My name is Peter Pitts and I am President of the Center for Medicine in the Public Interest and a former Associate Commissioner of the Food & Drug Administration. During my tenure at the FDA, I was proud to have served on the agency's Counterfeit Drug Taskforce.

When asked why he robbed banks, Willy Sutton, the depression-era desperado replied, "Because that's where the money is." And, as former FDA Commissioner Mark McClellan used to say, if Sutton were alive today he'd be selling counterfeit prescription drugs.

The bad news is that international prescription drug counterfeiting is on the rise and it's nothing less than international health care terrorism.

I estimate that, globally, counterfeit drug commerce will grow 13% ***annually*** through 2010. That means counterfeit drug sales will grow at nearly twice the rate of legitimate pharmaceutical commerce.

In 2010 this illegal business will generate $75 billion in revenues– a 92% increase from 2005. The profits are high and the risks are low. That's a deadly combination.

A large proportion of the world's counterfeit medicines originate in Asia and end up in the US and EU. In the EU, between 1998 and 2004 there has been **a 1000% increase** in seizures of counterfeit prescription drugs.

China in particular is a production center. In 2001 it was reported that Chinese authorities closed 1,300 factories while investigating 480,000 cases of counterfeit drugs worth $57 million.

The State Food and Drug Administration (SFDA) of China announced that, from January-November 2005, it banned 114,00 unlicensed drug manufactures, destroyed 461 illegal pharmaceutical factories.

It is estimated that in China between 200,000 to 300,000 people die each year due to counterfeit or substandard medicine. And these are reported cases: the true number of cases is likely to be far higher.

Unfortunately, ***their*** problem is fast becoming ***our*** problem.

This past December US customs agents intercepted more than 50 shipments of counterfeit Tamiflu, the antiviral drug being stockpiled in anticipation of a bird flu pandemic. The fake drugs had none of Tamiflu's active ingredients. Information on the packages was written in Chinese.

Jeffrey Gren, Director of the Commerce Department's Office of Health and Consumer Goods, announced in a recent speech that the U.S. government is working on stopping the illicit flow of active pharmaceutical ingredient (API), which can be used in counterfeit medicines. Gren said that the Commerce Department is focusing efforts on China and India. China maintains that it cannot be responsible for the API used outside of the country.

The production and trading of an active pharmaceutical ingredient in bulk form needs to fall under the same regulations that govern the production and trading of manufactured pharmaceuticals.

Today this is not the case in China and, as such, is not regulated by the SFDA.

On April 29, 2006 the Chinese Department of Health announced that fake medicines purporting to lower blood sugar resulted in at least three blood-poisoning cases last year. Patients have received fake medicines with illegal chemicals.

The SFDA has released a warning about counterfeit Glucobay, a diabetes medicine. After receiving a complaint from a consumer, SFDA worked with Bayer to determine that the suspect product was counterfeit. Currently, officials believe 6,000 boxes could be affected, and an investigation against the counterfeit producers has been launched. In Shanghai contraband and expired medicines are becoming a concern in open-air markets.

Since early 2005, health regulatory officials in Leizhou have seized 308 types of fake and substandard medicines and medical devices.

Nigeria's health agency NAFDAC recently issued a public criticism of China's perceived unwillingness to collaborate against counterfeit medicines. Counterfeit medicines account for approximately 68% of the drug market in Nigeria, with the vast majority of the illicit products coming from China.

Taiwan's Criminal Investigation Bureau (the CIB) announced this week that roughly $9 million worth of counterfeit drugs was seized recently in Taipei. Counterfeits included: cold treatments, gastrointestinal medicines, sedatives, anti-obesity and erectile dysfunction drugs, and "210,000" unknown pills. The CIB claims that the counterfeits were of mainland Chinese origin.

During a recent FDA blitz operation at airports in New York City and Miami over 25 different controlled substances were found including such drugs as Diazepam, Codeine, Valium, and Anabolic steroids. Many of these were counterfeit and of Chinese origin.

Imposing effective deterrent penalties on those engaged in prescription drug counterfeiting is the most important step the Chinese government can take to stem the tide of illegal and unsafe counterfeit drugs. An effective criminal deterrent is a requirement of TRIPS (trade related aspects of intellectual property rights) Article 61.

The EU Council of Ministers recently approved a plan issued by the European Commission to improve Customs coordination against counterfeit goods. Currently, 70% of seizures of counterfeits are from China.

At the beginning of my testimony I mentioned that I served on the FDA's Taskforce on Counterfeit Drugs. The taskforce recommended eight measures that should be taken to address this public health problem.

The eighth and final recommendation is:

Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

I strongly urge this Commission to help make the FDA's recommendation a reality, because if we wait for the current problem to become a disaster we will have only ourselves to blame.

As the Chinese proverb says,

An ant may well destroy a whole dam.

Thank you.