a wait-and-see attitude.⁶⁴ Rather than postpone the deadline for compliance, however, the SFDA took a hard-line stance and decreed that the original order must be honored and those firms that violated it would be dealt with as if they were manufacturers of fake medicine. This means they can be fined and prosecuted for a criminal offense (PRC Drug Administration Law: Art. 74).⁶⁵

In handling the string of drug safety incidents since 2006, the SFDA has also cut a more vigorous and professional profile. Take the case of Hualian, a unit of Shanghai Pharmaceutical Group. Hualian was a manufacturer of several anti-cancer drugs, including methotrexate, a drug commonly used to treat leukemia. In 2007, nearly 200 Chinese cancer patients were seriously harmed and even paralyzed after using the anti-leukemia drug

⁶⁰ ‘派驻监督员管理暂行规定’, December 18, 2007, <<http://www.sfda.gov.cn/WS01/CL0288/27213.html>>.

⁶¹ ‘国家食品药品监督管理局召开例行新闻发布会’, February 1, 2007, <http://www.china.com.cn/zhibo/2008-02/01/content_9625260.htm?show=t>.

⁶² 孙晨, ‘药监反腐面临“深度严查”’, 中国经营报, June 4, 2007, <<http://www.cb.com.cn/News/ShowNews.aspx?newsId=10282>>.

⁶³ 李亦菲, 杨俊坚, ‘国家药监局鼓励药企兼并重组’, 南方都市报, February 7, 2008, <<http://finance.sina.com.cn/chanjing/b/20080207/14064495780.shtml>>.

⁶⁴ 贺民, ‘中药饮片距标准之路还有多远?’ 中国产经新闻, November 18, 2007, <<http://finance.sina.com.cn/chanjing/b/20071118/03284186665.shtml>>.

⁶⁵ ‘关于加强中药饮片生产监督管理的通知’, February 1, 2008, <<http://www.sfda.gov.cn/WS01/CL0055/27837.html>>.

produced by Hualian. After reports of adverse reports came to light, Shanghai Pharmaceutical tried to play down the problem as that of side effects. The Shanghai Food and Drug Administration, together with a joint investigation team from the State Food and Drug Administration and the Ministry of Health, launched their own investigation and concluded that this was a case of serious contamination. In a failure to follow GMP operating procedures, a technician contaminated multiple batches of methotrexate, as well as another drug cytarabine hydrochloride, with vincristine sulfate, an anticancer compound. The SFDA accused Hualian's managers with "systematically covering up violations of production procedures." The defective drugs were recalled. In response to the results of the investigation, the Shanghai Food and Drug Administration revoked Hualian's drug production license, rescinded all 119 drug approvals held by Hualian, confiscated its earnings from the defective drugs and imposed the largest fine allowed by the Drug Administration Law. The SFDA revealed that the responsible individuals at Hualian had been arrested and would be prosecuted for criminal responsibility.⁶⁶

Proposals for Further Institutional Reforms

Whereas the SFDA under Shao Mingli has acquired more vigor, as well as rigor, as a regulator, the SFDA's failings under Zheng Xiaoyu have nonetheless prompted calls for thorough reforms. These calls have continued to reverberate in China. The default option for the SFDA would be to respond to the problems uncovered and strengthen itself along the model of the US FDA. After all, the US FDA has historically had its crisis moments and it was by politicians and the agency responding to the crises that the US FDA gradually acquired its good institutional reputation.⁶⁷ Unlike the drug regulators in the US and other developed economies, however, the SFDA can model itself on its counterparts and thus should find it easier to enhance its regulatory capability. Advocates for this trajectory have called for the SFDA to adopt full national integration (vertical administration) to curb local influences and thus enhance the agency's integrity. This is especially important in remote areas in China's interior, where the local administrations tend to be under-funded and may be asked by the provincial government to help attract business investment and thus divert itself from its regulatory mission.⁶⁸ Nonetheless, increased central government funding since 2006 has to some extent alleviated the budgetary pressures on the local administrations.

Others, however, contend that SFDA's regulatory portfolio, covering food and pharmaceuticals, is too large to be managed effectively in the Chinese context. One proposal, mooted in the *China Daily*, would separate food regulation from the SFDA into a separate agency to allow for greater attention to food safety regulation. Also being considered was a separation of drug approval and drug production safety regulation into separation agencies, with the remainder of the severely weakened SFDA being put into another ministry, such as the Ministry of Health.⁶⁹

⁶⁶ 上海华联制药厂被依法吊销药品生产许可证, December 13, 2007, at <<http://www.sfda.gov.cn/WS01/CL0051/26941.html>>; 叶洲, '上海华联药厂批号全被注销,' 京华时报, April 12, 2008, <<http://finance.sina.com.cn/chanjing/b/20080412/01294739270.shtml>>; Nicholas Zamiska and Avery Johnson, 'China Drugs: A Cautionary Tale', *Wall Street Journal*, January 31, 2008, <<http://online.wsj.com/article/SB120171630877229197.html>>; Jake Hooker and Walt Bogdanich, 'Tainted Drugs Linked to Maker of Abortion Pill', *New York Times*, January 31, 2008, <<http://www.nytimes.com/2008/01/31/world/asia/31pharma.html>>.

⁶⁷ Daniel Carpenter and Gisela Sin, 'Policy Tragedy and the Emergence of Regulation: The Food, Drug, and Cosmetic Act of 1938', *Studies in American Political Development*, 21 (Fall 2007), pp. 149–180.

⁶⁸ 蒋明倬 何忠洲, '谁来保证我们的药品安全', *中国新闻周刊*, March 9, 2007, <<http://news.sina.com.cn/c/2007-03-09/111712473735.shtml>>.

