Countering Counterfeiters
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Most P&T committee members agree that counterfeiting prescription medications, with the potential harm that could accrue to thousands of patients, is an egregious act and ought to be appropriately punished. Certainly, many of us remember high-profile stories widely reported in the media in which a pharmacist might have deliberately diluted essential medications, especially chemotherapy agents intended for patients with various forms of cancer. I am sure that the same P&T committee members would be surprised to learn the scope of the counterfeiting challenge in our nation and the paltry penalties that have been assessed to guilty individuals.

I first became aware of the widespread incidence of counterfeiting by way of a routine “Dear Doctor” letter from Ortho Biotech concerning counterfeit vials of epoetin alfa (Procrit®). Generally, I pay only cursory attention to these letters, but this one caught my eye. I was intrigued by the devilish nature of the counterfeiters and the skill with which they operate. Ortho Biotech provided side-by-side color photographs of genuine Procrit® and the counterfeit drug. I was sickened by the thought that patients could be receiving water—or worse yet—contaminated water filled with active Pseudomonas cultures.

I followed up on the “Dear Doctor” national mailing and spoke to several helpful individuals at Ortho Biotech, including Carol Goodrich, director of public affairs, and Collette Boyle, director of medical information. They, in turn, sent me documents from the state of Florida that detailed the situation there; apparently, the problem in Florida is similar to the one in many other states.

The Florida Office of Program Policy Analysis and Government Accountability (OPPAGA), which reports to the Florida Legislature, says that the problem of counterfeiting, along with the diversion of drugs, is a massive public health issue and one that ought to concern all P&T committee members, not just those in Florida. This report noted a key current trend: counterfeiting high-cost drugs that are used to boost the immune systems of patients with cancer and human immunodeficiency virus (HIV) infection or acquired immunodeficiency syndrome (AIDS).1

Think about it! Because these patients are seriously ill, physicians might not immediately recognize the effects of a counterfeit drug. According to the report, physicians might “attribute a patient’s failure to respond or adverse side effects to the disease and not to a counterfeit drug.”

A single fake drug can place thousands of individuals at risk and can result in huge profits for the criminals involved. For instance, investigators in 2001 discovered that criminals in southern Florida had relabeled more than 100,000 bottles of low-strength erythropoietin (Epogen®, Amgen) to make the bottle appear to contain high-potency Procrit®, which is 20 times stronger than Epogen®. The criminals resold the relabeled drugs into the wholesale market with forged pedigree papers and passed the drugs through four states and four wholesalers.

Eventually, the Florida investigators located 800 boxes of the counterfeit “Procrit®” in the warehouse of a large Texas wholesaler, who had unknowingly purchased it. The investigators also located some of the product in North Carolina. Eventually, they recovered less than 10% of the counterfeit drug, which meant, of course, that thousands of vials had already been dispensed.

These same investigators estimated that there were sufficient dosages to treat 25,000 cancer patients for one month, if it had been the high-strength Procrit®. Thus, “instead of receiving the proper dosage, a large number of seriously ill cancer or AIDS patients may have received lower dosages than needed.”1 Officials from Florida’s Bureau of Statewide Pharmaceuticals estimate that the criminals made an illicit profit of approximately $46 million.1

I had not been aware of several major weaknesses in the wholesale and retail drug market, including an absence of clarity in the law, which allows counterfeiters and diverters to introduce illicit drug wholesale shipment and diverters permit requirements. This in turn makes it easy for unscrupulous individuals to invade the wholesale market. The inadequate administrative and criminal penalties for drug counterfeiting and diversion, of course, do not deter criminal behavior.

Like most people, I had assumed that the prescription drug industry was relatively linear and simple, with drugs going from manufacturers to wholesalers and on to retail pharmacies; however, the situation is much more complex. There might be multiple wholesalers in different geographic locales who sell to one another. As it turns out, it is unclear as to who is defined as a so-called authorized distributor of record (ADR).

I was amazed that current law, especially in Florida, does not regulate who can be designated an ADR. Many legislators presume that drugs purchased from ADR wholesalers are safe and effective because they come directly from the manufacturers; however, there appears to be widespread forgery of “pedigree papers,” which help to track essentiality in the law, which allows counterfeiters to evade the wholesale and retail drug market, including an absence of clarity in the law, which allows counterfeiters and diverters to introduce illicit drug wholesale shipment and diverters permit requirements. This in turn makes it easy for unscrupulous individuals to invade the wholesale market. The inadequate administrative and criminal penalties for drug counterfeiting and diversion, of course, do not deter criminal behavior.

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Clarify the state law related to pedigree papers, and direct the bureau to enforce the state law.

- Authorize the bureau to strengthen the permit process.
- Authorize the bureau to levy increased administrative penalties and fines.
- Consider increasing criminal penalties for prohibited acts involving prescription drugs.

I am not optimistic that these recommendations, taken together, can halt the proliferation of counterfeit products. With the easy availability of pedigree papers and with multiple entry points into a vast national distribution network, one state acting alone cannot stem the tide. I believe that the pharmaceutical industry is working at the national level in an appropriate fashion to first call attention to this important problem and then to seek federal legislation to limit its impact.

What can we do at the local level? Certainly, becoming aware is the first step, and I hope that this editorial will contribute to the educational process. Every P&T committee member should understand the scope and depth of this significant problem.

Pharmacy directors also have an obligation to inspect all products carefully, especially those higher-cost items destined for use in cancer and AIDS care. Any product’s lot that arouses the least bit of suspicion should be impounded immediately, and the appropriate authorities at the regional and state level should be alerted.

We all have a frontline responsibility for protecting the drug-delivery chain. Countering the counterfeiters will take a collective effort and our continued vigilance.

As usual, I am interested in your views. If you are aware of an episode of counterfeiting, I would like to publish your experience. You can contact me at my email address, david.nash@jefferson.edu. You can also contact the OPPAGA at www.oppaga.state.fl.us.

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