

Washington, DC—Following the release of the Administration's import safety action plan, Congressman Steve Israel (D-NY) renewed his call for drug safety legislation inspired by a Long Island teenage victim of counterfeit drugs. Israel's legislation gives the FDA the tools it needs to fight counterfeit drugs, such as a recall authority, increased criminal penalties and tracking requirements.

"It's encouraging that the President has woken up to the threat posed by tainted and counterfeit products that my constituent, Tim Fagan, knows all too well," said Congressman Israel. "While addressing food safety, the Administration should not overlook the dangers posed by counterfeit drugs. Though the President has incorporated several components of 'Tim Fagan's Law,' such as increased penalties and recall authority, into his action plan, drug safety requires a comprehensive effort. Most Americans trust the doctors who write their prescriptions and the pharmacists who fill their prescriptions. What they don't know is that in between the manufacturer and pharmacy, prescription drugs can change hands up to a dozen times, in a shady gray market, where they can be tainted, diluted, relabeled and counterfeited. The best remedy against counterfeit drugs is 'Tim Fagan's Law' which I've introduced in Congress."

Yesterday, President Bush received an action plan from his Interagency Working Group on Import Safety. Among other recommendations, the working group urged stiffer criminal penalties to companies that sell unsafe products and authority for the FDA to recall tainted products, an ability it currently possesses for medical devices but not for prescription drugs.

In 2002, Israel's 16-year old constituent, Tim Fagan, was injected with prescription Epogen that his parents purchased from their neighborhood CVS to help him recover from a liver transplant. After injecting Tim with the drugs for several weeks, causing him to cry out in pain, Tim's parents learned that the drugs they had purchase were counterfeit. Before arriving at a CVS pharmacy in Long Island, Tim's medicine was traded multiple times between legitimate wholesalers and criminals seeking a quick profit. Among these many exchanges, Tim's Epogen was transported in paint cans, handled by criminals, and allegedly stored in a beer cooler at a Miami strip club.

The current distribution system for prescription drugs has significant loopholes that allow criminals to introduce counterfeits into our drug supply, reaching into reputable pharmacies. There are no enforced requirements for tracking drugs from their origination at a manufacturer to final sale at a pharmacy, despite a law that was passed in 1987 but never enacted. Furthermore, federal penalties for counterfeiting drugs are weak and the Food and Drug Administration (FDA) lacks the authority to recall drugs that they learn are counterfeit.

In 2003 and in each successive session of Congress, Israel has introduced legislation in Tim's name that would not only require that drugs are traced through electronic or paper chain-of-custody documents but also give the FDA that tools it needs to protect the American public. Israel's legislation, Tim Fagan's Law: The Counterfeit Drug Enforcement Act, gives the FDA the authority to recall drugs, implement harsher penalties for criminals who pawn fake medicine off on innocent consumers, and requires "chain of custody" pedigree documents.

"We, along with our son, are indebted to Congressman Israel for introducing a bill before Congress that will toughen the penalties for counterfeiters, empower the FDA to investigate and recall bad drugs, and make our nation's drug distribution system safer," said Tim Fagan's parents, Kevin and Jeanne Fagan.