

# THE CHINESE REGULATORY LICENSING REGIME FOR PHARMACEUTICAL PRODUCTS: A LAW AND ECONOMICS ANALYSIS

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*China's pharmaceutical market has expanded dramatically in the past twenty years and is expected to become the largest in the world by the year 2050. However, entry to the market remains difficult for many international pharmaceutical manufacturers due to the country's costly and complicated regulatory licensing requirements. This Article provides an overview of the regulatory licensing regime for pharmaceutical products in China. Then, the Article evaluates three key features of the regulatory licensing regime through a law and economics approach. These features include the use of licensing, as contrasted with alternative regulatory and non-regulatory mechanisms; the standards to be met by license applicants; and the procedures to be followed by applicants before licenses are granted.*

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I. INTRODUCTION

China’s pharmaceutical market has expanded dramatically in the past twenty years and is expected to become the largest in the world by the year 2050.<sup>1</sup> The production value of China’s pharmaceutical industry has experienced average annual growth of 20 percent over the past decade.<sup>2</sup> For example, from January to July of 2007, production reached RMB 342.449 billion, up 23.47 percent over the same period in 2006.<sup>3</sup> There has been “an increasing acceptance of western drugs in China, particularly among the younger generation, in spite of strong competition from the traditional Chinese medicine . . . industry. Western medicines are generally regarded as more effective for infectious dis-

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1. PRICEWATERHOUSE COOPERS, INVESTING IN CHINA’S PHARMACEUTICAL INDUSTRY (2006), available at [http://www.pwccn.com/webmedia/doc/632785588008556096\\_ts\\_invest\\_pharm\\_mar2006.pdf](http://www.pwccn.com/webmedia/doc/632785588008556096_ts_invest_pharm_mar2006.pdf).

2. *China’s Pharmaceutical Industry Has Been Growing at 20% on the Average in Production . . .*, REUTERS, Jan. 9, 2008, <http://www.reuters.com/article/pressRelease/idUS123158+09-Jan-2008+BW20080109>.

3. *Id.*

eases, acute symptoms and illnesses, and many surgical procedures.”<sup>4</sup> Although traditional medicines still play an important role in the Chinese healthcare systems for their weak adverse effects and some special values,<sup>5</sup> such as the potential to cure cancer, it is relatively difficult to standardize, and thus control the quality of traditional Chinese medicines.<sup>6</sup> These factors and changing attitudes have created an unprecedented opportunity for international pharmaceutical companies to market in China.

However, market entry remains difficult for many international pharmaceutical manufacturers due to China’s costly and complicated regulatory licensing requirements.<sup>7</sup> Under China’s regulatory licensing regime, international pharmaceutical firms must obtain licenses or authorizations from a specific governmental agency before lawfully engaging in business in China.

In this Article, I examine the Chinese regulatory licensing regime for pharmaceutical products through a law and economics approach. In Part I, I briefly introduce and describe the Chinese regulatory licensing regime, including its historical development and institutional contexts. Then, I evaluate three key features of the regime as follows: in Part II, I discuss the use of licensing, as contrasted with alternative regulatory and non-regulatory mechanisms; in Part III, I analyze the standards that applicants must meet to be granted a license; and in Part IV, I further examine the procedures that applicants must follow to be granted a license. Finally, in Part V, I reach some brief conclusions based on the sum of my analyses.

In 1963, the Ministry of Health, the Ministry of Chemical Industry, and the Ministry of Commerce jointly published the first comprehensive drug regulation in the People’s Republic of China: *Provisions for*

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4. CRYSTAL CAO, STAT-USA, PHARMACEUTICAL MARKET IN CHINA (2001), available at <http://www.stat-usa.gov/tradetest.nsf> (search database “Market Research Library”; view “ISA Reports by Country All”).

5. Drug Administration Law of the People’s Republic of China (promulgated by the Standing Comm. Nat’l People’s Cong., Feb. 28, 2001, effective Dec. 1, 2001) art. 3 (P.R.C.), available at <http://eng.sfda.gov.cn/cmsweb/webportal/W43879539/index.html> [hereinafter *2001 Drug Administration Law*]; Drug Administration Law Official Commentary (promulgated by the State Food & Drug Admin.), available at <http://www.sfda.gov.cn/WS01/CL0061/> (follow links to specific chapters and articles) [hereinafter *SFDA Commentary*].

6. Teresa Schroeder, *Chinese Regulation of Traditional Chinese Medicine in the Modern World: Can the Chinese Effectively Profit from One of Their Most Valuable Cultural Resources?*, 11 PAC. RIM L. & POL’Y J. 687, 697 (2002).

7. Here, I use “regulatory licensing” or “licensing” to express a form of regulatory control used by the government, which is to be distinguished from “commercial licensing”, denoting “[t]he sale of a license authorizing another to use something (such as computer software) protected by copyright, patent, or trademark” between private parties. BLACK’S LAW DICTIONARY 932 (7th ed. 1999).

*Pharmaceutical Administration*.<sup>8</sup> Designed to protect the public health, the provisions defined “new drugs,” stipulated new drug approval procedures, including clinical trial requirements, and established the Drug Approval Committee.<sup>9</sup> In order to provide more detailed rules for new drug approval, the Ministry of Health and the Ministry of Chemical Industry jointly issued *Interim Provisions of New Drug Administration* in 1965.<sup>10</sup> However, the Cultural Revolution, which lasted from 1966 to 1976, prevented these regulations from being enforced.<sup>11</sup>

In 1978, the State Council issued the *Pharmaceutical Regulation*, which governed clinical trials and new drug approvals.<sup>12</sup> Also in that year, the Ministry of Health published the *New Drug Regulation* to aid the implementation of the *Pharmaceutical Regulation*.<sup>13</sup> The *New Drug Regulation* re-defined and categorized new drugs.<sup>14</sup> Moreover, it also instituted more detailed rules for laboratory research, clinical trials, sample tests, approval, and the manufacturing process.<sup>15</sup> However, its enforcement remained problematic.<sup>16</sup> Under the regulation, the provincial departments of health had authority to grant market authorization for most new drugs, and no unified national standard existed for new drug approval.<sup>17</sup> Local pharmaceutical manufacturers were not required to test new drugs; authorization from the provincial department of health was easily obtained without it.<sup>18</sup> Accordingly, some of the marketed drugs were of poor quality and efficacy.<sup>19</sup>

In the early 1980s, China’s government began placing more importance on drug regulation. *The Drug Administration Law of the People’s Republic of China* was adopted in 1984, the country’s first comprehensive legislation regulating the research, production, and distribution of drugs; in 2001, a revised version of the legislation came into effect, the

8. Chinese Soc’y for Clinical Oncology, *New Drug Administration and GCP Development in China*, <http://www.cSCO.org.cn/gcp/class/zhn005.htm> (last visited Apr. 7, 2009).

9. *Id.*

10. *Id.*

11. *Id.*

12. *Pharmaceutical Regulation* (promulgated by the State Council, July 29, 1978, effective July 29, 1978) ch. 3 (P.R.C.), available at <http://law.lawtime.cn/d550697555791.html/pos=0>.

13. *New Drug Regulation* (promulgated by the Ministry of Health, Feb. 19, 1979, effective Feb. 19, 1979) (P.R.C.), available at <http://law.lawtime.cn/d551461556555.html>.

14. *Id.* art. 1.

15. *Id.* arts. 2–8, 11–12.

16. Chinese Soc’y for Clinical Oncology, *supra* note 8.

17. *Id.*

18. Rongling Deng & Kenneth I. Kaitin, *The Regulation and Approval of New Drugs in China*, 37 *DRUG INFO. J.* 29, 29 (2004).

19. Chinese Soc’y for Clinical Oncology, *supra* note 8.

2001 Drug Administration Law.<sup>20</sup> The law aims to “strengthen drug regulation, to ensure drug quality and safety for human beings, and to protect the health of people and their legitimate rights and interests in the use of drugs.”<sup>21</sup> Under the 2001 Drug Administration Law, licensing authority is vested in the State Food and Drug Administration (“SFDA”),<sup>22</sup> and the licensing scheme consists of nine different levels, each of which will be described below.

First, a prospective pharmaceutical product manufacturer must obtain a manufacturer’s license from a provincial-level branch of the SFDA by demonstrating that it has appropriate facilities, levels of staff, and other arrangements for quality control.<sup>23</sup>

Second, a prospective new drug cannot be clinically tested on humans until the sponsor has submitted the data and related samples from the laboratory stages of research and convinced the SFDA to grant it a clinical test certificate.<sup>24</sup>

Third, a new drug certificate (“NDC”) may only be obtained once the sponsor has demonstrated that its prospective new drug successfully passed laboratory and clinical tests, by which safety and efficacy are assumed.<sup>25</sup> The SFDA issues the NDC after verifying this process and the test data.<sup>26</sup>

Fourth, a prospective manufacturer must also obtain a Production Permit Number from the SFDA before beginning to manufacture a new drug or other drugs regulated by national standards.<sup>27</sup>

Fifth, a prospective drug wholesaler must obtain a pharmaceutical trader’s license from a branch of the SFDA at the provincial level. A prospective drug retailer must do so at the county level.<sup>28</sup> Among other

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20. Drug Administration Law (promulgated by the Standing Comm. Nat’l People’s Cong., Sept. 20, 1984, effective July 1, 1985); 2001 Drug Administration Law, *supra* note 5.

21. 2001 Drug Administration Law, *supra* note 5, art. 1.

22. The Chinese government established the State Drug Administration (“SDA”) in March 1998. By doing so, it consolidated the State Pharmaceutical Administration of China, the Bureau of Pharmaceutical Policy Administration, and the State Administration of Traditional Chinese Medicine, which is responsible for regulating traditional medicines. This consolidation of law enforcement and inspection activities and the elimination of functional overlaps in different agencies allowed the SDA to have centralized and streamlined regulatory authority. See Ames Gross, *Regulatory Trends in China’s Pharmaceutical Market*, PAC. BRIDGE MED. (1998), [http://www.pacificbridgemedical.com/publications/china/1998\\_regulatory\\_trends\\_in\\_chinas.htm](http://www.pacificbridgemedical.com/publications/china/1998_regulatory_trends_in_chinas.htm). In 2003, the State Council extended the SDA’s authority to the food industry and renamed the agency SFDA. See State Food & Drug Admin., About SFDA, <http://eng.sfda.gov.cn/eng/> (last visited Apr. 7, 2009).

23. 2001 Drug Administration Law, *supra* note 5, arts. 7–8.

24. *Id.* art. 29.

25. *Id.*

26. *Id.*

27. *Id.* art. 31.

