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March 14, 2003

The Honorable Tommy G. Thompson Health and Human Services Secretary 200 Independence Avenue, SW Washington, DC 20201

Dear Secretary Thompson:

I have reviewed your FDA proposals for medication bar coding to improve patient safety. This concept was something that the Health Industry Business Communications Council and my company, Precision Dynamics Corporation, supported for the last twenty years, but unfortunately until recently nobody paid any attention to the use of bar codes to prevent this kind of error. Now, bar codes are only one automatic identification technology and linear bar codes are bordering on obsolescence.

Now is not the time to force linear bar coding to be used for this purpose. Rather, we should encourage the use of Automatic Identification, which includes the use of RFID, linear bar codes, matrix codes, and other technologies.

It is essential, if the FDA plans to require bar coding, that it not be limited to the use of linear bar codes, inasmuch as these require far too much package space and would not allow small individual unit dose samples to be appropriately marked without repackaging in a much larger package. There are two-dimensional symbologies that are not a part of the obsolete UCC/EAN system, which could be used if it is intended to insist on using bar codes as the only means automatic identification.

In general one should never place technology limitations on problem solving directions. Performance standards should be used, not engineering standards. Linear bar codes are an engineering standard. Automatic Identification is a performance standard. For example a performance standard might require that a package shall be marked with some means of automatic identification that can be accessed prior to administering medication.

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I would appreciate hearing from you with respect to my comments. I look forward to a rule that will adequately address the medical error problem without limiting the technology used.

Sincerely,

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Walter W. Mosher, Jr., Ph.D. Chairman/Chief Technology Officer

WWM:clc

cc: Gary E. Hutchinson, President

Robin Barber, Vice President, Advanced Marketing & Technology Irwin Thall, Advanced Marketing & Technology Department Jim Bensman, Advanced Marketing & Technology Department Pam Bailey, AdvaMed, President Tess Cammack, AdvaMed, Director, Technology and Regulatory Affairs Dave Schlotterbeck, Alaris Medical Systems, President/COO