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YEAR 2000 COMPUTING CHALLENGE

Compliance Status Information on Biomedical Equipment

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Messrs. Chairmen and Members of the Subcommittees:

Thank you for inviting us to participate in today's hearing on 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, continues to be one 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 the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS). Since the fall of 1998, FDA has been providing information collected from medical device and scientific and research instrument manufacturers through its Federal Y2K Biomedical Equipment Clearinghouse.[3]

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 review the Y2K activities of manufacturers of computer-controlled, potentially high-risk devices, (4) information on the compliance status of health care providers' biomedical equipment, and (5) information on compliance testing of equipment.

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 FDA, and scientific and research instruments, which are not subject to FDA regulation.

[2]As is widely known by now, for the past several decades computer systems have often 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]This site can be accessed on the Internet World Wide Web at *http://www.fda.gov/cdrh/yr2000/year2000.html*.

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 or incorrect display of the date—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.

As part of its oversight and regulatory responsibility for domestic and imported medical devices, FDA has been collecting Y2K compliance status information on these devices, as well as on some scientific and research instruments. Its goal has been to provide a comprehensive, centralized source of compliance information on biomedical equipment used in the United States, and make this information publicly available through an Internet World Wide Web site. In addition, the Veterans Health Administration (VHA)—a key federal health care provider[5]—took a leadership role in determining the Y2K compliance status of biomedical equipment. Specifically, it obtained information from manufacturers on the compliance status of biomedical equipment in its inventory, and shared this information with FDA.

FDA has also acted to identify products within the array of medical devices used in health care for which Y2K problems could pose a risk to patient health and safety. It identified 90 types of products that it refers to as computer-controlled, potentially high-risk devices (PHRD).[6] These medical devices are characterized by their potential for immediate and serious adverse health consequences for a patient if they fail to function as designed or expected, including a failure to initiate or continue operation. These devices are

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

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

[6]Appendix I lists the 90 PHRD product types.

- used in the direct treatment or therapy of a patient, the failure of which could result in patient injury or failure of an intended treatment;
- used in the monitoring of vital patient parameters, information that is needed immediately for effective treatment; or
- necessary to support or sustain life during treatment or patient care.

PHRD products identified by FDA include breathing frequency monitors, electroanesthesia apparatus, hemodialysis systems and accessories, and fetal ultrasonic monitors and accessories.[7] Also included on the list of PHRD products is equipment used to collect human blood and manufacture blood products.[8]

Biomedical Equipment Status Information Available Through FDA Clearinghouse

HHS, on FDA's behalf, initiated action to collect biomedical equipment information in January 1998 by issuing a letter to domestic and foreign manufacturers requesting information on the Y2K compliance of their product lines. All information received from these manufacturers was then to be made available to the public through an FDA web site.

As we reported in September 1998, FDA's database did not include product compliance information from many manufacturers who had already provided such information to VHA;[9] further, VHA was not making this information available to the public. We therefore recommended that HHS and VHA jointly develop a single data clearinghouse containing information on the Y2K compliance status of biomedical equipment, and make this information publicly available.[10] In response to our recommendation, FDA—in conjunction with VHA— established the Federal Y2K Biomedical Equipment Clearinghouse.

[7]An electroanesthesia apparatus uses electricity to induce and maintain anesthesia during surgical procedures. Hemodialysis systems cycle blood from a patient's body to filter out body waste before returning the blood to the patient. Fetal ultrasonic monitors use sound to measure the heart rate of the fetus and uterine contractions of the mother during pregnancy and childbirth.

[8]Examples of such equipment include automated blood cell and plasma separators for therapeutic purposes and instruments used to screen the blood supply for blood-borne pathogens.

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

[10]GAO/AIMD-98-240, September 18, 1998.

