

November 8, 2006

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

Re: Unique Device Identification (Docket No. 2006N-0292)

Dear Sir or Madam:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical technology market, I am submitting these comments in response to the Food and Drug Administration's ("FDA's") recently published Federal Register Notice on Unique Device Identification ("UDI").¹ MDMA is particularly interested in ensuring that FDA only proceeds with a mandatory UDI policy if clear and convincing evidence is provided that directly impacts the safety or efficacy of medical devices. While there may be supply chain management benefits from a UDI system, there continues to be a lack of compelling evidence to support FDA's implementation of a mandatory system. In addition, given the current budgetary constraints FDA is facing, creating a mandatory UDI system would further strain limited Agency resources without a quantifiable benefit in return.

Voluntary Initiative

While MDMA supports a universal device identification system, we strongly believe that it should be a voluntary process. Much has been made of the potential health and safety benefits of UDI, comparing it to the mandatory drug bar coding system. The August 11, 2006 Federal Register Notice stated that requiring bar codes on certain human drug and biologic products helped to reduce "medication errors in hospitals and other health care settings". It further states, "The bar code is intended to enable health care professionals to use the bar code scanning equipment in conjunction with computerized medication administration systems to verify that the right drug, in the right dose, is being given to the right patient at the right time". However, unlike pharmaceuticals, there are very few, if any, compatibility issues that exist between two devices that would impact safety or efficacy. In addition, we are not aware of instances in which "dosage" has been an issue with medical devices. Therefore, the policy justifications that exist in the pharmaceutical industry for a mandatory unique bar coding system do not exist for medical devices. If however, FDA can provide data that suggests compatibility issues for particular devices or "dosage" issues are present, mandatory UDIs for those devices may be warranted.

¹ 71 Fed. Reg. 46233 (Aug. 11, 2006).

Universal System

The costs associated of complying with various systems around the country and across the world would be significant. Therefore, FDA should consider harmonizing to a single *voluntary*, universal unique identification system. This would provide greater efficiencies for industry and providers. However, this change must be developed with the input of all stakeholders worldwide to develop consensus around the appropriate universal system. Furthermore, a more promising and cost-effective solution would be to utilize a universal scanner that reads multiple systems. This would require less effort on behalf of manufacturers and providers and still provide the same information.

Scope of Identifiers

Unlike pharmaceuticals, medical devices exist in thousands of shapes and sizes. As a result, any voluntary UDI system should at most require placement on the external packaging, not on the device itself.

Costs of Implementation

With 80percent of medical technology companies having fewer than 50 employees, it is a much different industry than the pharmaceutical industry. Smaller companies are the engine that drives innovation in medical devices and the additional costs associated with complying with a UDI system would only serve to increase the overall cost of devices.

Some have argued that it would be more expensive for larger companies with more products to adopt a UDI system. This may be true in terms of overall dollars, but not in relation to income versus expenses. Large companies have existing revenues on products to cover these costs. Smaller companies, just starting out, do not have this luxury and a mandatory UDI system would create another barrier to entry for smaller companies.

Use of Data

MDMA is extremely concerned that this initiative is being driven by certain hospital group purchasing organizations (GPOs) who seek to exclude competitive products from the marketplace because of their own financial interest. The GPO industry has been the subject of multiple congressional hearings, federal and state investigations and various media reports documenting these exclusionary practices. Therefore, the data from any voluntary UDI system should only be used for safety and efficacy issues (if established) and never for contract management purposes.

In closing, MDMA appreciates this opportunity to comment on this important issue and looks forward to continuing to work with FDA and other stakeholders to develop a voluntary unique device identification system.

Sincerely,



Mark Leahey
Executive Director
Medical Device Manufacturers Association