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## Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety

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# Leaving the FDA Behind: Pharmaceutical Outsourcing and Drug Safety

CHENGLIN LIU\*

*Abstract*

During the 2008 heparin crisis, a tainted blood-thinning drug imported from China caused the deaths of at least eighty people in the United States. However, despite the Food and Drug Administration's (FDA) reactive measures, the American regulatory framework for drug safety remains largely unchanged. Currently, about 80% of active pharmaceutical ingredients, 40% of finished drugs, and 50% of all medical devices used in the United States are imported from over 100 countries. With the growth of product outsourcing, pharmaceutical companies in the United States have stopped manufacturing many essential medicines. Nevertheless, the FDA's foreign inspections have lagged. It would take the FDA more than eighteen years to inspect all the establishments in China that produce drugs for the United States, eight times longer than it would take to inspect all domestic firms. To offset inadequate foreign inspections, the FDA emphasizes cooperation with exporting countries in the hope that foreign governments will share the burden of ensuring the safety of imported drugs in the U.S. market. Essentially, the FDA is outsourcing its regulatory power to other countries, some of which are highly susceptible to corrupt regulatory practices and counterfeit production. Since China is responsible for the largest percentage of drugs imported into the United States, this Article uses China as an example and argues that the FDA's regulatory outsourcing approach is seriously flawed. The FDA has largely overlooked the unique challenges that Chinese regulators face in ensuring drug safety.

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## I. THE FDA’S CHALLENGES IN REGULATING IMPORTED DRUGS

The Food and Drug Administration (FDA) is responsible for “protecting public health by ensuring the safety of a wide range of food and medical products.”<sup>1</sup> The FDA is “the oldest comprehensive consumer protection agency in the U.S. federal government.”<sup>2</sup> Its modern function was first defined in the Pure Food and Drug Act (PFDA) of 1906.<sup>3</sup> In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) in response to a well-publicized accident involving an untested elixir drug that “killed 107 people, including many children.”<sup>4</sup> To regain public trust, the

1. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-46, FOOD & DRUG ADMINISTRATION: BETTER COORDINATION COULD ENHANCE EFFORTS TO ADDRESS ECONOMIC ADULTERATION AND PROTECT THE PUBLIC HEALTH 2 (2011), available at <http://www.gao.gov/assets/590/585861.pdf> [hereinafter GAO-12-46].

2. *About FDA: History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> (last updated July 29, 2010).

3. Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 79 (2000) (“The PFDA made it a misdemeanor to introduce adulterated food into interstate commerce. It granted the Secretary of Agriculture the authority to examine food specimens for possible adulteration and directed the Secretary to report potential violations to the Department of Justice.”).

4. *Regulatory Information: Legislation*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated July 9, 2012); MICHAEL SCHUMANN ET AL., FOOD

FDCA completely overhauled the public health system. The FDCA required drug makers to seek FDA approval before marketing any new drugs.<sup>5</sup> The law also authorized the FDA to conduct factory inspections to ensure drug safety.<sup>6</sup> The FDCA set forth the current food and drug regulatory framework in the United States. The FDA has developed into a powerful agency, which regulates approximately one quarter of total U.S. consumer expenditures.<sup>7</sup>

However, globalization and pharmaceutical outsourcing have dramatically increased the volume of imported products that fall within the FDA's jurisdiction. Approximately 80% of Active Pharmaceutical Ingredients (API), 40% of finished drugs, and 50% of all medical devices used in the United States are imported.<sup>8</sup> With the growth of product outsourcing, pharmaceutical companies in the United States have stopped manufacturing many essential medicines. A telling example is that Americans today rely entirely on imported antibiotics because no domestic firm produces a single dose.<sup>9</sup> Despite efforts to lure manufacturing jobs back to the United States, it is expected that China and India will continue to increase the exportation of FDA-regulated drugs and medical equipment to the United States by at least 12% in the next decade.<sup>10</sup> Cost minimization is the primary driving force for outsourcing. One survey indicates that the cost of producing an API can be as much as 40% lower in India than in the United States.<sup>11</sup> In addition, pharmaceuticals have seen increasing costs in the past decade.<sup>12</sup> However, due to limited breakthroughs, research and development (R&D) investments have led to largely disappointing results. "The number of New Molecular Entity approvals," an indicator of productivity, has decreased sharply since 2000.<sup>13</sup> Therefore, outsourcing remains the primary means for pharmaceutical companies to remain afloat in the overly competitive market. As a result of pharmaceutical outsourcing, importation of "high risk" medical products to the U.S. market quadrupled between 2000 and 2007.<sup>14</sup> Many medical devices, which were at one time produced domestically, are

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SAFETY LAW 7 (1997); Merrill & Francer, *supra* note 3 at 81.

5. SCHUMANN, *supra* note 4, at 7.

6. *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last visited July 23, 2012) [hereinafter *FDA Milestones*].

7. RONALD HAMOWY, THE INDEP. INST., INDEPENDENT POLICY REPORT: MEDICAL DISASTERS AND THE GROWTH OF THE FDA 2 (2010), available at [http://www.independent.org/pdf/policy\\_reports/2010-02-10-fda.pdf](http://www.independent.org/pdf/policy_reports/2010-02-10-fda.pdf); Gardiner Harris, *The Safety Gap*, N.Y. TIMES (Oct. 31, 2008), <http://www.nytimes.com/2008/11/02/magazine/02fda-t.html?pagewanted=all&r=0>.

8. GAO-12-46, *supra* note 1, at 2.

9. *The Diane Rehm Show: Addressing Prescription Drug Shortages*, NAT'L PUB. RADIO (Nov. 2, 2011), available at <http://thedianerehmshow.org/shows/2011-11-02/addressing-prescription-drug-shortages/transcript>; see also Gardiner Harris, *Drug Making's Move Abroad Stirs Concern*, N.Y. TIMES (Jan. 19, 2009), <http://www.nytimes.com/2009/01/20/health/policy/20drug.html> ("The critical ingredients for most antibiotics are now made almost exclusively in China and India.").

10. U.S. FOOD & DRUG ADMIN., PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY 20 (2011), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM259845.pdf> [hereinafter *GLOBAL PRODUCT SAFETY*].

11. *Id.* at 13.

12. *Id.* at 9–10.

13. *Id.*

14. *Id.* at 18.

“increasingly being manufactured overseas and imported.”<sup>15</sup> For example, it would take the FDA about eighteen years to inspect all of the establishments in China that produce drugs for the United States, almost eight times longer than if the FDA inspected domestic firms.<sup>16</sup> Nevertheless the FDA’s foreign inspections have lagged.

The FDA’s ineffective supervision of drug safety prompted the U.S. Government Accountability Office (GAO) to add “[t]he oversight of medical products” to its High-Risk List in 2009.<sup>17</sup> The GAO explained that the “FDA was facing multiple challenges that threatened to compromise its ability to protect the public health.”<sup>18</sup> The GAO identified several areas of weakness in the FDA’s oversight of drug safety, “including inspections of foreign manufacturing establishments, postmarket safety monitoring, and oversight of clinical trials.”<sup>19</sup> Because of its inadequate efforts to address serious problems identified by the GAO, the FDA has consistently remained on the High-Risk List since 2009.<sup>20</sup>

To offset inadequate foreign inspections, the FDA has expanded efforts to cooperate with exporting countries in the hope that foreign governments will share the burden of ensuring imported drug safety in the U.S. market.<sup>21</sup> Essentially, the FDA is outsourcing its regulatory power to other countries, some of which are highly susceptible to corrupt regulatory practices and counterfeit production. Since China has “more establishments manufacturing drugs that were offered for import into the United States than any other foreign country,”<sup>22</sup> this Article uses China as an example and argues that the FDA’s regulatory outsourcing approach is seriously flawed, because it has largely overlooked the unique challenges that Chinese regulators face in safeguarding drug safety. Part I of the Article examines the drug safety regulatory framework and the challenges that the FDA faces in conducting foreign inspections and preventing counterfeit drugs from entering the U.S. market. In Part II, the Article analyzes the FDA’s regulatory outsourcing approach and its agreement with China regarding drug safety. Part III offers a detailed analysis of the Chinese regulatory framework on drug safety and the unique challenges that China faces in enforcing its laws.

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15. *Id.*

16. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-961, DRUG SAFETY: FDA HAS CONDUCTED MORE FOREIGN INSPECTIONS AND BEGUN TO IMPROVE ITS INFORMATION ON FOREIGN ESTABLISHMENTS, BUT MORE PROGRESS IS NEEDED 15–16 (2010), *available at* <http://www.gao.gov/new.items/d10961.pdf> [hereinafter GAO-10-961].

17. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-278, HIGH-RISK SERIES: AN UPDATE 115 (2011), *available at* <http://www.gao.gov/new.items/d11278.pdf>.

18. *Id.*

19. *Id.*

20. *Id.* GAO will remove the listed government agency from its High-Risk List if the agency has made adequate efforts to address areas of weaknesses. *Id.* at 3.

21. *See* GLOBAL PRODUCT SAFETY, *supra* note 10, at 24–25 (calling for increased emphasis on cooperation with foreign governments to effectively regulate drugs being imported into the United States).

22. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-970, DRUG SAFETY: BETTER DATA MANAGEMENT AND MORE INSPECTIONS ARE NEEDED TO STRENGTHEN FDA’S FOREIGN DRUG INSPECTION PROGRAM 15 (2008), *available at* <http://www.gao.gov/assets/290/281366.pdf> [hereinafter GAO-08-970].

A. *The Heparin Crisis*

Heparin is a blood thinner that is commonly used in cardiac surgery and dialysis.<sup>23</sup> In 2008, at least eighty-one deaths in the United States were linked to contaminated heparin imported from China by Baxter International.<sup>24</sup> Hundreds of patients suffered allergic reactions after using the drug.<sup>25</sup> German health officials reported at least eighty cases of adverse reactions to heparin during the same period.<sup>26</sup> In response, Baxter International recalled “virtually all of its heparin products” from the U.S. market.<sup>27</sup>

China was the world’s biggest supplier of the active ingredient used in heparin.<sup>28</sup> The raw materials for making heparin came from mucous membranes in pig intestines, which were being processed in unregulated family workshops.<sup>29</sup> Pig farmers sold the cooked mucous membranes to consolidators, who in turn sold them to drug makers.<sup>30</sup> Neither the extraction process nor the working environment was subject to any regulation. Before the crisis, the FDA had never inspected Changzhou SPL, the Chinese manufacturer that exported contaminated heparin to the United States.<sup>31</sup>

After an intensive investigation, scientists finally determined that the contaminant was chemically altered chondroitin sulfate, which was twenty times cheaper than the real active ingredient in heparin.<sup>32</sup> Although the contaminant did not have blood-thinning properties, it had “such a close resemblance to heparin that it had fooled standard quality tests and made it into the United States.”<sup>33</sup> While it remains unclear at which stage the contamination occurred, the harmful chemical

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23. Heparin decreases the clotting ability of blood, thereby preventing formation of clots and stopping the growth of already existing clots. It has been marketed in the United States for nearly seventy years and is used in a variety of clinical settings, including during kidney dialysis and cardiac procedures, and for treatment or prevention of serious medical conditions, including pulmonary embolism and deep vein thrombosis. Over one million multi-dose vials of heparin are sold per month in the United States. Baxter supplies about half of the heparin sold in this country.

*In re* Heparin Prods. Liab. Litiga., MDL No. 1953, 2011 WL 1097637, at \*1 (N.D. Ohio Mar. 22, 2011).

24. Gardiner Harris, *Heparin Contamination May Have Been Deliberate, F.D.A. Says*, N.Y. TIMES (Apr. 30, 2008), <http://www.nytimes.com/2008/04/30/health/policy/30heparin.html>. According to The New York Times, “149 deaths from allergic reactions were reported among people who took heparin from Jan. 1, 2007, to May 31, 2008.” Bettina Wassener, *In China, Strong Debut for Supplier of Heparin*, N.Y. TIMES (May 6, 2010), <http://www.nytimes.com/2010/05/07/business/global/07drug.html>.

25. Walt Bogdanich, *Heparin Find May Point to Chinese Counterfeiting*, N.Y. TIMES (Mar. 20, 2008), <http://www.nytimes.com/2008/03/20/health/20heparin.html>.

26. *Id.*

27. *Id.*

28. David Barboza, *China Orders New Oversight of Heparin, with Tainted Batches Tied to U.S. Deaths*, N.Y. TIMES (Mar. 22, 2008), <http://www.nytimes.com/2008/03/22/world/asia/22heparin.html>.

