COUNTERFEIT MEDICINE: Is It Curing China?

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In September of 2001, a hospital near Chongqing was supposed to give Hu Zu Shuang a bottle of albumin, a blood protein, for intravenous use. Instead, the bottle contained a toxic liquid that killed him. Although the bottle was falsely labeled, the police have yet to determine who is to blame. The family’s lawyer has no idea who is responsible for the hospital’s drug purchasing and complained that the local police “won’t investigate the responsibility on the hospital side.” “How could we know this was going to happen? Medicine is supposed to help people,” Hu’s wife said. According to the family, the police discovered the hospital director attempting to discard the bottle into a public toilet shortly after Hu’s death. Hu’s daughter said that the hospital compensated the family with about $6,000, but the hospital received no punishment, and the factory that produced the fake medicine is still in operation.1

I. INTRODUCTION

Historically, the People’s Republic of China (China) has been a major source of counterfeit goods.2 For many Chinese, counterfeiting is not a foreign or unacceptable reality.3 In a recent survey in China, 84 percent

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2 LTC David J. Clark, Product Counterfeiting in China and One American Company’s Response, Secretary of Defense Corporate Fellows Program Report, Apr. 2003 at 1, available at www.ndu.edu/sdcfp/2003reports/Pfizer2003.doc (last visited June 8, 2004); see also Dexter Roberts and Frederik Balfour, China’s Pirates, BUS. WK., June 5, 2000, available at http://www.businessweekonline.com (last visited June 8, 2004) (noting that counterfeit Gucci purses sell in Chinese market stalls for about $10.00 US dollars compared to the genuine Gucci product price of more than $1,000 and even fake Safeguard soap sells for 20 cents a bar compared to the US $1.00 for the genuine soap).

of the respondents admitted purchasing counterfeit goods. To the average Chinese consumer, buying counterfeit “Calvin Clone” jeans might seem innocent enough, but over the last decade, consumers have been purchasing a less innocent and more dangerous, and yet more lucrative, product—counterfeit medicine.

As early as 1998, China’s pharmaceutical industry was already at a booming $22.5 billion and by 2010, China’s pharmaceutical industry is expected to be the fifth largest in the world. Because the pharmaceutical industry estimates that there are about 10-15 percent of the circulating drugs are fakes, these counterfeit medications account for about $3 trillion of annual pharmaceutical sales. Because of its moneymaking allure, the growth of this trade is not surprising. With a growing migratory population seeking job opportunities across China, a growing elderly population, and a government that is notorious for corruption, China is an easy breeding ground for counterfeit medicine manufacturers. Thus, with China’s long

4 See QBPC, supra note 3.


9 Julie Chao, Bribery Turns Creative as China Tries to Fight Corruption, COX NEWS SERVICE, Nov. 28, 2002, available at http://seattlepi.nwsource.com/national/97567_chinabribes28.shtml (last visited Dec. 8, 2003). Estimates by economist, Hu Angang of Tsinghua University, project 90 percent of lower level officials are corrupt, even though less than 1 percent of the highest provincial and ministerial level officials are corrupt. Id.
history of counterfeit goods and the profit potential of medicine, counterfeiting medicine is becoming one of China’s most pressing problems.

This article explores the impact of counterfeit medications in China. Part II looks at the history of legal protection of the pharmaceutical industry in China. Part III looks at the problems of reporting and the growing sophistication in production of counterfeit medication. Part IV examines China’s legislative framework and enforcement mechanisms. Part V, discusses why there is a market for counterfeit medication. Part VI and VII discuss the impact of counterfeit medication on China and the rest of the world.

II. OVERVIEW OF CHINA’S PHARMACEUTICAL INDUSTRY

In China, pharmaceuticals are regulated by the State Drug Administration (SDA), a central government body which reports directly to the State Council; the SDA is responsible for supervising and controlling all medicine. Companies wishing to obtain permission to manufacture or sell pharmaceuticals must first apply to the SDA. Prior to the SDA’s formation in 1998, United States pharmaceutical companies were not granted patents or licenses. Instead, the Central government issued Administrative Protection (AP), as governed by a Memorandum of Understanding (MOU) between the United States and China signed in 1992. Similar MOUs have also been reached between China with European countries and Japan as well. For American patents granted between 1986 and 1992, AP rights provided for 7.5 years of market


12 Id.; see also State Drug Administration, CHINA ONLINE, available at http://www.chinaonline.com/refer/ministry_profiles/SDA.asp [hereinafter SDA] (last visited Dec. 8, 2003). In lieu of using the word “patent,” Administrative Protection was the term given to a period of market exclusivity whereby the Chinese Central government would protect and enforce an American pharmaceutical product’s pharmaceutical patent. Id.

13 See AMCHAM, supra note 10.

14 Id.
exclusivity.\textsuperscript{15} However, American pharmaceutical companies realized few benefits under the MOU.\textsuperscript{16} For example, inconsistent or unpublished policies were enacted allowing local Chinese companies to capitalize on the AP’s lengthy evaluation period.\textsuperscript{17} Because the average wait for AP approval was 30 months, many local Chinese companies could also gain legal registration of the drug during the AP evaluation period.\textsuperscript{18} This meant local Chinese companies could start marketing the drug before the American pharmaceutical company.

In addition, one of the criteria for approving an American pharmaceutical drug was that the Chinese market did not already have a similar drug.\textsuperscript{19} However, if a local Chinese company started to sell the drug while the American company was waiting for approval, this meant that a “similar” drug was already in the Chinese market. Consequently, the SDA would find that similar products were already in the Chinese market, find that the pharmaceutical company did not need exclusive protection, and then reject its AP application. These tactics and loopholes often resulted in delays and denials of an AP application.\textsuperscript{20}

Faced with national legislation that often favored domestic companies, foreign pharmaceutical companies also found that local municipalities would enact biased legislation as well. In Guangdong province for example, protectionist policies like the “70/30 Rule” directed that at least 70 percent of hospital pharmaceutical purchases be of

\textsuperscript{15} See AMCHAM, supra note 10.

\textsuperscript{16} Id.


\textsuperscript{18} See AMCHAM, supra note 10. See also Cai, supra note 17 (noting that the unconfidentiality of the process and delays were barriers to China’s market for foreign pharmaceutical companies); see also United States State Department: National Trade Estimate Report on Foreign Trade Barriers, CHINA TRADE SUMMARY 2001, available at http://usinfo.state.gov/regional/ea/iprcn/2001nte.htm (last visited Dec. 9, 2003) (reporting that in July 1994, the SDA rejected AP applications from two major pharmaceutical companies, demonstrating the difficulties of obtaining AP).

\textsuperscript{19} Cai, supra note 17. The MOU provided 7.5 years of market exclusivity if the product was not previously marketed in China. Id.

\textsuperscript{20} See AMCHAM, supra note 10; see also Cai, supra note 17 (noting that such tactics undermined the competitive advantage of American companies).
domestically produced pharmaceuticals. These directives, however, violated the national treatment standards of the WTO, and were repealed, but some hospitals in the Guangdong area continue to abide by them. Because the system favors domestic manufacturers, such directives limit Chinese consumers’ access to life-saving medications and steer hospital pharmaceutical purchasers to local producers who might not adhere to the stringent production standards of an American pharmaceutical company. This means that less expensive, substandard or counterfeit medication is often the first thing China’s hospital purchasers and their patients reach for in their medicine cabinet.

III. WHAT IS THE REALITY?

China is facing a difficult dilemma of trying to provide affordable healthcare after privatizing its healthcare system. Because many Chinese cannot afford medicine, many Chinese hope they do not get sick. Yet if they do get sick, they must find cheaper alternative medicine or avoid the hospital altogether. When Chinese seek medicine as they would normally, such as through a doctor or hospital, if they happen to obtain counterfeit medicine, the reality is that more than half of all counterfeit medicines contain no active ingredients, contain the wrong ingredients, or contain contaminants.

