



A Serious Threat to Patient Safety

# Counterfeit Pharmaceuticals

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Pharmaceutical counterfeiting is on the rise in the United States and around the globe, potentially putting at risk the health of millions of patients who take for granted that the prescription medicines they buy are safe and effective.

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Counterfeit drugs are dangerous by their very nature – they are not produced under safe manufacturing conditions and they are not inspected by regulatory authorities. Therefore, it is impossible for consumers to know what ingredients these products actually contain.

While the U.S. pharmaceutical distribution system is among the safest in the world, incidents of counterfeiting nevertheless continue to increase.

A number of factors have contributed to the rise in pharmaceutical counterfeiting. Included among them are the growing involvement in the drug supply chain of under-regulated wholesalers and repackagers, the proliferation of Internet pharmacies, advancements in technology that make it easier for criminals to make counterfeit drugs, and the increased importation of medicines from Canada and other countries.

At a time when counterfeit pharmaceuticals are flooding the global market, Pfizer is trying to educate the public about the need for caution when purchasing their medicines and the importance of closing our borders to these potentially dangerous products. We are now up against large and sophisticated criminal organizations with global reach and we must address this problem on a global basis.

*Pfizer Global Security*

## Can You Tell The Difference?



Visually, the only distinction between these Lipitor tablets is that the counterfeits (far left) are slightly thicker than the authentic medicine.

### 1: What is a counterfeit medicine?

A counterfeit medicine is one that has been deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product. Counterfeit products include drugs with no active ingredient, drugs that are super potent, and drugs with dangerous impurities\*.

*\*Source: Pharmaceutical Security Institute*

### **Pfizer Medicines That Have Been Counterfeited Include:**

- Lipitor
- Viagra
- Norvasc
- Zoloft
- Celebrex
- Aricept
- Diflucan
- Dilantin
- Feldene
- Ponstan
- Vibramycin



## Deadly Consequences

In June 2005—following the discovery that an accredited pharmacy in Canada had dispensed counterfeit Norvasc, Pfizer’s popular blood pressure medicine—11 reported deaths were examined for a link to the fakes. The regional coroner reported that of the 11 deaths, the counterfeit medicine could not be ruled out as a cause for four of them.

### 3: What risks are associated with counterfeit medicines?

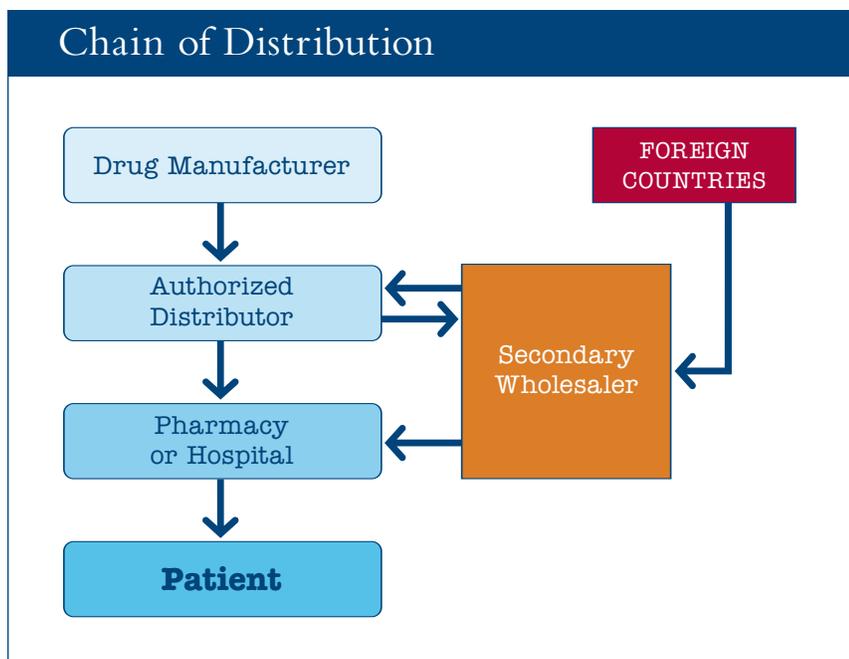
One of the biggest risks of counterfeit medicines is that patients may not get the therapeutic benefit expected from the product. For example, a drug for shrinking a cancerous tumor may not benefit the patient because it contains none, or too little, of the active ingredient. Conversely, the product may contain too much active ingredient or other potentially dangerous contaminants, which could also be harmful.

