

A Legislators and Consumers Guide to Prescription Drug Importation



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A LEGISLATORS AND CONSUMERS GUIDE TO PRESCRIPTION DRUG IMPORTATION



The desire for access to less-expensive prescription drugs has initiated a heated political debate in Washington and state legislatures. Even as the U.S. Justice Department, the Bureau of Customs and Border Protection and the Food and Drug Administration (FDA) multiply their efforts to stem the influx of counterfeit, diluted, mishandled, mislabeled and unapproved prescription drugs, others with little or no expertise in drug safety are assuring Americans that imported drugs are safe.

This “Legislators and Consumers Guide” answers some of the questions about the safety concerns associated with prescription drug importation and whether consumers ought to have the right to buy imported drugs even if they are aware of the significant risks. In addition, the section entitled “Articles Related to Importation” at the end of the Guide provides newspaper and periodical excerpts from around the world that highlight the growing problems and safety concerns over importation.

We believe that anyone who reads the Guide and the news reports will agree that imported drugs pose a significant threat to the safety of the U.S. prescription drug stock—and that the only proper response is to intensify our efforts to check this threat now, not weaken them by opening the floodgates to imported drugs.



A LEGISLATORS AND CONSUMERS GUIDE TO PRESCRIPTION DRUG IMPORTATION

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ARTICLES RELATED TO IMPORTATION

- Articles about the Growing Global Threat of Counterfeit Drugs
- Articles about U.S. Attempts to Reduce the Flow of Counterfeit Drugs
- Articles about U.S. Citizens Hurt by Imported Drugs
- Articles about People in Other Countries Hurt by Counterfeit Drugs

DRUG ASSISTANCE PROGRAMS

- Pharmaceutical Manufacturers’ Programs
 - State Assistance Programs
-

WHAT IS IMPORTATION?

As a public policy issue, importation refers to the practice of bringing prescription drugs into the United States, but avoiding the FDA's processes for ensuring drug safety. The method of importation can take several forms.

- Some Americans travel to another country, especially Canada and Mexico, buy prescription drugs and bring them back to the U.S.
- Increasingly, Americans are turning to mail order or going online to purchase prescription drugs, which are mailed or shipped to the U.S. customer from another country.
- There are storefront shops that call or fax or otherwise place an order with a pharmacy or drug wholesaler in another country, which then mails or ships the prescription drug order to the U.S. customer. Such groups often don't actually handle the drugs; they simply act as middlemen, getting a fee from the pharmacy or wholesaler for their service.

It is important to note that while importation bypasses the normal—and regulated—distribution process for prescription drugs, a small number of counterfeit and tainted drugs have found their way into U.S. pharmacies, a trend that would only increase if importation is legalized.



WHAT IS THE DIFFERENCE BETWEEN IMPORTATION AND “REIMPORTATION”?

Reimportation generally refers to the drugs that are made by U.S. drug manufacturers and sold and shipped to other countries, which are then sold and shipped back (reimported) to the states. Thus, reimportation is one form of the broader practice of importation.

Unfortunately, most U.S. consumers who are importing drugs think they are getting reimported drugs. That is, they believe that the brand name drugs they are buying—assuming they are brand names and not counterfeits—were made in the U.S. and could have been sold to U.S. citizens but just happened to be sold to another country. Therefore, they think there are no safety risks—or no more so than going into a U.S. pharmacy. While that assumption may be true for some of the drugs, there is very little way to know for sure.

For example, a prescription drug bought online may be a counterfeit of a brand name drug available in the U.S. Thus it would be an imported drug, not a reimported one, because a U.S. manufacturer did not make it. But even if it were made in the U.S.—and so would be considered a “reimported” drug—it still might not be safe if it were mishandled during shipping and storage. Many drugs need constant refrigeration, and FDA inspectors have identified a number of drug handlers and wholesalers who did not keep specific drugs properly refrigerated. Such carelessness may not only dilute a drug’s potency; it could be very harmful to patients.


IS IMPORTATION LEGAL?

It is against the law to import or reimport drugs into this country. The FDA allows U.S. citizens traveling internationally to return with a small amount (usually defined as 90-days worth) for personal use of prescription drugs that *are approved in another country but not in the U.S.* But that is the exception, not the rule.

Moreover, for practical and political reasons, the FDA allows people to bring back small amounts of prescription drugs for personal use even if those drugs have been approved in the U.S. But that doesn't mean it's legal; the law just has not been rigidly enforced.

Thus, U.S. politicians who encourage seniors—even help them arrange for buses—to travel to Canada and buy prescription drugs are helping those Americans break the law. Bizarrely, some U.S. politicians are threatening to punish drug companies that have chosen not to sell to Canadian pharmacies that break U.S. law.

Perhaps for some people the more important question is whether importation *should* be legal. In general, the government has taken the position that the greater the potential for harm, the greater the need for oversight and control. There is a reason why people have to go through their doctor to get a prescription drug: there is a huge potential for harm. If a person knowingly buys a fake designer purse, the customer takes a chance (because it may not be the same quality as the brand



name purse), but it's a small chance. A patient taking a fake prescription drug could suffer serious harm, even death. As Michael J. Mann, chief of investigations with the Florida Department of Law Enforcement, said to Reader's Digest about why importation is the perfect crime, "The witnesses will be dead."

HOW WIDESPREAD IS IMPORTATION?

