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YEAR 2000 COMPUTING CHALLENGE

Much Biomedical Equipment Status Information Available, Yet Concerns Remain

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Messrs. Chairmen and Members of the Subcommittees:

We are pleased to be here today to discuss the Year 2000 (Y2K) compliance status of biomedical equipment.[1] The question of whether medical devices such as magnetic resonance imaging (MRI) systems, x-ray machines, pacemakers, and cardiac monitoring equipment can be counted on to work reliably on and after January 1, 2000, is obviously of critical importance to our nation's health care. To the extent that biomedical equipment uses computer chips, it is vulnerable to the Y2K problem.[2] In the medical arena, such vulnerability carries with it possible safety risks.

Responsibility for oversight and regulation of medical devices, including the impact of the Y2K problem, lies with FDA--an agency within the Department of Health and Human Services (HHS). FDA is collecting information from medical device and scientific and research instrument manufacturers, and providing this information through an Internet World Wide Web site. In addition, the Veterans Health Administration (VHA)[3]--a key federal health care provider--has taken a leadership role in determining the Y2K compliance status of biomedical equipment by sharing the information obtained from manufacturers with FDA.

My testimony today will discuss (1) the status of FDA's Federal Y2K Biomedical Equipment Clearinghouse, (2) HHS' and VA's positions on our recommendation to obtain and review the test results supporting manufacturers' compliance certifications for critical care/life support medical devices, and (3) information on the biomedical equipment compliance status of health care providers.

Background

Biomedical equipment is indispensable; it plays a central role in virtually all health care. It is defined as any tool that can record, process, analyze,

[1]Biomedical equipment refers both to medical devices regulated by the Food and Drug Administration (FDA), and scientific and research instruments, which are not subject to FDA regulation.

[2]The Y2K problem will affect everyone because it is rooted in how dates are recorded and computed. For the past several decades, computer systems have typically used two digits to represent the year, such as "98" for 1998, in order to conserve electronic data storage and reduce operating costs. In this format, however, 2000 is indistinguishable from 1900 because both are represented as "00." As a result, if not modified, systems or applications that use dates or perform date- or time-sensitive calculations may generate incorrect results beyond 1999.

[3]A component of the Department of Veterans Affairs (VA).

display, and/or transmit medical data--some of which may include medical devices, such as pacemakers, that are implanted in patients--and laboratory research instruments, such as gas chromatographs[4] and microscopes. Such equipment may use a computer for calibration or for day-to-day operation. If any type of date or time calculation is performed, susceptibility to a Y2K problem exists, whether the computer is a personal computer that connects to the equipment remotely, or a microprocessor chip embedded within the equipment itself. This could range from the more benign--such as incorrect formatting of a printout--to the most serious--incorrect operation of equipment with the potential to decrease patient safety. The degree of risk depends on the role of the equipment in the patient's care.

According to officials at VHA, biomedical equipment manufacturers reporting products as noncompliant most frequently cite incorrect display of date and/or time as the main problem. For example, a noncompliant electrocardiograph machine, used to monitor heart signals, would print charts with two-digit dates, showing the year 2000 as "00." According to a VHA official, these cases generally do not lead to the devices' failing to operate and do not present a risk to patient safety because health care providers, such as physicians and nurses, are able to work around such problems.

However, VHA recognizes that incorrect date-time representation or use could pose a risk when the date is used in a calculation, or when records generated by the equipment are sorted automatically to present a picture of a patient's condition over time to a physician for diagnosis and treatment. Specifically, when records are sorted by date of recording, the accuracy of such dates can be critical to a physician's monitoring of patient progress in, for instance, the case of blood sugar readings. If readings were taken, for example, on December 25, 27, and 30, 1999, and again on January 1, 2000, the ordering might appear with the last entry first if it were abbreviated "00" and read as January 1, 1900. If the physician or other clinician did not pay close attention, a diagnosis or treatment decision could be made based on a misreading of the data trend.

VHA also recognizes that an equipment function that depends on a calculation involving a date, and that is performed incorrectly as the result

[4]Such instruments are used to separate the components of a solution with heat and measure their relative quantities.

of a date problem, could present a risk to the patient. Examples of such equipment include a product used for planning the delivery of radiation treatment using a radioactive isotope as the source. An error in the calculation of the radiation source's strength on the day the therapy is to be delivered could result in a dose that is either too low or too high, which could have an adverse impact on the patient. Other examples of equipment presenting risk to patient safety--identified by FDA--include hemodialysis delivery systems; therapeutic apheresis systems;[5] alpha-fetoprotein kits for neural tube defects;[6] various types of medical imaging equipment; and systems that store, track, and recall images in chronological order.