#### **Harmful Ingredients Found In Counterfeit Medicines Have Included:**

- Boric acid
- Leaded highway paint
- Floor polish
- Heavy metals
- Nickel
- Arsenic
- Brick dust

## 4: How do counterfeit medicines enter the United States and our supply chain?

In years past, we could take some comfort in the fact that counterfeits mostly appeared in illegal or unauthorized channels of distribution. Today that is no longer the case, as legitimate channels of distribution in developed nations like the U.S., Canada and the U.K. have been increasingly infiltrated by counterfeits.



Within the legitimate U.S. supply chain, medicines are commonly sold directly by pharmaceutical companies to major authorized distributors, which then supply them to hospitals and pharmacies where they are dispensed to patients. However, drugs may also move sideways from the authorized distributors to middlemen or secondary wholesalers who sell drugs to one another. It is at this point that fake or unapproved and potentially dangerous drugs from other countries can enter the U.S. supply chain.

Pharmaceuticals purchased over the Internet are another major and growing source of counterfeit medicines in industrialized and, to some extent, in poorer countries. This is a particular threat to those seeking cheaper medicines or unauthorized treatments, or who want to avoid a consultation with a doctor. While some Internet pharmacies are legitimate, others are illegal, selling medications without prescriptions and dispensing unapproved or counterfeit products. In some cases, illegal Internet pharmacies are operated internationally and sell products that have an unknown or vague origin.\*

\*Source: World Health Organization

## 5: Who profits from counterfeit medicines?

Counterfeiting is linked to many forms of organized crime, such as money laundering, drug trafficking and terrorism. Criminals have become increasingly involved in counterfeiting as it becomes more lucrative; in fact, profits from counterfeits can actually be larger than those from narcotics such as heroin and cocaine. Pharmaceutical products are attractive to criminal gangs because they are easily transportable and command a high price per unit. An added bonus for traffickers is that the criminal penalties for pharmaceutical counterfeiting are often less severe than for the trafficking of narcotics, and because law enforcement agencies do not have all the resources necessary to address the problem.\*

### Funding Terrorism



In March 2006, the U.S. Attorney's Office indicted 18 people for a multimillion-dollar international conspiracy to smuggle untaxed cigarettes, counterfeit Viagra and other goods to raise money for the Middle East terrorist group Hezbollah. The alleged scheme, operated from 1996 to 2004, was based in Dearborn, Michigan and received counterfeit Viagra from China and Eastern Europe for distribution across the United States.

\*Source: House of Commons debates January 26, 2006, [www.theyworkforyou.com](http://www.theyworkforyou.com)

# Know Your Source

The screenshot shows the WorldMeds website interface. At the top, it says "WorldMeds" and "Enjoy Low Cost Prescription From Canada". Below that, there's a navigation bar with "Home", "About Us", "Privacy", "Shipping", "Free", and "Order". A banner for "DISCREET & FREE SHIPPING" is visible. The main content area is titled "ENJOY THE BENEFITS OF GENERIC MEDICINE" and includes a quote: "It's your right to buy inexpensive generic drugs, and when you order from us you will get a FREE doctor consultation and FREE shipping." Below this, there are six product listings, each with a "Generic" and "Non-Generic" option and a "BUY NOW" button. The products are Ambien, Viagra, Valtrex, Xanax, Cialis, and Lovelina. A sidebar on the right features a photo of a doctor and a quote: "Because you're buying generic, you'll get the same treatment but for a greatly reduced cost." Below the quote is a "BENEFITS" section with a list of advantages.

Product	Generic Price	Non-Generic Price
Ambien	\$99	\$155
Viagra	\$179	\$350
Valtrex	\$119	\$190
Xanax	\$150	\$300
Cialis	\$299	\$499
Lovelina	\$199	\$249

- No Consultation Fee
- No Shipping Charge
- No Prior Prescription Needed
- No Appointments
- No Waiting Room
- No Insurance Cost
- Private and Confidential
- Discreet Packaging

In October of 2004, Pfizer investigated this online pharmacy claiming to be based in Canada. In reality, the domain name for the site was hosted in Korea and registered in St. Kitts. An order