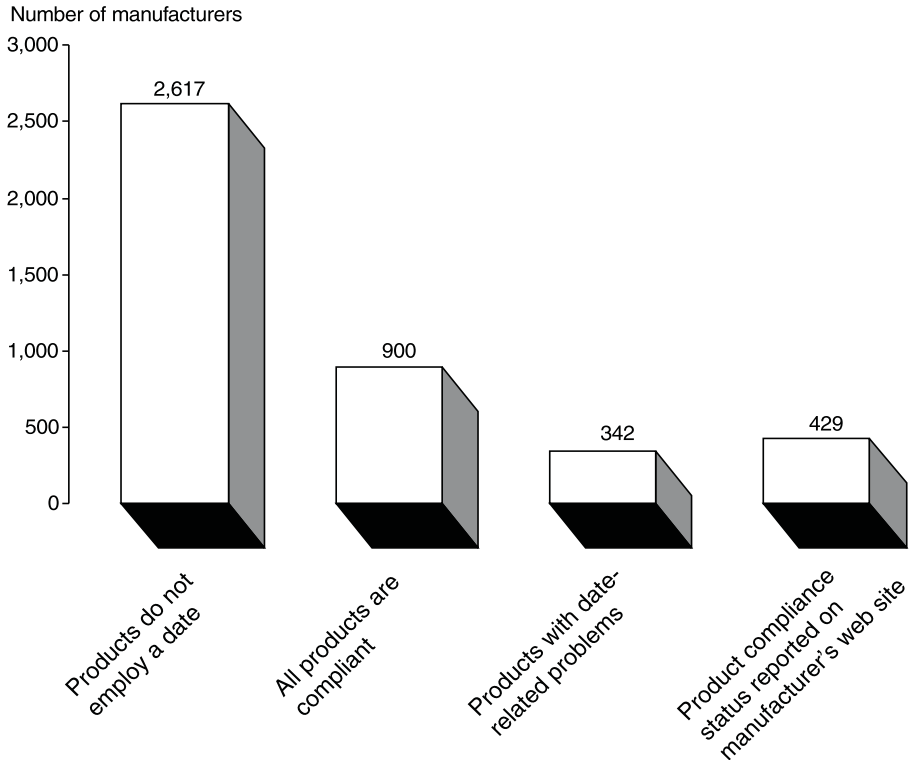
VHA, the Department of Defense, and the Health Industry Manufacturers Association all assisted FDA in obtaining compliance status information from manufacturers. According to FDA, 4,288 biomedical equipment manufacturers had submitted data to the clearinghouse as of October 4, 1999.

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

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

As shown in figure 1, as of October 4, 1999, 61 percent of the manufacturers reported having products that do not employ a date, while 8 percent (342 manufacturers) reported having date-related problems such as incorrect display of date/time. According to FDA, the 342 manufacturers reported 1,035 specific products with date-related problems. Compliance data for 429 manufacturers were reported on their web sites and linked through the FDA clearinghouse.

Figure 1: Biomedical Equipment Compliance-Status Information Reported to FDA by Manufacturers as of October 4, 1999



Note: Total number of manufacturers = 4,288.

Source: FDA.

This total (4,288) excludes 132 manufacturers who, according to FDA, had not responded to the agency's request for product compliance information as of October 4, 1999. According to a top official in FDA's Center for Devices and Radiological Health, most of these manufacturers have gone out of business, do not make computerized products, or just cannot be located. This official added that FDA nevertheless continues to follow up with these manufacturers through letters and telephone contact. The clearinghouse lists the names of these manufacturers who have not responded to FDA's requests for product compliance information.

Our September 1998 report also noted that information on the FDA web site was not detailed enough to be useful.[11] Specifically, the list of compliant equipment contained no information on equipment make or model. We therefore recommended that VA and HHS include in the clearinghouse information on the compliance status of all biomedical equipment by make and model. FDA agreed, subsequently requesting this information from manufacturers; users can now find specific information on the make and model of compliant medical devices on-line.

Quality of Compliance Information on Manufacturers' Web Sites Varies Significantly

As an alternative to obtaining biomedical equipment product compliance information from manufacturers and posting it to the Federal Y2K Biomedical Equipment Clearinghouse, FDA accepts equipment manufacturers' references to their own web sites for compliance information. The clearinghouse provides users with a direct link to these web sites. As of October 1, 429 manufacturers had chosen this option, linking their web sites through the clearinghouse.

While FDA is aware of the number of products and their reported compliance status for those manufacturers providing this information to the clearinghouse, in testimony before these Subcommittees this past May, officials stated that they did not know the total number of biomedical equipment products reported by manufacturers on their web sites, or how many of them were noncompliant. We subsequently reviewed information available through these web sites and reported in June that the quality of information available through them varied significantly.[12] Specifically, while most sites contained compliance information on at least one product, some contained insufficient information or did not clearly distinguish biomedical equipment from nonbiomedical products.