28. *Id.* art. 14.

requirements, licensing is conditioned upon having appropriate staff, facilities, and management systems.<sup>29</sup>

Sixth, before making medicinal preparations for patients, a medical organization must obtain prior approval from the Health Authority at the provincial level, as well as a dispensing permit issued by a branch of the SFDA at the same level.<sup>30</sup> To ensure quality, licensing is conditioned upon the organization's facilities, management systems, and sanitation, as well as other requirements.<sup>31</sup>

Seventh, drugs cannot be imported into China without a Registration Certificate for Imported Drugs ("RCID").<sup>32</sup> For a RCID to be issued, prospective importers generally must satisfy the SFDA criteria for safety and efficacy, but they may be exempt if the drug is for emergency hospital use or individual use.<sup>33</sup> Additionally, before every importation, the importer must obtain an imported drug customs clearance from an affiliate of the SFDA at the port designated for their drugs to enter China.<sup>34</sup> The *2001 Drug Administration Law* no longer imposes compulsory testing on imported drugs unless they are entering China for the first time; however, a pharmaceuticals testing institute appointed by an affiliate of the SFDA will carry out selective testing on imported drugs after they enter the Chinese market.<sup>35</sup>

Eighth, three kinds of pharmaceuticals—namely bio-products stipulated by the SFDA, drugs being sold for the first time in China, and other drugs stipulated by the State Council—must pass tests conducted by appointed institutes before being imported or marketed.<sup>36</sup> This compulsory testing ("a test pass license") is a *de facto* licensing requirement.<sup>37</sup>

Lastly, no over-the-counter drug can be advertised in China unless the sponsor obtains an advertising license from a branch of the SFDA at the provincial level and an advertising permit from a branch of the State Industry and Commerce Administration at the county level or above.<sup>38</sup> Only medicinal and pharmaceutical journals, jointly-authorized by the Health Authority under the State Council and the SFDA, can carry ad-

29. *Id.* art. 15.

30. *Id.* art. 23.

31. *Id.* art. 24.

32. *Id.* art. 39.

33. *Id.*

34. *Id.* art. 40.

35. *Id.* arts. 40–41.

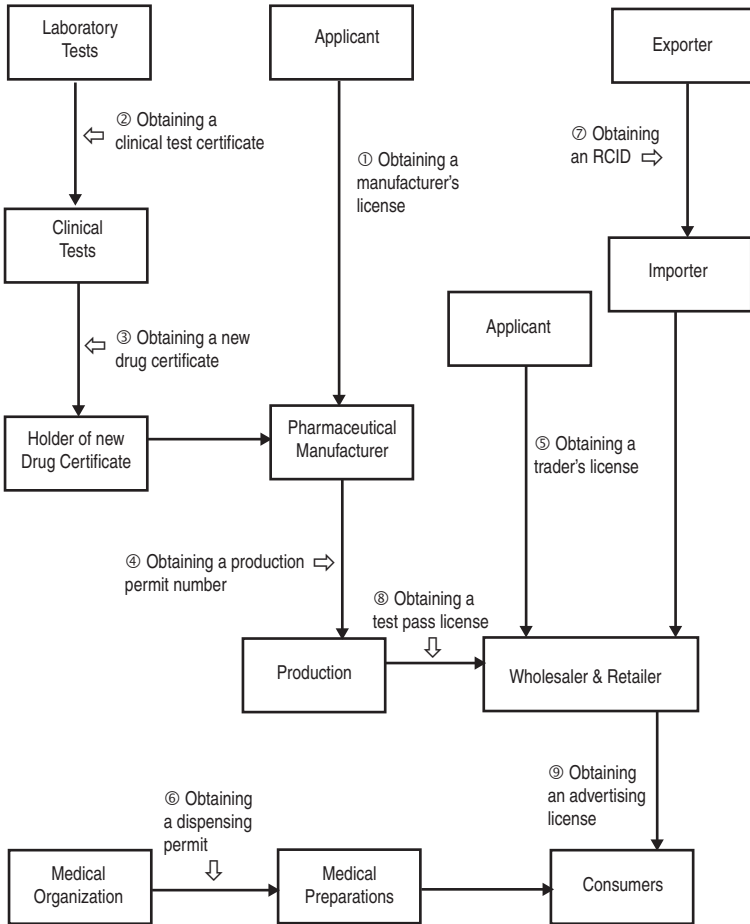
36. *Id.* art. 41.

37. *Id.*

38. *See id.* art. 60; Advertisement Law (promulgated by the Standing Comm. Nat'l People's Cong., Oct. 27, 1994, effective Feb. 1, 1995) art. 34 (P.R.C.).

vertisements for prescription-only drugs.<sup>39</sup> Chart 1 graphically describes the entire Chinese licensing scheme for pharmaceutical products.

CHART 1:



## II. THE USE OF LICENSING

In light of law and economics theories, this section will analyze the use of licensing, as opposed to alternative regulatory or non-regulatory techniques, to control the Chinese pharmaceutical industry. The regulatory licensing regime is just one of many instruments available for the government to achieve its socioeconomic policy objectives. The existing law and economics literature explains that, from a public interest

39. 2001 Drug Administration Law, *supra* note 5, art. 60.

perspective, the government mainly uses a licensing regime to address the problem of market failure.<sup>40</sup> Therefore, I will discuss the possible market failures which may justify regulatory intervention in the pharmaceutical market.

### A. An Overview of Drug Market Failures

One common type of market failure is information asymmetry, which exists between manufacturers and consumers in an unregulated pharmaceutical market. Given the considerable technological complexity of medicine, consumers often have insufficient information to choose the right medicine for themselves. Medical practitioners, who are regarded as regular purchasers or even expert purchasers, and who create the demand for prescription-only drugs, also have insufficient information about new drugs, whose defects may not be easily detectable.<sup>41</sup> Sometimes practitioners cannot make adequately-informed choices between competing drugs even when armed with data sheets and other officially-distributed materials.<sup>42</sup> When they depend on pharmaceutical companies for information to a significant degree, “most of this information is transmitted predominantly in terms of brand names” and thus “further market power may be in the hands of pharmaceutical companies.”<sup>43</sup> As far as over-the-counter drugs are concerned, the patients, who have no expertise, are the primary decision makers.

Under such unregulated circumstances, suppliers may perform insufficient pre-market testing of new drugs in order to gain the advantage of having the first product on the market or simply to avoid high costs; they may also overstate the merits and understate the disadvantages of the drugs in their promotional materials and labeling.<sup>44</sup> Accordingly, the drugs they supply may carry excessive risks to consumers.<sup>45</sup> In addition, information problems about a drug’s efficacy could lead to wasted expenditures on ineffective drugs.<sup>46</sup> Because the potential threats to human

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40. See Anthony Ogus & Qing Zhang, *Licensing Regimes: East and West*, 25 INT’L REV. L. & ECON. 124, 133 (2005); Shirley Svorny, *Licensing, Market Entry Regulation*, in 3 ENCYCLOPEDIA OF LAW AND ECONOMICS 296, 296–328 (Boudewijn Bouckaert & Gerrit De Geest eds., 2000).

41. See Harvey Teff, *Regulation Under the Medicines Act 1968: A Continuing Prescription for Health*, 47 MOD. L. REV. 303, 313 (1984).

42. See *id.* at 314–15.

43. ROBERT E. BALDWIN, *REGULATION IN QUESTION: THE GROWING AGENDA* 89 (1995).

44. HENRY G. GRABOWSKI & JOHN M. VERNON, *THE REGULATION OF PHARMACEUTICALS: BALANCING THE BENEFITS AND RISKS* 7 (1983).

45. *Id.*

46. Patricia M. Danzon, *The Pharmaceutical Industry*, in 3 ENCYCLOPEDIA OF LAW AND ECONOMICS, *supra* note 40, at 1055, 1058.



health from the consumption of unsafe and ineffective drugs can be severe and irreversible, information asymmetries justify government intervention to solve this problem.<sup>47</sup>

Externalities are another type of market failure. The Chinese government recently decided to spend 850 billion yuan (\$124 billion USD) to improve its health-care system.<sup>48</sup> The Basic Medical Insurance Program, which was established in the vast majority of Chinese cities and rural areas, will be expanded to cover more than 90 percent of the total population by 2011.<sup>49</sup> The government and other premium payers will now have to absorb the medical expenses of those harmed by unsafe drugs.

Meanwhile, medical doctors who do not buy or consume the drugs they prescribe could be less concerned about the safety and efficacy of those medicines.<sup>50</sup> “Bad” choices by doctors can also impose huge externalities on society. Due to the special character of drugs, free market drug transactions create the potential for substantial losses, including serious illness and death. If the illness is contagious, the externalities can be even greater.

### B. *Licensing to Better Address Market Failures?*

Many alternative measures are available for addressing market failures. These measures often include private law remedies, information regulation, and *ex post* standards. Before adopting the licensing technique to address the specific problems of market failure, it is very important to ensure that this technique would be more successful than other measures. First, I consider applying private law remedies. As I will explain, private law remedies remain an inadequate way of addressing market failures, particularly when tort law has trouble internalizing the enormous externalities that arise from some drug transactions and thus providing adequate compensation.

From a private law remedy approach, the first prominent difficulty lies in establishing the causation between the injuries and the particular drug at issue. Due to the complexities of both modern medical

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47. GRABOWSKI & VERNON, *supra* note 44, at 7.

48. Dune Lawrence & John Liu, *China's \$124 Billion Health-Care Plan Aims to Boost Consumption*, BLOOMBERG.COM, Jan. 22, 2009, <http://www.bloomberg.com/apps/news?pid=20601080&sid=aXFagkr3Dr6s&refer=asia>.

49. The State Council, *Opinions on Further Reform of the Health Care System* (Jan. 21, 2009) (P.R.C.), available at <http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohbgt/s3582/200901/38889.htm> (presenting the opinions of the State Council as published by the Ministry of Health).

50. BALDWIN, *supra* note 43, at 86; Cotton M. Lindsay, *Conclusion to THE PHARMACEUTICAL INDUSTRY: ECONOMICS, PERFORMANCE, AND GOVERNMENT REGULATION* 141, 142 (Cotton M. Lindsay ed., 1978).

treatments and contemporary society, it can be a struggle to identify a causal agent from the broad array of potential sources of a given illness.<sup>51</sup> Generally, most Chinese judges do not possess the scientific expertise to evaluate the validity of the substantive scientific evidence at issue and must rely on the testimony of competing expert appraisers (analogous to expert witnesses), which can be challenging for judges to understand.<sup>52</sup> Even if liability is established, compensation decided by the court may not be in line with the actual harm caused by the drug, and may thereby undermine the cost-internalization model.<sup>53</sup>

Additionally, the victim may have difficulty in identifying his or her legal privileges and finding competent counsel willing to pursue the claim.<sup>54</sup> It may take a long time, even years after the injury has occurred, before the victim becomes aware that the injury was or may have been drug related.<sup>55</sup> Since the “bad” drug may lead to serious illness and death for many individuals, full compensation may not be available in many cases. Finally, under current Chinese law, drug manufacturers are not liable for drug-related injuries if their products comply with the state standards or the industrial standards.<sup>56</sup> This also makes full compensation for victims unlikely.

