



November 3, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Unique Device Identifiers; Request for Comments, Docket Number 2006N-0292 (71 Fed. Reg. 46233; August 11, 2006)

Dear Sir or Madam:

Please accept this letter as our comments to the Food and Drug Administration's (FDA) request for comments on the implementation and use of a unique device identification (UDI) system. Given Cardinal Health's role as a leading provider of healthcare products and services, Cardinal Health respectfully submits the following comments voicing concerns, recommendations, and request for further evaluations before implementation of any UDI system.

The Agency reports in its announcement for comment that widespread use of UDIs will result in several patient safety benefits such as "reducing medical errors, facilitating recalls, improving medical device reporting, and identifying incompatibility with devices or potential allergic reactions."¹ In contrast, the March 22, 2006 ERG Final Report on Unique Identification For Medical Devices, reflects that more information is needed to assess the impact of UDIs to patient safety, that such benefits are not a certainty, and that the information required to obtain such benefits requires more information than just a basic unique identification number (e.g. manufacturer name, product code, and lot number).

For example, although the ERG report indicates that "UDI is essential for efficient patient safety monitoring," the ERG report highlights that "the benefits to patients will depend on the extent that potential medical device errors can be reduced" and that "much less is known about the contribution of medical devices to hospital or clinical errors in treatment."² ERG in fact documents that few studies to date have actually been performed to explore the extent and frequency of clinical errors related to medical device use.³ Additionally, in the one example of improved reporting and understanding of user error, Cardinal Health notes that the devices exemplified were "smart intravenous pumps" which recorded dosing information.⁴ As it is unclear as to whether "smart intravenous pumps" are representative of a device with a basic UDI, it is unknown whether a device with a basic UDI will achieve the same purported improvements in medical reporting as a "smart" device.

The ERG report also concludes that the use of UDIs should facilitate recalls. Specifically, ERG states that hospitals must currently search their inventories manually and that UDI will make recalls faster and more complete.⁵ Cardinal Health notes, however, that as only from 5 to 10 percent of hospitals have implemented

¹ 71 Fed. Reg. 46233 (Aug 11, 2006)

² ERG Final Report, Unique Identification For Medical Devices, 2-1 (March 22, 2006)

³ *Id.*

⁴ *Id.* at 2-2.

⁵ *Id.* at 2-2.

2006N-0292

C4

the technology for bar code checks on pharmaceutical dispensing,⁶ it is uncertain as to whether hospitals will expend the additional funds necessary to implement the technologies and automation required for managing UDIs. Such a capital investment on the part of the hospitals is doubtful as the ERG report also concludes that "recalls are not so constant that personnel are dedicated to tracking down errant materials."⁷ Additionally, Cardinal Health submits that current industry practices and procedures for recalls are effective in protecting patient health.

Although FDA announces the potential benefits of UDIs, such as improving identification of compatibility issues and potential allergic reactions,⁸ the ERG report only concludes that UDI "might" help reduce such issues.⁹ ERG does provide the single example of an MRI compatibility issue; however, the report does not clarify how a basic UDI alone will provide such additional information to the patient records to allow for the identification of such issues.¹⁰

In reviewing the ERG Report, Cardinal Health agrees that there would be some benefits to hospitals (e.g., more efficient purchasing, improved inventory control, enhanced asset utilization) and insurers (e.g., more efficient reimbursements); however, Cardinal Health is concerned that the cost for such benefits will be borne primarily by the manufacturers and distributors. As Advamed has pointed out and as ERG has summarized, there are several potential technical difficulties, which will require significant capital investments and expenditures depending on the scope of UDI requirements.¹¹ Cardinal Health roughly estimates that for one business unit alone the capital investments will add at least 5% to the final product costs. Additionally, there could also be significant system challenges and costs with distribution if distributors were required to maintain UDI traceability throughout the supply chain for all medical devices. Although such initial costs would be borne by the manufacturers and distributors, over time these costs would be shifted to the patients, private insurers, and government. This ultimately increases the cost of healthcare with arguably no real significant benefits to patients in return.

Prior to burdening industry with potentially significant capital investment costs, Cardinal Health would recommend that additional studies and evaluations be conducted to accurately assess the contribution of medical device use to clinical errors in treatment and whether a UDI system will in fact result in the additional patient benefits claimed. Additionally, as FDA already requires traceability for those devices with clear risks to patient safety,¹² any expansion of traceability requirements should only encompass those devices that are clearly appropriate to patient safety. Based on such a risk-based assessment juxtaposed to implementation concerns and costs to industry, Cardinal Health would recommend that all high-volume, lost-cost, non-life sustaining devices be excluded from any UDI requirement.

If you have any additional questions, please feel free to contact me at (847) 578-4565 or e-mail at david.g.perkins@cardinal.com. On behalf of Cardinal Health, we thank you for considering our comments and the efforts the Agency has made thus far in evaluating a UDI system.

Yours very truly,



David G. Perkins, J.D.
Director, Regulatory Affairs

cc: Gary Dolch (Cardinal Health)
Robert Giacalone (Cardinal Health)
Claude Grant (Cardinal Health)
Michael Groesbeck (Cardinal Health)

⁶ *Id.* at 1-8, 1-9, and 2-7.

⁷ *Id.* at 1-8.

⁸ 71 Fed Reg. 46233, Supplemental Information, I.B.

⁹ *Id.* at 2-2.

¹⁰ *Id.*

¹¹ *Id.* at 2-5.

¹² *See* 21 C.F.R. 820.65