

July 7, 2011 Hearing of the House Committee on Homeland Security: Subcommittee on Oversight, Investigations, and Management
“Homeland Security Investigations: Examining DHS Efforts to Protect American Jobs and Secure the Homeland”

**“Combating Counterfeit Pharmaceuticals”
Statement for the Record: Testimony of Michael Russo, Director of Global Security, Product and Asset Protection, Eli Lilly and Company**

Good morning, Mr. Chairman and members of the Subcommittee. First, let me thank the Committee for inviting Lilly to testify about the dangers of counterfeit pharmaceuticals and the efforts of ICE and CBP to stop these dangerous products which have serious consequences for Americans, global public health, our economy, national security and certainly our industry. In order to meet time constraints, I will request that my full testimony be submitted for the record, so that I can provide a summary of my comments today.

I am Michael Russo, Director of Global Security Product and Asset Protection for Eli Lilly and Company, a global researched-based pharmaceutical company based in Indianapolis. Lilly invests heavily to research, develop and manufacture safe and effective pharmaceutical therapies which treat many diseases and save lives. Criminal counterfeiters steal those innovations, by copying our branding attributes and packaging characteristics and deliberately misleading consumers to believe they are buying and using the legitimate, safe, quality-controlled products that we manufacture. In our experience with counterfeit products, we have observed that in many cases they are poorly made in filthy facilities, lack efficacy, and may contain dangerous and other unknown substances. There are several known cases in which counterfeit products have been responsible for patient deaths. And it is likely that counterfeit medicines have inadvertently caused a patient harm by denying the effective treatment of a genuine medicine.

We are also seeing that the problem is on the rise globally. Criminals cannot resist the allure of extremely high profits and surprisingly low risks associated with counterfeit pharmaceuticals. They are producing counterfeit versions of expensive and innovative

anti-cancer drugs, as well as less expensive generic medicines such as antibiotics and vaccines. They target developed markets in the U.S. and Europe, but also sell fake medicines to some of the poorest populations, in some cases contributing to drug-resistant strains of disease. I mention this because it is important to understand that this is a crime against global public health, not just our company, and not just our country. It threatens all of us, whether you buy medicine from a fake online pharmacy, or you are administered a counterfeit vaccine. If the fake products continue to proliferate; theoretically, they could overtake genuine product in some countries, and that is frightening.

For these obvious implications on public health, our company has prioritized the issue, acting as an industry leader to raise the matter with U.S. agencies and other governments. We have established a coordinated team of Lilly professionals who analyze the problem and directly assist U.S. and foreign governments in the fight against counterfeit pharmaceuticals. We also chair our industry association's Anti-Counterfeiting Working Group, working through PhRMA and in partnership with other sectors to combat this threat.

We have learned from our work that the counterfeiters are highly sophisticated and are associated with international organized crime networks. While our companies work to comply with numerous laws and regulations to ensure our medicines are safe for patients, criminal networks circumvent all of them with no concern for the patient's health or our company's brand. They are pretending to be us, but they do not regulate or control the quality of their products, and our patients suffer the consequences.

For this reason, the U.S. and other governments must continue work to disrupt and dismantle these organizations before the counterfeit drug trade extends so broadly that it undermines the legitimate global pharmaceutical supply.

Lilly is committed to assisting government agencies like ICE in tackling this threat. Lilly investigators work globally to develop information regarding the various manufacturing

and distribution networks involved in the counterfeit pharmaceutical trade and the individuals responsible for them. In order to succeed, we turn this information over to a law enforcement agency capable of developing the information we provide and ultimately bringing those responsible to justice. ICE and CBP have been highly supportive and responsive to our referrals. Their efforts have resulted in numerous criminal convictions and a significant number of seizures of counterfeit pharmaceuticals at our borders. Through their efforts, we have seen an increase in cooperation with foreign law enforcement agencies that target counterfeit operations outside the United States.

The effectiveness of ICE has been the result of not only the work of numerous individual Homeland Security Investigative (HSI) agents globally, but also the critical coordination and support provided by the National Intellectual Property Rights Coordination Center (IPR Center) which has served as a model of interagency and public-private coordination for government agencies and brand holders here in the U.S. The IPR Center maintains continuous communication with brand owners and uses the expertise of its member agencies to share information, test new initiatives, coordinate enforcement actions and conduct joint investigations. It also provides an effective forum for brand owners to share information directly with investigative professionals familiar with counterfeit/intellectual property (IP) crime and for us to provide training regarding the characteristics of our products.