Because of the Subcommittees' interest in the compliance information on the manufacturers' web sites, we reviewed this information to identify the total number of biomedical equipment products reported, and categorized

[11] GAO/AIMD-98-240, September 18, 1998.

[12] *Year 2000 Computing Challenge: Concerns About Compliance Information on Biomedical Equipment* (GAO/T-AIMD-99-209, June 10, 1999).

their compliance status.[13] We also reviewed these sites to assess the clarity and completeness of the information reported.

As of October 1, 1999, FDA's clearinghouse listed 429 manufacturers referring users to their web sites. Of this total,

- 354 manufacturers reported compliance status information for at least 32,598 individual biomedical equipment products;[14]
- 71 manufacturers' web sites either contained insufficient information on the number of products and their compliance status, or did not clearly distinguish biomedical equipment from nonbiomedical products;
- 3 web sites were those of vendors or distributors, not manufacturers; and
- 1 manufacturer's web-site link in FDA's clearinghouse did not work.[15]

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 higher than the 32,598 that we counted.

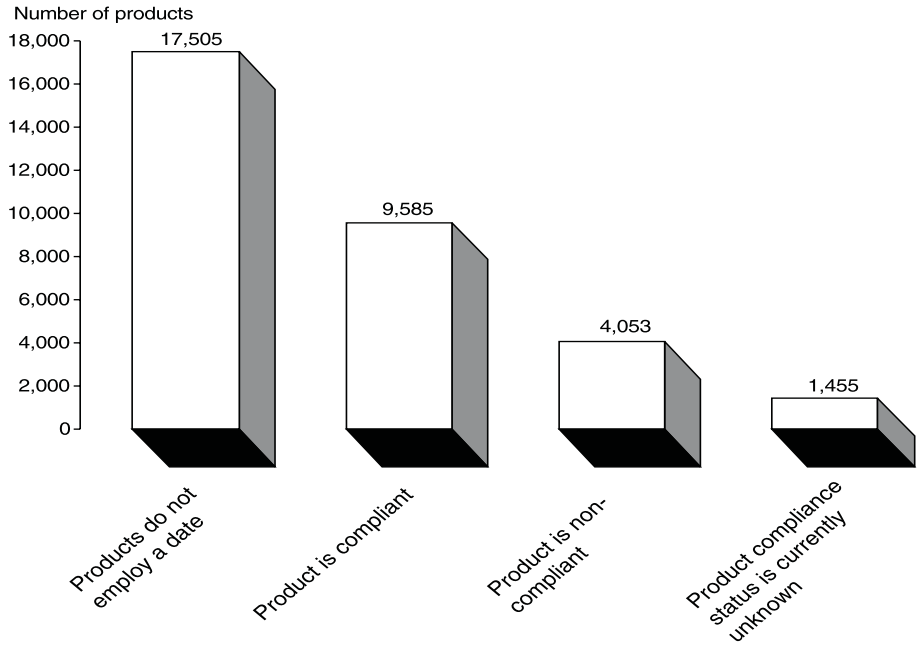
As shown in figure 2, of the 32,598 products that we were able to identify on manufacturers' web sites, about 54 percent reportedly do not employ a date, about 29 percent of the products are considered compliant, and about 12 percent are reportedly noncompliant. The compliance status of the remaining 5 percent of products was unknown, for reasons such as the manufacturer's ongoing assessment of the product.

[13]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.

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

[15]According to FDA, the contractor assisting it with the clearinghouse verified that this web site link was operable.

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



Note: Total number of products = 32,598.

Source: GAO analysis of manufacturers' web sites.

