

CHINA Rx, by Rosemary Gibson and Janardan Prasad Singh
Book Report and Commentary by David G. Schwartz, M.D.

So you think the safety and quality of your Rx and non-Rx drugs is protected by the FDA, and that the drugs are made by companies that take pride in the quality and purity of their products? This may have been so two decades ago, but much has changed. As with global industries in general, the pharmaceutical industry has become more focused on cutting expenses, procuring raw materials at the lowest possible cost, and skirting regulations and inspections whenever possible, not to give you, the consumer, lower prices, but to increase profit margins.

This means procuring the active ingredients in generic drugs and in many brand name drugs from the complex global supply chain. This usually means purchasing from manufacturers in China, or actually moving the domestic manufacturing plants to China. This reduces FDA oversight. China is now the major supplier of Rx drugs for several other countries, including the U.S.A., India, and European countries. This compromises the quality and safety of our drugs and our national security. We depend on a not so friendly dictatorial power for antidotes to biological terrorist attacks.</p>

Rosemary Gibson is the founding editor of a narrative series in JAMA Internal Medicine, and is the 2014 winner of the highest honor from the American Writers Association. She has written other books on health care and has earned many other awards. Janardan Prasad Singh is an economic advisor at the World Bank. This book is well documented with 57 pages of end notes, and has received positive acclaim from the 75th U.S. Attorney General, Edwin Meese III, the former president of Consumer Reports, the president of the United Steelworkers, the president of the Alliance for American Manufacturing, and many others.

The book begins with the narrative of the tragic death of Bob Allen, M.D., who was perfectly healthy until he went to the E.R. with digestive symptoms. In preparation for endoscopy to visualize the stomach, a routine injection of heparin for prevention of blood clotting actually caused multiple clots in several coronary arteries, heart failure, and eventually death. The heparin was contaminated, obtained from China, distributed by an American company, Baxter. It took a month for the puzzle to be solved that the heparin was the culprit, after two children at another hospital had similar reactions on the same afternoon following heparin injections, and finally the heparin was suspected. Baxter voluntarily recalled many batches of heparin, but 3 months later, many other batches in China were recycled and resold somewhere. Also 94 hospitals in the U.S. still had some of the recalled heparin in stock 3 months later. The FDA did not have the authority to mandate a recall or to require companies to test for the contaminants. The FDA did not ban all heparin from China for fear of shortage. Also the agency had only 94 port inspectors for more than 300 ports of entry. How many other patients had complications or deaths that we do not know about, before the drug was suspected as the cause, and how many afterward, because the tracking system for adverse events is poor to nonexistent?

Around 89% of all drugs used in this country are generic. Almost all generic and some brand name drugs are manufactured in China. Yet our consumers and pharmacists are not allowed by law to import drugs from Canada. The drug companies get to save huge sums of money by importing cheap ingredients, but patients are not allowed to save enormous amounts by importing already produced drugs. And the drug companies sell the same drugs to people in other countries at a fraction of what our people pay. Capitalists are not necessarily patriotic. (My comments.)

If present trends continue, in the next 10 years, even all brand name drugs will also be manufactured in China, except for new releases.

You won't see the country of origin on the label of your Rx drug. The FDA requires the bottle the pharmacist receives to have a label that tells the name and the place of the business of the manufacturer, packer, or distributor. The place of business may not be the country of origin. So a company in this country that distributes Chinese drugs has its place of business in the U.S.A. The company doesn't want you to know that the drug originated in China. This company may have even acquired the drug very cheaply from some shady wholesale supplier in China, so the company may not even know for sure the true origin of the drug and would rather not know.

Dr. Chris Oldenhoff, president of Active Pharmaceutical Ingredients Committee (APIC), in Chemistry Today, 2000, wrote that gigantic volumes of ingredients are made in about "3000 manufacturing sites, many operating under very primitive conditions." Further he states, "These sites are usually neither operating under any good manufacturing standard or in compliance with any regulatory submission to health authorities."

How did this come about? In 2000, China was given permanently a favorable trade status, and then drugs became a commodity. Chinese companies dumping cheap products on the market forced U.S. domestic companies out of business. Sometimes shortages were created deliberately to manipulate the market. China's government policy required this, in direct conflict with U.S. antitrust laws, and in violation of World Trade Organization's rules. By the time the WTO was able to stop China's unfair trade practices, the damage was already done. The U.S. companies had already gone under.

