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China's Healthcare Sector, Drug Safety, and the U.S.-China Trade in Medical Products

Twenty-five years ago China's contribution to the global supply of chemicals for medicines was insignificant, today it is the largest global supplier of active pharmaceutical ingredients (APIs) and excipients (the dyes and binding agents and other inert substances) that make up the rest of most medicine tablets and liquids. China's economies of scale in production and low wage costs meant that every chemical intermediary wanted to buy from China, but the rapid growth in demand has stretched and sometimes overtaken production capacity, and trade in substandard and counterfeit medicines has often overshadowed high quality supply[1].

I first investigated the semi-legal and fake drug industry in China in 2008. It became obvious why China is considered to be the largest source of falsified medicines around the world. Initially the Chinese government paid no attention to combatting the problem, possibly even encouraging it. In the past five years, the Chinese government has made some significant efforts toward reform, but the implementation of quality-control standards has been outpaced by growth in both the legitimate and illegitimate pharmaceutical industries, rendering government efforts insufficient. Domestic problems also plague reform efforts; corruption and willful ignorance on the part of the national government, and complicity with illicit production and distribution on the part of regional governments, have further exacerbated the situation. David Kessler, the former head of the US Food and Drug Administration, told a news conference in 2008 that "China is as close to an unregulated environment as you can get." He went on to imply it was a lot like the United States in 1906, which is "why we developed an FDA."

The China Food and Drug Administration, CFDA, has undergone many reforms since its former head, Zheng Xiaoyu, was executed in 2007 for corruption. It takes the matter of falsified drugs very seriously, but it is working to increase capacity from a low base and the problem is vast. It also has little knowledge about how to overcome the production of substandard but legal pharmaceutical chemicals that will be formulated into substandard medicines, which are probably more of a threat to US citizens.

Discovering the Source

China's pharmaceutical industry has grown at 15 percent per year within an emerging economy that has grown often at nearly 10 percent per year. The worldwide demand for low-cost drugs is vast, and today China provides at least 40 percent of US drug chemicals (80 percent are from overseas sources, of which China provides roughly half). Potential profits are huge, and production is romping ahead far faster than the government's regulatory capacity can adapt. There is an inevitable mismatch between the quality of drugs produced by the white-knuckle pace of development in China and what is demanded by the culture of risk aversion in mature economies.
As well as having to contend with the hangover of corrupt and increasingly dispossessed political and military elites, China is loath to lose face in the international arena and tends to brush-aside concerns and deploy tactics of blame avoidance when under pressure.

[1] The references and supporting documentation for the statements in this testimony can be found in my book *Phake: The Deadly World of Falsified and Substandard Medicines* (especially the chapter on China pages 177-203) or on the website www.searchingforsafety.com.

Pharmaceutical experts from around the world used to tell me that their complaints to authorities in China about fakes coming from China had little effect; today, responses are at least rhetorically better.

Private Investigations

Private investigators in China are very nervous about publicizing their work; they claim the authorities do not like bad publicity for China as a whole and make life difficult, and sometimes dangerous, for those speaking to foreigners.

Illegitimate Chinese producers range from small-scale "garage" producers to large-scale manufacturers of products of dubious quality. But China is unique in that it also has many semi-legitimate chemical producers that make intermediary compounds for pharmaceuticals in vast quantities. These are very hard to investigate because they sell to other businesses and not members of the public.

Phillipe Andre, Professor at the School of Pharmaceutical Science and Technology at Tianjin University, audits many of these companies. His clients are mostly Western pharmaceutical companies sourcing inexpensive chemicals from China. He says there is a "huge difference between the best and the worst" chemical suppliers. Some are "physically dirty" and operate plants that do not live up to GMP (good manufacturing practices) at all: more often than not these are owned by some part of the Chinese government. Other plants are as good as those in the West.

