

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:34 PM
To: Butler, Jennie C
Subject: FW: Request to speak at public bar coding meeting.



WordPerfect 6.1

-----Original Message-----

From: Dede Spitznagel [mailto:dspitznagel@HLC.ORG]
Sent: Friday, July 12, 2002 4:05 PM
To: grossm@cder.fda.gov
Cc: mgrealy@HLC.ORG
Subject: Request to speak at public bar coding meeting.

Dear Mary,

Following up on our telephone conversation in May, and the voice mail message I left earlier this week while you were on travel, I have attached the Healthcare Leadership Council's position statement on the FDA's intent to develop bar code label requirements. As I mentioned previously, HLC is unique in that it represents all health care industry sectors that would be impacted by such bar code requirements. The attached statement is 5 pages, but in summary, the specific recommendations begin at the bottom of page 3. If invited to participate on your panel, either Mary Grealy, our President, or one of our member executives would present. For more information about HLC, please see www.HLC.org. Thank you for your consideration. My contact information is below.
Dede Spitznagel

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**Statement of the
Healthcare Leadership Council**

**before the
U.S. Food and Drug Administration**

**Public Meeting on
Bar Code Label Requirements for Human Drug Products
[Docket No. 02N-204]
July 26, 2002**

BACKGROUND

The Healthcare Leadership Council (HLC) is a coalition of chief executives representing all disciplines within the healthcare system that jointly develops policies, plans and programs to achieve our vision of an effective 21st century healthcare system. The safety of the nation's health care system is a top priority for HLC. We appreciate the opportunity to submit the following comments in regard to the Food and Drug Administration's impending regulation on bar code labeling for human drug products.

The Healthcare Leadership Council is unique in that it represents all sectors of the health care industry that would be affected by the FDA's bar coding regulation, including hospitals and hospital systems, pharmacies, pharmaceutical companies, pharmaceutical and medical-surgical distributors, and medical device manufacturers.

In 2000, the Healthcare Leadership Council created a Chief Executive Task Force on Patient Safety so that these various sectors of the healthcare industry could work together to help elevate public confidence in the safety of the nation's healthcare system. The objective of this task force is to collaborate on specific, evidence-based, pragmatic solutions and innovations that have the potential to substantially improve quality and reduce patient errors. We believe that by focusing on measurable and achievable solutions as our core priority, the public will be assured of a system dedicated to safety and continual improvement. Based on a survey of potential patient safety initiatives that were consistent with this objective, HLC's Task Force on Patient Safety determined that electronic verification of drugs at the point of administration ("bedside bar coding") should be a high priority initiative. We believe that automated drug identification has the

potential to greatly limit the incidence of medication errors.

ISSUE

The delivery of medications is a complex process that requires the coordination of numerous disciplines and involves a variety of delivery and administration procedures. When these procedures rely on manual systems and memory, they create an environment that can promote errors. A 2000 study by the U.S. Pharmacopeia indicated that, while medication errors occur at all stages of the medication use process, they most frequently occur at the administration stage. This is critical since the administration stage is the final link in the medication process chain, with little opportunity left to halt an error before harming the patient. Medical researchers agree that most medication errors can be prevented and technology – specifically automated identification of unit of use packages at the patient bedside – has great potential for reducing the frequency of these errors.

A Veterans Affairs medical center implemented a bedside verification system for medication administration and found that zero errors occurred when the system was used as designed. The VA medical center found that bar coding significantly reduced medication errors. The system prevented 378,000 errors, or 5.6 percent of all doses.

The Institute of Medicine (IOM) announced in its 1999 report, *To Err Is Human: Building a Safer Health System*, that as many as 98,000 Americans die each year as a result of medical errors. This report specifically recommended more use of bar-coding for medications at the patient bedside.

RECOMMENDATIONS

HLC members have long been active in seeking to improve safety, and their efforts include a broad range of ongoing programs. Several of our hospital and pharmaceutical members, as well as our medical device and technology manufacturers, have extensive experience with automated identification of medical products using bar codes.

In preparation for this hearing, HLC assembled a panel of experts from our member organizations to evaluate auto-identification options and to develop recommendations for the FDA. This diverse group identified numerous issues and developed a consensus position and recommendations. Our recommendations consist of a set of broad guidelines and a set of specific recommendations.

A. Broad Guidelines

The impact on patient safety of any FDA regulatory standards for auto-identification will

be strongly dependent upon the “usability” and acceptance of the standards. The prevention of medication errors requires the cooperation of numerous parties along the drug supply chain, from the creators of the bar code printing equipment to the nurse administering the dose at the patient bedside. HLC recommends the following guidelines to ensure a harmonious system that will be highly effective in the reduction of errors.

