

China Rx Author Rosemary Gibson

Interview conducted by Dr. David G. Schwartz

1. What first alerted you to the problem, was it the issue with the heparin?

The contaminated heparin event in 2007-2008 was on my radar. This is the case where Chinese suppliers added a toxic ingredient when processing the raw material for heparin, a blood thinner that's widely used in hospitals. The Chinese suppliers did it for economic reasons. Official US reports say 246 deaths occurred associated with the toxic drug. But it's impossible to know the real number. That's because it's so hard to prove that a toxic drug is what harmed a person.

I searched for other medicines made in China and discovered a needle in a haystack, information about Chinese suppliers of ingredients for a number of generic drugs. That's when I knew there was an important story to tell in the public interest.

2. And what kind of difficulties did you have unearthing the evidence, and what efforts over what period of time did it take?

It was very difficult to find what has been outsourced to China. So, I pieced together conversations with good people in the industry, former government officials, the online trade press, and U.S. lawyers who know about the lack of consumer protections in China and the "buyer beware" mentality when it comes to buying anything there, from T-shirts to prescription drugs. It took three years to research and write the book. It has more than 900 footnotes spanning 57 pages. It's important to me that information is correct.

3. What percent of brand name drugs are estimated to be made in China or other countries?

This information is not publicly available. The industry considers it a trade secret. We do know that brand name drugs tend to be manufactured in western countries. But even some brand name drugs rely on key ingredients from China.

We also know that China is the dominant supplier of key ingredients in our generic drugs, which are about 90 percent of prescriptions.

China Rx is the first book to reveal that China is a growing supplier of generic drugs made in China by Chinese companies. They are ramping up production quickly and could eventually overtake India as a dominant generic drug maker.

4. Do European countries, the U.K., Canada, and Mexico have a similar situation, getting their bulk ingredients from a global supply chain?

Yes, other countries are in the same situation as the U.S. This is because China has gained a dominant global market share.

Let's take the case of penicillin. The last penicillin fermentation plant in the U.S. closed in 2004. That was the same time that Chinese companies formed a cartel, flooded the global market with product, and drove out all the producers in the U.S., Europe, and India. So even India, which makes a lot of generic drugs, is dependent on China for key ingredients.

5. How big a problem is the supply chain itself, regardless of where the drugs came from, such as interrupting the supply chain with counterfeit drugs?

The supply chain is so much more complex now compared with the time when drugs were made in the U.S. and Europe. It is far more difficult to assure quality products shipped from thousands of miles away to the U.S., especially when they are coming from a country that doesn't have a long history of making prescription drugs that meet U.S. standards.

A former FDA commissioner said that Americans have no idea how vulnerable we are. This statement made me realize that globalization is de facto deregulation.

FDA inspections in China aren't the same as they are in the U.S. Here, inspectors can walk into a U.S. manufacturing plant on a Monday morning without any notice. In China and other countries, the FDA gives notice 4-6 weeks in advance, although it can perform unannounced inspections. This is an unlevel playing field.

And yes, China is flooding the internet with counterfeit drugs which are illegal. China is also supplying toxic drugs in the legal supply chain to hospitals and drug stores. Recent recalls of blood pressure medicines sold in the U.S. in the legitimate supply chain, because of toxic key ingredients made in China, have not received the same attention as counterfeits. Both deserve attention.

6. Many people were injured or died because of the heparin contamination before it was discovered. Any guesses as to how many people are injured each year by contamination of other drugs before they get recalled?

It's impossible to know how many people are injured by contaminated medicines before they are recalled. The reason is that people and their doctors find it nearly impossible to show the link between a toxic ingredient in a prescription drug and subsequent illness or death.

Let's take the case of the carcinogen found in valsartan, the blood pressure medicine. The risk of cancer is low but there is still a risk. It's virtually impossible to prove that a contaminant in a blood pressure medicine caused a cancer a year or two later. That's why we have a chapter in China Rx called "The Perfect Crime." It's very hard to detect.