Of all the alarming statements he made to me, perhaps the most remarkable is that while Western firms demand audits of the suppliers of the chemicals they buy, his "own data show that American and European pharmaceutical companies are misinformed about the identity of the manufacturing site of 39 percent of the drug substances they purchase from China." This is a point echoed by Guy Villax, the CEO of drug manufacturer Hovione, who told the Pew Trust Conference "Ensuring the U.S. Drug Supply" in Washington, D.C., in March 2011, that the industry "suddenly discovered that to a large degree we do not have control over quality." While he agreed that it was important to combat the fakers of finished products in China, he said that going after those making poor APIs is the most important because substandard APIs can be deadly and their trade is so vast, affecting myriad supply systems.

Andre told me that a plant in Liaoning that had been certified as GMP-compliant by the European Medicines Agency (EMA) had parts of its factories in a terrible state. He said significant ambient levels of ammonia made it difficult to breathe as he walked around the facilities. While the ammonia apparently had not reached dangerous levels, he said it was "indicative of toxic solvents," which could be lethal. In other sites in Shanghai, Andre saw rusty equipment, mold, insects, and even a dog that had access to chemicals to be sold to Europe. Almost as worrying as these gross failures is the fact that in his audits only 6 percent of companies provide impurity profiles of the chemicals in question. This is critical, because many versions of common medicines like atorvastatin (generic Lipitor), have impurities that compromise their efficacy – in a recent study by Harvard University's Preston Mason, he found 36 different versions of atorvastatin which had an impurity that undermined performance of the drug, some of these being consumed by US patients[2].

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[2] See Mason's poster here: https://www.lipid.org/util/eposters/PDFs/183%20-%20Mason.pdf

In production of some chemicals, “residues of solvents and potentially genotoxic catalysts are rarely controlled” and could be present, Andre said, since only certain problems are easy to spot in the final chemical. Further, the tests required by the US FDA and United States Pharmacopeia do not find all of the problems. As was demonstrated by the falsified heparin incident of 2007-2008, tests are often only proven to be inadequate when they fail to catch a problem. This tragic case, involving the substitution of an inferior adulterated product, which resulted in the deaths of at least 81 Americans, had never been encountered before.

The Chinese supervisory authorities have not defined the exact starting point in the production process where GMP is required; this contributes to the problem. In a worrisome sleight of hand, a process may be certified as upholding GMP even if only the final process in the final location is actually GMP compliant; earlier suppliers often need not demonstrate that they meet these standards. As Andre put it: “Implementing GMP starting from a late intermediate [stage of production] is more economical.” Since “U.S./EU customers often neglect to specify their expectations,” he said, they may not realize that precursor chemicals were not made in GMP plants. While Chinese law prohibits the manufacture of drug substances without a pharmaceutical license and GMP certificate, many foreign purchases do not ask for evidence of these basic qualifications. Chemicals exported to the United States are supposed to be GMP certified, but many may not be. Most alarming of all, over 90 percent of the audits I have seen of Chinese drug substances bought by Western purchasers are conducted *after* purchase.

After speaking with Andre and conducting investigations of sites myself, there is little doubt many Chinese companies producing intermediate chemicals for US medicines make inferior products, and US companies often fail to verify purchases, to the extent that they often do not know what they are buying or from whom. Given this apparently cavalier attitude of some US pharmaceutical companies, it is not hard to imagine what this means for countries in other parts of the world where oversight is valued far less.

Despite government control on the Chinese media, reports of counterfeits in China proliferate from other news sources. Many stories are from Hong Kong media outlets, and several discuss Gao Jingde, a local hero who regularly fights counterfeiters. Jingde is a Shanghai-based private investigator and a past victim of counterfeit medicines. In 2007, Jingde reported that twenty-two of thirty-two drugstores investigated in Nanjing and four of fifteen drugstores supported by public medical insurance stocked counterfeit drugs. Jingde says the authorities would like to portray the problem as one of ignorance, but while that may be the case for most patients and some pharmacists, corruption also plays a large role in the prevalence of counterfeits in pharmacies and hospitals. According to Jingde, approximately two-thirds of drug stores in China sold counterfeit medicine in September 2008. From 2004 to 2008, Jingde conducted grassroots investigations of drugstores and hospitals and reported 289 separate incidents involving the sale of counterfeit medicines.