Much Biomedical Equipment Status Information Available in FDA Clearinghouse

Last September, we testified that FDA was trying to determine the Y2K compliance status of biomedical equipment.[7] FDA's goal was to provide a comprehensive, centralized source of information on the compliance status of biomedical equipment used in the United States and make this information publicly available on a web site. However, at the time, FDA had a disappointing response rate from manufacturers to its letter requesting compliance information. And while FDA made this information available to the public, it was not detailed enough to be useful. Specifically, FDA's list of compliant manufacturers lacked detailed information on the make and model of compliant equipment.

To provide more detailed information on the compliance status of biomedical equipment, as well as to integrate more detailed compliance information already gathered by VHA, we recommended that HHS and VA jointly develop a single data clearinghouse to provide such information to all users. We said development of the clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Office of the Assistant Secretary of Defense (Health Affairs) and the Health Industry Manufacturers Association. We recommended that the clearinghouse contain compliance status information by product make and model and identify manufacturers that are no longer in business. Finally,

[5]Such equipment allows therapeutic apheresis--the exchange or purification of blood plasma. Therapeutic apheresis is recognized as a successful treatment for more than 40 autoimmune diseases.

[6]These devices use computer calculations of gestational status to help assess the risk of neural tube defects in the fetuses of pregnant women.

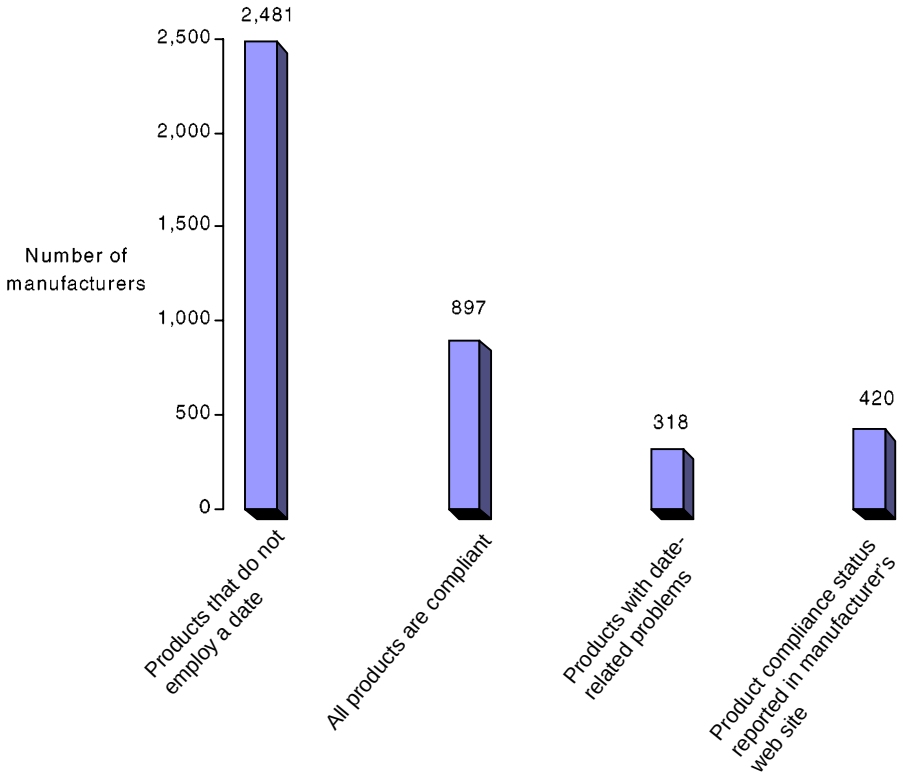
[7]Year 2000 Computing Crisis: Leadership Needed to Collect and Disseminate Critical Biomedical Equipment Information (GAO/T-AIMD-98-310, September 24, 1998).

we recommended that FDA and VHA determine what actions should be taken regarding biomedical equipment manufacturers that had not provided compliance information.

In response to our recommendation, FDA--in conjunction with VHA--established the Federal Y2K Biomedical Equipment Clearinghouse.[8] With the assistance of VHA, the Department of Defense, and the Health Industry Manufacturers Association, FDA has made progress in obtaining compliance status information from manufacturers. For example, according to FDA, 4,116 biomedical equipment manufacturers had submitted data to the clearinghouse as of May 10, 1999. As shown in figure 1, about 60 percent reported having products that do not employ a date, while about 8 percent reported having date-related problems such as incorrect display of date/time. Also, according to FDA, 232 manufacturers have not yet responded.

