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U.S. Attorney's Office
Southern District of Texas

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DISTRIBUTOR OF COUNTERFEIT PHARMACEUTICAL DRUGS SENTENCED

(HOUSTON) – Kevin Xu, 36, a citizen of the Peoples Republic of China, has been sentenced to prison for distributing counterfeit and misbranded pharmaceuticals in the United States, acting United States Attorney Tim Johnson announced today.

At a hearing this afternoon, United States District Judge Sim Lake sentenced Xu to 78 months in federal prison without parole, the maximum sentence under the applicable U.S. Sentencing Commission guideline range for conspiring with others in the Peoples Republic of China to traffic in counterfeit pharmaceutical drugs and causing the introduction of counterfeit and misbranded drugs into interstate commerce. Indicted in August 2007, Xu was convicted by a jury's verdict following a jury trial in August 2008. At today's sentencing hearing, Xu argued that the evidence was insufficient to prove he knowingly traded in counterfeit drugs. The court disagreed. Xu, who has been in federal custody since his August 2007, will remain in federal custody while awaiting transfer to a Bureau of Prisons facility to serve his sentence. In addition to the prison term, the court ordered Xu to pay \$1,286,060 in restitution with \$128,363 to Pfizer Pharmaceuticals and \$1,157,697 to Eli Lilly Pharmaceutical Company.

Xu was the owner of Pacific Orient International Ltd., a foreign company based in the Peoples Republic of China. Xu used his company to export and distribute counterfeit pharmaceutical drugs into the United States and the United Kingdom. During an undercover investigation of Xu conducted which began in November 2006 by the Department of Homeland Security, Immigration and Customs Enforcement (ICE) and the United States Food and Drug Administration, Office of Criminal Investigations (FDA), Xu discussed with undercover agents his ability to manufacture branded pharmaceutical drugs and packaging for the drugs. Xu provided an undercover agent with a list of 25 pharmaceutical drugs he could manufacture that included trademarked drugs manufactured and marketed exclusively by Pfizer Pharmaceuticals Inc., Eli Lilly Corporation, Hoffman La Roche, AstraZeneca and Sanofi-Aventis. Xu later shipped Tamiflu, Plavix, Zyprexa Aricept and Casodex to agents in Houston that appeared identical to the drugs manufactured by the legitimate trademark holder.

Xu later traveled to Houston from China to meet with an undercover agents to further

discuss a venture to supply counterfeit pharmaceutical drugs that would ultimately be dispensed to the public. Xu was considered a significant supplier of counterfeit pharmaceutical due to his ability to manufacture large quantities of various counterfeit pharmaceuticals and packing that was identical to authentic pharmaceuticals. Chemist employed by the pharmaceutical companies and the Forensic Chemistry Center of the FDA determined that the counterfeit drugs manufactured by Xu contained less than the active ingredient listed on the label and contained unknown impurities. Through their investigation, agents obtained sales records and discovered that Xu had actually sold counterfeit drugs to citizens of the United States via the using the internet. The income from the sales in the U.S. in 2007 totaled \$232,568. Because these counterfeit pharmaceuticals posed significant health risks, agents contacted several of the purchasers and seized the drugs. A chemical analysis of the seized drugs determined the drugs did not have the appropriate active ingredient as reflected on the label.

“Every effort will be made to assure that pharmaceutical drugs that enter into commerce in this country are safe for consumers,” said Johnson. “Those who deal in counterfeit or dangerous drugs will be prosecuted to the full extent of the law.”

"The public should take caution when purchasing any prescription drug sold on the Internet. The importation of substandard, tainted or counterfeit products violates U.S. laws and regulations, while threatening public health and safety and the U.S. economy," said Robert Rutt, Special Agent in Charge of the ICE Office of Investigation in Houston. "ICE and the FDA, Office of Criminal Investigations continue to work aggressively to provide a strong and appropriate response to this growing international threat."

Investigating agents also learned that Xu was involved in the distribution of counterfeit pharmaceuticals in the United Kingdom that had penetrated the legitimate supply chain in London, prompting a massive recall for Zyprexa, Plavix and Casodex by the Medicines Health and Regulatory Agency in London, England. These pharmaceuticals bore the same lot number as the counterfeit pharmaceuticals sent by Xu to agents in Houston.

Xu received more than \$1.5 million from the sale of counterfeit pharmaceuticals globally during 2007.

Plavix is a drug used in the treatment of blood clots. Zyprexa is a drug used in the treatment of schizophrenia. Casodex is used in the treatment of prostate cancer. Tamiflu is used in the treatment of influenza, commonly referred to as the flu, and Aricept is used in the treatment of Alzheimers.

This was prosecuted by Assistant United States Attorneys Samuel Louis and Vernon Lewis.

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