In 2008, after investigating Nanfang University Medical Center hospital, Jingde was attacked by four men he believes were hired by hospital authorities to prevent his exposure of their counterfeit dealings. Jingde has the fortitude and drive of other government anti-counterfeit fighters around the world, but none of the protection afforded as officers of a government.

Although things have rhetorically improved from authorities in Beijing, I have no reason to believe that matters have changed much for the better for private investigators in the intervening period. Jingde may eventually end up in jail because he is surely an embarrassment to Beijing: those who complained most

successfully against the melamine contamination of milk and other products in China—which killed several and harmed hundreds of thousands of babies—spent thirty months in jail for disrespecting the government.

Private investigators provide dossiers about criminal activity to the police, at least in parts of the country where the authorities will be responsive. Even in southeastern China, for most of the past decade, though, it was far from certain whether police would take any action based on such information. Investigators tell me there are still some problems with enforcement. For example, police in Yiwu City in Zheijing Province, south of Shanghai, follow up on investigations more often than not, but, as in India, the politically connected always seem to escape.

Locating the (Legal) Source of Substandard Ingredients

The array of fake products produced may be greater in India, but China almost certainly surpasses India in terms of volume. Actions against Chinese counterfeiters have been known to result in seizures of ingredients measuring tens of tons. Such large volumes do not exist anywhere else in the world. In terms of producing substandard API, China seems to dominate world trade.

I learned the details of one Chinese counterfeit drug ring that had been successfully broken up, resulting with the gang leader serving 3½ years for counterfeiting. He claimed, however, that he'd been set up in business by the manager of the prominent Beijing Silk Street Market, where the gang leader sold some of his finished product. The market manager was not prosecuted but was eventually forced to resign because so many of the market's traders were breaking trademark rules.

The drug ring made APIs for painkillers and sildenafil, the active ingredient in Viagra, antibiotics and antimalarials at any strength demanded by buyers. Requirements for authentic-looking packaging were always very high, of course. Because they were trading as chemical suppliers and not pharmaceutical suppliers, the CFDA had no jurisdiction over their activities, and few final producers demand certificates from apparently legitimate intermediaries. No other legislative body seems to have monitored what these companies and possibly many others were actually doing and supplying.

These small companies produced tons of API and finished products every month, and investigators believe most of the businessmen involved did not know where many of the drugs they made might have gone. Their finished products contained anything from zero API, to the correct amount of API, and almost any amount in between, with varying degrees of quality. Requirements varied according to the oversight in target markets – amounts of API were cut according to risk of detection.

From the information I was able to glean, most products from the gang's factory had zero percent API, maybe 15 percent of products contained 15–80 percent of the correct amount of API, and perhaps 25 percent had the proper amount of API. These 25 percent were ordered by producers who cut costs by skimping on the production process – substandard products. The zero API and varying quantity API drugs were ordered for manufacture of fake products, which all parties of the deal apparently understood and accepted.

N.B. It is important to stress what the above findings indicate; there is not a great deal of distinction in this part of the trade between fake producers and substandard producers. While experts in the field of drug quality are generally careful to differentiate the two (fakers breaking criminal codes, while substandard makers breaching regulatory rules), the reality is that often the two are very close.

In addition to first-hand experience, I spoke with Andre, three other investigators in Hong Kong, auditors, pharmaceutical executives, and several professors. All shared similar conclusions about China's substandard and fake-drug industry:

* Many legal but shoddy chemical factories and the makers of counterfeit and substandard finished products are producing enormous quantities of chemicals; the sheer size of these operations is alarming. Some produce tons of chemicals every week, much of which finds its way into Western medicines. Other operations make over 1 million pills, or 100,000 treatments of a variety of medicines, every single day. Some of these may make their way to the West via the Internet.