29. Walt Bogdanich, *The Drug Scare That Exposed a World of Hurt*, N.Y. TIMES (Mar. 30, 2008), <http://www.nytimes.com/2008/03/30/weekinreview/30bogdanich.html>.

30. *Id.*

31. *Id.*

32. Bogdanich, *supra* note 25.

33. Jake Hooker and Walt Bogdanich, *Scientists Near Source of Altered Heparin*, N.Y. TIMES (Mar. 19, 2008), <http://www.nytimes.com/2008/03/19/world/asia/19heparin.html>.

was apparently added to increase the yield of heparin by combining it with a counterfeit substance.<sup>34</sup> The heparin crisis has exposed two challenges facing the FDA: (1) inadequate foreign inspections, and (2) the lack of a mechanism to prevent counterfeit drugs from entering into the U.S. market.

*B. FDA Inspections and Challenges in Foreign Countries*

The FDA's authority to conduct regular inspections stems mainly from Section 704 of the FDCA. In addition, Sections 505 and 515 authorize the FDA to conduct inspections for the purpose of pre-market approval of new drugs and medical devices. Inspection of pharmaceutical facilities is one of the most important enforcement tools used to secure drug safety. In most cases, inspection is the only effective means through which the FDA is able to identify potential health threats. Without inspection, the FDA has no legitimate grounds for utilizing other post-market enforcement tools, such as seizure, injunction, or recall.

The FDCA grants the FDA wide discretion in deciding when and how it conducts an inspection.<sup>35</sup> The FDA is required to give advance notice with an owner's valid consent, or if the consent is withheld, to produce a warrant.<sup>36</sup> If the FDA reasonably believes that a serious violation of the FDCA has occurred, it may conduct a raid.<sup>37</sup> Refusing an FDA inspection may lead to one year of imprisonment and a fine of up to \$1,000.<sup>38</sup> The owner may also face government seizure or an injunction.<sup>39</sup> Forcible actions against inspectors can also lead to criminal punishment.<sup>40</sup> Because of serious punishments upon refusal, most U.S. firms cooperate with FDA inspections.<sup>41</sup>

The coverage of an FDA inspection of prescription drugs and restricted devices is broad. The inspection can reach "all things."<sup>42</sup> This includes not only the "factory, warehouse or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed or held,"<sup>43</sup> but also "records, files, papers, processes, controls, and [other] facilities."<sup>44</sup> Despite the FDA's broad discretion, it faces serious challenges in conducting inspections on foreign drugs and medical device manufacturers.

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34. *Id.*

35. *See* 21 U.S.C. § 374 (2012) (listing the broad powers granted to the FDA to conduct inspections).

36. *See* United States v. Jamieson-McKames Pharm., Inc., 651 F.2d 532, 540 (1981) ("[A]n inspection pursuant to a § 374 notice to inspect is authorized only when there is a valid consent. If consent is withheld, a separate violation of the Act occurs, and the FDA inspectors are required to obtain a warrant before the inspection can proceed.").

37. *Id.*

38. I JAMES T. O'REILLY, FOOD & DRUG ADMINISTRATION § 20:14 (3d ed. 2007).

39. *Id.* § 20:1.

40. *Id.* § 20:12.

41. *Id.* § 20:11.

42. *Id.* § 20:3.

43. *Id.* (internal quotation marks omitted).

44. *Id.*

### 1. Challenges to Foreign Inspections

The FDCA requires the FDA to inspect establishments in the United States every two years,<sup>45</sup> but it does not have the same requirement for inspecting foreign establishments exporting to the United States.<sup>46</sup> Instead, the FDCA relies on cooperative agreements with foreign governments to ensure that imported drugs or devices are manufactured properly.<sup>47</sup> The FDA has the power to refuse the entry of imported drugs or medical devices at the border, but it can only do so when it has sufficient evidence that the manufacturing process of a foreign establishment violated the FDCA.<sup>48</sup> Because the FDA cannot conduct an adequate inspection, this burden is very hard to meet. Thus, foreign inspection is crucial in keeping foreign-produced drugs and medical products in compliance with U.S. law and regulations.

The FDA began conducting foreign inspections of certain European antibiotic firms in 1955.<sup>49</sup> The 1976 medical device amendment to the FDCA extended the scope of the FDA's foreign inspections to include foreign medical device and diagnostic manufacturers.<sup>50</sup> However, the FDA did not have a written inspection procedure until 1983.<sup>51</sup> The current guide to foreign inspections is an updated version of the procedure created in 1999.<sup>52</sup>

Despite the FDA's continuous efforts to increase foreign inspections,<sup>53</sup> foreign establishments are subject to fewer inspections than their domestic counterparts.<sup>54</sup> In 2009, the FDA conducted 424 inspections of foreign establishments, which accounted for 11% of all foreign establishments.<sup>55</sup> At this rate, it would take the FDA about nine years to inspect all foreign establishments once.<sup>56</sup> In contrast, the FDA conducted 1,015 inspections in the United States, comprising approximately 40% of all domestic establishments.<sup>57</sup> At this rate, it would take the FDA about two and a half years to inspect all domestic firms.<sup>58</sup>

Since China has the largest number of establishments exporting to the United States, it would take the FDA even longer to cycle through inspections. It would take the FDA "about 18 years to inspect all of the 920 establishments in China."<sup>59</sup>

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45. 21 U.S.C. § 360(h) (2012).

46. *See id.* § 360(i)(3) (requiring only that FDA cooperate "with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining . . . whether drugs or devices . . . if imported or offered for import into the United States, shall be refused admission").

47. *Id.*

48. *Id.* § 381(a).

49. DIV. OF FIELD INVESTIGATION, U.S. FOOD & DRUG ADMIN., GUIDE TO INTERNATIONAL INSPECTIONS AND TRAVEL ch. 1 § 100 (2002), available at <http://www.fda.gov/ICECI/Inspections/ForeignInspections/ucm110616.htm#SUB100>.

50. *Id.*

51. *Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/Inspections/ForeignInspections/ucm110593.htm> (last visited Oct. 9, 2012).

52. *Id.*

53. GAO-10-961, *supra* note 16, at 11.

54. *Id.*

55. *Id.* at 15.

56. *Id.*

57. *Id.*

58. *Id.*

59. GAO-10-961, *supra* note 16, at 16.



Even worse, due to lack of resources and limited legal authority, nearly 64% of foreign establishments—or 2,394 out of 3,765 in the FDA’s inventory for the fiscal year of 2009—may never have been inspected by the FDA.<sup>60</sup> Almost half of the uninspected establishments are in China and India.<sup>61</sup>

The disparity between inspections of foreign and domestic establishments exists not only in frequency but also in coverage. There are two types of FDA inspections: preapproval inspections and Good Manufacturing Practices (GMP) inspections.<sup>62</sup> A preapproval inspection takes place when an establishment seeks approval of a new drug to be marketed in the United States. Upon receiving the application, the FDA may conduct inspections of the establishment to verify whether it in fact follows what it has promised in the application.<sup>63</sup> A GMP inspection is conducted at an establishment that has already marketed products in the United States.<sup>64</sup> The purpose of a GMP inspection is to determine whether the drugs produced in the establishment are of high quality.<sup>65</sup> Without GMP inspections, preapproval inspections cannot ensure the establishments’ continued compliance.<sup>66</sup>

In practice, however, relatively fewer foreign establishments have been subjected to GMP inspections compared with domestic establishments.<sup>67</sup> In 2009, only 17% of foreign inspections were GMP-only inspections.<sup>68</sup> In other words, 83% of foreign inspections had preapproval components, which means that the inspections were either preapproval-only or inspections that combined preapproval and GMP inspections.<sup>69</sup> In contrast, 82% of domestic inspections were GMP-only inspections, while only 18% were preapproval inspections or combined inspections.<sup>70</sup>

In addition, the FDA faces resistance from foreign firms, a challenge that it rarely encounters while inspecting domestic firms. Even with a cooperative agreement with a foreign government, the FDA is not likely to enjoy the foreign government’s assistance in its inspections, especially in times of crisis. For example, during the heparin crisis, a consolidator of the tainted raw heparin ingredient refused to cooperate with FDA inspectors.<sup>71</sup> FDA inspectors were denied access to the consolidator’s laboratory and records.<sup>72</sup> If the same crisis affected Chinese consumers, the Chinese government likely would have quickly raided the suspected plant and taken the managers into custody.<sup>73</sup> Furthermore, if the tainted products

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60. *Id.* at 16–17.

61. *Id.* at 17.

62. *Id.* at 7.

63. *Id.*

64. *Id.*

65. GAO-10-961, *supra* note 16, at 7.

66. See Chenglin Liu, *The Obstacles of Outsourcing Imported Food Safety to China*, 43 CORNELL INT’L L.J. 249, 268 (2010) (“Without regular periodic audits, foreign factories are not likely to take the GMP or the HACCP processes seriously because compliance with these procedures requires additional costs.”).

67. GAO-10-961, *supra* note 16, at 19.

68. *Id.*

69. *Id.* at 18.

70. *Id.* at 18–19.

71. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-11-936T, DRUG SAFETY: FDA FACES CHALLENGES OVERSEEING THE FOREIGN DRUG MANUFACTURING SUPPLY CHAIN 7 (2011), available at <http://www.gao.gov/assets/130/126943.pdf> [hereinafter GAO-11-936T].

72. *Id.*

73. See Chenglin Liu, *Profits Above the Law: China’s Melamine Tainted Milk Incident*, 79 MISS. L.J.

had caused the deaths of Chinese citizens, the CEO and other managers would likely be subject to criminal investigation.<sup>74</sup> If convicted, the CEO and other managers would face life sentences or even the death penalty.<sup>75</sup> However, since the victims of the heparin crisis were not Chinese citizens, the Chinese government was not subject to the mounting public pressure that it had seen in previous food and drug scandals that claimed lives in China.<sup>76</sup> The Chinese government did not even initiate its own probe, let alone prosecute anyone.<sup>77</sup> The only public response from the Chinese government after the heparin crisis was its vigorous denial that the tainted raw heparin had caused deaths in the United States.<sup>78</sup> Thus, the Chinese government's involvement in dealing with the heparin crisis was noticeably absent.<sup>79</sup>

Furthermore, the FDA cannot conduct foreign inspections without prior notice.<sup>80</sup> Surprise inspections are crucial for quality control, which explains why the FDCA grants the FDA wide discretion to conduct inspections of domestic firms.<sup>81</sup> According to FDA officials, it is very difficult for inspectors to get an accurate glimpse of the manufacturing process when the manufacturer has been notified months in advance.<sup>82</sup> However, unannounced inspections of foreign facilities are almost impossible to conduct because, in some cases, the FDA can only gain access to the facilities by first receiving permission from the foreign government.<sup>83</sup> For example,

During the pet food scandal of 2007, the FDA intended to inspect the suspected factories in China. The Chinese government deliberately delayed the FDA inspectors' visas. One report stated that when inspectors finally reached the two suspected plants in southern China, one plant had already been bulldozed and the other one was deserted. According to another report, the owner of the factory not only bulldozed the building, but also deeply plowed the ground to ensure that U.S. inspectors would not find any trace of melamine.<sup>84</sup>

Costs are another impediment to FDA inspections of foreign firms. Because of logistical hurdles and long-distance travel, the average cost for the FDA to conduct a foreign inspection is around \$52,000, which is more than twice the cost of a domestic inspection.<sup>85</sup>

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371, 386–88 (2009) (detailing the process of governmental confrontation of the sale of tainted baby formula in China).

74. *See id.* at 387 (explaining that a criminal investigation would be proper for the sale of poisonous food or drugs under the criminal law of China).

75. *Id.*

76. *Id.* at 373.

77. Alicia Mundy, *China Never Investigated Tainted Heparin, Says Probe*, WALL ST. J. (July 22, 2010), <http://online.wsj.com/article/SB10001424052748703954804575381540372921432.html>.

78. Gardiner Harris, *U.S. Identifies Tainted Heparin in 11 Countries*, N.Y. TIMES (Apr. 22, 2008), [http://www.nytimes.com/2008/04/22/health/policy/22fda.html?pagewanted=1&\\_r=1](http://www.nytimes.com/2008/04/22/health/policy/22fda.html?pagewanted=1&_r=1).

