

even more noteworthy because some FCC Commissioners did not favor significant regulatory intervention in the market (Ref. 38 at p. 1).

Our case is similar to the FCC's in the sense that we have an objective (reduction of medication errors) that can be achieved through bar codes, but hospitals are reluctant to invest in equipment because of the lack of bar coded products, and manufacturers, repackers, relabelers, and private label distributors are reluctant to invest in such bar codes or other technologies in the absence of a demand by hospitals or a requirement for such bar codes. If we fail to specify a particular measure, such as a symbology or standard, progress towards medication error reduction through bar codes could remain stalled; hospitals might still be reluctant to invest in equipment because of uncertainties in the marks, symbols, or technologies used on the drug or a limited amount of resources to buy different types of equipment to read the various marks, symbols, or other technologies. Likewise, manufacturers, repackers, relabelers, and private label distributors might not invest in bar codes or other technologies because no demand would exist or because their investments in such bar codes would be wasted if hospitals declined to buy the necessary equipment to take advantage of those bar codes or other technologies.

Consequently, proposed § 201.25(c)(1) would require the bar code for drugs and biological products (other than blood and blood products) to be any linear bar code in the UCC/EAN standard. This means that the bar code can be any linear bar code symbology, such as UCC/EAN-128, RSS, or UPC (if the UPC contains the NDC number), within the UCC/EAN standard. Adopting a linear bar code in the UCC/EAN standard, as opposed to a specific bar code symbology, should give firms some flexibility in selecting the bar code symbology that best fits their needs and should also give the rule some flexibility as linear bar code symbologies change, are added, or are phased out. For example, we know that the UCC has announced a "sunrise" date of 2005 for a new EAN-13 code because the commonly-used UPC code is running out of new company prefixes for that 12-digit code (Ref. 39). So, as new linear bar codes are added to the UCC/EAN standard, those new codes would be acceptable under the proposed rule as long as those new codes include the NDC number.

The UCC/EAN standard also has the advantage of being a widely used global standard. One comment submitted on behalf of the International Working

Group on Barcoding of Pharmaceuticals advocated the use of the UCC/EAN standard because it represents a "validated, testable global standard." The comment also suggested that regulatory authorities from Europe, Japan, and Canada are actively pursuing a bar code standard for pharmaceuticals and "are watching to see what the FDA decides." Comments from the UCC, EAN, and some pharmaceutical interests also mentioned the global applicability of the UCC/EAN standard.

We recognize that other bar code standards exist, notably those advanced by the Health Industry Business Communication Council (HIBCC). HIBCC bar code symbologies include code 39 and code 128. (The UCC/EAN system also has a UCC/EAN-128 symbology that is similar, but not identical, to the HIBCC code 128.) HIBCC also has the Universal Product Number (UPN) system which is used for medical and surgical products. Comments from drug and biological product companies, however, usually referred to UCC/EAN standards if they identified any standard at all, so we presume that the use of UCC/EAN standards would be less disruptive to those industries compared to requiring the use of a different bar code standard. However, a comment from HIBCC suggested that some drugs may use HIBCC bar codes, that medical devices, in particular, are "uniquely identified by the UPN number," and that the Department of Defense, Veterans Administration, and other organizations use the UPN numbering system. Therefore, we cannot preclude the possibility that some drug firms and organizations may use or prefer to use HIBCC bar codes, so we invite comment as to whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.

Our position presumes that, by the time any final bar code rule becomes effective (assuming that we do issue a final rule), bar code scanners will be able to read different UCC/EAN linear bar code symbologies reliably and efficiently. This is a critical consideration because the proposed rule's benefits are realized only if hospitals invest in bar code scanners, and we reiterate that their willingness to make that investment may depend on the number of different bar code symbologies that will be used and the ability of bar code scanners (particularly those scanners already in use at the hospitals) to read different symbologies. Comments from the public meeting disagreed on what capabilities different bar code scanning technology had to

read different symbologies. Some comments suggested that new bar code scanners can read different linear bar code symbologies, particularly those in the UCC/EAN standard. In contrast, others suggested that bar code scanners may be unable to read newer bar code symbologies or that older scanners cannot read new symbologies or composite codes. Our understanding is that scanner capability depends on how the scanner is programmed (because scanners are programmed to read individual symbologies) and whether scanners can be upgraded or modified to read new symbologies. For example, some bar code scanners might be programmed to read the most commonly used linear bar codes and might not be able to read the RSS symbology. Some scanner manufacturers may be able to upgrade or modify an existing scanner to read newer symbologies, while other scanners, due to their age or the manner in which they were made, might not be capable of being upgraded. We invite further comment on this point.

As for non-bar code technologies, we know that other technologies exist or are under development, but we decline to specify the use of DataMatrix or other nonlinear bar code formats or technologies, such as radio frequency identification (RFID). We realize that other technologies may be able to encode more data or be more versatile compared to linear bar codes. For example, in a meeting with the National Alliance for Health Information Technology, we heard how RFID could be used to facilitate inventory control and to track individual items because each RFID tag would have its own unique "electronic product code" (EPC) consisting of a header code, an "EPC manager" that would probably identify the product's manufacturer, an "object class" that would refer to the product type, and a "serial identifier" that would be unique to each individual item. RFID's ability to track individual items could help drug companies and public health agencies identify and eliminate counterfeit drug products. However, the costs associated with RFID tags and readers could be significant; literature provided by the Auto-ID Center conceded that current RFID tags are "fairly expensive" and that a firm might have to purchase more than one reader if multiple RFID frequencies exist (Ref. 40). A representative from the Auto-ID Center stated that the "target cost" is five cents per RFID tag, so the technology could become more available and less expensive in the future.

Nevertheless, we find that linear bar codes are sufficient for encoding NDC