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Y2K AND MEDICAL DEVICES: TESTING FOR THE Y2K BUG

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT

AND THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

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CONTENTS

Page

Testimony of:

Benson, James S., Executive Vice President for Technology and Regulatory Affairs, Health Industry Manufacturers Association; accompanied by Bernie Liebler, Director, Technology and Regulatory Affairs .. 48

Grob, George, Deputy Inspector General, Department of Health and Human Services 26

Horowitz, Bruce, Director of Product Assurance, Advanced Neuromodulation Systems, Inc 53

Hubbard, William K., Senior Associate Commissioner for Policy, Planning and Legislation, accompanied by Thomas Shope, Special Assistant to the Director, Office of Science and Technology, U.S. Food and Drug Administration 7

Neill, C. Thomas, Vice President of Corporate Services, Quorum Health Group 57

Willemssen, Joel C., Director, Civil Agencies Information Systems, Accounting and Management Division, General Accounting Office 14

Y2K AND MEDICAL DEVICES: TESTING FOR THE Y2K BUG

THURSDAY, OCTOBER 21, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT, AND
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittees met, pursuant to notice, at 10 a.m. in room 2123, Rayburn House Office Building, Hon. Fred Upton, Chairman, Subcommittee on Oversight and Investigations and Hon. Michael Bilirakis, Chairman, Subcommittee on Health and Environment, presiding.

Members present Subcommittee on Health and Environment: Representatives Bilirakis, Upton, Greenwood, Deal, Burr, Bryant, Brown, Green, and Barrett.

Members present Subcommittee on Oversight and Investigations: Representatives Upton, Bryant, and Green.

Staff present: Lori Wall, majority counsel; John Manthei, majority counsel; Chris Knauer, minority investigator; and Amy Davidge, legislative clerk.

Mr. UPTON. Good morning, everyone. As they say in Ann Arbor, welcome to the big house.

Today the Subcommittee on Oversight and Investigations and the Subcommittee on Health and the Environment are holding a joint hearing on the issue of the Year 2000 problem as it relates to medical devices. Over the past year, the Committee on Commerce has undertaken an extensive review of the progress that the Health Care Financing Administration's Medicare contractors and its hospitals, nursing homes, doctors and other providers have made in becoming Y2K compliant.

Earlier this year, these two subcommittees held hearings on the Y2K status of computer billing and financial systems as well as the Y2K compliant status of medical devices. Today, our hearing will follow up on the progress that the FDA, as well as the medical device manufacturers in hospitals, have made in ensuring the Y2K compliance of medical devices.

Medical devices and equipment such as cardiac monitoring systems, cardiac defibrillators and x-ray machines are critical to providing health care treatment in a variety of health care settings. These devices have the potential to adversely affect patient safety if they perform any type of date or time calculation. The degree of risk increases significantly if the machine is a critical care or life support device.

In 1997, the FDA began collecting data from device manufacturers regarding Y2K compliant status of their devices. After several letters and a small response rate from the manufacturers, the FDA joined in partnership with the VA, the Department of Defense and Health Industry Manufacturers Association to assemble a single database clearinghouse. The goal of the clearinghouse was to provide a centralized source of information on the Y2K compliance status of biomedical equipment in the U.S.

Since FDA began its database, the flow of information has increased significantly. However, the FDA is not ensuring that the information displayed on their clearinghouse is accurate or complete. In other words, the clearinghouse serves as a central point for data, but not a guarantee by the FDA that the data provided is accurate or complete.

In order to assess the reliability of the information submitted to the clearinghouse, the FDA announced at our last hearing that they would develop a list of potentially high risk devices that could cause serious consequences for the patient if they were to fail because of data related problems. The FDA would then identify those domestic and foreign manufacturers that have high risk devices for marketing in the U.S. and hire third party contractors to perform onsite visits to a random sample of manufacturers. The contractors would assess the manufacturers procedure and records, both for Y2K assessment of potentially high risk devices and for validation of any Y2K corrections made to those devices. We will hear today about the results of that study.

While information regarding the Y2K status of medical devices continues to increase, recent surveys from the HHS Office of Inspector General show that less than half of Medicare fee for service providers who responded to their survey reported that all of their biomedical equipment was Y2K ready. Although more than 90 percent of all providers who responded to the survey reported that their biomedical equipment will be completely ready by December 31st, there obviously is work remaining.

I hope that this hearing will demonstrate the need for all health care providers to ensure that their medical devices are Y2K compliant. It is crucial at the turn of the century that service to Medicare beneficiaries is uninterrupted, and that patient safety will never be jeopardized. The news we will hear today will not doubt be more encouraging than what we heard a few short months ago.

However, we must remain committed to ensuring that medical devices, particularly those that are potentially high risk devices, will be Y2K ready as we enter the new year.

I would like to welcome all of our panelists that are here to testify. Thank you for coming. At this point, I yield to the ranking member of the Health Subcommittee, Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. I am pleased to participate in our third joint hearing on Y2K issues. I would like to thank our distinguished panelists for joining us and thank Chairman Upton and Chairman Bilirakis for calling this hearing. I will keep my remarks brief.

The purpose of today's hearing is to get a progress report on efforts to forestall Y2K related problems affecting patients. I understand it remains difficult to assess Y2K preparedness on the part

of hospital and physician providers, due in part to low survey response rates from those providers. I am interested in hearing the views of our witnesses on the significance of this information gap, and what if anything is being done at this point to remedy it.

I look forward to an update from FDA and the medical device industry on their progress in their potential areas of concern. I think it would be useful to hear our witnesses' views on what is most and what is least likely to go wrong, and most importantly, to get a feel for your public awareness efforts and other strategies you plan to deploy as we move closer to Y2K.

Finally, I want to commend the FDA and those in the industry and health care communities who have made good faith efforts to resolve the public's concerns regarding Y2K. The product of your efforts will hopefully contribute to a blessedly uneventful New Year's.

I thank you, Mr. Chairman.

Mr. UPTON. I yield to the chairman of the Health and Environment Subcommittee, Mr. Bilirakis from Florida.

Mr. BILIRAKIS. I thank the gentleman, and it is so very nice to be able to agree 100 percent with the ranking members' opening statement. It is a rarity, I am afraid.

Mr. Chairman, I am pleased that we have again reconvened our two subcommittees to examine the readiness of medical devices and ensure that the delivery of health care will not be impacted by the arrival of the new century. And I, too, would like to welcome all of our witnesses who have taken the time to share their expertise on these important issues.

I believe that it is critical, as others have said, that we work together to convey a sense of security to the American people. The Y2K issue has received a great deal of publicity. Many Americans have expressed a sense of uncertainty and are seeking assurances that the new millennium will be a cause for celebration and not concern.

At the same time, we must convey a sense of urgency to members of the health care community. Any failed medical device is one too many. And 100 percent compliance is the only acceptable goal.

In our first panel, the FDA will update us on the Y2K readiness of biomedical equipment. Medical devices play a critical role, as we know, in the daily delivery of health care. And as most of us know, these can range from basic thermometers to more complex devices such as electrocardiograms and infusion pumps. If devices that utilize computer software fail to operate or give improper readings, patients all over the country and the world may be put at an unnecessary risk.

The FDA will describe the progress it has made on this issue since our hearing earlier this year. I also look forward to hearing from GAO and the HHS Office of the Inspector General.

Our second panel will describe the steps taken by individual hospitals and device manufacturers to address the unique challenges posed by the Y2K problem. Manufacturers are often the only parties that have complete access to all of the design and operating parameters of an individual device. Therefore it is essential to know what is being done by medical device manufacturers to ensure that computer software will operate properly without interruption.

I was particularly impressed by the testimony we received at our last hearing. I look forward to learning more from our witnesses today about the specific steps they have taken to ensure that patients will not be put at risk.

In that regard, Mr. Chairman, I would just like to communicate that I was very pleased to learn of the efforts of Tampa General Health Care, which serves many of my constituents in the Tampa Bay area. As of yesterday, Tampa General Hospital had individually tested more than 5,700 pieces of equipment crucial to delivering uninterrupted health care.

In so doing, it was able to report 100 percent compliance of respiratory therapy equipment, 97 percent compliance of biomedical devices and facilities, and 82 percent compliance for radiology equipment. Furthermore, I was assured that any equipment that is not determined to be Y2K compliant by December 15th will be removed from service.

So again, I want to thank all of our witnesses for joining us and I yield back the balance of my time. Thank you, Mr. Chairman.

Mr. UPTON. Thank you, Mr. Chairman. I yield to the gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

And I do thank both of my chairmen, with whom I serve on the two committees that are conducting this joint investigation. I appreciate very much your holding this hearing today.

Mr. Chairman, if you walk down Pennsylvania Avenue just past the Library of Congress, there is an interesting display in the front window of one of our local shops. It has a digital clock which counts down the actual days, hours, minutes, seconds, I think even microseconds, before the end of the millennium. Standing in front of the rapidly moving numbers gives one a strange sense of urgency, and maybe even a hint of concern about what will happen when the display finally reads zero across all of the numbers.

I think the clock is meant to persuade you to buy your New Year's Eve champagne before supplies run out. But it does serve an important reminder to all of us that New Year's Eve may be a little different than our past celebrations.

Talk to 10 different people and you will probably get 10 different answers about what will happen at 12:01 on January 1, 2000. The answers can be as extreme as the end of the world, or as mild as a possible shortage of aspirin and Rolaids for those who have been over-served the night before. Personally, I do not have any predictions, but I am glad to see for the most part our schools and businesses and Government institutions have taken a very serious approach on the problem.

And likewise in Washington, we have actually passed a liability bill as concerns Y2K problems that might come up. Certainly with an interest in trying to remediate those types of concerns. But in the health care industry, we face a little different situation, that we are simply not dealing with business records and those kinds of things that we are concerned about in the general commerce, but we are dealing with potential human life here. So I think it is very important that we take a serious approach to this and as GAO has pointed out in the past, the question of whether medical devices, such as MRIs, x-ray machines, pacemakers, and even fetal mon-

itors, can be counted on to work reliably after the stroke of midnight on December 31st is of critical importance to our Nation's health care system.

While I am glad to see the FDA has been working over the past couple of years to ensure compliance of our medical devices, I do have some questions regarding the FDA approval process and the Y2K problem. I would be interested in knowing how and when the FDA incorporated the millennium bug into its approval process. For instance, GAO lists several devices as high-risk, including the implantable pacemaker, pulse generator and the implanted cerebral stimulator. When, if ever, did such devices have Y2K compliance in order to gain approval? At what point could FDA and the device manufacturers, for that matter, know that the year 2000 could pose a serious health risk? And when did the FDA act upon this knowledge?

In the short, we should all be focusing on ensuring that our medical equipment and facilities will be functioning normally in January. But we should not ignore the long-term questions regarding how this problem might have been prevented. And I thank the Chair again for holding this hearing, and look forward to hearing from our two distinguished panels, including an expert witness, a truly expert witness, because he is from Tennessee, Mr. Neill, who is with Quorum Resources Group in Nashville, Tennessee. I welcome him and again, the other distinguished witnesses that will be testifying in the two panels before us today.

Thank you.

Mr. UPTON. Thank you very much.

I would note to the audience that we have a number of subcommittee and full committee meetings going on this morning, and the House is in session, so members will be coming in and out. At this point, I would ask unanimous consent that all members may enter their opening statement as part of the record, by unanimous consent.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

For the past year, this Committee has conducted an in-depth look at the health care industry and its efforts to become ready for the Year 2000.

This Committee has received regular updates on the progress the Department of Health and Human Services and industry has made in addressing their Y2K problems. The subcommittees on Oversight and Investigation and Health and the Environment held two previous hearings on Y2K readiness as it relates to health care.

Today, we are holding a follow-up hearing to determine the Y2K status of biomedical equipment, specifically critical care and life support devices. Medical devices are critical to medical treatment and research in both our federal as well as our private sector health care facilities. Any equipment that performs a date or time calculation is potentially susceptible to the Y2K bug.

Since this process began over two years ago, much progress has been made with regards to Y2K readiness. However, work remains to be done. For example, a recent survey conducted by the Health and Human Services Office of Inspector General stated that only 27 percent of hospitals who responded to their survey reported that their biomedical equipment was Y2K ready. Although most hospitals reported that they intend to be Y2K compliant by the Year 2000, only time will tell.

I hope this hearing will allow us all to gain a better insight into the process that medical device manufacturers, Medicare providers and the FDA have undertaken in order to ensure that medical devices and equipment will be Y2K compliant. And, to the extent that more work needs to be done, we must ensure that work is completed before the new year. The health and safety of Medicare patients is of the utmost importance.

I would like to welcome all of our panels here today. Thank you all for coming and testifying before us today.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you Mr. Chairmen for scheduling today's important hearing.

I am very concerned that health care consumers of all ages will be adversely effected by computer glitches caused by Y2K.

To date, there has been a great deal of confusion and uncertainty about the Y2K readiness of just about every public and private sector.

However, some things have a more pressing need to be fixed because of our reliance on them for survival.

I believe medical devices are as critical to protect against Y2K failure as anything else.

In today's technology-driven health care era, our reliance on complex and computer driven medical devices has never been greater.

Americans of all ages rely on these devices to not only maintain their health, but to keep them or their loved ones alive.

This is not the first hearing that we have had on this subject, and I would like to commend those who have cooperated with our efforts on this matter.

I look forward to hearing from our witnesses today to learn more about the Y2K readiness of medical devices and also to hear what work is left to be done on this critical issue.

The time for action is now, so that we can ensure the safety of all Americans.

Mr. UPTON. Our first panel today includes the following individuals. If you could come to the witness table. Dr. Thomas Shope, Special Assistant to the Director, the Office of Science and Technology, Center for Devices and Radiological Health, from FDA. Mr. William Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, again from U.S. FDA. Mr. Joel Willemssen, Director of the Civil Agencies Information Systems, from the GAO. And Mr. George Grob, Deputy Inspector General, Department of HHS.

As you gentlemen know, as some of you have testified before, the Oversight and Investigations Subcommittee always by practice has taken testimony under oath. Do you have any objection to that?

[Witnesses respond in the negative.]

Mr. UPTON. And under House and committee rules, you are entitled to have counsel. Do any of you require or need counsel this morning?

[Witnesses respond in the negative.]

Mr. UPTON. If you would stand and raise your right hand. Do you swear to tell the truth, the whole truth and nothing but the truth, so help you God?

[Witnesses respond in the affirmative.]

Mr. UPTON. You are now under oath. And as you know, your testimony will be made part of the record in its entirety. If you could limit your remarks to 5 minutes, it would be terrific.

Dr. Shope, we will start with you. Thank you very much.

Mr. SHOPE. I don't have any opening remarks. Mr. Hubbard is going to deliver those for FDA, and I will be here to help respond to questions.

Mr. UPTON. Terrific. Mr. Hubbard.

TESTIMONY OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, ACCOMPANIED BY THOMAS SHOPE, SPECIAL ASSISTANT TO THE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY, U.S. FOOD AND DRUG ADMINISTRATION; JOEL C. WILLEMSSEN, DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS, ACCOUNTING AND MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE; AND GEORGE GROB, DEPUTY INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. HUBBARD. Thank you, Mr. Chairman. And we of course have a written statement for the record, Mr. Chairman. So I will just summarize some of the points.

When we were last here, the committee had concerns about medical device failures, and concerns about drug availability. And although you are not focusing on that today, I would like to mention it briefly.