The government estimates that about 1 million Americans are importing drugs from outside the country. The Canadian International Pharmacy Association, which represents Canadian wholesalers selling to U.S. customers, estimates that its members' sales will be about \$800 million this year. But these numbers are growing rapidly as more and more Americans, and especially seniors, are encouraged by certain politicians, health care providers and "patients' advocates" to get their drugs outside of the U.S.

For example, an Oct. 2, 2003, USA Today article states: "Further west, sales to the USA over the Internet have become a big business. [Andy] Troszok, vice president of the Canadian International Pharmacy Association, says the boom has transformed little-developed Manitoba province into the hub of the Internet drug industry. With provincial government approval, the industry has created more than 3,000 jobs there."

Who goes to Canada for their drugs? Americans without insurance coverage for prescription drugs. Notably,



members of Congress do not go abroad for their prescriptions. Neither do 9 million federal employees, their dependants and federal retirees. Neither do employees of large corporations who happen to be near the Canadian border. The reason is that these people are fortunate enough to participate in generous private health insurance arrangements that rely on market-based competition to provide a high quality prescription drug benefit.

WHY IS IMPORTATION GROWING?

There has always been a small number of Americans willing to travel to other countries to get their prescription drugs. Often they were trying to get drugs available in another country that had not yet been approved for the U.S. by the FDA. Others were looking for quantities of certain drugs that would not be available to them in the U.S.

However, the recent explosion of interest in importation is almost entirely a result of prices: Americans think they can get brand name prescription drugs at cheaper prices and an acceptable level of risk.

But why are the prices of brand name drugs often lower (generic prices, by contrast, are often higher in Canada than the U.S.) in Canada and other countries? The answer is that those countries operate under a system of price controls that may lead to lower prices on some drugs but almost always also leads to decreased access.



A recent opinion piece in the Wall Street Journal by Canadian doctor David Gratzer contends that, “In Ontario, Canada’s largest province, the provincial government declined to add any new medications to its drug formulary for a full two years in the late 1990s. Even today, if a Canadian doctor wants to provide certain very basic medications—such as the anti-inflammatory Celebrex, or the antibiotic Cipro—he needs special approval first.”

In addition, Americans have one of the highest standards of living. Canada’s annual per capita GDP is about two-thirds that of the U.S.—\$22,300 vs. \$35,200 (2001, U.S. dollars). Mexico’s is a mere \$6,200. In fact, a recent study by Dr. Patricia Danzon of the Wharton School points out that the prescription drug price variation is roughly equal to the income variations in other countries. People in most other countries simply cannot afford to pay what Americans can, and so many industries—not just drug companies—charge them lower prices for many different kinds of goods and services.

However, the disproportionate prices mean that Americans shoulder the burden for most of the research and development costs needed to find new cures. In response to this disparity, FDA Commissioner Mark McClellan has begun a campaign to pressure other industrialized nations to share a greater percentage of those costs.




WILL EXPANDING IMPORTATION LEAD TO LOWER DRUG PRICES FOR AMERICAN CONSUMERS?

For years, a small number of U.S. citizens has been crossing the border into Canada to buy small amounts of prescription drugs for personal use at lower prices from licensed pharmacists. But now the word is out and everyone is rushing in to take advantage of the situation.

First are the middlemen. Canadians and others selling or brokering prescription drugs to Americans are in the business to make a profit. As a result, part of the savings gained by traveling to Canada is being redirected to the middlemen.

More importantly, the price will be affected by the growing demand. Canada represents 2.6 percent of the global prescription drug market, while the U.S. represents 53.4 percent. Internet pharmacy sales are redirecting drugs to the U.S., and Canadian drug wholesalers are scrambling to find more drugs in what's known as the secondary market, where middlemen from all over the world buy and sell drugs. According to the Wall Street Journal, "Barry Power, a director of the Canadian Pharmacists Association, says his organization has been hearing from members across the country that supply problems are cropping up more often and lasting longer than before the Internet pharmacies set up shop."

Any economist knows that when demand is greater than the supply, the price will rise—regardless of the price countries initially pay drug manufacturers for their prod-



ucts—or wholesalers will find other sources. That is exactly what is happening in Canada, according to an Oct. 31, 2003, story in the *Ottawa Citizen*: “Canadian imports of drugs from the developing world are skyrocketing. . . . Federal figures show, year over year, imports of medications from Bulgaria are up 300 percent, Pakistan 196 percent, Argentina 171 percent and South Africa 114 percent.”

DOES THE FDA ASSURE THE QUALITY OF IMPORTED DRUGS?

Absolutely not. The FDA oversees and regulates any pharmacy, drug wholesaler or manufacturer operating inside U.S. borders, whether those drugs are being sold to U.S. citizens or not. But the FDA does not—indeed, *cannot* given its budget and resources—monitor and approve all of the drugs coming into the U.S. by various means.

The FDA does some spot checking of the millions of prescription drug packages coming into the U.S. each year, and it often discovers counterfeit, mislabeled or mishandled drugs, which it may confiscate. In addition, the FDA has recently cracked down on counterfeiting rings here in the U.S. and abroad, when it can get another government to cooperate. And the FDA tries to work with other governments to help them shut down illegal or counterfeit wholesalers in foreign countries.



AREN'T IMPORTED AND REIMPORTED DRUGS AS SAFE AS THOSE BOUGHT IN THE U.S.?

Some are, others aren't. And it is almost impossible for the average consumer to know which are which. The reason is the explosion of counterfeit drugs in many countries outside the U.S. which conduct much less drug monitoring. But that would change with widespread reimportation.