Second, I consider using information regulation to address the problems of market failure. The typical way of regulating information in the pharmaceutical industry is through labeling, which is intended to ensure effective communication of the information necessary for an informed medical decision.<sup>57</sup> However, drug manufacturers face the dilemma that they may either be liable for providing inadequate warnings or face a

51. Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 784 (1990).

52. Yang Xiaochun & Wang Bai “Expert Witness Rule” in *U.S. Courts and Its Implications for Chinese Judicial Process in Medical Dispute Cases: Comparing Two Cases Respectively in Both Countries*, 78 J. SECOND NW. UNIV. FOR NATIONALITIES (Soc. Sci. Ed.) 100, 102 (2007) (in Chinese).

53. Note, *supra* note 51, at 781 n.44.

54. Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199, 234 (1992).

55. Teff, *supra* note 41, at 322.

56. Manufacturers are liable for their products only if they are defective. See Law on Protection of the Rights and Interests of the Consumers (promulgated by the Standing Comm. Nat’l People’s Cong., Oct. 31, 1993, effective Jan. 1, 1994) art. 40 (P.R.C.); Product Quality Law (promulgated by the Standing Comm. Nat’l People’s Cong., July 8, 2000, effective Sept. 1, 2000) arts. 26, 46 (P.R.C.) (defining a defect as an “unreasonable danger existing in a product that endangers the personal or other’s property safety; and if national or sector standards for safeguarding the health and personal or property safety are available, . . . any unconformity to such standards”).

57. Thomas Scarlett, *The Relationship Among Adverse Drug Reaction Reporting, Drug Labeling, Product Liability, and Federal Preemption*, 46 FOOD DRUG COSM. L.J. 31, 32–33 (1991).

rejection from the licensing authority because their “all-inclusive” warning weakens the efficacy of the labeling by creating “information overload”.<sup>58</sup> Choosing the appropriate amount of information required by the law is not easy. Even when supplied with sufficient information, patients often lack specific knowledge about medicines necessary for adequate understanding of the risks. Moreover, it is doubtful whether doctors always read and possess all of the information required by the regulations.<sup>59</sup>

Although information regulation can address the problem of information asymmetries to some extent, it often cannot overcome the externalities arising from drug transactions. In particular, it cannot effectively deter doctors from choosing ineffective but safe drugs for their patients. Currently, the Chinese pharmaceutical market is dominated by the hospital sector, which accounts for 80 percent of all sales of pharmaceutical products. Only the remaining 20 percent reach consumers through retail pharmacies and local clinics.<sup>60</sup> To make profits from selling drugs, hospitals may have an incentive to simply prescribe safe drugs to patients without concern for their efficacy.

Third, simply relying on *ex post* quality standards to ensure the safety and efficacy of the drugs may be inadequate, even though these standards are widely applied within the Chinese pharmaceutical regulatory regime. The *2001 Drug Administration Law* established statutory standards, such as Good Laboratory Practice (“GLP”), Good Clinical Practice (“GCP”), and Good Supply Practice (“GSP”).<sup>61</sup> However, opportunistic manufacturers may violate these standards for extra profits if the probability of being caught is low. For example, in Sichuan Province, China, selective inspections in 1996, 1997 and 1998 showed that 24 percent of the tested products failed to satisfy national standards and posed potential threats to the public health.<sup>62</sup>

Due to the high social costs incurred by such opportunistic activities, lawmakers may prefer an *ex ante* licensing regime that checks drugs before they are marketed. Other advantages of the licensing regime are as

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58. Note, *supra* note 51, at 789–90. See also Michael A. MacCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 261 (2005).

59. See generally W. Benjamin Fisherow, *The Shape of Prescription Drug Advertising: A Survey of Promotional Techniques and Regulatory Trends*, 42 FOOD DRUG COSM. L.J. 213, 215 (1987).

60. Hengpeng Zhu, *Who Should Be Responsible for High Drug Prices in China?*, 3 REV. OF CHINESE HEALTH REF. 16, 17 (2008) (P.R.C.) (in Chinese), available at [http://www.chinahealthreform.org/attachments/313\\_healthreview080523-www.chinahealthreform.pdf](http://www.chinahealthreform.org/attachments/313_healthreview080523-www.chinahealthreform.pdf).

61. *2001 Drug Administration Law*, *supra* note 5, arts. 16, 30.

62. Ames Gross, *China Pharmaceutical Update*, PAC. BRIDGE MED., Nov. 1999, <http://www.pacificbridgemedical.com/publications/html/ChinaNov1999.htm>.

follows: (1) given the technological complexity of pharmaceutical products, a centralized licensing authority consisting of pharmaceutical experts has better information to determine drug quality than general medical practitioners and patients;<sup>63</sup> and (2) given the often substantial length of time between the drug's marketing and people's awareness of any drug-related injuries, *ex ante* licensing will be more effective than other regulatory techniques, such as quality standards and private law remedies, which operate *ex post* and rely mainly or heavily on the victims' complaints.<sup>64</sup>

### C. Are Multiple Levels of Licenses Justified?

As shown in Chart 1, the Chinese legislature has established nine levels of licensing to regulate the drug market. I will next analyze whether all the licenses in the multi-level regime are indispensable or whether lawmakers can eliminate some of the licensing requirements in order to improve the efficiency of the system as a whole.

#### 1. Licensing of Manufacturers, Wholesalers, and Retailers

The licensing of manufacturers places an *ex ante* control on manufacturers' capacities and production conditions to ensure the safety, efficacy, and quality of pharmaceutical products.<sup>65</sup> The Chinese government has recognized that the enforcement of *ex post* standards has been problematic,<sup>66</sup> and this may justify the use of the manufacturers' licenses to some extent. At the same time, the Chinese government may want to prevent repeated and wasteful investment in the pharmaceutical industry.<sup>67</sup> A licensing regime for manufacturing may be able to meet China's goals less expensively and more easily than other regulatory instruments, including *ex post* standards.

As far as wholesalers and retailers are concerned, their business conditions and activities—including their management system, channels of purchase, storage conditions, and employees' knowledge—play an important role in maintaining the quality and proper use of pharmaceutical products.<sup>68</sup> For example, poor storage conditions may easily

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63. ANTHONY OGUS, REGULATION: LEGAL FORM AND ECONOMIC THEORY 234 (Hart Publ'g 2004) (1994) ("the information necessary to determine [the products'] quality may be secured and assimilated more cheaply by a centralized agency").

64. *See id.*

65. 2001 Drug Administration Law, *supra* note 5, arts. 7–8.

66. *Id.* art. 8; SFDA Commentary, *supra* note 5, art. 8.

67. *See* 2001 Drug Administration Law, *supra* note 5, art. 7; SFDA Commentary, *supra* note 5, art. 7.

68. *See* 2001 Drug Administration Law, *supra* note 5, art. 15; SFDA Commentary, *supra* note 5, art. 15.

transform a good drug into a bad drug. Wholesalers and retailers are also responsible for providing customers with instructions for choosing drugs and dosages, both of which are crucial to preserving drug safety. Because the potential losses from opportunistic activities are tremendous and good enforcement of *ex post* standards cannot be guaranteed, the Chinese government may be justified in adopting a system of licensing for wholesalers and retailers. Furthermore, licensing might help the government to ensure drug access through the reasonable location of wholesalers and retailers.<sup>69</sup>

## 2. Licensing Requirements for the Approval of New Drugs

Before marketing a new drug in China, a manufacturer must consecutively obtain four licenses: a clinical test certificate, an NDC, a production permit number, and a test pass license.<sup>70</sup> This series of licenses is assumed to reduce the risk of people consuming ineffective or dangerous pharmaceutical products.<sup>71</sup>

By requiring a clinical test certificate, the Chinese government's main aim is to reduce risks to healthy human volunteers and patients who will participate in clinical trials.<sup>72</sup> However, some doubt exists as to the effectiveness and efficiency of this requirement in controlling these risks. "Many initial investigations on animals may prove of little or no value, given both the limited ability to extrapolate from them to [humans] and the variations in the effects of drugs on different animals and species."<sup>73</sup> Even if the initial investigations on animals are valuable, *ex post* standards in the pre-clinical research stage may be an appropriate alternative to the licensing requirement of the clinical test certificate because applicants have strong incentives to comply with these standards.

Here, the famous Becker model on law enforcement is applicable to understand applicants' incentives.<sup>74</sup> The model indicates that enforcement may be problematic if potential offenders feel that  $PD < U$ , where  $P$  is the potential offender's perceived probability of apprehension by a public agency and condemnation by the public,  $D$  represents the offender's perceived costs that would be imposed following apprehension and condemnation, and  $U$  denotes the offender's perceived benefits

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69. 2001 Drug Administration Law, *supra* note 5, art. 14.

70. *Id.* arts. 29, 31, 41.

71. *See id.* ch. 5; *SFDA Commentary*, *supra* note 5, ch. 5.

72. 2001 Drug Administration Law, *supra* note 5, art. 29; *SFDA Commentary*, *supra* note 5, art. 29.

73. Harvey Teff, *Drug Approval in England and the United States*, 33 AM. J. COMP. L. 567, 577 (1985).

74. *See* Gary S. Becker, *Crime and Punishment: An Economic Approach*, 76 J. POL. ECON. 169 *passim* (1968); *see also* Anthony Ogus & Carolyn Abbot, *Pollution and Penalties*, 20 RES. IN L. & ECON. 493, 502 (2002) (discussing use of the Becker model).

derived from the contravention. For new drug sponsors, *U* is low and *PD* is high. A potential market applicant would be unlikely to contravene *ex post* standards in pre-clinical research because the benefits of contravention (e.g., early marketing) cannot be realized until the applicant obtains a test pass license. Also, any contravention will, at least in theory, be discovered, thus depriving the sponsor of any opportunity for obtaining the NDC, the production permit number, or the test pass license. Even without the requirement of a clinical test certificate, the applicant is assumed to remain very cautious about transitioning from pre-clinical tests to clinical tests because reckless or opportunistic embarkations on clinical testing are likely to have serious consequences. Furthermore, without the requirement of a clinical test certificate, more resources from the SFDA would be available for regulating the new drug's clinical testing, controlling the risks more directly and perhaps more effectively.

