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Date: June 5, 2003

To: Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

From: Medi-Span and Facts and Comparisons
Divisions of Wolters Kluwer Health
161 North Clark Street, 48th Floor
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Re: FDA proposed rule: Bar Code Label Requirements for Human Drug Products and Blood [Docket No. 02N-0204]

Medi-Span and Facts and Comparisons, divisions of Wolters Kluwer Health, would like to commend the FDA for its proposed rule requiring bar codes on all prescription drugs, some over-the-counter drugs and vaccines. We believe that widespread adoption of the use of bar codes will reduce medication errors and improve patient safety. We applaud the leadership role of the FDA and agree that government regulation will hasten the adoption of this technology.

Medi-Span has provided comprehensive, integratable drug databases for more than thirty years to healthcare professionals worldwide. The Medi-Span product line is an accurate and trusted drug information source that integrates with current software applications. For more than fifty years, Facts and Comparisons has been an essential source for drug information, offering trusted, unbiased drug information in a variety of formats. We, too, are committed to improving patient safety.

While we support the efforts of the FDA and adoption of the use of bar codes, we do have some concerns as they relate to other aspects of the proposed rule. Specifically, we have significant concerns regarding 1) the proposal to redefine the National Drug Code (NDC) number and 2) several aspects of the proposal implementation in general.

First, with regards to the redefinition of the NDC, we will submit complete comments to the FDA separately from our comments contained here, as we are not aware of any current proposed rule for this initiative. However, we feel compelled to raise some of our concerns here because this issue has been included in the bar code proposed rule.

The FDA implies that the current method of assigning and maintaining NDC numbers is inadequate, confusing and, ultimately, a negative impact on patient safety. While we agree that the current method has some limitations (e.g., duplicate NDC numbers), we also feel that these occur rarely and there is little evidence of compromised patient safety. Conversely, because current NDC numbers are used in millions of patient profiles to identify currently prescribed drugs, recent historical drug information and archived drug history, modifying tens of thousands of NDC numbers would create significantly more confusion, potentially resulting in harm to patients and therefore undermining the desired outcome of the proposed rule. Medi-Span and Facts and Comparisons are willing to collaborate on an on-going basis to bring these discrepancies to the attention of the FDA so that you can address compliance issues related to current regulations.

Again, we will address this issue fully in a separate response to the FDA.

Secondly, we disagree with many of the additional proposed interventions designed to "complement" this proposed rule. We think that they are burdensome, expensive and unnecessary to accomplish the stated goals of the proposed rule. In the absence of these additional interventions, several hospitals, including those operated by the Department of Veteran Affairs, that use bar code technology as is, have already seen significant decreases in their medication error rates ranging from 71% to 86%*. These percentages already exceed FDA estimates of a 50% increase in the interception of medication errors at the dispensing and administration stages.**

The FDA has expressed a desire to maintain a database of all NDC numbers, proposed the provision of a government maintained database that would contain bar code accessible information including drug strength, dosage form, route of administration, active ingredients and drug interactions and ensures availability for use in commercial computerized systems. It is not clear how they would ensure availability and exactly to whom it would be available. It is our belief that the industry, markets and customers are already well served with regards to the availability of such information. In addition, many users of this information rely on daily updates to this type of information. It is unclear how the FDA could reliably provide updates in this time frame. We feel that the creation of such a database is duplicative and that distribution of this data is best served by existing knowledge-base vendors through existing delivery channels. If the NDC-based database is to be provided by the FDA, the economic impact of commercial computerized systems to implement this file has not been addressed in the proposed rule.

We strongly support the requirement of manufacturers to provide bar codes on their products and feel it is an important step towards improving patient safety. Requiring manufacturers to include bar codes on their products will certainly provide incentive to speed the acceptance and use of this life-saving technology. We believe the goals of the proposed rule can be achieved through this intervention alone and that the additional interventions outlined in the proposal are unnecessary and may, in fact, have a negative impact on patient safety.

We urge the FDA to confine the proposed rule to only address the provision of bar codes by manufacturers and the bar code's symbology and to allow the private market to continue to address the other initiatives discussed in this proposal.

Should the FDA desire, we would be happy to discuss these issues further.

Sincerely,

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* - U.S. Food and Drug Administration. *"Questions and Answers Regarding the Bar Code Proposal"*. Available at http://www.fda.gov/oc/initiatives/barcode-sadr/qa-barcode.html.

** - U.S. Food and Drug Administration "FDA News". *"FDA Proposes Drug Bar Code Regulation"* March 13, 2003. Available at http://www.fda.gov/oc/initiatives/barcode-sadr/fs-barcode.html.