The 4,053 noncompliant products that we identified were from the web sites of 214 manufacturers. This number of noncompliant products is about four times the number reported directly by FDA in its clearinghouse (1,035). Examples of these noncompliant products included a bedside monitor, film digitizer, ultrasound systems, radiology information systems, and laboratory information systems. Included among noncompliant PHRDs were ventricular assist devices and hemodialysis equipment.[16]

In addition to supplying information on noncompliant products, most of the manufacturers with noncompliant products also provided solutions for correcting the problem. At least one solution to correcting a problem was

[16]A ventricular assist device is a small electromechanical pump that helps maintain blood circulation in patients suffering from end-stage heart disease. Hemodialysis equipment cycles blood from a patient's body to filter out body waste before returning the blood to the patient.

offered by 190 of the 214 manufacturers we identified with noncompliant products. The solutions generally involved upgrades to hardware or software, manual action (such as turning the equipment on and off on January 1, 2000), or workarounds.[17] We also noted that for these 190 manufacturers, at least 29 offered Y2K solutions to all their products at no charge, 9 offered no-charge solutions for more that 50 percent of their product line, 13 offered no-charge solutions to less than 50 percent of their product line, and 12 offered no solutions free of charge. For the remaining 127 of the 190 manufacturers, we were unable to determine if Y2K solutions were available to users free of charge.

Our review disclosed that the quality of the information on manufacturers' web sites continued to vary significantly. It ranged 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 theY2K readiness of 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 282 products, 79 were compliant, 50 were noncompliant, the status of 43 was currently unknown, and 110 were not affected by the Y2K problem. It also provided solutions for its reported noncompliant products.
- A manufacturer reported compliance information for 97 products, by make and model. Of these, 72 were compliant, 17 were noncompliant, 1 product was currently under assessment, and Y2K did not apply to 7 products. It also provided solutions for various noncompliant products, including information on the availability of solutions and whether to replace the noncompliant product.

Because both the quality of and access to compliance information are critical to biomedical equipment users, any problems with information on

[17]An example of a workaround is noting on the printout of an EKG machine the year "2000" instead of "1900."

manufacturers' web sites could have a direct bearing on the ability of health care providers to identify and correct any noncompliant equipment in their inventories. Accordingly, we believe that FDA should request that manufacturers that are providing information through their web sites clearly identify product make and model, compliance status, and availability of solutions for noncompliant equipment.

FDA Is Now Reviewing Manufacturers' Y2K Activities

While compliance information is available through FDA's Federal Y2K Biomedical Equipment Clearinghouse, we have raised concerns in the past year about the lack of independent verification and validation of biomedical equipment that manufacturers have certified as compliant. In addition to making sure that manufacturers provide detailed information on their products, we believe that it is essential that FDA provide some level of confidence that critical care and life support medical devices will work as intended.

In response to our previously reported concerns, FDA is now reviewing a sample of biomedical equipment manufacturers' Y2K activities, such as risk management, test planning and procedures, and implementation and contingency planning. In September 1998, we first reported that FDA did not require manufacturers to submit test results certifying product compliance.[18] Rather, we noted, FDA relies on the manufacturer to validate, test, and certify that it has adequately addressed any Y2K problem. As a result, we stated that FDA lacked assurance that biomedical equipment manufacturers had adequately addressed the Y2K problem for noncompliant equipment.

Accordingly, we recommended that HHS take prudent steps to review manufacturers' compliance test results for critical care/life support biomedical equipment, especially equipment once determined to be noncompliant but now deemed compliant, and that for which concerns about the determination of compliance remain. At the time, HHS and FDA did not concur with our recommendation. They reasoned that submissions of appropriate certifications were sufficient, further stating that they did not have the resources to undertake such reviews.

[18] GAO/AIMD-98-240, September 18, 1998.

As mentioned, HHS and FDA have now changed this position. In a May 25, 1999, hearing before these Subcommittees, FDA's Acting Deputy Commissioner for Policy testified that FDA proposed reviewing manufacturers' test results supporting compliance certifications for a sample of critical devices. FDA's proposal consisted of two phases. In the first phase FDA would

- develop a list of the manufacturers of these devices;
- from this list of manufacturers, select a sample of 80 for review; and
- hire a contractor to develop a program to assess manufacturers' activities to identify and correct Y2K problems with PHRDs.

The goal of the first phase of the survey is to extrapolate from the 80 assessments a level of overall confidence in the biomedical equipment industry's Y2K compliance activities. According to FDA, the second phase of the evaluation would be undertaken only if the results of the first phase indicated a need for further review of manufacturer Y2K activities because of concerns about how manufacturers are addressing the issue of product compliance.