A. Lack of Reported Cases

China has been slow to report, and has even underreported, cases of counterfeit medicine fatalities. Even more troubling, often these fatalities are reported, falsely, as resulting from natural causes—but in many instances the doctors do not even realize that the medicine is counterfeit. In a very recent and well-known health epidemic, numerous newspapers

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21 See AMCHAM, supra note 10; see also Cai, supra note 17 (noting that provincial protectionist policies made it difficult for American companies to get onto formularies in Chinese hospitals).

22 See id.


24 Id.

25 Goodman, supra note 1.

26 Fackler, supra note 1.
and news agencies reported that China failed to report the Severe Acute Respiratory Syndrome (SARS) forthright.\textsuperscript{27} Some experts argue that patients probably die everyday from counterfeit medication, but it goes unrecognized.\textsuperscript{28} For example, if a person has a heart attack, but receives a placebo, and then dies, it may become difficult to discern whether the death is the result of the heart attack or the placebo.\textsuperscript{29} Similarly, if a person takes an antibiotic, but remains uncured, it becomes difficult to determine whether this is due to a wrong antibiotic medicine provided, or because the recipient’s bacteria are resistant, or the possibility that there was no antibiotic in the tablet at all.\textsuperscript{30}

With the counterfeiters’ adeptness in creating and packaging counterfeit medicine, detecting and tracing counterfeit drugs to their source is becoming more and more difficult.\textsuperscript{31} Investigators have uncovered counterfeit medicines indistinguishable from genuine antibiotic medicines made of talcum powder and birth control pills made of rice flour.\textsuperscript{32} Some patients willing to buy what they think are cheaper drugs, purchased in plastic bags, which makes determining their origins difficult. For the Chinese people, however, buying medicine in plastic bags does not seem suspect because many Chinese who buy Traditional Chinese Medicine (TCM) receive their medicine in white butcher paper or in plastic bags.\textsuperscript{33} What’s more, because medicine is widely viewed as a commodity by the Chinese—something that is easily bought and sold using uncomplicated packaging—the buying of black market drugs is seldom viewed as improper or unlawful.\textsuperscript{34} More importantly, however, the problem remains that the Chinese consumer still has no way to determine whether the medicine is genuine or counterfeit. In brief, because of China’s history of underreporting, many believe that the actual number of casualties linked to

\begin{itemize}
\item[\textsuperscript{27}] Matt Pottinger, \textit{Outraged Surgeon Forces China to Take a Dose of Truth}, W\textsc{all} S\textsc{t}. J., Apr. 22, 2003 at A1. The article describes how Dr. Jiang Yanyong witnessed the atrocities of the 1989 Tiananmen Massacre and the SARS epidemic of late 2002, where China’s government failed to disclose the actual numbers for both events—those killed in Tiananmen and the total victims of the SARS outbreak. \textit{Id}.
\item[\textsuperscript{28}] Hajari, \textit{supra} note 6.
\item[\textsuperscript{29}] \textit{Id}.
\item[\textsuperscript{30}] \textit{Id}.
\item[\textsuperscript{31}] \textit{Id}.
\item[\textsuperscript{32}] Goodman, \textit{supra} note 1.
\item[\textsuperscript{33}] See e.g., \textit{A Visit to a Chinese Pharmacy}, A\textsc{wake}!, Nov. 8, 2000, available at http://www.watchtower.org/library/g/2000/11/8/article_01.htm (last visited Dec. 9, 2003).
\item[\textsuperscript{34}] Hajari, \textit{supra} note 6.
\end{itemize}
counterfeit medication could be far greater than reported.\footnote{Fackler, supra note 1.}

\section*{B. Sophistication of Counterfeitors}

Even more disturbing is how sophisticated counterfeiters produce fake packaging that is almost unmistakable from the genuine product. Typically, the packaging on pharmaceutical products sent to hospitals is very simple, featuring white labels with black lettering and sometimes a pastel colored stamp.\footnote{Geoff Power, \textit{Pharmaceutical Counterfeiting}, INT’L CRIM. POLICE REV., No 476-477 (1999), available at http://www.interpol.int/Public/Publications/ICPR/ICPR476_1.asp (last visited Feb. 10, 2004) [hereinafter Power].} Such simple packaging would be easy to counterfeit using any basic computer program. In an attempt to outsmart counterfeiters, the Pfizer Corporation developed a hologram for packaging as part of its anti-counterfeiting program.\footnote{Public Health Concerns of Counterfeit Medicine: Hearing Before the Spec. Comm. On Aging (July 9, 2002) (testimony of John Theriault, V.P., Corp. Sec., Pfizer, Inc.), available at 2002 WL 2031762 [hereinafter Theriault]; see also Hajari, supra note 6; see also Power, supra note 36.} Holograms are more difficult to replicate because they are metallic and labor intensive to reproduce. However, between November 1999 and May 2001, Taiwan police authorities seized 147,000 Norvasc tablets (the world’s best selling high blood pressure medicine) along with counterfeit packaging that included holograms.\footnote{Id.} This proved that the reproduction of holograms is not beyond the skills of the counterfeiters.

There are many facets to the reality here. United States pharmaceutical firms are learning that, excluding amateurs, not only are the counterfeiters from organized crime networks, local police, or the military, but they also may be their own suppliers.\footnote{Gabriel Kahn, \textit{What Happens When Knockoffs are Made by Your Own Supplier: U.S. Clothing Firms are Learning the Hard Way in Push into China}, ASIAN WALL ST. J., Dec. 19, 2002, at A1.} What’s more, China’s state-owned enterprises (SOEs) have participated in the manufacture and export of counterfeit medicine as well.\footnote{Counterfeiting in the Pharmaceutical Industry, CHINA HEALTH SCI. NEWSL. (Lehman, Lee & Xu, Beijing, China) Mar. 20, 2002, available at http://www.chinalaw.cc/newsletter/pharma/20020320.htm (last visited June 8, 2004).} When seeking patents, many foreign companies must disclose their formulas to receive patent protection. When these same companies open up shop in China, they form Joint Venture
Operations with local Chinese companies where they disclose manufacturing information. The reality is that sometimes these “partners” end up using the information they gained to make profits on the side.  

Another part of the reality is that local law enforcement is not merely dealing with companies or factories, but small households, too. “You close one, they move to another. It’s really impossible to eradicate this problem. We’re managing it more than solving it,” said Smiling Wolf’s general manager, Lui Dianlin. Few doubt the China central government’s resolve to deal with the problem. Between June 2001 and August 2002, Johnson & Johnson’s Shanghai-based attorney successfully established 38 criminal cases against counterfeiting factories compared to the three previous years when the total was only two. Nevertheless, with the adeptness of the counterfeiters and the lack of reporting, the reality is that the authorities are encountering great difficulty in stopping this epidemic.

IV. SOLVING THE DILEMMA—CHINA’S LEGISLATIVE SOLUTIONS

As an important part of facilitating access and competition into China’s pharmaceutical market, China has enacted laws and regulations to ensure the protection of intellectual property and the quality of patented medicine. The implementation, however, of these laws and regulations has been a great challenge to China.

A. Pharmaceutical Administration Law

China revised the Pharmaceutical Administration Law (hereinafter “Pharm. Law”) on February 28, 2001 to ensure the quality and safety of medicine. Specifically, Article 48 of the Pharm. Law defines and prohibits the sale of counterfeit or fake pharmaceuticals. There are set criteria designating certain pharmaceuticals as counterfeit or inferior. For example, if pharmaceuticals are expired, contaminated, passed off as being

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41 Kahn, supra note 39.

42 Goodman, supra note 1.

43 Goodman, supra note 1. Smiling Wolf Consultative is a Guangzhou-based, private investigative company frequently hired by pharmaceutical firms. Id.

