

TESTIMONY OF ELIZABETH G. DURANT
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Mr. Chairman, Members of the Committee, thank you for this opportunity to testify. I am Elizabeth Durant, Executive Director of Trade Programs at the U.S. Customs Service. Today I would like to discuss with you U.S. Customs efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products into the United States.

As you know, the top priority of the Customs Service following the events of September 11 is to help protect the United States from terrorist attacks. This is a formidable task given the number of passengers, vehicles, and goods that pass through our nation's borders each year. Customs is responsible for processing 470 million people, 129 million cars, and nearly 20 million trucks, railcars, and sea containers that arrive into the United States every year.

In our role as America's frontline, the Customs Service also enforces over 400 requirements for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, or FDA.

The challenge facing Customs today on this front is enormous. Although our main focus has shifted to anti-terrorism, we are committed to fulfilling all aspects of our mission. This includes enforcing FDA requirements on imported pharmaceuticals to help ensure the safety and well being of the American public. We are concerned about three particular ways that pharmaceuticals are imported: those that are purchased over the Internet and shipped through our international mail or express courier facilities; those carried into the United States by individuals transiting our land borders; and bulk shipments of adulterated or counterfeit pharmaceuticals.

Millions of packages come through mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and unapproved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying the same unapproved products. A disturbing trend is the increase in bulk shipments through the mail indicating that these products could be making their way to pharmacy shelves.

The growth of the Internet has spawned a wave of pharmaceutical purchases on-line. These purchases are commonly sent through international mail. We have Customs Inspectors stationed at fourteen international mail facilities across the United States to contend with these shipments. Customs is also located in or near twenty-nine strategically located express courier facilities throughout the country.

Detecting prohibited pharmaceuticals among the tens of millions of parcels passing through Customs each year presents a massive challenge. Our limited resources require a risk management approach, with which we utilize advance intelligence, records of past seizures, and other factors to locate packages that present the most significant threat.

A key difference between the mail and express environments is the level of automation. Customs

receives virtually no advance information on mail shipments, making it impossible to target shipments for closer inspection or referral to another agency. Express couriers are required to provide advance manifests, making targeting easier. We have found, however, that many express packages containing pharmaceuticals are manifested as documents.

Customs laboratories also play a critical part in our investigations. Their expertise in analyzing everything from textiles, to foreign oil, to food products to determine point of origin and composition is world-renowned. We maintain fully equipped labs at seven locations around the country and we have three mobile labs to deploy as needed.

We are confident in the forensic capability of our labs to find discrepancies in shipments of bulk and finished pharmaceuticals. But where we do require assistance, specifically from the FDA, is in the establishment of effective national standards for the interdiction of pharmaceuticals subject to FDA laws.

The development of such standards is critical to Customs. To that end, we have been working closely with the FDA to develop the needed guidelines. We began by forming a task force to examine pharmaceutical purchases shipped by U.S. mail. The task force set up a thirty-day pilot program at the Los Angeles mail facility in 2001. During the program, FDA detailed four full-time employees who observed first-hand the daunting volume of packages screened by Customs every day.

Over a period of twenty-four workdays, the FDA detained a total of 721 parcels. 677 parcels, or just over 93 percent of this amount, were denied entry and 44, or six percent, were released for delivery by the Postal Service. It is important to note that without the presence of FDA inspectors, U.S. Customs would have had to detain some 3,000 packages per week, or about 15,000 packages over an equal time span, under the existing guidelines provided to our personnel.

At that time, 102 parcels underwent detailed laboratory analysis to determine whether the pills and capsules contained the claimed active ingredient and/or contained a scheduled substance. The results of these analyses found 9 instances in which the imported pharmaceutical did not contain an active pharmaceutical ingredient, but were merely found to contain substances such as starch or sugar.

Customs also initiated a multi-faceted counterfeit pharmaceutical interdiction program called "Operation Safeguard." The first phase of Operation Safeguard was carried out between September and October of 2000 at the International Mail Branches at Dulles Airport and Oakland, California. This operation was intended to give Customs a snapshot of the types of pharmaceutical products entering the United States. That snapshot revealed that a vast percentage - - perhaps as much as eighty to ninety percent - - of the pharmaceuticals that enter the U.S. via the mail do so in a manner that violates present FDA or other requirements.

Counterfeit pharmaceuticals enter in both wholesale and retail quantities. Additional problems include expired materials, products that have not been approved by the FDA for usage, products made in facilities not under proper regulation and products not having the proper usage

instructions. To offer an example, one seizure included a three thousand-tablet shipment of a counterfeit drug with an expiration date of 1980 on it.

Additionally, it was found that many parcels contained different types of pharmaceuticals that, if taken simultaneously, could cause dangerous interactions. Individuals not under the direct supervision of a physician could easily purchase these products. Thus, we cannot assume that these products would be used properly. It is important to note that after three weeks of this phase of Operation Safeguard, the quantity of illegal and defective pharmaceutical shipments slowed significantly.

During a recent phase of Operation Safeguard that took place at two International Mail Branches, 31 parcels containing 52 different types of questionable pharmaceuticals underwent intensive chemical analysis. The analyses of these products showed that 8 of the so-called pharmaceuticals or 15% contained no identifiable active ingredient and 18 contained a substance that is regulated under the Federal Controlled Substance Act. Additionally, during this phase of the operation it was found that large parcels of questionable or illegal pharmaceuticals are being split into different mail shipments but arrive at the same address. Accordingly, there is a possibility that state side pharmaceutical distributors could be using these products as a source of supply.

In light of these results and the volume of imports, it is clear that this remains an overwhelming problem and Customs is seeking guidance from the FDA to develop a more practical and workable approach.

Travelers who attempt to import pharmaceuticals upon their return to the U.S. are also a source of concern. Customs is seeking the guidance of the FDA on this front. We are seeking direction that more sharply defines the current broad discretion given to Customs inspectors to decide whether or not an importation is for a "legitimate personal medical use."

In addition to Operation Safeguard, our Office of Investigations is continuing to work with the FDA to combat the sale of prohibited pharmaceuticals via the Internet. Customs Cybersmuggling Center is playing a leading role in these cases. Our efforts to date have included a successful investigation with authorities in Thailand that closed down seven on-line pharmacy sites operating in that country. As a result, we saw a marked decrease in subsequent pharmaceutical seizures from Thailand.

From an overall perspective, a spiraling volume of goods at our borders has put immense pressure on our ability to enforce the nation's laws while facilitating international trade. We have taken many steps to address anticipated challenges, including refinement of our targeting approach and development of a resource allocation model to project future staffing needs across the country. But we still face a daunting workload, which has been exacerbated by the need to secure the borders against the threat of terrorism.

I want to thank you and the members of the committee for considering the Customs Service in your review of the importation of personal and bulk pharmaceuticals. This is an issue that speaks directly to our mission. We will continue to make every effort possible to work with the

Congress and our fellow inspection agencies to address the health and safety concerns of the American people.

This concludes my statement. Thank you again for this opportunity to testify on this important issue. I will be happy to answer any questions you may have.