79. *Id.*

80. GAO-11-936T, *supra* note 71, at 7.

81. *Id.*

82. *Id.*

83. *Id.*

84. Liu, *supra* note 66, at 269.

85. GLOBAL PRODUCT SAFETY, *supra* note 10, at 24.

Additionally, the FDA's lack of information regarding foreign firms that export to the United States only contributes to inadequate inspections.<sup>86</sup> According to a 2008 GAO report, there was a large gap between the FDA's registration database, which had information on 3,000 foreign establishments, and its import database, which recorded around 6,800 foreign establishments.<sup>87</sup> One reason for the gap is that some foreign firms use FDA registration status as a marketing gimmick, attempting to trick local consumers to believe that their products have been either approved or endorsed by the FDA in the United States. Even though they remain FDA-registered establishments, such firms may not have actually offered products in the U.S. market.<sup>88</sup> Because the registration and import data are not electronically integrated, FDA officials have to manually compare some of the foreign establishments across the two databases.<sup>89</sup> Despite the FDA's recent effort to improve information management, it still relies on multiple, sometimes inaccurate, sources in determining which foreign establishments are subject to surveillance inspection.<sup>90</sup>

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86. GAO-08-970, *supra* note 22, at 18–19.

87. *Id.* at 5.

88. *Id.* at 18.

89. *Id.* at 17.

90. GAO-10-961, *supra* note 16, at 9.

**Number of Establishments in the FDA's Inventory That May Never Have Been Inspected by the FDA and Total Estimated Number of Establishments in the FDA's Inventory, by Country, Fiscal Year 2009<sup>91</sup>**

Countries with the largest number of establishments in FDA's inventory that may never have been inspected	Number of establishments in FDA's inventory that may never have been inspected	Estimated number of establishments in FDA's inventory	Percent of establishments in FDA's inventory that may never have been inspected
China	811	920	88
India	323	502	64
Canada	206	310	66
France	107	188	57
Japan	99	207	48
Germany	97	228	43
United Kingdom	82	191	43
South Korea	69	75	92
Mexico	57	76	75
Italy	55	168	33
All other countries	488	900	54
Foreign total	2,394	3,765	64
Domestic total	253	2,498	10

*C. Counterfeit Drugs*

Most Americans have confidence in the integrity of drugs in the U.S. market and believe that counterfeits are only a problem in developing countries.<sup>92</sup> In reality, however, the U.S. market has not been immune to counterfeit drugs. The World Health Organization (WHO) estimates that counterfeit drugs account for less than

91. *Id.* at 18.

92. See U.S. FOOD & DRUG ADMIN., COMBATING COUNTERFEIT DRUGS *i* (2004), available at <http://counterfeiting.unicri.it/docs/FDA%20combating%20ctf%20drugs.pdf> (“In many more countries, counterfeit drugs are common. In the United States, a relatively comprehensive system . . . has kept drug counterfeiting rare, so that Americans can have a high degree of confidence in the drugs they obtain through legal channels.”).

1% of drug sales in the United States.<sup>93</sup> In 2010, Americans spent over \$300 billion on medicine, nearly \$4 billion of which was spent on prescription drugs.<sup>94</sup> Even one-tenth of 1% of drug sales in the United States still equates to more than \$300 million worth of drugs that may have been affected by counterfeits each year.<sup>95</sup>

Counterfeit drugs pose a serious challenge to governments throughout the world. Global sales of counterfeit drugs were estimated to reach \$75 billion in 2010.<sup>96</sup> According to WHO, counterfeited drugs could account for 30% of the markets in Africa, Asia, and Latin America.<sup>97</sup> Because the majority of drug ingredients consumed in the United States come from countries that experience serious problems related to counterfeiting, American patients have become increasingly exposed to drug safety issues.<sup>98</sup>

The 2008 heparin crisis is only one of several incidents during which the FDA has discovered counterfeits in imported drugs. In June 2003, the FDA discovered 30,000 bottles of fake Lipitor, a top-selling anti-cholesterol pill.<sup>99</sup> It took the FDA over two years to complete its investigation of how the counterfeit drugs entered legitimate distribution channels and subsequently reached patients.<sup>100</sup> Investigators discovered that Mr. Julio Cruz conspired with other individuals to smuggle \$42 million worth of counterfeit Lipitor into the U.S. market.<sup>101</sup> Cruz and his co-conspirators pled guilty to their roles in distributing counterfeit, misbranded, and illegally imported drugs.<sup>102</sup> H.D. Smith Wholesale Drug Co., the fourth largest drug wholesaler in the United States, was also implicated in the counterfeit Lipitor scandal.<sup>103</sup> The investigation revealed that one conspirator paid more than \$400,000 in kickbacks to an employee of H.D. Smith who bought counterfeit Lipitor and other fake drugs for further distribution.<sup>104</sup> In the settlement with the federal government,

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93. *Counterfeit Medicines*, WORLD HEALTH ORG., [http://www.who.int/medicines/services/counterfeit/impact/ImpactF\\_S/en/](http://www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/) (last revised Nov. 14, 2006) [hereinafter *Counterfeit Medicines*].

94. IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2010*, at 4, 8 (2011), available at [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII\\_UseOfMed\\_report.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf).

95. This calculation was inspired by two sources. See Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 AM. J.L. & MED. 279, 283 (2006) (performing a similar calculation based on WHO estimates); PEW HEALTH GRP., *AFTER HEPARIN: PROTECTING CONSUMERS FROM THE RISKS OF SUBSTANDARD AND COUNTERFEIT DRUGS* 13 (2011), available at [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Health/Pew\\_Heparin\\_Final\\_HR.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Health/Pew_Heparin_Final_HR.pdf) (performing a similar calculation based on FDA estimates).

96. *Counterfeit Medicines*, *supra* note 93.

97. *Id.*

98. See GAO-12-46, *supra* note 1, at 2 (“The FDA Commissioner has said that globalization presents huge and growing challenges and that economic adulteration remains a public health threat.”).

99. *FDA Uncovers More Fake Lipitor*, USA TODAY (June 3, 2003), [http://www.usatoday.com/news/health/2003-06-03-fake-lipitor\\_x.htm](http://www.usatoday.com/news/health/2003-06-03-fake-lipitor_x.htm).

100. Stephanie Saul, *F.D.A. Hoping For Indictment Over Fake Pills*, N.Y. TIMES (July 26, 2005), <http://query.nytimes.com/gst/fullpage.html?res=9807E2DA123FF935A15754C0A9639C8B63>.

101. *Florida Man Gets 13 Years in Lipitor Case*, KANSAS CITY BUS. J. (Oct. 23, 2006), <http://www.bizjournals.com/kansascity/stories/2006/10/23/daily7.html?page=all>; *Florida Man Pleads Guilty in Lipitor Conspiracy*, KANSAS CITY BUS. J. (Nov. 6, 2006), <http://www.bizjournals.com/kansascity/stories/2006/11/06/daily2.html?page=all>.

102. *Id.*; *Illinois Company Settles Fake Lipitor Case for \$2.2M*, KANSAS CITY BUS. J. (May 11, 2006), <http://www.bizjournals.com/kansascity/stories/2006/05/08/daily27.html?page=all> [hereinafter *Illinois Company*].

103. *Illinois Company*, *supra* note 102.

104. *Id.*

H.D. Smith agreed to pay \$2.2 million in civil forfeiture to the federal government.<sup>105</sup> It remains unclear, however, whether H.D. Smith's civil forfeiture was derived from proceeds gained from distributing the counterfeit Lipitor.<sup>106</sup>

Despite the FDA's efforts after the heparin crisis, counterfeits remain a threat to public health in the United States. In 2010, the FDA warned consumers that a counterfeit version of Alli, an over-the-counter weight-loss drug, did not contain active ingredients.<sup>107</sup> Instead, the counterfeit Alli contained a controlled substance that could cause harm to consumers.<sup>108</sup> In the same year, the FDA discovered fake versions of Tamiflu, Viagra, and Lipitor sold over the Internet.<sup>109</sup> A Belgian citizen was sentenced to forty-eight months in prison for marketing counterfeit drugs through online sales.<sup>110</sup> In February 2012, Roche Co. warned physicians, hospitals, and patients that a counterfeit version of Avastin was found in the U.S. market.<sup>111</sup> Avastin is a widely used cancer drug with sales in the United States exceeding \$2.5 billion in 2011.<sup>112</sup> Roche's preliminary testing indicated that the counterfeit version of Avastin did not contain the active ingredient.<sup>113</sup> The FDA sent warning letters to nineteen physicians who were suspected of purchasing the counterfeit Avastin.<sup>114</sup> It remains unclear how much of the counterfeit Avastin was distributed in the U.S. market or whether the counterfeit caused any harm.<sup>115</sup>

### 1. Distribution Loopholes

Counterfeit drugs cannot harm patients without first entering legitimate distribution channels in the U.S. market. The heparin crisis and other counterfeit drug incidents demonstrate that the regulation of drug distribution is inadequate. While the FDA has exclusive power to regulate drug approval and manufacturing, it does not regulate the drug distributions that take place within state boundaries.<sup>116</sup> Each state has its own laws regulating drug distribution, repackaging, dispensing, and diversion.<sup>117</sup> For example, as of March 2012, twenty-six states required drug

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105. *Id.*

106. *Id.*

107. Press Release, U.S. Food & Drug Admin., FDA Warns Consumers About Counterfeit Alli (Jan. 18, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm197857.htm>.

108. *Id.*

109. Jonathan D. Rockoff & Christopher Weaver, *Fake Cancer Drug Found in U.S.*, WALL ST. J. (Feb. 15, 2012), <http://online.wsj.com/article/SB10001424052970204795304577223472661091252.html>.

110. Press Release, U.S. Dep't of Justice, Belgian Citizen Sentenced for Selling Counterfeit, Misbranded Drugs (June 3, 2011), available at <http://www.fda.gov/ICECI/CriminalInvestigations/ucm257945.htm>.

111. Rockoff & Weaver, *supra* note 109.

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

116. See PEW HEALTH GRP., *supra* note 95, at 70 ("The FDA and the U.S. Drug Enforcement Administration investigate suspected illegal activity by wholesalers and pharmacies when it crosses state lines, but states are responsible for most compliance oversight.")

117. Liang, *supra* note 95, at 288. An excellent source for drug pedigree requirements by state is available on the National Alliance for Model State Drug Laws' website at <http://www.namsdl.org/documents/StateStatutoryCompilationJuly2011.pdf>.

distributors to maintain pedigrees, or transaction histories, of the drugs they market.<sup>118</sup> Another two states are considering such legislation.<sup>119</sup> The purpose of the drug pedigree requirement is to prevent counterfeit drugs from slipping into the stream of commerce.<sup>120</sup> Nevertheless, twenty states still do not have such requirements.<sup>121</sup> The discrepancies among various states' requirements have created loopholes that allow counterfeit drugs to enter legitimate distribution chains in states that have no pedigree requirements. This lack of a pedigree-tracing system encumbers communication among distributors, healthcare providers, and patients, thus rendering recalls ineffective. A telling example is that nearly 8,000 patients in California were still exposed to the counterfeit heparin even after recalls were issued.<sup>122</sup>

## 2. Inadequate Penalties

Penalties for violation of the FDCA are too lenient to deter drug counterfeiting. The FDCA mandates two penalties for counterfeiting:<sup>123</sup> (1) a misdemeanor violation carrying only a maximum of one year in prison, a \$1,000 fine, or both;<sup>124</sup> (2) a felony violation, requiring proof of intent to defraud or mislead,<sup>125</sup> and punishable by three years in prison, a fine not to exceed \$10,000, or both.<sup>126</sup> Although there is an option to prosecute counterfeiting under trademark law, which could lead to a maximum of ten years in prison, counterfeit drug cases are often prosecuted under the FDCA.<sup>127</sup> The criminal penalties for drug counterfeiting are less rigorous than those for narcotic trafficking, even though drug counterfeiting can be more profitable.<sup>128</sup> Due to resource limitations, it is very difficult to uncover drug counterfeiting.<sup>129</sup> As a result, organized criminals have become increasingly involved in counterfeit drug trafficking.<sup>130</sup> Drug counterfeiting has even become an important source of financing for terrorist operations.<sup>131</sup>

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118. *Distributor Licensing and Pedigree Requirements by State*, HEALTHCARE DISTRIB. MGMT. ASS'N, [http://www.healthcaredistribution.org/gov\\_affairs/.state/state\\_legis-static.asp](http://www.healthcaredistribution.org/gov_affairs/.state/state_legis-static.asp).