1. **Be pragmatic:** Auto-identification standards for pharmaceuticals should support the highest level of patient safety possible through the most feasible and cost efficient approach that can be implemented in the shortest period of time.
2. **Build upon, but do not disrupt, current market forces:** Auto-identification, using bar codes in most cases, is growing in use. Many pharmaceutical companies are printing bar codes, when possible, on their unit of use packages, and hospitals are increasingly adding auto-identification to their information systems. This process has been self-initiated or facilitated through market demands. Any FDA standards should be careful not to disrupt this process or to discourage unit of use drug packaging by putting in place requirements that are overly expensive or highly difficult to implement.
3. **Consider the labor impact:** An FDA bar code labeling regulation should serve to reduce, rather than increase, the work force needs of health care organizations over current practices.
4. **Promote emerging technologies:** The FDA should allow for flexible regulations that can accommodate new, more effective technologies as they become available. While “barcoding” may be the auto-identification technology of choice at this time, radio-frequency, dot matrix, or other similar technologies may prove to be more effective and less costly in the future.

B. Recommendations Specific to Bar Code Labeling

Notwithstanding our above recommended guideline to accommodate evolving technologies, HLC is forwarding the following recommendations specifically related to the use of bar coding in response to the FDA’s published notice of its intent to develop a bar code labeling regulation.

1. **Products to be bar coded:** If the FDA determines it is necessary to *require* bar coding, the requirement should be limited initially to unit of use drug and biologic packages used in the institutional environment only, including both prescription and over-the-counter medications.

2. **Data elements to be included in bar code:** Initially, bar code data element requirements should be limited to the national drug code (NDC) number. The NDC contains the necessary information to ensure that the patient is being administered the right drug in the right dosage. The addition of lot number and expiration date should be considered when the technology for printing more dense bar codes is more widely available, and research is conducted showing that patient safety is enhanced with this additional information proportional to the cost of implementation. The FDA currently requires lot number and expiration date to be included in human readable form on the drug package, which should be sufficient for recall purposes and for determining if a drug is still within the effective date.
3. **Bar code symbology:** In the near term, the FDA should not require the application of bar codes beyond the widely used linear, one dimensional bar code symbology that conforms to HIBCC or UCC/EAN standards. Requiring the immediate use of reduced space symbology (RSS) or two-dimensional bar codes (as would be necessary if bar codes are required to include lot number and expiration date) would result in substantially increased pharmaceutical manufacturing and packaging costs. Using existing bar code printing equipment, RSS and two-dimensional bar codes could reduce package printing and verification productivity by 25 to 40 percent. In addition, existing hospital bar code scanning equipment must be reprogrammed to read the newer bar code symbologies. As mentioned previously, however, we strongly believe in supporting emerging technologies and we do not advocate *prohibiting* the use of two-dimensional, RSS, or other types of more advanced bar codes. We suggest that the FDA consider conducting research to determine an appropriate time line for introducing specific standards for RSS, two-dimensional, and other developing auto-identification symbologies.
4. **Bar code location:** The FDA should not limit flexibility by specifically mandating the location or position of the bar code on the package. In developing this regulation, the FDA should not include extraneous requirements that are only peripherally related to patient safety.
5. **Containers to be bar coded:** Bar code requirements should apply to containers that are the most critical to medication safety; this includes the immediate containers of unit of use-packaged drugs. Less than 30 percent of drugs are now bar coded at the unit of use level, whereas over 95 percent are bar coded at the outer carton level as a result of purchaser demand for inventory control and other reasons.

An additional consideration for FDA is that unit of use containers come in various shapes and sizes – and some are more easily barcoded than others. Examples of

such various unit of use forms include oral solids, oral liquids, topical creams, pre-packaged unit-dose syringes, vials, and ampules. Because of their very small size or irregular shape, some of these unit of use drug containers are more difficult to print with bar codes than others – especially in an automated printing system. Consideration should be given as to the difficulty of printing and scanning bar codes on very small, oddly shaped containers such as certain vials and ampules.

6. **Label approval requirements:** The FDA should re-evaluate its annual label review process with respect to label changes that may be necessary to accommodate bar codes. They may also need to consider eliminating some label information which is currently required.
7. **Phase-in schedule:** Any regulation should take into consideration the time and expense required to re-tool packaging operations, including purchasing new printing and verification equipment, redesigning package artwork, and re-filing for label reapprovals. A feasible phase-in schedule will help to ensure that the FDA's regulation does not discourage unit of use drug packaging.

It is important to note that printing bar codes on drug labels will not be effective unless medical facilities implement the equipment and systems necessary to use the bar codes for safety purposes. Less than five percent of hospitals in the U.S. have in place the hardware, software, and training programs to conduct patient bedside bar coding. Hospitals need to be assured that sustainable bar coding equipment and software compatible with their existing information technology is available. This should be taken into consideration when determining the effective date for this regulation. Additionally, we recommend that the FDA continue to revisit and update any standards developed in this area to ensure they are current in this environment of fast-paced technology development.

8. **Complementary funding initiative:** To maximize effectiveness of bar coding regulations, the FDA or other agencies within the Department of Health and Human Services should consider including a grant program to assist hospitals in acquiring technology necessary to implement auto-identification of drugs at the patient bedside.

CONCLUSION

The Healthcare Leadership Council believes that the combination of executive-led, holistic systems of safety, and automated information technology to corroborate human safety systems, will reduce the incidence of medication errors. Automated drug identification is an important element in the effort to achieve a zero-error health care environment and to instill even greater public confidence in our health care system. We are encouraged that the U.S. Food and Drug Administration is exploring ways to help

make implementing auto-identification increasingly effective and we stand ready to assist the agency at your request.