

Counterfeit Medicines - The Risks Are Real

I am pleased to have this opportunity to provide comments concerning an issue of growing importance to all Americans. I thank the Subcommittee members for devoting their valuable time to these hearing as together we explore the hidden aspects of the illegal counterfeiting of pharmaceuticals.

Today, there are transnational criminal organizations successfully ignoring regulations and violating laws designed to insure the integrity of the many life saving medicines widely available here in the United States. They easily manufacture and distribute counterfeit medicines indiscriminately and without regard to current good manufacturing practices. I hope these discussions will lead to a greater understanding that the risks facing the public are, indeed, real.

My name is Thomas T. Kubic and I am the Executive Director of the Pharmaceutical Security Institute, (PSI), a non-profit association based in the Washington D.C. area. The PSI members are the Security Directors from twenty-four pharmaceutical manufacturers with business operations in more than one hundred and sixty countries.

Prior to my association with the Institute, I acquired substantial investigative experience during my thirty year career as an FBI agent, supervisor, chief, inspector and Agent in Charge. As the Deputy Assistant Director, Criminal Division, I was responsible for the development

and implementation of the FBI's financial crimes and health care fraud programs which at that time, involved over 3,500 agents in the field.

The goal of PSI is to support its members in their efforts to insure the distribution of pharmaceuticals that are safe and effective. PSI's mission is to collect, analyze and disseminate information about the counterfeiting, theft and illegal diversion of medicines. This information is then shared with authorities so that they can initiate appropriate enforcement activities.

Because of the limited time, I want to focus my comments on defining for the Subcommittee the nature and scope of counterfeiting.

Counterfeiting Facts

PSI conducts an annual assessment of the worldwide counterfeiting situation. In the fifth annual report, "PSI - 2006 Situation Report," the Institute found that during 2006, many individual criminals and criminal organizations were actively involved in the counterfeiting, illegal diversion and theft of pharmaceuticals.

In support of this statement is the fact that PSI documented a record number of new incidents last year. There were 1,371 incidents of counterfeiting, illegal diversion and theft identified – a twenty-two percent (22%) increase in incidents reported to the Counterfeiting Incident System (CIS).

Also, continued collection identified 150 additional incidents from CY 2005, with a resulting revised total for that year of 1,123. Thus, for the first time the combined two-year total of incidents surpassed 2,400 – more than 100 incidents a month, as the incident total reached 2,494.

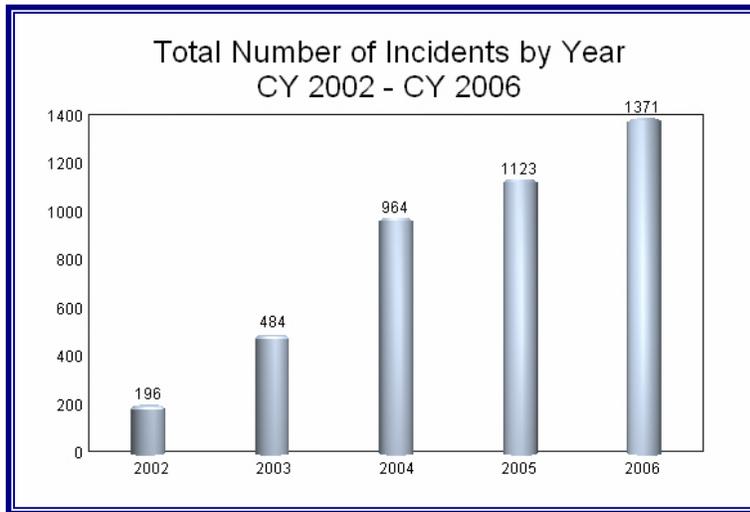


Chart One – “PSI 2006 Situation Report”

The increases seen in 2005 and 2006 were not isolated events. A five-year trend line has been graphically represented in my formal statement as Chart One. In general, since 2002, there has been at a minimum, an annual double digit increase in the recorded incidents.

While the number of incidents seems small, many involve an increasing quantities and wider varieties of medicines. For example, in November 2006, in Mexico City, eleven tons of counterfeit, stolen, expired and/or smuggled medicines were seized from fourteen locations.

In July 2007, four and one-half tons of illegal medicines were seized in Jakarta.

During 2006, the number of products found in a single incident ranged from one drug to forty-five drugs. In the Jakarta seizure, eighty-eight different drugs were seized. These seizures uncovered drugs from virtually every therapeutic category as the number of therapeutic categories detected ranged from one to eleven.

The analysis of CIS data reveals other trends which can be identified from the information collected.