[8]The clearinghouse can be found on the World Wide Web at *http://www.fda.gov/cdrh/yr2000/year2000.html.*

Figure 1: Biomedical Equipment Compliance-Status Information Reported to FDA by Manufacturers as of May 10, 1999



Note: Total number of manufacturers = 4,116.

Source: FDA.

In addition, FDA did not have complete information on the number of products with date-related problems because some manufacturers did not clearly identify their products this way in their original submissions. However, according to FDA, on March 3, 1999, it requested information on specific product types for products with date-related problems. FDA told us it is now receiving updated data.

Also, in response to our recommendation, FDA has expanded information in the clearinghouse; users can now find information on manufacturers that have merged with or have been bought out by other firms. Further, in

collaboration with the National Patient Safety Partnership,[9] FDA is in the process of obtaining more detailed information from manufacturers on noncompliant products, such as descriptions of the impact of the Y2K problem on products left uncorrected. FDA also sent a March 29, 1999, letter requesting that medical manufacturers submit to the clearinghouse complete lists of individual product models that are Y2K compliant.

FDA Is Now Considering Reviewing Manufacturers' Certifications

Last September, we expressed concern that FDA relied on manufacturers alone to validate, test, and certify that their medical devices were Y2K compliant.[10] Further, we said, since FDA did not require manufacturers to submit test results certifying compliance, the agency lacked assurance that manufacturers have adequately addressed the Y2K problem for noncompliant devices. Accordingly, we recommended that HHS and VA take prudent steps to review manufacturers' compliance test results for devices previously determined to be noncompliant but now deemed by manufacturers to be compliant, or devices for which concerns about compliance remain. We also recommended that HHS and VA determine what legislative, regulatory, or other changes were necessary to obtain assurances that the manufacturers' devices were compliant, including the need to perform independent verification and validation (IV&V) of the manufacturers' certifications.

In response to our report, HHS stated that it did not concur with our recommendation to review test results supporting medical device equipment manufacturers' compliance certifications. It reasoned that submission of appropriate certifications was sufficient, further stating that it did not have the resources to undertake such reviews. However, we were not aware of HHS' requesting resources from the Congress for this purpose.[11] In February 1999, FDA's Special Assistant to the Director of the Office of Science and Technology, part of the Center for Devices and Radiological Health, likewise said that FDA saw no need to question manufacturers' certifications. VA stated that it had no legislative or

[9]The National Patient Safety Partnership is a coalition of public and private health care providers, including VA, the American Medical Association (AMA), the American Hospital Association (AHA), the American Nurses Association, and the Joint Commission on Accreditation of Healthcare Organizations.

[10]Year 2000 Computing Crisis: Compliance Status of Many Biomedical Equipment Items Still Unknown (GAO/AIMD-98-240, September 18, 1998).

[11]Year 2000 Computing Crisis: Readiness of Medicare and the Health Care Sector (GAO/T-AIMD-99-160, April 27, 1999).

regulatory authority to implement the recommendation to review manufacturers' test results.

In contrast to FDA's and VHA's positions, several hospitals in the private sector said that testing of biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. Officials at three hospitals told us that their biomedical engineers established their own test programs for biomedical equipment and, in many cases, contacted manufacturers for their test protocols. Several of these engineers informed us that their testing identified some noncompliant equipment that the manufacturers had previously certified as compliant. According to these engineers, to date, the equipment found to be noncompliant all had display problems and was not critical care/life support equipment. Equipment found to be incorrectly certified as compliant included a cardiac catheterization unit, a pulse oxymeter, medical imaging equipment, and ultrasound equipment.

According to FDA, VHA, and the Emergency Care Research Institute,[12] manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. They further believe that manufacturers are the ones with full access to all design and operating parameters contained in the internal software or embedded chips in the equipment. VHA believes that such testing can potentially cause irreparable damage to expensive health care equipment, causing it to lock up or otherwise cease functioning. Further, a number of manufacturers have recommended that users not test for these same reasons.

We continue to believe that organizations such as FDA can provide medical device users with a greater level of confidence that their equipment is Y2K compliant through independent reviews of manufacturers' compliance test results. The question of whether to independently verify and validate biomedical equipment that manufacturers have certified as compliant is one that must be addressed jointly by medical facilities' clinical staff, biomedical engineers, and corporate management. The overriding criterion should be ensuring patient health and safety.

[12]An international, nonprofit health services research agency. This organization believes that superficial testing of biomedical equipment by users may provide false assurances, as well as create legal liability exposure for health care institutions.