But let me update you on what we have done since we were last here. For medical devices, as we testified last spring, we have identified those manufacturers of devices that are potentially high risk if a Y2K failure should occur. That turned out to be just over 300 manufacturers who make about 90 different types of computer-controlled devices. We then launched an intensive audit initiative to sample 80 of those 300 manufacturers, about 25 percent, to determine if there were any problems, and as I said that was a random sample, with the intent that if we found problems in those 80, we would do more.

And I am pleased today to tell you that none of those audits raised any significant concerns about failures of manufacturers to properly address computerization of their devices. So we do believe that the industry has done what it needs to do in this area, and that while we can't claim success until after January 1, we are very, very optimistic that things are moving very well.

For drugs and medical supplies, things like tubing and blood bags and those sorts of things, we surveyed the industry to ask if their manufacturing processes were Y2K compliant. This was done both to gather safety information but also to be able to say to the public that they don't need to worry when they get their prescriptions filled at the end of December or January 1, that those drugs and other products will be in stores.

We have followed that survey with comprehensive audits of a list of the priority manufacturers, the people that are the sole source manufacturers of a drug or hospital supply, orphan drugs, and the makers of the top selling 200 prescribed drugs. And again, I am pleased to inform you today that the vast majority, over 95 percent of these priority manufacturers, are Y2K compliant, and that none of those manufacturers, we believe, will experience problems that will deprive patients of critically needed drugs and hospital supplies.

In addition, we have done quite a bit in the way of outreach. One of the important things is to get the word to hospitals that there is a way to get information about these devices, to know whether they are compliant or not, and if they are not compliant, how to get the fix they need. So we and the Health Care Financing Admin-

istration and the industry and others have attempted to reach out intensively to the hospitals to let them know that.

We have also done various public announcements and have other things in the works to tell the public they don't need to worry about these products and do things like over-purchase and that sort of thing. We have a toll-free number, a web site, brochures, and I believe the committee has been given a consumer article, a major article about how we are doing this, and why consumers can be reassured. We also have an emergency operations center going up at FDA which we will staff 24 hours a day, so that if any evidence comes to us in late December or early January that there is a problem, investigators, engineers and other scientists can rush into that problem and make sure it gets fixed promptly.

I would like to close with the comment that I think the real praise here is deserved by the industry, that the device and drug manufacturers have done what they needed to do, invested the resources and otherwise made sure that these products are not going to be a problem, by and large. There may be a few isolated instances which we will attempt to track down.

And in fact, we are still looking and asking hospitals and others to tell us if they find a medical device that may fail that we did not know about. Dr. Shope is constantly hearing stories or rumors and trying to track those down. So far, we have not found them and we are glad of that.

So with that, Mr. Chairman, I will be glad to take questions.

[The prepared statement of William K. Hubbard follows:]

PREPARED STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING AND LEGISLATION, FOOD AND DRUG ADMINISTRATION

INTRODUCTION

Good morning, my name is William K. Hubbard. I am the Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration (FDA or the Agency). I am pleased to be here today to provide an update on the Year 2000 (Y2K) date issue as it relates to medical devices, drugs and biologics. In May of this year, I appeared before the Committee and discussed with you the need for FDA to allay the fears of the American public whether life-sustaining medical devices will function as intended and whether there will be a sufficient supply of high priority pharmaceuticals due Y2K issues. At that time, I told you that we were optimistic that the industries were taking the necessary steps to guard against Y2K breakdowns. Now that it is October and the year 2000 draws near, I am here today to tell you about FDA's efforts to validate our optimism.

FDA stepped up its efforts to gather more information on the Y2K readiness from industry through additional surveys and audits. This additional data provides FDA with a high degree of confidence in assuring the health care community and the American public that essential medical supplies will be available; and medical devices will function as intended; and that there will be a safe and adequate supply of drugs available. The Agency's efforts to obtain additional data and the high degree of confidence we have today is a tribute to the collaborative efforts among the Federal sector, healthcare community and industry. Let me summarize for you the Agency's efforts.

Y2K STATUS OF BIOMEDICAL DEVICES

FDA has taken a number of steps to enhance the confidence of the American public that medical devices will function as intended as the year 2000 approaches. For the past two years, FDA has continued to add to its knowledge of the Y2K status of medical devices and to make this information available to healthcare facilities. In developing this high level of confidence FDA has taken a number of constructive actions to work with manufacturers and provide information to users about the Y2K compliance of medical devices.

FDA'S Y2K DATABASE

An important tool for obtaining information about biomedical equipment is FDA's Federal Year 2000 Biomedical Equipment Clearinghouse database. It is available via the World Wide Web at www.fda.gov. While the database has proven to be useful to healthcare facilities, professionals and consumers—receiving over 236,691 "hits" from 197,461 users over a period of 17 months—FDA has continued to collect information from medical device manufacturers. FDA believes that approximately 2,300 of the 16,000 biomedical equipment manufacturers could produce equipment that could be affected by the Y2K problem. The vast majority of these 2,300 manufacturers have responded to FDA's requests for Y2K status information, and every effort is being made to locate the remaining companies .

SURVEYS AND ASSESSMENTS

To bolster public confidence in industry's efforts to identify and resolve Y2K problems and to assure a continued supply of needed pharmaceuticals, biologics and essential medical supplies, FDA conducted a voluntary survey of manufacturers of drugs, biologics and consumable medical devices for Y2K readiness. These surveys assessed manufacturers' preparations and plans to continue operations after January 1, 2000. FDA then audited the survey results for a sample of the firms, as well as a high proportion of high priority firms to confirm the survey reports. These surveys indicate that the regulated industries have devoted considerable efforts to Y2K preparations and we do not expect significant interruptions of necessary supplies.

POTENTIALLY HIGH RISK DEVICES (PHRDS)

Although FDA firmly believes that its normal regulatory processes provide the necessary assurances that Y2K problems with high-risk devices will be carefully addressed, FDA implemented a plan to provide additional assurance to the public and healthcare facilities about the Y2K status of medical devices. FDA addressed concerns about the adequacy of the medical device industry's actions taken to avoid serious Y2K problems by independently validating their Y2K self-assessments.

FDA developed and posted on the FDA Y2K website a list of types of potentially high risk devices (PHRDs) that are likely to be computer-controlled and that could present a significant risk of immediate harm to the patient should the devices fail to operate as expected due to a Y2K problem. The PHRDs list contains 90 types of potentially high-risk devices for which FDA has identified 803 PHRDs manufacturers. An FDA contractor contacted these 803 firms and learned that approximately 60 percent have no computerized devices.

FDA initiated a special study designated as a "Special Year 2000 Data Gathering Request" to examine the Y2K programs of a random sample of potentially high-risk device (PHRD) manufacturers. Eighty of the PHRDs manufacturers were randomly selected for an on-site assessment by an FDA contractor with extensive experience in information technology and Y2K verification and validation. The study was designed to:

- provide a high level of assurance that manufacturers have properly assessed the Y2K status of their computer-controlled medical devices;
- examine manufacturers' processes to evaluate how they assess the Y2K status of their products;
- verify that the manufacturers have developed and properly validated appropriate upgrades to correct any Y2K problems for these devices; and,
- confirm the information provided by manufacturers for the Federal Year 2000 Biomedical Equipment Clearinghouse database by examining the supporting documentation of the manufacturers.

RESULTS OF PHRDS ASSESSMENTS

As of October 15, 1999, the contractor has completed all 80 on-site reviews of records to assess the existence and adequacy of manufacturers processes and procedures implemented under a quality system. The assessments are intended to assure that potentially vulnerable devices have been adequately assessed and that upgrades are correctly implemented and appropriately tested and evaluated by the manufacturer. As part of this process, FDA is evaluating the reports as they are completed and to date has found no serious problems related to Y2K. The contractor will provide FDA with a final report of the assessments in early November. FDA will review the contractor's report and will issue a summary report in early November. FDA is confident that the evaluation of these manufacturers will demonstrate the thoroughness with which manufacturers have assessed and provided information and corrections for non-compliant products.

Now that manufacturers should have completed their assessments of Y2K compliance status and identified non-compliant devices, FDA will review this information to identify any manufacturers of PHRDs for which information is not available, or whose non-compliant products pose an actual significant risk to patient health. For firms that have declined to voluntarily participate in the PHRDs assessments, if these firms have not been inspected recently by FDA, the Agency will consider by the middle of November whether an FDA inspection of the firm should be conducted, based on the possible level of risk that the product may present. In these situations, FDA will review the steps taken by the manufacturers to notify users regarding any problems that might exist and to assure that appropriate corrections are implemented.

In any case where the action by the manufacturer has been inadequate to assure patient safety, FDA will use its statutory authorities to require corrections and publicize the situations. FDA is prepared to take action which would include public advisories to device users, suggestions to manufacturers regarding voluntary recalls, mandatory recalls or seizure of the non-compliant devices in extreme risk situations. FDA expects, however, that the situations where such actions will be required will be rare as there are many incentives in addition to possible FDA regulatory action which lead manufacturers to address any such potentially high risk situations before FDA regulatory action is needed.

PHARMACEUTICAL INDUSTRY AND Y2K COMPLIANCE

FDA also has been examining the intersection of Y2K risk mitigation and the availability and quality of certain prescription drugs. In fact, government agencies and organizations within the pharmaceutical industry supply system (including manufacturers, distributors, pharmacies, hospitals, physicians, pharmacists, insurers and others) have been working closely together to prepare for the year 2000 date change and its potential impact on the supply of pharmaceuticals.

In an effort to obtain additional data on this issue, on April 21, 1999, the FDA Commissioner, Dr. Jane E. Henney, sent a letter to the Presidents and CEOs of approximately 4,228 pharmaceutical manufacturers, which includes prescription, over-the-counter, and bulk drug manufacturers; distributors-repackagers; and, medical gas manufacturers. The letter requested their assistance in assuring FDA and the American public that their firms have addressed the Y2K problem as it affects the adequate supply of safe and effective drugs. Included with the letter was a "Y2K Assessment Survey" concerning the status of actions pharmaceutical firms have taken to address this issue and assess Y2K readiness within the pharmaceutical industry. The focus of this effort is on prescription products with emphasis on the priority firms (sole source, orphan and the top 200 prescribed products).

Survey of Pharmaceutical Manufacturers

As of October 8, 1999, 3,132 or 74.1 percent responded to the survey, including 1,053 of the 1,070 or 98 percent of the prescription drug manufacturers that were surveyed. Of the approximately 274 priority manufacturers (160—excluding subsidiaries) which includes sole source, orphan and top 200 prescribed, 270 or 99 percent have responded. Of the firms that completed the survey, 95 percent state they will be ready for Y2K by the end of October with both the foreign and domestic firms having a similar pattern of Y2K readiness. Priority companies who indicated a later date are being contacted to determine their Y2K readiness and to make sure they are on track for meeting their goals. FDA is committed to maximizing the response rate particularly from the 274 priority manufacturers.

Pharmaceutical Audits

Many have urged that FDA take additional actions beyond the survey program that will provide independent assurance of the adequacy of manufacturers' Y2K assessments and any resulting Y2K corrections. As a result, FDA decided to have a contractor, with extensive experience in information technology and Y2K verification and validation, audit each of the 160 highest priority pharmaceutical firms, as well as a random sampling of other drug manufacturers. The surveys, by the contractor via telephone or on-site interview, were begun on July 19, 1999.

As of October 8, 1999, 88 percent of the assessments have been completed. It is important to note that to date the audit results have confirmed the findings of the survey. These results provide the basis for a clear message to reassure the American public that prescription drugs will continue to be available.

FDA and the pharmaceutical industry will continue to monitor the Y2K status and availability of pharmaceutical supplies. FDA has processes in place to address product availability and has used these procedures to help get necessary products

to patients. FDA will continue to work with the health professional community, industry and patient groups regarding Y2K readiness and product availability.

BIOLOGICS INDUSTRY AND Y2K COMPLIANCE

Another section of the pharmaceutical industry produces biological drugs as well as vaccines and blood products. We took the same survey/audit approach with these manufacturers as well.

Survey of Biologics Manufacturers for Y2K Manufacturing Processes

On June 30, 1999, a survey was mailed to 1,576 licensed biologics manufacturers and registered blood establishments. Letters to the biologics trade organizations requesting their assistance in encouraging participation in the survey effort were sent on June 30, 1999. Of the responses that have been received, 92 percent report that they will be Y2K ready by the end of October.

As of October 15, 1999, we have received responses from 1,483 or 94 percent of the firms. Highest priority has been placed on 110 priority firms, which include licensed manufacturers of vaccines, therapeutics, allergenic products, viral marker test kits and major blood organizations. As of October 15, 1999, 101 or 90 percent of the high priority firms have responded.

Biologics Audits

Telephone/site visit audits of these 110 high priority firms began in late August and as of October 14, 1999, audits have been completed for 83 or 75 percent of the high priority firms. To date, we have no reports of problems regarding firms that have been audited. We also have begun audits of a random sample of the firms that are not in the high priority group. As of October 14, 1999, we have completed audits of 48 of these firms with no problems identified.

CONSUMABLE MEDICAL SUPPLY INDUSTRY AND Y2K COMPLIANCE

Survey of Manufacturers of Consumable Medical Supplies for Y2K Manufacturing and Distribution Processes

On June 18, 1999, surveys were mailed to 3,070 consumable medical supplies manufacturers (approximately 2,000 domestic, 1,000 foreign). The focus of the survey is on those manufacturers that produce essential medical devices that are used and consumed on a recurring basis during the delivery of essential healthcare services and whose availability is critical to the uninterrupted delivery of health care and patient welfare. The survey requests information on mission critical automated manufacturing and distribution systems rather than Y2K status information on specific products. A follow-up letter was sent to non-respondents on July 23, 1999. As of October 14, 1999, 2,074 responses and/or returned mail have been received with approximately 90 percent of the fully analyzed responses (1309) reporting Y2K readiness by October 31.

Consumable Medical Supplies Audits

For a sample of survey respondents, validation of survey responses by the contractor via telephone or on-site interview is being conducted. Highest priority for these assessments will be the 225 manufacturers that produce a device only manufactured by 3 or fewer firms, so called "few sources" devices, and the 57 manufacturers that are the sole source for a supply (the 57 manufacturers are included in the 225). Of the 225 "few sources" firms, 197 have responded, and of the 57 sole source firms, 48 have responded. Attention also will be focused on those manufacturers with inconsistent responses. As of

October 14, 1999, approximately 58 percent of the assessments of the priority firms have been completed with no serious problems reported. Eighty-nine percent report that they will be Y2K ready by the end of November. It is important to note that the initial audit results confirm the survey results. We will continue to follow-up with those manufacturers that are not Y2K ready and whose supplies, if not available, could have a significant impact on health care delivery.

RECENT AGENCY WIDE OUTREACH EFFORTS

The FDA website, including the Federal Y2K Biomedical Equipment Clearinghouse database, provides much of the information needed by healthcare providers and consumers regarding Y2K and FDA-regulated products. For answers to questions that can not be found on the Y2K website, FDA recently established a Y2K telephone hotline which can be reached by calling FDA's main information line toll-free at 1-888-INFO-FDA or using the Y2K e-mail form on the FDA Y2K website.