First - the counterfeiting of pharmaceuticals was the most common type of incident documented in CIS. Counterfeiting was involved in eighty-six percent (86%) of the incidents. Ten percent (10%) involved illegal diversion of drugs and the remaining four percent (4%) concerned pharmaceutical thefts.

Second - the number of countries experiencing counterfeiting, theft and illegal diversion remained about the same at one hundred. The top three countries in terms of counterfeiting, illegal diversion and theft incidents were the China, Russia, and the United States. When considering only counterfeiting incidents, the top three countries were Russia, China, and Uzbekistan.

Third - counterfeiters appear to have concentrated their efforts on fewer types of drugs in 2006, a trend which was reversed during the first nine months of 2007. In the

1,371 incidents, 560 different pharmaceutical products were identified. This represented a reduction of nearly twenty percent (20%) from the 687 products identified in CY 2005.

The largest number of incidents occurred in the same therapeutic categories as last year – genito-urinary, anti-infectives and central nervous system.

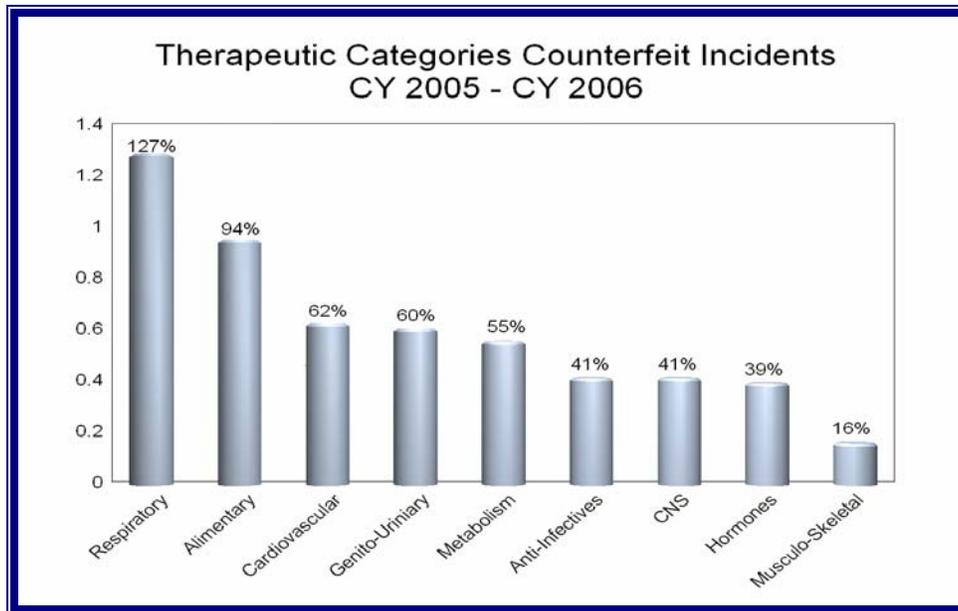


Chart Two – “2006 PSI Situation Report”

However, as illustrated in Chart Two, in terms of percentage increases, the respiratory therapeutic category led with the largest percentage increase at one hundred twenty-seven percent (127%). Alimentary medications were second with an increase of ninety-four percent (94%) and cardio vascular at sixty-two percent (62%).

Counterfeiting is no longer limited only to the so called “life style drugs” as virtually every type of medicine has been counterfeited.

Finally, CIS data disclosed that during CY 2006, reported law enforcement activity, when measured by “number of arrests made” decreased by ten percent (10%), when compared to CY 2005. There were 755 individuals arrested in fifty-six countries for crimes relating to counterfeiting, illegal diversion, and theft incidents.

While these reductions concerned us, there was a noticeable increase in arrests in the manufacturer category. If sustained, this trend will lead to diminished supplies of counterfeit medicines in the international marketplace.