In China, an NDC cannot be obtained unless the prospective new drug successfully passes clinical testing, expert evaluations, and technical verification.<sup>75</sup> Therefore, the licensing requirement can, in theory, ensure the safety and efficacy of a new drug. As far as the production permit number is concerned, it can be used to make sure that the successful applicant is a qualified manufacturer who has the ability to produce the new drug.<sup>76</sup> In practice, not every entity with a manufacturer's license has adequate staff, technology, and equipment to produce a new drug. Even qualified manufacturers may still produce some unsafe and ineffective new drugs that deviate greatly from original expectations and clinical research conclusions and thus their production permit number could be revoked even after the drugs are marketed.<sup>77</sup> Accordingly, the test pass license may be a final safety valve to prevent unsafe drugs from flowing into the market.

These arguments might be plausible at first glance; however, fewer licensing requirements may, at the very least, shorten the overall approval time, save administrative costs, and accelerate the market entry of a new drug. The delayed marketing of a new drug can impose huge costs on patients in urgent need of that drug. From this perspective, the replacement of the production permit number licensing requirement with an *ex post* standard regime may be more efficient since, in light of the above analysis, the test pass license can be used later to stop opportunistic activities on the part of manufacturers.

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75. 2001 Drug Administration Law, *supra* note 5, art. 29.

76. *Id.* art. 31; SFDA Commentary, *supra* note 5, art. 31.

77. Xiujuan Wang, *Understanding Production Permit Number*, 9 MED. & HEALTHCARE 52 (2004) (in Chinese).

### 3. Licensing of Advertising

Advertising control is very important in the pharmaceutical market because information is a key aspect of the business.<sup>78</sup> Competition within this market is mainly through product differentiation among branded drugs,<sup>79</sup> as opposed to price-cutting, so demand is inelastic to price.<sup>80</sup> Professor Stigler argues that producer advertising is equivalent to numerous searches by many consumers; it reduces price disparities and enhances competition.<sup>81</sup> Therefore, a restriction on advertising may reduce competition by increasing consumers' search costs.<sup>82</sup> However, misleading information in the pharmaceutical market can also impose huge costs on consumers. According to the SFDA, the advertising license was established to prevent or eliminate false or misleading advertisements and representations.<sup>83</sup> In China, only over-the-counter drugs are allowed to be advertised in the public media, including on television and in newspapers.<sup>84</sup> The *2001 Drug Administration Law* bans the advertising of prescription-only drugs in the public media and only allows medicinal and pharmaceutical journals that are jointly-appointed by the Health Authority under the State Council and the SFDA to carry such advertisements.<sup>85</sup> The advertising of prescription-only drugs is also subject to a licensing requirement.<sup>86</sup>

However, the rationale for the licensing of over-the-counter drug advertising remains open to question. *Ex post* standards may be more appropriate than licensing to control misleading claims by pharmaceutical advertisers, and the claimed advantage of licensing over *ex post* standards (i.e., better enforcement) may not be that significant. The probability of catching those who contravene *ex post* standards is very high, since the advertisement must be issued via the media. Also, few risks can be reduced or better prevented by *ex ante* licensing than *ex post*

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78. See J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L. REV. 1370, 1370 (1994).

79. Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of "Authorized Generics"*, 62 FOOD & DRUG L.J. 739, 754 (2007).

80. In China, even though the pharmaceutical market is dominated by generics, the demand is still considered to be inelastic to price. See Hengpeng Zhu, *Crazy Drug Price?*, <http://www.chinahealthreform.org/index.php/professor/zhuhengpeng/33-zhuhengpeng/282-2008-05-12-07-51-25.html>.

81. George J. Stigler, *The Economics of Information*, 69 J. POL. ECON. 220, 220–24 (1961).

82. Lee Benham & Alexandra Benham, *Regulating Through the Professions: A Perspective on Information Control*, 18 J.L. & ECON. 421, 422 (1975).

83. *2001 Drug Administration Law*, *supra* note 5, art. 60; *SFDA Commentary*, *supra* note 5, art. 60.

84. *2001 Drug Administration Law*, *supra* note 5, art. 60.

85. *Id.*

86. *See id.*

standards. Two reasons may exist for this: (1) over-the-counter drugs pose no significant side effects or toxicities;<sup>87</sup> and (2) even under the licensing regime, opportunistic advertisers can easily advertise their drugs without a license or revise the approved version of the advertisement in their favor.<sup>88</sup> However, an *ex ante* licensing regime may incur greater costs than *ex post* standards by limiting competition and hindering consumers' access to the most appropriate therapy.<sup>89</sup>

#### 4. Licensing of Imported Drugs

For the same reasons that new drugs are licensed, checking the quality, safety, and efficacy of imported drugs before they enter the Chinese market makes logical sense. The argument for licensing imported drugs is further supported by the fact that the SFDA has difficulty in enforcing *ex post* regulatory controls against foreign manufacturers outside its jurisdiction.

### III. LICENSING STANDARDS

Licensing standards refer to those conditions for compliance by any person conducting the licensed business or activity. "Entry standards" are those conditions that must be met before conducting the business or activity. Other conditions that require compliance while the business or activity is being conducted are referred to as "ongoing performance standards." Because this Article focuses on licensing requirements controlling market entry, and because entry standards for the RCID are almost the same as those for the NDC, this section will only discuss the entry standards for the manufacturer's license, trader's license, and NDC.

#### A. *Entry Standards for a Manufacturer's License*

In China, any applicant for a manufacturer's license must meet certain standards. First, the prospective pharmaceutical manufacturer must employ qualified pharmacists, engineers, and skilled workers.<sup>90</sup> It must also keep appropriate worksites and facilities, as well as a sanitary envi-

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87. Currently, only those drugs which have few side effects or toxicities can be classified as OTC drugs in China. *See id.* art. 60; *SFDA Commentary*, *supra* note 5, art. 60.

88. According to the SFDA, from January to August 2006, 91 percent of the drug advertisements in Chinese newspapers violated the licensing requirements for drug advertising, out of a total of 11,564 drug advertisements in 250 newspapers. *See* [http://www.gov.cn/jrzg/2006-10/24/content\\_422020.htm](http://www.gov.cn/jrzg/2006-10/24/content_422020.htm) (official central government website).

89. Beales, *supra* note 78, at 1392.

90. 2001 *Drug Administration Law*, *supra* note 5, arts. 7–8.



ronment suitable for pharmaceutical production.<sup>91</sup> In addition, the manufacturer must retain sufficiently competent staff, departments, and equipment to carry out quality control and monitoring.<sup>92</sup> Furthermore, it must establish a management system to check the quality of pharmaceutical products.<sup>93</sup> Finally, the formation of any new pharmaceutical manufacturer must be consistent with national development plans for the pharmaceutical industry and related industrial policies (“national plan standard”) in order to avoid repeated and wasteful developments.<sup>94</sup>

The safety, efficacy, and quality of drugs cannot be established just by testing a sample product but must be built into the product at all stages of production.<sup>95</sup> In order to guarantee those standards, a drug manufacturer needs adequate capacity, staff, and equipment, as well as an appropriately-structured management system to carry out its activities. In the pharmaceutical industry, the management system is referred to as Good Manufacturing Practice (“GMP”).<sup>96</sup> GMP is a quality management system for ensuring that products are consistently produced and controlled according to quality standards.<sup>97</sup> According to the World Health Organization:

GMP covers all aspects of production: from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process—every time a product is made.<sup>98</sup>

GMP is designed to minimize the risks of unsafe and ineffective drugs, risks that are involved in any pharmaceutical production and that cannot be eliminated solely by testing the final product.<sup>99</sup> Also, monitoring GMP

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91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. MEDICINES CONTROL AGENCY (MCA), U.K. DEP’T OF HEALTH, TOWARDS SAFE MEDICINES: A GUIDE TO THE CONTROL OF SAFETY, QUALITY AND EFFICACY OF HUMAN MEDICINES IN THE UNITED KINGDOM 32 (1997).

96. 2001 Drug Administration Law, *supra* note 5, art. 9; SFDA Commentary, *supra* note 5, art. 9.

97. WORLD HEALTH ORGANIZATION, WHO GOOD MANUFACTURING PRACTICES: MAIN PRINCIPLES FOR PHARMACEUTICAL PRODUCTS 7, 17 (2003), available at [http://whqlibdoc.who.int/publications/2004/9241546190\\_part1.pdf](http://whqlibdoc.who.int/publications/2004/9241546190_part1.pdf).

98. See Good Manufacturing Practices (GMP) WHO Training Workshops on Good Manufacturing Practices (GMP), [http://apps.who.int/prequal/trainingresources/Training\\_gmp\\_info.htm](http://apps.who.int/prequal/trainingresources/Training_gmp_info.htm) (last visited June 22, 2009).

99. *Id.*

may be a more efficient use of SFDA resources than checking samples of every final product. Generally speaking, it may not be difficult to justify the above entry standards concerning staff, equipment, capacity, and management system, which must be met to obtain a manufacturer's license.

As far as the national plan standard is concerned, this particular entry standard incorporates many residual aspects of planning mechanisms in China. Specifically, the government is reacting to criticism that too many pharmaceutical enterprises have been established in China without sufficiently advanced technology.<sup>100</sup> This constitutes unnecessary, repeated, and low-efficiency investments, thus wasting considerable state-owned resources.<sup>101</sup> The government hopes that the national plan standard can be used to control such investments.<sup>102</sup> Reliance on the national plan standard assumes that the licensing authority will have better information and expertise than the potential manufacturers to judge the likelihood of competitive advantages in the market. However, the relative superiority of a licensing authority, such as the National Development and Reform Commission or SFDA, is doubtful in this respect.

Another possible reason for this entry standard may be that state-owned manufacturers are not motivated to pursue maximum profits in the long run and are thus likely to make low-efficiency investments. Currently and generally, Chinese bureaucrats have the right to decide whether and how to invest in a state-owned enterprise and to appoint its managers.<sup>103</sup> Once bureaucrats perceive a personal interest, including greater prestige or power, in forming a pharmaceutical enterprise, they may be tempted to do so even if they realize that the enterprise may not be profitable after their term of office. Given that the Chinese pharmaceutical industry is still a hybrid of the old state-planned system and modern market-oriented forces,<sup>104</sup> it seems appropriate to limit the use of the national plan standard to state-owned applicants. When applied to all manufacturers, the national plan standard may be used by the licensing authority to protect incumbent manufacturers from competition with prospective entrants or to favor state-owned applicants over private applicants.