FDA also has developed an extensive outreach initiative that will provide video and audio news releases, brochures and articles designed to address the concerns of the consumer and the healthcare community regarding Y2K issues. Additional FDA outreach efforts are noted in the Appendix.

CONCLUSION

In summary, Mr. Chairman, there is now extrinsic and objective evidence that drug and device manufacturers have taken the necessary steps to ensure that their products and production facilities are ready for Year 2000 conversion.

Indeed, I believe that manufacturers, wholesalers, and retailers of these products should be commended for taking this issue seriously and for devoting the necessary resources to protect their customers and, ultimately, patients from Y2K related failures. For those few firms that have not taken these steps, FDA will be vigilant in following up on any reports.

FDA will continue to work with other Federal agencies, patient groups, healthcare provider associations and industry to optimize data collection and information sharing. Together we can provide the American public with the needed assurances that manufacturers will be Y2K ready. We all share a common goal of having medical devices that will function as intended and a safe and adequate drug supply available for the American public as we continue through the year-end transition.

Thank you for the opportunity to testify.

APPENDIX

LETTERS TO MEDICAL DEVICE INDUSTRY

1997

- June 25, 1997, notice to all medical device manufacturers (8,322 domestic and 5,085 foreign) registered with FDA's Center for Devices and Radiological Health (CDRH) indicating that they needed to address this issue and review both embedded and non-embedded software products.

1998

- January 21, 1998, letter which was sent by DHHS to approximately 16,000 medical device and biomedical equipment manufacturers to ask them to voluntarily provide information on the Year 2000 compliance status of their products.
- June 29, 1998, targeted, follow-up letter to specific manufacturers of potentially vulnerable computerized devices.
- September 2, 1998, follow-up to the June 29, 1998, letter directed to the manufacturers of potentially computerized devices who had not responded to the previous requests.
- August 14, 1998 and September 2, 1998, letters from Dr. Bruce Burlington, then Director, CDRH, and Dr. Friedman, then Acting Commissioner of the Food and Drug Administration, to the Health Industry Manufacturers Association (HIMA) requesting that the Association take aggressive and immediate actions to encourage and assist medical device equipment manufacturers in providing information to FDA.
- Late September 1998, FDA posted on the website those manufacturers of selected product categories that are likely to include vulnerable products that had not provided a response to FDA's inquiries.

1999

- March 3, 1999, letter requesting that the 2,300 targeted biomedical equipment manufacturers carefully review the Year 2000 status information that they have provided or intended to submit, and, where necessary, provide more specific information on non-compliant products.
- March 29, 1999, letter requesting that targeted medical device manufacturers submit a complete list of individual product models that are Year 2000 compliant. Responses from 572 manufacturers have been received as of June 1, 1999.
- July 16, 1999, Public Health Notification regarding date-related computer controlled medical devices to administrators, risk managers and biomedical/clinical engineers of 67,000 hospitals and healthcare facilities. The notification urged them to develop contingency and remediation plans to avoid serious adverse events; provided information to assist them in contingency planning; provided information about the Federal Y2K Biomedical Equipment Clearinghouse website; and encouraged them to report problems or adverse events associated with Y2K and computer-controlled devices to FDA's MedWatch Program.

Additional Outreach and Guidance

In an effort to reach the widest group of individuals, both to get information and to spread information, CDRH also has been conducting extensive outreach to the device industry and to other consumers on this issue. These efforts are as follows:

- CDRH's Division of Small Manufacturers Assistance provided an article in May 1998 entitled "Biomedical Equipment Manufacturers Urged to Share Year 2000 Information" to 12 medical device trade press contacts and to 65 U.S. and 35 foreign medical device trade associations in order to facilitate the dissemination of information to their members regarding the website database and to encourage the posting of data by manufacturers.
- The website and database were mentioned in the FDA Column of the June 3, 1998, *Journal of the American Medical Association* and in an article in FDA's Medical Bulletin that was sent to approximately 700,000 healthcare practitioners this past summer.
- In the spring of 1998, CDRH developed a Guidance Document on FDA's expectations of medical device manufacturers concerning the Year 2000 date problem. The guidance is available on the FDA website.
- FDA also developed an article addressed to the users of radiation treatment planning systems regarding the need to assess these systems. The article was published in the newsletters of relevant professional associations.
- Staff of CDRH have participated in numerous conferences and video teleconferences devoted to the Year 2000 problem in healthcare in order to communicate with healthcare facilities regarding the Biomedical Equipment Clearinghouse and the need to address the Year 2000 issue with devices.
- March 29, 1999, memorandum issued by the Director, Division of Emergency and Investigational Operations, Office of Regulatory Affairs (ORA), to the FDA field instructing investigators to expand the Year 2000 activities to include asking questions regarding what the firm has done to assure that the computer controlled and date-sensitive products, manufacturing processes and distribution systems are Year 2000 compliant.
- On May 17, 1999, the President's Council on Year 2000 Conversion in conjunction with the Veterans Health Administration hosted a Roundtable event. The discussion focused on those services and supply chains that are critical to the health and well-being of all Americans, and in particular the ready availability of pharmaceuticals from their manufacture to the filling of prescriptions at the drug store. The consensus of those present at the Roundtable (the brand name and generic drug manufacturers, wholesalers, and health care providers, payers, along with consumer advocates and government regulators) is that allowing patients to obtain a substantial advance (buying or stockpiling) is not necessary and may actually cause the shortage that this kind of action is trying to prevent. FDA continues to work with the pharmaceutical industry, associations, and other Federal agencies to assure a safe and adequate pharmaceutical supply.
- In a letter to providers, Health Care Financing Administration (HCFA) noted the FDA website for providers to obtain information on medical devices and Y2K compliance status information.
- FDA has participated in 18 national and regional HCFA conferences and three National Association of Rural Health Clinics regional conferences which included discussions of FDA's Y2K activities, status of the Federal Y2K Biomedical Equipment Clearinghouse, pharmaceutical supply issues and future Agency activities.
- On April 16, 1999, a Guidance for Industry and the Clinical Community on "Medical Device Reporting for Date-Related Problems Including Y2K."
- On June 7, 1999, FDA participated in a President's Council on Year 2000 Conversion Roundtable event on medical supplies.
- On August 18, 1999, FDA staff participated in a Health Resources and Services Administration (HRSA) teleconference entitled "Making Your Health Facility Y2K Compliant" directed to HRSA funded rural health clinics.
- On August 24, 1999, FDA issued a *Talk Paper* entitled "The Year 2000 Date Problem and Medical Devices."

Although most devices are regulated by CDRH, FDA's Center for Biologics Evaluation and Research (CBER) regulates blood bank software, which is of particular concern for potential Year 2000 problems. In January 1998, CBER posted guidance for industry entitled "A Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products" on the FDA website. The guidance provided specific recommendations to assist industry in its evaluation of computer and software systems used in the manufacture of blood products and to

assist in evaluating the impact of potential Year 2000 problems. CBER is aware of the status of these individual products and believes that the blood bank software will be Y2K compliant or will have a "patch" or "work-around" for the systems to ensure that the systems will work through Year 2000.

Mr. UPTON. Thank you.

Mr. Willemssen?

TESTIMONY OF JOEL C. WILLEMSSEN

Mr. WILLEMSSEN. Thank you, Mr. Chairman, Chairman Bilirakis, Ranking Member Brown, members of the subcommittees, thank you for inviting GAO to testify today.

As requested, I will briefly summarize our statement. Over 4,000 manufacturers have submitted data to FDA's biomedical clearinghouse. And about 61 percent of them reported having products that do not use a date, while about 8 percent or 342 manufacturers reported having date related problems. According to FDA, these manufacturers reported about 1,000 products with date-related problems.

FDA also accepts links to manufacturers' web sites for compliance information, rather than requiring individual submissions. And 429 companies have provided these links. As we testified before you in May, FDA stated it did not know the total number of products reported by these companies and how many had date-related problems.

We reviewed all of those web sites and identified a total of more than 32,000 biomedical products, and we found that about 4,000 are considered non-compliant by the manufacturer. This is about four times the total number of non-compliant products that manufacturers individually reported to FDA.

In addition, the quality of the compliance information on web sites varied significantly ranging from general assurances of compliance to detailed information on specific make and model. We believe it is critical to have that kind of detailed information and therefore think FDA should request manufacturers to provide this information on their web sites.

Let me next turn to FDA's review of biomedical manufacturers. Last year, we recommended that HHS take steps to review manufacturers' compliance test results for critical care and life support biomedical equipment to give added assurance that such equipment was compliant. At your hearing in May, FDA agreed that it would compile a list of computer controlled potentially high risk devices and develop a list of manufacturers of these devices and select a sample of them for review.

FDA has now done that, and has identified 90 types of products considered potentially high risk devices and 803 manufacturing sites for these products. It should be noted that about 200 of those sites are in other countries.

Our review of the first 25 site assessment reports that were available to us showed that most of the assessments were identifying a low level of concern and that until recently, no assessments were showing a level of concern that would be considered a risk to patient safety. However, earlier this week, FDA informed us that a report had been submitted showing a high level of concern for one site.

Next, turning to health care providers, available data indicate that most providers responding to surveys who have used the FDA clearinghouse view it as helpful. However, many of the providers who have responded to surveys stated that they have not used the clearinghouse.

And finally, the question of whether to test biomedical equipment for Y2K compliance is a difficult one that confronts many users such as hospitals and physicians' offices. In contrast to FDA's position that manufacturers' submissions of Y2K certifications provide sufficient assurance of compliance, some hospitals believe that testing of equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety.

Our review of manufacturers' web sites disclosed that manufacturers' opinions on whether users should test equipment vary, with many providing information on Y2K testing and others saying that testing could disrupt the operation of software. We continue to believe that the overriding criterion in deciding whether to independently test is patient health and safety.

That concludes a summary of my statement, and I would be pleased to address any questions.

[The prepared statement of Joel C. Willemssen follows:]

PREPARED STATEMENT OF JOEL C. WILLEMSSEN, DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GAO

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, 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

[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.

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 where 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

- 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 that 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.

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.

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[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.

[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).

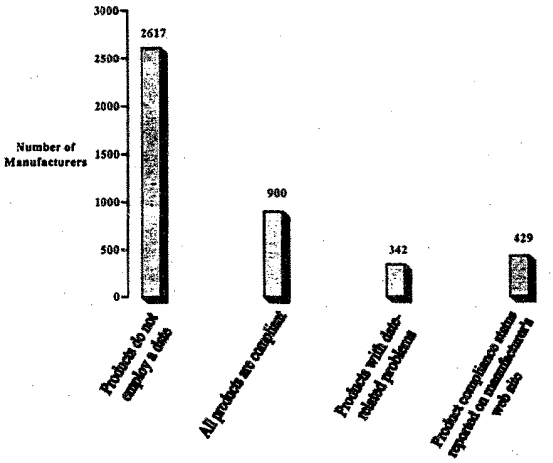
[10] GAO/AIMD-98-240, September 18, 1998.

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.

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

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 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.

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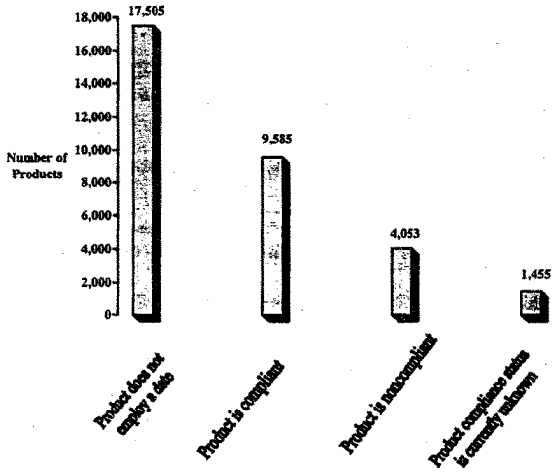
[12] *Year 2000 Computing Challenge: Concerns About Compliance Information on Biomedical Equipment* (GAO/T-AIMD-99-209, June 10, 1999).

[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 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.

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[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.

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

- 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 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.

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 comprised of 726 biomedical equipment manufac-

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

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

turing sites and 77 manufacturing sites of blood and blood products equipment which 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,
- 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 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 assess-

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[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, multi-site 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.

ment. 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 7000 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.

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.

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

[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	1000	[1] 53	27	5
NURSING FACILITIES	1000	[1] 230	50	25
HOME HEALTH AGENCIES	1000	[1] 159	48	27
PHYSICIANS	1000	[1] 79	56	22
American Hospital Association (AHA) (February 1999)	2,000	583	6	2
American Medical Association (AMA) (July/August 1999)	7,000	544	[3]	[4]
American Health Care Association (AHCA) (March 1999)	12,000	[5] 342	24	[4]
American Medical Group Association (AMGA) [2] (March 1999)	230	99	42	[4]

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

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

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

[3] 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.

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

[5] 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 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.

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[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).

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 to October 1999. We 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 carry 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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APPENDIX I

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 systemBlood 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

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

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

Classification Name
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
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 pumpInstruments 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 monitorMedical charged-particle radiation therapy system [1]
Medical Neutron radiation therapy system [1]
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
Pulse-generator, single chamber, sensor driven, implantable
Pump, drug administration, closed loop
Pump, infusion, implanted, programmable
Radionuclide radiation therapy system [1]
Remote controlled radionuclide-applicator system [1]

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

Classification Name
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 [1]

Source: FDA.
[1] These device classifications include radiation treatment planning systems that are accessories to these device types.

APPENDIX II

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; Thailandand the United Kingdom.

Mr. UPTON. Thank you.

Mr. Grob, welcome back.

TESTIMONY OF GEORGE GROB

Mr. GROB. Thank you, Mr. Chairman.

I was here in April, and at that time, you asked us all if we thought the health care providers, whom I will talk about in my testimony, as opposed to the manufacturers, would be ready. And I stated that I thought they would.

I am less confident now. I think some might not be ready.

In the April testimony, shortly after that, you asked our office, did the Senate Special Y2K Committee, to repeat the surveys that we had done in January. We did do that in July, and provided the copies of those surveys to you.

Overall, we found that providers reported improvements in their level of Y2K readiness in the 6 months between our two surveys. Approximately two-thirds of providers reported that their billing and medical records systems were ready, compared to about half in the January survey. Almost all the providers predicted that these systems would be ready by the end of the year.

However, when we examined these results more closely, concerns arose about the overall readiness of health care providers. For instance, at least a third of respondents reported that they had not yet tested their billing and medical records systems. Even fewer had reported that they had tested data exchanges with external vendors or said that an independent party had verified their readiness.

Less than 60 percent reported that they had completed contingency plans, with some providers indicating that they had no plans to do so. Because of these findings, it causes me to view some providers' assertions of complete readiness with a degree of skep-

ticism. If the providers have not tested their systems, there is really no way they can be sure that the systems are ready.

With this background in mind, let me now turn to biomedical equipment. Health care providers were even less confident in the readiness of their biomedical equipment than other systems. Specifically, only 27 percent of hospitals reported that their biomedical equipment was completely ready. Other provider types reported around 50 percent of their equipment was ready.

However, it is important to note hospitals may have many more pieces of equipment than other providers. Furthermore, even those who said their equipment was not completely ready did say that on average, 85 percent of it was. This indicates that hospitals are confident that most pieces will function properly into the new year.

Between 60 and 70 percent of providers reported that they are relying on the manufacturers of biomedical equipment for Y2K information. However, almost half the hospitals said that they have had trouble getting the necessary information from these manufacturers. In addition to relying on the equipment manufacturers, some providers, especially hospitals, reported taking actions themselves.