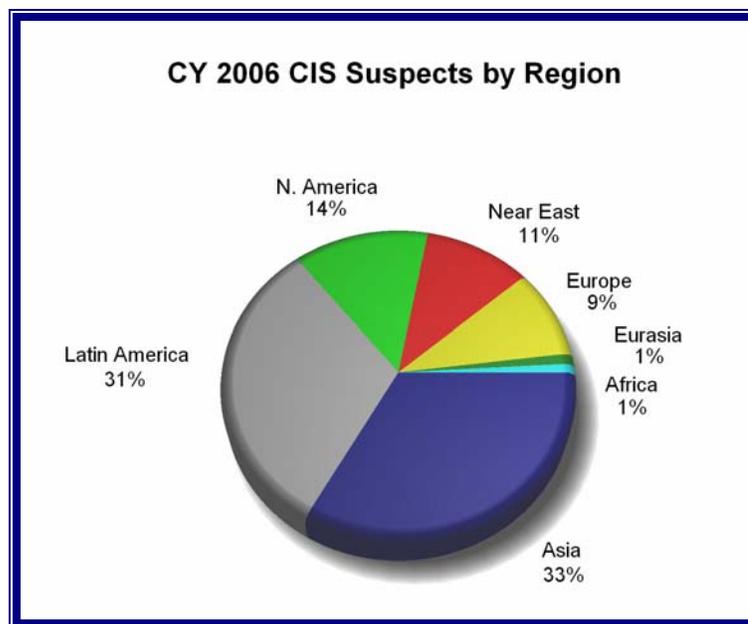


Chart Three – “PSI 2006 Situation Report”

In my written statement is a pie chart, designated Chart Three, which illustrates the relative percentage distribution of arrests by region. This chart shows that for the second year, the Asia region lead with thirty-three percent of the worldwide arrests; this is a particularly important fact since much of the counterfeit medicines are sourced to this region.

Trends in the Worldwide Response

The Institute analyzed two hundred and five public reports from a wide variety of sources to supplement CIS data concerning the extent of counterfeiting and to gauge the response by international organizations, national governments and manufacturers. In 2006 and continuing during 2007, the following major trends were identified:

Increased efforts at improved international coordination in the fight against counterfeits were initiated.

A greater number of international anti-counterfeiting events were sponsored by an increased number of organizations engaged in assessing the problem and devising strategies to address it. The World Health Organization (WHO) emerged as the clear leader in the development of a major anti-counterfeiting effort, known as the IMPACT initiative, along with twenty international partners. Taking a broad approach, the WHO launched a comprehensive scheme to help national authorities safeguard their populations from counterfeit medicines. This effort was clearly the most significant endeavor of the

year and holds the promise of stemming the tide of counterfeit medicines.

The U.S. FDA, European Commission and the European Medicines Agency (EMA) have agreed to increase cooperation in the area of pharmaceutical regulation. Additional public health priority areas, including counterfeit medicines, are high on their agenda.

Multi-lateral efforts progressed under the leadership of national drug regulatory authorities. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) entered into an agreement with the government of the People's Republic of China and Sweden to stem importation of fake and substandard pharmaceuticals through their ports.

A better understanding of the global nature and extent of the sale and distribution of counterfeit products over the internet emerged.

The Austria-based International Narcotics Control Board (INCB) highlighted the threat of rogue online pharmacies which were found to be engaged in smuggling unlicensed drugs using bogus prescriptions.

The European Commission issued a warning that counterfeit weight loss drugs were being sold via several websites in March 2006. The warning underscored the European Commission's concern that criminals are taking advantage of the anonymity of the internet to sell fake,

adulterated and unlicensed medicines to an unsuspecting public.

The Irish Medicines Board (IMB) confirmed that forty percent of the enforcement cases undertaken in the preceding year involved illegal importation of medicines, many of which were purchased over the internet.

In August 2006, the U.S. Food and Drug Administration issued a warning that U.S. patients should be aware that counterfeit medicines were being sold by a major internet pharmacy in Canada. Ten specific drugs were listed in this advisory.

Individual countries began prioritizing their efforts to more closely monitor the market place and committed additional resources to these projects.

The authorities in China initiated a major effort to increase drug inspections at the provincial level. By placing state of the art testing equipment in vans, these mobile laboratories are fully equipped with drug registration data, drug instruction information, adverse drug reaction records and chemical “fingerprinting” information.

The Korean Customs Service formed a special task force with 446 officials to improve their efforts against the importation of illegal medicines.

The U.K. Royal Pharmaceutical Society (RPS) collaborated with the MHRA and provided pharmacist with new guidance which identified the causes and consequences of counterfeiting. RPS gave practical advice on detecting and reporting suspected counterfeit medicines.

Summary

The challenge of counterfeit, diverted and stolen pharmaceuticals is clear from the Situation Report. While more incidents have occurred, fewer arrests have been made. Counterfeiters have modified their activities and now seem to be concentrating on fewer types of drugs. The international community has begun to recognize the need to better coordinate their efforts, to address the problem of internet sales of pharmaceuticals and to more closely monitor the market place.

Americans need to know that the U.S. market has been, is now and will continue to be a tempting target for counterfeiters. Their safety is endangered when they venture outside of the current closed system – and the risk to their health and welfare is real.

More than ever before, it is essential to work together to protect public health, share information and initiate investigations with drug regulatory authorities and law enforcement officials in order to stem this illegal trade.