Prescription Washington

Technology Solutions Might Help Pharmacists Fight Counterfeit Drugs

by Stephen Barlas

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rescription drug counterfeiters have turned pharmacists, along with many other unsuspecting innocent people, into unwitting pawns. That conclusion, sad as it is, is unmistakable after reading the Counterfeit Drug Task Force interim report, issued by the Food and Drug Administration (FDA) in October 2003.

Counterfeiters are usually small, secondary wholesalers, not one of the Big Three distributors upon whom hospitals most frequently depend. These counterfeiters may go as far as to produce faux labels and containers for big-name drugs, fill those containers with fake or diluted products (sometimes even with water if the medication is a liquid), and then pass them off as legitimate drugs to unsuspecting pharmacists in hospitals or retail pharmacies. Because the original drug products had no “tamper-proof” tracking or authentication features—most drug products do not—pharmacists have no way of knowing whether the look-alike products that they are dispensing to hospital patients and retail customers are fakes, lower-dose varieties, or authentic products.

At an FDA meeting held on October 15 in Washington, DC, to hear the public’s comments on that interim report, a room was set aside for displays of technological advances that might help solve the counterfeiting problem. The availability of all sorts of caps and seals, invisible inks for labels, and DNA tags for containers has the potential to give pharmacists a chance to discover whether a drug might be a fake. The question is whether drug manufacturers will adopt these technologies—and how soon.

Joe Murawski, sales director for DuPont Authentication Systems, was one of the vendors hawking potential solutions. DuPont, like all of the vendors there, thinks that it has the best solution. The company is selling a hologram that it claims is unique because it affords a parallax image. The person opening the cap looks at an image on the inner seal and can observe the image on all four of its sides, similar to a three-dimensional view.

Mr. Murawski thinks that the parallax hologram—which he claims cannot be counterfeited—makes more sense for pharmacists than another popular, projected solution: a hand scanner for authenticating overt or covert codes, like a DNA tag, on packages or labels. Because pharmacists must take the cap off the container anyway, the DuPont solution saves a step, in that there is no need to scan anything.

DuPont, says Mr. Murawski, is in the final stages of a deal with a major drug manufacturer that would be the first to use DuPont’s photopolymer hologram. Many of the other vendors at the FDA’s mini-trade show said much the same thing: “We have deals in the works, but we can’t talk about them.”

Another popular response: “We signed confidentiality agreements with our clients.”

A few companies have spoken publicly about their voluntary adoption of counterfeiting technologies. Bayer Biological Products began selling intravenous immune globulin (Gamunex®), an injection to bolster weak immune systems, with logo-embossed shrink-wrapping over each vial. It is the first in a more tamper-resistant product line. One wonders, though, whether it would be difficult for an inventive counterfeiter to produce shrink-wrapping with the Bayer logo.

These voluntary efforts—should they pick up substantial steam and, more important, should they prove effective—will go a long way toward heading off any FDA regulatory mandates, which are definitely in the wind but must await, at a minimum, publication of the Counterfeit Task Force’s final report sometime early next year.

But anti-counterfeiting technologies are not the only thing the FDA may mandate. Another part of the solution is ensuring that “dirty” secondary drug wholesalers don’t get hold of products in the first place.

This is also an area of special interest to the American Society of Health-System Pharmacists (ASHP). The ASHP has adopted a new policy calling for regulations that restrict or prohibit licensed drug distributors from purchasing prescription drugs from unlicensed entities. The organization also plans to issue guidance to its members about how to assess pharmaceutical suppliers. These types of safeguards are all well and good, but they are not as foolproof as the technology solutions.

It is a sad state of affairs when pharmacists must depend on drug manufacturers and wholesalers to arm them in the fight against counterfeit drugs. Perhaps they will find some powerful allies in modern technology. ■