This is important, because the equipment needs to be working in the real world. And I would like to address for a moment the issue of testing. We should not confuse the need for bench testing and laboratory with the need to test it where it is being used. Much of the equipment needs to be connected to computers. It needs to be connected to other systems in the hospital or the nursing home setting.

And when you look on the FDA web site, and manufacturers offer upgrades of their equipment to make them Y2K ready, those upgrades will have to be installed and they will have to be tested in conditions.

If I may stretch my time, just to give you one analogy—if you went out today and you bought a brand new computer in the department store and a nice office suite to bring home with you, I'll bet you the computer would work and I'll bet you that the program is okay. But I will also bet you that it will be several days before you get that working in your home. It would be for me, at least.

With this in mind, then, the increased attention to the readiness of the providers is very important. And I am hoping that this committee's hearing may help rouse those who are complacent from their unearned confidence.

[The prepared statement of George Grob follows:]

PREPARED STATEMENT OF GEORGE GROB, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Good morning, Messrs. Chairmen and members of the Subcommittees. I am George Grob, Deputy Inspector General for Evaluation and Inspections, Department of Health and Human Services. I am here today to discuss our concerns about the readiness of health care providers for the Year 2000 (Y2K), especially with regard to their biomedical equipment.

BACKGROUND

The Y2K problem presents many concerns for health care providers. Not only must providers evaluate their billing and medical records systems; they also need

to ensure that their biomedical equipment will operate correctly in the new millennium. Some biomedical devices, such as infusion pumps, pulse generators, blood handling and storing equipment, chemistry analyzers, monitors, and arrhythmia detectors and alarms, contain embedded microchips that perform date-sensitive functions. The Y2K problem may impact the performance of these devices by shutting down the equipment, administering the wrong dosage, providing an inaccurate diagnosis, or recording the wrong date.

According to the Food and Drug Administration (FDA), the vast majority of biomedical devices will function without any problems after December 31, 1999. Furthermore, the FDA adds that most of those that do malfunction will only have minor problems, such as displaying an incorrect date, which will not significantly affect a patient's health. The FDA concludes that only a small number of devices will have serious operational flaws if they are not corrected before January 1, 2000. On its website, the FDA maintains a searchable database which lists the Y2K status of pieces of biomedical equipment as reported by the manufacturers.

Today, I wish to discuss with you the IG's work in assessing the status of biomedical equipment, and also highlight some of our work with regard to how Y2K could impact health care providers.

OIG'S SURVEY OF HEALTH CARE PROVIDERS

Overview

Before I talk more specifically about biomedical equipment, I need to set up some background in order to lend context to the discussion. In April of this year, I testified before this Committee about the results of a survey on Medicare provider readiness conducted by my office. That survey, administered in January of 1999, covered a variety of issues, including billing systems, medical records systems, biomedical equipment, and contingency planning. Your Subcommittees, along with the Senate Special Committee on the Year 2000 Technology Problem, requested that we repeat the January survey in order to gain an updated assessment of provider readiness.

The July survey covered the same basic areas as the initial survey, with a few minor improvements. The surveys were developed with assistance from the Health Care Financing Administration (HCFA) and several provider associations, including the American Association of Homes and Services for the Aging, the American Health Care Association, the American Hospital Association, the American Medical Association, the Health Industry Distributors Association, the National Association for Home Care, and the National Association for Medical Equipment Suppliers.

As with the initial study, anonymous surveys were sent to 5,000 randomly selected Medicare providers representing five provider groups: acute-care hospitals, nursing facilities, home health agencies, durable medical equipment (DME) suppliers, and physicians. Response rates ranged from a high of 56 percent for hospitals to a low of 20 percent for physicians. As I discuss the results of our survey, please keep in mind that this is anonymous self-reported data. The advantage of promising anonymity to respondents was that it may have increased response rates and diminished some barriers to honest replies—such as fear of liability for unreadiness. The disadvantage is that the data cannot be verified for accuracy. Additionally, we cannot make any assumptions about the Y2K-readiness of those providers who did not respond to our survey.

Overall, we found that providers reported improvements in their level of Y2K readiness in the six months between our two surveys. Approximately two-thirds of providers reported that their billing and medical records systems were Y2K ready, compared to about half in the January survey. Almost all providers predicted these systems would be ready by the end of the year.

However, when we examine the results more closely, concerns arise about the overall readiness of health care providers. For instance, at least a third of respondents reported that they had not yet tested their billing and medical records systems. Even fewer reported that they had tested data exchanges with their external vendors, or said that an independent party had verified their readiness. Less than 60 percent reported that they had completed contingency plans, with some providers indicating that they had no plans to do so. Because of these findings, it causes me to view some providers' assertions of complete readiness with a degree of skepticism. If the providers have not tested their systems, there is really no way they can be sure that the systems are ready.

Reported Readiness of Biomedical Equipment

With this background in mind, let me now turn to biomedical equipment. Health care providers were even less confident in the readiness of their biomedical equipment than their other systems. Specifically, only 27 percent of hospitals reported

that their biomedical equipment was completely ready. Other provider types reported that around 50 percent of their biomedical equipment was Y2K ready. However, it is important to note hospitals have many more pieces of biomedical equipment than other providers. Additionally, even hospitals whose biomedical equipment was not completely ready still reported, on average, that 85 percent of their equipment was Y2K ready. This indicates that hospitals are confident that most pieces will function properly into the new year.

Reliance on Manufacturer Statements

Between 60 and 70 percent of providers reported that they are relying on the manufacturers of biomedical equipment for Y2K information. However, almost half of hospitals said that they have had trouble getting necessary information from these manufacturers.

Four out of five hospitals who responded to our survey knew about the FDA's website, which has a searchable database of Y2K readiness information as reported by biomedical equipment manufacturers. Almost 60 percent of hospitals said that they had actually been to the FDA's site. However, less that half of the other provider types knew about the site, and even fewer had visited it. On the other hand, nearly all providers who had visited FDA's website found it to be helpful.

Testing

In addition to relying on equipment manufacturers, some providers, especially hospitals, report taking action themselves. This is important because equipment needs to be working in the conditions in which it is actually installed and used and not just under ideal laboratory conditions. About 70 percent of hospitals reported that they had tested their biomedical equipment to ensure that it would function properly after Y2K. Less than 50 percent of other providers said that they had tested. However, even hospitals have not done particularly well in getting independent parties to verify the readiness of their biomedical equipment. Less than 40 percent of responding hospitals and 25 percent of physicians, home health agencies, and other providers have had third parties come in and validate the readiness of their devices.

Survey Summary

As with their billing and medical records systems, many providers are not taking the necessary steps to ensure that their biomedical equipment will be ready. Hospitals, though reporting less readiness than the other provider groups, actually seem to be ahead of the others in terms of knowledge and testing. Many hospitals seem to realize that while manufacturers' statements are a good starting point, relying on them is not enough. Again, testing of the equipment is the only way that providers can assure their equipment will function properly after December 31, 1999.

OIG WORK AT INDIVIDUAL HOSPITALS

In addition to our survey work, we also have garnered information on hospital testing of biomedical equipment by conducting interviews with a number of hospitals. These interviews complement our survey results, and fill in some important details about how providers are dealing with Y2K and their biomedical equipment.

In March of 1999, our auditors conducted interviews with representatives from 10 hospitals and 10 hospital groups representing a total of 411 facilities. The auditors gathered information through on-site, mail, and telephone interviews. The purpose of these interviews was to determine the efforts used by hospitals to assess, inventory, repair or replace, and test biomedical equipment. These hospitals placed their biomedical devices into one of three categories, depending on the seriousness of consequences associated with its failure. The high risk category was comprised of equipment whose malfunction could cause injury or death to the patient or operator. The medium risk category contained equipment which may affect patient monitoring or lead to inaccurate diagnoses in a non-life threatening manner. Finally, low risk equipment failures will have no impact on the patient care, but the wrong date will appear on a report.

We found that hospitals had three main methods of determining the readiness of a piece of biomedical equipment: the FDA website; direct communication with the manufacturer; and performing their own tests. The hospital representatives interviewed in March stated that the FDA's database was useful in determining the status of a piece of equipment. Hospitals reported that they were relying on testing conducted by the manufacturers in order to verify equipment readiness. According to our respondents, only 39 of the 411 hospitals were testing equipment to verify manufacturer statements.

The preliminary results of this audit were presented to the FDA on March 31, 1999. We recommended that the FDA solicit test results from the provider community in order to determine if their tests contradicted the manufacturer statements in FDA's database.

On June 10, 1999, the Deputy Secretary announced that the FDA would conduct on-site assessments of equipment manufacturers' procedures for determining compliance. In addition, on July 16, the FDA issued a notice which urged hospitals and other health care providers to report to FDA any test results which differed from manufacturer assertions.

CONCLUSION

Most health care providers report improvements in the readiness of their biomedical equipment and other systems. Nevertheless, there are still many uncertainties about their readiness and the ramifications to patients if they are not ready on time. When comparing our most recent survey results to the findings from the March audit, we have hope that providers are beginning to realize the importance of doing their own testing, and not simply relying on their manufacturers to identify potential problems. Hospitals generally seem to be responding accordingly. We are less confident of other providers' plans and actions.

This concludes my testimony. Thank you for the opportunity to discuss the Y2K readiness of biomedical equipment. I would be happy to answer any questions you may have.

Mr. UPTON. Thank you. All of you did not use your full 5 minutes. I think that is a record.

I would just note, using your time still, Mr. Grob, that I just got that Sega Dream Quest for my son, and with the football NFL game. That was a couple of weeks ago, and I still don't have it working yet. So I have to do that soon, before I lose the money.

I will recognize the chairman of the Health and Environment Subcommittee first for questions, Mr. Bilirakis.

Mr. BILIRAKIS. Well, thank you, Mr. Chairman. I want to welcome the gentlemen. You have all testified, I am not sure whether Mr. Hubbard has, but I know the other gentlemen has testified here before. Dr. Shope, we commend you and thank you for your real concentration on this particular problem at FDA. You have shown that commitment in the past. And it is really good to see Mr. Willemssen and Mr. Grob again.

However, it's not good to hear what they have to say. Now, we have all sorts of specific questions. Your last point, Mr. Grob, the independent validations on the equipment, damned good point, obviously. You have indicated your optimism of the last hearing has plummeted. And why it has plummeted, even though your survey says one thing, about 70 percent reporting they tested, your auditors conducted specific information on hospital testing and biomedical equipment and only 39 out of the 411, according to the written testimony, or roughly 10 percent, less than 10 percent of the hospitals, responded that they were testing their equipment to verify manufacturers' statements. So it seems to me there is quite a disparity there.

And I can maybe get to that. I guess I intend on getting to an awful lot of specifics. But dadblast it, we are talking about people out there who are depending on all of us. And it does not look to me like progress is being made. I don't mind telling you, I don't get an opportunity as often as I should to read the newspaper in the morning. But I saw that the IBM stock, for instance, plummeted in after-hours trading. And one of the reasons was Y2K.

Now, IBM apparently is not going to be ready. I say apparently, because I did not go into the details and I do not know what the

details are. So we have to be concerned. And Mr. Hubbard, I think probably there is more dependence upon FDA here than any other source. So I mean, do you have the authority that you feel you need to make sure that all of these devices that are out there will be safe and will be conducive to the good quality of health care? And if you do not have that authority, by gosh, you've got to get it. You have to check with us to make sure you have the authority.

Go ahead, sir.

Mr. HUBBARD. Well, as I say, Mr. Chairman, we believe that the industry has assured that devices are compliant, or they have provided the means for hospitals and other users to make them compliant via a software fix or whatever. But——

Mr. BILIRAKIS. But sir, I just read here that 39 out of 411 hospitals did not respond that they were testing their equipment.

Mr. HUBBARD. Mr. Grob, correct me. I believe the issue is whether the hospitals have availed themselves of the information that exists, that does exist, and therefore, either assured themselves that a given device in their hospitals is compliant, or gone to the manufacturer and gotten the appropriate fix and included it in their product.

I think that is really the issue. I do not think we have an issue of lots of devices out there that may fail but no one knows about it.

Mr. BILIRAKIS. Well, who should we expect is in the best position to determine whether its products will operate properly? Should it be the manufacturer? Should it be the hospitals? Who should it be, in your opinion? I am going to ask all four of you.

Mr. HUBBARD. I will say it is the manufacturer's job to assess their device, and either notify the public that it is compliant, or to provide a fix so that it can be made compliant. Of course, hospitals have to, as I said, they have to avail themselves of that information, and if they have non-compliant devices go to the manufacturer and get the fix, or if it is a workaround or whatever it could be.

There are a number of things to protect themselves from the device causing a problem. But the hospital needs, if the information is there, the hospital needs to get it.

Mr. UPTON. Dr. Shope?

Mr. SHOPE. Right. I want to clarify, I think, the statistic you are talking about. And I think that was in response to the survey asking hospitals, have you, the hospital, done independent testing of devices in your own facility to verify or to assure yourselves, in addition to the information from manufacturers. And I think what the response reflects is a somewhat difference of opinion. The vast majority of hospitals are relying on the information provided by the manufacturer who designed the product, who has FDA oversight, and who is providing information. There are a set of hospitals that, in addition to relying on manufacturer information have decided that they want, for whatever reasons, to test themselves, additionally, in addition to the information from manufacturers.

It depends on the kind of product as to whether the testing in a hospital facility is really necessary, or, I think, adds all that much additional value over the information that comes from the manufacturer. If a device in a hospital has been hooked into a sys-

tem, made part of a system with components from different vendors, and there is no one really responsible for that overall system, of course, the hospital needs to assess how that is working, those kinds of setups.

But in terms of hospitals relying on manufacturers' information, I think they can rely on the manufacturers' information with a high degree of confidence.

Mr. BILIRAKIS. Well, I know my time has expired, Mr. Chairman. I would sure love to hear very briefly from the other two gentlemen, if you would be so kind.

Mr. WILLEMSSEN. Certainly. From a provider perspective, the first step for providers, whether they are hospitals or physician offices, is to know what they have. They have to have an inventory of their devices. And then they have to map that inventory against available information on what the manufacturers are saying. We think the FDA site is one good source of information. On the other hand, some hospitals contact the manufacturers directly.

And then it is incumbent on the provider to make a risk determination, especially for critical care devices, or how much more information should we get. Should we independently test it ourselves or should we ask for test results from the manufacturer? There are a number of steps that they need to go through in order to make that determination.

And it is quite a time consuming process, because once they get that information back, they will have to go back to their inventory and decide which items they are going to take out of inventory and which items are going to be okay.

In addition to that, each major provider should have their own day one strategy for the last days of December and the first days of January. They should have detailed plans on how they are going to respond.

Mr. BILIRAKIS. They should have.

Mr. WILLEMSSEN. Yes. They should have detailed plans on how they are going to respond in the event that disruptions occur and what kinds of contingencies they are going to rely on if they do occur.

Mr. BILIRAKIS. Well, my time has really expired. But there is a bottom line here. And the bottom line is somebody has to be responsible either the manufacturer does this, or the hospital has a responsibility, or FDA has a responsibility. Somewhere along the line there has to be one set responsibility to make sure. The month of October is virtually gone. We have 2 months to go. And we have not seen progress, it has gone the other way according to what Mr. Grob has told us.

