

**STATEMENT OF**  
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**“CANADIAN PRESCRIPTION DRUG RE-IMPORTATION: IS THERE**  
**A SAFETY ISSUE?”**  
**BEFORE THE**  
**COMMITTEE ON GOVERNMENT REFORM**  
**SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS**  
**U.S. HOUSE OF REPRESENTATIVES**

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## **INTRODUCTION**

Mr. Chairman, and Members of the Subcommittee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to testify at today's hearing on behalf of FDA. We are pleased to come before the Subcommittee once again to discuss the safety of prescription medicines obtained from foreign sources and to report on our actions since your hearing on this issue on April 3, 2003. We will not repeat information provided in our April 3, 2003, statement, but will focus on additional activities that have occurred over the past eight weeks.

As we have previously testified, the overall quality of drug products that consumers purchase from United States pharmacies is very high. The public can be confident that the drugs they use are safe and effective. In order to help maintain these high standards, FDA works diligently on many fronts to ensure that consumers receive safe and effective drugs.

However, FDA cannot offer the same assurances to the public about the safety of drugs they buy from foreign sources.

The issue of U.S. consumers purchasing drugs from foreign sources is a significant concern for FDA. A growing number of Americans are obtaining their prescription medications from foreign locations. They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, FDA cannot ensure the safety of drugs purchased from foreign sources.

## **SAFETY CONCERNS**

For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies licensed under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to avoid degradation. There is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such unsafe or inappropriate medications, they face risks of dangerous drug interactions and other serious health consequences.

Over the last twelve to eighteen months, FDA identified a proliferation of websites that sell drugs purportedly from Canada directly to U.S. consumers. A number of these websites claim it is legal for Canadian pharmacies to sell drugs to U.S. consumers. This is false. Some websites are merely ordering services, taking orders from consumers that are then filled

by other pharmacies. In some cases, American consumers cannot be certain that the drugs they receive are actually dispensed by the person from whom they are ordered.

A number of Canadian drug websites and ordering services indicate that the Canadian drugs are dispensed pursuant to existing prescriptions that are rewritten by a Canadian doctor in order to comply with Canadian law. However, dispensing medication based on a prescription written by a physician who has not seen the patient or conducted a physical exam is contrary to medical practice standards. In addition, the Canadian Medical Association has stated that under the Canadian Code of Ethics, physicians have a responsibility to do a patient history, conduct a physical exam and discuss the risks and benefits of the medication with the patient. In many cases, these activities simply do not occur.

Consumers who buy prescription drugs from foreign countries are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or side effects due to drug contamination. Patients are also at risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some patients may receive genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperately seeking a cure for a serious medical problem may be more willing to accept a product of unknown origin.

In the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, they have little or no recourse either because the physical location or operator of the pharmacy often is not known or the seller is beyond the consumer's reach. In addition, as a condition of doing business, many of these foreign operators require the U.S. consumer to sign a document releasing the operator from all potential liability. FDA has little or no ability to take effective action against these foreign operators to assist U.S. consumers.

In addition to these safety concerns, it is also important to point out that it is illegal, under the Federal Food, Drug, and Cosmetic (FD&C) Act, to import unapproved, misbranded, and adulterated drugs into the U.S. This includes foreign versions of U.S.-approved medications. It is also illegal for anyone other than the drug's manufacturer to re-import a prescription drug that was originally manufactured in the U.S.

#### **UPDATE ON FDA ACTIVITIES AND NEW ACTIONS**

At the April 3, 2003, hearing, we discussed our efforts to address the potential safety concerns of illegally imported prescription medicines by: 1) increasing consumer awareness of the potential risks associated with imported drugs, 2) working with the states to crack down on Internet pharmacies selling illegal products, and 3) analyzing the quality of drugs coming into the U.S. from foreign sources.

I would like to provide you with an update on our activities and some ongoing activities that were mentioned when we last testified before this subcommittee nine weeks ago.

## **1. Rx Depot**

At the April hearing we told you about a warning letter that was issued on March 21, 2003, to a storefront operation known as Rx Depot. We commenced this action in conjunction with the Arkansas State Board of Pharmacy. Rx Depot generally obtains unapproved drugs from Canada for U.S. consumers, exposing the public to the significant potential risks associated with unregulated imported prescription medications. Rx Depot and similar companies have often stated incorrectly to consumers that FDA condones their activities and even that their prescription medications are “FDA approved.” This could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA.

