

Made in the USA Reports

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Foundation Files FDA Complaint Against Major Drug Retailers

The Made in the USA Foundation filed a complaint with the U.S. Food and Drug Administration against CVS, Walgreens, Rite Aid and Costco Pharmacy for failing to label the country of origin of prescription drugs. The Foundation currently is pursuing a federal case against Costco, but wanted to open another front concerning this important issue. Both actions are part of our COLD: Country of Origin Labeling for Drugs project.

The complaint cites FDA, U.S. Customs and International Trade Commission rulings and regulations that require the drug labeling. About 40% of all over-the-counter and generic drugs used in the United States are produced in India. A similar amount of prescription drugs are imported from China.



Indian Drugs

In 2014, inspectors from the FDA investigated 160 drug plants in India. What they found was often quite alarming. Drugs were sometimes adulterated or contaminated. Facilities were often filthy or infested with insects. The FDA also caught some executives lying to them, leading to felony charges. Because of unhealthy conditions, the FDA banned the importation of drugs from several Indian factories.

The F.D.A.'s increased enforcement has already cost Indian companies dearly — Ranbaxy, one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a \$500 million fine last year, the largest ever levied against a generic company. "If I have to follow U.S. standards in inspecting facilities supplying to the Indian market," G. N. Singh, India's top drug regulator, said in a recent interview with an Indian newspaper, "we will have to shut almost all of those."

The World Health Organization estimated that one in five drugs made in India are fakes. One widely used antibiotic was found to contain no active ingredients after being randomly tested in a government lab. The test was kept secret for nearly a year while 100,000 useless pills continued to be dispensed. "Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections," said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at the University of Kashmir. "That's very serious."

Chinese Drugs

China, unlike India, has blocked U.S. efforts to send FDA inspectors. "China is the source of some of the largest counterfeit manufacturing operations that we find globally," said John P. Clark, Pfizer's chief security officer. Prescription drugs are pouring in from China, but U.S. regulators are not ensuring their quality, safety or proper labeling.

Federal regulators have inspected only a fraction of the hundreds of Chinese

factories making prescription drugs for the U.S. market, a recent report from the Government Accountability Office says.

Consumers can't tell where imported drugs and dietary supplements are made because country-of-origin labeling laws are not being enforced.

Chinese officials and businesses defend the quality of their products and say their defect rates have been decreasing. But problems with Chinese products keep cropping up — such as a recent case of Viagra contaminated with a drywall ingredient.

Leo Hepner, an international consultant on food and dietary supplement ingredients, said U.S. consumers did not realize that China now supplied most of the world's vitamin C and antibiotics, along with substantial amounts of other drugs and supplements.

Foreign drug and supplement plants producing for the U.S. market are supposed to meet FDA standards. But the GAO report said the FDA over the past few years had checked only 12 percent of the hundreds of Chinese plants producing pharmaceutical ingredients or finished products for the U.S. market.

The FDA did get to 52 of the plants in China in one year the report said, but that meant it had yet to visit 811 of the 920 Chinese facilities it is supposed to oversee. At the current inspection rate, it will take the FDA more than 15 years to get to the rest of China's plants.

In contrast, the FDA inspects 1,000 facilities in the U.S. a year, a pace that will allow it to cover all U.S. plants in 2½ years.

One consequence of the lack of regulation has been a rising number of counterfeit drugs, said Peter Pitts, a former associate commissioner of the FDA. One case, he said, involved counterfeit influenza medicine from China that was supposed to be Tamiflu, but contained none of its active ingredients.

Another involved counterfeit Viagra, the erectile dysfunction drug that

contained a drywall ingredient. En Wang, the owner of a Houston company, was convicted in that case of conspiring with others in China to import the counterfeit Viagra.

“It’s a nascent public health crisis and we shouldn’t wait until we have bodies in the street,” said Pitts, president of the Center for Medicine in the Public Interest, a New York nonprofit group that promotes drug and food safety.

Besides the counterfeiting, there have been cases of drug contamination. In 2008, a contaminated ingredient from China showed up in heparin, a blood-thinning medicine that was linked to 149 deaths.

North China Pharmaceutical Group Corp. claims to be the second-largest producer of penicillin in the world. It says the Chinese government has made it a “top priority” that it become one of the top 500 companies in the world selling antibiotics, veterinary medications, pesticides and vitamins.

An expert on Chinese health at the Council on Foreign Relations, Yanzhong Huang, explained the big difference between Chinese and U.S. medicine safety. “U.S. vaccines are kept safe by supporting institutions such as “the market economy, democracy, media monitoring, civil society, and a business ethics code, plus inspections and regulations, severe punishment for violators and lawsuits by trial lawyers. Communist China doesn’t tolerate any of those safety precautions.”

Conclusion

With all the problems mentioned in this article about the dangers of drugs from China and India, the only way that consumers can protect themselves is to refuse to purchase these risky products. And the only way that we can do this is to force companies to provide the country of origin of their products. That is why we asked the Food and Drug Administration to enforce the law that requires pharmacies to label all prescriptions with the country of origin of the pills that we take to treat serious health problems.