119. *Id.*

120. *States, FDA Pressing Forward with Pedigree, Track and Trace Rules and Regulations*, NAT'L ASS'N OF BDS. OF PHARMACY (May 3, 2011), <http://www.nabp.net/news/states-fda-pressing-forward-with-pedigree-track-and-trace-rules-and-regulations/>.

121. *Distributor Licensing*, *supra* note 118.

122. PEW HEALTH GRP., *supra* note 95, at 70.

123. 21 U.S.C. § 333(a) (2012).

124. *Id.*

125. *Id.*

126. *Id.*

127. PEW HEALTH GRP., *supra* note 95, at 53.

128. PFIZER, A SERIOUS THREAT TO PATIENT SAFETY, COUNTERFEIT PHARMACEUTICALS 5 (2007), available at <http://www.pfizer.com/files/products/CounterfeitBrochure.pdf>.

129. *Id.*

130. *Id.*

131. *See id.* ("In March 2006, the U.S. Attorney's Office indicted 18 people for a multimillion-dollar international conspiracy to smuggle untaxed cigarettes, counterfeit Viagra and other goods to raise money for the Middle East terrorist group Hezbollah.").

## II. THE FDA'S REGULATORY OUTSOURCING

Several well-publicized scandals in 2007 prompted the FDA to engage with foreign governments and set up overseas offices to improve import safety. First, the FDA found melamine, a harmful chemical usually used to make plastics, in pet food.<sup>132</sup> The FDA's investigation further revealed that Chinese producers had deliberately adulterated the pet food.<sup>133</sup> Melamine was much cheaper than real protein and was still able to pass inspection.<sup>134</sup> Approximately 17,000 consumers complained that their pets were injured after eating Chinese-made pet food.<sup>135</sup> As a result of the contamination, more than 2,000 dogs died.<sup>136</sup> Shortly after the pet food scandal, the FDA discovered that Chinese-made toothpaste sold in Miami and other cities contained a toxic chemical agent.<sup>137</sup> The FDA estimated that over \$3 million worth of toothpaste in the U.S. market was imported from China.<sup>138</sup> In the same year, Chinese-made toys were found to contain high levels of lead, which could have resulted in injuries to children throughout the United States.<sup>139</sup>

Consequently, food and product safety became the top issue in U.S.-China bilateral trade relations in 2007.<sup>140</sup> President George W. Bush issued an executive order to create the Interagency Working Group on Import Safety (IWG).<sup>141</sup> The IWG's mission was to "identify actions and appropriate steps that can be pursued, within existing resources, to promote the safety of imported products."<sup>142</sup> Against this background, the Department of Health and Human Services (HHS) and the FDA issued action plans to improve import safety.<sup>143</sup> The plans called for the federal

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132. Brenda Goodman, *Pet Food Contained Chemical Found in Plastic*, *F.D.A. Says*, N.Y. TIMES (Mar. 31, 2007), <http://www.nytimes.com/2007/03/31/us/31petfood.html>.

133. David Barboza, *China Finds Two Companies Guilty in Tainted Pet Food Export*, N.Y. TIMES (May 8, 2007), <http://www.nytimes.com/2007/05/08/business/worldbusiness/08iht-petfood.5.5627364.html>.

134. David Barboza & Alexei Barrionuevo, *Filler in Animal Feed Is Open Secret in China*, N.Y. TIMES (Apr. 30, 2007), [http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html?page\\_wanted=all](http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html?page_wanted=all).

135. U.S. FOOD & DRUG ADMIN., IMPORT ALERT 99-29 (Aug. 14, 2012), [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_267.html](http://www.accessdata.fda.gov/cms_ia/importalert_267.html) [hereinafter IMPORT ALERT 99-29].

136. *Id.*

137. Walt Bogdanich, *Toxic Toothpaste Made in China Is Found in U.S.*, N.Y. TIMES (June 2, 2007), <http://www.nytimes.com/2007/06/02/us/02toothpaste.html>.

138. *Id.*

139. Eric S. Lipton & David Barboza, *As More Toys Are Recalled, Trail Ends in China*, N.Y. TIMES (June 19, 2007), <http://www.nytimes.com/2007/06/19/business/worldbusiness/19toys.html?pagewanted=all>.

140. Glenn Somerville, *Paulson—Food Safety a Top Issue for US-China Talks*, REUTERS (Dec. 7, 2007), <http://uk.reuters.com/article/2007/12/07/usa-china-idUKWAT00856120071207>.

141. Exec. Order No. 13,439, 72 Fed. Reg. 40,053 (July 20, 2007), available at <http://www.gpo.gov/fdsys/pkg/FR-2007-07-20/pdf/07-3593.pdf>.

142. *Id.*

143. Major reports on import safety to the President include: (1) INTERAGENCY WORKING GRP. ON IMP. SAFETY, IMPORT SAFETY—ACTION PLAN UPDATE: A PROGRESS SUMMARY (July 2008), available at <http://archive.hhs.gov/importersafety/report/actionupdate/actionplanupdate.pdf> [hereinafter ACTION PLAN UPDATE]; (2) INTERAGENCY WORKING GRP. ON IMP. SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT (Nov. 6, 2007), available at <http://archive.hhs.gov/importersafety/report/actionplan.pdf> [hereinafter ACTION PLAN FOR IMPORT SAFETY]; (3) INTERAGENCY WORKING GRP. ON IMP. SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENT IN IMPORT SAFETY (Sept. 10, 2007), available at <http://archive.hhs.gov/importersafety/report/report.pdf> [hereinafter PROTECTING AMERICAN CONSUMERS].



government to negotiate cooperative arrangements with foreign governments on product safety to include measures for (1) conducting inspections in foreign countries; (2) collaborating with foreign governments to conduct joint investigations; and (3) expanding information-sharing channels on product safety.<sup>144</sup> Since 2008, the FDA has set up more than ten overseas offices in China, India, Europe, the Middle East, and Latin America, three of which are in China.<sup>145</sup> Cooperation with foreign governments has become the primary means for the FDA to regulate import safety. Currently, the FDA has sixty-seven agreements with foreign governments regarding the safety of food, drugs, and medical devices manufactured for the U.S. market.<sup>146</sup>

#### A. *Agreement with China*

The FDA and China's State Food and Drug Administration (SFDA) signed a Memorandum of Understanding Agreement regarding drug and medical device safety (the Agreement) in December 2007.<sup>147</sup> Renewed in 2009, the Agreement will remain effective until 2013.<sup>148</sup>

The purpose of the Agreement is to exchange information between the two parties and encourage regulatory cooperation on the safety of drugs and medical devices manufactured for their respective markets.<sup>149</sup> Thus, the parties will "improve their mutual understanding of, and gain greater confidence in," each other's drug safety systems.<sup>150</sup> The Agreement covers a number of products designated by each party based on actual or potential risk of fraudulent practices in previous trade.<sup>151</sup> The FDA designated ten drugs and devices including gentamicin sulfate, atorvastatin, sildenafil, dietary supplements intended for erectile dysfunction or sexual enhancement, human growth hormone, oseltamivir, cephalosporin manufactured in facilities that also manufacture non-cephalosporin drugs, glycerin, glucose test strips, and condoms.<sup>152</sup> Heparin is noticeably missing from the

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144. ACTION PLAN FOR IMPORT SAFETY, *supra* note 143, at 24–25.

145. The three Chinese offices are in Beijing, Shanghai, and Guangzhou. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO 10-960, FOOD & DRUG ADMINISTRATION: OVERSEAS OFFICES HAVE TAKEN STEPS TO HELP ENSURE IMPORT SAFETY, BUT MORE LONG-TERM PLANNING IS NEEDED 8 (2010), available at <http://www.gao.gov/assets/320/310614.pdf>.

146. See *Memoranda of Understanding and Other Cooperative Arrangements*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm> (last updated Nov. 30, 2012) [hereinafter MOU] (listing the memoranda of understanding currently in existence between the FDA and foreign governments).

147. Agreement Between the Department of Health and Human Services of the United States of America and the State Food and Drug Administration of the People's Republic of China on the Safety of Drugs and Medical Devices, U.S.-China, Dec. 11, 2007, T.I.A.S. No. 07-1211, available at <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm107512.htm> [hereinafter Agreement].

148. MOU, *supra* note 146.

149. Agreement, *supra* note 147, art. I.

150. *Id.* art. II(B).

151. *Id.* art. IV(A)(1).

152. *Id.* art. IV(A)(2). SFDA designated drugs and devices are: recombinant human insulin, lysine fat and lysine salt, cefoperazone and its salts, paclitaxel injection, penicillin and its finished dosage form, diagnostic kit for blood screening (specifically, for HIV/AIDS and hepatitis B & C), intraocular lenses, and cardiac pacemakers. *Id.*

designated list because the agreement was signed before the heparin crisis broke out.<sup>153</sup>

The most problematic provision in the agreement is that the FDA will eventually rely on the SFDA to verify whether Chinese firms that export drugs and medical devices to the U.S. market are in compliance with U.S. law.<sup>154</sup> According to this provision, when the FDA deems that regulatory conditions in China are met, the FDA will recognize that SFDA-certified products satisfy U.S. requirements and may enter the U.S. market.<sup>155</sup> The provision essentially sets a goal for the FDA to outsource its regulatory power to the Chinese government. While the provision may greatly facilitate bilateral trade of drugs and medical devices, the potential risk to U.S. patients has been largely overlooked. Soon after the signing ceremony for the Agreement, the Chinese government faced yet another domestic food scandal in which at least nine infants died and over 300,000 children were sickened by adulterated milk powder laced with melamine, the same chemical responsible for the pet food crisis in the United States.<sup>156</sup> Will the Chinese government live up to the job of safeguarding drug and medical devices destined for the U.S. market? In order to answer this question, it is necessary to examine the Chinese drug safety regulatory framework.

### III. DRUG REGULATION IN CHINA

During the Korean War,<sup>157</sup> a number of wounded soldiers died of infection after using expired drugs or unsanitary medical devices provided by Dakang, a privately owned pharmaceutical company in Shanghai.<sup>158</sup> Investigation revealed that Wang Kangnian, the owner of Dakang, bribed sixty-five officials in twenty-five government departments in order to win the defense contract.<sup>159</sup> Chairman Mao was furious and ordered Wang's immediate execution, despite the fact that there were no drug safety laws in place.<sup>160</sup> The harsh punishment showed that Mao was determined to root out

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153. The Agreement was signed on December 11, 2007. Agreement, *supra* note 147. The heparin crisis took place in 2008. Wassener, *supra* note 24.

154. Agreement, *supra* note 147, art. IV(C).

155. *Id.*

156. Mark McDonald, *Death Sentences in China Milk Case*, N.Y. TIMES (Jan. 22, 2009), <http://www.nytimes.com/2009/01/22/news/22iht-23MILK.19584434.html>; Elizabeth Weise & Julie Schmit, *FDA Limits Chinese Food Additive Imports*, USA TODAY, [http://usatoday30.usatoday.com/money/industries/2007-04-30-chinese-imports-usat\\_N.htm](http://usatoday30.usatoday.com/money/industries/2007-04-30-chinese-imports-usat_N.htm) (last updated May 1, 2007).

157. Otherwise known in China as the War Resisting America and Aiding Korea. *Jianshang Wang Kangnian Pianqv Zhiyuanjun Gouyao Jvkuan Shanghai Shi Gong'an Ju Genjv Dianyuan Jianjv Ba Gaifan Daibu* (奸商王康年骗取志愿军购药巨款上海市公安局根据店员检举把该犯逮捕) [*Wang Kangnian Defrauded Huge Sum of Money from Troops, Shanghai Public Security Bureau Arrested Wang Based on Information Provided by a Sales Clerk*], XINHUANET, Feb. 16, 1952, [http://www.cass.net.cn/zhuantil\\_y\\_kmyc/review/1952/mouth2/19520216-04.htm](http://www.cass.net.cn/zhuantil_y_kmyc/review/1952/mouth2/19520216-04.htm) (on file with author).

158. In the early 1950s, like other major industries, pharmaceuticals were privately owned. *Wuer Nian Quanguo Dajia Qiangbi Liang Jianshang Zhenshe Ji Shi Nian* (五二年全国打假枪毙俩奸商震慑几十年) [*The Execution of Two Swindlers in 1952 Had Deterrence for Decades*], FENGHUANG LUNTAN (Jan. 13, 2009), <http://blog.ifeng.com/article/2047317.html> (on file with author) [hereinafter *Two Swindlers*]. After the socialization movement at the end of the 1950s, the Chinese government nationalized all major industries. Liu, *supra* note 66, at 282.