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100. See 2001 Drug Administration Law, *supra* note 5, art. 7; SFDA Commentary, *supra* note 5, art. 7.

101. See 2001 Drug Administration Law, *supra* note 5, art. 7; SFDA Commentary, *supra* note 5, art. 7.

102. See 2001 Drug Administration Law, *supra* note 5, art. 7; SFDA Commentary, *supra* note 5, art. 7.

103. Joel R. Samuels, Comment, "Tain't What You Do": Effect of China's Proposed Anti-Monopoly Law on State Owned Enterprises, 26 PENN ST. INT'L L. REV. 169, 189 (2007).

104. HONGBING MA, DRUG MANUFACTURERS RAISE THRESHOLDS OF THE MARKET BY CRM (2003), available at <http://www.ctiforum.com/technology/CRM/2003/08/crm0810.htm>.

### B. Entry Standards for a Trader's License

Any applicant for a trader's license (e.g., a wholesaler's or retailer's license) must have qualified pharmacists, suitable business places, appropriate equipment and storage facilities, a sanitary environment, competent quality control staff and departments, and appropriate management systems.<sup>105</sup> These entry standards serve regulatory goals by addressing information problems and relevant externalities. In addition, when deciding whether to issue a trader's license to an applicant, the SFDA considers another criterion: the reasonable location of pharmacies for convenient drug purchases ("reasonable location standard").<sup>106</sup> To apply the reasonable location standard, the SFDA has enumerated factors it considers in evaluating an application. For example, the SFDA analyzes the local population, territory, transport conditions, and real demand for drugs when deciding whether to grant a retailer's license.<sup>107</sup>

Theoretically, and unlike the other entry standards mentioned, the reasonable location standard was not designed to solve market failures in the pharmaceutical sector. Nevertheless, it seems to solve the so-called "cream-skimming"<sup>108</sup> problem. That is, suppliers concentrate on those areas of the market where the costs of supply are lowest, whether for geographical or other reasons.<sup>109</sup> Because the Chinese pharmaceutical market is highly regulated and the government exercises *de facto* control of drug prices,<sup>110</sup> many pharmaceutical retailers may be unwilling to supply drugs to poor or remote areas where costs of supply are higher.

In order to solve this problem, the Chinese government has committed to developing a rural distribution network for pharmaceutical products.<sup>111</sup> In poor or remote areas, a pharmacy may be staffed by senior middle school graduates provided that they have received some training and passed the examinations organized by the SFDA or its branches.<sup>112</sup> In light of this, the reasonable location standard implies a relaxation of other entry standards, such as the competence of pharmacy staff, in order

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105. 2001 Drug Administration Law, *supra* note 5, art. 15.

106. *Id.* art. 14.

107. Regulations for Implementation of the Drug Administration Law (promulgated by the State Council, Aug. 4, 2002, effective Sept. 15, 2002) art. 12 (P.R.C.) [hereinafter Pharmaceutical Implementing Regulation]; *see also* Regulation of Drug Trader's License (promulgated by the SFDA, Feb. 4, 2004, effective Apr. 1, 2004) art. 5 (P.R.C.), available at <http://www.sfda.gov.cn/WS01/CL0053/24476.html>.

108. OGUS, *supra* note 63, at 32.

109. *Id.*

110. 2001 Drug Administration Law, *supra* note 5, arts. 55–56.

111. *Id.* art. 14; SFDA Commentary, *supra* note 5, art. 14.

112. 2001 Drug Administration Law, *supra* note 5, art. 14; Pharmaceutical Implementing Regulation, *supra* note 107, art. 15; Regulation of Drug Trader's License, *supra* note 107, art. 5; SFDA Commentary, *supra* note 5, art. 14.

to encourage the supply of drugs to poor and remote areas. However, this entry standard relaxation is probably not the best solution to cream-skimming because it involves other costs. For example, poorly educated pharmacy workers may lead to great risks to consumers' health. Alternative solutions, including publicly financed subsidies, may better address the cream-skimming problem.<sup>113</sup>

Another concern is that the reasonable location standard may be used to reject applications. According to an official opinion of the SFDA:

At present, there are many drug traders that are organized in small sizes and unreasonable structures. It is one of the major problems which may hinder good development of the medical economy . . . therefore, it is crucial to apply the reasonable location standard to evaluate every application for a drug trader's license . . . . [A]ll branches of the SFDA should . . . encourage drug traders to become larger and exclude disadvantaged traders from the market.<sup>114</sup>

This official opinion is not always clear, particularly regarding such terms as "unreasonable structure" and "disadvantaged traders"; however, it does indicate that the SFDA does not favor too many traders, especially if they are small in size.

Here is an example for further contemplation of the reasonable location standard: suppose that a branch of the SFDA concludes that a particular community only needs two pharmacies after considering its population, transport conditions, and real demand for drugs; it issues two retailer's licenses in this community. Should it grant more retailer's licenses to small traders in this community? If the answer is no, we will have to consider any negative effects caused by this direct numerical limitation. The costs of limiting competition are not trivial, especially when small drug retailers are very flexible in meeting consumer demand.<sup>115</sup> The more significant question is whether the branch of the SFDA has sufficient information and expertise to choose the numerical limitation. From this aspect, free market forces often provide a better solution than a licensing authority.

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113. 2 ALFRED E. KAHN, *THE ECONOMICS OF REGULATION: PRINCIPLES AND INSTITUTIONS* 235 (1971).

114. State Food & Drug Admin., *A Notice Concerning Several Problems in Implementing the Regulation of Drug Traders' Licenses* (Apr. 29, 2004) (P.R.C.), available at <http://www.sfda.gov.cn/WS01/CL0055/10115.html>.

115. Lingzhi Zhu, *The Future of Community Pharmacy After Deregulating the Retail Market*, <http://health.sohu.com/20071128/n253659975.shtml> (last visited June 14, 2009).

Some entities will benefit from the use of the reasonable location standard, but the standard allows too much discretion to the SFDA and its branches. Discretion can fetch more power, prestige, funding, and even opportunities for bureaucratic corruption. Additionally, discretion as to this standard is likely to be used to limit competition, to the considerable benefit of existing drug traders and large state-owned applicants, and at the expense of new entrants and small drug traders.

### *C. Entry Standards for a New Drug Certificate*

The *2001 Drug Administration Law* and its implementing regulations do not provide precise entry standards for granting an NDC. According to Article 29 of the *2001 Drug Administration Law*, “. . . after an applicant completes clinical tests on the prospective new drug and gets this process or data verified by the SFDA, it shall be issued an NDC by the SFDA.”<sup>116</sup> No standards for verification are indicated. However, an official commentary on Article 29 of the SFDA states that “in order to ensure the quality, safety, and efficacy of a new drug, it is necessary to regulate new drug research and establish licensing rules. That is the purpose of this Article.”<sup>117</sup> Furthermore, the SFDA declares that it should evaluate prospective new drugs for safety, efficacy and the controllability of quality when deciding whether to grant an NDC.<sup>118</sup> Both the SFDA commentary and declaration imply that the entry standards for an NDC could be safety, efficacy, and quality or “quality controllability.” There are no further official explanations of these three entry standards. Literally speaking, “safety” is opposed to potential or actual harmful effects. “Efficacy” relates to the beneficial effect of the medicine on the patient or, in other words, “Does it work?” Finally, “quality” seems to relate to stability and control in the process of drug development and manufacturing.

In order to facilitate the application of these three entry standards, some further parameters have been developed. To prove the safety, efficacy, and quality of its prospective new drug, an applicant must ensure that the drug has passed laboratory and clinical tests and has then been properly manufactured.<sup>119</sup> These tests and manufacturing activities are governed by GLP, GCP, and GMP.<sup>120</sup>

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116. *2001 Drug Administration Law*, *supra* note 5, art. 29.

117. *SFDA Commentary*, *supra* note 5, art. 29.

118. Provisions for Drug Registration, Order No. 28 (promulgated by the SFDA, July 10, 2007, effective Oct. 1, 2007) art. 3 (P.R.C.), *available at* <http://eng.sfda.gov.cn/cmsweb/webportal/W45649039/A64028429.html> [hereinafter Provisions for Drug Registration].

119. *Id.* ch. 4.

120. “Good Laboratory Practice,” “Good Clinical Practice,” and “Good Manufacturing Practice,” respectively.

Like the previously-discussed GMP, both GLP and GCP are quality management systems. GLP provides the organizational process and the conditions under which laboratory studies (including non-clinical health and environmental safety studies) are “planned, performed, monitored, recorded, archived and reported.”<sup>121</sup> “These studies are undertaken to generate data [about] the hazards and risks to users, consumers and third parties, including the environment.”<sup>122</sup> GLP helps the licensing authority verify that the data submitted truly reflect the results obtained during the studies and can therefore be relied upon when making risk and safety assessments.<sup>123</sup>

The GCP sets ethical and scientific quality standards for “designing, conducting, recording, and reporting clinical trials that involve the participation of human subjects.”<sup>124</sup> Compliance with these standards will ensure that the rights, safety and well-being of trial subjects are secured and that the clinical trial data are credible.<sup>125</sup> Obviously, these quality management systems save the SFDA a great deal of information-gathering and monitoring costs in assessing applicants’ laboratory and clinical trials. Furthermore, they reduce the possibility of unsafe and ineffective drugs being approved to enter the market, therefore reducing larger social costs.

#### IV. LICENSING (ENTRY) PROCEDURES

This section focuses on licensing procedures for the NDC and RCID for two reasons. First, the licensing procedures for a manufacturer’s license, a trader’s license, a clinical test certificate, a production permit number, or an advertising license are simpler than the procedures for an NDC or RCID. Second, if the licensing procedures are divided into several individual steps, almost every step of the licensing procedures used for a manufacturer’s license, a trader’s license, a clinical test certificate, a production permit number, or an advertising license has its counterpart in those procedures for an NDC or RCID.

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121. ORG. FOR ECON. CO-OPERATION & DEV. (OECD), OECD PRINCIPLES OF GOOD LABORATORY PRACTICE 14 (1998), available at [http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/NT00000C5A/\\$FILE/01E88455.PDF](http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/NT00000C5A/$FILE/01E88455.PDF).

122. MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA), UK DEP’T OF HEALTH, GOOD LABORATORY PRACTICE (2009) <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodLaboratoryPractice/CON009680>.

123. *Id.*

124. INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH), GUIDANCE FOR INDUSTRY: E6 GOOD CLINICAL PRACTICE: CONSOLIDATED GUIDANCE 1 (1996), available at <http://www.fda.gov/cder/guidance/959fn1.pdf>.