The World Health Organization estimates that roughly 6 to 8 percent of the world drug supply is counterfeit. In India, about 30 percent is counterfeit. In Pakistan, it's about half. And in some African countries, 80 percent. Counterfeiters—who can range from foreign generic drug manufacturers to low-budget operations working out of a garage to organized crime and terrorists—are looking for ways to get their products into the U.S.

Recognizing the growing threat to the safety of the U.S. drug system, the FDA has drastically increased its efforts to identify, locate and shut down those not following strict FDA guidelines.

DOESN'T CANADA ASSURE THE QUALITY OF DRUGS SHIPPED FROM WITHIN ITS BORDERS TO THE U.S.?

The notion that drugs bought from a business with a Canadian address (or one purporting to have a Canadian



address) are as safe as those in the U.S. is driving the importation debate. For example, according to a USA Today story about a transplant patient named Jerry Cox, “Cox, who retired because of health problems, says he is not worried about drugs mailed from Canada, which he says has a safety record similar to the USA.”

However, Canada’s safety record is irrelevant because Health Canada, the Canadian agency overseeing prescription drug sales and safety, does not monitor businesses that don’t sell to Canadians.

According to a May 9, 2003, letter from Health Canada to the Washington Post:

The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada to the United States, or any other country for that matter. Health Canada is first and foremost concerned with the health and safety of Canadians. Drugs that are manufactured in Canada for export to other countries must comply with regulations that have been established by the importing country. Indeed, a drug manufactured in Canada can be sold without having been approved for sale in Canada as an export to the United States, *but only if the manufacturer has obtained authorization to market the drug from the U.S. Food and Drug Administration.*” (emphasis added)

Thus, the Canadian government makes it very clear that it does not regulate drugs being sold to the U.S. and,



most importantly, that any drugs being manufactured in and/or shipped from Canada should comply with U.S. law—which is why the FDA is cracking down because drugs being imported by individuals don’t comply with U.S. law.

EVEN IF THE WHOLESALERS AREN’T REGULATED, ISN’T CANADA SAFE AND ITS BORDERS SECURE?

Canada is certainly safer than many other countries, but an April 21, 2003, Wall Street Journal story also identifies problems—or should we say “leaks”? “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 work 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.”

Moreover, a recent report from the Royal Canadian Mounted Police stated that Canada has an “established counterfeit industry”—referring to counterfeiting in the broad sense of the term—in part because of lighter penalties, and that counterfeiting in Canada has reached an “epidemic.”



CAN'T THE FDA BE REQUIRED TO GUARANTEE THE SAFETY OF PRESCRIPTION DRUGS MAILED TO THIS COUNTRY?

Congress passed legislation in 2000 under the Clinton administration that would allow Americans to buy prescription drugs from Canada. But the legislation stipulated that the secretary of Health and Human Services had to determine that the legislation would not create safety risks, which neither Sec. Donna Shalala nor Sec. Tommy Thompson has been able to do. And they aren't alone: 10 former FDA commissioners, the Bureau of Customs and the Drug Enforcement Administration 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.

In other words, the law is already on the books that allows importation—as soon as the secretary deems it safe for U.S. consumers.

Some politicians think these concerns are overblown. Reps. Gil Gutknecht (R-Minn.) and Jo Ann Emerson (R-Mo.) have cosponsored a bill that would allow U.S. citizens to buy U.S.-made prescription drugs from other industrialized countries.

In addition, some governors are looking at plans that would allow state employees to purchase drugs from Canada. And one mayor has already established a pro-



gram that allows city employees to buy prescription drugs from a Canadian supplier. However, the FDA investigated some of the insulin coming from the supplier and found that it had not been properly stored.

CAN'T DRUG MANUFACTURERS BE REQUIRED TO GUARANTEE THE SAFETY OF PRESCRIPTION DRUGS REIMPORTED TO THIS COUNTRY?

It is virtually impossible for brand name manufacturers to monitor their products after they leave the U.S. It can even be difficult trying to monitor the drugs in this country once they go into the secondary market, where they may pass through a number of middlemen before finally landing in a pharmacy.

However, the drug manufacturers and the FDA are trying to change that situation by devising new, innovative ways to track a drug's transfers. For example, manufacturers are looking at putting small tracking devices on packaging so that pharmacists and regulators will know just where a drug has been. Such procedures would help ensure some accountability in the secondary wholesale market.

ISN'T IMPORTATION THE SAME TYPE OF FREE TRADE THAT THE U.S. GOVERNMENT USUALLY ENCOURAGES?

The U.S. has been a strong defender of free trade between countries as a way to promote economic growth. So why not simply apply that principle to prescription drugs?



The answer is that free trade assumes it is legal trade; importation is illegal. Even though it might foster economic growth, the federal government does not permit U.S. companies to sell certain technology—especially that which can be used militarily—to other countries that eventually might be used against the U.S.

In addition, importation undermines contractual relationships. Once two parties enter a voluntary agreement, they have a contract. When pharmaceutical manufacturers enter into a sales agreement with another country, the contract usually restricts or prohibits the reselling of the drugs back to U.S. citizens—because to reimport the drugs is illegal.

Normally, when a party to a contract breaks it, the aggrieved party can seek a remedy through the legal system. But reimportation is an agreement across international lines, and even though selling the drugs back to U.S. citizens is illegal, the U.S. government has been reluctant to compel other governments to honor their contracts. As Richard Epstein of the University of Chicago Law School has pointed out, when a contract cannot be enforced, turning to statutory restrictions (in this case, laws against reimportation) may be a reasonable and appropriate alternative.