So Mr. Chairman, I am very disappointed. Thank you.

Mr. UPTON. Mr. Brown, I would just like to note for everyone here, we are going to try to keep this rolling through this vote, so some of our colleagues went to vote, they are going to come back, so we will be able to vote, hopefully.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

The last 8 or 10 months, I have been impressed listening to testimony and in reading testimony and reading and looking at other things that Government agencies such as HCFA, such as FDA,

such as Social Security Administration, others, are pretty well prepared for Y2K and have done a lot to sound the alarm for private sector agency, private sector groups, whether it is banks or Social Security or the providers that you work with for those private sector groups to be ready.

But I am disappointed, and this is my reason for concern, especially the comments of Mr. Grob and Mr. Willemssen, of the response rates from the private sector, the HHS, the Inspector General, sending surveys to nursing facilities, home health agencies, physicians, all had less than 50 percent response. The AHA, the Hospital Association, had, I believe, a 29 percent response, according to the testimony of, this was the GAO testimony. And the AMA had an even poorer response of 8 percent. That's a cause for major concern.

Then I listened to Mr. Grob say that the significant amount of equipment is not, even of the ones that have responded, a significant amount of equipment is not ready, the providers tell you. And then I heard Mr. Grob say, talk about drawing the distinction between the generic Y2K or susceptibility of a particular device, and how actually that device might function in the real world. I think your analogy with computers was something I could even understand, so thank you for that.

What does all this mean? Mr. Grob, does this mean that, what are you expected to do when you can't get this kind of response from the private sector and people love to blame Government for everything, but it seems that Government agencies have done this right, and if Government agencies had done as poorly as the private sector seems to have done in this, we would have you in front of this subcommittee beating you up hourly instead of just every month or 2 or 3.

Talk through that, if you would.

Mr. GROB. I think we just still need to keep beating the drums here. I think that it is the last part of the game now, and it is going to require a full court press to make it happen. The respondents all said they will be ready, and I certainly think they can be ready. The question now is simply a matter of getting ready. And I think the process right now isn't that hard. I do agree that the Food and Drug Administration and others have done a good job of providing tools for people to be ready.

And I must say, with respect to the health care industry, I really have to point out that the various provider groups that are mentioned in my testimony did help us with the survey. They did encourage their members to respond. We even got responses from people we did not send the surveys to, I think as a result of their doing that.

Mr. BROWN. Their umbrella organizations, the associations.

Mr. GROB. Exactly, right. So we appreciate their help in doing this. And there is a lot going on.

I just think that there might be some complacency, maybe some insensitivity or lack of understanding, and perhaps this hearing and just everyone continually beating the drum on this should be the case.

As far as the readiness is concerned, the testing we are talking about, the real world testing is going to occur on January 1, 2000.

There is just no need to wait until then. It can occur earlier than that. It is just, I think, a matter of doing it. The tools are there, it can be done.

Mr. BROWN. Mr. Willemssen, do we have enough information to be able to predict if we will have failures? And will we have enough information if we do not know?

Mr. WILLEMSSEN. I think the more that we've got into this, especially in these key sectors, and as the unknowns intensify, the uncertainty also increases. One thing that we've done when we do surveys is we have been a large proponent of publicizing the names of non-respondents. When we did surveys, for example, on 25 large school districts, the 21 largest cities in this country, and State surveys, we have told the respondents that you are free to respond or not respond, but we are going to publicize that fact one way or the other.

The response rates for 25 school districts were 100 percent, for the 21 largest cities, it was 100 percent, and for all States, all States responded except one. In my opinion, letting them know in advance that if they don't respond we are going to publicize the information has been a crucial factor in enhancing the response rate.

Mr. BROWN. Are you confident that of the failures that perhaps are inevitable, at least some number of them, in the types of equipment, that where there might be failures, are you comfortable that there will be at least, that we will not see critical failures that might cause death or severe injury in equipment where that might happen?

Mr. WILLEMSSEN. I am more comfortable of that today, actually, than in the May hearing, because of the efforts FDA has undertaken with the critical high-risk devices, and the work that it has done at selected manufacturers. This gives us a higher degree of comfort for those critical care and life support items. So I actually am more optimistic today on this particular subset.

Mr. BROWN. One last question real quick, Mr. Chairman, if I could. What grade would you, A meaning they have absolutely done things right, F meaning they have absolutely done nothing right, what grade would you give the provider community regarding their Y2K readiness?

Mr. WILLEMSSEN. Incomplete.

Mr. BROWN. You have to do better than that.

Mr. WILLEMSSEN. If I had evidence on what the data showed in terms of preparedness, I think I would be in a position to give a grade. But the biggest compelling factor is unknown.

Mr. BROWN. But if it is incomplete on December 31, it is an F.

Mr. WILLEMSSEN. Well, it depends on who is incomplete. Those providers may know very well where they stand, but they choose not to provide the information to others.

Mr. BROWN. Okay, thank you.

Mr. UPTON. We will just adjourn temporarily here until Mr. Greenwood comes back, and he can continue the hearing. We have to go vote.

[Brief recess.]

Mr. BILIRAKIS. This was a general vote, a very important vote. I believe it is Mr. Bryant's turn to inquire. Please proceed, sir.

Mr. BRYANT. I thank you, sir.

I think Mr. Willemssen and Mr. Grob, to some extent, well, not to some extent, very extensively, in Mr. Grob's testimony, talked about the testing issue. That is something that is very near and dear to my heart, because I have constituents who are in the hospital business come up to me and say, well, should we test these or not. And our lawyers worry about that, because if we test it, then maybe we are making ourselves more liable if something should fail. Or on the other hand, if we do not test it, are we also making ourselves liable if we do not test it.

And that is an issue that will have to be decided outside of these four walls at some point. But the liability protection bill that we passed for Y2K purposes does really concern the two parties to the contract, and whether the computer works or not, the microchip or whatever.

But the third party lawsuits and the potential that we are not dealing with just business records or just in commerce documents, but we are dealing with human lives, potentially, here, concerns me. So let me turn to the FDA if I could and ask you, I see a very clear cause of action to an injured third party, a patient that is in a hospital or a patient that has some sort of device that FDA has approved. And if it is not Y2K compliant, I see some lawsuits here.

Beyond the lawsuits, though, what is FDA's role, and what has it been in identifying last year or 2 years ago that, hey, there are some problems here, and before we give the FDA stamp of approval, it has to be Y2K compliant. Because again, some of these devices you have approved could affect a human life dramatically. Were those steps taken a year, 2 years ago, 3 years ago, when this Y2K issue came up? Were they taken to ensure that everything you have approved the last several years since this issue has been identified, does the FDA stamp of approval mean that they are Y2K compliant, and if it does not, why not? What assurance is the FDA approval if it is not Y2K compliant?

I might also add, why was it not done if it was not done, but is it being done now, and is there any effort to, once you have identified these problems, to recall these things before we have people injured or die as a result of this?

Mr. SHOPE. There are a couple of pieces to that, let me try to work our way through those. First of all, we began to pay attention to the Y2K issue around the middle of 1996, in terms of raising the issue in the agency and saying, we need to pay attention to the impact of this issue on devices. At that point, we discussed with our pre-market review staff the need to pay attention to this issue in terms of new submissions.

But I have to say that technically, a manufacturer could today even bring a product to market that was not Y2K compliant. Let me give you an example of what I mean by that. If that product is accurately described in labeling, if the user instruction accurately describes the manual operation that needs to be done, say, on Leap Year day, to reset the clock, and that is acceptable to the purchaser in terms of, I can buy a product that is described like that and make it work, then there is not a requirement that devices coming to market now be Y2K compliant.

There is a very small chance that manufacturers are going to bring a product to market like that and we are not seeing manufac-

turers bringing us products that are not Y2K compliant. But if a manufacturer, say a small company, has a product that has been on the market for several years, he is developing a fix that his next model will have, but it is a very minor kind of a problem, he would be free, under our approach right now, to relabel, to basically change the labeling and the description of that product to lay out clearly the non-compliant nature, the small non-consequential kind of problem that it has, and the user actions necessary to repair that and continue to market the product like that.

Mr. BRYANT. Let me stop you real quick. The user actions to reset that on the Leap Year, on January 1, are you expecting the patient to, if it is an implant, I mean, we're not really talking about that?

Mr. SHOPE. No, there are no implants that are affected by the date problem.

Mr. BRYANT. Are you expecting a patient to affect a medical device, or is the doctor supposed to tell him, you'd better be back in here on midnight, so I can test you?

SHOPE. No, no. We are talking about typically displaying the correct date, and that is all the device does. The manufacturer would have to go through a risk analysis to evaluate any risk associated with this date non-compliance, not a regulatory non-compliance. And if he can come to the judgment that the non-compliance presents no risk to the patient, no additional risk, no change in the impact on safety or effectiveness of the device, that is the condition under which this non-compliant product could continue to be marketed.

I think it is only the rare circumstance of manufacturers who have an existing product that has a very minor problem, and they would like for the economic reasons to continue to produce that product, and buyers are willing to buy it under those circumstances, then that would be possible. But the vast majority of manufacturers have already corrected their products, and that is what they are selling now. They are not selling the product that still has a problem. They developed the fix, and their current models have the fix available.

There are some manufacturers that have identified a Y2K problem that is a very minor problem, and they have told their customers, this product has a problem, it is minor, we are not going to offer a fix, live with it, basically. You can, it does not introduce any risk to patients. It means the date printed or displayed is not correct.

Let me also add, maybe I can put a little bit of context here, a number of the large hospital systems that we have talked to about their Y2K efforts, investigating their products and remediating their products, we are talking about very large systems that have hundreds of thousands of medical devices. Several have told me personally that, we have not identified any product other than one or two types in our entire inventory that would put a patient directly at risk due to a Y2K problem.

The radiation treatment planning systems are well known. There are a few models of the older types of those systems that do need to be replaced, they could lead to inappropriate radiation therapy. But as far as devices that fail and their direct failure having a di-

rect impact on patients, we are just not aware of devices that present that kind of a problem due to Y2K that would warrant FDA immediately taking the kind of regulatory action that we can take in those circumstances when there is an immediate risk to patient health.

So there are certainly a lot of computer-controlled systems, record keeping is done, but devices that use dates and calculations that present a problem if that date calculation is inappropriately done, the manufacturers have addressed, have identified those, have provided fixes, and the hospital, the user of those types of products have to avail themselves of that upgrade in order to continue to use the product.

Mr. BRYANT. Mr. Chairman, I see my time is up, and I will not ask for additional time. But I would hope that GAO and HHS, if they get a chance to comment during the answering of other questions, they might comment on that, too. I think that is very important. Thank you.

Mr. BILIRAKIS. It is important. We will recognize Mr. Greenwood at this point, and hopefully get to that.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I would like to address a question to Mr. Hubbard, if I might. Would you describe for this panel the type of information that FDA has with respect to individual specific devices, either through product approval applications or through reporting and accountability requirements, pursuant to FDA's quality system regulation about specific devices, and then the follow-up question is, do you need more information?

Mr. HUBBARD. I think that is a better question for Dr. Shope, if you do not mind, Mr. Greenwood.

Mr. GREENWOOD. All right.

Mr. SHOPE. We have basically two types of information I would characterize. One is our registration and listing database, which is manufacturer supplied information that tells us who is in the business of making medical devices and the types of products that they make. This is the basis for our inspection program, knowing where the factories are and what is made at those factories. The second kind of information we have is the premarket approval submissions that come in from manufacturers, that are the information that describes the products in terms of their safety and effectiveness for the premarket notifications, their substantial equivalence to existing devices, or for pre-market approval applications, the more detailed scientific and technical data that show their safety and effectiveness.

Mr. GREENWOOD. Let me interrupt you for a second. Has FDA ever required that in those submissions, there be Y2K specific information?

Mr. SHOPE. Oh, yes. If it is the kind of device currently that would be relevant, that is certainly a question that is asked during the review process.

Mr. GREENWOOD. For how long has that been the case?

Mr. SHOPE. Since mid-1997 I would say.

Mr. GREENWOOD. Okay.

Mr. SHOPE. But we also, I have to point out, to be clear about it, there were some products that came to us in 1997 that the man-

ufacturer had in development for several years, and they said, this product is not Y2K compliant, but we will have an upgrade by 1999 that will be, and we will provide that at no cost to the users. So there was no reason in the marketplace sense to deny that firm access to the market for that product.

So we did make a few of those types of decisions, but not a large number of them.

In terms of our database, we do not get, in our record keeping system in a computerized fashion, access to information readily available about, is the device computerized, what is the type and nature of that computerization. So that is not readily available to us from a database type approach. We have to rely on the manufacturers to tell us, I make this kind of a product, and it is computerized in some sense.

Mr. GREENWOOD. Do you feel you need that information?

Mr. SHOPE. I am not sure how we would use that thorough or detailed information, the staff to stay on top of that kind of information I think would be a challenge. I think when we have a specific——

Mr. GREENWOOD. Do you think there is any risk to the public because you do not have that information?

Mr. SHOPE. No, sir, not currently. Because any time there is a specific device that has an issue, we do have the complete description that we can go to and hone in on it. When we have had this question of all devices all at once, it has been a challenge. And then we relied, going back to the manufacturer, who best knows the device, to give us that information.

Mr. GREENWOOD. Does that complete your response, sir?

Mr. SHOPE. I am trying to remember if I covered all your points.

Mr. GREENWOOD. Let me address a question for Mr. Grob. In your opinion, who is in the best position to determine whether a device will be impacted by the Y2K issue? As you know, FDA and the device manufacturers on our second panel are very concerned about hospitals conducting independent validations on equipment. How do you respond to the concerns raised by FDA and the device manufacturers?

Mr. GROB. I think, this is an opinion, it is not a legal opinion, it is a personal opinion, because I have not delved into the liability issues. My work was restricted to the surveys and related issues. But my opinion is that it is the provider that is in the best position to know whether the equipment works. Because they are going to know on January 1, 2000, no matter what happens in between, they are going to know on that day.

There is not any reason why they do not know before then, not a good reason. The information is generally available, so they should just find out and get ready.

So I really think that is where the knowledge ought best to be. I think you asked me a second question.

Mr. GREENWOOD. How do you respond to the concern that the providers may not have the expertise to validate in advance? You certainly do not know if the lights go off on January 1.

Mr. GROB. Right. I think this is probably the most important distinction that is coming about as a result of the survey work that we did and the discussions that we are now having. I think that

there was quite a bit of policy discussion as to who should be responsible for the testing of the equipment. And both FDA and the manufacturers were coming on the side that that should properly be done by them, because of the need to carefully calibrate it, and——

Mr. GREENWOOD. By them, you mean?

Mr. GROB. The manufacturers.

Mr. GREENWOOD. By the manufacturers.

Mr. GROB. I do not disagree with that at all. I have to defer to them on that matter, as to the proper procedures for testing.

What I am trying to focus on is the testing that has to occur in real life. Let me give you an example, if I can. There was one piece of equipment that was listed on the FDA web site, and it reported that it was a minor problem, because the date would be displayed, but it was okay, it was two digits and 00 would mean year 2000, in other words, it was not incorrect, it was not calculating wrong, everyone could understand that, but you just needed to be alerted to that.