125. *Id.*

### A. Licensing Procedures for a New Drug Certificate

First, a sponsor applies to a provincial branch of the SFDA by submitting clinical data and other supporting documents.<sup>126</sup> At the same time, the applicant must supply the data and raw materials needed to make standard substances to the National Institute for the Control of Pharmaceutical and Biological Products (“NICPBP”).<sup>127</sup>

Second, the provincial branch of the SFDA shall, within 5 days from the date it receives an application, check the format of the dossiers and make a decision whether to accept it.<sup>128</sup>

Third, if the provincial branch of the SFDA decides to accept the application, it shall, within 5 days from the date of acceptance, prepare to conduct an on-site inspection, perform a preliminary evaluation of the submitted dossiers, and provide review opinions. The branch shall deliver its opinions, inspection reports and application dossiers to the Center for Drug Evaluation (“CDE”) of the SFDA within 30 days from the date of acceptance.<sup>129</sup> By that same deadline, the branch shall also draw samples and notify the appointed testing institute to conduct tests for drug registration. The testing institution shall verify the sample and its claimed standards, and then give its reports to the CDE within 60 days.<sup>130</sup>

Fourth, after receiving the dossiers from the provincial branch, the CDE shall organize pharmaceutical, medical and other technical personnel to conduct a technical assessment, which is to be completed within 150 days, or 120 days when the special approval procedure applies.<sup>131</sup> During the technical assessment, if necessary, the CDE may request the applicant to supply additional data.<sup>132</sup> The applicant must supply the requested information in one submission within four months; otherwise, its application will be returned as invalid.<sup>133</sup> The CDE must finish assessing the additional data within 50 days, or 30 days when the special approval procedure applies. If the technical assessment fails to support the application, the CDE will report to the SFDA, and the application will be rejected by the SFDA accordingly. When the technical assessment supports the application, the CDE will invite the applicant to apply for an inspection at the plant site.<sup>134</sup>

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126. Provisions for Drug Registration, *supra* note 118, art. 56.

127. *Id.*

128. *Id.* arts. 57, 147.

129. *Id.* art. 148.

130. *Id.* arts. 59, 149.

131. *Id.* arts. 60, 150(2).

132. *Id.* art. 60.

133. *Id.* arts. 151, 154.

134. *Id.* art. 60.

Fifth, the applicant must, within six months after receiving the invitation, apply to the Drug Certification Center (DCC) of the SFDA for an on-site inspection.<sup>135</sup> The DCC shall, within 30 days after receiving the application, conduct the on-site inspection, verify the applicability of the manufacturing processes and take samples, all at the same time.<sup>136</sup> It shall provide a report to the CDE within ten days after the inspection. An appointed testing institute will test the new samples and report its conclusion to the CDE.<sup>137</sup>

Sixth, the CDE shall make suggestions based upon the technical assessment, on-site inspection report, and sample testing. Acting on these suggestions, the SFDA will decide whether to grant the NDC to the applicant either within 20 days or, alternatively, within 30 days if the chief of the SFDA agrees to this extension.<sup>138</sup>

Seventh, once the SFDA decides to grant the NDC, the agency shall issue and deliver it to the applicant within 10 days. If the SFDA refuses to grant the NDC, the applicant can apply for a review within 60 days of receipt of the SFDA's decision.<sup>139</sup> The SFDA shall complete the review and make a decision within 50 days of receipt of the application.<sup>140</sup>

Chart 2 describes the licensing procedures in detail:<sup>141</sup>

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135. *Id.* art. 61.

136. *Id.* art. 62.

137. *Id.*

138. *Id.* art. 152.

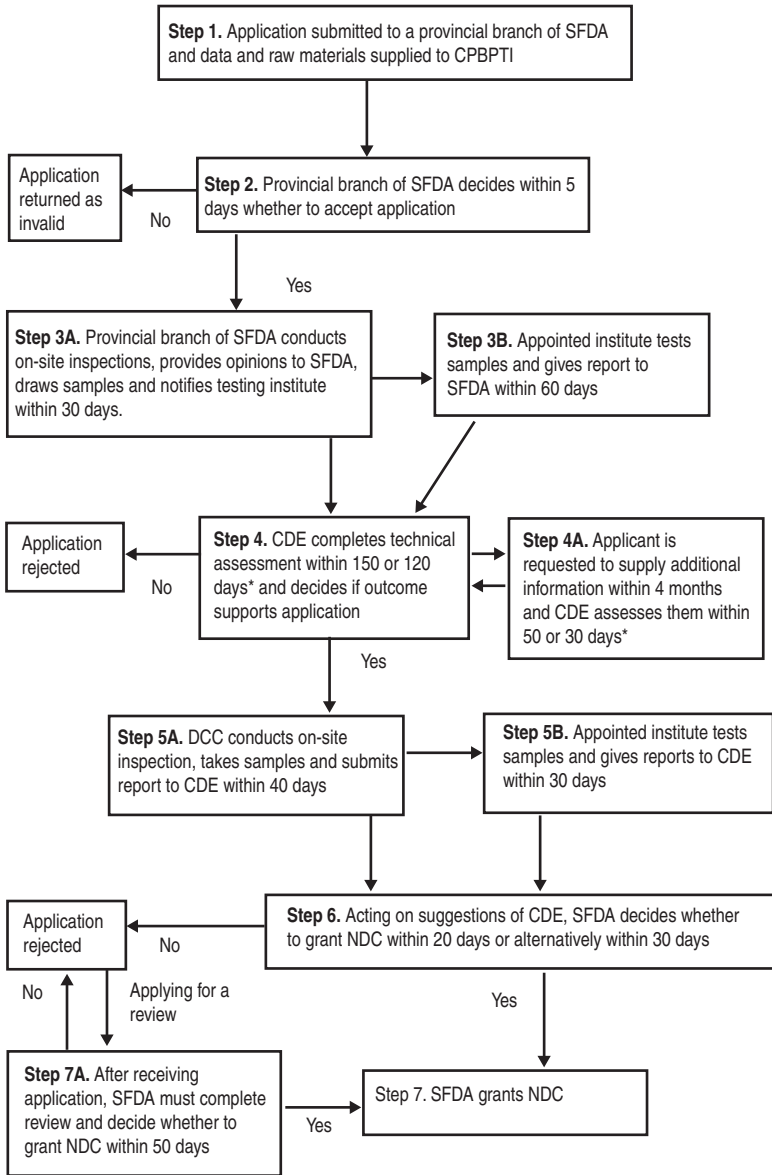
139. *Id.* art. 156.

140. *Id.* art. 157.

141. *Id.* arts. 45, 56–59, 148–151, 153.



CHART 2:



Note: The shorter time limits marked as "\*" apply to the special approval procedure

*B. Licensing Procedures for Registration Certification of Imported Drugs*

Generally speaking, the licensing procedures for an RCID are similar to those for a new domestic drug sponsor to obtain a CTC and an

NDC.<sup>142</sup> This similarity demonstrates that China has adopted an approach similar to many other developed countries, such as the United States, where the importation of drugs is generally subject to the same controls as the marketing of domestic drugs.<sup>143</sup> For convenience, I refer to this approach as the “reassessment procedure.”

In contrast, other countries adopt an alternative approach to the reassessment procedure: developing countries in particular “tend to be guided by registration decisions made in the country where the drug is manufactured or in countries where the drug is used.”<sup>144</sup> Under this approach, the importing countries base their licensing decisions on the information supplied by the licensing authority in the exporting countries concerning the safety, efficacy and quality of the drugs, rather than on clinical trials or other tests carried out in the importing countries. I refer to this approach as the “recognition procedure.” A typical example of the recognition procedure is the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.<sup>145</sup> Another example is the harmonization and mutual recognition of drug licensing decision-making among EU member states.<sup>146</sup>

Because China has adopted the reassessment procedure, the analyses regarding licensing procedures to obtain an NDC can also be generally regarded as applying to the procedures to obtain an RCID. My analysis

142. RCIDs and NDCs have two main distinctions. First, for imported drugs, the SFDA is responsible for the initial inspection of the application, supporting documents, data, and samples; and the China Pharmaceutical Biological Products Testing Institute or an appointed testing institute initially examines the samples and issues a report. In contrast, for new domestic drugs, a provincial branch of the SFDA is responsible for the initial inspection of the application, and its appointed testing institution initially examines the samples and issues a report. Second, unlike imported drugs, new domestic drugs are subject to a second on-site inspection and sample test organized by the DCC of the SFDA.

143. See *2001 Drug Administration Law*, *supra* note 5, art. 39; *SFDA Commentary*, *supra* note 5, art. 39.

144. D. C. JAYASURIYA, *REGULATION OF PHARMACEUTICALS IN DEVELOPING COUNTRIES: LEGAL ISSUES AND APPROACHES* 55 (WTO 1985).

145. “The WHO certification scheme is an international voluntary agreement, devised to enable countries with limited drug regulatory capacity to obtain partial assurance from the exporting countries concerning the safety, quality and efficacy of the products they plan to import. The voluntary agreement requires that the regulatory authorities of exporting countries issue Certificates when requested by the importing countries . . . [The Certificate at least can attest] whether a specific product is approved for use in the exporting country, or if not, why not.” WORLD HEALTH ORGANIZATION, *WHO CERTIFICATION SCHEME ON THE QUALITY OF PHARMACEUTICAL PRODUCTS MOVING IN INTERNATIONAL COMMERCE* (2000), available at [http://whqlibdoc.who.int/hq/2000/WHO\\_EDM\\_QSM\\_2000.2.pdf](http://whqlibdoc.who.int/hq/2000/WHO_EDM_QSM_2000.2.pdf). At present, China has not participated in the WHO certification scheme.

146. See generally John Abraham & Graham Lewis, *Europeanization of Medicines Regulation*, in *REGULATION OF THE PHARMACEUTICAL INDUSTRY* 42, 42 (John Abraham & Helen Lawton Smith eds., 2003).

of the licensing procedures for an RCID will therefore be limited to a comparison of reassessment procedures and recognition procedures in order to determine their advantages and disadvantages.

### C. *Some General Analyses*

From an economic perspective, a procedural system aims to minimize two kinds of costs; in particular, erroneous judicial decisions and operations of the procedural system.<sup>147</sup> Although the above principle was originally presented by Judge Posner to explain civil and criminal procedure, it applies to licensing procedures as well. For analytical purposes, I consider the cost of operating the licensing system (“administrative costs”) and the system’s function of reducing the costs resulting from erroneous licensing decisions (“error costs”). Accordingly, the goal of every licensing procedural requirement should be to minimize the sum of the error costs and the administrative costs.