Finally, the U.S. often restricts the trade of dangerous products that can harm humans, animals and the environment. Prescription drugs are not like many other



consumer products: they are inherently dangerous. That is why a prescription is required to purchase them.


ISN'T THE BEST APPROACH TO ALLOW IMPORTATION BUT WARN BUYERS TO BEWARE?

The importation issue is not about a small number of patients crossing the border, going to a reputable pharmacy with a licensed pharmacist and buying a small amount of a prescription drug for personal use. It is about millions of consumers:

- Trusting drug vendors they have never seen;
- Having no idea if their facilities are safe and located where they claim to be; and,
- Not knowing whether the drugs are counterfeit, diluted, mishandled, mislabeled or unapproved.

As a general principle, buyers should be free to make informed choices, which may include taking more risk for a lower price. However, those tradeoffs almost always assume that vendors are honestly representing their product. People may turn to the used car market in order to get a lower price, but the law requires the speedometer to accurately reflect the car's mileage. In other words, the buyer should be cautious; but the seller must be truthful.

The problem with importation is that there are so many fraudulent vendors misrepresenting their products—and that number is growing exponentially. Consumers may



be willing to pay a lower price for the same drug bought online, but they wouldn't pay anything for it if they knew it was a fake.

WHO WOULD BE HELD ACCOUNTABLE IF PATIENTS WERE HARMED BY COUNTERFEIT DRUGS?

Certainly not the Internet pharmacies, if they have anything to say about it. Many Internet pharmacies have disclaimers similar to this one taken from a website: “The products and information presented on this Web site are provided ‘as is,’ without any warranty. (Company names) are not liable for any damages arising from the use of the products or information appearing on this Web site, regardless of whether the damages are incidental, indirect, direct, or consequential.”

Not the kind of thing you see at your local pharmacy.

If reimportation becomes widespread, some Americans will be harmed—it is only a matter of time. And then the question will be who will be held responsible.

At least one city has decided to import drugs from Canada for city employees and retirees. Several states are considering a similar program, even though the FDA has adamantly opposed such actions and has sent warning letters to those attempting it. Moreover, the FDA examined some of the insulin shipped to the city employees and found some of it had been mishandled and compromised.



Thus, when a city or state employee is harmed by imported drugs, trial lawyers will have a good case that the elected officials promoting the program acted negligently. Just consider the possibilities. State and local governments have at times been sued when they were engaging in commercial activity, even if the government wasn't directly profiting from the program (though it would be indirectly profiting if importing drugs saved money).

In addition, the local and/or state government might be sued for negligence if it can be shown that its officials did not exercise reasonable caution to ensure the quality and safety of the drugs. And if an employee were harmed by an imported drug, that would be a pretty easy case to make.


Knowingly breaking federal law is criminal activity. Doing it in spite of repeated warnings by the federal agency of jurisdiction is gross negligence. If elected officials think their budgets are tight now, wait until they are faced with a multi-million dollar jury verdict.



ARE THERE BETTER OPTIONS THAN IMPORTATION FOR FINDING LESS EXPENSIVE, BUT SAFE, PRESCRIPTION DRUGS?

There are a number of options available. (Note: See the Drug Assistance Programs section at the back of this Guide.)

- To begin with, virtually every state and drug manufacturer has programs to provide low-income patients with access to greatly discounted or free prescription drugs.
- Most of the major manufacturers have created nationwide programs for low-income seniors. For example, a qualifying senior can buy any Pfizer drug for \$15 per month and any Eli Lilly drug for \$12 per month. In addition, GlaxoSmithKline has a program that provides significant discounts, and several drug companies have created the TogetherRx program.
- Pharmacies tend not to post their prices so that customers can easily comparison shop, which has led many to believe that prices don't vary much from pharmacy to pharmacy. However, numerous surveys have shown that prices can vary significantly, especially for generic prescription drugs. The point is that patients don't have to go across the border to get less-expensive prescription drugs; they often can do it just by going across town.
- There are online pharmacies, especially those connected with well-established "brick and mortar" stores, that are reputable businesses with licensed pharmacists



who can provide prescription drugs at lower prices. However, buying online is not like walking into the store where you know you are dealing with a pharmacist. A business that has no scruples about selling customers counterfeit drugs would surely have no scruples about misleading consumers into thinking they are visiting a well-known drug chain's site. Buyers must be cautious about whom they are dealing with.

CONCLUSION.

For generations, U.S. patients have gone to their local pharmacy confident of the quality and safety of the drugs they bought. Some are now transferring that trust to online vendors that may or may not be reputable, licensed dealers. Unfortunately, it may take a tragedy before some of our politicians and patients get the message that importation is illegal and unsafe.

ARTICLES RELATED TO IMPORTATION



Many people seem unconvinced that there really is a growing threat of counterfeit drugs. The following excerpts from well-respected publications around the world are arranged into four different categories, though the content often overlaps. Only a portion of each article is reprinted (primarily for space reasons), so ellipses mark the places where parts of the article have been omitted.

In addition to these articles, one of the most thorough examinations of the dangers of importation is a series of five articles that ran in the Washington Post from Oct. 19-23, 2003.

ARTICLES ABOUT THE GROWING GLOBAL THREAT OF COUNTERFEIT DRUGS

“What’s in That Pill?”