* Many fake drugs are made during "windows" in the middle of the night in an otherwise law-abiding firm. For these counterfeiters, speed is essential and packaging is usually made at a different location to minimize risk.

* Some of these factories are owned by companies selling APIs or finished products to the legitimate supply chain.

* Some are approved chemical producers that operate to poorly enforced standards and are not registered as pharmaceutical companies in China. Others are entirely bogus companies not registered for any trade.

* Some appear to establish brands they then cannibalize by selling poorer-quality and cheaper versions of them, likely to benefit from the highly segmented illegal markets.

* Generally, these companies have convoluted company structures and operations, making it nearly impossible to get to the bottom of any supply chain. Steps taken to muddle the chain include packaging fake drugs at locations other than where they are produced, mixing legitimate production with substandard production, and layering cross-ownership structures protected by state authorities.

* These operations are huge. International orders come from various parts of the world, most often from Chinese operators at hubs (largely Free Trade Zones) in India, East Africa, the Middle East, and southern Europe. Cargo containers leave busy Chinese ports full of millions of treatments of varying quality. These containers arrive weekly in busy ports from Alexandria, Egypt, to Dubai to Valetta, Malta to Rotterdam, Netherlands to Mombasa, Kenya to Dar es Salaam, Tanzania to Chennai and Mumbai, India.

I am convinced China is the largest manufacturer of fake drugs in the world, and nearly every investigator of fake drugs, both inside and outside of China, concurs.

Waking the Dragon: China Begins to Make an Effort

While the lack of government transparency in China is frustrating, Beijing is slowly responding to calls from its citizens and trading partners to increase transparency and allow greater individual freedom. Despite some encouraging reforms, progress is impeded by erratic implementation and corruption at the highest levels of government. Of course, with China's population of 1.3 billion people, surface area of 3,700 million square miles, a 9,000-mile coastline, and land borders with fourteen countries, it is little wonder that even reforms implemented in good faith seem to produce results very slowly.

China has had a modern, comprehensive, and properly functioning regulatory agency for about 15 years. In 1998, Beijing established the State Drug Administration (SDA)—which later became the SFDA (State Food and Drug Administration) and then in 2013, the CFDA —to consolidate the duties of the Ministry of Health's Drug Administration Bureau, the State Pharmaceutical Administration Bureau, and the State Administration of Traditional Chinese Medicine. The CFDA is to provide unified leadership and oversight to what would become 31 provincial drug agencies, 2,321 county agencies, and 339 municipal departments.

In 2001, China established a national, unified system of pharmaceutical registration and quality standards, and in 2004, more than 200 monitoring institutions that already existed in thirty-one provinces were coordinated into a national system for reporting and monitoring adverse drug reactions. By 2004, China had also started to make progress curbing illegal pharmaceutical manufacturers through criminal prosecution of large-scale networks. A greatly increased budget for 2006–2007 meant 90 percent of provincial drug-control departments and 60 percent of city ones were capable of conducting at least some full-scale drug tests and included buying more than 300 near-infrared spectrometers to be used in portable labs in vans that would fan out throughout China to screen for substandard drugs.

Between March and August 2006, the SFDA screened 110,426 batches of antimalarial pharmaceutical drugs in mobile labs and found that only 2.8 percent (3,122 batches) contained counterfeit or substandard drugs. Zhong-Yuan Yang, former head of the Guangzhou Municipal Institute for Drug Control, reports that approximately 0.5 percent of all medicines in China are counterfeit, depending on the sampling venue. These official reports have some problems, though; these figures differ markedly from other independent reports, do not differentiate between counterfeit and substandard drugs, and mask regional and product-specific differences. In 2002, the Shanghai Drug Administration Bureau found that 12.2 percent (1,833 drugs) of 14,980 drugs inspected were below quality standards. Regardless, China's efforts to increase testing represent an improvement.