159. *Two Swindlers*, *supra* note 158.

160. *Id.*

counterfeiting by any means necessary. Mao later waged an all-out crusade against private businesses, which led to the nationalization of major industries in the late 1950s.<sup>161</sup>

In 1963, the State Council promulgated its first drug regulation, titled the Rules of Drug Administration.<sup>162</sup> In 1984, the People's Congress enacted the Drug Administration Law (DAL), which was amended in 2001.<sup>163</sup> The 2001 DAL sets forth the current regulatory framework for drug administration in China.<sup>164</sup> To implement the DAL, the government subsequently issued a number of regulations on drug approval and registration.<sup>165</sup>

Influenced by the U.S. model, the State Council decided to merge several then-existing government agencies that were in charge of drug administration and create a single entity in 1998—the Drug Administration.<sup>166</sup> In 2003, the State Council renamed the Drug Administration the State Food and Drug Administration (SFDA).<sup>167</sup> The head of the SFDA enjoys administrative privileges at a level only slightly lower than that of ministries. According to the DAL, the SFDA is responsible for drug registration, approval, and quality control.<sup>168</sup> Provincial and local governments are responsible for supervision of drug production and distribution within their jurisdictions.<sup>169</sup>

#### A. *The Drug Administration Law*

Like U.S. law, the DAL requires that drug makers seek premarket approval from the SFDA for the production of new drugs.<sup>170</sup> The DAL also requires that drug makers have certified drug specialists, maintain sanitary condition in facilities, designate personnel and equipment for quality control, and establish internal rules and procedures for safe production.<sup>171</sup> Additionally, the DAL states that drug makers must comply with “Drug Production Quality Administration Protocols,”<sup>172</sup> which serve as a legal basis for the SFDA to require all drug makers to meet GMP

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161. *Shehui Zhuyi Sanda Gaizao (社会主义三大改造) [Three Big Socialist Reforms]*, XINHUANET, [http://news.xinhuanet.com/ziliao/2003-09/03/content\\_1060054.htm](http://news.xinhuanet.com/ziliao/2003-09/03/content_1060054.htm) (last visited July 6, 2012).

162. *Woguo Yaopin Guanli Fa he Yaopin Zhuce Guanli Banfa de Lishi Yanghe (我国《药品管理法》和《药品注册管理办法》的历史沿革) [Historical Development of Drug Administration Law and Drug Registration Law in China]*, BEIJING YIYAO WEISHENG FAXUE LVSHI (Jan. 6, 2011), <http://www.yixuefalv.com/oneas.asp?id=3409> (on file with author) [hereinafter *Yange*].

163. *Id.*

164. *Id.*

165. *Id.*

166. *Zhuce Fengbao Zhong Yiyao Hangye Xianzhuang (注册风暴中医药行业现状) [Current Situation of the Pharmaceutical Industry in the Midst of Registration Storm]*, ZHONGYAO, <http://www.zhongyao.net/shi/32170.htm> (last visited July 6, 2012).

167. SFDA OF CHINA, <http://www.sfda.com> (last visited July 23, 2012).

168. *Yange*, *supra* note 162.

169. *Yaopin Guanli Fa (药品管理法) [Drug Administration Law]* (promulgated by the Standing Comm. Nat'l People's Cong., Feb. 28, 2001, effective Dec. 1, 2001) art. 5 (China), available at <http://www.sfda.com/drug-administration-law-of-the-peoples-republic-of-china.html> [hereinafter DAL].

170. See generally 1 FOOD & DRUG ADMIN. § 13:79 (2011) (explaining the four stages of U.S. FDA proceedings for drug approval); DAL, *supra* note 169, arts. 29–31.

171. DAL, *supra* note 169, art. 8.

172. *Id.* art. 9.

standards.<sup>173</sup> In addition to the production process, the DAL further requires that drug makers ensure the safety and quality of active drug ingredients and excipients.<sup>174</sup>

### 1. Inspections

The SFDA may inspect drug production and distribution.<sup>175</sup> Drug makers and distributors must permit SFDA inspectors to access drug facilities and must cooperate with inspections.<sup>176</sup> The SFDA may also conduct random inspections without notice.<sup>177</sup> During the inspections, if the SFDA finds evidence indicating that a drug may cause harm to human health, it can seize that drug and halt production.<sup>178</sup> If the SFDA does so, it must issue an administrative decision within seven days.<sup>179</sup> If the SFDA needs to conduct further analysis of the suspected drugs, it must issue a decision within fifteen days.<sup>180</sup> The SFDA must also periodically publish inspection results.<sup>181</sup> If the drug maker being inspected disagrees with the SFDA's inspection results, it can request an administrative retest.<sup>182</sup> In addition, the DAL established an adverse drug reactions system, which requires that drug makers, distributors, and health providers make timely reports to the SFDA once they discover severe adverse drug reactions.<sup>183</sup>

### 2. Fake Drugs

Since fake drug scandals prompted changes to the DAL, the new law has several sections devoted to combating fake and substandard drugs. According to Article 48, a fake drug is defined as a drug produced under any of the following circumstances:

- (1) The ingredients in the drug are different from those specified by the national drug standards;
- (2) A non-drug substance is substituted for a drug, or a substitute drug is mislabeled as a genuine drug;
- (3) Use of the drug is prohibited by law;
- (4) The drug is produced or imported without required approval, or marketed without required testing;
- (5) The finished drug has been spoiled or deteriorated;

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173. See discussion of GMP regulations *infra* Part III.B.1.

174. DAL, *supra* note 169, art. 11.

175. *Id.* art. 64.

176. *Id.*

177. *Id.* art. 65.

178. *Id.*

179. *Id.*

180. DAL, *supra* note 169, art. 65.

181. *Id.* art. 66.

182. *Id.* art. 67.

183. *Id.* art. 71.

- (6) The finished drug has been contaminated;
- (7) The drug has been produced using ingredients prohibited by law or substances without approval numbers as required by law; or
- (8) The effects of the drug are misrepresented or beyond the drug's specified scope.<sup>184</sup>

Drug makers that engage in drug production without SFDA permits will face closure and forfeiture of all illegal gains.<sup>185</sup> In addition, they will be fined two to five times the sale amount.<sup>186</sup> Those who manufacture fake drugs may face termination of production licenses, closure, forfeiture of all illegal gains, and fines of two to five times the sale amount.<sup>187</sup> Owners of drug manufacturers that produce fake or substandard drugs causing severe consequences are barred from re-entering the drug industry for ten years.<sup>188</sup> In any case, if circumstances are serious enough, criminal prosecutions will be initiated.<sup>189</sup>

### 3. Criminal Penalties and Civil Liabilities

The criminal law of China imposes severe sanctions on those who produce counterfeit or substandard products that cause serious bodily injury or death.<sup>190</sup>

Product safety in China is regulated by China's Product Quality Law,<sup>191</sup> which requires sellers to inspect and verify the quality of products<sup>192</sup> and prohibits the production or sale of products that fail to meet that standard.<sup>193</sup> The consequences for producing adulterated products range from halt of production to confiscation to fines equaling up to 300% of the total sale.<sup>194</sup> Under the most serious circumstances, the penalty may include revocation of the producer's business license and even criminal investigation.<sup>195</sup> If the fake drugs cause serious harm or death, the responsible parties will face penalties ranging from three years to life

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184. *Id.* art. 48.

185. *Id.* art. 73.

186. DAL, *supra* note 169, art. 73.

187. *Id.* art. 74.

188. *Id.* art. 76.

189. *Id.* arts. 73–75, 77.

190. See *Zhonghua Renmin Gongheguo Xingfa* (中华人民共和国刑法) [Criminal Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., July 1, 1979, effective Jan. 1, 1980, amended Mar. 14, 1997) arts. 140–42 (China), available at <http://www.cecc.gov/pages/newLaws/criminalLawENG.php> [hereinafter PRC Criminal Law] (imposing sentences of up to fifteen years imprisonment and fines up to ¥2 million).

191. *Zhonghua Renmin Gonghe Guo Chanpin Zhiliang Fa* (中华人民共和国产品质量法) [The Product Quality Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., effective Sept. 1, 1992, amended July 8, 2000) art. 32 (China), available at <http://www.chinalawandpractice.com/Article/1694405/Channel/9942/PRC-Product-Quality-Law-Revised.html> [hereinafter PRC Product Quality Law] (synonymous with products liability law).

192. *Id.* art. 33 (“Sellers shall implement the system of examination and acceptance of goods procured, verifying the product quality certificates and other marks.”).

193. *Id.* art. 32 (“Producers shall not adulterate their products or pose fake products as genuine or shoddy products as good or substandard products as standard.”).

194. *Id.* arts. 49–50

195. *Id.* art. 50; PRC Criminal Law, *supra* note 190, arts. 141–42.

imprisonment.<sup>196</sup> If the circumstances are particularly serious, the death penalty may be imposed.<sup>197</sup> In either case, responsible parties will face a fine of 50% to 200% of the sale amount or a confiscation of the total amount of the illegal proceeds.<sup>198</sup>

A series of recent counterfeit drug scandals prompted lower courts to seek guidance from the Supreme People's Court on how to interpret Article 141. In 2009, the Supreme People's Court and the Supreme People's Procuratorate Communique jointly issued a judicial interpretation of Article 141 (the Interpretation).<sup>199</sup> The Interpretation clarifies the meanings of terms such as "seriously endanger human health" and "particularly serious harm."<sup>200</sup> Furthermore, the Interpretation expressly extends criminal penalties to medical institutions, such as hospitals and clinics, which knowingly administer fake drugs to patients.<sup>201</sup>

In terms of compensation, the producer of a defective product may be liable for medical expenses as well as any lost earnings as a result of the injury.<sup>202</sup> Compensation may also cover the living expenses of a party's dependants if the defective product left the victim disabled.<sup>203</sup> In cases that result in the victim's death, the law entitles the decedent's surviving dependants to funeral and living expenses.<sup>204</sup>

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196. PRC Criminal Law, *supra* note 190, arts. 141–42.

197. *Id.*

198. *Id.*

199. Zuigao Renmin Fayuan Zuigao Renmin Jianchayuan Guanyu Banli Shengchan Xiaoshou Jiayao Lieyao Xingshi Anjian Jüti Yingyong Falü Ruogan Wenti de Jieshi (最高人民法院、最高人民检察院关于办理生产、销售假药、劣药刑事案件具体应用法律若干问题的解释) [Interpretation of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Regarding the Specific Application of Law in Handling Criminal Cases about Production and Sale of Counterfeit or Substandard Drugs] (promulgated by Sup. People's Ct. & Sup. People's Proc. Communique, Feb. 24, 2009, effective May 27, 2009), 2009 SUP. PEOPLE'S CT. GAZ. 7 (China), *available at* [http://www.court.gov.cn/qwfb/sfjs/201002/t20100210\\_1060.htm](http://www.court.gov.cn/qwfb/sfjs/201002/t20100210_1060.htm) [hereinafter Interpretation].

Article 1 Where any fake medicine produced or sold falls under any of the following circumstances, it shall be deemed as "seriously endangering the human health" as prescribed in Article 141 of the Criminal Law:

(1) The fake medicine contains toxic or hazardous substances that are prohibited by the national drug standards, or the toxic or hazardous substances that it contains exceed the national drug standards;

(2) The fake medicine belongs in the category of narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, contraceptive drugs, blood products or vaccines;

(3) The fake medicine is mainly administered to pregnant and lying-in women, infants, children, or critically ill patients;

(4) The fake medicine belongs in the category of injection drugs or first aid drugs;

(5) There is no drug production license or production approval code or the said license or code is counterfeit, and the fake medicine belongs in the category of prescription drugs; or

(6) Any other circumstance of seriously endangering the human health.

*Id.*

200. *Id.* art. 2.

201. *Id.* art. 4.

202. PRC Product Quality Law, *supra* note 191, art. 44.

203. *Id.*

204. *Id.*

### B. Law in Practice

In 1998, Mr. Zheng Xiaoyu became the first director of the Drug Administration, which would later become the SFDA.<sup>205</sup> During Zheng's eight-year tenure, he was credited with transforming the Drug Administration's framework and initiating numerous reforms that helped China become one of the world's leading pharmaceutical exporting countries.<sup>206</sup> However, Zheng's career ended tragically. In 2007, Beijing's No. 1 Intermediate People's Court sentenced Zheng to death for corruption and dereliction of duty.<sup>207</sup> Although corruption cases were common in China, Zheng was one of a few high-ranking officials to receive the death penalty in a decade. Zheng's trial offered a rare glimpse of the inner workings of the SFDA and the challenges that the Chinese government faces in enforcing the laws and regulations on drug safety.