The efforts by ICE to combat counterfeit pharmaceuticals have resulted in several criminal convictions. In 2009, Kevin Xu was convicted and sentenced in US District Court in Houston for distributing counterfeit and misbranded pharmaceuticals. Xu's criminal activities resulted in him profiting in the amount of \$1.5 million in one year from the sale of counterfeit pharmaceuticals. He was also responsible for distributing counterfeits in Europe which resulted in the recall of three pharmaceutical products. In Houston, Lawrence Chow was sentenced to 12 months and one day for conspiring to distribute counterfeit pharmaceuticals and trafficking in pharmaceuticals bearing false labeling and counterfeit trademarks. In St Louis this February, Mark Hughes was

sentenced to 48 months in Federal prison on multiple charges including the sale of counterfeit and misbranded pharmaceuticals. These convictions send an important deterrent message to criminals who engage in this activity. We are thankful for and support additional criminal investigations and resulting prosecutions to send a clear message to drug counterfeiters who target the United States and elsewhere. That said, the convictions are paltry compared to the severity of the offense and do not send a strong enough message to future criminals.

As this Committee may know, the Internet has posed a significant challenge by facilitating criminal counterfeiting. It is used as a conveniently anonymous platform by manufacturers, distributors and buyers of counterfeit pharmaceuticals. Criminal organizations dupe customers into buying counterfeits through fake online “pharmacies” which use trademarked images of branded pharmaceutical products. In response to this, ICE has responded to complaints by brand owners with Operation in Our Sites II – a new approach to the Internet trade in counterfeits. In late 2010, the Justice Department Criminal Division, ICE and nine U. S. Attorneys’ offices across the country executed seizure orders against 82 internet domain names of websites engaged in the sale and distribution of counterfeit goods and illegal copyrighted works. These actions sent a message that the Internet was no longer a safe haven for the distribution of counterfeit product. We would like to see more attention by this committee and relevant U.S. government agencies to the number of dangerous counterfeit pharmaceuticals that are being sold on the Internet. Law enforcement operations such as Operation in Our Sites are crucial deterrents, but more must be done to take down fake online pharmacy sites and interdict incoming shipments from these sites. This will undoubtedly require more active support from the private sector companies that are indirectly facilitating the registration and advertisement of new sites every day as well as processing and shipping the purchased fake and illegal medicines through their services. They can do a lot to support law enforcement and prevent this criminal activity. We endorse the excellent work of the Intellectual Property Enforcement Coordinator (IPEC), Victoria Espinel, in fostering this collaboration and seeking ways to work more robustly with the

private sector as part of her Joint Strategy. We also endorse the work of the Alliance for Safe Online Pharmacies (ASOP) (www.safeonlinerx.com) of which Lilly is a member.

International cooperation aimed at coordinated law enforcement operation and training is another vital element of how ICE is working to address this problem. In addition to operations and trainings conducted through such multi-lateral institutions as the Asia Pacific Economic Cooperation (APEC), there is regular bilateral engagement through the ICE and CBP Attaché's posted in U.S. Embassies. These attaches are critical to the success of international counterfeit pharmaceutical investigations. They develop the critical links and relationships with foreign law enforcement authorities that are necessary to effectively dismantle counterfeit networks. In addition, they provide brand owners with a professional investigative resource in-country with whom to discuss and refer cases. ICE attachés coordinate important training between local authorities and brand owners that increase the importance and awareness of IP crimes and familiarize local authorities with the dangers of counterfeit pharmaceuticals and how these products can harm local populations. We support the continued and expanded posting of ICE and CBP attachés outside the U.S. and we encourage effective resourcing to enable an increase in focus on counterfeit pharmaceuticals, given the unique threat they pose to global public health and our own national security.

Customs and Border Protection (CBP) officers who inspect the millions of shipments entering the U.S. have also increased their efforts to combat counterfeit pharmaceuticals. There are thousands of illegal small parcels and express mail packages entering the U.S every day facilitated by illegitimate on-line drug sellers posing as legitimate pharmacies. CBP officers have effectively responded to our concerns about these shipments by implementing coordinated efforts to inspect large volumes of packages for counterfeits and referring those in violation to ICE HIS agents for follow-up. Lilly, along with other industry partners, provided product identification training as well as on-site analysis of seized products. These efforts are critical to protecting U.S. consumers. They send an important deterrent and educational message to U.S. consumers. We support continuing and increasing high profile

interdiction operations, as well as using the collection of data to inform and educate Americans about the dangers of purchasing medicines online.