In carrying out its plan to assess manufacturers' Y2K activities, FDA issued a task order on July 1, 1999, for a contractor, assisted by two subcontractors, to perform assessments of the Y2K compliance activities for a sample of PHRD manufacturers. FDA identified 803 PHRD manufacturing sites that produce equipment sold in the United States.[19] These were composed of 726 biomedical equipment manufacturing sites and 77 manufacturing sites of blood and blood products equipment that manufacture product types listed in appendix I.

FDA's contractor then randomly selected 325 of the 803 sites for possible assessment. These manufacturing sites were then contacted and asked if they would volunteer to participate in the assessment process. As of October 4, 1999, of the 325 randomly selected sites,

- 197 were identified as producing no computer-controlled equipment,
- 80 agreed to participate,

[19]The 803 consisted of those manufacturers among the 90 types of PHRDs identified that had registered PHRD products with FDA.

- 26 declined to participate,[20]
- 18 were duplicates,[21] and
- 4 did not respond.

To carry out the on-site assessments of manufacturing sites, the contractor developed a guide for its examiners. This guide focused on the firm's Y2K activities in six areas: (1) executive leadership and control, (2) risk management, (3) corrective and preventive actions, (4) test planning and procedures, (5) communication with the consignee (user of the products), and (6) implementation and contingency planning.

After completing these assessments at the manufacturers' sites, examiners were required to prepare a report of concerns in each of the six areas reviewed. Concerns were identified as high, medium, or low, as defined below:

- high—actions that are not timely, inadequate planning, inadequate or incomplete resources, incomplete or inaccurate deliverables, inability to validate results, and/or inadequate due diligence;
- medium—actions that are somewhat late, incomplete planning, insufficient or incomplete resources, deficiencies in deliverables, and/or incomplete validation of results; and
- low—actions that are on schedule and have adequate resources.

According to FDA's PHRD survey project manager, as of October 15, 1999, examiners had completed all 80 manufacturer site assessment visits, and had prepared 62 assessment reports.

We reviewed the 25 manufacturer site visit reports that were completed by the examiners and available to us as of September 10, 1999. For 20 of these assessments, the examiners' assessed concern was low. At the five remaining manufacturing sites, the examiner found at least one item of moderate concern in the six areas, such as test planning and procedures. According to the PHRD survey project manager, the areas identified in the

[20]According to FDA, reasons given by manufacturers for declining to participate included scheduling or resource limitations and recent regular FDA site inspections. Five manufacturing sites declined without giving a reason.

[21]These sites involved large, multisite manufacturers where the FDA contractor had already selected two or more of the same manufacturer's sites. According to FDA, the contractor did not assess duplicates if they came up in later samples.

site visit reports as medium risk do not constitute a risk to patient health or safety.

Until recently, none of the site visit reports submitted to FDA contained a concern assessed as high. However, earlier this week, the PHRD survey project manager informed us that FDA had just received a site visit report with concerns assessed as high in two areas—leadership and control, and test planning and procedures. The report stated that the manufacturer's policies and procedures were found to be inconsistent, ambiguous, and were not followed in a manner that would meet due diligence requirements. It also noted that the qualifications of the manufacturer's personnel for specified tasks were not well defined, and that some personnel assigned to tasks identified in the policies and procedures were not qualified to perform those tasks. The report concluded that the manufacturer's procedures for Y2K assessment and corrective and preventive action were less than adequate, and that assessment procedures had not been applied consistently. The manufacturer subsequently told the examiner that action would be taken on the issues raised. FDA officials told us that they plan to follow up with the manufacturer.

The project manager also told us that FDA's contractor is in the process of preparing a final report summarizing the overall findings from the 80 site visit assessment reports, detailing any problems encountered during the project. This individual indicated that FDA expects to receive the final report from the contractor later this month. Although FDA initially expected to submit a final report to HHS by October 1, it has not yet established a date for when this will occur.

To assess how the contractor was executing FDA's task order, we observed selected site assessments. At the five manufacturing site assessments we observed, examiners generally followed the contractor-developed audit guide and were knowledgeable about information technology management, Y2K testing, and risk assessment. During our two initial visits, we noted that examiners sometimes could not answer questions from the manufacturers relating to the FDA clearinghouse and the processing of the final report on the site assessments. We subsequently shared these observations with FDA officials. FDA agreed to consider our suggestions, such as better communicating to the firms the final reporting process and how the FDA Federal Y2K Biomedical Equipment Clearinghouse works. During the later three visits, we did not observe any similar areas of concern.

