I am pleased to take the opportunity to provide comments concerning the United States Department of Health and Human Services effort to identify issues and seek answers to the many vexing questions relating to the new legislation that will liberalize the importation of prescription drugs.

My name is Thomas T. Kubic. I am the Executive Director of the Pharmaceutical Security Institute, Inc. (PSI), a non-profit trade association based in the Washington D.C. area. PSI members are researched based, pharmaceutical manufacturers with business operations in more than one hundred and forty countries. Collectively, pharmaceutical sales from these members comprise more than fifty-eight percent of the worldwide sales of ethical drugs.

In late 2001, in order to strengthen their response to the growing threat posed by the counterfeiting of pharmaceutical products, sixteen research-based pharmaceutical manufacturers established the current Institute.

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 diversion of medicines. This information is shared with authorities so that they can initiate appropriate enforcement activities.

A Fragmented World Market

Regulatory standards differ substantially from country to country. Often, manufacturers and governments will tailor their respective decisions to comport to each country's unique conditions in terms of access, affordability and quality of medicines. For instance, government authorities in a developing country may choose to favor local production over a more stringent manufacturing quality regime in order to facilitate widespread access to cheaper medicines. Accordingly, pricing, marketing, manufacturing and intellectual property protection standards differ sharply even between bordering countries.

Prescription drugs approved for sale in the U.S. must meet the Food and Drug Administrations' requirements in terms of safety and efficacy. Additionally, the different forms, dosages, and strengths are individually authorized for marketing. The current pharmaceutical distribution chain provides for accountability at each stage. Most of the pharmaceuticals marketed abroad do not undergo such an intense monitoring. Even drugs deemed as equivalent in terms of active ingredient and dosage present clinical issues because medicines obtained in foreign countries may differ in formulation and bioavailability well beyond FDA standards.

Thus, the liberalization of pharmaceutical importation has far-reaching implications in areas such as product tracking, testing, and labeling; foreign export laws; and

liability. The requirement to maintain and inspect "pedigrees" is unlikely to deter well organized criminal counterfeiters who operate on a transnational level. Additionally, cross-border online retail sales provide new opportunities for greater anonymity of the counterfeiters.

Many point out that the European Union (EU) already has a working, unrestricted importation system in place for pharmaceuticals moving within the EU member countries. However, the general objectives of the European Union cover not only the free flow of goods and individuals, but also the harmonization of legislation and regulations that ensures minimum quality and safety standards for all citizens. In contrast, unrestricted importation into the U.S. will not bring about any guarantee of quality up to FDA standards by foreign governments or supranational entities.

Furthermore, many studies indicate that, in the EU, the flow of medicines across the borders of this group of countries with dissimilar pharmaceutical pricing policies was not beneficial to the final consumer and may have caused irreparable harm to the research-based industry. [1]

Recent publicly reported cases disclose many instances the infiltration of the EU pharmaceutical trade by criminals selling counterfeit or tainted drugs.

[1] See "The Economic Impact of Pharmaceutical Parallel Trade in Europe;" Panos Kanavos, PhD; London School of Economics & Political Science, London, UK; December 2003. And, "Parallel Trade in Europe – Assessing the Reality of Payer and Patient Savings;" Janice Haigh; Scrip World; June 13, 2003. Also, "Addressing the Innovation Divide;" Jim Gilbert & Paul Rosemberg; Bain & Company Inc.; January 22, 2004.

Global Nature of Counterfeiting

Pharmaceutical counterfeiting is a worldwide phenomenon. In the "PSI 2003 Situation Report," three hundred and twenty seven (327) incidents of theft, counterfeiting and diversion were identified in sixty-three (63) different countries. Many of these incidents implicate organizations capable of churning out millions of dosage units a day and offering them for sale at places thousands of miles away from the base of the operations.

Through the first four months of FY 2004, one hundred and eight-nine (189) incidents have been documented. The incidence of counterfeiting is definitely on the rise. Critical therapeutic areas, such as anti-infective and central nervous system drugs, are heavily weighted among the products reported to have been counterfeited.

I fully expect this trend to continue as PSI's experience demonstrates that well-organized counterfeiting groups are expanding and developing their operations worldwide.

The increasing number of investigations undertaken by the FDA is but one indicator of the success that counterfeiter organizations have had at infiltrating the U.S. market – and these are just the instances we know about. Counterfeit, mislabeled, diluted, expired and contaminated drugs have entered into the American pharmaceutical supply system. This is because the U.S. presents an

irresistibly lucrative target for counterfeiters because of the size of the market.

Many of the pharmaceuticals targeted for counterfeiting by criminals are products which should only be taken only with the guidance and oversight of a health care professional. Currently, FDA resources working with other Federal and State agencies, healthcare professionals and the pharmaceutical industry, are stretched in their efforts to provide enough surveillance and enforcement resources to effectively reduce to a minimum the occurrence of undesirable incidents.

It is my opinion that this situation would drastically change under an open importation regime. Regulatory authorities and law enforcement officials would be unable to maintain the levels of surveillance necessary to keep unapproved and unsafe drugs from the U.S. markets.

Limits of Technology

Some have suggested that a technological magic bullet may exist to solve the counterfeiting problem. Unfortunately, this is wishful thinking. Last fall, the FDA reported that there are limits to each and every technological fix. There simply is no single technological solution to counterfeiting. Criminal counterfeiters and their associates will continue adapting to new anti-counterfeiting measures. They will continue to copy overt markers. They will continue to refill vials. They will continue to over-label packages. They will continue to seek co-conspirators

who will accept counterfeit products irrespective of the lack of the appropriate packaging.

Technology can be combined with stricter enforcement of counterfeiting laws and a stiffening of criminal penalties to form the basis of a comprehensive approach to help deter counterfeiters. PSI members will continue their on-going efforts to incorporate the latest appropriate anti-counterfeiting technologies into their product packaging as one element in their overall strategies to keep counterfeit medicines out of circulation.

Conclusion

PSI believes that the safety and efficacy of the pharmaceuticals currently in the U.S. market cannot be replicated under an open importation system. Despite the suggestion that technical and regulatory measures can be implemented to keep our pharmaceuticals safe, the standard set under the existing system will not be attained under the new scenario. The flow of counterfeit, stolen or diverted medicines from countries where U.S. authorities have no jurisdiction or presence will represent a formidable, if not impossible, challenge to them and ultimately, the public.

To date, other that individual anecdotes, little credible evidence has been presented to demonstrate that liberalizing importation of pharmaceuticals is a prudent course for the U. S. or that the benefits outweigh the risks.