

I've been **thinking**...



Fingers crossed as FDA considers modifying drug bar-code packaging rule  
July 2011

**I've been thinking** about baseball, movies, ambiguous bar codes, and the FDA.

On June 26, 1974, New York Yankee All-Star Derek Jeter was born, two-time Academy Award winner Elizabeth Taylor divorced (for the fifth time), and Sharon Buchanan, a young grocery clerk in Troy, Ohio, was the first ever to ring up a retail purchase by scanning a bar code. On the same day in 2011, I drove from Arlington, Virginia, to Silver Spring, Maryland, to meet with people at the FDA to talk about the future of bar-code labeling on drug packaging.

Speaking of movies and baseball, did you enjoy Sandlot as much as I? The movie is set in a Los Angeles suburb like Lynwood where I played little league during the early 1960s—the era in which the drama unfolds. One afternoon, some little boys of summer bump into a game delay. Their sandlot, gloves, and bat are not much good without a ball. Scotty, the least-skilled, most-ridiculed boy on the field, wears a quick path to acceptance by borrowing a baseball from his stepfather's collection of sports memorabilia. The treasure had been autographed by the pin-stripped legend—Babe Ruth. “Play ball!”

At the turn of the millennium, forward-thinking hospitals, interested in incorporating bar coding at the point of care, met with their own game delay. We had access to computers, scanners, and electronic-medication-administration software—everything but bar-coded medications.

Finally, in February 2004 (after several years of drafts, comments, hearings, and more comments), the FDA issued a [requirement](#) that manufacturers and repackagers must include bar codes containing National Drug Code (NDC) numbers on all immediate drug packages. “Play ball.”

While some of us were disappointed the regulation restricted machine-readable codes to a simple linear format (why not more complex data-rich codes?), we were just glad to have a ball to hit. And, though many of us had hoped the Feds would also have required encoding lot numbers and expiration dates, we were consoled by their promise to revisit such requests at a later date.

In retrospect, I believe the FDA's decisions were wise. Including lot and expiration would have necessitated two-dimensional (2-D) codes at a time when the advanced-imager technology required to read them was outside the reach of most hospitals.

Like Liz's unions, prior to the regulation, numerous marriages of scanning with medication administrations had their struggles. But I could argue there would have been many more failures in the ensuing years had Silver Spring not restricted their regulation to linear bar codes and minimal information.

Keeping true to their promise, on May 31, 2011, the FDA posted a [notice](#) entitled, “Updating regulations in recognition of changing technology.” The announcement said they had been considering which economically significant rule to subject to a cost-benefit reassessment, and they have tentatively concluded that the Bar Code Rule is the best candidate for such review. “The goal of the review,” the memo stated, “will be to assess the costs and benefits and to determine if the rule should be modified to take into account changes in technology that have occurred since the rule went into effect.”

This announcement prompted my FDA visit where the thoughtful people I met with listened carefully and spoke sparingly. They did agree that “changes in technology” include (whatever else) newer machine-readable codes and the devices required to read them. However, they also made it clear that the FDA has not and will not make modifications to the bar-code rule before receiving comments, holding hearings, and weighing the input.

While newer codes could range from 2-D bar codes to radio-frequency ID (RFID) tags, which require devices from imagers to RFID readers, I cannot imagine that the FDA’s next rule modification would be so encompassing. If the administration acts, and I believe it will, I predict that “linear” will be lifted from the requirement, allowing 2-D into the game. I can’t imagine they’ll write RFID into the rulebook this time around. Expect their 2004 logic to prevail and accommodate technology that most hospitals have or can readily obtain rather than allow for technology whose ubiquity is years if not decades away. Presently, most bar-coding hospitals utilize imagers capable of processing today’s 2-D as well as yesterday’s linear codes.

Once the linear limitation is removed from the bar-code requirement, I anticipate manufacturers will move rapidly toward 2-D for both external and internal reasons. Externally, I anticipate numerous hospitals asking drug companies for 2-D, and if (or should I say when?) any one of them rushes to comply, competitors will waste little time following. Internally, drug manufacturers and repackagers will be happy to use 2-D codes since they require less label real estate than linear codes.

If FDA modifies the rule to require lot and expiration date (they might, and I hope they do), labelers will surely have to convert to 2-D formatting to include this additional information without making their packages bigger. However, even if FDA doesn’t require lot and expiration, I anticipate most manufacturers will add both simply because with 2-Ds they can.

Beyond their value to accommodate lot and expiration, I will push for 2-D codes because it will help solve another problem we have with today’s drug package codes—namely, the ambiguity inherent in strings of non-delineated numbers embedded in linear bar codes.

Stick with me through one complex paragraph of explanation. Each NDC contains a triplet of numbers: one number for the labeler code, another for the drug code, and a third for the package code. To make matters worse, labeler codes may be four or five characters, and drug codes may be three or four characters, and package codes may be one or two characters—making it impossible to tell where one piece of information ends and the other begins. Since these numbers appear without delineators, computing systems can’t discern if 1234567890 means 1234-5678-90, 12345-678-90, or 12345-6789-0.

Human eyes bump into a similar problem with some URLs. Though computers get the addresses correct, sometimes it's impossible for us to know exactly where one word ends and another begins. Note the ambiguity of these examples:

shortstoponsubway.com<sup>1</sup>

lionstalking.com<sup>2</sup>

therapistfinder.com<sup>3</sup>

Ambiguity may be fun when decoding URLs but it's no laughing matter when it shows up in strings of numbers, which can create medication errors if not rightly divided.

Two-D codes carry enough characters to allow for the insertion of delineators to correctly parse the numbers represented in bar codes.

Please, FDA, help us get this right.

What do you think?



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PS I just got off the phone with Sharon Buchanan. She told me she had her wristband scanned during a recent hospital stay. Oh, and that she's a Red's fan, and her husband thought Liz was a knockout back in the day.

Last month I had dinner with people from Liz Taylor's hospital. They've hit the ball out of the park! Shortly after the actress passed away, Cedars Sinai rolled out bar coding house wide.

Derek Jeter was not available for comment.

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<sup>1</sup> short stop on subway or shortstop on subway or shorts top on

<sup>2</sup> subway lion stalking or lions talking

<sup>3</sup> therapist finder or the rapist finder