



## The FDA Ruling: **A Tipping Point for Bar Coding at the Bedside?**

I'VE BEEN THINKING ABOUT HUSH PUPPIES, THE THREE STOOGES, AND the FDA drug bar code rule.

In *Tipping Point*, author Malcolm Gladwell explains “how little things can make a big difference.” His bestseller opens with the Hush Puppies success story. Remember those goofy, albeit comfy, crepe-soled shoes that made it big in the late '50s? The all-but-dead brand had barely survived, and by 1995, sales were down to 30,000 pairs a year. Wolverine, the company that makes Hush Puppies, was considering phasing out the shoe that made them famous.

That same year, some funky kids in New York's East Village started wearing Puppies, and soon the shoes were not only in Big Apple nightclubs, but also on campuses across the country. By year's end, 400,000 pairs had sold.

What was the tipping point that caused the dominos to fall? The Village kids? Or was it when the Oxygen Network's fashion guru, Isaac Mizrahi, started wearing the shoes on his television show? Or perhaps the hip fashion designer who chose them for his runway models? In any instance, the president of the shoe company soon found himself on stage at the Council of Fashion Designers awards dinner accepting an award for “best accessory of the year.” The following year, over 1.5 million pairs were sold.

### Bar Codes on Medications

Bar code scanning first appeared at check out stands in 1974, and inside 10 years, they were on virtually every item in drug stores and super markets throughout America. Within another five, bar codes were also on duct tape at Home Depot and—you guessed it—Hush Puppies at Sears. Yet, they were curiously missing from medications in hospitals.

At the 1990 ASHP Midyear Meeting, Gerald Meyer, PharmD, appealed to his colleagues in hospital pharmacy, and to the drug industry in general, to catch up with the times and apply bar code technology at the point of care to ensure a safer medication-use process. He wasn't the first to think of the concept. In 1985, Ed Nold published “Bar codes and their potential applications in hospital pharmacy” in *AJHP*, and there were countless informal discussions on the subject among hospital pharmacists. The dominos were being put in place, but we couldn't figure out how to get them to fall.

Meyer's appeal did serve to motivate one manufacturer to apply bar codes to a handful of unit-dose packages (all oral solids in blisters) in 1991, and some thought this might be the tipping point. Yet, we endured another decade of the status quo. When we entered the new millennium, studies showed that 60 to 70% of immedi-

ate drug packages still arrived at hospitals without bar codes, and of the drugs that were bar coded, many were not properly configured for successful reads by the less than 3% of hospitals using bar code scanners.

Many, including the FDA, had incorrectly assumed that the market would drive the manufacturers to put bar codes on drug packages. Manufacturers figured, “Why should we bar code medications when no one has scanning systems in place?” Hospitals reasoned, “Why should we buy scanning technology if bar

coded medications aren't available?” And the automation vendors were losing the desire to invest R&D dollars for bar code point of care (BPOC) systems if no one was going to buy them. It reminds me of the Three Stooges standing forever at a doorway, each saying to the other, “After you.” and “No, after you.”

Quietly, but persistently, a handful of vendors had the vision to continue developing BPOC systems. These mature and

ready-for-action systems were installed in a small, but noteworthy number of hospitals across the country. The greatest barrier to progress was that too many medication labels still lacked bar codes. Over the years the chorus of hospital pharmacists calling for bar codes grew, and formal statements from ASHP and others were issued, all appealing to the FDA to mandate bar code labeling on all drug packages.

### The Tipping Point

Then, in 2002, the FDA announced that they would hold hearings related to a “proposed rule” that would require manufacturers to include bar codes on all medication packages. This, I believe, was the tipping point we had been waiting for. Immediately, a handful of manufacturers saw the handwriting on the wall and decided to lead the industry into the inevitable by bar coding their medications. This, in turn, freed more vendors to focus on bringing BPOC products to maturity and to market, and hospitals started believing that BPOC was finally going to happen.

The full impact of the FDA's final rule goes into effect this month. For drugs approved by the FDA after April 26, 2004, drug companies have 60 days to include bar codes on their labels. For drugs approved before April 24, 2004, the manufacturers had until April 26, 2006 to comply with the rule.

The domino has fallen, albeit in slow motion. Starting this month, the FDA requires all manufacturers and repackagers to include a linear bar code on the labels of virtually all immediate drug packages. If the manufacturer produces single blister packages of oral solid medications, each blister must have a bar code. A bar code must also be included on the label of syringes, ampoules, vials, bottles, ointments, patches, and inhalers.

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Some drug companies will opt to retreat from packaging oral solids in blisters and ship them in bottles instead. This means that hospitals will have to contract with repackaging houses for “unit dose” packages of these items or they will have to repack-age them in house.

The good news is there is excellent technology, which, if properly used, produces safe packaging of oral solids and liquids with bar coded labels. The best news is that all syringes, ampoules, and vials will come direct from the manufacturer with the proper bar codes. The latter had been the slowest in coming.

Look for hospitals to fall in line at an increasing rate. According to this year’s HIMSS survey, over 60% of responding hospitals say that BPOC is on their list to implement over the next two years. For several years, I have been predicting that by 2010, 80% of hospitals with 100 beds or more will be scanning medications at the point of care. I see no need to amend my prediction.

We’ve made it through the door. The dominos have fallen. Expect bar code scanning to be more popular than Hush Puppies. Other than this, I have no opinion, but I am interested in yours. ■

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