Professor Shaohon Jin of Beijing University is director of China's National Institute for the Control of Pharmaceutical and Biological Products. His data are probably more reliable: Jin's research found that "14 percent of the many thousands of drug samples tested in 1998 were of low quality." Degraded antibiotics like amoxicillin were prevalent. Since 1998, this failure rate has dropped to under 10 percent. The latest figures he presented at a conference in London in July 2013 showed that after analyzing tens of thousands of samples, about 5 per cent failed quality control.

My research team had limited resources, so we could not buy chemicals in bulk to covertly assess quality of the individual components, however, my research team did take random samplings of drugs from Beijing pharmacies. Through these we discovered only a few drug-quality problems. If our sampling and Jin's figures are accurate, Chinese cities appear to have a problem with between 2 percent and 5 percent of products on the market.

The testing regime China instituted is only part of the solution. China has also made examples of criminals in order to act as a deterrent. In November 2007, the government executed former head of the CFDA Zheng Xiaoyu in a highly-publicized event for taking bribes to falsify drug registrations and arrested 279 manufacturers on criminal charges. The government announced that it would impose stiffer penalties, including heavy fines, life imprisonment, and the death penalty, in counterfeit drug cases.

By December 2007, the (then) SFDA reported stopping 900 counterfeit-drug operations, shutting down 300 drug and medical-instrument manufacturers for making inferior products, and withdrawing 150 GMP certificates. Pharmaceutical companies in the country voluntarily withdrew more than 7,300 drug-registration applications (24 percent of the total). In 2008, the SFDA increased supervision of Internet drug distribution, investigated 300,000 cases of illegal activities related to medicine and medical products; shut down 363 producers of fake drugs, charged ninety-four people with counterfeiting, and shut down twenty-three websites, one haul from a ring involving Greek and Chinese nationals included 880 pounds of counterfeit Tamiflu and about forty tons of raw chemical materials.

The SFDA blacklisted twenty-five websites in 2009, for selling fake medicines claiming to cure high blood pressure, skin diseases, diabetes, and other chronic diseases. China's State Administration of Traditional Chinese Medicine blacklisted forty-six websites that same year for selling fake herbal medicines. SFDA director Shao Mingli reported that 36,000 illegal drug advertisements were handed over for investigations and 231 suspects involved in major cases were arrested in 2009. In January 2010, the SFDA shut down another 558 websites for releasing false drug information. These examples show just a few recent actions the Chinese government has taken to address the massive international trade in counterfeits that originates in China.

In 2012, the government announced thirty-four new GMP standards (for a total of 259) and an export licensing and registration system for ten categories of drugs. Beijing also established a network of drug-safety coordinators (which included more than 97,000 individuals) and information specialists (more than 514,000 in 2007), made qualification examinations and ongoing training for pharmacists mandatory, and issued a set of regulations to standardize nursing practices. It is one thing to have these standards and quite another to enforce them.

Made in India, Faked in China

Indian companies provide vast amounts of generic drugs to middle-income and developing countries and increasingly in US too. By some estimates, 80 percent of HIV drugs and half of the developing world's supply of antimalarials and antibiotics come from India. It has become increasingly popular for Chinese fakers to copy the common local brands, which often means copying Indian brands. Chinese companies' use of the "Made in India" label on counterfeit drugs reflects Indian companies' dominance in low-to-middle income markets.

Counterfeiters prefer to copy the most popular brands even when they are not the most expensive. Though counterfeiters could make more money faking more expensive products, a familiar product is more easily accepted in the market without suspicion, meaning more fakes may be sold before they are detected. Further, the multinational companies that produce more expensive (name-brand) products are more likely to protect their brands with highly trained security personnel, postmarket surveys and laboratory tests. Since Indian generics dominate many therapeutic categories, it is not surprising they are the medicines most often faked.

