Drug Safety and the FDA

By Sonja Sherritze, Editor, P&T

Two days before deadline (which is when these things usually happen), an e-mail message from the “biomednews” group popped up, announcing a conference in Paris on counterfeit drugs.

Knowing that I couldn’t rationalize a trip to my favorite European city, even for a conference as important-sounding as this one, I opened the message in the hope of finding out how many people were expected to attend or, more generally, to get a sense of how many people in the world are truly concerned about this topic.

According to the news release, which cited information from the World Health Organization, one in 20 drugs sold today is counterfeit, with the incidence rising to one in three in some developing countries. Counterfeit drugs have killed and injured thousands worldwide. It is thought that one of the reasons that the counterfeiters continue to get away with murder—literally, in some cases—is that the activity is not treated as a murder (or attempted murder or manslaughter) but rather as a trademark crime. This is one of the issues that will be addressed in Paris.

Why is this not headline news? I wondered, especially during this time when some scapegoat-seeking American mass media journalists (I use that term loosely), who shall remain nameless, are seemingly looking for opportunities to blame and bash the FDA? Perhaps there is an awareness that this is one area where the agency’s powers are, or have been, seriously limited. And whatever people might think about the FDA’s accountability for the very public problems associated with antidepressants or COX-2s, for instance, common sense dictates that the agency can’t be held responsible for the evil actions of determined criminals. That argument most likely won’t be persuasive for long, though.

I had not planned to do a special issue on the FDA and drug safety until Dr. Tanya Nelson called me out of the blue last October—my first direct contact with the FDA—and asked if I’d be interested in an article on the agency’s position on drug importation. Who could say no to that? She sent me the first draft the day before I got on the plane to attend the American Society of Health-System Pharmacists’ (ASHP’s) midyear meeting, and we talked about the article briefly while sitting on the steps inside an overcrowded convention center cafeteria and eating stale $9 Caesar salads. I learned that one of Dr. Nelson’s colleagues was going to be giving a talk about counterfeit drugs at the meeting, which suggested to me that the topic was still widely considered to be timely and important.

Then shortly after the meeting, Dr. Alan Kaell, a member of our editorial board, informed me that he had made contact with Dr. Valerie Jensen, also at the FDA, and that the members of their Drug Shortage Team at the Center for Drug Evaluation and Research (CDER) were interested in writing about drug shortages. It had been a while since we covered this topic in depth, so who could say no to that either? (By now you’re probably thinking I have the easiest job in the world, and that dozens of wonderful manuscripts routinely, magically appear on my desk. Not so; the articles eventually materialize, but magic is less a factor than blood, toil, tears, and sweat—to borrow a phrase from Sir Winston Churchill.)

After reading Dr. Nelson’s article, with its focus on counterfeit drugs, I fished out another article that had been submitted earlier by editorial board member Dr. Marvin Goldenberg, about the FDA’s two 2004 reports on efforts to fight the spread of counterfeit drugs, and I concluded that it was a good fit with the drug importation article. Dr. Nelson and her coauthor, Dr. Jerilyn Petropoulos, agreed. And then, about a week before deadline, a news release about the FDA’s new drug safety board landed in my “in box,” and to my amazement, long-time P&T author Dr. Richard Stefanacci graciously agreed to compose a commentary about it and get it to me in two days. Suddenly we had the makings of a special thematic issue. That could only mean one thing: time to write another editor’s memo.

It might seem strange to see articles addressing the dangers of counterfeit drugs when this particular topic has not been in the headlines in a while. Of course, our forward-thinking editor-in-chief, Dr. David Nash, wrote about this topic back in January 2004 (“Countering Counterfeiters”) but it has been some time, for instance, since we’ve heard about fake cancer vaccines making their way onto pharmacy shelves at the local drugstore.

But the topic of drug importation has been and remains a major concern to the American public, and regardless of your opinion about the overall safety of drugs imported from Canada and elsewhere, the potential for a large-scale crisis always exists. Consequently, the FDA, along with other government organizations, is now facing with the daunting challenge of anticipating the many ways that terrorists and others might use modern technology to wreak havoc on unsuspecting consumers—and so it is being forced to become more technologically savvy than ever to stay one step ahead of the bad guys.

By now I’m sure that you, dear readers, are well aware that the FDA is not without its problems. Some of these are touched upon in Dr. Stefanacci’s commentary, and even implicitly acknowledged by the FDA authors who appear in this issue. I hope that by calmly and openly discussing these problems and challenges, we can work together to minimize the risks to the food and drug supply in this country.