44 Id.

another pharmaceutical, mislabeled, the batch number is missing or altered, or the medicine is determined inferior, they will be deemed unfit. The Pharm. Law also attaches administrative and criminal penalties where applicable. Pharmaceuticals produced or sold illegally allow for revocation of pharmaceutical approval certificates, and/or a deprivation of all revenues derived from transportation and an imposition of a fine between 50 percent to not more than three times the illegal revenue. The Pharm. Law also allows the confiscation and imposition of fines on the pharmaceutical trader or the medical institution for purchasing counterfeit pharmaceuticals from a vendor who does not possess a Pharmaceutical Trading or Production License. Thus, with the possibility of monetary fines and confiscation, some hospitals should be dissuaded from purchasing cheaper, inferior medicine. Adding the possibility of criminal liability, on top of seizure of illegal revenue and fines, should further deter some counterfeit sellers. Theoretically, the Pharm. Law should be effective since it attempts to shut down both ends of the transaction by deterring hospital

46 PHARM. LAW art. 48 (“The production . . . and sale of fake pharmaceuticals is prohibited. A pharmaceutical shall be deemed a fake pharmaceutical if: (1) ingredients do not conform with the ingredients specified . . . or (2) it is a non-pharmaceutical product being passed off as a pharmaceutical.”); see also, art. 49 (“The production and sale of inferior pharmaceuticals are prohibited. Pharmaceuticals the ingredient content of which does not conform with the State pharmaceutical standards shall be deemed inferior pharmaceuticals. A pharmaceutical shall be treated as inferior pharmaceutical is: (1) . . . time of expiration is not indicated or altered, (2) batch number is not indicated or is altered, (3) its expiration date has passed . . . ”).

47 See generally PHARM. LAW, ch. 9 Legal Responsibility. See PHARM. LAW art. 73 (proscribing pharmaceuticals illegally produced or sold may incur criminal liability); see also art. 92 (proscribing criminal liability for pharmaceutical enterprises that falsely advertise); see also art. 94 (proscribing criminal liability for illegally issuing proof of certification when enterprises do not comply with the [Pharm. Law]).

48 PHARM. LAW art. 75 (“If inferior pharmaceuticals are produced or sold, the pharmaceuticals illegally produced or sold and the illegal income derived therefrom shall be confiscated and a fine of not less than once and not more than three times the merchandise value of the illegally produced or sold pharmaceuticals shall be imposed.”).

49 PHARM. LAW art. 77 (“If anyone provides such facilitating conditions as transportation, safekeeping or storage for what he knows or ought to know to be fake or inferior pharmaceuticals, all revenue derived from the transportation, safekeeping or storage thereof shall be confiscated and a fine of not less than 50 percent and not more than three times the illegal revenue shall be imposed.”).

50 See generally PHARM. LAW art. 80 (detailing the application process for obtaining a pharmaceutical license). First the pharmaceutical manufacturer’s representative or authorized agent must open a file with the SDA who must verify the quality specification and perform sample test on three batches of the drug. A legal document is awarded, granting the manufacturer the right to register, import, sell, and use the import drug in China. See Gross, supra note 5.
purchasers from buying cheap unauthenticated drugs and preventing the sellers’ distribution.

B. **Civil and Administrative Penalties**

Civil or administrative penalties can also attach in conjunction with violations of the Pharm. Law.\(^{51}\) The penalties are set forth in the Law of the People’s Republic of China on Protecting Consumer Rights and Interests (hereinafter “Consumer Law”), adopted on October 31, 1993.\(^{52}\) The Consumer Law mandates that both producers and consumers must conduct business transactions voluntarily with quality, fairness, honesty, and credibility.\(^{53}\) Chapter VII of the Consumer Law lays out in detail the legal liabilities for selling counterfeit products. Civil liability applies to any defective product sold—including if it does not function as expected, does not match the description, or if the product is sold in a manner whereby it loses its efficacy.\(^{54}\) Articles 49 and 50 explain the most stringent penalties for violating the Consumer Law. Under these provisions, the seller must compensate the consumer, and either, have their earnings confiscated by authorities, or pay authorities a fine equivalent to one to five times the amount of their illegal earnings.\(^{55}\) In cases where there are no illegal earnings, the department in charge of the administration can still impose a fine of up to 10,000 yuan (or Renminbi).\(^{56}\) By expanding the coverage of liability, China may be able to arm local authorities with more legal tools to penalize offenders.

\(^{51}\) See Pharm. Law art. 97 (“If an enterprise that has obtained a Pharmaceutical Production License or Pharmaceutical Trading License produces or sells fake or inferior pharmaceuticals, then, in addition to pursuing the legal liability of the said enterprise in accordance with the law, the personnel directly in charge and other directly responsible personnel of the pharmaceutical regulatory department who have been neglectful or derelict in their duties shall be subject to administrative punishments in accordance with the law.”); see also Drug Law Targets Counterfeit Products, China Daily, Aug. 2000, available at http://www.16congress.org.cn/english/2000/Aug/1083.htm (noting the current Pharm. Law provides civil, administrative, and criminal liabilities for producing and selling counterfeit medicine).


\(^{53}\) Consumer Law art. 4.

\(^{54}\) Consumer Law art. 40.

\(^{55}\) Consumer Law art. 49; see also Consumer Law art. 50.

\(^{56}\) Consumer Law art. 50.
C. Criminal Penalties

To deter counterfeiting further, China’s Criminal Law\(^{57}\) (Crim. Law) prohibits the sale and production of counterfeit medicinal products. Emphasizing that counterfeit medicine can cause serious dangers to human health, the law imposes a sentence not more than three years of imprisonment or criminal detention, in addition to a fine for not less than 50 percent and not more than 200 percent of the sale amount when it causes serious harm to human health.\(^{58}\) In instances where the counterfeit medicine causes death, the sentence imposed may be no less than a ten-year fixed term and up to life imprisonment, as well as an additional fine not less than 50 percent and not more than 200 percent of the sale amount or confiscation of the property.\(^{59}\) Other sections of China’s Criminal Law list similar penalties.\(^{60}\)

Despite these stringent penalties, the Chinese government quickly learned that deterrence was insufficient. In 1993, the Eighth National People’s Congress adopted a supplement to the Crim. Law to boost the penalties, titled the Decision of the Standing Committee of the Nationals People’s Congress on Punishing the Crimes of Production and Sale of Fake or Substandard Commodities (hereinafter “Supplement”).\(^{61}\) The Supplement lengthens fixed term prison sentences and increases fines to up to one million yuan.\(^{62}\) However, there are no stiff penalties imposed upon

\(^{57}\) CRIMINAL LAW OF THE PEOPLE’S REPUBLIC OF CHINA (adopted at the Second Session of the Fifth National People’s Congress, July 1, 1979, revised at the Fifth Session of the Eighth National People’s Congress, Mar. 14, 1997 (Chinalaw Web trans.), available at http://www.qis.net/chinalaw/prclaw60.htm (last visited n.d., on file with author) (also available at LEXIS PRCLEG 354) [hereinafter CRIM. LAW].

\(^{58}\) CRIM. LAW art. 141 (“Whoever produces or sells fake medicines which are sufficiently able to seriously endanger human health is to be sentenced to not more than three years of fixed-term imprisonment or criminal detection and may in addition or exclusively be sentenced to a fine of not less than 50 percent and note more than 200 percent of the sale amount.”).

\(^{59}\) CRIM. LAW art. 142. (“Whoever produces, sells inferior medicines thereby causing severe harm to human health is to be sentenced to not less than three years and not more than ten years fixed-term imprisonment and may in addition be sentenced to a fine.”).

\(^{60}\) See e.g., CRIM. LAW art. 347.