As the head of the SFDA, Zheng carried out two reforms: (1) establishing GMP standards, and (2) consolidating all new drug approval processes.<sup>208</sup> These initiatives were aimed at increasing drug quality control. Zheng strongly believed that the Chinese pharmaceutical industry would not be able to face challenges in the international market without these two reforms. Ironically, it was Zheng's tenacious efforts in pushing the whole industry forward that sent him on the path towards the death penalty.<sup>209</sup>

#### 1. Good Manufacturing Practices (GMP)

During the first year of his tenure, Zheng oversaw the promulgation of many major regulations, several of which addressed quality control processes, such as good manufacturing practice (GMP), good clinical practice (GCP), and good laboratory practice (GLP).<sup>210</sup> His contribution towards institutionalizing China's drug safety framework was profound.<sup>211</sup> In 2001, China became a member of the World Trade Organization (WTO), which provided the Chinese drug industry with unprecedented opportunities in the international market. With its abundance of cheap labor and its lax environmental regulations, China had great potential to become a powerhouse for drug manufacturing. Zheng's push for GMP certification among China's drug makers greatly facilitated their cooperation with western pharmaceutical firms, all of which had already incorporated GMP into their production processes in the 1960s. Therefore, GMP certification was a valuable ticket for Chinese pharmaceuticals to

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205. David Barboza, *A Chinese Reformer Betrays His Cause, and Pays*, N.Y. TIMES (July 13, 2007), <http://www.nytimes.com/2007/07/13/business/worldbusiness/13corrupt.html?pagewanted=all>.

206. *Id.*

207. David Barboza, *China Sentences Former Drug Regulator to Death*, N.Y. TIMES (May 29, 2007), <http://www.nytimes.com/2007/05/29/world/asia/29end-drug.html>.

208. Barboza, *supra* note 205.

209. *See id.* (arguing that companies' profit losses due to the reforms led to the corruption of the SFDA and Zheng, which consequently resulted in Zheng's execution).

210. Heping Jia, *China Syndrome—a Regulatory Framework in Meltdown?*, 25 NATURE BIOTECHNOLOGY 835, 835 (2007); *see also* Zheng Xiaoyu *Zai Di Sanci GAP Qicao Gongzuo Huiyi Shang de Shumian Jianghua* (郑筱萸在第三次GAP起草工作会议上的书面讲话) [*Zheng's Speech On the Third GAP Drafting Meeting*], CHINAPHARM (Sep. 22, 2004), <http://www.chinapharm.com.cn/html/gap/09300720040922.html> (last visited Oct. 11, 2012).

211. *See* Jia, *supra* note 210, at 836 ("You cannot deny those achievements by SFDA simply because Zheng did a poor job in the end.").

enter the world stage.<sup>212</sup> Even after Zheng's execution, scholars agreed that he guided the Chinese drug industry in the right direction.<sup>213</sup> Professor Yang Yue commented that the GMP requirement was a necessary step to improve drug quality and safety: "You don't know what horrible conditions some drug makers had been in. For example, in some traditional Chinese medicine companies, workers stirred the drugs with their feet."<sup>214</sup>

In practice, however, Zheng's idealistic regulations were met with strong resistance from the pharmaceutical industry for several reasons: First, the industry viewed these regulations as a straitjacket that increased production costs and limited the profit margin.<sup>215</sup> To upgrade facilities and hire qualified staff would add unbearable financial burden to the drug industry.<sup>216</sup> Many firms had to divert funds originally budgeted for research and development to meet GMP compliance, which seriously reduced these firms' competitiveness.<sup>217</sup> Second, since Zheng ardently pushed the regulations through, the drafters did not conduct adequate research or broad discussion with the drug industry.<sup>218</sup> After promulgation of the regulations, the SFDA did not take the time to educate the industry on how to comply with the regulations.<sup>219</sup> As a result, the industry found the new regulations confusing.<sup>220</sup> Third, the industry, which was accustomed to deregulation and state stimulus, was never before subject to any strict regulations.<sup>221</sup> Therefore, most drug makers reacted poorly to Zheng's rigorous demands. Fourth, the government capped the price of drugs to combat growing health care costs.<sup>222</sup> In addition, the cutthroat competition among drug makers added pressure to cut production costs.<sup>223</sup> Drug makers were squeezed between government price control and the cost of GMP compliance.

Despite growing discontent from the drug industry, Zheng required all pharmaceuticals to meet GMP standards by 2004.<sup>224</sup> Failure to comply with GMP standards would result in closure.<sup>225</sup> Of 6,700 drug makers, nearly 2,000 lost their production licenses for not meeting GMP by the end of 2004.<sup>226</sup> The GMP

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212. See He Xin et al., *Zhe Yaojian Gaoguan Luoma Gongchu Zheng Xiaoyu* (浙药监高官落马供出郑筱萸) [A Disgraced High Official at the Zhejiang Drug Administration Tipped off Zheng Xiaoyu's Corruption Case], SOHU (Feb. 9, 2007), <http://news.sohu.com/20070209/n248140809.shtml>.

213. *Id.*

214. Barboza, *supra* note 205.

215. See *id.* ("Companies complained that because of their shrinking profit margins, they did not have the money to develop new drugs.").

216. Gai et al., *GMP Implementation in China: A Double-Edged Sword for the Pharmaceutical Industry*, 1 DRUG DISCOVERIES & THERAPEUTICS 12, 12-13 (2007).

217. Jia, *supra* note 210, at 836.

218. Zheng Xiaoyu Shouhui, Wanhua Zhishou An Xingshi Panjue Shu (郑筱萸受贿,玩忽职守案刑事判决书) [In re Zheng Xiaoyu's Bribery and Abuse of Power], 2007 Beijing No. 1 Interm. People's Ct. Criminal Judgment No. 1799, § 2 (May 19, 2007) (China) (hereinafter Zheng's Judgment).

219. Jia, *supra* note 210, at 836.

220. *Id.*

221. REGULATION IN ASIA: PUSHING BACK ON GLOBALIZATION 145 (John Gillespie and Randall Peerenboom eds., 2009).

222. See Barboza, *supra* note 205 ("Some producers switched to the drugs not covered by the government's price caps.").

223. Jia, *supra* note 210, at 837.

224. *Id.* at 836.

225. *Id.*

226. *Id.*



regulations created enormous opportunities for rent-seeking. Many drug makers bribed Zheng with gifts in exchange for speedy approval and other special favors. Further investigation revealed that at least one in six pharmaceutical companies in Zhejiang Province that were GMP-certified had once bribed Zheng and other high-ranking officials.<sup>227</sup> Unable to resist the temptation of cash, cars, and a free villa, Zheng directed his wife and son to form a consulting company in Shanghai to take bribes from desperate drug makers.<sup>228</sup> According to court documents, Zheng and his family accepted more than \$850,000 worth of gifts.<sup>229</sup> In his confession, Zheng wrote, "Why are the friends who gave me money all the bosses of pharmaceutical companies? Obviously because I was in charge of [the] drug administration."<sup>230</sup> Even though Zheng secretly paid back many of the gifts he received after he stepped down from the SFDA, he was not able to avoid the death penalty in the end.<sup>231</sup>

## 2. National Standards

Another of Zheng's signature initiatives was to centralize drug registration based on a national standard.<sup>232</sup> Before this reform, each province had the power to approve new drugs and define its own drug standards for packaging and labeling.<sup>233</sup> In addition, each provincial health department held independent power over drug registration.<sup>234</sup> The inconsistency among provincial drug standards and registration systems not only confused consumers, but also stiffened market competition across provincial borderlines. Furthermore, the close ties between drug makers and local drug administration officials were often tainted by corruption.<sup>235</sup> In 2001, the government passed the new DAL, which established a national standard for drug registration and marketing.<sup>236</sup> According to the new law, the SFDA would review all drugs that were already approved by provincial governments and re-register them on the condition that they complied with the national standard.<sup>237</sup> Neither drug makers nor local governments liked the new changes. Because of the new law, drug makers incurred substantial costs in meeting the national standard. Local governments resisted the law because it deprived them of influence over local drug makers.

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227. Chen Xiaoying, *Shouhui Qianwan Zheng Xiaoyu Wo'an Dujia Jiemi (受贿千万 郑筱萸窝案独家解密)* [Exclusive Report on Mr. Zheng's Corruption Case], XINJING DAILY (Apr. 9, 2007), <http://finance.sina.com.cn/roll/20070409/15061321771.shtml>.

228. Barboza, *supra* note 205.

229. *Id.*

230. *Id.*

231. *Id.*

232. *Quanli Da Jizhong Jie "Dibiao" Sheng "Guobiao" Zhiji Zheng Xiaoyu Kuangmai 2600 Duojuan Piwen (权力大集中 借“地标”升“国标”之际 郑筱萸狂卖2600多件批文)* [Centralization of Power: Zheng Xiaoyu Took Advantage of Drug Standardization and Sold More Than 2,600 Drug Registrations], SHIDAI SHANGBAO (Feb. 8, 2007), <http://news.sohu.com/20070208/n248109796.shtml>.

233. *Id.*

234. *Id.*

235. Liu Wei, *Woguo Yaopin Jianguan de Fengyu Jiunian (我国药品监管的风雨九年)* [Nine Tumultuous Years of China's Drug Regulation], XINHUANET (Mar. 9, 2007), [http://news.xinhuanet.com/health/2007-03/08/content\\_5816477.htm](http://news.xinhuanet.com/health/2007-03/08/content_5816477.htm).

236. DAL, *supra* note 169.

237. Yaopin Zhuce Guanli Banfa (药品注册管理办法) [Provisions for Drug Registration] (promulgated by the St. Food & Drug Admin., July 10, 2007, effective Oct. 1, 2007) (China), available at <http://www.sfdachina.com/info/64-1.htm>.

In practice, the SFDA failed to implement the law because the agency did not have a proper procedure in place or enough staff to handle the re-registration process. At trial, Zheng was accused of dereliction of duty for not anticipating the massive amount of work that resulted from the overhaul.<sup>238</sup> To reduce the workload and speed up the process, Zheng delegated to provincial governments the work of verifying the authenticity of documents that drug makers submitted for re-registration.<sup>239</sup> The SFDA only reviewed a photocopy of the documents.<sup>240</sup> This simplified the procedure but seriously compromised the integrity of the registration process because it provided loopholes for fraudulent applications.<sup>241</sup> Court documents indicate that the SFDA granted registration to a large number of drug makers that submitted fake application documents. For example, Mr. Qingxiang Yu, a high-ranking official in Jilin Province, abused his entrusted power and assisted local drug makers in falsifying documents in exchange for over ¥1 million (\$158,510).<sup>242</sup> Yu was sentenced to fifteen years in prison.<sup>243</sup>

Furthermore, Zheng disregarded the central government's requirement that the power of drug registration and approval must be shared among several subdivisions within the SFDA in order to prevent power concentration and corruption.<sup>244</sup> Instead, Zheng designated only one division with fewer than twenty employees to handle re-registration applications from all across China.<sup>245</sup> He appointed his longtime friend, Mr. Cao Wenzhuang, to head the division. Cao instantly cashed in his unchecked power by taking about ¥2 million (\$317,020) from pharmaceutical companies in exchange for granting registrations.<sup>246</sup> In a three-month period, Cao's division re-registered 147,900 drugs previously registered by provincial governments.<sup>247</sup> Given the flawed system and corrupt officials, it came as no surprise that at least six SFDA-registered drugs were counterfeits.<sup>248</sup>

### 3. New Drug Approval

Unsurprisingly, the SFDA's new drug approval process was as chaotic as that seen in the drug registration process. The new DAL granted the SFDA the sole power to approve new drugs by stripping provincial governments of such power.<sup>249</sup> The new change coincided with the central government's price control on generic

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238. Zheng's Judgment, *supra* note 218, § 2.

239. *Id.*

240. *Id.*

241. *Id.*

242. Luo Changping & Zhang Yingguang, *Zheng Xiaoyu Zui yu Fa (郑筱萸罪与罚) [Zheng's Guilt and Punishment]*, XINJING DAILY (Apr. 18, 2007), <http://finance.sina.com.cn/g/20070418/11223513657.shtml>.