They then added the following caution: however, if you connect this piece of equipment to another computer in your outfit, and the date is processed by that computer, you really do not know how that computer is going to process the two-digit date that it gets, because that equipment may not be ready or it may not be used properly. So they now caution the provider that you need to check that out for yourself to make sure that is okay.

It is that kind of testing that I am talking about, it is when you write in to the manufacturer to get your free upgrade, you have to get it, you have to install it, you have to shake it down. So perhaps the word testing means different things to different people. In the way that I am using it, I certainly mean it in the terms of what I would call real life testing.

Mr. BILIRAKIS. The gentleman's time has long expired.

Without objection, we will give an additional 2 minutes to Mr. Bryant. Well, before we do that, is there somebody else here? Mr. Brooks?

Mr. BARRETT. Thank you, Mr. Chairman.

I Just have a couple of questions. Mr. Willemssen, maybe you can help me out. After looking at a lot of today's testimony, I am still not sure that I have a precise picture of what it is we want both the regulatory agencies, FDA and the device manufacturers to do to ready themselves for January 1. If you could, what two or three major recommendations would you make to the FDA at this point, and why?

Mr. WILLEMSSEN. One is for those manufacturers who provide links to their web sites. FDA should request that these manufacturers provide detailed information on product make and model information. Second, FDA is in the process of putting together a report on the efforts that it has undertaken on critical care and life support devices. I believe that report was initially expected to be out October 1. It is not out yet.

FDA needs to commit to a date as soon as possible, so that the American public can get a sense of what level of risk there is on those critical care and life support items. In addition, as part of that effort, I would publicize all 803 manufacturing sites. I would

publicize the names of all 325 that were in the initial sample. I would publicize and disclose those who decided not to participate in the exercise. We have a few other suggestions, but those would be among the most important ones.

Mr. BARRETT. What about the device manufacturing industry? What recommendations would you have for them?

Mr. WILLEMSSEN. I think it fair to say that I come out a little bit in between the Inspector General and FDA. I think from a provider perspective, the first thing you have to do is go back to the manufacturer and see what the manufacturer is saying.

In many cases, the manufacturers are providing details on their web sites, on how to go about testing the equipment, including testing hook ups to other equipment. I am a little reluctant for providers to just go out and test without having that kind of information in hand. The ideal is for a partnership between manufacturer and provider to test in a real operational environment. This will give you the best result.

Mr. BARRETT. What about the users, the hospitals, the doctors, nursing homes? Are there things they should be doing now? What would recommendations would you have for them?

Mr. WILLEMSSEN. I would certainly hope that they have already taken these steps. But if they have not, they obviously need to know what they have in their inventory. They need to match that inventory up against available information from sources such as the FDA clearinghouse. Then, based on that, look at what their critical care and life support items are and what kind of steps they need to take to assure themselves that these are going to work as expected. Those steps could entail independent testing on their own, or asking manufacturers to give them their own independent test results.

Those are the kinds of steps that should have been taken by now. I fear in some cases they may not have been taken by some providers.

Mr. BARRETT. Do any of the other panel members want to comment on any of the suggestions?

Mr. GROB. Yes, I do. I just want to clarify, there is no disagreement in policy regarding testing at all. I have never advocated and I am not advocating now that the providers substitute their bench testing for that of the manufacturers. The way Mr. Willemssen put it is exactly what I would agree with. The providers need to get the best information they can get, which probably is initially going to come from the manufacturers, then they have to absorb it, and then they need to make sure it works in their setting.

Mr. BARRETT. I would yield back my time.

Mr. BILIRAKIS. If you would yield. Well, here it is again, near the end of the year, and we are about to finish up in 3 weeks, who knows. I am not sure that God knows.

Mr. UPTON. He does know.

Mr. BILIRAKIS. He does know? He has not told us.

But the thing is, is there anything that we can do at this point in time, yes, the providers have the equipment and I have, I think we all have a sense of confidence in providers that they want to practice good medicine and they care about these things. The thing

that concerns me is the lack of responses from the hospitals regarding your survey.

So is there anything that we can do to help FDA, to do this job better, considering that our session is virtually over, and by the time we get back in again, it will be after January, or after the end of the year? Mr. Hubbard, can we help you in any way? I know you are concerned about it, on top of all your other responsibilities, you have this, too.

Mr. HUBBARD. Mr. Brown was talking earlier about the poor response rate from hospitals, and he is absolutely right. I will say that from the manufacturers, we have almost 100 percent response rate. So we have very good information about what the manufacturers have done.

The providers, the hospitals, do need to avail themselves of the information. As a legislative body, I do not know how you help make that happen. But the hospitals and other health care providers do need to seek out that information and make sure that the devices they have in their institutions are compliant, or if they are not, they need to go get the fix and get it put into their device. That seems to be the challenge, given the response rates that the others have been receiving from those providers.

Mr. BILIRAKIS. Thank you.

Mr. Upton to inquire.

Mr. UPTON. Thank you, Mr. Chairman. I do not know if my comfort level is getting better or worse from the hearing that we had last spring. I thought that this was certainly a good topic. I visited with a number of my providers, both private practitioners as well as device manufacturers as well as hospitals, and asked the Y2K question almost everywhere I went.

And I use the analogy, I have a smart little daughter. She is a sixth grader, she is very honest and she is very smart. And my guess if that if her science teacher asked her if she had done her homework, asked everyone in the class if they had done their homework or not, excuse me, if the teacher asked, did any one of you not complete your homework, probably some people in that class might not raise their hand, particularly if they knew that the teacher was not going to check.

And Mr. Hubbard, as I listen to you, you just indicated that you had almost 100 percent compliance, I look at 132 providers who are on the internet, never responded at all. I do not know if anyone has gone to their door and said, did you do your homework or not.

At the beginning of your testimony, you indicated, and I did not write it down word for word, but you said that no, there were no manufacturers with high concern, in essence, not a single one. Yet Mr. Willemssen in his testimony a couple of minute later said, in fact there was one major device manufacturer, is that not correct, who you identified this week, and they told that to the FDA, is that not right, Mr. Willemssen?

Mr. WILLEMSSEN. There is one that FDA informed us of as part of their evaluations and assessment.

Mr. UPTON. If I may, I would like to defer to FDA on the naming of that particular organization.

Mr. UPTON. Mr. Hubbard?

Mr. HUBBARD. Under your act, we have promised these groups not to reveal information about these. Is that something perhaps we could talk with the committee about privately?

Mr. UPTON. I will accept that, but does that not contradict what you said in your statement?

Mr. HUBBARD. First of all, Mr. Chairman, I was focusing on the firms that really matter here, the priority firms, those that make very important products that if they fail could cause harm, drugs that if not available could not be available elsewhere. The 132 you are referring to, if I am correct, and I will ask Dr. Shope to elaborate, are firms that we have not been able to find. We do not think they exist.

There was a much larger number of those that never responded to us, the addresses were wrong or whatever, they come from a registration system that we employ at FDA, but it depends on the manufacturer——

Mr. UPTON. Can you put an APB out on these folks? I mean, they had a place at one time that certainly maybe still today employ people, and they have a manufacturing site, and their equipment is all licensed.

Mr. HUBBARD. We do not believe they exist. If Dr. Shope would like to elaborate.

Mr. SHOPE. Well, that is partially right for some of them. Some of them——

Mr. UPTON. We do not have the addresses for any of these?

Mr. SHOPE. We have diligently tried to contact all of those folks. There are some there that are definitely, clearly out of business. They were out of business in our database when we started. We were not fine enough in our filtering of our database to eliminate those. When we went out with the broad brush for 13,000, we tried to get everybody. We tried to be all inclusive and not miss any potentials. So we knew that our database was not perfect.

There are also people on that list who are only distributors of devices, they do not make anything. There are also manufacturers on that list who probably make no computer products, and we have looked at that list carefully. There is not really a strong incentive for them to respond to us. We have not sent inspectors to each door, but we have looked at the list, looked at who the manufacturers are, what kinds of products they make, and there are not areas of large concern there for us.

Mr. UPTON. Well, Mr. Willemssen indicated in response to a question by Mr. Bilirakis that he thought that the FDA should be responsible in making sure that those manufacturers would follow up, and that the FDA should be responsible to make sure that in fact that happened. Do you feel that you are responsible for their actions, and have you thought about recalling any of their products for those that may not fit that definition?

Mr. SHOPE. We do not know of any of those manufacturers that have products that would raise any kind of concern that would lead to the situation of a recall. We also have to say that we have not heard people saying to us, we can't find this firm, there is no information available about this product. In general, we hear that for a few firms, and I know of several where they have not been real cooperative. But they do not make a kind of product that would fit

the risk of a high-risk device that would warrant a recall. They are the aggravation kind of Y2K problems that the firm has not dealt with.

So I do not have a lot of concern about the firms on that list. We will continue to look at them as we finish our work with this list to make sure there is nobody there that makes the kind of product we will be concerned about.

Mr. UPTON. If I can just ask one quick follow-up to my initial question, were there other manufacturers, other than this one firm that Mr. Willemssen indicated that you all knew about that you did not mention in your testimony, is it only one?

Mr. HUBBARD. Yes, Mr. Upton. The audits were very intensive. They lasted three or 4 days. They were done by very skilled IT professionals, and they were very intensive.

This one firm had some lower documentation than this very high standard required. So when the auditor reported back to us that they had concerns, we then sent FDA investigators to the firm who did a full examination under FDA's legal authority. They found that the firm had adequate contingency plans, that the firm was attending to the problems, and that there were no serious health concerns here.

There were some documentation, other paperwork concerns, that caused the auditors to flunk them, as it were, but the subsequent inspection has given us confidence that that firm is not truly a problem. However, we will continue to watch that firm as well.

Mr. UPTON. I yield back my unexpired time.

Mr. BILIRAKIS. Without objection, the Chair yields an additional minute to Mr. Bryant to get a couple of responses he was looking for.

Mr. BRYANT. Thank you, Mr. Chairman. I am kind of like Mr. Upton, I am not sure whether I feel better or worse after this hearing. But I do get a general sense that perhaps the Inspector General and GAO do not feel as comfortable as the FDA does on this matter, that maybe they feel it is a little worse.

Just very quickly, I might ask, I think maybe I will cover the answers a little bit more than I asked for. Very quickly, Mr. Grob, if you can tell me, do you pick up what I pick up nationwide, what I pick up in my district, the concern from the providers of whether or not to test these devices, and so forth, because of liability? It seems to me the stronger case is if you do not do anything, you are better off than if you test it and then it goes bad. It seems like from a lawyer's standpoint.

But is that concern out there? Do either one of you at GAO by any chance hear that?

Mr. GROB. Let me address that in a variety of different ways. First of all, with regard to liability, the reason we did our report anonymously, and we did talk to this committee about that, which we also did the first time, was so that we would get a good response rate. We had been told that people were reluctant to even respond to our survey by name, if they were to be advised that maybe some answers they gave could create a liability problem for them.

So we used this approach, and actually, it turned out to be effective. Our response rates are nowhere near what we want them to

be, but they are still double or triple what most surveys in this arena get. So at least it gave us a bigger view inside than before.

So I think liability was certainly, that was evidence, I think, that the liability was on people's minds. Again, I am really guessing here now, I will venture a bit of one. I think the liability matter was more of an issue earlier. Because according to our survey, the hospitals particularly seemed to be doing a lot of testing. Those that did respond seemed to have a pretty ambitious program.

And where they report now, no change, even a slight dip in the overall readiness of all their equipment, their answers to other questions indicate that the hospital industry seems to be pretty systematically checking everything out and doing things other than just relying on the manufacturer. They seem to be relying on their own actions as well.

So that does actually inspire a lot more confidence. The hospital industry has the biggest problem. They have the most and the most sophisticated equipment. And they seem to be most methodically going after it. Perhaps in some of the other groups there may be more complacency among say, nursing homes, home health, physicians, durable medical equipment manufacturers, etc., on this matter.

So what I really see now is just a matter of keeping up the intensity of the effort right now, of making the full court press, here in the last quarter of the year.

Mr. BRYANT. Mr. Hubbard, very quickly, of the 80, I think, contractors you assessed, some 14 were located in other countries, 8 other countries. How about those foreign manufacturers?

Mr. HUBBARD. They were also visited. We actually sent auditors to those firms in those countries and did the same audit we did for domestic firms. And they had to meet the same high standard.

Mr. BRYANT. And they passed?

Mr. HUBBARD. Yes.

Mr. BRYANT. Good. Thank you, sir. Thank you, Mr. Chairman, for your generosity with the time.

Mr. UPTON. You are very welcome.

Mr. Brown has a couple more questions.

Mr. BROWN. Just one more question, Dr. Shope. I sit here and as the hearing evolves, I went from a good deal of confidence to less confidence as I have listened for the last 1½ hours or so. I am really perplexed by this whole situation, first of all, the lack of response to surveys that you have issued, asked people to return, that you have too little information, that there is an incomplete score card in Mr. Willemssen's response. And from Mr. Grob's comments, that there is just little experience in how this will work in the real world.

So for some senior citizen or anybody for that matter listening at home to this or watching this at home, I have to think they are very confused about all of this. And then Dr. Shope, I hear you say that you are confident that there is not going to be serious injury or death from any piece of equipment that might not function the way that it should because of Y2K.

Assure me, if you would, why that will not happen.

Mr. SHOPE. My opinion is based on the kinds of products that have date problems and the nature of those date problems, and

that those kinds of failures will not directly impact the patient directly or immediately. The vast majority of the Y2K problems we are talking about have to do with record keeping, historical records of what the device did as opposed to being involved in the device functionality.

There are certainly, though, some devices that do use dates and computer calculations. It is a rather small number of devices where that is true, and those have been well addressed by their manufacturers. Those are the kinds of manufacturers who have communicated to each and every one of their customers about the issue, and in many cases have provided free upgrades because of the risk associated with this, the manufacturer wants no liability that they have left any stone unturned to address this issue.

So I think it is the cooperation between the industry recognizing their exposures to other than just FDA that has given this kind of a problem the kind of attention it needs.

I think the industry has well responded to this issue. If there is a place that continues to need attention and concern, I think it is the health care facilities that need to complete their assessment.

Mr. BROWN. Exactly. Mr. Grob, what you said, and this is my last question, Mr. Chairman, you talked about, Dr. Shope just mentioned that the manufacturers have worked out all the problems potentially in his opinion. But you had talked about the interaction between two computers. One is Y2K ready, the manufacturer or maybe the health facilities is not, one of those health facilities that is not responding to your questionnaires or your surveys.

Are you concerned about the issue of some serious injury because of that interplay?

Mr. GROB. I just do not know about how serious it would be. And for that, I really have to defer to FDA about the nature of the equipment. Again, I think it is true that most of the problems that are reported on the internet are primarily the reporting of data, or the reporting of dates, which could be inaccurate. Sometimes that reporting of dates can affect the way the equipment functions or some of it may not function at all, because the computer cannot figure out the date, and they actually report some gibberish there.

But whether or not any of that will relate to a serious health problem for an individual, I simply cannot address that. My sense from what FDA is saying is that they do not see any evidence of that.

It is just that you do not know, and there is not any reason not to know. It is a fairly straightforward matter, I think, to just try it out. That clearly is just something that should be done.

Mr. BROWN. Mr. Willemssen, do you have an opinion on that?

Mr. WILLEMSSEN. Only to say, as I briefly mentioned, I believe on the high risk devices, I am more optimistic now than I was in May. This is because FDA is taking additional efforts that it originally did not plan to take, and it will have additional independent evidence of where those manufacturers are.

