

Drug Counterfeiting: A Bitter Pill

San Diego, a city of roughly 1.25 million inhabitants, has about 125 pharmacies. As of a year ago, according to the San Diego Weekly Reader, Tijuana, Mexico, with a population about the same size of San Diego's, had 1,000 pharmacies. Tijuans probably weren't eight times more likely to need pharmacies than San Diegans; these retail operations opened up in response to a growing demand among U.S. citizens for more affordable prescription drugs.

Unfortunately, as experts recently testified before the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations, many of the pills sold are counterfeit and dangerous. In fact, an estimated 5 to 8 percent of worldwide trade in pharmaceuticals is counterfeit, according to the World Health Organization, a figure that John D. Glover, vice president of corporate security for Bristol-Myers Squibb Company, told the committee is probably an underestimate.

The numbers and anecdotal evidence on diversion and counterfeiting are staggering. Donald deKieffer, an attorney who represents many pharmaceutical companies, told the subcommittee that since 1997, more than 4,600 foreign drug manufacturers have shipped product to the United States without its being inspected by the Food and Drug Administration (FDA). In addition, new counterfeit drugs are found in the United States all the time. For example, two counterfeit growth hormones (Serostim and Nutropim) and a cancer drug (Neupogen) were recently found within a 30-day period. Making the problem particularly difficult is the profusion of Internet sites through which counterfeiters can now market their bogus goods.

James Christian, vice president and head of corporate security for Novartis International AG, recounted his company's efforts in the uphill battle: In the last five years, the company has been involved in more than 100 investigations of counterfeiting operations in more than 30 countries. They involved more than 11 Novartis products and more than 200 products manufactured by other companies. In one raid of a counterfeiter's facility, Novartis turned up "tens of thousands of vials of a drug whose expiration date had long since passed." New labels were being attached to update the expiration date.

Novartis came across another product, Christian testified, that closely resembled Novartis's own but was made of floor wax, boric acid, and a lead-based yellow paint used for road markings. Glover told the panel that the illicit pharmaceuticals trade increasingly "resembles the worldwide narcotics trade, where product is sourced in one country, formulated into tablets or capsules in another country, packaged in yet another country, and then transshipped through other countries to its final destination."

For the United States, ground zero for counterfeiting activity appears to be Mexico, where U.S. citizens routinely cross the border in search of cheaper alternatives to legitimate prescription drugs. Central America, Argentina, Colombia, China, and India are other major loci of the problem, and Glover added that the latter two countries serve as major sites of manufacturing. A March 2001 raid by Novartis and other

pharmaceutical companies in Shantou, China, resulted in the seizure of 1,800 cartons of counterfeit pharmaceuticals from 14 multinational companies.

Not only do diversion and counterfeiting endanger patients, said Glover, but they also undermine public confidence in the pharmaceutical industry, destroy a company's ability to gauge market needs, and decrease funds required for new research. Because legitimate and bogus product are almost indistinguishable, legitimate companies may be liable for harm caused by knockoffs. In addition, Glover testified that it is "often impossible for a consumer suffering from an adverse reaction to identify and contact the manufacturer of...knockoffs."

Suggested solutions included better cooperation between relevant government agencies, the elimination of Internet pharmacies dealing in illegal imports, and increased penalties for prescription drug abuse. DeKieffer recommended that the government and pharmaceutical companies work together to better oversee philanthropic drug distribution abroad and to create a better system for tracking drugs destined for distressed markets, where diversion is likely. He also suggested that the government help subsidize prescription drugs for the poor and elderly to make them less vulnerable to enticements of cheap alternatives from counterfeiters pushing their wares.