

International Council for Commonality in Blood Banking Automation, Inc

Incorporated in 1995 in the Commonwealth of Virginia as a not-for-profit organization



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Dr Jay Epstein, Director
CBER, FDA
1401 Rockville Pike
Rockville, MD 20852

Dear Jay:

In all the years that I have enjoyed working with CBER representatives on *ISBT 128* there has never been an adversarial moment. I have developed the utmost respect for the difficulty of the job you all do, and the manner in which you try to accomplish your tasks. This letter is written in that spirit.

It is occasioned by some ideas that were percolating at the recent AABB Annual Meeting in Orlando, FL and which, from personal observation, were coming from the FDA.

First, the concept, which is extraordinarily sound, that each product that comes into a nurse's, or other health professional's, hands for administration should bear what can only be called a universal bar code. It may require a shift to some other technology in the future but, for the present, would almost certainly be a bar code. It would be my hope that you would not lock yourselves for ever into bar code technology (in other words, please write any regulation very carefully). My wife and I, many years ago, wrote an editorial I for *Transfusion* in which we expressed the opinion that transfusion medicine is *not* different from other disciplines in this respect: therapy is therapy.

It is the proposed manner of execution with which we have trouble. Restricted Space Symbology (RSS) looks attractive. However, with a nod to our friends in the grocery business who have done such a magnificent job, it is not a can of peas we are labeling. RSS is a compromise. It trades space for security. It is not the right bar code for the job. Why eliminate one source of error but incorporate a new, more insidious problem?; one that will be more difficult to track because we shall, in this instance as all others, come to rely on the "security" of the bar code.

The compromise the FDA must make to achieve the, once more, correct concept is to be willing to totally re-examine labeling requirements in order that a secure two-dimensional bar code symbology (such as PDF 417 or Data Matrix) can be used.

Nor is this the end of the problem. Even were you to ignore this advice, whatever bar code

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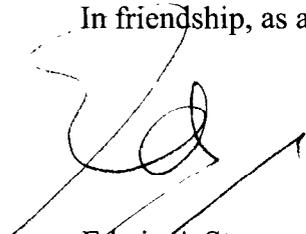
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symbology you choose requires an eye-readable representation of the bar code content to appear somewhere in conjunction with the bar code. This is not trivial. The eye-readable representation is likely to take up *more space* than the bar code itself, particularly if, as we heard suggested, that since the bar code is so small, it can be packed with information. A totally unsound approach.

When I spoke at the recent FDA meeting on this subject, I implored the officials in attendance to print any — an example of essentially every — proposed bar code solution *before* you write the rules. This advice is from bitter experience. I urge you to consider it at CBER, and get your colleagues at CDER to do likewise.

I would like to make one final suggestion. Whatever this universal bar code is, it should contain but one piece of information if possible, at most two. The recipient *must* be “labeled,” and that labeling must be matched to the product labeling. To put any information about the recipient of the product *on the product* only insures the continuity of the problem you are trying to address. This is simply an exercise in process control, a concept for which the basic concepts are well delineated. In the case of blood components, with which we are both familiar, this would be the Donation Identification Number. It might be *nice* to have the Product Code and the Expiration Date, but they simply take up space and shift the responsibility for ensuring their accuracy from the laboratory to the administration area; that does not make the system work as you would like to see it. KISS remains operative: the more simple the procedure, the more likely the errors will disappear. Please let us be involved in the discussion process. We desperately want to see you succeed.

In friendship, as always,



Edwin A Steane, PhD, Executive Director
ICCBBA, Inc