



Terrorism's Next Target



By David J. Gibson, MD

PHARMACEUTICAL PRODUCTS not only cost a great deal. They also could be a source of danger.

Because of concern over another terrorist attack, alert levels have been issued and defensive resources have been deployed. Amid all of this activity, it is worth reflecting upon the terrorists' past behavior to predict their next initiative. They have consistently sought to strike us where we were not looking.

From the terrorists' point of view, the ideal attack will be unexpected, meet minimal resistance and cripple an essential industry. This attack will not only injure Americans, it will also demonstrate that our government is incapable of protecting its citizens.

From the terrorists' perspective, discrediting the government is much more important than causing physical damage. This ability to discredit is significantly enhanced if a known threat has been ignored. That happened on September 11. That is what is likely to happen again.

America's pharmaceutical inventory

For some time, it has been known that the Food and Drug Agency's (FDA) ability to protect the drug inventory in the United States has been compromised. As far back as 1996, the FDA warned that it had lost control over bulk drug shipments that enter the U.S. market. A recent FDA/U.S. Customs investigation revealed that 88 percent of the imported pharmaceuticals examined contain counterfeit drugs. Most counterfeit products are now produced in Pakistan, China, Columbia or India.

Since 1997, some 4,600 foreign drug makers have shipped medication into the U.S. without product inspection. In the past two years, the number of parcels containing prescription drugs entering the U.S. from other countries has risen by 1,000 percent. Current screening by customs and postal authorities is inadequate to stop more than a token amount of prescription drugs being illegally shipped into the United States to individuals, distributors or various buyers' clubs, wholesalers or storefront pharmacies.

Once in the United States, these prescription drugs journey through a convoluted distribution chain before reaching the consumer. Each link along the way is vulnerable to theft and tampering. Stolen products can readily be resold to wholesalers, where they seamlessly mesh back into the distribution chain.

Only Florida and Nevada have actively investigated the contamination of their drug inventories. A report by Florida's grand jury in 2003 found that counterfeiters "through greed and malice expose our most vulnerable citizens to death or grave injury every day." The report said "the wholesale pharmaceutical industry in Florida has been corrupted by the infiltration of a criminal element which is making a fortune while tainting our drug supply."

An almost perfect crime

Drug counterfeiting is an almost perfect crime. The evidence is destroyed once the

medicine is ingested and the packaging is thrown away. If the patient doesn't get any better, the physician and patient, neither being able to visually identify a counterfeit product, believe the underlying disease process is causing the problem. The World Health Organization has warned that the trade in bogus drugs could be worth as much as \$32 billion a year.

Counterfeiting of medicines is hugely lucrative, due to high demand and low production costs. Profits often rival those of narcotics trafficking — but the potential misdemeanor penalties for counterfeiting are far lower.

There is mounting evidence that counterfeit drugs have permeated the U.S. drug inventory. FDA Commissioner Mark B. McClellan has warned the FDA is "increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized criminal networks."

Unfortunately, drug counterfeiting primarily occurs with the most expensive products. These are medications upon which individuals' lives depend. Drugs used to treat AIDS, transplants, malignancies and chronic debilitating diseases are generally the target of counterfeiters.

Terrorists and our drug inventory

Recently, Lester Crawford, the FDA Deputy Commissioner, warned of a "real risk" of a terrorist attack on this country through the U.S. drug supply. His warning was met with skepticism because he focused his remarks on the Internet-based purchases of imported drugs.

The warning is valid but incomplete. Counterfeit drugs are *already* deployed in the U.S. and now contaminate inventories at both the wholesale and the retail level.

Remember the Tylenol scare? That episode, occurring in 1982, involved the lacing of Tylenol bottles on pharmacy shelves with cyanide. Seven people died and Tylenol's manufacturer, Johnson & Johnson, recalled 31 million bottles at a cost of more than \$100 million. And this tragic episode involved only a handful of bottles.

Today, terrorists have the opportunity to contaminate thousands of bottles of multiple counterfeit pharmaceutical products with chemical or biological toxins. This product tampering could occur in manufacturing sites in other countries. These counterfeit products would arrive in the United States, be inserted into the drug distribution system — and patients would begin to die. It would take several days if not weeks to establish the connection.

The casualty count, and the fear generated from such an attack, would have incalculable consequences. The reliability of the entire deployed pharmaceutical inventory in the U.S. would immediately be called into question.

What could be more efficient from a terrorist's point of view than recruiting a patient's physician and community pharmacist into their nefarious plot? Not only could the terrorists inflict injury and death upon America's civilian population through prescription medications, they could also demonstrate our government cannot protect its citizens from a known threat.

Why would terrorists engage us in a frontal attack on the streets of New York, where we have prepared, when they can safely remain in unstable countries and inflict chaos upon America's health care system?

What should be done?

For openers, we need to think more creatively to prepare for the next terrorist attack. Protecting America's vulnerable health care system must be addressed — now.

We need to immediately implement the recommendations contained in the FDA's recently released report on "Combating Counterfeit Drugs."¹ America also needs an independent organization to sample deployed inventory at both the wholesale and the retail levels of distribution. The results of this monitoring should be made public.

The Fraud Prevention Institute is starting to collect deployed drug samples. These samples are being supplied by concerned community pharmacists to determine the extent of the counterfeit drug problem here in California. In essence, we are creating the equivalent of an "Underwriters Laboratory," to give California consumers the information they need to protect themselves and their families at the point-of-dispensing. This is a community-based response to a clear and present danger that must be recognized and addressed immediately.

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1. www.fda.gov/oc/initiatives/counterfeit/report02_04.html

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