7. Should we doctors be preferentially prescribing brand name drugs if the patients can pay for them?

In China Rx, I asked people who have worked in the industry for many years what they do when they go to the drug store to pick up a prescription. A common theme I heard is that a brand name manufacturer has a brand to protect. It also has more resources than generic companies to invest in good manufacturing.

Doctors and consumers would be better off knowing where their medicine and the key ingredients are made. They could make an informed choice, and good companies would be proud of where their products are made. But the industry killed legislation that would require drug companies say on labels where their products are made. When I asked an industry person why they killed it, the person said that companies know it wouldn't be good for business if their customers knew where their drugs are made. Only about 5 percent of Americans trust medicines made in China.

8. Many of my patients are appalled when I tell them that their drugs are probably made in China with poor monitoring and oversight, but they are not very surprised because they are accustomed to the pharmaceutical companies betraying the best interests of the patients in favor of higher profits. What can patients do?

When people go to a pharmacy, they can ask the pharmacist to show them the box that the prescription drug comes in. Some companies do put country-of-origin on the label. Others don't. Whatever the case may be, take a picture of the label with a smartphone, call the company, and ask where the finished drug and active ingredient are made. Some will tell you and others will not. A good company would be proud to tell its customers where its products are made.

In China Rx there's an appendix with additional information including websites that people can go to and find the label for their medicines.

9. Was the FDA prepared for drug manufacturing overseas?

The FDA was completely unprepared. It didn't even have a list of all the manufacturing plants in China and elsewhere that were making drugs and their ingredients for Americans' medicines. Very few inspections were conducted in China. We found a 1996 FDA memo that said the agency had no idea where a lot of drug ingredients were coming from and they could get to the President of the United States. Meanwhile, many companies in the U.S. and Europe chose suppliers without even inspecting them before buying products from them. It's shocking what went on.

Four years after the heparin incident, congress passed legislation that gave the FDA more authority and resources to inspect plants in China. This allowed US-based companies to say, "Our products are manufactured in an FDA inspected facility." As noted above, inspections are not a guarantor of quality.

10. What about tariffs? Can they interrupt supply?

The pharmaceutical industry lobbied heavily against tariffs on drug products made in China. In some cases, China is the only supplier of some key ingredients.

If there were tariffs, prices could increase. This would help domestic manufacturers compete against China. But China has cut the value of its currency, which offsets the impact of tariffs and keeps prices of its products low.

11. Why isn't this a big scandal? Why aren't we hearing about this from Congress?

The pharmaceutical industry censors information that it considers unfavorable to its interests. It doesn't want the public to know that it has outsourced medicine-making to China.

China also doesn't want unfavorable media coverage in the United States and censors coverage here as well.

Finally, the pharmaceutical industry provides campaign funding for many members of congress and looks unfavorably upon elected officials who stray from its political agenda. Hence, the public interest is not served. That said, there is a growing grassroots awareness of dependence on China for medicines. This blog is contributing to awareness.

12. Will people be willing to pay more for medicines made in the US?

People are rightly concerned about the price they pay for medicines. There needs to be transparency in the gap between how much the final consumer pays and how much manufacturers receive. A lot of middlemen make a lot of money from drugs. If we cut out the middlemen, more money would be available for high quality manufacturing in the U.S.

When it comes to China, if we don't diversify and have suppliers in other countries, China will gain even more control over the supply of our medicines. Once it controls supply, it can set prices as high as it wants because Americans won't have any alternative. We need to act now to avoid this.

13. What is the solution?

We need to consider our medicines as a strategic asset like we do oil and food commodities like wheat. The first step is knowing who makes America's medicines, identifying where we are at risk because of dodgy suppliers and countries that are unreliable, and setting up a permanent forecasting system in the federal government to track supply, demand, and risks. The next step is diversifying suppliers and providing incentives for domestic drug manufacturing for high-priority medicines.