⁶⁹ 'Anti-graft campaign hits drug watchdog', *China Daily*, February 5, 2007,

Still others in China have called for empowering NGOs, including consumer organizations, patient groups, pharmaceutical enterprise associations, hospitals, and the media to serve as monitors, so that it would be extremely difficult for regulators to buy off all of them.⁷⁰ In light of the travails the few whistle-blowers had suffered, such proposals are not likely to go far without significant improvement in press freedom and the protection of civil society groups.

In the end, no institutional tinkering is adequate without more robust supervision of the SFDA's administrative powers. Unlike the US FDA, which is part of the Department of Health and Human Services and watched intently by Congress, the SFDA gained great autonomy in setting its agenda and had relatively little supervision, whether from the State Council or the National People's Congress. Some analysts in China attribute the SFDA's institutional autonomy to the professional nature of drug regulation. Yet, as we know, the mess at the SFDA on Zheng Xiaoyu's watch occurred precisely because Zheng enjoyed a dominant position. Zheng himself warned against exactly the problems that he caused and benefited from at various times. Against this background, the government restructuring plan, approved by the National People's Congress in March 2008, placed the SFDA under the fold of the Ministry of Health, much like the US FDA is in the Department of Health and Human Services. Shao Mingli received a concurrent appointment as vice minister of Health. At the time of this writing, it is not yet clear how the revamped "super-ministerial" administrative setup will work. The Ministry of Health will likely be in charge of overall policy formulation on food and drug regulation while the SFDA is likely to focus on regulatory implementation, thereby providing some check on the SFDA.

Conclusion

The pharmaceutical industry is not just about profits but about the safety of drugs and medical devices, and the protection of people's health. Seen from this perspective, the Chinese initiatives to centralize drug regulation in one regulatory agency and the efforts by the State Food and Drug Administration to unify drug standards and promote GMP and other international standards did not come one moment too soon. Seeking to emulate the US FDA, these Chinese initiatives symbolize China's eagerness for globalization.

Sadly, the SFDA's efforts during the Zheng Xiaoyu administration have not led to a straightforward elevation of standards but have instead produced a contorted and corrupt regulatory apparatuses, even by Chinese standards. The entire drug regulatory system became distorted and the reforms were twisted beyond recognition and became tools for rent-seeking and personal profiteering. And the consequences of the SFDA's failure go far beyond the agency in this case, as they have undermined the development of an industry and resulted in harm to the health and safety of the public, including the loss of lives.

This analysis of the tortuous development of the SFDA over the past decade thus does not condemn the reformist goals, which were highly desirable and well intended. It speaks instead to the complexities of globalization, and, especially in this case, of how institutional development does not occur in a political vacuum, but is often the results of negotiations and compromises. The tragedy of Zheng Xiaoyu is that he set lofty goals and accelerated deadlines even though the SFDA did not possess the requisite funds and personnel to meet the targets on time and, unlike the US FDA, had no recourse to the Academy of Sciences. Even worse was the profound lapse in judgment and moral integrity shown by Zheng and his colleagues as they sought to meet the publicly-announced deadlines. In GMP certification, for example, Zheng could have accepted the reality he faced and set more modest objectives

<http://www.chinadaily.com.cn/china/2007-02/05/content_800730.htm>.

⁷⁰孙晨, '郑筱萸案: 中国"治人救药"', 中国经营报, May 20, 2007, <<http://www.cb.com.cn/News/ShowNews.aspx?newsId=9906>>.

(such as by phasing in GMP compliance based on certain priorities and perhaps even enlisting international help including third-party certification). Instead, the vanity of simply having met a deadline—a common practice during the days of central planning—took hold of Zheng and his lieutenants, at the expense of the SFDA's mission of protecting people's health.

One could argue that the problems with the SFDA reforms were over-determined because of the socio-political context in which Zheng and his colleagues had to function. While the SFDA's regulatory scope may be short of the FDA's (25 cents of every consumer dollar spent), it nonetheless oversees thousands of firms in the pharmaceutical industry alone and these firms are often seen as vital to the local economy by local governments. The SFDA's reforms under Zheng stepped on the toes of powerful local and industrial interests and, given the pressures these interests exerted, it was not too surprising that Zheng—the quintessential man of the pharmaceutical industry—would cave in to these pressures and lower regulatory standards. While this argument of over-determination has a grain of truth, it cannot explain why other regulatory administrations, notably the Civil Aviation Administration of China and the State Administration of Coalmine Safety, have been able to rise up to the challenge and raise the bar of regulatory standards. Ultimately, it was Zheng himself who was responsible for the key decisions regarding the nationalization of drug standards and the promotion of GMP. The socio-political structure was a major influence, but Zheng was a key agent who could have chosen to act differently, even though doing so would have exposed him to tremendous pressure (but, in retrospect, would have saved him from the death penalty).

Zheng's execution on July 10, 2007 marked a milestone in the institutional development of the SFDA. Despite Zheng's execution, the deleterious impact of the corruption that infested the drug approval and GMP certification processes during the Zheng era will not disappear overnight. The drug safety incidents at Shanghai Hualian and others are symptoms of the problems that have accumulated during the Zheng era with lax GMP certifications and inspections. For now, however, the SFDA has yet to emerge from its darkest hour. Nonetheless, it appears that the initiatives that have been taken in the post-Zheng era, whether in raising the standards for drug approvals, strengthening GMP inspections, or regulatory enforcement in cases of safety incidents, will gradually help the SFDA, now in the Ministry of Health, gain the sort of institutional credibility that China can be proud of.