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YEAR 2000 COMPUTING CHALLENGE

Concerns About Compliance Information on Biomedical Equipment

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Mr. Chairman and Members of the Committee:

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 with FDA information it obtained from manufacturers.

My testimony today will discuss (1) the status of FDA's Federal Y2K Biomedical Equipment Clearinghouse, (2) compliance status information on manufacturers' web sites referred to in FDA's clearinghouse, (3) FDA's efforts to address our recommendation to obtain and review the test results supporting manufacturers' compliance certifications for critical care/life support medical devices, and (4) information on the biomedical equipment compliance status of health care providers.

[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] As is widely known by now, 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).

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, 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.

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

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

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 to 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 specific 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 that 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

[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).

clearinghouse identify compliance status information by product make and model and identify manufacturers that are no longer in business. Finally, 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, 4,142 biomedical equipment manufacturers had submitted data to the clearinghouse as of June 1, 1999.

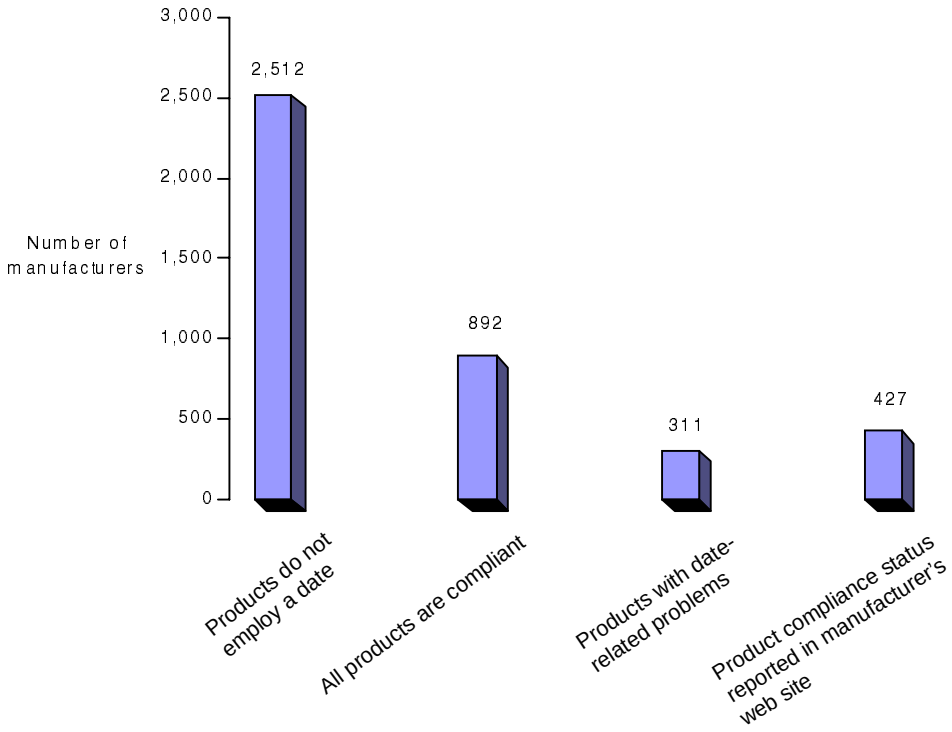
Based on the data submitted, FDA places a manufacturer into one of four categories:

- Products that do not employ a date—manufacturer that reported Y2K status to be "All Products Do Not Use a Date."
- Products that are all compliant—manufacturer that reported products as Y2K compliant.
- Products with date-related problems—manufacturer that reported its Y2K status to be "Products With Date Related Problem."
- Product status is on the manufacturer's web page—manufacturer that reported its Y2K status to be "Product Status Specified on a (Web) Page."

As shown in figure 1, as of June 1, 1999, about 61 percent of the manufacturers reported having products that do not employ a date, while about 8 percent (311 manufacturers) reported having date-related problems such as incorrect display of date/time. According to FDA, the 311 manufacturers reported 897 products with date-related problems.

[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 June 1, 1999



Note: Total number of manufacturers = 4,142.

