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**Comments on "Bar Code Label Requirements for
Human Drug Products"**

By

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My name is Joseph Cranston. I am a pharmacologist by training and I currently serve as the Director of Science, Research and Technology at the American Medical Association (AMA). The AMA is the largest national professional association representing physicians and physicians-in-training, and I am speaking on behalf of the AMA at this public meeting.

The AMA has had a longstanding commitment both to improve the quality of medical care delivered by physicians to patients and to promote efforts that will improve patient safety. For example, the AMA established the National Patient Safety Foundation in 1997 and has participated in a number of initiatives on clinical quality improvement. The AMA also has been a partner and strong supporter of MedWatch, the FDA's adverse event reporting program.

In 1999, the Institute of Medicine published its seminal report, *To Err is Human*, which raised public awareness to the important issue of patient safety. As discussed in that report, there is considerable documentation in the medical literature that medication errors result in numerous patient injuries and deaths. This situation is unacceptable and efforts must be made to minimize medication errors.

Evidence suggests there are numerous causes of medication errors and, therefore, a variety of approaches will be needed to address this problem. The implementation of new information technologies is an area that offers enormous opportunities to improve patient safety. The use of machine-readable coding, i.e., bar coding, is one such technology.

The incorporation of scannable bar codes, in a standardized format, on all medication packages and containers should help ensure that the right drug and dose are administered to the correct patient. Thus, the AMA supports and encourages efforts to create and expeditiously implement a national machine-readable coding (bar coding) system for prescription and over-the-counter (OTC) medicine packaging in an effort to improve patient safety. The extension of bar coding to other FDA-regulated products, such as blood products, vaccines, and certain medical devices, also appears to be a reasonable and attainable goal.

The AMA has no official position on the specific elements that should be included in a Proposed Rule on bar coding. As a general comment, the AMA encourages the FDA to balance the need to put uniform bar code standards into place as soon as possible to reduce medication errors with the need to not stifle further innovation in bar code technology.

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As a start, the AMA believes the June, 2001 recommendations of the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) entitled, "Preventing and Standardizing Bar Coding on Medication Packaging: Reducing Errors and Improving Care," should be given strong consideration by the FDA. The NCCMERP recommendations were developed by a coalition of stakeholders, including representatives from medicine, pharmacy, nursing, consumers, risk managers, hospitals, accrediting bodies, the pharmaceutical industry, and government agencies (including the FDA). In developing its recommendations, the Council conducted a thorough literature review and held a conference of invited experts in August 2000 to discuss needs assessment, current standards, equipment manufacturers, and cost implications. While the NCCMERP recommendations on bar codes focused on institutional settings, such as hospitals, the recommendations may be applicable to other settings.

The FDA is undoubtedly very familiar with the NCCMERP recommendations. However, the AMA would just like to briefly mention some of the key points for the record.

1. The FDA, the USP, the pharmaceutical industry, and other appropriate stakeholders should establish and implement uniform bar code standards down to the immediate unit-of-use package, as defined in the USP/NF.
2. The bar code should contain three data elements:
 - A uniform National Drug Code (NDC) number as the primary unique product identifier;
 - Either the lot/control/batch number as one secondary identifier; and
 - The expiration date as another secondary identifier.
3. The three data elements, i.e., the NDC, lot number, and expiration date, should be uniformly ordered on the bar code using existing symbologies.
4. There should only be one bar code on the label and it should have a standardized location.
5. The bar code should be included on the immediate container labels of all commercially available prescription and OTC medications, in any dosage form, on intermediate containers or cartons, and on shelf keeping units.

As emphasized by NCCMERP, its recommendations are a "first step to the ultimate use of bar codes in the medication use process." Before hospitals, physicians, pharmacists, nurses, and especially patients can benefit optimally from this technology, bar codes must be uniformly present in a standardized format on unit-of-use packaging of all commercially available prescription and OTC drug products.

In conclusion, the implementation of a national system for bar coding of commercially available drug products, and possibly other FDA-regulated products, should help physicians and other health professionals to decrease the number of medication errors and the harm to patients that is associated with these errors. The AMA urges the FDA to quickly move forward with a Proposed Rule to require bar codes on drug product packaging.

Thank you.