



August 9, 2002

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

Re: Docket No. 02N-0204

Dear Sir/Madam:

The Academy of Managed Care Pharmacy (AMCP) is pleased to be able to provide input to the Food and Drug Administration on the topic of bar code labeling of human drug products.

AMCP is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to over 200 million Americans served by managed care.

The Academy supports the labeling of all drug product containers with a standardized machine-readable code (bar code), including single-unit containers, which are critical in health care drug distribution systems. The reasons for endorsing the use of bar-coding for all drug products include:

- The improved efficiency in the processes of drug purchasing, storage and distribution in the pharmacy setting;
 - The increased safety for patients that would result as the medication and dose are verified for accuracy at the point of dispensing;
 - The ease of patient dosage history record-keeping;
 - The availability of the technology required for such practice;
 - The positive identification of a drug from the vast array of other available drug products;
 - The willingness of pharmacists and pharmacies to embrace the new technology in an effort to improve patient service and safety;
- and

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College of Pharmacy
Columbia, SC

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Consultants, Inc
Northridge, CA

Director
Debbie Stern, RPh
Rxperts
Irvine, CA

Executive Director
Judith A Cahill, CEBS
AMCP
Alexandria, VA

02N-0204

C10

100 North Pitt Street
Suite 400
Alexandria, VA 22314

703 683 8416
800 827 2627

- The use of automation can reduce the demands on pharmacist's time; thereby freeing them for patient drug therapy management.

This is consistent with the Academy's policy digest statement on drug distribution systems (emphasis added):

*"AMCP encourages the use of new technologies for the dispensing of medications that can improve the quality of care. AMCP supports the use of unit-of-use packaging and **standardized machine-readable coding (e.g., barcodes)** to enhance patient safety, patient compliance and efficiencies in drug distribution and medication use processes."*ⁱ

AMCP believes that this issue is a top priority because of the safety implications for patients in this country. The inclusion of machine-readable coding on all drug product packages is a key step in applying technology to the prevention of medication errors. When machine-readable coding is used in centralized automotive prescription filling operations, (e.g. mail service), the medication error rates may range from **0.0000002%**ⁱⁱ to **0.002%**ⁱⁱⁱ depending on sources consulted. This compares to ambulatory medication errors rates of prescription dispensing ranging from **0.4%**^{iv} to **1.6%**^v where machine-readable coding is not used. As presented at the FDA Public Meeting on July 26th, 2002 regarding Bar Code Label Requirements for Human Drug Products, Kay Willis, Chief of Pharmacy at the VA Medical Center of North Chicago made the point that one Veterans' Affairs medical facility cut medication errors by 86% in the first year of adopting a bar code system.^{vi}

The Institute of Medicine's (IOM) 1999 Report, "To Err is Human: Building a Safer Health Care System," notes that bar coding is an "effective remedy" for medication errors, "a simple way to ensure that the identity and dose of the drug are as prescribed, that it is being given to the right patient, and that all of the steps in the dispensing and administration processes are checked for timeliness and accuracy."^{vii}

The Federal Register Notice for Bar Code Label Requirements places emphasis primarily on medication errors in the institutional setting; however, as described below, three times the amount of money is spent on prescription drugs in the ambulatory retail setting compared to institutional spending.

Total sales for 2001 for all prescription sold - based on 2001 Wholesale Acquisition Costs prices is **\$207.9 billion.**^{viii}

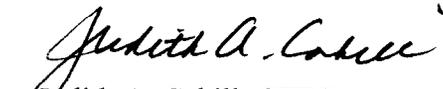
Retail / non-institutional sales (based on 2001 WAC prices) = \$154.6 billion (74%)^{viii}
Institutional sales (based on 2001 WAC prices) = \$ 53.3 billion (26%)^{viii}

There is not a one-to-one correlation of drugs dispensed to dollars spent, however. The dollar expenditure at the retail level reflects increased opportunities for medication errors to occur because the number of prescriptions dispensed based on dollars spent in the retail setting is far greater. In most cases, prescription drugs dispensed in the ambulatory setting are not as expensive as IV drugs and other complex drug regimens that are dispensed in the institutional setting. Therefore, one can conclude that the ratio of drugs dispensed in the ambulatory versus institutional settings is at least 3 to 1. Based on this phenomenon, it is essential to focus on reduction of medication errors in the ambulatory setting.

AMCP urges the FDA to address medication errors in this venue.

AMCP appreciates the opportunity to comment on this extremely important issue. We stand ready to assist the Agency in any way should we be requested.

Sincerely,



Judith A. Cahill, CEBS
Executive Director

¹ AMCP Policy Digest, Use of Drug Distribution Systems, 2001-11.

² Merck Annual Report 2000.

³ Live Life Well – Home Delivery Pharmacy, Merck-Medco, 2000.

⁴ Am J Health-Syst Pharm 1999, Jul 1:56(13):1319-25.

⁵ School of Pharmacy Takes Lead in Addressing Patient Safety Issues. UMB News. www.oea.umaryland.edu/news/2001/2001_101_medications_errors.htm, October 4, 2001.

⁶ FDA Told Barcodes on Drug Would Cut Errors. Reuters Medical News, www.medscape.com/viewarticle/439347_print.

⁷ Institute of Medicine, Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health Care System. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors. National Academy Press, p. 195.

⁸ NDCHealth Source® Database



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