There are two sources of errors that can be made in the licensing process: Type 1 errors (the licensing authority grants a license to an applicant who should have been rejected) and Type 2 errors (the licensing authority rejects an applicant who should have been granted a license). Type 1 errors in drug licensing decisions result in costs to public health and clinical trial subjects. These costs can easily be identified from subject or patient injuries and deaths, as well as the related costs imposed on the government and judicial system. In contrast, the costs caused by Type 2 errors in drug licensing decisions generally include: (1) health losses to patients who need the drug—their inability to access the potentially better treatment can have relatively adverse health effects;<sup>148</sup> (2) financial losses, including investments and expected profits, to the research sponsors and drug manufacturers; and (3) socioeconomic losses arising from limited innovation and competition—consumers may have to pay higher prices for existing drugs without the new drug on the market.

Type 1 error costs are much more obvious to the public than Type 2 error costs. “[M]embers of the public do not always take the same approach to risks as experts, and in consequence they may attribute a higher value” to Type 1 error costs than Type 2 error costs, which might not be objectively justified.<sup>149</sup> When faced with public pressure, the government may be easily influenced by the very same biases and errors as

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147. RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 599 (5th ed. 1998).

148. GRABOWSKI & VERNON, *supra* note 44, at 10.

149. Ogus & Zhang, *supra* note 40, at 135; *see also* Roger G. Noll & James E. Krier, *Some Implications of Cognitive Psychology for Risk Regulation*, in *BEHAVIORAL LAW AND ECONOMICS* 325 *passim* (Cass R. Sunstein ed., 2000).

lay persons.<sup>150</sup> This will lead the government, and hence the licensing authority, to pay more attention to Type 1 errors than to Type 2 errors. Large pre-existing drug manufacturers may also exploit this bias to limit competition from prospective market entrants. A licensing authority will risk very little by refusing to grant a license, but risk a great deal if it approves a drug like thalidomide.<sup>151</sup> In other words, an official of the SFDA may have to bear heavy personal costs if he approves a drug that is subsequently proven not to be safe. However, if the official rejects a good drug, he is rarely held responsible because the costs of rejection are much less visible than those of Type 1 errors and are borne largely by other parties.<sup>152</sup> Since licensing officials are prone to making Type 2 errors, more procedural controls, such as hearings and appeals, must be available to applicants at a lower cost to correct Type 2 errors.

In addition to the error costs associated with licensing decisions, the delay costs, as a kind of administrative cost, are significant in the case of the drug licensing process. Delay costs include the losses experienced by patients, research sponsors, drug manufacturers and the general public. Those patients who need a treatment or just a better treatment will suffer more because the drug's marketing is delayed. Some patients who die might have survived if a particular drug had arrived on the market earlier. Meanwhile, the research sponsors and drug manufacturers will inevitably lose revenue due to the late arrival of their new drug. Finally, the public will be disadvantaged because the delayed approval of a new drug drives up entry costs and hence limits competition to a greater extent.

#### D. *Selective Analyses of Individual Licensing Procedures*

As shown earlier, Chinese licensing procedures for an NDC and an RCID has several steps. The analysis below will focus on some of the steps that characterize drug licensing procedures.

##### 1. Procedure of Technical Assessment

The drug licensing procedures rely a great deal on the technical assessment.<sup>153</sup> The *2001 Drug Administration Law* requires the SFDA to organize health and medical professionals, as well as other technicians,

150. Christine Jolls, Cass R. Sunstein & Richard H. Thaler, *A Behavioral Approach to Law and Economics*, in *BEHAVIORAL LAW AND ECONOMICS*, *supra* note 149, at 13, 48.

151. Teff, *supra* note 73, at 591. The 1961 thalidomide disaster attracted considerable attention to the error costs arising from licensing decisions concerning pharmaceutical products.

152. GRABOWSKI & VERNON, *supra* note 44, at 10–12.

153. See, e.g., *supra* Chart 2, steps 4, 4A.

to perform technical assessments for all new drug applications.<sup>154</sup> Given the unique nature of pharmaceutical products, the SFDA usually does not have adequate expertise to assess the applications by itself. Instead, it has to base its licensing decisions on technical assessments made by a professional body in order to ensure that its decisions are scientifically justified. These professional technical assessments probably reduce the error costs of licensing decisions more effectively than would assessments by the SFDA itself. Moreover, the technical assessments must be based on a set of technical standards or norms.<sup>155</sup> These norms must be indicated in the licensing decision, thus effectively increasing the accountability of the decision and reducing the relevant error costs.<sup>156</sup>

It may also be reasonably concluded that the professional assessor's growing independence from government may decrease the hazards of political interference and encourage more open decision-making.<sup>157</sup> On the other hand, the procedural arrangement for the professional assessment can, to a large extent, shield the SFDA from criticism if erroneous licensing decisions cause great harm to society. In such a case, the professional assessor, rather than the licensing authority, will bear the brunt of the criticism.<sup>158</sup>

In China, the SFDA has established a subordinate institute, the CDE, and also arranged a back-up list of outside experts to perform assessments.<sup>159</sup> The CDE is not a governmental agency and its staff members are not civil servants.<sup>160</sup> Theoretically, the scheme should ensure that their technical assessments are independent from the SFDA's influence, at least for short-term political purposes. In fact, since the SFDA influences its budget and personnel, the CDE may have difficulty maintaining its independence.

The outside experts are more likely than the CDE to stay independent from the SFDA. Most of them are highly respected scientists from academia or industry. However, use of these outside experts is probably more expensive for the SFDA than simply relying on the CDE. Outside experts are justified only when the additional reduction of error costs

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154. 2001 Drug Administration Law, *supra* note 5, art. 33.

155. See, e.g., Provisions for Drug Registration, *supra* note 118, arts. 59, 60.

156. Administrative License Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Aug. 27, 2003, effective July 1, 2004) art. 55 (P.R.C.), available at <http://www.asianlii.org/cn/legis/cen/laws/allotproc500/>.

157. OGUS, *supra* note 63, at 105–06.

158. *Id.*; see also William Bishop, *A Theory of Administrative Law*, 19 J. LEGAL STUD. 489, 500 (1990).

159. 2001 Drug Administration Law, *supra* note 5, art. 33; SFDA Commentary, *supra* note 5, art. 33.

160. See Center for Drug Evaluation, SFDA, <http://www.cde.org.cn> (last visited Mar. 5, 2005) (P.R.C.).

exceeds the additional administrative costs incurred. Certainly, outside experts cannot be guaranteed to always reach an unbiased conclusion because most of them have close relationship with the pharmaceutical industry. According to the *2001 Drug Administration Law* and its official commentary, the SFDA should abolish its former arrangement of having an expert committee with fixed members and replace it with a list of outside experts.<sup>161</sup> The commentary explains that a fixed committee cannot always be competent to handle all technical assessments and may even lead to corruption.<sup>162</sup> Due to the different cultural and political environment, the outside experts' independence from the SFDA is not as great as that of their counterparts in western countries.

## 2. Dual Levels of On-Site Inspections and Sample Tests

As shown in Chart 2, two on-site inspections are conducted: the first by a provincial branch of the SFDA, and the second by the DCC of the SFDA.<sup>163</sup> Both draw samples and appoint an institute for testing,<sup>164</sup> but the additional on-site inspection by the DCC and the subsequent sample tests are intended to reduce the possibility of the sponsor submitting a false dossiers and samples.<sup>165</sup> To some extent, this implies that the SFDA does not always trust the ability of the provincial branches and their appointed institutes to verify the dossiers and samples and, therefore, makes arrangements with the DCC to double check their work. However, the efficiency of maintaining this dual level of inspections and tests for the purpose of reducing error costs is worth analyzing. If the DCC has more advanced facilities and more competent technicians, the provincial branch inspections and sample tests are more difficult to justify. The system may reflect the private interests of Chinese bureaucrats, as this procedural arrangement allows the staff at the provincial branch, the DCC and their affiliated testing institutes to secure their employment with fewer problems and perhaps even more opportunities for corrupt practices.

## 3. Procedure for Supplying Additional Information

The procedure for supplying additional information for the technical assessment gives applicants an opportunity to further influence decision-

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161. *2001 Drug Administration Law*, *supra* note 5, art. 33; *SFDA Commentary*, *supra* note 5, art. 33.

162. *SFDA Commentary*, *supra* note 5, art. 33.

163. *See supra* Chart 2, steps 3A, 5A.

164. *See id.* steps 3B, 5B.

165. Zheng Wu, *What Is New for the New Drug Registration Regulation?*, July 12, 2007, [http://www.gov.cn/jrzg/2007-07/12/content\\_681311.htm](http://www.gov.cn/jrzg/2007-07/12/content_681311.htm).

making.<sup>166</sup> This procedural control not only reduces the error costs in relation to licensing decisions, but also saves considerable administrative costs by not requiring a new application and thus accelerating the new drug's approval for market. Chinese law allows only the SFDA to initiate this procedure.<sup>167</sup> Applicants are not allowed to supply additional technical information during the assessment on their own initiative, unless the information concerns a new discovery about the safety of the drug or the special approval procedure applies.<sup>168</sup> Otherwise, if an applicant believes the additional information is absolutely necessary, it should withdraw the original application and begin a new application.<sup>169</sup>

Why does Chinese law set a limit on the applicant's right to supply additional information? One explanation is that, without the statutory limitation, many applicants may adopt a strategy of hurrying to begin an application with insufficient information and planning to supply the missing information in the future. If that happened, many applications would be of little value but would still occupy the time and resources of the SFDA. However, this result is far from guaranteed. At least some applicants may often be reluctant to submit an unpromising application because they, too, pay considerable administrative costs for it. And they may be unwilling to generate a poor reputation with the SFDA from this application.<sup>170</sup> Moreover, even without this limitation, a short statutory time limit (four months) to provide additional information complicates an already risky application strategy.<sup>171</sup>

As licensing officials have less motivation to avoid Type 2 errors, there is accordingly reason to doubt that the SFDA has sufficient incentive to initiate the procedure for supplying additional information, since the main aim of this procedure is to address Type 2 errors.<sup>172</sup> From that perspective, allowing the applicant to initiate this procedure may be more efficient. Administrative costs would likely rise, but the SFDA may be able to reduce more error costs or delay costs than those in the current arrangement. This desire to save administrative costs at the cost of applicants and the public could explain the limitations on the SFDA's incentive to supply additional information.

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166. See *supra* Chart 2, step 4A.

167. See Provisions for Drug Registration, *supra* note 118, art. 49.

168. *Id.*

169. *Id.*

170. At a press conference on August 8, 2007, the SFDA declared its intention to use a blacklist for monitoring those enterprises with bad reputations. See Cheng Wang, *The SFDA Will Set Up a Blacklist*, <http://life.people.com.cn/GB/1089/6090163.html> (last visited June 14, 2009).