\(^{62}\) CRIM LAW SUPPLEMENT para. 1, 2.
State officials who exploit or abuse their office to shield such enterprises engaged in counterfeit medicine trade, but instead they are merely subject to investigation.63

D.  Enforcement—Has the Solution Worked?

China has taken steps to increase their penalties and revised their regulations in accordance with some of the pharmaceutical industry’s recommendations. Although many legislators argued for the increase in penalties and the need for more regulations, statistics show that this zero tolerance attitude has not been entirely successful.64 China’s central government believes that the SDA, armed with stiffer penalties and more authority to carry out raids and prosecute offenses, is adequate to eradicate the trade.65 In fact, last year China reported closing 1,300 factories and investigated 480,000 cases involving counterfeit medications worth $57 million.66 However, three years have passed since the Pharm. Law’s enactment in 2001, and the evidence shows that the counterfeit medicine in circulation continues to rise.67 Although amateur counterfeiters may dig up empty medicine bottles from the trash and refill them or might label a bottle with a similar sounding name and packaging, counterfeiting medicine is fast becoming a part of the business of organized crime networks.68 Counterfeiting now ranges from repackaging to re-labeling outdated, ineffective, or unsafe drug products.69 To date, examples of the kinds of

63 Id. para 10.

64 Xiao Xie, Deputies - Drug Counterfeitors Fall Ill of the Rules, CHINA DAILY, Mar. 12, 2002. “We suffer a shortage of legal instruments to penalize such illegalities, and our punishment is too weak to be effective,” said Song Yadong, the deputy director of the Drug Administration of Suihua City and an NPC deputy from Northeast China’s Heilongjiang Province. Id.

65 Goodman, supra note 1.

66 Id.


68 See Goodman, supra note 1 (noting that law enforcement officials and diplomats report that the high profit business of medicine is attracting organized crime).

counterfeit medicine found throughout China include eye-drops made of tap water, antibiotics made of turmeric or talcum powder, cough syrup made of anti-freeze, or even antivenom with no active ingredients. These types of counterfeit medicine are some of the most dangerous kinds. Because the counterfeiters know medicine prices are soaring, they are replicating the more expensive drugs.

1. Entry of Organized Crime

Since counterfeiting is a business marked by high demand and low production costs, it is a “golden business” for organized crime syndicates as one pharmaceutical director noted. “If you’re in the business of selling heroin or cocaine, the police are on your tail. If you are making fakes meningitis medicine, they don’t even know you’re there.” Lacking real enforcement, the collusion of police and crime networks means counterfeiting medicine is more lucrative than the illegal drug trade. And with organized crime working with police support, the laws go unenforced and remain inadequate.

The central government went to great lengths to strengthen the penalties, but organized crime networks are learning how to find the loopholes in the system. Organized crime networks’ counterfeit production

visited n.d., on file with author) (describing how outdated and re-labeled medication can reenter into circulation as counterfeit medication); see also Therihault, supra note 37 (noting extensive efforts counterfeiters use to repackage medication)

70 Hajari, supra note 6.

71 Douglas Pasternak, Knockoffs on the Pharmacy Shelf: Counterfeit Drugs Coming to America, U.S. NEWS & WORLD RPT., June 11, 2001 (stating that chemotherapy treatments like Neupogen, which cost a patient between $150-$250 per vial, and Serostim, which costs about $12,000 for a 12-week supply, are highly expensive. However, for counterfeiters who can produce mass quantities for fraction of the real cost, it translates into a very lucrative business).


73 Id.

74 Goodman, supra note 1; see also Xie, supra note 64 (noting that the general manager of a renowned pharmaceutical joint venture company in China stated, “the work [to arrest counterfeiters] is even harder when some of the counterfeiter makers are protected by local authorities.”).

75 Gross, supra note 5, at 10.
in China is typically set up in small households keeping low quantities of supplies in case of criminal prosecutions. If people are caught, at most they are only liable for civil fines or a maximum sentence of seven years. If selling the counterfeit medications results in the death of a user, a death sentence is possible, but the government rarely seeks that extreme of a sentence.

“If you get caught selling sugar pills, it could be a criminal offense. But if you put in some active ingredients, all of a sudden it becomes a trademark violation, and the penalties are much less severe,” says a drug company official. Moreover, corrupt officials usually face only insignificant punishment. They are merely subject to an investigation, and may possibly lose their job. For there to be a real threat of punishment, the law needs to impose prison terms or confiscation of their illegal bribes or kickbacks. The police authorities know they are not subject to criminal prosecution. As a result, corrupt officials try to profit from these schemes.

There have been numerous reports of police needing a “travel allowance” before they would even attempt a raid on local manufactures. This kind of corruption is a telling sign. If the meagerly paid government officials are taking bribes to help cover the illegal trade that means the companies that are interested in having these authorities enforce and do their jobs must make it financially worth their while. Without toughening

76 Goodman, supra note 1; see also WHO, supra note 72 (describing how production facilities for counterfeit medicine do not require large facilities, but in small households, backyards, and cottage industries).

77 WHO, supra note 72, at 10.

78 Hajari, supra note 6; see also Goodman, supra note 1 (elaborating on the difficulties with detection, “If you’re in the business of selling heroin cocaine, the police are on your tail. If you’re making fake meningitis vaccine, they don’t even know you’re there.”).


80 Goodman, supra note 1. Even when a major Western pharmaceutical manufacturer said his Guangzhou office recently received a tip from police bureau finding a factory with $120,000 worth of fake copies of their products, the police were happy to launch a raid provided his company first pays a $40,000 “travel allowance,” which the company declined. Id.

81 James Mulvenon, To Get Rich Is Unprofessional: Chinese Military Corruption in the Jiang Era, (June 6, 2003), available at http://www.chinaleadershipmonitor.org/20032/jm.htm (last visited Dec. 8, 2003); see also Fackler, supra note 1 (noting that in many cases, penalties for counterfeit medication violations amounted only to US $50).
laws on the officials who are aiding the counterfeit trade system, there can be no real deterrent to curb corruption.

2. Military and Police Corruption

There are also reports that the military is now involved in the counterfeit pharmaceutical trade.\(^{82}\) Newspapers are reporting that the military is involved in shipping counterfeit medicine across the country and even tipping off home factories before raids transpire.\(^{83}\) Although the government recently removed the People’s Liberation Army’s (PLA) formal involvement with most businesses, the old network remains.\(^{84}\) Trucks with military license plates bring counterfeit goods out of Puning’s pharmaceutical market, and retired military officers control many of these counterfeiting operations.\(^{85}\) In April 2002, for example, private investigators and local police found $60,000 worth of counterfeit medication, but no one to arrest, which raised suspicions of an early tip off.\(^{86}\)

The Central government has recognized the difficulty of bringing military members to justice. “Every time our custom officials tried to snare [them], some powerful military person appeared to speak on their behalf,” stated Premier Zhu Rongji.\(^{87}\) Moreover, in the 1990s, President Jiang Zemin called on the PLA to rid itself of corruption and launched an anti-

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\(^{82}\) Goodman, supra note 1; see also Clark, supra note 2, at 10 (noting the coordination of military, police, political officials, and prosecutors through bribes, kickbacks, and extortion exacerbate the problem).

\(^{83}\) See generally, Mulvenon, supra note 81 (discussing various newspaper accounts of military involvement in smuggling counterfeit goods).

\(^{84}\) See Tim Ito, China Special Report—Overview: Military, WASH POST, July 1998, at http://www.washingtonpost.com/wp-srv/inatl/longterm/china/overview/military.htm (last visited Dec. 8, 2003). The PLA controls an estimated 15,000 businesses, some seemingly innocent, but some companies also accused of counterfeiting. Id. Official estimates put PLA business profits over $1 billion. Id. See also Mulvenon, supra note 81, at 24 (describing how China under Jiang Zemin carried out campaigns to rid corruption from the military, but by 1998, smuggling in other areas increased such as in cigarettes, counterfeit money, fruits, guns, and counterfeit drugs).

\(^{85}\) Goodman, supra note 1. The city of Puning is a major pharmaceutical port and is fast becoming a hub for counterfeit pharmaceuticals. Id. See also Ito, supra note 84 (noting that PLA companies have also been accused of smuggling because their trucks do not pay tolls and are not stopped by the police).

\(^{86}\) Goodman, supra note 1.

\(^{87}\) Mulvenon, supra note 81, at 25.
corruption campaign a year later. Regardless of senior leaders’ efforts, very few PLA members were indicted. Corrupt military officials need to be brought under stricter control so others realize the military and those counterfeiters working with them are not above the law.

