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Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:25 PM
To: Butler, Jennie C
Subject: FW: AHA Presentation

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

From: John Combes [mailto:JCOMBES@Haponline.org]
Sent: Friday, July 12, 2002 2:18 PM
To: grossm@cder.fda.gov
Subject: AHA Presentation

Hi Mary, A summary of my presentation is attached. Please let me know the format of the panel: powerpoint or reading a statement etc. Thanks, John

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**Summary of the Testimony of the American Hospital Association
before the Food and Drug Administration on Bar Code Label Requirements for Human
Drug Products on July 26, 2002**

John R. Combes, MD, senior medical advisor for the American Hospital Association will present testimony on behalf of the AHA's nearly 5,000 hospital, health system, network, and other members. Our members are committed to providing safe, effective care and are pleased that the FDA is considering requiring the bar coding of drugs, devices and biologics to improve safety.

The lack of standards and uniformity in the technology has inhibited hospital use of bar coding. The AHA supports swift action to standardize the coding so it can be widely used. We believe the FDA should codify bar coding for pharmaceuticals now because it would be possible to accomplish this rapidly, and the FDA and the health care industry should develop a plan for the timely phase-in of bar codes on devices and other medical products for which bar coding cannot begin immediately. The AHA stands ready to assist the FDA in these efforts.

The AHA is a member of the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP) and supports its recommendations on standard preprinted uniform bar codes down to the unit-of-use level for all pharmaceutical products. At a minimum, the bar code for pharmaceuticals should include the National Drug Code (NDC). Including the expiration date and lot number would also be beneficial.

The AHA supports the labeling of certain medical devices with machine-readable codes when doing so will improve patient safety by allowing the tracking of device failures, device-related infections and unintended outcomes related to the use of the devices. Prior to proposing a rule for the labeling of devices, we need to determine for which devices bar coding has the potential to effect patient safety. The label for devices should include a unique identifier, including an indication of the manufacturer and the lot number.

Putting the bar code on the label is only the first step in a complex and costly series of changes that must be made. To use bar coding, hospitals must have information systems in place, complimentary technology and trained personnel to create a safer system. Some hospitals have already made significant investments in scanning technologies. Bar codes are currently used for laboratory specimen identification, blood and blood products, inventory control and automated dispensing cabinets. Any symbology adopted by the FDA should be compatible with current scanning devices. Thus, symbologies requiring optical scanning should not be mandated.

Recently the AHA convened multiple stakeholders interested in standardizing health care information technology to form the National Alliance for Health Information Technology. The first initiative of the Alliance is to promote the use of bar coding technology to create safer, more efficient and effective patient care. The AHA and the member of the Alliance are eager to work with the FDA and all stakeholders in advancing the science of safety for our patients.