FDA believes that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines. FDA’s “warning letter” notified the firm that the Agency considers the firm’s operations to be a risk to the public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. Although FDA addressed its “warning letter” to the Rx Depot in Arkansas, FDA also sent a letter to the President of Rx Depot, in Tulsa, Oklahoma. The “warning letter” applies to all locations of Rx Depot and its affiliates. While Rx Depot responded to FDA’s “warning letter,” that response was inadequate.

We issued our “warning letter” in conjunction with action by the Arkansas State Board of Pharmacy. The Arkansas State Board of Pharmacy issued its own letter to the firm on the same day as our “warning letter” instructing the firm to cease violating state law immediately.

## **2. Additional Information on Counterfeit Drugs**

On April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced the adoption of a voluntary program to report counterfeit drugs to FDA. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. The announcement affirmed that the information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply by quickly and effectively removing counterfeit drugs from the marketplace.

Under the voluntary program, PhRMA member companies agree to notify FDA's Office of Criminal Investigations within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. The reporting program went into effect on May 1, 2003.

In an April 22, 2003, press release, FDA praised PhRMA's commitment to actively help FDA identify and remove counterfeit drugs from the U.S. market. "This action adds to our tools for protecting the public against counterfeit drugs," said FDA Commissioner, Mark B. McClellan, M.D., Ph.D. "The FDA works with local, state, and Federal law enforcement authorities to protect Americans from the health risks of bogus drugs. PhRMA's members already assist in these efforts by actively investigating credible reports about the distribution

of counterfeit drugs. This formal collaborative agreement will strengthen the FDA's ability to assure the safety and effectiveness of drugs used by Americans.”

FDA supports the activities of the manufacturers of legitimate drugs to identify counterfeit products and inform the public about counterfeits. The Agency is committed to rooting out counterfeiting activity and alerting the public to the existence of counterfeit product.

### **3. NABP Annual Meeting**

On May 7, 2003, FDA officials spoke at the National Association of Boards of Pharmacy (NABP) Annual Meeting in Philadelphia, Pennsylvania. FDA reiterated the message it delivered in the call it hosted in February 2003 with 38 state boards of pharmacy, other state regulatory agencies and consumer groups. FDA is working with states to address concerns regarding the importation of foreign prescription drugs. The Agency is actively engaged with a number of states in jointly pursuing illegal Internet prescription drug sites. FDA continues to expand its cooperative activities with states in order to effectively address the many challenges of prescription drugs sales via the Internet.

### **4. Statement by U.S. and Canada Pharmacy Groups**

On May 7, 2003, the NABP and the Canadian National Association of Pharmacy Regulatory Authorities endorsed a statement opposing illegal importation of prescription drugs. In the statement, the two groups state that they are mutually committed to working together to support the individual members of their organizations as they fulfill their regulatory mandates. The Canadian and American regulatory bodies are calling on law enforcement agencies to promote compliance with Federal, state, and provincial pharmacy laws and standards of Canada and the U.S. in their respective jurisdictions. This is the first time that the regulatory

authorities of the two nations have jointly responded to the growing practice of importation of drugs into the U.S. from Canada.

On May 13, 2003, 44 U.S. pharmacy groups joined forces with the Canadian Pharmacists Association (CPhA) to endorse a statement opposing illegal importation of prescription drugs. These groups include many of the state boards of pharmacy and academic institutions schools of pharmacy.

#### **5. Other actions with states**

FDA sent a letter to the Executive Director and General Counsel of the West Virginia Board of Pharmacy expressing support for the May 13, 2003, “warning letter” issued to Discount Prescription Center of Fairmont, West Virginia, telling that firm to cease violating the law. Discount Prescription Center solicits patients and arranged for a Canadian pharmacy to dispense and ship prescription drugs to the patients. FDA considers the firm’s operations to be illegal and a risk to public health. FDA expressed support for the Board’s effort to stop this firm from violating the law. In addition, FDA offered assistance in any future efforts by the Board to stop similar firms.

FDA stated in the letter that we believe that operations such as Discount Prescription Center expose the public to the significant potential risks associated with unregulated imported prescription medications.

We have been working closely with our partners in the states such as West Virginia on this issue, and we intend to continue working closely with the states in support of our mutual efforts to protect the public health by curtailing illegal and potentially dangerous operations.