In my ongoing research, I have come across Chinese fakes in many countries that carried a "Made in India" label. After one incident in April 2010, I was informed by sources in both India and China that the New Delhi government protested to Beijing about this misrepresentation. Indian private investigators of fake drugs and Indian company representatives and consultants also suspect this is a deliberate, Beijing-sanctioned attempt to undermine India's reputation and gain market share. Certainly, my research

found that 'Made in India' counterfeit drugs bought in US, Africa and Asia, could definitely be traced back to China; establishing any government involvement was beyond our resources.

Not all fake drugs from China are copies of Indian products, though. Chinese gangs will copy anything of value, so every major drug company and every country probably has drugs faked by the Chinese. Artesunat, a brand-name, Vietnamese antimalarial made by the Ho Chi Minh–based company Mekophar Chemical Pharmaceutical, is widely faked by Chinese criminals. Ongoing research has found fake Artesunat in Nigeria, Ghana, Kenya, Uganda, Tanzania, and Thailand; in each case, the fakes were traced to the handiwork of Chinese counterfeiters.

Within the overall policy of copying popular brands whose trademarks are less likely to be enforced, counterfeiters may produce copies of the most expensive drugs that are significant sellers within each category. In the antibiotic category, then, counterfeiters are more likely to fake ciprofloxacin than erythromycin, since the former is twice the price in some markets. The API is more expensive, but counterfeiters who do not include any API can make a white pill in the correct shape for the same price whether it is packaged as ciprofloxacin or a cheaper product.

Counterfeiters adapt their product quickly and cleverly in response to technologies deployed by anticounterfeiting agencies. For much of the past decade, rapid dye tests have been used to test for the presence of API in medicines surveyed in markets in Africa and parts of Asia. These simple tests have been deployed by a variety of aid agencies and nongovernmental organizations operating in resource-constrained environments. Since these were able to detect fakes only with zero API content, some counterfeiters changed their game and started to add some API to fool this test. Partly as a response to this, anticounterfeiting agencies started deploying technology, which can detect whether a drug has the *right* amount of API content.

Given that counterfeiters can cut processing and GMP costs and still pass these tests, they still make handsome profits in comparison with legitimate producers. They will go to great lengths to tailor their products to target markets.

China and Free Trade Zones - another area of risk

Other than using free trade zones (FTZs) for their own benefit, most interested parties are focused on preventing specific dangers. Western businesses monitor FTZs in their attempt to prevent production, repackaging, and transit of counterfeit versions of its own products. Similarly, Western governments are focused on trade in lethal products (some of which overlap with trademark infringements of Western products) and the money trails of the criminal entities, especially terrorist organizations or funders that use FTZs. These are understandable priorities, but far less attention is paid to trade in other products that ironically might be of as much danger to the public and cause even greater financial losses.

Simply by spending a few days in and around major FTZ ports exposes one to the vast volumes of container traffic passing through the area. I looked into the trade in bulk chemicals that circulate, seemingly without inspection, around the world. Guy Villax of Hovione, explained to me how the provenance of many of the chemicals that go into the production of medicines and foods are unknown, even by European and US firms.

While groups like Rx360, a US industry group focusing on supply chain assurance, is improving the situation for Western manufacturers, the transit in bulk chemicals is still far from secured. With the help

of some private security officers, I saw the manifests of cargo ships coming in and out of FTZ ports in three countries and the unloading of the products in one. In at least one instance, the chemicals in the container did not match the chemicals on the manifest. And in half of the dozen manifests that I saw, the original source of the products was not correctly identified. Nearly all of the chemicals had originated in China, but their production was in several locations identified as Italy or UAE.

According to Amir Khan, an Indian pharmaceutical consultant based in Delhi who monitors the chemicals trade, none of the chemicals could be easily turned into explosive materials and none were immediately lethal or toxic. Thus there is little attention paid to the trade by Western authorities. Chemicals like these have been sold at major annual trade events like the CPhI Global Conference, most recently in Frankfurt in October 2013. The vast majority of the buyers, sellers, distributors, and middle men operating at this massive trade fair are legitimate; but, in the past at least, amongst these players are a few disreputable traders who know the real provenance of these chemicals.

