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August 9, 2002

Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0204
Bar Code Label Requirements for Human Drug Products; Notice of Public Meeting

To Whom It May Concern:

Thank you for this opportunity to respond to the U.S. Food and Drug Administration's (FDA) request for information that may be use of to the agency in "exploring issues surrounding bar coding on medical devices."¹ AdvaMed appreciated, too, the opportunity to participate in the industry panel at FDA's public hearing on this issue on July 26, 2002.

The Advanced Medical Technology Association (AdvaMed) is the largest medical technology association in the world, representing more than 1100 manufacturers of medical devices, diagnostic products and medical information systems – a diverse range of hundreds of thousands of distinct products.

AdvaMed and its members are committed to the voluntary use of industry-approved automatic identification for medical devices, where it is economically and technically feasible, and where it is clinically practical.

AdvaMed's use of the term "automatic identification" is carefully chosen. While traditional "bar codes" on retail packages are easily recognizable, there are other configurations of auto-identifiers, including radio frequency technology that uses an imbedded chip. All these technologies can use various data structures under the Universal Product Numbering (UPN) system, and most modern scanning technology can read them all. Because these technologies will continue to evolve, AdvaMed refers to "automatic identification" rather than "bar coding," which could inappropriately lock industry into one standard, one coding language, or one technology.

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¹ 67 Fed. Reg., 41360-41361 (June 18, 2002)

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AdvaMed is concerned that the request for FDA to require bar coding on all medical devices² falls short of the needs of a heterogeneous industry. Devices come in all sizes. They are packaged individually, or by the hundreds. They are made from a wide range of materials requiring various sterilization and storage needs. They may be designed for single use or multiple use. Their clinical applications vary greatly.

AdvaMed submits these comments with the intent of challenging FDA regulators to acknowledge the unique design characteristics and usage of devices as significantly different from drugs and biologics – particularly in light of the agency's interest in exploring whether UPNs on devices can improve patient safety.

For this reason, AdvaMed recommends that FDA not include devices in its forthcoming rule on bar coding for drugs and biologics, and that any consideration of auto-identification for devices be addressed separately.

Industry surveys indicate that from 1995 to 1997 there were approximately 30 percent more UPNs on devices at the "unit of use" level, and a nearly 17 percent more at the shelf-pack level. Unfortunately, these older data are soft, and there is a need for updated, unbiased surveys that look at not only the number of UPNs on devices, but also the extent to which healthcare professionals utilize the products that are coded and why they do so. Even so, available data confirm that manufacturers – even without regulation – increasingly are auto-identifying medical devices.

Decisions are best made when manufacturers work with healthcare professionals to clearly identify the goals and practical limitations of auto-identification. They may ask how a device is used, how often it is used, and how it is packaged. The manufacturer will consider lot size, device and packaging size, and surface material. They should consider how hospital protocols might be changed by the use of UPNs, which format might be appropriate, and at what level of packaging UPNs should be used. All this is a process to determine whether the expected benefits warrant the additional burden to the health care system.

Firms use UPNs on devices for various reasons. Most temporary and permanent orthopedic implants, for example, are auto-identified to provide traceability. Other products are auto-identified to assist in inventory control. And while some products may be auto-identified to reduce medical errors, there is a notable lack of statistically significant data to indicate that UPNs on all medical devices will reduce medical errors.

There are, unfortunately, significant obstacles to auto-identifying medical devices:

- The packaging material may inhibit the use of printable codes.
- Small devices with limited packaging may need to rely on two-dimensional symbols or RF technology instead of a linear bar code, or they may require larger, costlier packages.
- Because a UPN may be applied at different levels of packaging, the UPN may not be present at the point of use, especially for multiple use devices that have been sterilized in-house.

² Letter to HHS Secretary Tommy Thompson from Premier, Inc., the Federation of American Hospitals, VHA, Inc., National Association of Public Hospitals and Health Systems, American Hospital Association, Association of American Medical Colleges, and the Catholic Health Association of the United States, dated January 24, 2002

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- Most device companies are small firms for whom, in particular, auto-identification reflects significant investments. The costs to hire technology experts and purchase printers, scanners and software must be weighed against the expected benefits of auto-identification. Identifying each and every throat swab at the "unit of use" level, for example, would not be practical or beneficial.
- On the other end of the spectrum is capital equipment, for which auto-identification at the "unit of use" may not be appropriate. What would be the patient safety benefit in requiring UPNs on these products?

