

Combating counterfeit Rx from China

July 16 2007

Agencies worldwide are cracking down on counterfeit pharmaceuticals, and much of the focus has been on China, where an official was recently executed for approving fake medicines. While most of these drugs reach consumers through online or illegal suppliers, there's a growing threat to outlets considered more safe, like the neighborhood pharmacy, said Temple University pharmacoeconomist, Albert Wertheimer, Ph.D., who will talk about combating counterfeit pharmaceuticals coming out of China at a U.S. Patent and Trademark Office (USPTO) seminar on July 23 and 24 in Philadelphia.

Internet pharmacies, which are extremely difficult to monitor and regulate, pose the biggest threat, but counterfeits could soon make their way into mainstream channels via sophisticated fakery and old-fashioned bribery.

“Counterfeiters have gotten very good at replicating labels and packaging,” said Wertheimer, who will focus on techniques used in other fields to identify fake goods, as well as the importance of detecting counterfeits early in the supply chain.

“Governments and industry must realize that when the danger actually becomes visible, patients may already have suffered harm,” he said.

Global efforts are underway to develop an international database that documents all counterfeit drug activity. Experts also urge greater coordination with the pharmaceutical industry.

Additionally, officials are looking at effective strategies used in other fields to fight counterfeiting including a pedigree system, which would record the path of ownership and location of a drug shipment. Each purchaser along the supply chain would add information and verify authenticity. Another technique uses sensors, inert substances that can be added to a liquid or pill, that would verify authenticity. Officials could also borrow a strategy from the retail industry – radiofrequency identification, whereby drugs would be tagged similar to clothing items.

“Still, technology cannot be a permanent, foolproof solution, and only by improving importation and regulation policy can counterfeiting be contained further. The Food and Drug Administration's Counterfeit Drug Task Force believes that attacking the problem through multiple routes will be the most effective way to combat drug counterfeiting,” Wertheimer said.

In general, counterfeit means that a drug can lack an important ingredient, contain a harmful ingredient or be mislabeled. Some of the most commonly counterfeited drugs include those for erectile dysfunction, depression, anxiety and infection. In a recent study, the World Health Organization determined global sales of counterfeit drugs to be \$32 billion in 2003 – 10 percent of all medicines sold worldwide.

“Drug counterfeiting is a threat that every nation faces and the activity is very difficult to identify, trace, and combat. The growth of online drug sales, counterfeiters' increasing technologic skill, and a false sense of security in countries with stringent regulatory measures are among the factors that are enabling the spread of this criminal activity,” Wertheimer said.

U.S. and Chinese speakers at the USPTO event will be drawn from the academic and governmental fields as well as industry. Conference attendees will include businesses and companies doing or contemplating

doing business with or in China, as well as those who want to protect themselves against counterfeiting and piracy from China.

Source: Temple University

Citation: Combating counterfeit Rx from China (2007, July 16) retrieved 28 April 2024 from <https://medicalxpress.com/news/2007-07-combating-counterfeit-rx-china.html>

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