Any organization that does not conduct serious audits will not know that chemicals allegedly made in Italy were actually made in China. These chemicals could be inferior, the origin concealed because of substandard ingredients, which will probably lead to substandard products that endanger lives. It is likely that the purchasers of these chemicals will be at the most cost-conscious end of production, but even major brand name suppliers might procure these by mistake – most likely to occur if there are shortages in usual suppliers. Manufacturers do conduct tests on the chemicals that they procure, but some important and dangerous problems (e.g. trace impurities can be carcinogenic and are rarely spotted unless specifically measured, which is expensive and in 99 percent of cases not required) are not easily seen in routine tests.

The trade in these chemicals also occurs outside of the FTZs for sure, but the rapid transit of chemicals through FTZs and the apparent relabeling that can occur without any oversight at all means that these areas enable this vast trade. It is arguable that this keeps the price of medicines low, but it also has a potentially lethal side effect. Moreover, numerous corporate names are used within FTZs that make it difficult to trace the source of products and help to obscure the parties responsible. While a regular port can have just as many corrupt officials, FTZs have proven to be particularly vulnerable to political interference aimed at protecting domestic consumers. FTZs not only introduce a legal and psychological barrier to the interference by national authorities, they also allow blame to be shifted to the more amorphous “international community.”

Big Trouble in Little Chinas

There seems to be one universal when it comes to counterfeit products and their trade through FTZs: regardless of the product, between 50 percent and 90 percent of all international fakes appear to originate in China. And the World Customs Organization claims 75 percent of seized counterfeit products come from East Asia, primarily China.[3] The majority of the transshipment points revolve around contacts and facilities that are connected to the Chinatowns that stretch from Panama and Paraguay to Kuala Lumpur and Kenya. A century ago, most Chinese triads and tongs were insular and rarely cooperated outside their own dialect groups (and even then they were limited in scope to specific villages and clans). One side-effect of the Chinese unity cultivated after 1989 has been a pan-Chinese

[3] United Nations Office on Drugs and Crime, "Transnational Organized Crime in East Asia and the Pacific: A Threat Assessment." Last modified April 2013. Accessed October 1, 2013. http://www.unodc.org/documents/data-and-analysis/Studies/TOCTA_EAP_web.pdf.

identity that has even infiltrated criminal syndicates, allowing them to scale up and staff their organizations while China is able to run far-flung operations that are often staffed and even enforced by local ethnic groups under Chinese leadership.

With Chinese middleman minorities thoroughly dominating legal and illegal commerce in Southeast Asia, counterfeiters in the Middle Kingdom are able to take full advantage of the geography that rings the South China Sea and which is ideal for moving goods in and out of tens of thousands of islands, inlets, and other shelters. These century-old networks allow illicit distributors to scatter and reform their shipments in any number of locations and configurations, and sometimes with the assistance of local governments and militaries. By the time their shipments reach Panama or Dubai, Latin and Arab syndicates are often the partners of choice for accessing their own markets or using paths and techniques perfected by narco-traffickers to enter North American and European markets.

When convenience suits them, many countries treat their free trade zones as separate from the responsibilities of their own sovereign territory. Even in Singapore, one of the best run pro-capitalist nations of the world, there is disquiet amongst some US security officials that Singaporean officials will often wait a full week after a ship has left to review the documentation and other information; by this time, any perpetrators of frauds would be long gone and would prove hard to hunt down after the fact. Dubai levies severe penalties for fakes found inside domestic markets, but there are no similar penalties (let alone actual enforcement) for goods being exported. With small local markets that are easy to protect, massive revenues from their positions as major transshipment hubs, state-of-the-art transportation facilities and lax regulations, both these ports have enabled smugglers and counterfeiters.

