

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:18 PM
To: Butler, Jennie C
Subject: FW: Bar code testimony ISMP



FDA Bar Coding
7-26 doc

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

From: Mike Cohen [mailto:mcohen@ismp.org]
Sent: Friday, July 12, 2002 12:43 PM
To: grossm@cdcr.fda.gov
Subject: FW: Bar code testimony ISMP

Attached is ISMP testimony for BC meeting. Thanks, Mike

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02N-0204

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Summary of presentation by Michael R. Cohen, RPh, MS, ScD at the Food and Drug Administration's July 26, 2002, public meeting on bar code labeling for drug products.

Docket No. 02N-0204

Good afternoon. Thank you for the opportunity to speak with you this afternoon about this important health care safety regulation. I am Michael R. Cohen, president of the Institute for Safe Medication Practices (ISMP). ISMP is an independent, nonprofit organization that works closely with practitioners, regulatory agencies, health care institutions, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. A board of trustees representing the health care community at large governs this interdisciplinary effort by nurses, pharmacists, physicians and health care consumers. Our primary focus has been on proper and safe use of medications. We have a long history of learning about medication errors from health care practitioners and consumers who voluntarily report medication errors and hazardous conditions through a national reporting program operated by the United States Pharmacopeia. All reports are shared directly with the US Food and Drug Administration, Office of Drug Safety. Dialog with FDA is ongoing when reports relate to drug nomenclature issues (proprietary and nonproprietary names), or pharmaceutical labeling, packaging and medical device design.

Medications are a blessing, but humans must safely prescribe, prepare, dispense, and administer these drugs. Yet humans are fallible, and as clearly articulated in the recent reports by the Institute of Medicine (IOM), errors and other adverse events occur and cause unbearable human and financial cost. Medication use has been further complicated by the large number of new drugs introduced every year, an increasing elderly population with chronic and acute conditions requiring complex treatment strategies, and the proliferation of over-the-counter products. In light of this fact, much can and should be done to enhance medication safety.

An important advance to help identify medications in the processes of drug procurement, inventory, storage, preparation, dispensing, and administration has been the use of bar code scanning of medications. This technology used in many other industries has gained rapid acceptance in the health care industry. Today many community pharmacies, mail order pharmacies, and hospital pharmacies have adopted bar code scanning of medications to ensure the correct preparation and dispensing of medications. In the acute care setting especially, the use of bar code scanning of the health care provider, the medication, the patient's medical record, and the patient themselves helps assure the safety in drug administration. Rather than repeat many of the reasons why bar coding of

medications by manufacturers are needed and the symbologies and components of the bar code I wish to focus my attention on the necessity of bar codes on unit dose packages of medications and most importantly that bar coded unit dose packages of medications remain readily available from the manufacturers.

The importance of unit dose medication dispensing in the acute care setting has been advocated since the 1960's. The American Society of Health-System Pharmacists, the Joint Commission on Accreditation of Healthcare Organizations, and other organizations are leaders in promoting unit dose drug dispensing. Although this is a proven safe way to provide medications in the acute care setting, especially with the recent use of bar code scanning to match patient specific doses with the patient and their record we are experiencing a decrease of the availability of unit dose packaging by many manufacturers. Our fear is that many more manufacturers will cease to provide unit dose medications if a bar coding regulation is put in place. We believe that a regulation is needed but that an important component of the regulation must be that manufacturers provide unit dose packaging of medications with a bar code. As I mentioned previously, ISMP receives error reports from practitioners but we also receive reports of hazardous conditions and safety concerns from practitioners. One of their concerns that have been brought to our attention repeatedly in the last few years is the unavailability of unit dose packaging by manufacturers. This is not only on new medications introduced into the marketplace but also the discontinuance of previously available unit dose packaging of medications.

I would like to review a survey ISMP did of the readership of its *ISMP Medication Safety Alert!* in the late winter of this year. The safety alert is distributed to the majority of hospitals in the United States as well as several foreign countries and many ambulatory health care settings. Our readership exceeds 500,000 per issue. We inquired from our readers their experiences with the availability of unit dose packaging of medications. The results of the survey showed that:

- Three-quarters of respondents reported problems with unit dose packaging of both new and well-established **brand** oral solid products on the market, including those that had been previously available in unit dose packages. A third reported about 6-10 *brand* products that have not been available in unit dose packaging in the past year. Another quarter reported problems with 11-20 *brand* products, and over 6% reported problems with more than 40 different *brand* medications that were no longer available in unit dose packages last year! Even more experienced problems with **generic** oral solid products.
- Most respondents who repackaged medications now estimated a 1-10% error rate due in some part to the repackaging process. Many also told us they were worried about the cost of implementing bar code technology, especially in small, rural hospitals, and in pediatric hospitals because so many drugs are not available in unit dose packages.

It was clear from our survey that, despite some initial worry about costs, many hospitals are ready to do their part to move bar coding technology forward. About half now consider the availability of unit dose packaging when making decisions about new drugs for the formulary, and two-thirds reported that they would be more likely to select a therapeutically equivalent product if it is available in unit dose packaging. More to the point, 84% felt that a slight increase in cost would not deter them from purchasing a

specific vendor's unit dose medication with a bar code. About 62% felt very strongly on this issue. Only 11% felt that a slight cost increase would be a deterrent. On behalf of its members, group-purchasing organizations have begun to stipulate the need for bar coded unit dose packaging.

ISMP strongly recommends that the FDA require bar codes on all medications. This includes proprietary as well as nonproprietary medications. We also support the specific bar coded requirements included in the recommendations of the American Society of Health-System Pharmacists but also encourage the FDA to ensure that the pharmaceutical industry does its part and make all products available in unit dose packages with this uniform bar code.

Thank you for the opportunity to speak today.