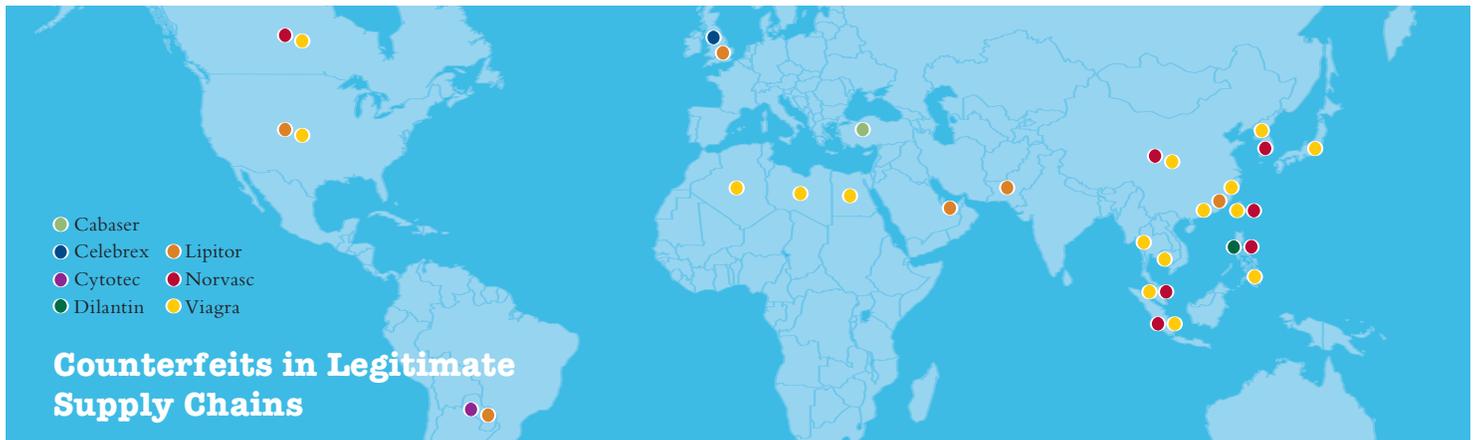
placed on the website was delivered, not from a pharmacy in Canada, but in a plain envelope with an Oklahoma City postmark. The investigation revealed that the return address was an empty lot.

## 6: What are the safest ways to purchase medicines?

The best way to avoid counterfeit drugs is to purchase prescription medicines from a reputable pharmacy with which you are familiar.

If you choose to purchase your medicines online, always see your doctor and get a written prescription first. Use an online pharmacy certified by the National Association of Boards of Pharmacy (NABP) through its "Verified Internet Pharmacy Practice Sites" (VIPPS™) program. These pharmacies can be located using the VIPPS™ certified pharmacy list available at <http://www.nabp.net>. Don't buy medications from an online pharmacy that isn't licensed in your country, that offers to write prescriptions, or that sells medications without prescriptions.

Remember that if the price of a medicine seems too good to be true, it probably is.



## 7: Is it safe to buy medicines from other countries?

Pfizer's experience has shown that the major counterfeiting threat to the American pharmaceutical supply is not from within the United States but from other countries. Importation raises safety concerns due to the significant difficulties in identifying whether imported prescription drugs have been mishandled, adulterated or counterfeited while under foreign control.

American consumers expect their pharmaceutical products to be produced under controlled conditions. The importation of pharmaceutical products from foreign countries actually opens a gaping hole in the United States' regulatory system and the processes that have been in place for years to protect American patients. The governments of a number of countries, including Canada, have said they cannot guarantee the safety of exported products, which do not go through the same inspection processes as those medicines that are sold domestically.

*"An importation system that can assure that medicines being imported are safe and effective does not appear to exist."\**

### Securing Our Borders

In August 2005, the U.S. Food and Drug Administration conducted an operation at multiple U.S. airports and found that nearly half of the imported drugs intercepted were shipped to fill orders that consumers believed were being placed with "Canadian pharmacies." Of the drugs being promoted as "Canadian," 85 percent actually came from 27 other countries around the globe. A number of these products also were found to be counterfeit.\*

\*Source: Pharmaceutical Security Institute

\*Source: Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States, April 2005, Giuliani Partners

## 8: How can I tell if I receive a counterfeit medicine?

Technology to produce everything from labels to active pharmaceutical ingredients is now widely available. With growing technological sophistication, counterfeiters are often able to make fake medicines look almost identical to authentic ones.

Consumers may not know that the medicines they've purchased are counterfeits. That's why it's important to purchase prescription products from a pharmacy and pharmacist with whom you're familiar.

In some cases, patients have noticed a different taste, consistency, or appearance of products that are later identified as being counterfeit, or they may have a different reaction to the counterfeit drug. Talk to your doctor or pharmacist if you notice anything unusual about the medication you are taking.

