

item. Also, if the FDA changes its mind and requires compounded drugs to be tracked, how does someone trace a product that is converted from a powder to a liquid?

### **Product Verification**

The FDA is requiring manufacturers, wholesale distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.<sup>7</sup> There are two issues with how this one is worded by the FDA. The first issue is the use of the word *identifier*. Currently there are companies that provide multiple layers of identifiers on the drug packages, from overt to covert to forensic markers. The bad guys are smart—one singular identifier? It won't take long for the bad guys to figure it out. The second issue revolves around the question of who will verify the product identifier. I feel that the FDA is behind the curve on what is happening in the marketplace on product verification.

### **Detection and Response**

The FDA is requiring manufacturers, wholesale distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect, meaning that it may be counterfeit, unapproved, or potentially dangerous.<sup>8</sup> This is a very good requirement, and most of the good companies already do the proper investigation. The investigation is only as strong as the weakest link in the supply chain. Education, training, and common processes and procedures are needed across all entities. In addition, every company will need a strong internal audit/security group to deal with issues when they arise.

### **Notification**

The FDA is requiring manufacturers, wholesale distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify the FDA and other stakeholders if an illegitimate drug is found.<sup>9</sup> The internal audit/security groups will need to know not only how and to whom they need to report the finding of an illegitimate drug, but also, more importantly, when to pass along their investigations to governing agencies and law enforcement for their handling.