Source: FDA.

FDA accepts references to manufacturers' web sites for compliance information rather than requiring individual submissions to the clearinghouse; 427 manufacturers provided FDA with links to their web sites as of June 1. However, FDA stated that it did not know the total number of biomedical equipment products reported by these manufacturers, or how many of them were noncompliant. Also, according to FDA, 192 manufacturers have not yet responded.

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 those products with date-related problems. FDA told us it is now receiving updated data.

FDA has also expanded, in response to our recommendation, data 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.

Quality of Compliance Information on Manufacturers' Web Sites Varies Significantly

Because FDA could not provide detailed information on the compliance status of products listed on manufacturers' web sites, at the request of the Committee we reviewed these web sites. Specifically, we obtained from FDA's clearinghouse a listing of the manufacturers referring users to their web sites, downloaded information from these sites, and reviewed this information to identify the total number of biomedical equipment products reported, and categorized their compliance status. [10] We also reviewed the information reported on the manufacturers' web sites to determine its quality in terms of clarity and completeness.

As of June 1, 1999, FDA's clearinghouse listed 427 manufacturers referring users to their web sites. Of this total,

- 328 manufacturers reported compliance status information for at least 35,446 individual biomedical equipment products; [11]

[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]We summarized the results of our review in four compliance categories—products that do not employ a date, products that are compliant, products that are noncompliant, and products whose compliance status is currently unknown. This last category includes those manufacturers who reported that they have not completed an assessment of their products, have discontinued a product, or have a product that is now obsolete.

[11]This includes medical devices, scientific and research instruments, and other supporting products, such as printers and software.

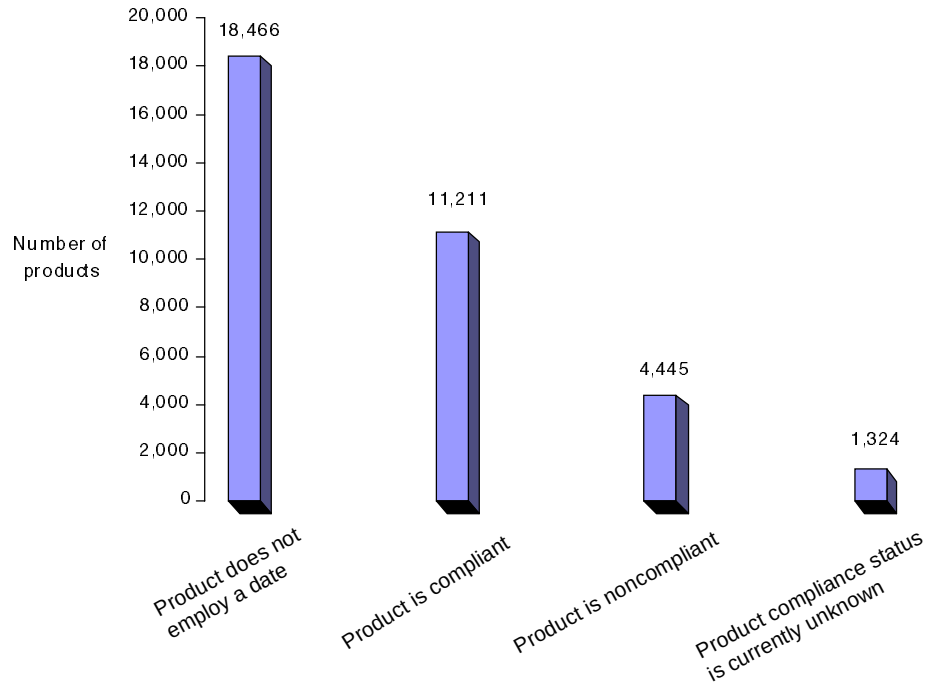
- 33 manufacturers reported information under a parent company included in the list of 328 manufacturers;
- 3 manufacturers' web site links in FDA's clearinghouse did not work; [12]
- 42 manufacturers' web sites contained insufficient information on the number of products and their compliance status;
- 18 manufacturers' web sites did not clearly distinguish biomedical equipment from nonbiomedical products; and
- 3 of the listed manufacturers are actually distributors of products, such as scientific equipment, video camera recorder, printers, chemicals, and furniture.