Sometimes U.S. companies made agreements with China, that in order to sell their drugs in China, they had to partner with Chinese firms and help train them how to manufacture drugs. This was a short-term gain for that company, but a long-term loss to the whole U.S. pharmaceutical manufacturing sector. Often U.S. companies moved to China and laid-off their highly trained people, with a loss of a lot of intellectual capital. If manufacturing tried to rebuild in the U.S, it would be a lot harder to start up. China also gains technological superiority by theft of intellectual property, by hacking, and by infiltrating U.S. companies. China has a unified strategy directed by the state, and U.S. companies are each on their own, competing with each other, and used as pawns by the Chinese economic strategy. This book comments, "China thinks long term, America thinks short term. China plays chess, America plays checkers."

The U.S. China bilateral investment treaty allows Chinese companies to seek compensation for losses and even future losses caused by U.S. regulation, and caused by the blocking of imports of dangerous and contaminated drugs from China. These were some of the many objections people had with the proposed TPP, the undermining of sovereign nations' rights to make their own regulations, in favor of large corporations writing the trade agreements in their favor, not considering the rights of the people in each country. (My comments.)

The book states that China has “a centralized plan, designed and executed at the highest level of government, to drive out global competitors, dominate the world market, instill fear of retribution, or use its leverage to extract economic and political concessions from countries dependent upon it.”

So, for the foregoing reasons, the U.S. is now dependent upon China for medications, and has no capability to quickly ramp up domestic production in case China halts drug shipments to the U.S.

It is now clear that we depend on a source of drugs that is not assured of quality and safety. The FDA has a mandate to ensure that, but it has only the fraction of the budget and staff to do that enormous task of inspecting a multitude of Chinese companies. When they do inspect, they are met with many kinds of obstruction, requiring advanced notification of inspections, sometimes refusing access, and falsification and obfuscation of documents, taking advantage of the language barrier.

Even if inspections were adequate, Susan Winckler, former chief of staff at the FDA says, “We can't inspect our way to assurance of good manufacturing. There has to be an ethos.” It's like inspecting a child's room for cleanliness, and the day after inspection, it's dirty again. U.S. companies, having lost a lot of institutional knowledge, people with tenure, pride in the company's quality, and the culture of ethics, in favor of lower costs and greater efficiency, have lost that ethos.

Craig Langsdale, an industry veteran, describes the gold standard for manufacturing, which, unfortunately, is no longer common. “The company I work for is very ethical. We test absolutely everything that enters our facility, and we have a vigorous audit program where we audit every vendor... We spend a lot of money to make sure we get the best of everything.”

FDA Commissioner Dr. Margaret Hamburg said, “The risks are greater at every step in our increasingly complex global supply chain networks today. Sometimes these hazards are the result of quality control... and sometimes stem from intentional acts of diversion, counterfeiting, or adulteration.” Dr. Hamburg continues, “I think people have no idea in this country and around the world about the vulnerability of things we count on every day, food, drugs, medical devices, and other products, and we have a system that has big gaps in our protective mechanisms, and that's a growing problem.”

What Dr. Hamburg is referring to as counterfeiting and adulteration is a large problem, aside from the China issue. Katherine Eban, investigative reporter and Rhodes Scholar, wrote Dangerous Doses, a possible subject for another whole article, regarding counterfeiting. The supply chain involves wholesalers and distributors, and at many places in the chain can be sabotaged. Brand name drugs' packaging can be used to market counterfeit drugs, inserting fake drugs or diluted drugs into the brand name's packaging. Since 2000, increasing numbers of Americans are getting counterfeit drugs. The packaging is identical. The pharmacists can't tell the difference. The author recommends that consumers examine carefully their drugs for size, shape, and color, and to look for altered or unsealed packaging, or changes in design, or sticky residue, that is, if you can see the packaging that the pharmacist received, instead of just the orange bottle in which your pills are dispensed.

I wrote a previous article about The Danger Within Us, the poor vetting and testing of medical devices. Well, guess what? Many of these are also made in China. The FDA approved MRI machines, dental implants, screws for spine surgery, and catheters for coronary angioplasties. Medtronic partners with Chinese manufacturers to make pacemakers!

