

***FDA issues warning to consumers to avoid purchasing flu drugs online
WHO says counterfeit drugs are a \$35 to \$40 billion a year industry***

Huntington, NY – On Friday, Rep. Steve Israel (D-Huntington) called for Congress to act on his legislation, the Counterfeit Drug Enforcement Act of 2009 (H.R.2726) – also known as Tim Fagan’s Law, amid warnings about counterfeit drugs related to the H1N1 virus. Websites selling fake Tamiflu and other purported flu treatments are proliferating and preying on fears of the H1N1 virus.

“Consumers need to be able to trust the medications that doctors say will make them better. Unfortunately, there are criminals who are injecting fake drugs into the marketplace and preying on the public’s fears about the H1N1 virus,” said Rep. Israel. “We need to do more to shutdown these counterfeiters, which is why I introduced legislation to help educate the public about identifying fake drugs, expand FDA authority to target counterfeiters and increase penalties for these vile criminals.”

“At a time when consumers are scrambling to get access to the medicines they need, Rep. Steve Israel’s efforts to strengthen protections against counterfeit prescription drugs are badly needed,” said Chuck Bell, Programs Director of Consumers Union, publisher of Consumer Reports. “HR 2726, Rep. Israel’s proposed legislation, has the enthusiastic support of a broad range of consumer organizations and medical professionals. The bill would put better recordkeeping and chain-of-custody procedures in place to ensure the integrity of the drug supply chain, and impose tough criminal penalties for individuals and companies that distribute fake and adulterated drugs, and try to pass them off as the real thing.”

Rep. Israel’s legislation is endorsed by the Consumers Union, Pew Prescription Project, National Research Center for Women & Families, U.S. PIRG, Partnership for Safe Medicines and National Consumers League.

On Thursday the FDA issued a warning to consumers to use “extreme care” when buying medications to combat the flu online. The warning came after the FDA purchased and analyzed several products represented online as a flu treatment called Tamiflu (oseltamivir), which may pose risks to patients. One of the orders, which arrived in an unmarked envelope with a postmark from India, consisted of unlabeled, white tablets taped between two pieces of paper. When analyzed by the FDA, the tablets were found to contain talc and acetaminophen, but none of the active ingredient oseltamivir. The website disappeared shortly after the FDA placed the order. At the same time, the FDA also purchased four other products purported to diagnose, prevent, treat or cure the H1N1 influenza virus from other websites.

These products contained various levels of oseltamivir but were not approved for use in the United States. Several of the products purchased did not require a prescription from a health care professional. Additionally, the products did not arrive in a timely enough fashion to treat someone infected with the H1N1 influenza virus, or with an immediate exposure to the virus.

Rep. Israel's legislation is named for one of the Congressman's constituents, Tim Fagan, who received counterfeit medication in place of the prescription he needed following a liver transplant. The injections he received only had a small amount of the medicine he actually required and wreaked havoc on Tim.

Counterfeit drugs are defined as those without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging. The World Health Organization estimates counterfeit drugs are a \$35 to \$40 billion a year industry.

Tim Fagan's Law to combat counterfeit drugs will:

- Give the FDA recall authority, the same way the FDA can recall faulty medical equipment;
- Increase criminal penalties for counterfeiting;
- Mandate that drug manufacturers alert the FDA in 2 days when they learn that one of their drugs has been counterfeited;
 - Authorize funds specifically for spot-checking (\$300 million over 5 years);
 - Provide the FDA with the authority to require companies to use anti-counterfeiting technology;
 - Require the FDA to remove the stay placed on paper pedigree requirements, which were mandated in the Prescription Drug Marketing Act of 1988;
 - Authorize \$5 million for each year between fiscal years 2010 and 2014 for educating the public and health care professionals on how to identify counterfeit drugs; and
 - Authorize the FDA to issue subpoenas with respect to preventing threats to public health.

Rep. Israel has led the charge against counterfeit drugs for the last seven years. His efforts are documented as part of the book *Dangerous Doses* by Katherine Eban.

Rep. Israel serves on the House Appropriations Committee.