The efforts by ICE to combat counterfeit pharmaceuticals are noteworthy but going forward more needs to be done to protect Americans. We view the following as key areas for concern and where we recommend additional focus going forward:

- More operations and public education is needed to disrupt the thousands of illegal shipments entering the U.S. daily in small parcels and express mail. CBP needs more resources and technology to interdict these shipments and all appropriate agencies need the authority to destroy the known counterfeit and illegal drugs seized instead of shipping them back to the criminals who are sending them to our country. We refer to the March 2011 Administration's White Paper on Intellectual Property Enforcement Legislative Recommendations and Counterfeit Pharmaceutical Interagency Working Group Report to the Vice President and Congress, which provided important insight and suggestions related to this challenge.
- We recommend legislation to increase penalties for counterfeit and diverted products, which pose a direct threat to public health and safety. Increased penalties will help to send an important message to criminals engaged in counterfeiting pharmaceuticals.
- More attention needs to be focused on a broad international internet strategy to address the thousands of illegal websites that are selling fake and dangerous pharmaceutical products to U. S. patients. We are currently providing ICE with lists of offending internet websites which are infringing on our trademarks and placing patients at risk. While their investigative/deterrent work continues, more must be done with education and voluntary action to compliment that effort.
- As part of this strategy, we believe a major public awareness campaign is needed to educate citizens about the dangers of fake products and the

importance of purchasing medicine safely on the Internet. The FDA and IPEC are working to develop a coordinated education effort, and we believe that funding and resources for this kind of a campaign are critical to preventing this crime and protecting the homeland. Though government funding is needed to kick-start the effort, its success requires the participation of several stakeholders, from non-governmental organizations such as patient advocates, to health-care professionals such as doctors, nurses, and the local pharmacist. It must be a comprehensive education effort to inform people about the dangers of fake drugs and why they should go through legitimate channels when purchasing medicines.

- DHS has the unique ability to contribute to this campaign by providing real data about what is coming across our borders as well as information about the true nature of the criminal organizations involved in the fake drug trade. DHS is needed to help tell the story of the criminals involved in making fake medicines in order to educate the public and health care professionals.
- Additionally, more should be done to encourage and realize outcomes from the voluntary initiative of companies like Google and Go Daddy to stop providing services to illegal online drug sellers and distributors of counterfeit drugs. Google and Go Daddy have initiated a new nonprofit called the Center for Safe Internet Pharmacies (CSIP) with membership that includes search engines, domain name registrars, credit card companies, and shippers. CSIP is a vital development in efforts to reduce this crime on the Internet over the long term, and it is an important compliment to the day-to-day work that ICE is doing. CSIP has the potential to drastically reduce the threats posed to patients and reduce the burden on law enforcement agencies; therefore, we encourage this Committee to support the work that CSIP is doing.
- Specifically, we ask for your support of the section in the Protect IP Act of 2011 (S. 968) which provides legal immunity to CSIP and other Internet-related companies who stop providing services to websites that endanger the public health. No House version has been introduced yet, but that section would be

very helpful in any final House legislation. It helps to remove any final disincentive to voluntary action that will protect American citizens.

- As a final part of the Internet strategy, more effort is needed through investigations to track websites back to the source of supply and the major distributors of counterfeit medicines. This requires increased international law enforcement cooperation in response to leads developed and aggressive enforcement action to follow up when justified. The counterfeit drug trade is providing enormous profit that fuels other dangerous criminal activity by organized criminal networks. Dismantling these counterfeit pharmaceutical networks must become a higher priority for law enforcement agencies globally.
- In this spirit, we support and encourage the ongoing work of the IPR Center to bring together the various government authorities and brand holders to fight this criminal activity that is endangering our homeland and national security. It is critical that all of the relevant agencies, ICE and CBP, the FDA, the FBI, and local authorities, are working together with the utmost coordination to fight the counterfeit drug trade. This growing threat of counterfeit pharmaceuticals poses a very unique and frightening threat, and it must not be viewed as an economic or IP crime alone.

In conclusion, I want to underscore that combating counterfeit pharmaceuticals is a very complex issue requiring the cooperation of many agencies and governments, as well as the private sector, health care professionals, and non-government organizations. None of us can do it alone. We stand with you in the effort to protect U.S. consumers and the homeland from counterfeit medicines and dismantle the international crime networks that profit from the counterfeit drug trade. There is a lot of work needed, and we do believe it is vital to the mission of preventing crime and protecting patients everywhere. Again, I thank the Committee for inviting Lilly to testify today and for your commitment to this important issue and look forward to any questions.