

# MDDI

Medical Device & Diagnostic Industry®

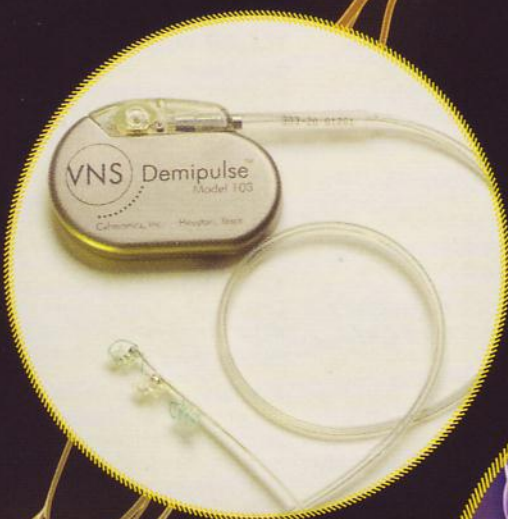
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# Do Labeling Requirements Address Patient Safety?

Dear Editors:

I am writing in response to the item "GPO Forges Ahead with Device Identification Standards," which appeared in the September 2008 issue NewsTrends section. This item contains an endorsement of the GS1 standard by Premier Healthcare Alliance. I believe GS1 is an unfortunate backward step for patient safety efforts in product labeling.

Although Joe Pleasant cites patient safety as the rationale for endorsement, his logic doesn't ring true. Premier's abandonment of the well-established universal product number (UPN), which is already on 90% of medical product packaging, will only lead to ill-advised and risky cross-referencing that will increase identification errors. GS1 labeling is already an option for UPN.

Equally perplexing is the fact that the UPN has been actively promoted by Premier in the past. Even though FDA has recognized UPN standards in its recently issued pharmaceutical packaging requirements, Premier has chosen to ignore FDA's work on this issue.

A mandated migration to GS1 would require many manufacturers to abandon directly encoded alphanumeric product identifiers and replace them with numeric-only proxies, thereby reverting to the days when computer scanners could only recognize numbers and could not scan the alphabet. Cross-referencing or replacing existing identifiers in this way is a risky

other than patient safety is driving Premier's endorsement. In this regard it is noteworthy that Pleasant, who is the architect of the initiative, also serves on the GS1 board of governors. A link of that nature calls Premier's stated motive for the requirement into question, particularly in light of Pleasant's work on behalf of GPO advocacy groups during the past 10 years. There is an obvious contradiction between his patient safety claims and the risks associated with ignoring well-established product identifiers.

The bottom line is that Premier will force many manufacturers to choose between sales and safety when they are confronted with its clout in awarding contracts. This action is bound to tarnish GPO credibility even further.

*Robert Hankin, PhD  
President and CEO  
Health Industry Business  
Communications Council*

Pleasant responds:

Premier has been a strong advocate of a UPN for the healthcare industry for many years. Premier believes having a standard method for identifying products will absolutely assist in the recall of medical devices. An effective process for recalling products has been demonstrated in the retail industry, and we believe patients and the healthcare industry should have such a process.

By endorsing the GS1 standards, Premier has strengthened its commitment to a UPN. The GS1 standard works for healthcare for the following reasons:

- It's global. Healthcare manufacturers sell products globally, and it makes sense that product numbers should be globally recognized.
- It's used by other industries. Healthcare providers purchase many non-medical products and these are

identified by the GS1 standards.

- It has users groups that continuously update the standards.

Industry experts agree that a uniform system increases patient safety and supply-chain efficiency, as well as reduces supply-chain costs. According to a survey of nearly 1000 healthcare professionals conducted by Premier's Safety Institute, more than 80% of survey respondents believe an industry-wide identification system can enhance patient safety.

Premier has teamed with organizations such as the Association for Healthcare Resource & Materials Management, the Coalition for Healthcare Standards, and the Healthcare Supply Chain Standards Coalition, in studying the system. The conclusions reached by each review and pilot was to move forward with the GS1 standards for the healthcare supply chain. Similarly, Congress took an important step by requiring FDA to develop a unique device identification (UDI) system, which can be supported by GS1 standards.

A national UDI system represents the future of healthcare. These systems are the foundation of ongoing efforts to automate processes and enhance efficiencies, including rapid device identification and tracking in the hospital, product identification, and accurate billing. Combined, these enhancements could save the U.S. healthcare system \$16 billion, according to an Arizona State University study.

By endorsing the GS1 standards, the healthcare industry will only strengthen its commitment to safety. Having a standard for identification of the product down to the individual item is extremely important for patient safety. The current system does not offer this level of detail and standardization, but a GS1 system would.

*Joe Pleasant  
Chief Information Officer  
Premier Healthcare Alliance* ■

**MD&I** online  
 READ THE NEWS ITEM "GPO FORGES AHEAD WITH DEVICE IDENTIFICATION STANDARDS" AT  
[devicelink.com/mddi/archive/08/09/012.html](http://devicelink.com/mddi/archive/08/09/012.html)

practice that will impose huge costs, which are ultimately borne by hospitals and patients.

The only beneficiary would be GS1, which will collect significant registration fees from manufacturers and group purchasing organizations (GPOs).

These facts suggest that something