

## FIVE REASONS TO OPPOSE REIMPORTATION

By Dr. Merrill Matthews Jr.

Access to less-expensive prescription drugs has become the holy grail of Washington and state legislatures, as politicians consider imposing various types of price controls on drugs or helping Americans buy their prescriptions from other countries—primarily Canada—where government price controls mean lower prices on many popular drugs.

IMS Health, a company that tracks prescription drug sales, estimates that Americans spend \$650 million in cross-border prescription drug purchases—often referred to as “reimportation,” since drugs made in the U.S. and sold and shipped to other countries are then sold to U.S. customers who bring them back (reimported) to the states.

It is important to understand that it is against the law to import (or reimport) drugs into this country. For practical and political reasons the Food and Drug Administration and the U.S. Bureau of Customs and Border Protection allow U.S. citizens traveling internationally to bring back or to purchase online small amounts of prescription drugs for personal use. That doesn't mean the practice is legal; the law is just not rigidly enforced.

**The Issue Is Safety.** Why is importation illegal? The answer is safety. Twice Congress has passed legislation that would allow Americans to buy their drugs from Canada, but the legislation came with a caveat: the Secretary of Health and Human Services had to determine that U.S. consumers would be safe, which the secretaries have been unable to do. And they aren't alone: 10 former FDA commissioners, the Bureau of Customs and the Drug Enforcement Administration (DEA) have raised serious concerns about the safety of drugs coming from other countries, even those drugs alleged to have been made originally by U.S. manufacturers.

Some politicians think these concerns are overblown, but a look at the growing number of news articles about counter-

feit drugs, organized crime, terrorist threats and patient injuries tells a different story.

**Reason #1: U.S. Government Agencies Recognize the Problem of Illegal Imports.** The House of Representatives' Energy and Commerce Oversight and Investigations Subcommittee recently held hearings on the illegal importation of drugs and the serious safety concerns.

The government says it will launch “A major operation ... this summer at international mail centers to counter a flood of counterfeit and unapproved drugs entering the country,” according to the *Associated Press*.

Travelers bringing pharmaceuticals into the country may also be targeted by the “blitz,” the *Associated Press* noted.

Over the last two years, federal officials say they have seen a 1,000% increase in the number of mailed packages of prescription medicines—“many of them adulterated or counterfeit”—imported into the U.S., *Reuters* reported.

The hearings disclosed instances in which Americans ordered drugs that turned out to be nothing but water, drugs that would soon reach their expiration dates and illegal generic copies of popular U.S. prescription medicines such as Viagra, according to the *Associated Press*.

In some areas, the numbers are far higher. In Pakistan, for example, counterfeits may make up 50% of all drugs privately sold, the pharmaceutical trade group noted. It also cited the results of a survey in Nigeria where “50% of the products on the market were described as useless.” (Excerpted from the *Wall Street Journal*, June 25, 2003.)

**According to the *Boston Globe*, which covered the same hearing:**

Subcommittee Chairman Rep. James Greenwood, R-Pa., observed that the Miami international mail facility alone receives as many as 7 million packages containing drugs annually, a flow that has increased sharply in recent years as a growing number of people order pharmaceuticals through the mail.

William Hubbard, associate commissioner of the Food and Drug Administration, presented a selection of drugs people had bought through the mail that turned out to be illegal, counterfeit or simply to have no active ingredient at all.

Counterfeit drugs can be fake products or may be generic copies of a real drug made and sold without FDA supervision or approval.

Counterfeit drugs have long been problems in parts of the world. One study found one-third of malaria pills tested in parts of Asia contained no medication.

One Internet site that sells drugs shows an address in the United States but operates out of Thailand, Hubbard said. Another that claims to be Canadian ships drugs from India.

The FDA has no way to monitor the quality of drugs made abroad, Hubbard said, and in many cases what arrives has improper labeling or has not been properly stored or handled.

One man spent \$1,500 for a four-year supply of a drug that has an expiration date in August, he said, and another received a vial containing tap water instead of the vital drug claimed on its label. (Excerpted from the *Boston Globe*, June 24, 2003.)