V. Why is There a Market for Counterfeit Medications?

With a growing elderly population and a high demand for medicine, the Chinese people are facing huge changes within their healthcare system. Along with these changes, there are several reasons why the counterfeit pharmaceutical market is still thriving.

A. Lack of Consumer Education

Although China’s citizens are reaching higher levels of general education then before, there is a dangerous gap in understanding between the counterfeit distributor and buyer of counterfeit medicines. Counterfeit designer handbags and watches are common in China, but with these types of goods, the consumer and distributor are usually both in on the fraud. A recent survey illustrated this indifference to counterfeit goods; the majority of Chinese were found more likely to buy counterfeit goods. However, in the counterfeit pharmaceutical trade, the distributor will realize a greater profit margin from the consumer, who buys the counterfeit medicine, only if the consumer thinks the product is the genuine, name brand product. In fact, in the same survey, there was overall strong opposition to buying counterfeit medicine. Thus, it is highly unlikely most Chinese would put their health at risk if they thought that the potentially life-saving drug they were paying for was in fact likely to be a fraud. The counterfeit distributor only has to lower slightly the price to make a substantial profit. He will make a substantial profit based on his non-existent research and development, lack of advertising costs, and dependence upon the public’s trust of the name brand’s product reputation, which he is taking advantage of with counterfeit goods.

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88 Mulvenon, supra note 81, at 25.

89 Id.

90 Goodman, supra note 1.

91 QBPC, supra note 3.

92 Id. On a scale of 1 to 5, with 5 being strongly opposed, most respondents noted a 4.7 when it came to buying counterfeit medication. Id.
B. Unaffordable Medication

1. Looking for Alternatives

Perhaps the predominant reason there is a market for counterfeit medications is that the high cost of essential drugs drives people to seek less costly alternatives. Today’s consumers have a wide selection of medicinal products. Alternative medicine, self-medication, and especially holistic and nutritional supplements are very popular. The Chinese Commerce Department statistics estimate that the nutritional supplement market is valued at $3.63 billion, and expects the market value to grow to over $10 billion by 2010. As the birthplace of Traditional Chinese Medicine (TCM), China is the world center of alternative medicine. The Chinese are accustomed to using TCM, especially in rural areas where Chinese have lower incomes. However, over-the-counter medicines (OTC) sales have recently seen a significant increase, and the number of stores carrying OTCs

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95 See Commerce, supra note 94.


97 China Has 136,000 Clinics, Mostly For TCM, CHINA DAILY, Jan. 22, 2003, available at http://ce.cei.gov.cn/enew/new_h1/fg00hao6.htm (last visited Dec. 8, 2003) (noting that a survey by the State Administration of Traditional Chinese Medicine indicated that of the patients seeking private medical clinics, 60 percent favored TCM).
has boomed across China.\footnote{Jayshree Ramsurun, \textit{Profile Changing China}, Pharma Profile, Sept. 2002, \textit{available at} http://www.chccgroup.com/Archive/PPR\%20China\%20doc.pdf; \textit{see also} Cai, \textit{supra} note 17, at 2; \textit{see also} China's OTC Market Prospers, [hereinafter OTC Market], \textit{available at} http://www.asiabiotech.com/readmore/vol5/v5n14/china.html (last visited Dec. 8, 2003) (noting that in 2000, the OTC market was valued at $1.5 billion, and is expected to reach $7.3 billion by 2005, and expand 30 percent annually).} According to Hu Shengyu, Vice-Chairman of China’s OTC Commission, because of the high cost of prescription medicine, the Chinese are looking towards TCM and OTC medications to fill the gap.\footnote{OTC Market, \textit{supra} note 98; \textit{see also} Dequan Ren (Deputy Director of SDA), Current Status of TCMs in China, \textit{available at} http://search.weforum.org/ (last visited Apr. 22, 2004) (noting the average rate of increase of TCM sales between 1991 and 2001 was 23.4 percent).} Unfortunately, for those who want Western medicine, finding affordable medication can push many Chinese, who are from a culture that largely condones counterfeits, to buy counterfeit medications that may be ineffective and dangerous.\footnote{See QBPC, \textit{supra} note 3 (noting that on a scale of 1 to 5 (5 being strongly opposed), respondents averaged 4.7 to a survey of whether they would purchase counterfeit pharmaceuticals). However, 84 percent of respondents also noted that they have purchased counterfeit goods, and further noted that the respondents were more inclined to buy premium name brands. \textit{Id. See also} Clark, \textit{supra} note 2, at 9 (noting the Chinese acceptability with buying counterfeit goods).}

2. The Added Costs of Manufacturing Medicine

There are also many medicine-monitoring regulations that keep medicine in China unaffordable.\footnote{Commerce, \textit{supra} note 94, at 2.} China has set up a monitoring program to ensure the quality of medicine sold in the Chinese market called GMP, which is short for Good Manufacturing Practices.\footnote{Ramsurun, \textit{supra} note 98 (noting the added costs of $20-30 million RMB to manufacturing costs).} It is difficult to criticize these well-intentioned monitoring efforts, but they add to the price tag of medicine sold to the public and therefore increase inaccessibility. Since December 2001, all pharmaceutical companies are required to meet GMP monitoring standards by 2004.\footnote{\textit{New Drug Rule for Pharmaceutical Labs}, \textit{China Daily}, Jan. 10, 2003, \textit{available at} http://www.newsgd.com/business/laws/200305140334.htm (last visited Dec. 9, 2003). GMP licenses which all pharmaceutical labs must comply with by 2004, cost millions of yuan to obtain. \textit{Id.}} This is costly to the pharmaceutical businesses and costs an average of 20-30 million yuan for the more than...
6,000 pharmaceutical companies in China.\textsuperscript{104} Experts predict half of those
6,000 manufacturers will be put out of business or acquired by other companies.\textsuperscript{105} This translates into additional costs that fall onto the Chinese consumer. Only consumers who can afford the higher cost of medicine, like the more than 55 percent in urban dwellers and only 13 percent of rural residents, may be able to get access to these medicines.\textsuperscript{106} However, in a predominantly rural nation like China with over a billion people, this means that many millions of Chinese cannot afford medicine that has gone through the GMP quality control system.\textsuperscript{107}

3. Is Social Insurance to Provide Healthcare to More Chinese?

The central government is trying to control prices for its citizens.\textsuperscript{108} Attempting to facilitate affordable medicine and provide health coverage for more people, China has implemented a Social Insurance system for employed Chinese, but this places a heavy burden on employers. Employers must contribute 6 percent of their annual payroll to the Urban Employee Basic Medical Insurance System in China.\textsuperscript{109} Employees have to make up the cost the insurance does not cover.\textsuperscript{110} Because the Insurance System only covers employed Chinese, the unemployed do not get adequate medical insurance.\textsuperscript{111} Even for the employed, the insurance is often not

\textsuperscript{104} Ramsurun, \textit{supra} note 98 at 266; see also Cai, \textit{supra} note 17, at 2 (describing the lack of competition for medication).

\textsuperscript{105} \textit{Id.} at 266.

\textsuperscript{106} \textit{Id.} at 267.

\textsuperscript{107} Williams, \textit{supra} note 23.


\textsuperscript{109} Ramsurun, \textit{supra} note 98 at 267.

\textsuperscript{110} \textit{Id.} In January 2001, the Economic Restructuring Office of the State Council (SERO) announced the introduction of a new basic national healthcare system called the Urban Employee Basic Medical Insurance System. It is set up for employees/workers in urban areas. The government hopes to have this up and running in the next two years, but for now it is being tested in main urban areas. \textit{Id.}

sufficient. The bottom line is that both groups, insured and uninsured, will look to save money, and buy cheaper medicine where they can.