171. See Provisions for Drug Registration, *supra* note 118, arts. 151, 154.

172. The licensing authority may find it less costly to reject the application than to request additional information from the applicant.

#### 4. Special Approval Procedure

The special approval procedure stipulates shorter time limits for the SFDA to approve an NDC application,<sup>173</sup> and can, at most, save 50 working days from the approval process.<sup>174</sup> As a general principle, the Chinese government encourages innovation in new drugs and applies the special approval procedure to original new drugs or new drugs that treat serious, complicated or fatal diseases.<sup>175</sup> Specifically, the SFDA may apply the special approval procedure to applications for the following: (1) active ingredients and their pharmaceutical preparations made from any plant, animal, mineral, or other raw material, including newly-discovered crude herb medicines and their preparations, provided that they have not been previously marketed in China; (2) chemicals, preparations containing such chemicals, and biotechnology products, provided that they have not been authorized for marketing in China or any other country; (3) new drugs used to diagnose, treat, or prevent AIDS, or to treat malignant tumors or rare diseases; and (4) new drugs used to treat diseases without effective cures.<sup>176</sup> Upon receipt of an application that qualifies for the special approval procedure, the CDE will arrange an expert committee to make a decision.<sup>177</sup>

The special approval procedure may be reasonably justified if the reduction in delay costs exceeds the potential increase in errors and other administrative costs. The third and fourth categories of drugs are usually urgently needed to treat patients with serious or life-threatening conditions. Even though a universal schedule would result in similar approval time for all drugs, a longer approval process for those categories would entail much greater delay costs. Therefore, in order to reduce these significant delay costs, use of the special approval procedure is normally justified. However, adoption of the special approval process may be inappropriate with respect to the first and second categories of drugs because the normal approval process will not generate delay costs as great as those for the third and fourth categories of drugs. If Chinese lawmakers aim to encourage innovation with the adoption of the special approval process for the first and second categories of drugs, they must also be aware of the possibility of increased error costs due to the shorter time period for the SFDA to make decisions. In fact, Chinese lawmakers can rely on patent law and other regulatory arrangements to encourage innovation with reduced social costs. A more precise analysis of this

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173. See *supra* Chart 2, steps 4, 4A.

174. See Provisions for Drug Registration, *supra* note 118, arts. 45, 150–51.

175. *Id.* art. 4.

176. *Id.* art. 45.

177. *Id.*



process should also take into account the delay costs imposed on other drug applications that are not processed via the special approval procedure. Due to limited governmental resources, the special approval of some drugs usually implies delays on other drug approvals.

The special approval procedure functions not only as a fast track for drug approval, but also creates a window for communication between the applicant and the SFDA. If the special approval procedure applies, the applicant can freely supply additional technical information during the assessment, and the licensing officials of the SFDA can provide feedback and guidance for the applicant's research.<sup>178</sup> This arrangement will reduce error and delay costs even though it may increase some administrative costs for the SFDA.

### 5. Review Procedure

The Drug Registration Regulation entitles applicants to apply for a review if they are dissatisfied with the SFDA's refusal to grant a license.<sup>179</sup> Applicants should apply for a review within 60 days of receipt of the SFDA's decision.<sup>180</sup> The SFDA should complete the review and make a decision within 50 days of receipt of the application.<sup>181</sup> However, if the review requires a technical assessment, then the time limits on the technical assessment in the original application should be applied.<sup>182</sup> Under the review procedure, the SFDA acts as both the original decision-maker and the appellate body. For the sake of its own reputation, it may have a disincentive to reconsider or correct its formal decision even if that decision is wrong. As indicated before, the Type 2 error costs are usually externalized to all of society. Error costs would undergo greater reductions if the applicants rejected by the SFDA were entitled to appeal to an external body consisting of independent experts.

### 6. The Time Limit

Perhaps in order to deal with delay costs, the SFDA is obligated by a number of statutory time limits. For example, the SFDA must determine whether to grant an NDC within 20 days of receiving the suggestions of the CDE.<sup>183</sup> This type of procedural control does not necessarily increase administrative costs. In many cases, it can even reduce them by pushing the SFDA to improve its efficiency. However, in some cases, the SFDA

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178. Wu, *supra* note 165.

179. Provisions for Drug Registration, *supra* note 118, art. 156.

180. *Id.*

181. *Id.* art. 157.

182. *Id.* art. 158.

183. *Id.* art. 152.

may have to increase its budget or staff in order to meet deadlines. The time limits, if designed inappropriately, may even increase the error costs of licensing decisions because officials may not have sufficient time to fully consider their decisions. In terms of efficiency, the statutory time limits can only be justified if the reduction in delay costs resulting from their use exceeds the possible increase in error costs and other administrative costs. Accordingly, there is reason to doubt whether the statutory time limits on Chinese drug licensing procedures are set at an efficient level.

### 7. The Reassessment Procedure Versus the Recognition Procedure

As previously mentioned, the licensing procedure for an RCID in China is a reassessment procedure. If the exclusive aim of this licensing requirement is to prevent unsafe and inferior drugs from entering the country and to make good drugs available to domestic consumers, can we simply rely on recognition procedure rather than reassessment procedure in China?

Economically speaking, the purpose of procedures is to minimize the sum of the error costs and administrative costs.<sup>184</sup> Let letters  $A$  and  $E$  respectively represent the administrative costs and error costs for a procedural arrangement. Accordingly,  $A_1$  and  $E_1$  represent the administrative costs and error costs of reassessment procedure;  $A_2$  and  $E_2$  denote the administrative costs and error costs of the recognition procedure. Furthermore, assume that letter  $T_1$  represents the aggregation of  $A_1$  and  $E_1$ , and letter  $T_2$  denotes the sum of  $A_2$  and  $E_2$ . If  $T_1 > T_2$  (i.e.,  $A_1 + E_1 > A_2 + E_2$ ), then recognition procedure is more efficient. If  $T_1 < T_2$  (i.e.,  $A_1 + E_1 < A_2 + E_2$ ), then reassessment procedure is superior. Since the reassessment procedure usually takes more time and requires more steps than the recognition procedure, it involves more delay and other administrative costs (i.e.,  $A_1 > A_2$ ). Under such circumstances, if  $E_1 \geq E_2$ , then  $T_1 > T_2$ , the recognition procedure is superior. Even when  $E_1 < E_2$ , if  $A_1 - A_2 > E_2 - E_1$ , then  $T_1 > T_2$  and the recognition procedure is still the more efficient choice.

Whether  $E_1 \geq E_2$  mainly depends on the relative competence of regulatory agencies in the importing and exporting countries. If the regulatory agency in the exporting country can give a more accurate evaluation of the safety and efficacy of a drug than the agency in the importing country, then  $E_1 > E_2$  and  $T_1 > T_2$ . In that case, it makes economic sense for the regulatory agency in the importing country to choose the recognition procedure. Generally speaking, developing countries have

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184. POSNER, *supra* note 147, at 599.

fewer resources and less technology to carry out drug evaluations than do developed countries. Therefore, developing countries are justified in adopting the recognition procedure for drugs imported from developed countries, which are likely better at evaluating drug quality.

Of course, the practical usefulness of the recognition procedure depends on the credibility, competence and accessibility of the regulatory agency that supplies the guiding information. Also, it is vital to ensure that the regulatory agency can supply accurate and complete information on the imported drugs. At the very least, the information must not be biased in favor of drug manufacturers or exporters. Moreover, it must be noted that the evaluation of the regulatory agency was conducted in the exporting country and may not always be accurate for use in the importing country. In the above analysis, we assume that a drug deemed safe for use in the exporting country must have the same function in relation to health needs in the importing country, or at least not cause more harm to the public health. However, in practice, the safety and efficacy of a drug is a relative concept.<sup>185</sup> There are different factors that each country may consider in defining safety and efficacy, including the status of the health care system in their country, patients' compliance with dosage regimens, alternative therapies that may be available and other specific characteristics of its population.<sup>186</sup>

In spite of these limitations, the recognition procedure, with its great advantage of reducing administrative and delay costs, should be allowed to play a more important role than in current practice, especially when there is only a small difference between the error costs associated with it and those caused by the reassessment procedure. The Chinese government may not be justified in regulating all imported drugs under the reassessment procedure. Some imported drugs from developed countries have weak side effects and toxicities so that the error costs of licensing decisions related to them are not very significant. In such cases, using the reassessment procedure would be one means of trade protection for domestic pharmaceutical industries. In contrast with the recognition procedure, the higher entry costs associated with the reassessment procedure will put foreign manufacturers at a disadvantage in the market of the importing country.

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185. Donald Kennedy, *Food and Drug Administration and Pharmaceuticals for Developing Countries*, in PHARMACEUTICALS FOR DEVELOPING COUNTRIES: CONFERENCE PROCEEDINGS 187, 190 (Nat'l Acad. of Sci. 1979).

186. *Id.*

## V. CONCLUSION

The Chinese regulatory licensing regime for pharmaceutical products continues to evolve. Further improvements can protect the public health with even fewer social costs. The above analysis suggests, first, that information problems, together with the externalities affecting patients and public medical expenditures, seem to be a prerequisite for the justification of licensing in the Chinese pharmaceutical market. Furthermore, the problematic enforcement of *ex post* standards in China often constitutes a strong argument in favor of the current drug licensing regime. However, too much concern about enforcement might lead to a proliferation of licensing requirements. Chinese lawmakers already tend to use too many levels of licensing arrangements to control one kind of business or activity. The replacement of the production permit number and the clinical test certificate with *ex post* standards is strongly justified. Such replacement will not jeopardize the public health, but in fact, will reduce compliance costs for businesses, administrative costs for bureaucrats, and other indirect costs to the public.

Second, among the entry standards for China's pharmaceutical market, the national plan standard for a manufacturer's license and the reasonable location standard for a trader's license cannot be justified from the public interest perspective. However, these standards can easily be used to protect state-owned enterprises and incumbent suppliers against competition from new market entrants.

Third, although the vast majority of drug licensing procedures in China can be used to reduce error costs and administrative costs, Chinese lawmakers have not made full use of the licensing procedures to prevent flawed rejections of applicants by the SFDA. Additionally, there is reason for concern regarding the replication of on-site inspections and sample tests. The procedures operated by the provincial branches of the SFDA and their affiliated institutes are difficult to justify because they are used together with their parallel procedures operated by the SFDA and their affiliated institutes. Likely the consequence of private interest influences, at least the procedures can be a means for Chinese bureaucrats to secure their employment opportunities.