Many of the 803 PHRD manufacturing sites identified by FDA are in foreign locations. Specifically, our review of the 803 sites on FDA's list showed that 203 were located in 27 foreign countries (appendix II lists these countries). Of the 325 randomly selected for assessment, 233 were in the United States and 92 were in 22 foreign countries. Finally, of the 80 locations where manufacturers agreed to be assessed by FDA, 65 are located in the United States and 15 are located in 8 other countries—Canada (1 site), Finland (2), Germany (4), the Netherlands (1), Norway (1), Sweden (2), Switzerland (1), and the United Kingdom (3).

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 317,000 inquiries between April 1998 and September 1999. However, according to FDA, it is not possible to determine the sources 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.[22] For example, the American Medical Association (AMA) surveyed a random sample of 7,000 of its members in July/August 1999 on whether they were aware of the FDA clearinghouse; only 17 percent of respondents indicated that they were.

In addition, a July 1999 HHS Office of Inspector General (OIG) survey sent to hospitals, nursing facilities, home health agencies, and physicians contained three questions on FDA's clearinghouse. These questions related to awareness, usage, and whether the clearinghouse was helpful.

[22]These include HHS' Office of the Inspector General, American Hospital Association (AHA), and AMA.

Responses to the HHS OIG survey varied significantly. For example, about 80 percent of the hospitals responding stated that they were aware of the clearinghouse, but less than half of the nursing facilities, home health agencies, and physicians responding stated this same awareness. Further, while about 60 percent of the responding hospitals reported that they used the clearinghouse, 25 percent or fewer of the responding nursing facilities, home health agencies, and physicians reported using the clearinghouse to obtain readiness information about their biomedical equipment.

The HHS OIG survey noted that there was general agreement among the respondents that the clearinghouse information was helpful. Specifically, 100 percent of the physicians, 95 percent of the nursing facilities, 91 percent of the hospitals, and 87 percent of the home health agencies that said they had used clearinghouse data said they found the information to be helpful.

Although compliance information on biomedical equipment is available through FDA's clearinghouse, theY2K readiness status of equipment at health care providers' offices is not known because a significant number of providers did not respond to the surveys. As shown in table 1, the response rates to the July survey from the HHS OIG to nursing facilities, home health agencies, and physicians were all less than 50 percent. The response rates to surveys from AHA and AMA on this subject were even less, at 29 and 8 percent, respectively. Lastly, the response rate to a survey from the American Health Care Association (AHCA)[23] was even more disappointing, at less than 3 percent.

[23]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 subacute-care providers.

Table 1: Reported Survey Results of Y2K Readiness of Biomedical Equipment

Entity performing survey/group surveyed	Number surveyed	Number of responses	Percentage responding currently compliant	Percentage responding don't know
HHS Office of the Inspector General (July 1999)				
Hospitals	1,000	537[a]	27	5
Nursing facilities	1,000	230[a]	50	25
Home health agencies	1,000	159[a]	48	27
Physicians	1,000	79[a]	56	22
American Hospital Association (AHA) (February 1999)	2,000	583	6	2
American Medical Association (AMA) (July/August 1999)	7,000	544	[c]	[d]
American Health Care Association (AHCA) (March 1999)	12,000	342[e]	24	[d]
American Medical Group Association (AMGA)[b] (March 1999)	230	99	42	[d]

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

[a]The number of respondents who selected "not applicable" for the question were excluded from the number of responses.

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

[c]According to the survey results, 67 percent of responding physicians rent or lease biomedical equipment that will be affected by Y2K; 62 percent of them were confident that their vendors have prepared the equipment for Y2K. Data were not provided on the remaining 33 percent of responding physicians.

[d]The survey did not have "Don't Know" as a response choice.

[e]Twenty-eight percent of the respondents said this question was not applicable to them.

The survey results also indicated that much work remains in making biomedical equipment Y2K-ready. Table 1 shows that less than one-third of the hospitals responding to HHS' OIG survey stated that all of 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.