This discussion reveals several important aspects about industry working with its customers to voluntarily apply UPNs to certain devices:

- There is no "one-size-fits-all" approach, because:
 - Medical devices come in too many shapes and sizes.
 - They are packaged differently and in different quantities.
 - They may be used singly, or multiple times.
 - They are manufactured in lot sizes that vary from firm to firm.
- Requiring auto-identification on all devices could unnecessarily increase health care costs without improving patient safety.

In considering this last point, i.e., whether FDA should require automatic identification on devices to reduce medical errors, AdvaMed suggests that FDA first look at the root causes of medical errors. A 1999 Institutes of Medicine report suggests that medication errors, transcription errors, user errors, staffing shortages, and lack of training are the prevailing root causes of medical errors. Those attributed to medical technology are notably absent from this list. One could argue, therefore, that a mandate to auto-identify all devices would have only proportional success and would impose a significant cost burden on the health care system.

Secondly, it is unclear how health care professionals are expected to use auto-identifiers on devices to improve patient safety. For drugs, the application is certainly clearer: a patient's list of drugs, dosages, and administration times can be benchmarked against actual usage to minimize the risk of errors. But a similar expectation to benchmark device usage is far more vague.

A UPN is one piece of a system that requires a commitment to scan products, identify patients, update code information, and analyze data if benefits are to be realized. Increased patient safety may be attainable for only a subset of medical devices, depending on the nature of the device and its use in a clinical setting.

A UPN identifies a product. It provides traceability, not patient safety. For instances where FDA has determined that traceability of devices is necessary, device tracking already has been ordered. Effective systems to track devices have been in place for years, and applying a UPN to a device will not necessarily improve this process.

Clearly, auto-identification is not a panacea to resolve device-related medical errors. Firms have already auto-identified thousands of devices, and they will continue to work with customers to decide which other products should be auto-identified. It is a dynamic process that moves forward –

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albeit deliberately – in a way that is responsive to customer needs and is cost effective, employing UPNs selectively where benefits can be realized.

Lastly, in response to FDA's inquiry (in the above-referenced *Federal Register* notice) regarding "bar coding" for reprocessed, repackaged, refurbished or multiple-use medical devices, AdvaMed recommends that reprocessed, repackaged, refurbished and multiple-use devices be treated no differently than other medical devices with respect to automatic identification. In other words, manufacturers, in consultation with their customers, should voluntarily apply automatic identification where it is economically and technically feasible, and where it is clinically practical. In many cases, original equipment manufacturers (OEMs) are already voluntarily automatically identifying their disposable products. Due to size limitations, auto-identifiers for these disposable, single-use devices are frequently on the packaging that is discarded when the products are used. In the event that OEMs provide auto-identifiers on their devices, refurbishers and reproducers of those devices must be required to remove or permanently obliterate the OEM's bar code. If this is not done, products could be misidentified and failures could be mistakenly attributed to OEM devices rather than the reprocessed or refurbished device.

In conclusion:

- AdvaMed encourages greater communications between health care stakeholders to ensure that automatic identification is voluntarily applied to devices where it is economically and technically feasible, and where it is clinically practical.
- AdvaMed strongly encourages providers and purchasers to fully utilize UPNs when they appear on medical devices. Using auto-ID to prevent medical errors requires not only that manufacturers apply a UPN, but also that users commit to its appropriate employment.
- AdvaMed recommends that reprocessed, repackaged, refurbished and multiple-use devices be treated no differently than other medical devices with respect to automatic identification. In the event that OEMs provide barcodes on their devices, refurbishers and reproducers of those devices must be required to remove or permanently obliterate the OEM's bar code.
- AdvaMed supports the voluntary use of UPNs on medical devices, which allows for the use of industry-approved UCC.EAN or HIBC standards – a decision that reflects the clinical use of devices, the interests of healthcare professionals, and the challenges faced by manufacturers in auto-identifying medical technology. The UPN system provides greater consistency with global identification trends. AdvaMed specifically does not recommend that there be any consideration of requiring NDC numbers on medical devices. The NDC is a pharmaceutical-based numbering system exclusive to FDA and, if applied to medical devices, could force an overhaul of current identification practices for the medical device industry or, at minimum, result in confusion over the use of multiple product identifiers on products sold both domestically and internationally.



AdvaMed
Advanced Medical Technology Association

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- For all these reasons, AdvaMed strongly encourages FDA to recognize that the unique diversity of medical devices is so significant that they should be excluded from the agency's forthcoming rule on bar coding for drugs and biologics.

Thank you for your interest in this important discussion. AdvaMed would welcome any additional opportunities to address this issue with the agency.

Sincerely,



Therese M. Cammack
Associate Vice President
Technology & Regulatory Affairs