Mr. BROWN. Okay, thank you. Thank you, Mr. Chairman.

Mr. UPTON. Thank you.

I have just a couple of questions, and I would like each of you to respond to this. This sort of goes to the heart of the concern by all members on this committee. It is my understanding that the

FDA identified 803 manufacturers with potentially high risk devices. And in an effort to see where things were, identified 325 of those trying to do a random test to see exactly where things were.

Of those 325, 197 had no computer chips, so everything is fine, scissors, whatever it might be. Eighty of them said yes, but we are okay, 80 of those said yes, we do have a computer chip. Eighteen were duplicates. I would subtract that as well. Four did not respond at all. And 26 said, we are not telling. We are not going to participate. And going back to my student-teacher analogy, that student would probably be sent down to the principal's office. But 26 said, we are not going to say yes or no, we just ain't saying.

And I just, you know, as we look for the comfort level here, January 1 is not all that far down the road, we are all sort of figuring out where we are going to be that day. Mr. Grob, what is your comfort? Knowing those stats and knowing that is about a little less than half the sample, do you think everyone has done their job on this?

Mr. GROB. You asked me that before and I changed my mind on the answer.

Mr. UPTON. You know, on one hand, on the internet, some of these, a lot of these maybe have shut their doors. But at the same time, we have a number of firms who are not on the internet, nobody knows, maybe FDA knows for sure, but other folks do not know who these manufacturers—and they have already been identified as high risk device manufacturers.

Mr. GROB. Could I add some speculation to the survey work?

Mr. UPTON. Sure.

Mr. GROB. My speculation would be that in a hospital setting, the hospitals would be pretty sensitive to the equipment that could cause harm if they did not check it out. Really, really big harm. So I think that alone would be a good force that would help people to check it out.

I think for other things they are trying now to get it all checked out, and that is a big logistical problem for the hospitals. But I do think that generally they are trying to do that. Although I do detect, myself, some complacency that is unwarranted in that regard. I think in the other provider groups, I detect much more complacency, or a feeling that someone else will take care of it, when I don't think that really will solve the problem.

So my report card, I would have to do like in history and math have different grades, I would give the hospitals maybe a B, others C, D, depends on the question.

Mr. UPTON. Or do not know if they turned in their homework?

Mr. GROB. Or don't want to answer the question as to whether they have done their homework, right.

Mr. UPTON. Does not work for my sixth grader.

Mr. Willemssen. I will go back to what I mentioned a little bit earlier, in that I think FDA should name the names of the 803 sites, name the names of those who declined to participate.

Unfortunately, FDA should have let them know that in advance. And I would guess that they would have had a lot fewer declinations than they did if they had let those sites know that they were going to publicize what the response was.

Mr. UPTON. Now, in your own investigation, do you know who these 26 firms are?

Mr. WILLEMSSEN. Yes, we know who the 26 are.

Mr. UPTON. Mr. Hubbard, I came to you last by design.

Mr. HUBBARD. Let me say, Mr. Chairman, that all of those firms, those 325 firms, have reported to the FDA web site, the clearinghouse. So we know what devices they have that are compliant or non-compliant. So it is not like there are unknowns.

Most of them ask not to be given an audit because of various reasons, they were trying to get their Y2K work completed and other things. And those reasons may have been very legitimate.

However, we still are looking at those firms to make sure they do not make products that are of concern, and if we find that there are some that could be a concern, and they still say no, they may get a visit from an FDA investigator who, as you know, has legal authority to enter that firm and do a full inspection. So we are not really concerned that those folks will not get a look.

Mr. UPTON. Have FDA inspectors actually gone to any of these identified 26 firms?

Mr. HUBBARD. So far, we have reached a level of concern on only one firm that triggered an inspection by an investigator. All the other work has been done by IT professionals contracted just for the Y2K work.

Mr. UPTON. Okay, well, I appreciate, we all appreciate your testimony this morning. And I would like to think that none of us need to hold our breath very long, coming up to December 31st. We appreciate all of your work on this and certainly your appearance today, and we will move to panel two. Thank you very much.

Our second panel will include Mr. James Benson, Executive Vice President for Technology and Regulatory Affairs of the Health Industry Manufacturers; Mr. Bruce Horowitz, Director of Product Assurance, representing the Medical Device Manufacturers Association; and Mr. Thomas Neill, Vice President of Corporate Services of Quorum Health Group, representing the American Federation of Health Systems.

As you heard from the first panel, we have a long tradition of taking testimony under oath. Do any of you have objection to that?

[Witnesses respond in the negative.]

Mr. UPTON. And under House and committee rules, you have the right to have counsel with you. Do any of you desire to have counsel?

[Witnesses respond in the negative.]

Mr. UPTON. If you would stand and raise your right hand. Do you swear to tell the truth, the whole truth and nothing but the truth, so help you God?

[Witnesses respond in the affirmative.]

Mr. UPTON. You are now under oath. And Mr. Benson, as you also heard, your testimony is made part of the record in its entirety. We had pretty good compliance with the 5 minute rule with this little clock, and if you could continue that, we would appreciate it. Thank you.

TESTIMONY OF JAMES S. BENSON, EXECUTIVE VICE PRESIDENT FOR TECHNOLOGY AND REGULATORY AFFAIRS, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; ACCOMPANIED BY BERNIE LIEBLER, DIRECTOR, TECHNOLOGY AND REGULATORY AFFAIRS; BRUCE HOROWITZ, DIRECTOR OF PRODUCT ASSURANCE, ADVANCED NEUROMODULATION SYSTEMS, INC.; AND C. THOMAS NEILL, VICE PRESIDENT OF CORPORATE SERVICES, QUORUM HEALTH GROUP

Mr. BENSON. Thank you. I shall.

Mr. Chairman, or I should say, chairmen, and members of the committee, I am Jim Benson, and I am with the Health Industry Manufacturers Association. We represent more than 800 companies, accounting for nearly 90 percent of the medical device sales in the U.S.

I am here today to tell you about the medical device industry's readiness to function effectively into year 2000. But before I begin, I would like to introduce my colleague, Bernie Liebler. Bernie has been responsible for coordinating HIMA's Y2K efforts.

I want to say clearly that the medical device industry views Y2K as a serious patient safety issue. The industry has invested significant resources assuring that its products will function safely. We are confident when we look back on New Year's Day 2000, medical devices will have provided their usual high standard of reliability and service.

FDA has just reported the results of their study in which they reviewed company processes for evaluating product Y2K compliance. The participating HIMA members viewed the study as a valuable third party assessment of their work. We believe this program demonstrated that the device industry has taken effective action on Y2K and that the industry and FDA will work cooperatively to ensure the safety of products and patients into 2000 and beyond.

Over the past year, I have developed a great appreciation for the depth and scope of the various company efforts to address the Y2K issue and avert any problems in both products and operations. In mid-summer, HIMA published a member survey that reflects this dedication. All of the companies in our analyzed sample predicted that their products, production systems and supply chain systems would be ready by year-end. The total annual domestic revenues of these companies was $47 billion, while the total domestic revenue was about $60 billion.

They predicted an aggregate Y2K investment of $700 million. The members of the industry understand their obligation to protect patient safety. The device manufacturers' goal is to enhance patient care. Y2K is a unique event, but the industry has addressed it with the same directness and dedication that it applies to all patient safety issues.

I want to take a moment and highlight some actions that HIMA has taken, along with its member companies to assure Y2K readiness. This summer we worked on and distributed the Y2K guide that the Oden Group prepared for a coalition of health care related organizations, and we will leave a copy with you of that. We also worked actively to plan the White House roundtable on consumable medical surgical supplies, held in early June, and to develop the

roundtable final statement issued by the President's Council on Y2K Conversion.

Following the roundtable, HIMA published its own position paper, recommending the same business as usual approach to year-end purchasing. The industry built its current state of readiness on a strong foundation of company participation. HIMA worked closely with FDA and the National Patient Safety Partnership to make the FDA's Y2K web site the principal collection point for year 2000 device compliance information.

We urge medical device companies to provide requested Y2K status information, co-sponsor ads in prominent trade magazines and held continuing conversations with FDA and others aimed at making the FDA clearinghouse as useful as possible.

Before I conclude, I want to compliment FDA on their fairness and openness regarding Y2K. In particular, I want to acknowledge Dr. Tom Shope, of CDRH, whose work has been critical to the success of these efforts. I have tried to provide you with a current picture of the device industry's Y2K readiness, which is based not only on the work of HIMA companies, and the device industry as a whole, but on the work of many other groups from Government and the private sectors.

This industry's primary efforts have been directed at maintaining patient safety. We are confident that as we enter year 2000, events will show that we have succeeded. In the meantime, we commit to continue to work cooperatively with all parties to ensure that the transition from 1999 to 2000 is safe and uneventful.

[The prepared statement of James S. Benson follows:]

PREPARED STATEMENT OF JAMES S. BENSON, EXECUTIVE VICE PRESIDENT, TECHNOLOGY & REGULATORY AFFAIRS, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

My name is James S. Benson, Executive Vice President, Technology & Regulatory Affairs for the Health Industry Manufacturers Association. HIMA is a Washington, D.C.-based trade association that represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $62 billion in health care technology products purchased annually in the United States and more than 50 percent of the $147 billion purchased annually around the world. As such, HIMA is the largest medical technology trade association in the world. I am pleased to have this opportunity to tell you about the medical device industry's Y2k readiness to function effectively into year 2000, most frequently referred to as Y2k, and HIMA's efforts to both ensure and support that readiness.

Before I continue, I would like to introduce my colleague, Bernie Liebler, HIMA's Director, Technology & Regulatory Affairs. Mr. Liebler has been responsible for coordinating HIMA's efforts regarding Y2k, and he is here with me to provide his expertise in responding to questions that you may pose.

I plan now to review what we believe are some of the industry's more significant activities. Before I begin, I want to say clearly that the medical device industry views Y2k as a very serious patient safety issue. The industry has invested a great deal of resources to assure that its products will function safely into year 2000 and that the industry will be able to continue to deliver vital products as the year changes. We are confident that when we look back on the change from 1999 to 2000, medical devices will have provided their usual high standard of reliability and service.

In this context, I would like to add that I believe that HIMA's members have done a fine job of responding to the public needs surrounding the Y2k issue over the past year and a half. In 1998, its members formed a working group to address both the strategic and technical aspects of the Y2k issue. Keith Brauer, Vice President and Chief Financial Officer, Guidant Corporation, has provided excellent leadership as the Chair of the Working Group with the active participation of many HIMA mem-

ber companies. In my testimony today, I will reference for you some of the activities that the group has undertaken.

CURRENT STATUS

Voluntary Y2k Program Examinations

The most recent major activity relating to the device industry's readiness is the Food and Drug Administration's (FDA's) Y2k review project that examined the Y2k programs of a significant sample of medical device manufacturers. FDA undertook this project as a means of allaying the concerns regarding medical device readiness that the General Accounting Office expressed at a hearing this Committee held in May. To perform the study, they hired Battelle Laboratories, a highly reputed consulting firm with documented skills in the software area. The Battelle representatives examined the processes employed by the manufacturers to determine whether a device was Y2k compliant, and for those devices determined to be non-compliant, the processes used to make them compliant.

We expect FDA to describe the results of these examinations in today's testimony. It is our understanding that the testimony will confirm that the medical device industry has done a proper job in evaluating its devices and modifying those that required it. We have spoken with several of the HIMA members that participated in this voluntary program. Each of them described the visit as professional and non-confrontational. Overall they believed that the visits were a valuable third-party assessment of work in which they had invested considerable resources. Needless to say, they were gratified that the evaluations of their work were positive.

Let me describe the role HIMA played in this activity. The Association sees one of its major roles as ensuring patient safety. HIMA decided that for the Y2k issue, this was best accomplished by ensuring that its members and, in fact, the entire medical device industry, were aware of their responsibilities related to the issue and aware of relevant activities both in the government and in the private sector. When we were told of FDA's plans to pursue this program, our president, Pamela Bailey, wrote to all HIMA members both to inform them of the program and to encourage them to participate in it, if requested by the agency. We followed up that letter by initiating and coordinating a joint letter from HIMA and other trade associations to each of the companies in FDA's initial sample selection, urging them to cooperate with the request to permit the voluntary examination of their Y2k systems. (We have attached copies of these documents to this testimony.)

Over the past year I have developed a great appreciation for the depth and scope of the various company efforts to ensure that they have completely addressed the Y2k issue and averted any problems in both products and operations. The larger companies have all established dedicated Y2k teams charged with handling all aspects of this issue. The member company teams have been in contact continuously with their vendors, customers, and service suppliers (e.g., utilities, etc.), and with their trade associations and relevant governmental bodies.

Many went beyond simple correspondence to scheduling in-person visits with their customers and suppliers and hosting broad-based meetings with multiple constituencies to ensure that all aspects of Y2k were being properly addressed. They have also been generous with their time and resources in supporting HIMA's activities.

We believe that the successful completion of this program and the positive results it generated demonstrate several critical facts:

- The medical device industry has taken effective action on the Y2k issue.
- The industry and the FDA have worked cooperatively to ensure the safety of products and patients into 2000.
- The level of concern over the safety of biomedical equipment is now low.

HIMA Y2k Readiness Survey

I would now like to move a bit further back in time to mid-summer, when we published the results of a survey of the Y2k readiness of our members. The survey found that the companies that sell the vast majority of medical devices sold in the U.S. expect to be Y2k compliant with respect to both their products and their operations. It also produced several other salient results.

- The total revenues of the companies in the analyzed sample were $47 billion; total domestic sales of medical devices were approximately $60 billion.
- 90% of the companies predicted that their products would be compliant by the end of September. The remaining 10% predicted total product readiness by year-end.
- Almost 70% expected to complete operations planning by the end of September; the remainder expected to finish through the fourth quarter.

- 75% expected to complete both manufacturing and supply chain contingency plans by the end of September with the remainder finishing during the remaining three months of the year.
- The companies anticipated spending an aggregate total of $700 million by the end of 1999.

The members of the industry understand fully their obligation to protect the safety of the patients they serve. The goal of medical device manufacturers is to enhance medical care. Thus, ensuring Y2k readiness has been, and continues to be, an integral part of the industry mission.

Besides the industry survey, there were a number of important milestones this summer. HIMA also contributed to the completion of the *Health Care & Y2k Personal Planning Guide*. This document was developed by the Odin Group under the direction of a coordinating group comprising a spectrum of health care-related organizations including medical device companies, insurance carriers, pharmaceutical companies, trade associations, and others. Several HIMA members also individually supported this work. The guide contains clear, common-sense recommendations for consumers on how to approach health care issues as they relate to personal planning for Y2k. HIMA endorsed the guidance and distributed copies of the booklet to all of its member companies with suggestions on how they could use it.

HIMA also represented its membership in working with the American Hospital Association and others in developing the final statement that was issued by the *President's Council on Year 2000 Conversion*, and signed by its chairman, John Koskinen, and Kevin Thurm, Assistant Secretary of the Department of Health and Human Services. The statement distilled the results of the President's Council on Year 2000 Roundtable, Consumable Medical and Surgical Supplies held in early June. The statement reflected the meeting consensus that hoarding or stockpiling of medical supplies is fundamentally counterproductive and recommended following historical ordering patterns based on current needs. We devoted significant time to planning this meeting, and two company representatives were speakers at the meeting. We believe this very useful activity once again demonstrated the cooperative relationship between the government and private sectors that has characterized our experience with the Y2k issue.