Because of the limitations cited above for many of the manufacturers' web sites, our ability to determine the total number of biomedical equipment products reported and their compliance status was impaired. Accordingly, the actual number of products reported by these manufacturers could be significantly higher than the 35,446 products that we counted.

As shown in figure 2, our analysis of the 35,446 products indicates that over half of these reportedly do not employ a date, while just under one-third of the products are considered compliant. About 4,445, or 12.5 percent, are considered noncompliant by the manufacturer.

[12] According to FDA, the contractor assisting it with the clearinghouse verified two of these web site links as operable.

Figure 2: Biomedical Equipment Compliance-Status Information Reported on Manufacturers' Web Sites as of June 1, 1999



Note: Total number of products = 35,446.

Source: GAO analysis of manufacturers' web sites.

The 4,445 reported noncompliant products on their web sites is almost five times the number of individual noncompliant products (897) that manufacturers reported to FDA's clearinghouse. The compliance status of the remaining 1,324 products was unknown for reasons such as the manufacturer's ongoing assessment of the product.

Examples of noncompliant products reported by manufacturers on their web sites included a bedside monitor, film digitizer, ultrasound systems, radiology information systems, and laboratory information systems. For these noncompliant products, in many cases the manufacturer provides users with solutions to correct the problem, such as software upgrades and manual calculations.

The quality of the information on the manufacturers' web sites varied significantly, ranging from general assurances of compliance to detailed information on specific product make and model. For example:

- A manufacturer reported that its products had no Y2K issues, but it did not identify the products.
- A manufacturer reported that it was still assessing its products, and did not provide any detailed information on its web site.
- A manufacturer did not list any of its products but did report that the only Y2K problem it was having was with the software it used to run its business.
- A manufacturer listed about 65,000 products, but did not sort them by type so that the biomedical products could be easily identified.
- A manufacturer reported that for its 279 products, 79 were compliant, 50 were noncompliant, the status of 43 was currently unknown, and 107 were not affected by the Y2K problem. It also provided solutions for its reported noncompliant products.
- A manufacturer reported compliance information for 70 products, by make and model. Of these, 53 were compliant, 14 were noncompliant, 2 products were currently under assessment, and Y2K did not apply to 1 product. It also provided solutions for various noncompliant products, including information on the availability of solutions and whether to replace the noncompliant product.

In addition, at least nine manufacturers noted that some of their products were obsolete. Of these, four manufacturers indicated that they had not or would not assess such products for compliance, three stated that they would not support obsolete products, and two did not list their obsolete products. Obsolete products reported by these manufacturers include defibrillators, chemistry analyzers, and blood gas analyzers.

It is critical that users have specific information on product make and model to determine the compliance status of their medical devices. Accordingly, FDA should request that manufacturers who have not already provided this information to the clearinghouse include this on their web sites. FDA should also consider having its clearinghouse contractor verify that manufacturers are providing information on product make and model.

FDA Is Planning to Review 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.[13] Further, we said, since FDA did not require manufacturers to submit test results certifying compliance, the agency lacked assurance that manufacturers had adequately addressed the Y2K problem for noncompliant devices. Accordingly, we recommended that HHS and VA take prudent steps to jointly review manufacturers' test results for critical care/life support biomedical equipment. We were especially concerned that HHS and VA review test results for equipment previously determined to be noncompliant but now deemed by manufacturers to be compliant, or equipment 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 its response to our draft report, HHS did not agree 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. 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. Similarly, VA stated that it had no legislative or regulatory authority to implement the recommendation to review manufacturers' test results.

In contrast to this position, several hospitals in the private sector consider testing of biomedical equipment 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 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

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

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, [14] manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. Further, they 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.

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.

