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DOCKET NO. 02N-0204 Bar Code Label Requirements

Thank you for the opportunity to comment on this very important issue impacting the entire healthcare industry from manufacturers, to distributors, to healthcare facilities and in many cases, patients.

My name is Karen Longe. My company, Karen Longe & Associates specializes in assisting the healthcare industry in the use of automatic identification and data capture including bar coding. I am here as Chair of the Healthcare Committee for AIM, the association for automatic identification and data capture technologies. AIM, founded in 1974, is committed to standards development, education and market promotion and has a global membership of over 900 companies that provide the equipment and systems that capture, track and transfer information about people, places and things.

I would like to complement the healthcare industry for developing and approving standards (Health Industry Bar Code Supplier Labeling Standard, EAN/UCC, ISBT) The most important part of developing the standards was to identify the nature of the information that should be contained in a bar code and how various elements of information should be identified and presented. The really important work, that perhaps went unnoticed, was the realization that before considering a particular bar code symbology or any other machine readable technology such as RFID or Contact Memory, the business problem had to be clearly defined. This is because the various technologies that can be used to automatically identify products and collect information are only tools. These technology "tools" continue to change and improve.

I must also voice a word of caution. Some are proposing that the method to encode the information be limited to bar code only and further to specify only one bar code symbology (Example, Code 39 or UCC/EAN 128). This would be like a specification in the mid 1960's stating that all information must be on "punch cards" or the record industry saying that music must be recorded on 331/3 LP.s or the home movie industry saying that only VCR tape can be used.

While I agree that standards are a must, please do not let us limit the technical advancements that surely will come as time marches on.

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Another point that should be made. The industry is looking at bar coding as a tool to improve patient safety but the many other business benefits of bar coding should not be overlooked. Manufacturers, distributors, and healthcare facilities will all benefit from the ability to identify and track any type of product (drug, medical device, blood) from the point of manufacturing, through distribution, to receiving and use at a healthcare facility,

and then reordering. The technology that works best on a pallet of products is not necessarily the one that works best at the unit-dose or unit-of-issue level. Again my concern over legislating a technology rather than identifying the elements of information and how they are presented (data structures).

That is why the healthcare industry developed and approved standards are based on data structures. The standards allow for the use of several different AIM approved and tested symbologies. Data structures provide a description and the order of the data to be encoded in a symbology, a RFID tag, a contact memory button, etc. Current bar code printer and scanner technologies produce and read the full range of publicly available bar code symbologies identified in the healthcare standards.

Mandating the use of appropriate machine readable technology, using a healthcare industry developed and approved standard will help improve patient safety and improve efficiencies in healthcare supply chains. It will allow the industry to take advantage of advancements in technology to meet their own business needs. However, mandating a particular technology or particular bar code symbology will limit the industry's ability to reach its goals.