243. *Id.*

244. Zheng's Judgment, *supra* note 218, § 2.

245. Luo & Zhang, *supra* note 242.

246. Li Xinyue, *Yaojian Ju Yuan Yaopin Zhuce Sizhang Cao Wenzhuang Beikong Shouhui 200 Wan (药监局原药品注册司长曹文庄被控受贿200万) [Mr. Cao Wenzhuang, Former SFDA Drug Registration Head Accused of Taking ¥2 Million in Bribes]*, XINJING DAILY (May 21, 2007), <http://news.sina.com.cn/c/1/2007-05-21/044213034442.shtml>.

247. *Id.*

248. Zheng's Judgment, *supra* note 218, § 2.

249. Luo & Zhang, *supra* note 242.

drugs, which severely squeezed drug makers' profit margins. To avoid government price control, drug makers used new drugs to compensate for the loss in generic drug sales.<sup>250</sup> In addition, the SFDA's regulation defined the term "new drug" loosely. For example, even mere dosage changes or technological improvements could cause a drug to be approved as a new drug.<sup>251</sup> The SFDA's inadequate definition created a loophole for drug manufacturers that allowed them to manipulate the system. Rather than relying on research and development, drug makers reshuffled ingredients of generic drugs, claimed them as "new drugs," and sought the SFDA's approval.<sup>252</sup> In 2005, the SFDA approved 1,113 applications for "new drugs" that were in fact generics with only dosage changes.<sup>253</sup> During the same period in the United States, the FDA only approved eighty-one new drugs.<sup>254</sup> As in the registration process, some drug makers used falsified documentation for new drug applications.<sup>255</sup> The cozy relationships between Zheng and drug makers that sought approval often gave rise to corruption. "Court records show that when a company named the Double Doves Group sought to register disposable syringes, it offered shares to Mr. Zheng's wife; his son received a used Audi, consulting fees and property in Shanghai."<sup>256</sup>

#### 4. Fake Drug Scandals

The impact of counterfeit drugs is difficult to quantify. For obvious reasons, the drug industry does not want to reveal any irregularities. The government tends to censor any damaging information that could cause public unrest. As a result, there are no reliable statistics revealing to what extent fake drugs have caused death and illness in China.<sup>257</sup> A series of food and drug scandals, however, have had a profound impact on public consciousness. In a widely cited survey, over 70% of the Chinese public has lost confidence in the Chinese food and drug regulatory system.<sup>258</sup> In addition, scholars believe that a series of fake-drug scandals contributed to the doom of Zheng's reign.<sup>259</sup>

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250. Dali Yang, *Regulatory Learning and Its Discontents in China: Promise and Tragedy at the State Food and Drug Administration*, Address at Conference on Pushing Back on Globalization: Local Asian Perspectives on Regulation (Nov. 28–30, 2007), available at [http://www.daliyang.com/files/Yang\\_SFDA\\_paper.pdf](http://www.daliyang.com/files/Yang_SFDA_paper.pdf).

251. Jia, *supra* note 210, at 836.

252. Yang, *supra* note 250, at 7.

253. Jia, *supra* note 210, at 836.

254. *Id.*

255. Luo & Zhang, *supra* note 242.

256. Zheng's Judgment, *supra* note 218, § 2.

257. See Barboza, *supra* note 205 (explaining that the government does not know how many deaths or illnesses have resulted from faulty drugs).

258. Xie Xiaoliang, *Diaocha Xianshi: Wenti Yao Rang 72.7% de Gongzhong Danxin Yaopin Anquan (问题药让 72.7% 的公众担心药品安全) [72.7% of the Public Worried About Drug Safety]*, CHINA YOUTH DAILY (July 10, 2006), [http://news3.xinhuanet.com/politics/2006-07/10/content\\_4811420.htm](http://news3.xinhuanet.com/politics/2006-07/10/content_4811420.htm).

259. See Zhao Bingzhi et al., *Zheng Xiaoyu Weihe Bei Panchu Sixing? Zhongguo Xingfa Xuejie Zhuanjia Jiedu (郑筱萸为何被判死刑? 中国刑法学界专家解读) [Why Was Xiaoyu Zheng Sentenced to Death? Analysis by China's Criminal Law Experts]*, CHINALAWINFO.COM, [http://article.chinalawinfo.com/Article\\_Detail.asp?ArticleID=38924](http://article.chinalawinfo.com/Article_Detail.asp?ArticleID=38924) (last visited Oct. 11, 2012).

a. Xinfu (clindamycin phosphate glucose)

In July 2006, approximately 100 patients across sixteen provinces became violently ill after receiving antibiotic injections of Xinfu.<sup>260</sup> At least ten people died as a result of using the drug.<sup>261</sup> Since the SFDA was extremely slow to react to the incident, physicians scrambled to find out what exactly caused the severe reactions to Xinfu, a very commonly used drug.<sup>262</sup> On August 3, 2006, a week after the death of a six-year-old girl, the SFDA issued a public notice warning about adverse reactions to Xinfu.<sup>263</sup> Had the SFDA acted more quickly, doctors would not have given Xinfu to the girl.<sup>264</sup> Further investigation uncovered that Huayuan, the maker of Xinfu, violated GMP standards in the production process to curb costs.<sup>265</sup> Ironically, Huayuan was one of the first drug makers to receive GMP certification from the SFDA in 1999.<sup>266</sup> However, neither the SFDA nor the local drug administrative bureau has ever conducted thorough inspections to verify whether Huayuan actually enforced GMP standards in the production process. Local officials and inspectors stated that they rarely went to pharmaceutical plants to conduct GMP inspections, except for occasional symbolic tours.<sup>267</sup> According to these officials, it was Huayuan's responsibility to conduct self-inspections to ensure GMP standards were observed.<sup>268</sup>

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260. Beiyuan Chen, *Quanguo Ge Shengshi Diqu Yin Zhushu Xinfu Buliang Fanying Tongbao* (全国各省市地区因注射欣弗不良反应通报) [National Report on Instances of Pathological Reactions to the Injection of Xinfu], QIYE FALV FENGXIAN PEIXUN LVSHI TUANDUI BLOG (企业法律风险培训律师团队博客) [LEGAL RISK MANAGEMENT BLOG] (Aug. 11, 2006, 6:35 PM), [http://blog.sina.com.cn/s/blog\\_4a1afcff0100059j.html](http://blog.sina.com.cn/s/blog_4a1afcff0100059j.html).

261. "Xinfu" Shijian Yuzhen: Anhui Huayuan Yaoye Yuan Zong Jingli Zisha ("欣弗"事件余震: 安徽华源药业原总经理自杀) [Latest Development on the Xinfu Scandal: The Former CEO of Huayuan Pharmaceutical Company Committed Suicide], CHINA SECURITIES NEWS (Nov. 3, 2006), <http://news.qq.com/a/20061103/000995.htm>.

262. Xie Ding, *Anhui Huayuan Wenti Yaopin Shijian Tuxian Ke Lin Mei Su Jianguan Queshi* (安徽华源问题药品事件凸现克林霉素监管缺失) [The Huayuan Scandal Reveals Lack of Supervision], XINJING DAILY (Aug. 8, 2006), <http://news.sina.com.cn/c/2006-08-08/005010655080.shtml>.

263. *Id.*

264. *Id.*

265. *Xinfu Shijiang Shimo: Qian gui ze Yia de Dianxing Daibiao* (欣弗事件始末: 潜规则下的典型代表) [The Xinfu Scandal Reveals Hidden Rules in the Drug Industry], XINJING DAILY (Aug. 16, 2006), <http://news.sina.com.cn/c/2006-08-16/02109758112s.shtml>; *Shipin Anquan Ju Jiu "Anhui Huayuan" Yaopin Buliang Shijiang Dawen* (食品药品监督管理局就“安徽华源”药品不良事件答问) [SFDA's Comment on the Anhui Huayuan Fake Drug Scandal], XINHUANET (Aug. 16, 2006), [http://www.gov.cn/zwhd/2006-08/16/content\\_363425.htm](http://www.gov.cn/zwhd/2006-08/16/content_363425.htm).

266. Wang Yue, *Cong Xinfu Zhiliang Shijian Kan GMP Renzheng Hou de Guanli Quewei* (从欣弗质量事件看GMP认证后的管理缺位) [The Xinfu Scandal Revealed Lack of Supervision of GMP Standards], CHINA QUALITY DAILY (Aug. 18, 2006), <http://www.5ijk.net/show.aspx?id=50979&cid=865>.

267. Gu Ping, Jiang Longfei & Wang Liping, *Xinfu Chuchang Qian You Huayuan Zijian Shengshi Yaojian Ju Tuiwei Choujian Zeren* (欣弗出厂前由华源自检 省市药监局推诿抽检责任) [Huayuan Conducted Self-Inspection of Xinfu; Both Provincial and City Drug Administrations Refused Responsibilities], XINJING DAILY (Aug. 8, 2006, 12:43 AM), <http://news.sina.com.cn/c/2006-08-08/004310655075.shtml>.

268. *Id.*

b. Qiqihar No. 2 Pharmaceutical

At about the same time that the Xinfu scandal broke out, thirteen patients died in Guangzhou after receiving Armillarisi A, made by Qiqihar No. 2 Pharmaceutical (Qiqihar No. 2).<sup>269</sup> Like Huayuan, Qiqihar No. 2 received GMP certification from the SFDA in 2005.<sup>270</sup> Mr. Guo Xingping, deputy general manager, testified that the company obtained GMP certification by paying ¥10,000 (\$1,566) even though the company was clearly incapable of meeting the GMP standards for production.<sup>271</sup> The company's drug-ingredient acquisition manager, Mr. Niu Zhongren, only had a middle-school education.<sup>272</sup> In 2005, Niu ordered one metric ton of counterfeit propylene glycol, which in fact was diethylene glycol, a toxic material used in making plastic and industrial dyes.<sup>273</sup> If the company had enforced the GMP protocol, its laboratory would have discovered the counterfeit materials. However, most of the company's laboratory staff had never studied chemistry nor received any formal training.<sup>274</sup> No one conducted any analytical screening of the fake materials before they were put into the manufacturing process.<sup>275</sup>

c. Toxic Toothpaste and Pet Food

Even though the counterfeit scandals involving Huayuan and Qiqihar No. 2 caused far more damage in China than the tainted pet food caused in the United States, American media outlets did not pay much attention to the safety issues in the Chinese pharmaceutical industry.<sup>276</sup> The FDA did not take serious precautions until after it received reports from owners that their dogs had fallen ill, or had died, after consuming Chinese-made pet food.<sup>277</sup> Further laboratory testing indicated that the counterfeit pet food contained melamine, a cheap chemical that was often used to make plastics and fertilizers.<sup>278</sup> Some Chinese pet food makers had found that melamine mimicked protein so closely that it easily passed regular inspections.<sup>279</sup> It

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269. *China Bans 2 Factories from Exporting Toys*, N.Y. TIMES, Aug. 9, 2007, <http://www.nytimes.com/2007/08/09/business/worldbusiness/09iht-yuan.1.7054901.html>.

270. *Qi Er Yao Jiayao An Beigao Cheng Changfang Hua 10 Wan Gou Mai GMP Renzheng* (齐二药假药案被告称厂方花10万购买GMP认证) [Qiqihar No. 2 Pharmaceutical Company Official Admitted that the Company Bought the GMP Certification for 10,000 Yuan], SOHU (Aug. 9, 2007), [http://news.sohu.com/20070809/n251491059\\_1.shtml](http://news.sohu.com/20070809/n251491059_1.shtml) [hereinafter *Renzheng*].

271. *Id.*

272. Cao Jingjing, "Qi Er Yao An" Dusi 13 Ren 5 Ming Zeren Ren Guangzhou Bei Kong Zhongzui ("齐二药案" 毒死 13 人 5 名责任人广州被控重罪) [Qiqihar No. 2 Pharmaceutical's Fake Drugs Killed Thirteen People, Five Managers Received Severe Criminal Prosecution in Guangzhou], XINQUAI DAILY (Apr. 13, 2007), <http://news.sohu.com/20070413/n249397187.shtml>.

273. Wu Xiaodong et al., *Qi Er Yao SanNian ZaoJia DiaoCha* (齐二药三年造假调查) [Investigation Report on Qiqihar No. 2's Three-Year Counterfeiting], XINJING DAILY (May 22, 2006), <http://news.sina.com.cn/c/2006-05-22/02128985883s.shtml>.

274. *Renzheng*, *supra* note 270.