Trish Saywell and Joanne McManus

Far Eastern Economic Review, Feb. 21, 2002

In China, authorities have even found veterinary drugs repackaged for human use. In other cases, drugs specifically designated for injection have been used as oral medications. Industry estimates of counterfeits in China range from 10% to 15%. For some products and brands, the average is about 50% and can reach as high as 85% in some cities such as Shantou. . . .



Most experts agree, however, that the situation is worst in India. Regulating the country's more than 20,000 drug companies is a huge challenge. Dilip Shah, secretary general of the Indian Pharmaceutical Alliance, an association of 12 Indian pharmaceutical companies, estimates 15%-20% of the drugs on the market in India are fake and in certain cities, for certain brands, it's as high as 35%-40%.

"It's one of the most serious problems facing the Indian health system," notes Ranjit Roy Chaudhury, president of the Delhi Society for the Promotion of the Use of Rational Drugs, a consumer advocacy group. "It started as a cottage industry," he says, "but others found it to be easy money and now there are highly organized cartels."

"International Terrorism: The Threat to Canada"

Canadian Security Intelligence Service

Vol. 63, No. 6, 2001

While incidents of violence on this scale [in a few other countries] are relatively uncommon in Canada, the support activities of terrorist groups here are far more prevalent, and well-documented. Over the past 15 years, we have witnessed a disturbing trend as terrorists move from significant support roles, such as fundraising and procurement, to actually planning and preparing terrorist acts from Canadian territory.



**“One-tenth of medicines sold in Russia
said to be fake”**

BBC Monitoring Service, June 23, 2003

Moscow – Some 7 to 12 per cent of medicines sold in Russia are fakes, a Health Ministry official said. . . .

He also stressed that his inspectorate, which employs 19 people, cannot control such a large number of market players, as there are about 7,000 domestic producers and about 70,000 pharmacies in the country.

**“Testimony before the House Committee on Energy
and Commerce”**

Lester M. Crawford

Deputy Commissioner, FDA, July 17, 2002

Because Canadian law explicitly exempts pharmaceuticals intended for export from any regulatory oversight whatsoever; there is absolutely no effective way to prevent unscrupulous individuals from using Canada as a location from which to ship counterfeit and contaminated drugs. Third World countries seeking to peddle counterfeit drugs would gain access to the lucrative U.S. market by using Canada as a point of entry. The drugs merely take a slight detour on their way to unwary American consumers.



“EU members agree to measures to cut out flood of fake goods”

Daniel Dombey (Brussels)

Financial Times, July 23, 2003

Europe is in danger of being overwhelmed by a flood of counterfeit goods, including fakes of foodstuffs and medicines as well as clothes and CDs, the European Commission warned yesterday.

In welcoming agreement among European Union member states on new measures to deal with counterfeit goods, the Brussels body said the problem had increased “massively” in recent years.

While 10 million counterfeit items were intercepted on the EU’s borders in 1998, by 2001 the figure had increased tenfold to almost 100 million. Levels for the first half of 2003 have confirmed the trend.



ARTICLES ABOUT U.S. ATTEMPTS TO REDUCE THE FLOW OF COUNTERFEIT DRUGS

“Phony Prescription Drugs Deluge U.S.”

John A. MacDonald

Hartford Courant, June 25, 2003

Washington – Federal regulators are overwhelmed by a tidal wave of counterfeit and unapproved prescription drugs entering the United States from other countries and must revamp their procedures to protect the health of Americans, congressional investigators said Tuesday. . . .

John M. Taylor, the FDA’s associate commissioner for regulatory affairs . . . seemed at a loss about how to stem the flow of counterfeit or unapproved drugs into the country.

He told lawmakers he has 537 investigators, who have to handle cases ranging from illegal drug imports to homeland security concerns, “Increasing the resources will not make a dent,” he added, because the demand for cheaper foreign drugs is so great. . . .



Many of the [Internet] sites advertise that they are shipping drugs from Canada, but often that is not the case, said William K. Hubbard, the FDA's associate commissioner for policy. In reality, the drugs often come from Thailand, India, Russia, the former Soviet republics, Barbados and other Third World nations, Hubbard said. There is no way for the FDA to ensure the safety or effectiveness of drugs from these nations, he said.

“Effort planned to block counterfeit, unapproved drug imports in mail”

Randolph E. Schmid, June 24, 2003

Associated Press

Washington – A major operation is planned this summer at international mail centers to counter a flood of counterfeit and unapproved drugs entering the country, the government said Tuesday.

Scientists and inspectors will target, examine and test packages, Elizabeth Durant of the Bureau of Customs and Border Protection told the House Energy and Commerce subcommittee on oversight and investigations. . . .



William Hubbard, associate commissioner for 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 have no active ingredient at all. . . .

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. . . .

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.

“Drug Wholesalers Are Indicted for Selling Fake, Diluted Drugs”

Associated Press, July 22, 2003

A Florida grand jury investigating pharmaceutical wholesalers indicted 19 people on charges of peddling bogus or diluted medications often prescribed for cancer and AIDS patients, authorities said Monday.

“It’s hard to imagine a more heinous crime perpetrated upon an individual who’s counting on what they believe to be a legitimate drug to save their lives,” state Attorney General Charlie Crist said.



Investigators said the defendants made tens of millions of dollars from the scheme, and that the bogus drugs eventually found their way into common chains in Florida such as Walgreens and Eckerd drug stores.

“This isn’t just about drugs being diverted and rediverted. It’s also in some cases about empty bottles being filled with chalk and water and labeled with fake labels,” said state Department of Health Secretary John Agwunobi. “In some cases it’s about tap water being injected into bottles and sold as if it was a prescription drug.”