*Immediately report suspected counterfeiting to the FDA MedWatch Program (1-800-FDA-1088) and to the manufacturer of the medicine.*

### Identifying a Counterfeit



The counterfeit tablet (far left) had a pinkish tinge and a rougher surface texture than the authentic. The debossing was poorly rendered, particularly “Pfizer”, and in a narrower font. The counterfeit contained little, or none, of Norvasc’s active pharmaceutical ingredient.

## Who would you trust to make your medicines?



Counterfeiter



Pfizer

### 9: What are the economic consequences of counterfeiting?

Counterfeiting has significant economic consequences. In reality, it “hijacks” the brand and infringes the patent and trademark rights of legitimate pharmaceutical manufacturers. Additionally, counterfeiters take full advantage of the fact that someone else paid the upfront money for research and development expenses; all counterfeiters have to do is to copy the appearance of the product.

Consumers lose because they are paying good money for inferior products, which not only is a bad deal economically but also can be a significant health threat.

The government loses as well. Incredible resources are necessary to combat counterfeiting, not to mention the negative effect on tax revenues. In 2004, U.S. Customs seized over \$138 million in counterfeit products, which represented a significant loss in taxes. Additionally, health plans are being defrauded:

Counterfeiting is a lose-lose situation for consumers, the government, and legitimate manufacturers.

*\*Source: U.S. Department of Commerce*

## 10: What can be done to address the problem?

There is no easy solution to the counterfeiting problem, and pharmaceutical companies, consumers and government all have important roles to play. It is clear that, as counterfeiters grow in number and sophistication, now is not the time to loosen regulatory and enforcement processes.

The FDA—like Pfizer and other research-based pharmaceutical companies—is concerned about an increase in the importation of pharmaceuticals that provides additional opportunities for counterfeiting and potentially threatens the overall safety and effectiveness of our medicines. The FDA is aggressively taking steps to address the issue and Pfizer is committed to supporting those anti-counterfeiting efforts in any way we can. The company recently made several recommendations to the FDA for improving FDA/industry coordination and increasing the allocation of financial resources to support federal and state anti-counterfeiting endeavors.

Pfizer also called for the agency to establish a more formalized system to encourage the quick exchange of lab analyses, product tracking, sourcing and other information when counterfeiting problems arise. In addition, the company recommended more intense oversight of secondary wholesalers and repackagers to reduce opportunities for counterfeiting, and tougher penalties for those who fail to comply with reasonable preventative measures.

An increased financial commitment by the FDA and state regulators also is vital to improve oversight of distributors and repackagers; to increase inspection coverage; to monitor distribution channels; and to enforce Good Manufacturing Practice (GMP) requirements for repackaging. The industry and regulators must work cooperatively to guarantee the integrity of the pharmaceutical supply chain, and Pfizer is committed to do just that.



## 11: What does Pfizer do to protect consumers from the dangers of counterfeiting?

Pfizer believes that there is no higher priority than ensuring that consumers have safe and effective medicines. We continue to explore and implement new technologies, such as special packaging and printing techniques, that make counterfeits both more difficult to make and easier to spot.

Pfizer also has established business practices designed to further secure the distribution system; increase cooperation with law enforcement agencies to successfully prosecute counterfeiters; and promote proactive public policy that will help eliminate counterfeiting.

Pfizer is working with wholesalers, the pharmacy community, regulators and law enforcement agencies around the world—including the FDA, the British Medicines and Healthcare products Regulatory Agency (MHRA), and the Australian Therapeutic Goods Administration (TGA)—to determine how to best keep the drug distribution system safe for patients.

### **New Technology for Patient Safety**

Pfizer uses radio frequency identification (RFID) tags on certain highly-counterfeited products in order to further ensure patient safety in the United States. RFID technology enables pharmacies and wholesalers to track medicines from manufacturer to pharmacy by verifying the unique electronic product code, or EPC, on the product packaging. Pfizer is the first pharmaceutical company to put in place a comprehensive program of this type focused on EPC authentication as a means of deterring counterfeiting.

“With the global supply of counterfeit drugs huge and growing, it’s obvious that the U.S. drug market—which accounts for fully half of the world’s medicine sales—would be a prime target for counterfeiters if we make their job easy by weakening our current drug import protections.”

–Peter Pitts, Co-Founder, *The Center for Medicine in the Public Interest*, August 2006, Former FDA Associate Commissioner for External Relations

“Raising public awareness that these ‘fake’ drugs are out there is the first step in securing not only our own health, but the health of our country. We need to be able to identify these products and penalize those who are putting our safety at risk.”

–Carmen Catizone MS, RPh, DPh, Executive Director, NABP, November 2006

“Counterfeiters are willing to fake life-saving treatments, and our Institute’s data shows that they are. Law enforcement and health authorities must stay vigilant and work together.”