275. Wu et al., *supra* note 273.

276. Barboza, *supra* note 133.

277. *Id.*

278. *Id.*

279. *See id.* ("[T]wo companies had cheated pet food companies by adding a fake protein into the feed to make pet food suppliers believe they were purchasing high protein feed when in fact they were getting lower protein feed.").

was the U.S. media's pervasive reporting on the pet food scandal that severely tarnished the reputation of Chinese-made products in the U.S. market.<sup>280</sup> Since exportation was a driving force for China's economic growth, the pet food scandal put the Chinese government under enormous pressure.<sup>281</sup>

Even though corruption crimes in China are subject to capital punishment, the sentence of immediate execution took both Zheng and his lawyer by surprise.<sup>282</sup> Some scholars observed that Zheng's punishment was indeed much heavier than those imposed on other high-ranking officials who accepted more bribes than Zheng.<sup>283</sup> In addition, Zheng's passionate confession and efforts to pay back bribes were mitigating factors that could have persuaded the court to sentence him to the death penalty with a two-year suspension, which would have eventually been commuted to life imprisonment.<sup>284</sup> According to scholars, the reason the court disregarded Zheng's mitigating actions was that his dereliction and corruption had threatened the public health and damaged the reputation of China's food and drug industry in China.<sup>285</sup> In essence, the Chinese government used Zheng's execution to prove that it was serious about food and drug safety.<sup>286</sup>

## 5. Problems Continue

Zheng's execution did not put an end to corruption in China's drug industry. Recent scandals demonstrate that corrupt officials continue to cash in on their power over drug registration and approval. As a result, fake drugs continue to claim lives and inflict grave injuries to patients.

In 2010, the rabies vaccine manufactured by Yanshen Pharmaceutical Co. (Yanshen) caused injuries to more than one million people.<sup>287</sup> Yanshen was a leading

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280. See generally May Hongmei Gao, *The 2007 Chinese Pet Food Crisis: On U.S. Media's Coverage and U.S. Pet-Owners Reactions*, 3 J. EMERGING KNOWLEDGE ON EMERGING MKTS. 411 (2011) (discussing the American and Chinese reactions to the contamination of Chinese-produced pet foods).

281. *Id.*

282. Li Kejie, *Zheng Xiaoyu Mei Xiangdao Ziji Hui Pan Sixing (郑筱萸没想到自己会被判死刑) [Zheng Xiaoyu Did Not Expect the Death Penalty]*, MODERN DAILY (June 11, 2007), [http://news.xinhuanet.com/newmedia/2007-06/11/content\\_6225167.htm](http://news.xinhuanet.com/newmedia/2007-06/11/content_6225167.htm).

283. *Id.*

284. *Id.*

285. *Id.*

286. See Joseph Kahn, *China Quick to Execute Drug Official*, N.Y. TIMES (July 11, 2007), <http://www.nytimes.com/2007/07/11/business/worldbusiness/11execute.html?ref=business> (stating that Zheng's case "allow[ed] senior leaders to show that they have begun confronting the country's poor product-safety record"); Zhu Zhe, *Ex-Official Gets Death for Graft*, CHINA DAILY (May 30, 2007), [http://www.chinadaily.com.cn/china/2007-05/30/content\\_882994.htm](http://www.chinadaily.com.cn/china/2007-05/30/content_882994.htm) ("[Zheng's] sentence reflects the concern of Chinese top leaders about issues such as corruption and food safety.").

287. Sha Ke, *Jia Yimiao Zaici Tiaozhan Baixing Chengshou Dixian (假疫苗再次挑战百姓承受底线) [Fake Vaccines Challenge the Tolerance of Ordinary People]*, DONGFANGNET (Mar. 31, 2010), <http://finance.ifeng.com/opinion/special/yimiaoshijian/mssd/20100331/1991801.shtml>; Li Songtao, *Jiangsu Kuangquan Yimiao Qunian Sanyue Chushi Niandi Cai Gongbu Yin Zhengyi (江苏狂犬疫苗去年三月出事年底才公布引争议) [Investigation of Jiangsu Fake Vaccine Scandal in March Finally Made Public by the End of the Year, the Delay Has Caused Controversy]*, CHINA YOUTH DAILY, April 5, 2010, <http://finance.ifeng.com/news/special/yimiaoshijian/bgt/20100405/2008646.shtml>; Xiao Sisi & Wu Tao, *Jiangsu 20,000 Duofen Wenti Yimiao Liuru Guangdong Yinfa 1 Li Buliang Fanying (江苏2万份问题疫苗流入广东 引发1例不良反应) [Over 20,000 Problematic Vaccines Slipped from Jiangsu into Guangdong]*,

manufacturer of the rabies vaccine in China, with annual sales of ¥180 million (\$28 million).<sup>288</sup> In 2008, the local health department imposed fines on Yanshen for multiple violations, which included cutting corners, falsifying data, and evading inspections.<sup>289</sup> To recoup the loss, Mr. Zhongyi Zhang, the vice-manager of Yanshen, was secretly ordered to release substandard vaccines to the market.<sup>290</sup> According to regulations regarding vaccine production, a firm must seek approval from the health department before marketing vaccines.<sup>291</sup> Zhang directed the company's chief scientist to fabricate lab reports and send false samples to the state quality control office, which quickly approved the products.<sup>292</sup> As a result, Yanshen sold 53,293 doses of substandard rabies vaccines in seventeen provinces for ¥1,601,282 (\$252,658).<sup>293</sup> At trial, Zhang admitted that it was a common practice to falsify lab reports and provide false samples to ensure approval for marketing.<sup>294</sup> Zhang further testified that among the dozens of vaccine makers in China, only some were up to international standards, while others lagged far behind.<sup>295</sup> To stay in the market, many manufacturers without the required technology and facilities took illegal measures to get their products approved, such as falsifying documents, bribing officials, or both.<sup>296</sup>

Shortly after the fake vaccine scandal, a criminal investigation led to the arrest of five SFDA officials, including Mr. Wei Liang, a subdivision director in charge of biological drug supervision and GMP certification.<sup>297</sup> Wei allegedly received bribes totaling ¥1,470,000 (\$232,594) from at least twenty-five different pharmaceutical companies that were seeking drug registration and approval.<sup>298</sup> Despite the public's wide suspicion that the fake vaccine scandal prompted the arrest, the government openly denied a direct link.<sup>299</sup> Having learned a lesson from previous scandals, the

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*Causing One Adverse Reaction*] XINHUANET (Apr. 3, 2010), <http://finance.ifeng.com/roll/20100403/2007369.shtml>; Ye Wentian & Chen Jiyong, *Yimiao An Yinfa Yaojian Xitong Fanfu Fengbao* (疫苗案引发药监系统反腐风暴) [*The Fake Vaccine Scandal Likely to Prompt an Anti-Corruption Storm*], CHINA MARKETING DAILY, Apr. 3, 2010, <http://finance.sina.com.cn/roll/20100403/10307688350.shtml>.

288. *Jiangsu Changzhou Kuangquan Bing Yimiao Shejia An Kaiting, Beigao Dangting Jie Heimu* (江苏常州狂犬病疫苗涉假案开庭 被告当庭揭黑幕) [*Suspects Revealed Hidden Secrets at the Fake Rabies Vaccine Trial*], CHINA YOUTH DAILY (Aug. 17, 2010), <http://finance.ifeng.com/news/special/yimiaooshijian/20100817/2520606.shtml>.

289. Han Wei, *Yimiao Hangye Zai Bao Chouwen Pingzhuang Shengli Yanshui Yijia Luanzhen* (疫苗行业再爆丑闻瓶装生理盐水以假乱真) [*Fake Vaccine Scandal Resurfaced: Selling Pharmacy Physiological Saline as Vaccine*], TIMES WEEKLY (June 10, 2010), <http://finance.ifeng.com/news/special/yimiaooshijian/20100610/2297762.shtml>.

290. *Id.*

291. *Id.*

292. *Id.*

293. *Id.*

294. *Id.*

295. Han, *supra* note 289.

296. *Id.*

297. Wen Shuping, *Yaojian Ju Zaibao Fubai Woan Wu Ren Beibu* (药监局再曝腐败窝案5人被批捕) [*Corruption Scandal Resurfaced in the SFDA, Five Officials Arrested*], ECONOMIC OBSERVER (Apr. 16, 2010), <http://finance.ifeng.com/news/20100416/2063592.shtml>.

298. *Shoushou 25 Jia Qiye Huilu: Yaojian Ju Wei Liang An Kaiting* (收受25家企业贿赂:药监局卫良案开庭) [*Wei Liang, an SFDA Official, at Trial, Accused of Receiving Bribes from 25 Drug Companies*], 21 CENTURY ECONOMY (Nov. 20, 2010), <http://finance.sina.com.cn/g/20101120/11218984470.shtml> [hereinafter *Wei Liang An*].

299. Wu Xiaolei, *Yaojian Ju Shuyue Nei Fasheng 16 Qi Renshi Renmian Founen Yin Yimiao Shijian* (药监局数月内发生16起人事任免 否认因疫苗事件) [*The SFDA Dismissed 16 Officers within Several*

government restricted information regarding the case.<sup>300</sup> At a ninety-minute-long trial (unusually short even by Chinese standards), the Beijing court invoked a summary procedure and limited the audience to two of Wei's family members.<sup>301</sup> There was no information about which drug makers bribed Wei in exchange for what special favor, nor was any information released regarding what happened to the drugs produced by the companies that bribed Wei.<sup>302</sup> By all appearances, the government tried to put a quick end to Wei's case in order to prevent further public suspicion of other officials and drug makers.

There is no punishment more extreme than the death penalty. By executing the country's top drug regulator, the Chinese government has shown its dedication to drug safety. However, Zheng's execution has failed to deter corrupt dealings between regulators and the food and drug industry. Scandals continue to claim lives and inflict injuries. Despite the Chinese government's genuine efforts to clean up corruption, drug safety will remain one of the top issues in the foreseeable future.

### CONCLUSION

Judging by appearances alone, there is no great disparity between the United States' Food, Drug and Cosmetic Act (FDCA) and China's Drug Administration Law (DAL). Even the English translation of the Chinese agency's name underscores the similarities between China's SFDA and the United States' FDA. The reason for the similarities between the two laws is that the U.S. law serves as a model for China's DAL. Despite their differing political structures and legal systems, each country's law designates a special agency in charge of drug safety supervision. Both laws emphasize pre-market approval, inspection, and post-market sanctions to ensure drug safety. In terms of legal provisions, regulatory agencies, and desire to ensure drug safety, the two systems are very much aligned. Perhaps due to this perception, the FDA had engaged with its Chinese counterpart in hopes that the SFDA would share the burden of regulating drugs made for the U.S. market. In practice, however, the Chinese law as it is written on paper is entirely different from what is put into action. Unfortunately, the FDA either completely overlooked or unwisely disregarded this critical factor when it reached agreement with China.

The ideal outcome of the FDA's agreement is that its foreign counterpart will regulate manufacturers exporting drugs to the U.S. market as rigorously as the FDA regulates U.S. manufacturers producing similar products for domestic consumption. However, even if the foreign government makes genuine efforts and does what it promised in the agreement, the risk of adulteration and counterfeiting remains. This is because the regulatory framework and environment of the foreign country is drastically different from that of the United States. While scholars often criticize lenient penalties for counterfeiting and cite a lack of resources for prosecuting such crimes in the United States, the criminal penalties, albeit inadequate, are wholly

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*Months, but Denied Any Link to the Fake Vaccine Scandal*], TIMES WEEKLY (Apr. 8, 2010), <http://china.huanqiu.com/roll/2010-04/771391.html>.

300. *Wei Liang An*, *supra* note 298.

301. *Yimiao She Jia An Tingshen Jingbao Hangye Heimu (疫苗涉假案庭审惊曝行业黑)* [*Fake Vaccine Trial Shockingly Exposes Shady Industry*], CHINA YOUTH DAILY (Aug. 17, 2010), [http://article.cyol.com/law/content/2010-08/17/content\\_3378568.htm](http://article.cyol.com/law/content/2010-08/17/content_3378568.htm).

302. *Id.*



inapplicable in foreign jurisdictions. It is therefore quite naïve to expect a foreign government to cooperate with the FDA in times of crisis. Even under the existing agreement, the FDA's attempt to investigate a Chinese firm in the heparin crisis was met with enormous resistance from the Chinese government. When its reputation and profit are at stake, a foreign government will make every effort to protect its own business interests, even at the expense of U.S. consumers. Therefore, the FDA's reliance-on-foreign-governments approach to drug safety is seriously flawed.