“FDA Faults Quality of Imported Drugs”

Gardiner Harris

New York Times, Sept. 30, 2003

Most imported drugs are counterfeit knockoffs that could seriously endanger the health of those taking them, say federal drug and customs officials who conducted a spot inspection over the summer that they disclosed yesterday.

The inspection “illustrates the real and serious public health risks created by the importation of unapproved drugs,” said Mark B. McClellan, commissioner of the Food and Drug Administration. . . .



The FDA and customs agents conducted their spot inspections during two three-day periods at mail processing centers in Miami, New York, San Francisco and Carson, Calif. They pulled out 1,153 packages that appeared from the outside to contain drugs. They said they found that 1,019, or 88 percent, contained unapproved drugs.

ARTICLES ABOUT U.S. CITIZENS HURT BY IMPORTED DRUGS

“Man blames illness on drug from bus trip”

Associated Press, Aug. 17, 2000

A man who rode U.S. Senate candidate Mark Dayton’s “Rx Express” to Canada to buy prescription drugs says he was sickened by some of the medication he received.

Stanley Kampa, 83, of St. Cloud (Minn.) was rushed to the hospital Tuesday after his heart slowed and he passed out. Kampa blamed his Canadian-purchased medication, and the emergency room doctor who treated him said it was the likely culprit.



“Congress: Imported Drugs a Public Health Threat”

Sean Martin, June 7, 2001

WebMD

Meanwhile, DEA and Customs officials pointed out import abuses by individuals making repeated trips to Mexico and Canada to obtain controlled substances. . . .

Virginia officials say that more than 50 people have died in their state from overdoses of OxyContin, a much-abused prescription opioid that is obtained through illicit channels including smuggling from Mexico. In Tijuana alone, [Rep.] Greenwood noted, there are an estimated 1,700 pharmacies. But in San Diego, a similar-sized city just north of the border, there are only 125 pharmacies.

“Bogus Viagra Business Booms”

Sharyl Attkisson

CBS Evening News, Oct. 2, 2002

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.



Undercover investigators, through e-mail and phone conversations, pretended to be involved in selling counterfeit Viagra in New York.

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. Also, a chemical company in China was a prime source for counterfeit Viagra sold by two of the indicted drug brokers and their companies.

“Fakes in the Medicine Chest”

Leila Abboud, Anna Wilde Mathews and Heather Won Tesoriero

Wall Street Journal, Sept. 22, 2003

Many counterfeits go unreported. Sometimes pharmacists or distributors have stopped suspicious packaging. But often it is the patients who notice their medication looks or smells unusual or who have bad reactions. Rick Roberts, a San Francisco college professor with AIDS, felt an odd stinging sensation when he injected Serostim by Serono SA, an antiwasting drug he got at a pharmacy in December, 2000. The he noticed other anomalies



with the packaging, such as a rubber stopper in a vial normally sealed with plastic. “I was very afraid,” says Mr. Roberts, who confirmed his batch of medicine was fake when he checked Serono’s Web site. But “what happened to those people who didn’t know?” Mr. Roberts asks. “We don’t really know how injurious this was. And that’s scary.”

To date, there have been few reports of serious injuries from counterfeit drugs. But experts sense that a combination of factors—including weakness in the drug-distribution system, the rise of Internet pharmacies and the huge disparities in drug prices—have paved the way for fakes.

“Fake drugs show up in U.S. pharmacies”

Julie Appleby

USA Today, May 15, 2003

As more high-priced prescription medications hit the market, they are proving irresistible to counterfeiters, who have successfully shipped fake, mislabeled and mis-handled drugs into U.S. pharmacies.

Investigators have seized vials of anemia treatments Procrit and Epogen containing 20 times less active ingredient than labeled.

AIDS patients who rely on Serostim to prevent muscle wasting have fallen ill after injecting a fake.



Pharmacists have alerted the Food and Drug Administration to white pills labeled “aspirin” in bottles of schizophrenia treatment Zyprexa.

Ten types of counterfeit drugs moved through Florida in the past two years, investigators say, including Procrit, Epogen, Serostim, Zyprexa, antifungal Diflucan and AIDS drugs Combivir and Retrovir.

Many of the fakes are so good that pharmacists have trouble telling them from the real thing. Investigators and pharmacists say the problem of counterfeit, mislabeled, or mishandled drugs could spread beyond the relatively few medications affected now unless state and federal regulators tighten requirements for the nation’s drug wholesalers.

I’ve been in this business for 40 years,” says pharmacist Lowell Anderson of Bel-Aire Pharmacy in White Bear Lake, Minn. “I have less confidence in the integrity of the supply line today than ever before. It scares me.”

“It’s a Fake, and your pharmacist doesn’t know it”

Katherine Eban

Reader’s Digest, Oct. 2003

It’s impossible to know exactly who has been hurt by corrupt wholesalers. By taking their medicine, patients unwittingly dispose of the evidence. If they die, what



actually harmed them remains unclear, because they were already sick. In many ways, this makes pharmaceutical counterfeiting the perfect crime. Says Michael J. Mann, chief of investigations with the Florida Department of Law Enforcement, “The witnesses will be dead.”

ARTICLES ABOUT PEOPLE IN OTHER COUNTRIES HURT BY COUNTERFEIT DRUGS

“India admits to unapproved drug formulations in market”

Ganapati Mudur (New Delhi)

The British Medical Journal, June 14, 2003

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. . . .