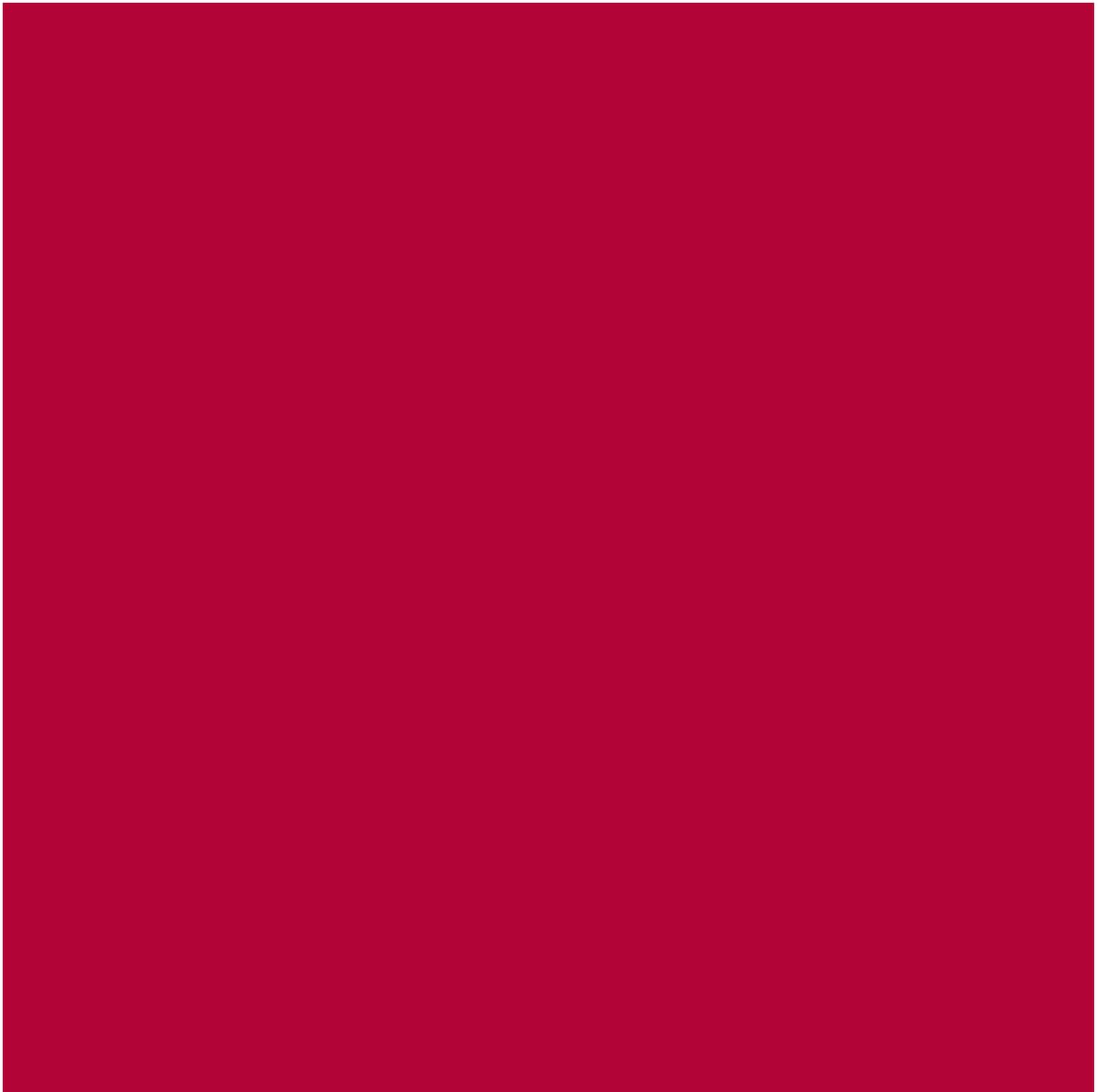
–Tom Kubic, Executive Director, *Pharmaceutical Security Institute*, December 2005

“Counterfeiting of medications is a particularly devious practice. Drug counterfeiters not only defraud consumers, they also deny ill patients the therapies that can alleviate suffering and save lives”

–HHS Task Force on Drug Importation, “*Report on Prescription Drug Importation*,” December 2004

“The potential exists for the nation’s medicine supply to be exploited by organized criminals or drug traffickers or to be used as a vehicle for terrorist activity”

–Giuliani Partners, “*Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States*,” April 2005





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