4. Changes to China’s Healthcare System

Hospitals in China also are affected deeply by changes to China’s health care system. The government is now attempting to separate hospitals from their hospital pharmacies hoping that this may reduce the high price of medicine by cost-containment. The Chinese typically buy their prescription medication from the hospital pharmacies, which account for 80 percent of drug consumption in China. Hospitals are very dependent upon these hospital pharmacies because they account for 60 percent of the hospital’s revenues. Since hospitals rely on the profits of these pharmacies, officials frequently accuse hospitals of over-prescribing or corruption. The central government’s response to reduce over-prescribing is to take away the hospitals main source of revenue and make them more independent. Although the government’s purpose is to lower medicine costs, hospitals are forced to look elsewhere to replace lost revenue they were receiving from hospital pharmacies. In order to gain back this lost revenue, the cost of other medical services for patients will undoubtedly increase and patients will have to look elsewhere for affordable medical services and products. The fear is that patients will look towards cheaper, and more dangerous, counterfeit medicine.

As almost 60 percent of the PRC’s spending on health goes towards pharmaceuticals, making medicine more affordable is a necessary but difficult goal. Many point out that although pharmaceutical prices are, in

112 Pharmaceuticals in China: Overdosed, THE ECONOMIST, Nov. 5, 1998, at 71 [hereinafter Overdosed]; see also Ramsurun, supra note 98 at 268 (discussing China’s restructuring of its healthcare system).

113 Ramsurun, supra note 98 at 268.

114 Id. at 268, Bill Liang, managing director of China Healthcare Consulting states, “Hospital reform is complex and difficult” as China moves away from government supported ventures to independent entities. Id.

115 Id. at 268.

116 See Williams, supra note 23. According to Dr. Xu Yonghai, many doctors are over-prescribing medications and receiving kickbacks from drug companies. Id.


118 See Overdosed, supra note 112.
theory, controlled by the state, in practice, however, prices are inflated artificially by those who distribute the pharmaceuticals.\textsuperscript{119} This system has led to rampant corruption because the hospitals demand deep discounts of drugs from the hospital’s official purchasing list and use that price difference and the state’s reimbursement to subsidize hospital operations.\textsuperscript{120} If there are drugs available from other distributors at even steeper discounts, then hospital purchasers will make more money from purchasing cheaper medicine. The genuine pharmaceutical distributor is thus at a severe disadvantage when he can only offer the medicine at the state’s price cap and the counterfeiter can offer his product for a fraction of the state-controlled price. It has been reported that hospital purchasers, doctors, and nurses often cannot tell the difference between the counterfeit and the genuine medicines.\textsuperscript{121} If the hospital purchaser cannot distinguish between genuine and counterfeit medicine, the purchaser will be inclined to buy the lower priced medicine to make a bigger profit for the hospital. In sum, the patient must swallow a bitter pill if the hospital purchaser buys the counterfeit.

C. Black Market Provides Jobs

Furthermore, China is pressured by the changes in its economy to keep up a supply of jobs for its population. Local governments understand the need to keep people employed at a time when many of the country’s reforms in areas like agriculture are putting people out of work.\textsuperscript{122} Government officials cite statistics of a downward trend in economic growth from 1997 to 1999, from 1.1 to 0.36 percent. Because the job market is not growing in China, black market jobs provide income to the otherwise unemployed.\textsuperscript{123} In fact, an estimated 3-5 million people currently are engaged in black market jobs.\textsuperscript{124}

\textsuperscript{119} See Overdosed, supra note 112.

\textsuperscript{120} Id.

\textsuperscript{121} Goodman, supra note 1; see also New FDA Initiative to Combat Counterfeit Drugs, U.S. FOOD AND DRUG ADMINISTRATION, available at http://www.fda.gov/oc/initiatives/counterfeit/backgrounder.html (last visited Dec. 8, 2003) (noting the difficulty with detection).


\textsuperscript{124} Clark, supra note 2, at 9 (noting that revenues from these jobs amounted to $40-$80 billion a year).
Only recently, when an investigator tried to sneak into a household operation that was counterfeiting a German kidney-stone medication, the local residents beat him so severely he stayed in the hospital for one month.\textsuperscript{125} The government cannot disregard the unemployed who are in dire need of steady work and income. Thus, authorities are often “quietly tolerating” the market that fuels counterfeit medicines because the trade provides jobs.\textsuperscript{126}

Local governments are sensitive to the economic needs of the unemployed citizens and thus hesitant to carry out a harsh crackdown because these businesses provide much needed income and jobs. These factors contribute to the success and growth of the counterfeit medicine market.

VI. IMPACT OF COUNTERFEIT MEDICATIONS IN CHINA

A. Population Development

Counterfeit medicine is having a tragic impact in China. Due to privatization and modernization of healthcare, the health industry is starting to offer various levels of private medical services.\textsuperscript{127} Because people are becoming wealthier, the expectation for higher-quality medical services will also likely rise.\textsuperscript{128} The Chinese people’s growing wealth and expectations is giving the government concern because officials are expecting a 120 percent increase in demand for basic medical services.\textsuperscript{129} Officials are troubled that the rural population, which represents 70 percent of China’s total population, only receives 20 percent of public spending on health, and may suffer disproportionate access to health care.\textsuperscript{130}

\textsuperscript{125} Goodman, \textit{supra} note 1.

\textsuperscript{126} \textit{Id.} “Unsavory industries” are “quietly tolerated” by local government because China’s economic reforms are putting people out of work. For example, China’s has cut subsidies in agriculture and put farmers out of work. \textit{Id. See also} Fackler, \textit{supra} note 1 (describing local authorities’ collusion with counterfeiting criminals because they do not want to cause a loss of jobs or lose tax revenues).


\textsuperscript{128} \textit{Id.}

\textsuperscript{129} Feng, \textit{supra} note 127.

Moreover, when 20 million urban residents and 30 million rural residents remain at the State’s absolute poverty line, this causes great concern about the availability and accessibility to medicine. With 60 million rural residents who are barely able to dress warmly or afford enough to eat, one can only imagine what access they would have to medicine. Indeed, one can easily understand why the poorest Chinese would be most susceptible to buying counterfeit medicine when sold at a discount compared to the genuine product. This disparity in wealth means there is a growing sector of the population who is wealthier and demands higher quality, more expensive name brand medicines. However, there remains a large portion of China’s population, who cannot afford name brand medicine, and these people are likely to turn elsewhere in search of the “rich-man’s” medicine.

There is also an increasingly large elderly population that will be seeking name brand medications. In 20 years, there will be more than 170 million people over the age of 60 in China, increasing the number of patients who might suffer from chronic diseases and demand more medication. Add to that the growing number of AIDS patients, which China currently estimates at one million; this number is expected to increase 30 percent annually and reach 10 million by the end of the decade. China quite possibly may have a severe crisis on their hands.

Attempting to provide more health coverage, the government’s response has been to pledge $10 yuan ($1.20 USD) per year into the medical accounts of each rural resident as part of its Social Insurance system. However, with the high cost of name brand medicine, no doubt many Chinese will find counterfeit medicine more obtainable for their ailments. Counterfeit medicines have reached greater numbers of Chinese; in 2001 alone, more than 192,000 people in China died from using fake or

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131 Feng, supra note 127.

132 WHO, supra note 72, at 3.


135 Gill & Palmer, supra note 133.

136 Id.
poor quality medicine.  These figures illustrate that using medicine containing substances made of anything from chalk dust to fruit peels means that these counterfeit “cures” can be as deadly as the diseases themselves.

B. Danger to AIDS Treatments

As China is now just beginning to deal with its AIDS epidemic, the counterfeit medicine market poses a serious problem in terms of counterfeit AIDS medication. “One of the things we are going to see, very surely, is a lot of these bogus [AIDS] drugs will be in the slipstream. . . . [T]he market will be flooded with these for sure,” states Richard Feachem, Executive Director of Global Fund to Fight AIDS.