Manufacturers Vary on User Testing of Biomedical Equipment

The question of whether to test their biomedical equipment for Y2K compliance is a difficult one that confronts many users, such as hospitals and physicians' offices. FDA has taken the position that manufacturers' submissions of Y2K compliance certifications provide sufficient assurance of product compliance, and that such testing on the part of users is not necessary. VA and the Emergency Care Research Institute (ECRI)[24] have also stated that manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. Accordingly, they do not encourage user testing of biomedical equipment for Y2K compliance. ECRI guidelines, however, suggest that health care facilities should consider testing interfaces between medical devices in cases where the facility cannot determine theY2K compliance of the interface from the device manufacturers.

In contrast to VHA's and FDA's positions, some hospitals in the private sector believe that testing biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. We have testified that officials at three hospitals told us that their biomedical engineers established their own test programs for biomedical equipment and, in many cases, contacted the manufacturers for their test protocols.[25] Several of these engineers informed us that their testing identified some noncompliant equipment that the manufacturers had earlier certified as compliant. According to these engineers, the equipment found to be noncompliant all had display problems and was not critical care/life support equipment. We were told that equipment found to be incorrectly certified as compliant included a cardiac catheterization unit, a pulse oxymeter, medical imaging equipment, and ultrasound equipment.

Our review of manufacturers' web sites disclosed that manufacturers' opinions vary on whether users should test their biomedical equipment. We noted that at least 37 manufacturers provided information on their web sites about Y2K testing. Of these, 30 encouraged testing; 15 provided end users with information such as test protocols and instructions. Fifteen manufacturers also encouraged users to test their devices in configuration

[24]ECRI is an international, nonprofit health services research agency. It believes that superficial testing of biomedical equipment by users may provide false assurances, as well as create legal liability exposure for health care institutions.

[25]*Year 2000 Computing Crisis: Action Needed to Ensure Continued Delivery of Veterans Benefits and Health Care Services* (GAO/T-AIMD-99-136, April 15, 1999).

with related equipment to ensure that the devices operate as intended. Seven manufacturers did not encourage testing; two of these stated that such testing could disrupt operation of software.

As we testified in May, 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.[26] The overriding criterion should be ensuring patient health and safety.

In summary, compliance status information on biomedical equipment can be found in FDA's clearinghouse or on manufacturers' web sites. The quality of the compliance information on the web sites, however, varies significantly, ranging from general assurances of compliance to detailed information on specific product make and model. Given the criticality of having medical devices function as intended on and after January 1, it is important that FDA encourage manufacturers to provide detailed information on the product make and model, compliance status, and availability of solutions for noncompliant equipment.

To its credit, FDA has assessed the Y2K compliance activities of 80 PHRD manufacturing sites. Although most appeared to have been assessed as having low degrees of concern, one site had a concern in two areas assessed at high. FDA is currently reviewing this site to make sure that there are no unresolved issues affecting patient safety.

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. Lastly, although there are varying views on whether end users should test their biomedical equipment for Y2K compliance, the overriding criterion should be ensuring patient health and safety.

We performed this assignment in accordance with generally accepted government auditing standards, from July 1999 through October 1999. We

[26] *Year 2000 Computing Challenge: Much Biomedical Equipment Status Information Available, Yet Concerns Remain* (GAO/T-AIMD-99-197, May 25, 1999).

reviewed and analyzed information listed in the Federal Y2K Biomedical Equipment Clearinghouse. We also reviewed and analyzed information listed on the web sites of biomedical equipment manufacturers referred to in FDA's Federal Y2K Biomedical Equipment Clearinghouse. In addition, we reviewed and analyzed FDA documentation on the agency assessments of PHRD manufacturing sites, including selected contractor's final reports to FDA on the manufacturers. We also visited five PHRD manufacturing sites and observed FDA's contractor examiners carrying out the assessment of the firms' Y2K compliance activities. We interviewed FDA officials responsible for the Federal Y2K Biomedical Equipment Clearinghouse and oversight and management of the agency's survey of PHRD manufacturer Y2K compliance activities.

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.

