



May 9, 2005

The Honorable Lester Crawford, Acting Commissioner
Food and Drug Administration
5600 Fisher Lane
Parklawn Bldg., Rm 14-7
Rockville, MD 20857

Dear Acting Commissioner Crawford:

As organizations with a continuing interest in improving patient care and efficiency for our nation's hospitals, we are interested in the Food and Drug Administration's (FDA) intentions to require the bar coding of medical devices and in fact, encourage swift action to promote public health and welfare.

As you will recall, in February 2004 the administration required electronically-readable bar codes on the packaging of hospital-administered drugs, biologicals and blood products. The measure, applicable to most drug manufacturers, repackagers, private label distributors and blood establishments, was billed by the department as a key strategy for protecting patients from preventable medication errors, improving overall patient safety, and reducing the cost of health care by driving greater delivery and supply chain efficiency.

When the FDA began its rule making process in 2002, it solicited comments on the bar coding of medical devices as well. As expected, the comments received spoke largely to the inherent promise of improved risk management through reductions in supply chain and medical errors. However, the FDA decided to only require the bar coding of drugs and biologics in the final rule due to the difficulty of implementing such a far reaching regulation – not because of any perceived error in extending this to medical devices. However, now that implementation of the February 2004 rule is almost complete, we urge you to revisit the issue of bar coding medical devices. It is a common sense next step in our shared goal of promoting patient safety, improving quality of care, and encouraging cost effectiveness and supply chain efficiency.

Furthermore, bar coding medical devices has vast potential for improved clinical product and service innovation. As the FDA itself has recently noted, a compelling patient safety interest also lies in requiring bar codes for medical devices that could be subject to recalls. Comprehensive data on – and the ability to conduct rigorous comparisons of – emerging health practices, products, and services is essential for both clinical and economic decision making.

We look forward to hearing from you and working with you on this important health care issue.

Sincerely,

Margaret R. Reagan
Corporate Vice President, Advocacy
Premier, Inc.

Rick Pollack
Executive Vice President
American Hospital Association

Larry S. Gage
President
National Association of Public Hospitals and
Health Systems

Charles N. “Chip” Kahn
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