

I've been thinking...



The FDA Bar Code Rule on Year Later
May 2007

I've been thinking...about the FDA's bar-code rule one year later and about the complaining that has followed.

The FDA Bar Code Rule, requiring pharmaceutical manufactures to include bar codes on all immediate drug packages, went into full effect on April 26, 2006. The past twelve months, however, have witnessed a good bit of complaining—even by those who praised the FDA when it happened. I hear pharmacists groaning about how drug companies have dropped the ball by dropping unit-dose packaging. I hear nurses griping about the quality of too many bar codes on manufacturer drug packages being too poor for their scanners to read. And everyone goes nuts when the package arrives without a barcode at all.

Well now there is something we can do about it besides complain. However, if you have a few minutes, I'd like to share a few reasons why its not really as bad as we might think before I suggest a way we can make things better than they are. In case you don't have time to read the next few hundred words, I understand but hope that you at least skip down and read how "**There is something you can do to make it better.**"

In regard to oral solids, things are not as bad as you might think.

When safety advocates lobbied the FDA to require bar codes on all immediate drug packages, they also warned that such a requirement would result in a decrease of unit-dose packages, that is, unless the FDA also mandated that drug houses package their pills in unit-dose.

While the FDA did pass a regulation requiring bar codes on all drug labels, like it or not, it is simply outside their jurisdiction to require drug companies to package all pills down to single packages. Thus, bottles of hundreds meet the regulation as long as the bottles are properly bar-coded.

Yet, even if the FDA could require it, I suggest that such a mandate would not only fail to solve all packaging problems, but it could actually create new ones. I'm thinking of two examples. First, some companies would be tempted to limit the dosages they produce. Those producing 5mg, 10mg, and 20mg tablets of their patented products today could drop the 5mg and 20mg tablets tomorrow and still meet FDA requirements. I suggest that three dosage forms we now have are better than the one we could end up

with, even if it means hospitals must lean on drug packaging machines to get some unit-dose packages.

Second, there are some really good arguments for using packaging machines in hospital pharmacies. These bar-code-driven devices, if filled and operated as directed, produce safe unit-dose bar-code packages. They also *pick* the medications more efficiently and more accurately than humans selecting unit-dose blisters from bins at manual picking stations—like selecting nuts and bolts from orange bins at Home Depot. Having pills available in bulk has its advantages. Could you imagine having to de-blisters tablets in order to fill packaging machine canisters? Of course, in an ideal world we would have access to blisters and bulk—sort of like paper and plastic at Kroger.

In regard to injectables, things are actually better than you might think.

Because of the FDA rule we have seen a slight decrease in the industry's formulary of unit-dose oral solids. However, virtually every ampoule, vial and syringe is now bar-coded. That's a huge gain. No more need to line up those high-risk liquids and employ high-risk manual-labeling practices. We've got a lot to be grateful for from the FDA's rule.

Having said all that, I'm right in there with my pharmacy and nursing friends who are understandably upset that not that all medications are available in single-item packaging, that too many bar codes can't be read by perfectly good scanners, and that some unit-dose packages reach them with no bar codes at all.

Well, finally, there is something you can do to make it better.

Recently, the ASHP unveiled an easy-to-use online tool for hospitals to report when drug packages have unreadable bar codes or do not have bar codes at all. Go to ASHP Drug Product Bar-Code Problem Reporting Center:

http://www.ashp.org/s_ashp/doc1c.asp?CID=4060&DID=7025

Widespread, faithful reporting will aid ASHP in identifying packaging issues and facilitating communication with manufacturers, FDA, PhARMA, and safety advocacy groups to encourage them to address the problems.

It's sort of like a neighborhood crime-watch program that works best when everyone exercises vigilance. So start reporting barcode problems, send this link to your colleagues, and encourage them to become reporters too.

In all honesty, if we don't hold the manufacturers' feet to the fire on this, then I believe we must share some of the blame and have little reason to complain about those unscannable meds.

Please, tell the manufactures what you've been thinking!

A handwritten signature in black ink, appearing to read 'MNU' with a long horizontal flourish extending to the right.

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May 2007