## **6. Lipitor investigation**

On May 23, 2003, FDA issued an alert on counterfeit Lipitor. The alert warned health care providers and others that three lots of counterfeit Lipitor represent a potentially significant risk to consumers. One in five people have high cholesterol that may lead to cardiovascular disease, such as heart disease and stroke. According to the American Heart Association (AHA), every 33 second, someone in the U.S. dies due to cardiovascular disease. (Source: AHA 2002 Heart and Stroke Statistical Update) Lipitor is the number one prescribed cholesterol-lowering medication, and is currently used by more than 18 million people. Lipitor is proven to lower total cholesterol and decrease the risk of developing cardiovascular disease. FDA investigators have aggressively pursued a variety of leads all along the supply and distribution chain in an effort to identify the source of this counterfeit activity.

In conjunction with the manufacturer of this product, FDA published a list of lot numbers to identify the counterfeit product. We urged health care providers and patients alike to check the packaging very carefully before using this product. Patients who have any of the product (labeled as “Repackaged by MED-PRO, Inc.”) with the specified lot numbers were told not to consume it, and to return the product to their pharmacies. On June 3, 2003, FDA announced that its continuing investigation of counterfeit Lipitor identified additional counterfeit quantities of the cholesterol-lowering product. The investigation is ongoing.

FDA's advice to health care providers and consumers remained the same as when the Agency issued its original [\*alert on counterfeit Lipitor\*](#). They should check the packaging very carefully before using Lipitor. Patients who have any of the product with any of the lot numbers we identified should not take it, and they should return the product to their pharmacies. We want to reemphasize this warning today.

As part of the FDA's ongoing efforts to investigate and respond to unscrupulous counterfeiting activities, FDA's Office of Criminal Investigations is investigating this case of counterfeit Lipitor in carrying out its public health mission. FDA regularly conducts investigations and testing to identify and remove from market products that are counterfeit, have been tampered with, or are otherwise unsuitable.

FDA is working closely with the individual states and with health professionals, particularly pharmacists and pharmacy associations, to alert them to this counterfeit product. Many patients taking Lipitor do not receive it in the 90-tablet bottles, but in smaller quantities from their pharmacists. Patients who are not sure whether they have the tainted product were instructed to check with their pharmacist.

FDA will continue to work closely with the manufacturer of Lipitor, Pfizer, Inc., on this counterfeiting problem. FDA supports the activities of legitimate manufacturers to inform the public about counterfeit products and how to identify them. In addition the manufacturer of Liptor, Pfizer, issued their own press release supporting the vigorous enforcement of the

law to protect patient safety. The company continues to work closely with the FDA and other regulatory authorities to help prevent the importation of counterfeit medicines.

## **7. CPhA public statement**

On May 31, 2003, the CPhA Board of Directors approved a public statement on international prescription services. The statement emphasizes that there is potential for the existing public protection safety net to be bypassed by illegitimate operators or unaccredited pharmacies, or by licensed pharmacies that do not comply with practice standards and regulation. Such practices can undermine the drug regulatory systems established to protect consumers and could expose the public to improper prescribing, monitoring or dispensing of pharmaceuticals, or to harmful or ineffective drugs.

In part, this statement criticizes international prescription services provided to residents of foreign countries. Some of the key elements of their public statement emphasize that:

1. A relationship between the patient and pharmacist is essential for medication management and to ensure that patients understand how to use their medications safely and effectively.
2. Face-to-face communication between patients and pharmacists builds a relationship that is critical to the optimal management of drug therapy and is a key element of the expanded role of pharmacists on the primary health care team.
3. All pharmacies operating in Canada, including those that provide distance dispensing or offer prescription drug services over the Internet, must comply with Federal/provincial/territorial legal and regulatory requirements as well as meet established standards of practice for patient care and dispensing.
4. CPhA opposes international prescription services where the patient does not have a relationship with the pharmacist and the prescriber. CPhA also opposes international prescription services if such services violate laws in the jurisdiction that the patient resides in.

## **CONCLUSION**

FDA is working to address its continued safety concern about increased importation of prescription drugs. However, despite continued efforts to identify ways to assure the safety of imported drugs, FDA for many years has consistently stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system.

We appreciate the subcommittee's interest in assuring that the American public has access to safe and affordable medicines and we look forward to working with you in furtherance of this goal. Thank you for the opportunity to update you on events and activities since our last hearing. I will be happy to answer any questions you may have.