Dr. Gulhati said that over 70 unapproved combinations are sold under several hundred brand names. These include combinations of antibiotics that could contribute to the emergence of drug resistant organisms.

“Fake Drugs Make Inroads”

Pinaki Roy

The Daily Star (Bangladesh), June 25, 2003

Counterfeit versions of a number of life-saving medicines are being made and sold in Bangladesh,



putting patients at serious risk. . . .

Most of the fakes are made by dishonest pharmacists, according to industry sources. But some small pharmaceutical companies appear also to be involved. . . .

In 2001 the government canceled licenses of 44 small companies for producing counterfeit drugs. It is not however known how many were prosecuted. Twelve others were restricted to producing particular items. But the clampdown has not stopped the practice.

Richard Knox (National Public Radio reporter)

NPR's Morning Edition, July 28, 2003

As many as 80,000 children in Nigeria have gotten fake meningitis vaccines. India has seen bogus polio vaccines. In Southeast Asia, one study found that 1/3 of drugs contained no active ingredient. These are crimes on a grand scale. They hurt not only the unsuspecting people who get worthless vaccines and medicines, they sabotage the campaign to rid the world of polio and other infectious diseases.

Global trade is only one source of the problem. Computers and laser printers make it easy for criminals to mimic drug labels and packaging. The Internet makes it cheap to market fake drugs to consumers anywhere in the world.

DRUG ASSISTANCE PROGRAMS



Comparative Chart of Pharmaceutical Manufacturers' Drug Discount Cards

Program	Prescriptions Covered	Annual Income Below (For households of 3 or > people, there may be higher income limits)	Benefit	Contact & Misc. Info.
GlaxoSmithKline Orange Card	All Drugs	\$30,000/Individual \$40,000/Couple	At participating pharmacies receive a 30% average savings	1-888-672-6436 Patients can participate in either the Orange Card or Together Rx for GSK medications (the Orange Card has higher income limits)
LillyAnswers (Eli Lilly & Company)	All drugs except controlled substances	\$18,000/Individual \$24,000/Household	At participating pharmacies pay \$12.00/prescription for a 30 day supply	1-877-795-4559 www.lillyanswers.com
Novartis Care Card	Select Drugs	Two Income Categories A. \$18,000/Individual \$24,000/Couple B. \$28,000/Individual \$38,000/Couple	At participating pharmacies: A. Pay \$12.00/mo. (per prescription) B. Receive a 25%-40% off	1-866-974-2273 www.NovartisCarePlan.com Enrollment for the Novartis savings program will be through Together Rx.
Pfizer for Living Share Card	All Drugs	\$18,000/Individual \$24,000/Couple	At participating pharmacies pay \$15.00/ prescription for up to a 30 day supply	1-800-717-6005 www.pfizerforliving.com
Together Rx Card This one card can be used for many medications manufactured by: Abbott Laboratories, AstraZeneca, Aventis Pharmaceuticals, Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson and Novartis	Selected Drugs	\$28,000/Individual* \$38,000/Couple* *Alaska & Hawaii have higher income limits	At participating pharmacies receive a 20-40% savings off the regular prescription price of over 150 medications	1-800-865-7211 www.together-rx.com

All programs require that applicants be Medicare recipients and have no other prescription coverage. These drug discount cards have no enrollment or annual fees.

Other Drug Discount Cards

Program	Prescriptions Covered	Income Guidelines	Benefit	Contact & Misc. Info.
Nonprofit Warehouse	All Drugs	No Income Limits	At participating pharmacies receive up to 50% off regular retail price on generic drugs and up to 15% on brand name prescriptions	1-770-541-7777 www.nonprofitwarehouse.com

Drug Assistance Locator Programs

The federal government sponsors an agency known as the Eldercare Locator, which helps seniors age 60 and older in finding assistance programs, such as the Area Agency on Aging, in their local communities. You can reach the Eldercare Locator at 1-800-677-1118 or at www.eldercare.gov.

www.helpingpatients.org is a free, confidential Web-based service sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA) to help patients find assistance programs

Drug Assistance Programs by State

STATE	Population Served E - Elderly D - Disabled M - Medicare U - Uninsured	NAME OF PROGRAM	CONTACT INFORMATION
Alabama	E	SenioRx	800-AGE-LINE (800-243-5463)
Alaska	---	No Program	---
Arizona	M	Prescription Medication Coverage Pilot Program	Not yet operational
Arizona	E or D	Arizona Prescription Drug Discount Program RxAmerica	888-227-8315
Arkansas	E	Prescription Drug Access Improvement (Medicaid waiver for Rx drug coverage)	Not yet operational - Contact Dept. of Human Services
Arkansas	All low income	Arkansas Health Care Access Foundation, Inc.	1-800-950-8233 or 1-501-221-3033
California	M	Drug Discount Program for Medicare Recipients	Show your Medicare card at participating pharmacies to get drugs at Medi-Cal prices.
California	M	Golden Bear State Pharmacy Assistance Program (revision of discount program above)	Medi-Cal 916-552-9557 not yet in effect
Colorado	---	No Program	---
Connecticut	Anyone	Citizens Health (program being piloted in MA, CT & RI)	800-JOE-K-4RX (800-563-5479)
Connecticut	E or D	Connecticut Pharmaceutical Assistance Program Contract to the Elderly and the Disabled Program (ConnPACE)	CT Dept. of Social Services 860- 832-9265 or toll free in-state 800-423-5026
Delaware	E or D	Delaware Prescription Assistance Program (DPAP)	Division of Social Services 800-996-9969 x.17;302-577-4900
Delaware	E	Nemours Health Clinic Pharmaceutical Assistance Program	800-292-9538
District of Columbia	All low income	DC Healthcare Alliance	202-842-2810

