Re: Docket number [2005N-0510]

Dear Sir/Madam:

What struck me most about the FDA counterfeit drug task force public workshop on Feb 8 & 9, 2006, was the speaker list. There were three speakers from HDMA, two speakers each from McKesson, EPCglobal and SupplyScape, and zero speakers representing the interests of hospitals, nurses, or physicians. I hope that this is not an indication of the FDA's perception of issues or solutions.

One could argue that counterfeit drug issues do not concern hospitals, nurses or physicians, since these are only supply chain issues. However, everybody at the meeting brought up patient safety as one of the major reasons for the meeting. Everybody would agree that the last mile of the pharmaceutical supply chain is managed by hospitals, nurses, and physicians. Everybody will also agree that one of the key issues related to counterfeit drugs is how to authenticate medications before they are given to patients. If this step is neglected, then any other technological improvements will do very little, if anything at all, to improve patient safety. Thus, any solution without enough thought about the roles of hospitals, nurses and physicians in managing patients, could be flawed.

It is not technology which improves patient safety, but the people who use the technology. By introducing new technology, we should not increase liabilities on these people. During the meeting I had the impression that several technology companies, without a clear understanding of what is needed to improve patient safety, were claiming to have solutions. I believe, most, if not all, of the solutions offered were not proven to work in critical healthcare environments. If not careful, these solutions may only transfer counterfeit drug liability issues from pharmaceutical manufactures to hospitals, nurses and physicians, at a great cost to consumers without improving patient safety.

In summary, I would like to urge the FDA to be more cautious about the promises being made by these technology companies, regardless of their legal statues of for-profit or non-profit. I am certain that managing patient safety is very different from managing bottles of water or bottles of Viagra / OxyContin at Wal-Mart.

I would like to urge the FDA to look at the larger picture, which includes patients and people who are delivering healthcare services to real patients, before making a decision.

In closing, I would like to thank the FDA for allowing a forum where my concerns can be heard and considered.

Best regards,

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