

Congress of the United States
Washington, DC 20515

May 24, 2005

Lester M. Crawford
Acting Commissioner
Food and Drug Administration
5600 Fisher Lane
Parklawn Bldg., Rom 14-7
Rockville, Maryland 20857-0002

Dear Commissioner Crawford:

As members of Congress with a strong interest in improving health care quality and efficiency, we write to inquire about the Food and Drug Administration's (FDA) intentions for plans to require the bar coding of medical devices.

As you will recall, FDA issued a final rule in February 2004 that 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. Industry representatives also testified to the fact that inventory and warehousing accuracy, as well as product movement, including recall, could be made more efficient. Also in support of these points, a 2001 Efficient Healthcare Consumer Response (EHCR) report concluded, data captured and managed through the supply chain via bar coding technologies can provide the basis for benchmarking analyses of supply management, including contracts, total cost and supplier performance.

However, as you know, 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. 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 improving quality, cost effectiveness and supply chain efficiency.

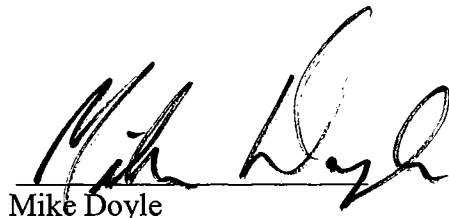
A model in which critical data use bar code media for transmission and translation has vast potential for improved clinical product and service innovation, and cost-efficiency at the supply chain level. A compelling patient safety interest also lies in requiring bar codes for certain medical devices including implantable items like hip/knee prosthetics, stents, and CRM pacers, which 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 appreciate your addressing this issue and would like to request that you provide a written response to us by June 15, 2005.

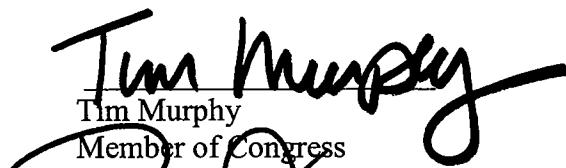
Sincerely,



Pete Sessions
Member of Congress



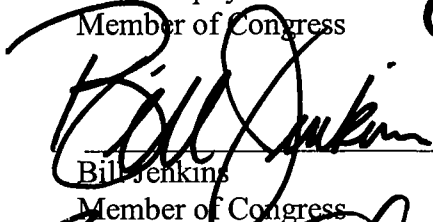
Mike Doyle
Member of Congress



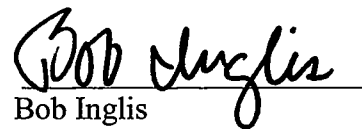
Tim Murphy
Member of Congress



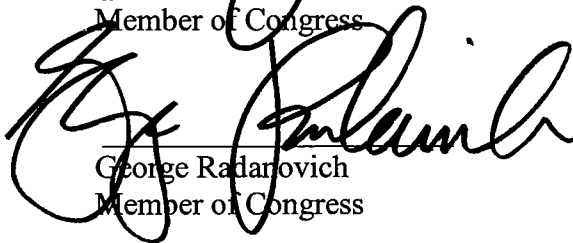
Michael Conaway
Member of Congress



Bill Jenkins
Member of Congress



Bob Inglis
Member of Congress



George Radanovich
Member of Congress