Steve Dickinson, an attorney who advises U.S. companies that conduct business in China said, "My wife is Chinese-born engineer. A good friend of mine in China is a US-trained biochemist, who works for a drug manufacturer in Shanghai. I mentioned your question to them today. They both said, 'I would not take drug that I knew was manufactured in China.' These people are not ignorant peasants. They are both highly trained scientists/engineers. This shows what this is all like for us folks who live in China. We all think the Americans are a bit naive. There is a reason for the China price." He further elaborates. The reason Chinese products are so cheap is something like this. They say, "We are not liable for consumer protection. If we were liable, the product would be very, very, expensive. If you want a cheap product, the price is that we do not take any liability for consequential damages." Good luck in trying to sue a Chinese company.

A U.S. Citizen can sue the U.S. distributor of a Chinese product, but people who have been injured by a drug have very little chance of recovering anything from a liability suit. It is hard to prove that the reaction came from the drug. The patient is nearly always forced into arbitration with not nearly enough to cover basic expenses such as hospital bills. In the narrative about Bob Allen, his wife, Charlisa, after much deliberation and litigation, she was finally allowed to go to a jury trial against Baxter. That is still pending. She had a lot of experience in the medical field, and knew what questions to ask. Most people don't have that advantage.

In the chapter, "The Perfect Crime," the authors state, "A poorly made or deliberately contaminated prescription drug is a perfect crime. It is hard to detect. Manufacturers keep the public in the dark. Regulators are tight-lipped so they don't offend manufacturers. Perpetrators are rarely caught. Most victims are unaware."

Only manufacturers, distributors, and packagers are required to report adverse events to the FDA. Doctors, nurses, and hospitals don't have to. Deaths are misreported or underreported, as too many could cause a drop in stock price. The FDA does not inform doctors or the public about adverse events. "The pharmaceutical industry exerts substantial control over the agency." If a drug doesn't work, doctors think it's a patient compliance problem, not a problem with the drug.

In the chapter subtitle, "How Come I Don't Know This?" the book states, "U.S. media conglomerates have financial interest in China that trigger self-censorship and the cover-up of important events in China." China is very careful to not let foreign reporters investigate disasters or contamination of drugs. The FDA did not reveal the names of the drugs that were contaminated in an explosion in China, and even a Freedom of Information Request by the authors was denied expedited processing.

An article in the Economist entitled, "Watch What You Say at Home" reads, "Today the Communist Party wields its now formidable leverage in all manner of ways, successfully muting criticism from CEO's and world leaders." The Daily Telegraph reports that Western banks are effectively gagged if they do business in China.

The authors' recommendations for public policy are:

1. Consider medicines to be a strategic asset, not a commodity to be bought at the lowest price.
2. Track and forecast vulnerabilities in the supply of medicines. Supplies of wheat, corn, meat, and fuel are tracked, but not drugs. Hospitals should be informed of impending shortages.
3. Prioritize which medicines are most critical to supply interruption.
4. Investigate Chinese cartels for drug shortages.
5. Provide incentives to bring drug manufacturing home.
6. Ensure that the U.S. military does not depend on China for essential medicines. Strengthen government oversight of drug manufacturing. Don't cede U.S. regulatory oversight of drug manufacturing to China.
7. Increase FDA testing.
8. Identify problem products rapidly.

For the consumer, the book recommends: Get the pharmacist to let you take a picture of the drug package, not the orange bottle given you. Call the service phone number of the company and ask for the country of origin. Go to DailyMed's website and get a list of companies that make your medication. Check the pictures of drug packaging. Call the company. Talk to your doctor if you have a problem with any medication. Call FDA 1-800-332-1088 or go online to www.fda.gov/medwatch.

My advice is to do all that you can do to be as healthy as possible so you don't need drugs. This problem is one more reason, among many others, to avoid drugs when possible. Use natural methods for most health problems, such as chiropractic, acupuncture, herbal medicine, nutritional supplements, and number one is healthful lifestyle. Exercise, eat real food, sleep and rest, manage stress, and avoid addictive

substances. Drugs, Rx and non-Rx, are appropriate in certain situations, such as emergencies, and very severe disease, but don't look to pharmaceuticals as the main source of health care. Unfortunately, too many people are addicted to the medical system, and this allows the medical and pharmaceutical industry to abuse the general population, to take advantage of their vulnerabilities and to use them to make enormous profits while patients go bankrupt and get sicker. If you've read my other articles, you get the drift of what I'm talking about. The pharmaceutical companies generally don't have your best interests at heart, or they wouldn't be outsourcing their manufacturing to China and charging you enormous prices.

Be healthy and, whenever possible, "Just say no to drugs."