Florida	M	Prescription Discount Program	Show your Medicare card at participating pharmacies to get drugs at Medicaid prices.
Florida	M	Silver Saver Program	888-419-3456
Georgia	All low income	Georgia Partnership for Caring Foundation	800-982-GPCF (4723)
Georgia	M	GeorgiaCares	800-669-8387
Hawaii	Anyone	Hawaii Rx Discount Program	Not yet operational: possible implementation 7/1/04
Idaho	---	No Program	---
Illinois	E or D	Circuit Breaker/Pharmaceutical Assistance Program (PAP)	800-624-2459
Illinois	E	Illinois Senior Care	800-356-6302
Indiana	E	Hoosier Rx	317-234-1381 or 866-267-4679
Indiana	M	Senior Health Insurance Info Program	800-452-4800
Iowa	M eligible	Iowa Priority Prescription Savings Program	866-282-5817
Kansas	E	Kansas Senior Pharmacy Assistance Program	Contact Dept. of Aging 785-296-4986 or 800-432-3535
Kentucky	All low income	Health Kentucky	800-633-8100
Louisiana	E	Louisiana SenioRx Program	225-342-3570 www.louisianaseniorx.org
Maine	All low income	Healthy Maine Prescriptions	866-796-2463 (TTY/TTD 207-622-3210)
Maine	E, D	Maine Low Cost Drugs for the Elderly & Disabled Program	866-796-2463
Maryland	All low income	Maryland Medbank Program	410-821-9262; 877-435-7755
Maryland	D, Any age, Low income	Maryland Pharmacy Assistance Program	800-226-2142
Maryland	M	Senior Short-term Prescription Drug Plan (Care First Plan)	BC/BS 800-972-4612
Massachusetts	Anyone	Citizens Health (program being piloted in MA, CT & RI)	800 -JOE -K-4RX (800 -563-5479)
Massachusetts	E, D	The Prescription Advantage Program	Exec. Office of Elderly Affairs 800-243-4636; 617-727-7750
Michigan	E	Elder Prescription Insurance Coverage	866-747-5844 (Program is currently closed except for emergency coverage)
Minnesota	E, D	Minnesota Prescription Drug Program	800-333-2433; 651-297-5418 www.dhs.state.mn.us/healthcare/asstprog/prescription drugs.htm
Mississippi	---	No Program	---
Missouri	E	MO Senior Rx Program	866-556-9316 or www.missouriseniorx.com
Montana	E	Prescription Drug Expansion Program	Not yet operational - estimated date of 2004
Nebraska	---	No Program	---
Nevada	E	Senior Rx	800-262-7726
New Hampshire	E	Senior Prescription Program (discount card)	888-580-8902

New Hampshire	All low income	NH Medication Bridge Program	800-852-3456
New Jersey	E, D	Pharmaceutical Assistance for the Aged and Disabled (PAAD)	609-588-7048; 800-792-9745
New Jersey	E	Senior Gold Program	609-588-7048; 800-792-9745
New Mexico	E	New Mexico SenioRx Program	866-244-0882
New York	E	Elderly Pharmaceuticals Insurance Coverage (EPIC) Program	800-332-3742
North Carolina	E	North Carolina Senior Care Program	866-226-1388
North Dakota	---	No Program	---
Ohio	E, D	Golden Buckeye Card Program	866-301-6446
Ohio	All low income	Rx for Ohio	877-794-6446
Ohio	Seniors over 60 and the uninsured at or below 250% of the federal poverty level	Best Rx	---
Oklahoma	---	No Program	---
Oregon	E	Senior Prescription Drug Assistance Program	800-359-9517
Pennsylvania	E	Pharmaceutical Assistance Contract for the Elderly (PACE) & PACE Needs Enhancement Tier (PACENET)	PA Dept of Aging 717-787-7313 800-225-7223
Rhode Island	Anyone	Citizens Health (program being piloted in MA, CT & RI)	800-JOE-K-4RX (800-563-5479)
Rhode Island	E	Rhode Island Pharmaceutical Assistance for the Elderly (RIPAE)	Dept. of Elderly Affairs 401-462-3000 or 1-800-322-2880
South Carolina	E	Silver Rx Card	Silver Rx Card Hotline 877-239-5277
South Carolina	All low income	Commun-I-Care	803-933-9183
South Dakota	E	Senior Prescription Discount Card	800-257-9946
Tennessee	All low income	TennCare Rx Program	Not yet operational
Texas	M	State Prescription Drug Program	Not yet operational, postponed
Utah	---	No Program	---
Vermont	E or D	Vermont Health Access Program (VHAP) & VScript Expanded (state only VScript)	800-250-8427 or instate 800-529-4060
Vermont	All low income	Vermont Medication Bridge Program	866-887-4276
Virginia	---	No Program	---
Washington	E	Pharmacy Plus	Not yet operational
West Virginia	E	Golden Mountaineer Discount Card Program (replaces SPAN II)	877-987-3646
Wisconsin	E	Senior Care	800-657-2038
Wyoming	All low income	Prescription Drug Assistance Program	800-438-5785 or 307-777-7531

About the Authors

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