

SOAPBOX

By Binseng Wang

An Open Letter to Healthcare Professionals

Let me inform you about an alarming trend. If not managed promptly and properly, it may hold severe consequences for public health and safety.

I am referring to the Y2k compliance of medical devices. While I agree with the FDA that only a very small fraction of the medical devices currently in use will fail and cause an injury or death, I believe the FDA misjudged the reaction of clinical professionals, who fear litigation, and device manufacturers, who see Y2k as a business opportunity. Please allow me to explain.

The FDA takes the strict view that unless a device will cause an injury or death, the manufacturer is not required to notify users or initiate a recall. The FDA created a Web site (www.fda.gov/cdrh/yr2000/year2000.html) where manufacturers can voluntarily post information, but so far it contains little about critical devices. The FDA did not seek authority from Congress to demand information from the manufacturers within a reasonable timeframe, so many manufacturers allege they are "still evaluating." Furthermore, the Web information is use-

less to healthcare institutions because their legal counsels require something "written, dated and signed" (WDS).

The WDS requirement has created a monumental flood of correspondence. Every hospital must write to manufacturers and vendors asking for data, proofs and warranties of Y2k compliance, and each manufacturer must respond to at least 15,000 inquiries. Often this correspondence requires a law degree to read, much less to understand. Energy and resources that the healthcare indus-

try should have spent acquiring and analyzing its inventory of products is now dissipated on paperwork and the hope that documents will provide a proof of "due diligence."

Worse, many manufacturers are using the situation to force healthcare providers to replace equipment, much of it recently

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purchased. Y2k responses often state that equipment is non-compliant, without providing any details. Presumably, a good portion of non-compliant equipment will not harm patients, otherwise it would be subject to an FDA-mandated recall, so this is clearly a scare tactic. Manufacturers also have the option of declaring non-compliant products "obsolete," or setting the update/upgrade fee so high that replacement is more attractive. It is not surprising that the device industry's trade organizations abstained from helping their members distribute Y2k information before the onset of the correspondence flood.

In principle, if an institution sticks to devices that are certified Y2k compliant, it has a good chance of passing the "reasonableness" standard in litigation.

But restricting operations to Y2k-compliant devices may require replacing several million dollars worth of equipment, and there may not be enough new products to fill that need before the year 2000. Institutions will be forced to decide how to cope with non-compliant products, often without assistance from the manufacturers.

If fear provokes healthcare providers to withhold non-compliant devices, many patients will not be diagnosed, monitored, or treated due to the lack of technology. This is a large and serious threat to public health. I do not understand why the FDA does not consider this issue to be its true responsibility, instead of its current, narrow interpretation.

There is precious little time left, so I suggest that you encourage your organization to demand certification, by the end of the year, from every manufacturer your healthcare institution does business with as to the Y2k status of every medical device those firms ever manufactured. The certification should clearly indicate one of the following possibilities:

The device is fully Y2k compliant (per FDA or GSA definition);

The device is not Y2k compliant (per FDA or GSA definition), but will NOT cause harm or injury to patients and users; or

The device is not Y2k compliant (per FDA or GSA definition), but may cause harm or injury to patients and users (and therefore, is subject to a recall.)

As a health care professional, if you are given clear information on which devices can and cannot be used, I believe you will continue to deliver the world's best healthcare, without fear of risks and liabilities that you cannot control. ²⁰⁹⁷

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