In the summer of 2003, pharmaceutical companies found alarming trends of AIDS pharmaceutical counterfeiting. On May 10, GlaxoSmithKline, a major pharmaceutical company with production factories in China reported that it received bottles of Ziagen incorrectly labeled as Combivir from California, Connecticut, Florida, and Maryland because of third party tampering. Both drugs are approved for treatment of HIV. On May 16, another pharmaceutical company, Serono, became aware of counterfeit Serostim, which is a treatment prescribed for wasting due to AIDS. On June 6, Johnson & Johnson also reported that counterfeit vials of Procrit, which is used to treat anemia associated with chemotherapy as well as zidovudine treatment in HIV patients, were found in Texas. These are only some of the incidents reported within a span of four weeks. The growing trend is alarming.

Goodman, supra note 1; Fackler, supra note 1.

Hajari, supra note 6.


Theriault, supra note 37.

Id.

Id.

Action, supra note 139. Counterfeit medications are frequently found in China, Cambodia, Laos Democratic Republic, Myanmar, Thailand, and Vietnam. Id.
expensive, and China has a population that must now deal with AIDS treatments. Counterfeiters have proved that they are very adept at mastering even the most complicated packaging and can capitalize on a growing trust in Western medicine.\textsuperscript{145} There are even reports in Beijing of counterfeiting drugs claiming to cure SARS.\textsuperscript{146} With China’s history of counterfeiting and the growing number of counterfeit drugs, China will face a dilemma of trying to provide quality medical care as well as trying to change the Chinese way of thinking that counterfeits are a cheaper, and therefore better, version of the real thing.

C. Easily Accessible—The Example of Viagra

Viagra is now the most popular counterfeit drug in China.\textsuperscript{147} Reports indicate that within the first four months of 2002, more than one million counterfeit Viagra tablets were seized.\textsuperscript{148} A growing trend in China is the selling of fake medicines in sex shops.\textsuperscript{149} Because sex is still sometimes a taboo subject for many men, many would rather go to a sex shop to purchase medicine touted to cure sexual dysfunction than see a doctor.\textsuperscript{150} With longer business hours, including some stores open 24-hours, these sex shops offer quick and easy access whereas getting these pharmaceuticals through hospitals is more time-consuming.\textsuperscript{151} In hospitals, patients must make an appointment, talk to a doctor, and have their sexual dysfunction noted on their permanent medical chart. However, shopping for medication at these shops spells danger for the average consumer. A

\begin{footnotes}
\footnote{145}{Power, supra note 36.}
\footnote{146}{Anthony Kuhn & Tyler Marshall, \textit{Inspectors to Comb China for Unreported Cases of SARS}, \textit{Los Angeles Times}, April 23, 2003, \textit{available at} http://www.latimes.com/ (last visited Dec. 11, 2003). Residents of Beijing have been reporting the sale of counterfeit medicine in response to the SARS epidemic. \textit{Id.}}
\footnote{148}{Theriault, supra note 37.}
\footnote{151}{\textit{Id.}}
\end{footnotes}
recent survey cited that of the more than 95 percent of sex shops in China selling medicine to cure erectile problems, half of them receive revenue from counterfeit medicinal products.\textsuperscript{152}

Because Chinese consumers can easily obtain counterfeit medicine from such shops or obtain undetectable counterfeit medication from hospitals,\textsuperscript{153} the consequences are troubling.

VII. IMPACT OF COUNTERFEIT MEDICINE OUTSIDE OF CHINA

A. Presence in Developed Countries

The worldwide healthcare industry’s goal is to ensure the highest standards of professionalism and product quality while considering the best interests of the patient’s well being.\textsuperscript{154} Many might think that because of stricter quality controls and with advancements in health care, developed countries like the United States are in no danger of counterfeit medications. However, one must also consider that 80 percent of the active ingredients in United States prescription medicines come from overseas.\textsuperscript{155} Due to the exploitation of the public’s trust and the public’s reliance upon the good name of well-known products, one can see the danger counterfeit medications pose to countries other than China.\textsuperscript{156} The World Customs Organization now estimates that counterfeiting activities cost the pharmaceutical industry $12 billion USD a year.\textsuperscript{157} Because many pharmaceutical companies are moving manufacturing plants overseas and

\textsuperscript{152} Id. A random inspection in Shanghai revealed 197 forged approval numbers for distribution. Furthermore, over 90 percent of the shops in Shanghai sold counterfeit Viagra. Id. See also Shops, supra note 149 (citing a survey conducted by China Consumers’ Association of Beijing, Shanghai, and South China’s Guangzhou province).

\textsuperscript{153} Power, supra note 36. Simple packaging presents little challenge to resourceful counterfeiters, making counterfeit medicine easy to make and difficult to detect. Id.

\textsuperscript{154} Power, supra note 36.


\textsuperscript{156} Power, supra note 36; see also ICC, supra note 155.

\textsuperscript{157} Power, supra note 36 (stating that according to the World Customs Organization statistics, 5 percent of all international trade is falsified).
the lucrative appeal of selling pharmaceuticals, the United States and the rest of the developed world is not incapable of being affected.

In developing countries like China, estimates show that as much as 25 percent of pharmaceuticals are counterfeit. In some Chinese cities, as much as 40 percent of the medicine supply is counterfeit. Developed countries, where most believe protected by tight controls that make counterfeits rare, consume about 85 percent of the world’s prescription medicines. Although a majority of the counterfeit drugs impact developing countries, developed countries, including the United States, are proving they are not immune from this growing problem. “Despite existing regulatory and legal efforts, the counterfeiting of pharmaceuticals remains a very serious public health concern,” said Peter Lowe, International Crime Services Counterfeiting Intelligence Bureau.

In 1996, 89 children in Haiti died after they were given a Chinese manufactured cough syrup that contained anti-freeze. In 2002, five women in Japan and Singapore died and more than 60 became sick after taking Chinese manufactured diet pills. The packaging failed to list ingredients that cause liver and thyroid damage. Only recently, authorities in Wisconsin and Minnesota found empty bottles of Eli Lilly’s drug Zyprexa, a drug prescribed for schizophrenia and acute bipolar mania, filled with white tablets marked “aspirin.” Authorities in New York intercepted a counterfeit Viagra distribution ring linked to factories in China. In another case, Pfizer recalled 200,000 bottles of falsely labeled Lipitor, an anti-cholesterol drug; they were copied so well that Pfizer only

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158 Goodman, supra note 1.

159 Id.

160 Id.


162 See ICC, supra note 155.

163 Fackler, supra note 1; see also ICC, supra note 155.

164 Id.

165 Id.

166 Therihault, supra note 37.

167 Goodman, supra note 1.
received 20 complaints. 168

1. Smuggling through Mexico

The counterfeit medication is across United States borders through the same means used to smuggle illegal drugs. It can come smuggled inside speakers or teddy bears. 169 Undercover investigators from the Manhattan District Attorney’s Office in New York found import-export brokers in Las Vegas operating out of their homes who were selling counterfeit Viagra over the internet that originated from Chinese pharmaceutical companies. 170

The U.S. charged seven people and five companies in this particular ring; the suppliers boasted that they could import 2.5 million tablets a month. 171

Perhaps a greater problem for authorities in the United States is that some of the counterfeit medicines are coming across the border when Americans buy prescription drugs in Tijuana in search of lower prices. 172 U.S. Custom’s Officials cannot quantify the amount, but they acknowledge that Americans are unwittingly bringing in counterfeit medications from Mexico. 173 On an average day more than 82,000 people cross the Port of Entry at San Ysidro, California into the United States from Mexico. 174 Recent surveys of travelers returning to San Diego estimate that a sample group of 200 travelers would be carrying more than 7,000 doses of potentially harmful pharmaceuticals. 175 Many of China’s counterfeit medicines end up in Mexico where experts say that as many as one in four pharmaceutical products sold are counterfeit or substandard. 176

Like China, the U.S also has a significant poor population with little or no health insurance, but they want name brand medications. 177 The