Internet-sourced Chinese medicines

I have undertaken original research of the US-internet drug market. Buying 365 medicine samples from 41 internet pharmacies, analyzing the products with a spectrometer, and publishing the results in two peer reviewed papers. The conclusions of the research are that one can buy safely from online pharmacies, as long as one buys from credentialed sites.

However, all 8 of the fake samples we procured were manufactured in China. The attached photo shows one fake version of Viagra sent by courier from Shanghai to my address in DC. In other instances the fakes came via India.

US efforts to limit this trade are warranted given the potential dangers involved, and the millions of Americans who buy online, however boycotting all foreign sites (including those in Canada), will be counterproductive because most Americans buying online state cost of medicines as the main reason for doing so.

The Way Forward for China

Ultimately, Beijing needs to implement and enforce laws to outlaw the odious practices of substandard and falsified chemical production. Historically, chemical companies escaped being monitored by the CFDA by claiming to be chemical suppliers and not pharmaceutical suppliers. Although the Chinese government insists it no longer tolerates such sleight of hand, Deborah Autor, head of drug compliance at the US FDA told me in July 2013 that this “loophole has not been closed.”

We should all hope China’s drug makers eventually internalize quality management best practices. Efforts to do this are underway. Article 9 of the 1984 Drug Administration Law already mandates that

manufacturers adhere to GMP, but enforcement continues to be a problem. Even where Beijing has issued clear guidelines for how inspectors will measure GMP, there are too few inspectors to examine all suspicious manufacturing sites and those inspectors rarely demand immediate and significant responses by poor performing firms. Beijing needs to make a commitment to inspection as well as to laws. As Professor Andre pointed out, although people think of China as having endless numbers of people, there are not sufficient qualified staff to perform audits and inspections, to say nothing of higher-level jobs. Indeed, Andre and Hovione CEO Villax say more attention must be paid to GMP in the entire supply chain, not just whether final production facilities are GMP compliant. "Many problems can occur between compliant plants," Andre said.

To help remedy the lack of qualified staff, Zheng Qiang of Peking University started a program to improve manufacturers' understanding of and adherence to best practices. His inaugural class of twenty-five students (twenty-one of whom were on sabbatical from Chinese pharmaceutical companies) started their master's degree program in best practices in March 2007 at Peking University's new Institute for Pharmaceutical Excellence. One hopes more efforts like this will ensure better quality Chinese producers and products will come to dominate the market and eventually force out most fake drugs.

Laboratory capacity is expanding due to huge investment, but tensions exist since, according to business sources within China, upholding GMP may put up to 20 percent of the drug-production workforce out of business. Until such improvements take hold, problems with fake and substandard drugs will continue, and inexperienced staff will dominate production and aspects of oversight, particularly in enforcement and the judiciary, such that dangerous products will continue to leave China's shores for other countries.

Conclusion

China is the largest supplier of the chemicals that make up the pharmaceuticals millions of Americans take every day. Unfortunately some of this supply is inferior in quality, leading to substandard products around the world, including the US. China is also the manufacturer of outright fake versions of chemicals and finished products, notably available to Americans over the internet.

The Beijing government has made efforts to clamp down on the problem of poor quality medicines, by expanding testing of products on the market and presumably sanctioning those failing. It has arrested, prosecuted and sentenced, sometimes to the death penalty, those involved in the fake drug trade or colluding in illegal activity.

However, much remains to be done. Large manufacturers of inferior quality chemicals are not sanctioned, indeed CFDA does not have the capacity to assess the products it makes for export, nor apparently does any other Chinese agency. US FDA conducts inspections, but since it only inspects known pharmaceutical production sites once a decade, it is unlikely to find much, especially since the Chinese government is slow to approve the visas for those undertaking inspections.

All in all, the only way to improve product quality in the short run, is for US manufacturers to improve their supply chain security. Meanwhile Congress should continue pressure on the Chinese government to speed up visa approval for US FDA inspectors, and fund FDA to batch test all Chinese (and Indian) finished products coming into US.