Contact and Acknowledgments

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FDA's List of Computer-Controlled Potentially High-Risk Medical Device Types

Classification Name
Anesthetic vaporizer
Arrhythmia detector and alarm
Autotransfusion apparatus
Automated blood cell and plasma separator for therapeutic purposes
Automated blood grouping and antibody test system
Blood and plasma warming device
Blood storage refrigerator and blood storage freezer
Breathing frequency monitor
Breathing gas mixer
Cardioconverter, implantable
Cardiopulmonary bypass heart-lung machine console
Cardiopulmonary bypass on-line blood gas monitor
Cardiopulmonary bypass pulsatile flow generator
Cardiopulmonary bypass pump speed control
Centrifugal chemistry analyzer for clinical use
Continuous flow sequential multiple chemistry analyzer for clinical use
Continuous ventilator
DC-defibrillator low energy (including paddles)
Defibrillator, automatic implantable cardioconverter
Defibrillator, implantable, dual-chamber
Device, thermal ablation, endometrial
Discrete photometric chemistry analyzer for clinical use
Electroanesthesia apparatus
Environmental chamber for storage of platelet concentrate
External counter-pulsating device
External negative pressure ventilator
External pacemaker pulse generator
External programmable pacemaker pulse generator
Fetal ultrasonic monitor and accessories
Gas machine for anesthesia or analgesia
Glucose test system
Hemodialysis systems and accessories
High permeability hemodialysis systems
Hyperbaric chamber
Hysteroscopitc insufflator

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Classification Name
Implantable pacemaker pulse-generator
Implanted cerebellar stimulator
Implanted diaphragmatic/phrenic nerve stimulator
Implanted electrical urinary continence device
Implanted intracerbral/subcortical stimulator for pain relief
Implanted nueromuscular stimulator
Implanted peripheral nerve stimulator for pain relief
Implanted spinal cord stimulator for bladder evacuation
Implanted spinal cord stimulator for pain relief
Indwelling blood carbon dioxide partial pressure (PCO2) analyzer
Indwelling blood oxygen partial pressure (PO2) analyzer
Infant radiant warmer
Infusion pump
Instruments used to screen the blood supply for bloodborne pathogens
Intermittent mandatory ventilation attachment
Intra-aortic balloon and control system
Isolated kidney perfusion and transport system and accessories
Kit, test, alpha-fetoprotein for neural tube defects
Laproscopic insufflator
Lipoprotein, low density, removal
Lung water monitor
Medical charged-particle radiation therapy system[a]
Medical Neutron radiation therapy system[a]
Membrane lung (for long term pulmonary support)
Micro chemistry analyzer for clinical use
Neonatal incubator
Neonatal transport incubator
Nonroller-type cardiopulmonary bypass blood pump
Oxygen-uptake computer
Pacemaker programmers
Peritoneal dialysis system and accessories
Portable oxygen generator
Powered emergency ventilator
Processing system for frozen blood
Pulse-generator, dual chamber, implantable
Pulse-generator, program module
Pulse-generator, single chamber

Continued from Previous Page

Classification Name
Pulse-generator, single chamber, sensor driven, implantable
Pump, drug administration, closed loop
Pump, infusion, implanted, programmable
Radionuclide radiation therapy system[a]
Remote controlled radionuclide-applicator system[a]
Roller type cardiopulmonary bypass blood pump
Software, blood bank, stand alone products
Separator for therapeutic purposes, membrane automated blood cell/plasma
Sorbent hemoperfusion system
Stimulator, cortical, implanted (for pain)
Stimulator, electrical, implanted, for Parkinsonian tremor
Stimulator, sacral, nerve, implanted
Stimulator, spinal-cord, totally implanted for pain relief
Stimulator, subcortical, implanted for epilepsy
System, pacing, temporary, acute internal atrial defibrillation
Ventilator, high frequency
Ventricular bypass (assist) device
X-ray radiation therapy system[a]

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[a]These device classifications include radiation treatment planning systems that are accessories to these device types.

Source: FDA.

Listing of Foreign Countries With PHRD Manufacturing Sites

Argentina
Australia
Belgium
Brazil
Canada
Costa Rica
Denmark
Finland
France
Germany
Ireland
Israel
Italy
Japan
Malaysia
Mexico
Netherlands
New Zealand
Norway
Pakistan
People's Republic of China
Republic of Korea
Singapore
Sweden
Switzerland
Thailand
United Kingdom

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Washington, D.C. 20548-0001

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