**Reason #2: Drug Counterfeiting Is Rampant Outside the U.S. The World Health Organization (WHO) estimates that about 6 percent of the world prescription drug market is counterfeit, but almost all is outside of the U.S. That is changing as more U.S. citizens buy their drugs from other countries.**

The Indian government has admitted that drug formulations unapproved by India's drug regulatory agency and not evaluated for effectiveness are prescribed and sold across the country.

Documents submitted to the court said dozens of unapproved formulations of nimesulide combined with various other drugs, such as analgesics, anti-allergy drugs, muscle relaxants, and other non-steroidal anti-inflammatory drugs, remain unapproved.

Dr. Gulhati said that over 70 unapproved combinations are sold under several hundred brand names. (Excerpted from the *British Medical Journal*, June 14, 2003.)

**Reason #3: Canada Isn't Safe Either. U.S. politicians think they can get around the safety issue by restricting the importation of drugs from Canada.**

"Canada is boosting security at its seaports following stinging criticism that they are rife with crime and could be used to smuggle weapons of mass destruction into North America." According to the story, this action is the result of a Canadian Senate committee which said that "crime groups including Asian Triads, the Russian mafia and the Hell's Angels motorcycle gang are active at Canada's ports, using them to smuggle illegal drugs, weapons and refugees into North America." (*Wall Street Journal*, April 21, 2003.)

**Reason #4: The U.S. May Not Be Safe Much Longer. While the U.S. has escaped the brunt of these problems, the quest for cheaper drugs may change that.**

An investigation by the Manhattan District Attorney's office that began in January 2001 and went on for 17 months uncovered four supply streams of counterfeit Viagra; three from China and one from India.

The investigation revealed that pharmaceutical companies in China and India were involved in the manufacture and illegal importation of the counterfeit Viagra into the U.S. (*CBS Evening News*, October 2, 2002.)

**Besides "lifestyle drugs," counterfeiters target life-saving drugs:**

The complaints from nurses began trickling in to Bayer Corp. earlier this year. Something struck them as odd about the vials of Gamimune N, the company's drug to treat patients with weakened immune systems. The liquid in the vials was unusually cloudy.

Bayer recalled one lot of the drug and then another, trying to isolate the problem. By mid-March, the company concluded that someone had tampered with the drug. At least 13 vials—found in warehouses of U.S. distributors and on pharmacy shelves—had been diluted.

Bayer's was the first of five cases of adulterated and counterfeit prescription medications that have found their way to US distributors, pharmacies, and patients this year. The Bayer alert was followed this month by a warning from Eli Lilly that criminals had filled at least six bottles with generic aspirin and disguised them as the Indiana company's schizophrenia drug, Zyprexa.

Within days, other warnings were issued. Watered-down vials of Epogen, an anemia drug made by California's Amgen, had been discovered. Bottles of an HIV drug, Combivir, made by Britain's GlaxoSmithKline, filled with another drug and fraudulently labeled as Combivir were found in Maryland, Connecticut, California, and Florida. A phony version of Serostim, a drug made by the Swiss company Serono to treat AIDS wasting, had been found.

Until recently, strict state and federal regulations have kept the flow of counterfeit drugs in the United States to a trickle. But industry and public health officials see the recent cases as evidence of a mounting problem. The regulatory system is straining under the pressures of an increasingly global economy. Counterfeiting techniques are more sophisticated, and the lure of high drug prices is more tempting. (*Boston Globe*, May 29, 2002.)

**Reason #5: The Trial Lawyers Are Waiting. The FDA has clearly stated that once U.S.-made drugs leave the country, drug companies have very little control over them, and other countries simply don't impose the kind of controls the U.S. does. That fact will not discourage class action attorneys who will sue the pharmaceutical manufacturers for not ensuring the safety of their products, even when they have no control over them.**

Enriched and emboldened after successful fights against asbestos and tobacco companies, some of the nation's top plaintiffs' lawyers have trained their sights on drug makers, claiming that many giant pharmaceutical companies have hidden the dangers of medicines the lawyers say have harmed thousands of people. (*New York Times*, May 18, 2003.)

**In an effort to make it easier for Americans to buy prescription drugs abroad, Congress will make it easier for counterfeiters to reap billions of dollars for counterfeit, diluted or impotent drugs and give unscrupulous trial lawyers one more reason to file suit.**

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