FDA has subsequently changed its position. On May 25, 1999, FDA's Acting Deputy Commissioner for Policy testified that FDA now plans to review manufacturers' test results supporting their compliance certifications for a sample of critical devices. Specifically, FDA's proposal consists of two phases. The first phase is to

- develop a list of critical care/life support medical devices, referred to as "computer-controlled potentially high risk devices" (PHRD) [15] by June 1;
- develop a list of the manufacturers of these devices;
- from this list of manufacturers, select a sample of manufacturers for review; and
- hire a contractor to develop a program to assess manufacturers' activities to identify and correct Y2K problems with PHRDs.

[14]The Emergency Care Research Institute is 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.

[15]According to FDA, these devices, whose failure could result in patient injury or failure of an intended treatment, are used in the direct treatment or therapy of a patient and in the monitoring of vital patient parameters, the information for which is immediately necessary for effective treatment or necessary to support or sustain life during treatment or patient care.

According to FDA, the second phase of the evaluation would be undertaken only if the results of the first phase indicated that there is a need for further review of manufacturer Y2K activities to provide confidence that manufacturers are properly addressing this issue. In this second phase, the contractor would review a portion of the remaining manufacturers of PHRDs not yet reviewed. The extent to which this review would be comprehensive and include all manufacturers of PHRDs would depend on the types of problems noted in the first phase. According to FDA, any manufacturer whose quality assurance system appeared deficient based on the contractor's review would be subject to additional review by FDA to determine what actions would be required to eliminate any risks posed by noncompliant devices.

We recently met with FDA's Acting Deputy Commissioner for Policy and the Special Assistant to the Director of the Office of Science and Technology to discuss the agency's timetable for carrying out these tasks. The Special Assistant informed us on May 27, 1999, that FDA had developed a draft list of "computer-controlled potentially high risk devices." This draft list currently contains about 70 devices, including a powered emergency ventilator, infusion pump, glucose test system, fetal cardiac monitor, implanted spinal cord stimulator for bladder evacuation, and radiation therapy simulation system. As of June 7, FDA officials could not tell us when this list would be finalized, even though the initial target date of June 1 had already been missed.

Further, although FDA has established a target date for completing a review of the first sample of manufacturers by the end of August, as of June 8, it had not demonstrated that it had established milestones for completing interim steps in the proposal. In addition, while FDA told us that the contractor's statement of work would clearly spell out the steps in FDA's proposal, FDA has not yet developed a statement of work. It is critical that FDA expeditiously develop such a statement of work and establish milestones for implementing its proposal to ensure that the necessary work can be completed no later than August.

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 185,000 inquiries from April 1998 through May 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. [16] Except for the AMA's survey, none referred to the FDA clearinghouse. Eleven percent of the respondents to the AMA survey indicated that 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, 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) [17] was very disappointing, at less than 3 percent.

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

[17] 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.

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	[d]
American Medical Association (AMA) (February 1999)	7,000	522	[c]	[d]
American Health Care Association (AHCA)[a] (March 1999)	12,000	342	24	28
American Medical Group Association (AMGA)[b] (March 1999)	230	99	42	[d]

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

[b]This organization represents approximately 45,000 physicians in more than 230 medical groups across 40 states.

[c]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.

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

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, a large amount of information can be found on the manufacturers' web sites referred to in the clearinghouse. However, the quality of the compliance information on the manufacturers' web sites varies significantly, ranging from general assurances of compliance to detailed information on specific product make and model.

To identify and correct Y2K problems with potentially high-risk devices, FDA now plans to hire a contractor to assess manufacturers' activities. Such reviews would provide the American public with a higher level of confidence that medical devices will work as intended. FDA needs to establish and meet milestones for this effort to ensure that it is finished in time.

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.

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

Contact and Acknowledgments

For information about this testimony, please contact Joel Willemssen at (202) 512-6253. Individuals making key contributions to this testimony included Gwen Adelekun, Nabajyoti Barkakati, Tim Case, Michael Fruitman, Seth Goodman, Robert Kershaw, Tonia Johnson, Linda Lambert, Helen Lew, Barbara Oliver, Michael Resser, Glenn Spiegel, Aaron Ulm, Sonal Vashi, and Greg Yenner.

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