168 See ICC, supra note 155.

169 Viagra, supra note 147.

170 Id.; Goodman, supra note 1.

171 Viagra, supra note 147.

172 Goodman, supra note 1.

173 Id.


175 Id.

176 Id.

177 Shirley Eiko Sanematsu, Taking a Broader View of Treatment Disputes: Beyond Managed Care: Are Recent Legislative Efforts the Cure?, 48 UCLA L. REV. 1245,
demand for name brand medication is increasing with more pharmaceutical advertisements in print and broadcast media. Most at risk in the U.S. are also those in the Latino, Asian and Russian immigrant communities, some of whom are undocumented.178 Fearing discovery of their illegal immigrant status, some seek health care backrooms.179 In 1999, a baby girl died from injections in a backroom clinic of the pain and fever medication NeoMelubrina, which was banned by the Food and Drug Administration (FDA) 20 years ago.180 Like China, there is a sizable cross section of Americans who are looking for more affordable medication or who go to unlicensed clinics seeking unqualified medical care.181 Our borders are inadequate roadblocks to the influx of counterfeit medicine.182

2. At the Canadian Border

However, Mexico is not the only route of entry into the United States. With Canadian pharmacies regulated by individual provinces and no federal government oversight,183 Canada may be the bigger problem. The potential danger of this problem is increasing as some American insurance companies are now reimbursing patients who buy their medicines from Canada.184 Most believe that if people are going to buy medicine outside of the United States it is safer to buy it from Canada than from Mexico.185 There are even companies that arrange tourist trips for seniors

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179 Id; See also Victoria Stagg Elliot, Doctors Try to Fix Backroom Damage, AMERICAN MEDICAL NEWS, Feb. 24, 2003, available at http://www.ama-assn.org/amednews/2003/02/24/hlsa0224.htm (last visited Dec. 9, 2003) (noting that many of these unlicensed clinics are patronized by immigrant communities who do not understand about the proper care they need).

180 Meadows, supra note 178.

181 Elliott, supra note 179.

182 Id. See also Meadows, supra note 178.


184 Id.

185 See Baglole, supra note 183.
to cross the Canadian border to purchase prescription drugs.\textsuperscript{186} Taking advantage of government price caps and the strong American dollar, some can save as much as 70 percent off their prescriptions in Canada.\textsuperscript{187} Seniors a fixed income face difficult challenges to find needed medicines at low costs. The rising cost of prescription medicine means buying lower cost medications from Canada to satisfy their medical needs provides an attractive alternative.

Acknowledging these needs, the FDA has regulations in place allowing for the re-importation of drugs otherwise known as gray market goods or medicine for personal use.\textsuperscript{188} Although many might feel that Canadian regulations should be the same as United States regulations, there are risks that the re-imported drugs may not have approved United States labeling or may contain unapproved ingredients used in other countries.\textsuperscript{189} Failing to list all ingredients or untested substances on a label could prove fatal for anyone who might suffer allergic reactions to certain ingredients. The patient who unknowingly ingests a medicine containing allergens, and the hospital that treats these patients in the United States, will not know what they are dealing with if the label does not list the ingredients properly.

Because the FDA cannot approve drugs sold in Canada, there is no monitoring on this side of the border.\textsuperscript{190} Further complications can arise if the distributor in Canada is only selling drugs there for distribution in the United States. One can find many duty free shops or pharmacies in Canada that only sell to visiting tourists, not Canadians. Because the Canadian authorities do not approve drugs made for sale to the US buyers,\textsuperscript{191} means the seniors on their organized bus trips are buying prescription medications regulated by no one.

\textsuperscript{186} Meadows, supra note 179.

\textsuperscript{187} Baglole, supra note 183.

\textsuperscript{188} Meadows, supra note 178. The FDA enacted the Medicine Equity and Drug Safety Act in 2000 that allows prescription drugs manufactured in the United States and exported to certain countries to be re-imported into the US by the original manufacturer. This bill was enacted in the hope that the lower pricing could be passed onto the American Consumer. \textit{Id.}

\textsuperscript{189} \textit{Id.} See also Ingredients, supra note 155. Importing unapproved prescription drugs is illegal, but the FDA recognizes an exception for personal use in certain serious health conditions like AIDS or a rare form of cancer. \textit{Id.}

\textsuperscript{190} Meadows, supra note 155.

\textsuperscript{191} \textit{Id.}
B. Internet Facilitates Distribution

The internet also poses numerous problems for pharmaceutical regulatory agencies all across the world. In 1999, Americans bought $158 million worth of medication over the internet.\footnote{Pasternak, supra note 71.} In November 2001, the FDA reported that eleven vendors were marketing Ciproflaxin to American consumers over the internet to treat anthrax.\footnote{Rastetter, supra note 174.} When it comes to enforcing the internet, the most the FDA can do is send letters to suspicious sites as well as to their home governments.\footnote{Meadows, supra note 155.} However, seeking out the cooperation of foreign governments is a difficult task.\footnote{Meadows, supra note 155.} It is relatively easy and convenient to purchase medicine through the internet.

In the late 1990’s, internet pharmacies and doctors sprouted all over the internet.\footnote{Melissa Healy, A Web of Drugs and Deceit, NEWSDAY, Dec. 9, 2003, available at http://www.newsday.com/ (last visited Dec. 11, 2003). Online pharmacies sprang up in the 1990s because of easy access and frequently originate from foreign countries. Id.} Desperate women were ordering PhenFen over the internet even after it was banned.\footnote{Healy, supra note 196.} Men were ordering Viagra after its release to the market without prescriptions.\footnote{Id.} Clinics were stocking their shelves with medicine bought over the internet because they were cheaper than those bought through their normal medical suppliers. The FDA has taken notice and tried to crack down on internet medicine, but it is still not adequate.\footnote{Id.} Customs agents in New York, Los Angeles, and Washington confiscated more than 2,600 packages of steroids, tranquilizers, and other drugs purchased online that are only available by prescription in the US.\footnote{Rastetter, supra note 174.} With so many Americans uninsured and seeking cheaper and less costly ways to avoid doctor visits, one can understand how counterfeit

\begin{itemize}
  \item \footnote{Pasternak, supra note 71.}
  \item \footnote{Rastetter, supra note 174.}
  \item \footnote{Meadows, supra note 155. The FDA will send a warning letter to the suspicious sites and the home government if the country can be identified. Id. See also FDA Authority and Enforcement Activity, available at http://www.hivandhepatitis.com/hep_c/specrpts/pharm2.html (last visited Dec. 10, 2003) (noting also the limited jurisdiction of the FDA and State governments to prosecute sellers from foreign countries).}
  \item \footnote{Meadows, supra note 155.}
  \item \footnote{Melissa Healy, A Web of Drugs and Deceit, NEWSDAY, Dec. 9, 2003, available at http://www.newsday.com/ (last visited Dec. 11, 2003). Online pharmacies sprang up in the 1990s because of easy access and frequently originate from foreign countries. Id.}
  \item \footnote{Healy, supra note 196.}
  \item \footnote{Id.}
  \item \footnote{Id.}
  \item \footnote{Rastetter, supra note 174.}
\end{itemize}
medications can easily get into the hands of Americans who order online. As one FDA investigator warned, “We really have no control over drugs that enter into the U.S. These drugs can reach anyone, including the President.”

VIII. CONCLUSION

China’s problem is now beginning to be the world’s problem. With the rising cost of medicine, lack of a coordinated policing network, and lack of awareness of the dangers of counterfeit medications, counterfeit medicine is springing up in other developing countries, and developed countries such as the United States and Canada. To curb counterfeiting at home and abroad, China must increase cooperation with international governmental organizations and the pharmaceutical industry. Through these coordinated efforts, China can mobilize and report cases of counterfeiting more efficiently.

If China cannot contain the problem within her own country, then the likelihood of halting the impact of counterfeit medicine is dim. China must educate its people to buy medicine from licensed pharmacies and hospitals, which would lessen the chances of buying counterfeit medicine from unlicensed vendors. Only by educating the public to buy medicine through the normal channels and curbing the corruption now rampant in its police, military, and hospitals can China begin to cure this malady.

201 Viagra, supra note 147.