We recently met with HHS' Chief Information Officer and FDA's Associate Commissioner for Policy Coordination to discuss options for FDA to obtain and review test results supporting manufacturers' Y2K compliance certifications. FDA said that it is now thinking about reviewing manufacturers' IV&V reports that support compliance certification. FDA also informed us last week that it is developing a list of critical care/life support biomedical equipment. It plans to complete this list by June 1, and use it to identify manufacturers of such equipment that have not yet responded to its requests for compliance information. In addition, an FDA official stated that the list would be used in considering options for reviewing manufacturers' test results supporting compliance certifications.

Information on Biomedical Equipment Compliance of Health Care Providers Incomplete

While information is available on the Y2K compliance status of biomedical equipment through the FDA clearinghouse and other sources, it is not clear at this time how extensively health care providers are using this information to determine their Y2K readiness. According to FDA, it has taken steps to make users aware of the clearinghouse. For example, FDA has published articles in professional trade journals and participated in conferences aimed at health care facilities.

FDA also informed us that the Federal Y2K Biomedical Equipment Clearinghouse had received about 101,000 inquiries from May 1998 through January 1999. However, according to FDA, it is not possible to determine the source of the inquiries.

To determine whether health care providers were using the FDA clearinghouse to assess the Y2K compliance status of their biomedical equipment, we reviewed readiness surveys sent to providers by several federal agencies and professional health care associations.[13] Except for the AMA's survey, none referred to the FDA clearinghouse. Eleven percent of the respondents to the AMA survey indicated they were aware of the FDA clearinghouse.

In addition, the Y2K readiness status of biomedical equipment at health care providers is not known because a significant number of providers did not respond to the surveys. As shown in table 1, the response rates to a survey from the HHS Office of the Inspector General to urban hospitals,

[13]These include HHS' Office of the Inspector General, the AHA, and the AMA.

nursing facilities, home health agencies, and physicians were all less than 50 percent. The response rates to surveys from the AHA and the AMA on this subject were even less, at 29 and 7.5 percent, respectively. Lastly, the response rate to a survey from the American Health Care Association (AHCA)[14] was very disappointing, at less than 3 percent.

Table 1: Survey Results of Y2K Readiness of Biomedical Equipment

Entity performing survey/group surveyed	Number surveyed	Number of responses	Percentage responding currently compliant	Percentage responding not applicable
HHS Office of the Inspector General[a] (December 1998)				
Hospitals				
Rural	500	281	31	3
Urban	500	208	23	4
Nursing Facilities				
Rural	500	221	21	31
Urban	500	191	21	27
Home Health Agencies				
Rural	500	136	26	41
Urban	500	133	21	39
Physicians				
Rural	500	124	30	36
Urban	500	95	20	52
American Hospital Association (AHA) (February 1999)	2,000	583	6	n/a
American Medical Association (AMA) (February 1999)	7,000	522	[b]	n/a
American Health Care Association (AHCA)[a] (March 1999)	12,000	342	24	28

(Table notes on next page)

[14]This is a federation of 50 state health organizations that represent nearly 12,000 nonprofit and for-profit assisted living, nursing facility, long-term care, and sub-acute care providers.

[a]The survey instructions directed respondents to mark n/a if a question did not apply.

[b]According to the survey results, 65 percent of responding physicians rent or lease biomedical equipment that will be affected by Y2K; 41 percent of them were confident that their vendors have prepared the equipment for Y2K. Data were not provided on the remaining 35 percent of responding physicians.

Source: Organizations listed. We did not independently verify this information.

The survey results also indicated that much work remains in renovating, testing, and implementing compliant biomedical equipment. Table 1 shows that less than one-third of the hospitals responding to HHS' Office of the Inspector General stated that their biomedical equipment was currently compliant, and only 6 percent of the hospitals responding to the AHA survey stated that their biomedical equipment was currently compliant. At the same time, more than one-third of the home health agencies and physicians responding to HHS' Office of the Inspector General stated that the survey question on biomedical equipment compliance did not apply to them.

In summary, while compliance status information is available for biomedical equipment through the FDA clearinghouse, FDA has not yet reviewed test results supporting manufacturers' certifications. FDA has now begun to think about obtaining and reviewing IV&V reports that support manufacturer compliance certifications. Such reviews would provide the American public with a higher level of confidence that medical devices will work as intended. However, because a significant number of health care providers are not responding to Y2K surveys sent by federal agencies and professional associations, the public lacks information on the readiness of providers. Such information would help alleviate public concerns about the Y2K readiness of health care providers and the biomedical equipment they use in patient care.

Messrs. Chairmen, this concludes my statement. I would be pleased to respond to any questions that you or other members of the Subcommittees may have at this time.

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