As a result of the Roundtable, HIMA developed and issued its own position paper, *Ensuring Patient Access—HIMA Position on Preparing for Y2k*, which also recommends a "business as usual" approach to year-end purchasing of consumable medical/surgical supplies. (We have attached a copy of this document to this testimony.)

OTHER Y2K ACTIVITIES

I have just described to our most recent information on the industry's readiness and some of the ways in which HIMA worked to support industry's efforts. All of HIMA's work was built on a strong foundation of member participation that began in 1998.

Effective Industry Communications

As I mentioned earlier, HIMA sees one of its roles on this issue as a provider of information in support of industry activities. HIMA used its Internet site, HIMAnet.com, to provide relevant information to the entire industry. To accomplish this, we created a special section on the site devoted entirely to Year 2000 issues. We have used this Y2k area to publicize the events in which we have participated and to promote industry participation in and cooperation with a variety of government activities. These have included the FDA's Federal Y2k Biomedical Information Clearinghouse, the President's Council on Year 2000 Roundtable, Consumable Medical and Surgical Supplies, which I just discussed, and the Community Conversations suggested by John Koskinen. Although the Community Conversations were aimed primarily at providing information to the public regarding local facilities and services, we recommended that medical device companies participate. We have also published a steady stream of articles in our newsletter, In Brief, reaching almost 10,000 readers in all parts of the medical device industry, including senior executives and the press.

In August 1998, HIMA formed its Year 2000 Issue Working Group. This Working Group's first task was to develop working relationships with the National Patient Safety Partnership, the FDA, and any groups concerned with the Y2k readiness of electronic medical devices. The working group reached out to the Partnership, an important coalition comprising the Department of Veterans' Affairs, the American Hospital Association, the American Nurses Association, and the American Medical Association, among others. The Partnership proposed the development of a central clearinghouse on the compliance status of medical technology.

HIMA worked diligently and closely with FDA and the Department of Veterans' Affairs to help the FDA's Federal Y2k Biomedical Equipment Clearinghouse (Clearinghouse) become the principal central collection point for Year 2000 device compliance information. The initial focus of the FDA Clearinghouse effort was to gather information on *non-compliant* devices. In support of that critically important goal, HIMA:

- Encouraged the industry to respond to FDA's requests for information for the Clearinghouse, resulting in a 100-percent response rate from HIMA member companies.
- Communicated with more than 6,000, primarily small, non-member companies in the industry urging them to respond to the FDA request for Year 2000 status information and to ensure that their devices are Year 2000 compliant.
- Sponsored advertisements with the FDA, the Department of Veterans' Affairs, and other industry associations in key trade magazines urging device companies to respond to FDA's request for Year 2000 status information.

In addition, HIMA worked to ensure the effectiveness of communications with our own member companies by:

- Asking each member company to designate the individual responsible for coordinating Year 2000 activities.
- Working with the FDA and the VA to ensure that their communications were reaching the right people, especially in instances where they were receiving no response.
- Making calls to non-member companies who had failed to respond to the VA and FDA requests for Year 2000 information to urge them to post their compliance information on FDA's Federal Y2k Biomedical Equipment Clearinghouse.

Federal Y2k Biomedical Equipment Clearinghouse

After the initial cooperative efforts to make the Clearinghouse an effective tool for providing information on non-compliant devices, HIMA and the Partnership made further recommendations to improve it. For example, there have over the years been many mergers and acquisitions within the medical device industry. This changing business landscape makes it difficult in some cases to trace the provenance of some devices. One of the joint recommendations was for device manufacturers to provide more information to the clearinghouse on company and device histories to assist device owners in locating information for older devices.

After the Clearinghouse was working effectively to provide information on "non-compliant" devices, FDA expanded its content to include information on Year 2000 compliant devices. This provided "one stop shopping" for health care providers on compliance information. HIMA worked closely with the FDA to help develop a template to facilitate a better industry response. We also strongly encouraged our members to respond to this new FDA request for information. HIMA's President urged all HIMA members to provide the requested information. HIMA also used its Web site to promote compliance with the request.

I want to take a moment now to compliment FDA on the way they have conducted their Y2k operations. They have been extremely fair and have welcomed industry assistance and cooperation. I want particularly to acknowledge the work of Dr. Thomas Shope of the Office of Science and Technology at the Center for Devices and Radiological Health, whose work with the industry has been both helpful and professional. We are pleased to have been able to work with him so productively on this issue.

CONCLUSION

What I have tried to do is provide the Committee with a current picture of the medical device industry's Y2k readiness. This current level of readiness is based not only on the work of HIMA companies and the device industry as a whole, but also on many other groups from the government and private sectors. Both HIMA staff and members have had very positive experiences working with many dedicated employees of the Federal agencies involved in monitoring the Y2k issue. In the final analysis, these have been highly cooperative and very productive and have resulted in broad expectations that medical devices will function safely as we enter year 2000.

This industry's primary efforts have been directed at maintaining patient safety and high quality. We are confident that as we enter year 2000, events will show that we have been successful. In the meantime, the medical device industry commits to continue working cooperatively with all parties to ensure that the transition form 1999 to 2000 is safe and uneventful.

Mr. UPTON. Thank you.
Mr. Horowitz?

TESTIMONY OF BRUCE HOROWITZ

Mr. HOROWITZ. Good morning, chairmen and subcommittee members.

I am Bruce Horowitz, Director of Product Assurance for Advanced Neuromodulation Systems, Inc., of Plano, Texas. I appear before you today on behalf of the 130 members of the Medical Device Manufacturers Association. Thank you for this opportunity to tell you how our industry has responded to the year 2000 computer date problem.

MDMA is the national voice for the entrepreneurial sector of the medical device industry. The association as established in 1992 by a group of executives of small and mid-sized companies who believed that medical technology and entrepreneurs need distinct representation before the Federal Government.

As in most industries, small and startup companies have different perspectives and needs than their larger counterparts. This is particularly true in highly regulated industries such as ours. MDMA appreciates the attention paid by your subcommittees to the year 2000 computer date problem.

On behalf of the 300,000 employees of the American medical technology industry, I am pleased to tell you that we are ready for the calendar to turn on January 1. In my written testimony, I have outlined several reasons why the public should rest assured that the turn of the millennium will be business as usual for medical devices. The very nature of our industry, in fact, mitigates the potential impact of the Y2K problem.

Since the pace of innovation in our industry is so rapid, most medical devices have very short life on the market, before companies and their competitors introduce a next generation of product. Many of the current generations of products on the market, therefore, were introduced during a time when engineers and computer programmers were well aware of the Y2K problem and its significance.

Here is how our company dealt with the Y2K problem. ANS develops and markets implantable medical devices for the neuromodulation market. Neuromodulation is the electrical or chemical stimulation of the central nervous system to reduce pain or improve neurologic function. Our products include implantable spinal cord stimulation systems to manage chronic, intractable pain. The FDA has identified this device as potentially high-risk.

We at ANS had already assessed that our devices were Y2K compliant, even before the FDA announced in January its intent to expand the information maintained in the Y2K clearinghouse. However, we recognized the importance of publicly assuring our customers and patients that our products would not be affected by the Y2K problem. Therefore, our senior management approved a program to expand the Y2K compliance program. This program was based primarily on guidelines provided by the U.S. General Accounting Office and the British Standards Institute.

At ANS, we assessed our in-house equipment, evaluated our devices, and notified our customers that we are Y2K compliant, and

that our product and service sources had addressed any potential problems. In my written statement, you will see the specific steps ANS took to deal with the various aspects of Y2K readiness and disclosure.

To inform our customers, the most important people in this equation, we composed a letter that summarized the Y2K status of our products in the field. We decided to respond to customer inquiries in this way, since we literally had hundreds of inquiries on this subject, some of them containing multiple page surveys.

As a small company, we did not have the resources to fill out these surveys, so we determined that a summary letter would be the best and most appropriate solution. So far, all of our customers have indicated that the letter met their needs.

We have also responded promptly to all FDA requests for information. So far in 1999, we have provided data on our products four times.

While at ANS we will not consider our Y2K compliance program to be complete until we have processed our last customer request for information, we were able to complete the actual assurance of Y2K compliance throughout all phases in April. We at ANS have worked with MDMA over the last 2 years to help the medical technology address Y2K concerns. You should know that MDMA has collected information from its members for inclusion in the FDA's database, published public service announcements, worked with the FDA to redefine their Y2K surveys and databases, and helped develop industry-wide guidelines to assure the smooth operation of the health care supply chain during the Y2K transition period.

Nevertheless, we are concerned that the health care providers are not using the resources available to them to find out information on the Y2K status of biomedical equipment. Furthermore, we are concerned that providers may be conducting unnecessary tests of biomedical equipment that may create problems where none would otherwise exist.

MDMA respectfully disagrees with the OIG's recommendation that testing is the only way to ensure device functionality. Instead, MDMA encourages providers to heed the advice of the well-respected Emergency Care Research Institute, that testing when complete compliance information is available is not necessary. ECRI has received only a few confirmed reports of hospital tests that contradict manufacturers' statements. And in none of these instances was the essential functionality of the device an issue.

Furthermore, ECRI rightly points out that problems could be introduced during the testing of a device. MDMA is confident that the safety, effectiveness, performance and reliability of medical technology will be largely unaffected by the Y2K computer date program. However, to ensure as smooth a Y2K transition as possible, MDMA encourages health facilities and professionals to consult the FDA's Y2K clearinghouse and to contact manufacturers for more detailed information if necessary, to refrain from unnecessary testing of biomedical equipment when complete compliance information is available, and to preserve the integrity of the supply chain by not hoarding or stockpiling medical supplies and equipment.

Thank you again for this opportunity to appear before you.

[The prepared statement of Bruce Horowitz follows:]

PREPARED STATEMENT OF THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION

Good morning, chairmen and subcommittee members. I am Bruce Horowitz, director of product assurance for Advanced Neuromodulation Systems, Inc. (ANS), located in Allen, Texas. I appear before you today on behalf of the 130 members of the Medical Device Manufacturers Association (MDMA). Thank you for this opportunity to tell you how my company and the medical device industry have responded to the Year 2000 computer-date problem.

MDMA is the national voice for the entrepreneurial sector of the medical device industry. The association was established in 1992 by a group of executives of small and mid-sized companies who believed that medical technology entrepreneurs needed distinct representation before the federal government. As in most industries, small and start-up companies have different perspectives and needs than their larger counterparts, and this is particularly true in highly regulated industries such as ours. For our part, we at ANS are proud to be one of the founding members of MDMA.

MDMA appreciates the attention paid by your subcommittees to the Year 2000 computer-date problem. The 300,000 people employed in the medical device industry share your concern about the possible effects that Year 2000 or "Y2K" malfunctions could have on patient safety. I am pleased to tell you, however, that the medical technology industry is ready for the calendar to turn on January 1.

Significance and Potential Impact of the Y2K Computer-Date Problem

The nature of the Y2K problem has been documented at previous hearings and by previous witnesses today, so I won't add to the technical description. I will say, however, that we recognize the significance of the problem for certain medical device manufacturers and the potential impact on patient safety that the Y2K problem could have if not addressed properly.

As businesses, medical device manufacturers have numerous business-related reasons for wanting to address and fix any potential Y2K problems with our products. However, as businesses involved in healthcare, we also have a public-health responsibility to prevent Y2K problems from harming patients. Clearly, it is not in our best interests as businesses or as responsible members of the healthcare community to neglect the Y2K situation.

There are other reasons for the public to rest assured that the turn of the millenium will be "business as usual" for medical devices. Under the FDA's quality systems regulation, medical device manufacturers must ensure that our production processes and other computerized processes function properly and will not be disrupted by any Y2K problems. The FDA has enforced this regulation fairly, and we are pleased to hear the agency publicly state that the Y2K problem will not have a major effect on medical technology. The subcommittees also should note that while many medical device manufacturers depend on computer hardware and software for their products to function or to enable production, very few devices depend critically on date-related information to function properly.

The very nature of our industry also mitigates the potential impact of the Y2K problem. Since the pace of innovation in our industry is so rapid, most medical devices have a very short life on the market before companies and their competitors introduce a next generation of products. Many of the current generations of products on the market, therefore, were introduced during a time when engineers and computer programmers were well aware of the Y2K problem and its significance.

How ANS Addressed the Y2K Problem

Here's how our company dealt with the Y2K problem. ANS develops and markets implantable medical devices for the neuromodulation market. Neuromodulation is the electrical or chemical stimulation of the central nervous system to reduce pain or improve neurologic function. Our products include implantable spinal cord stimulation systems to manage chronic intractable pain. We are also developing an implantable pulse generator and an implantable drug administration system, both of which will be used in the management of chronic pain and nervous system disorders.

We at ANS had already assessed that our devices were Y2K-compliant, even before the FDA announced in January its intent to expand the information maintained in its Federal Y2K Biomedical Equipment Clearinghouse [www.fda.gov/cdrh/yr2000/year2000.html], the main centralized information source on the Y2K status of biomedical equipment. However, we recognized the importance of publicly assuring our customers and patients that our products would not be affected by the Y2K problem.

Therefore, our senior management approved a program to expand our Y2K compliance program. This program was based on guidelines provided by the General Accounting Office in a document called "Year 2000 Computing Crisis: An Assessment Guide." We also relied upon "DISC PD2000-1, A definition of Year 2000 Conformity Requirement," published by the British Standards Institute (BSI).

At ANS, we assessed our in-house equipment, evaluated our devices, and notified our customers that we are Y2K-compliant and that our product and service sources had addressed any potential problems. The four key elements of this Y2K compliance program were general integrity, date integrity, explicit/implicit century and leap year.

Here are the specific steps ANS took to deal with the various aspects of Y2K readiness and disclosure:

Computer systems—We tested all hardware and software or assured that our supplier had certified to Y2K compliance. Our tests and assurance included all computer systems and key software, such as our operating systems, our manufacturing management systems, and our quality management software.

Products—We assured that all of our computerized or microprocessor-based products had been tested or evaluated according to the conformity requirements contained in the BSI document. This encompassed the transmitter, the receiver and the programmer in our devices.

Manufacturing equipment and test equipment—We assured that all computerized or microprocessor-based equipment in manufacturing or testing had either been tested or certified to Y2K compliance by its maker.

Suppliers—We queried our suppliers of products and services as to their Y2K readiness. At this point, we have assured that all key suppliers will be in compliance by December 31 or have contingency plans to ensure an uninterrupted supply of components.

Customers—We composed a letter to our customers that summarized the Y2K status of our products in the field. We decided to respond to customer inquiries in this way since we literally had hundreds of inquiries on this subject, some of them containing multiple-page surveys. As a small company, we did not have the resources to fill out these surveys, so we determined that a summary letter would be the best and most appropriate solution. So far, all of our customers have indicated that the letter met their needs.

FDA—We have responded promptly to all FDA requests for information. So far in 1999, we have provided data on our products four times, in January, March, June and September.

Ongoing Activities—We continue to require and evaluate information regarding Y2K compliance for any new products, equipment or suppliers.

While we at ANS will not consider our Y2K compliance program to be complete until we have processed our last customer request for information, we were able to complete the actual assurance of Y2K compliance throughout all phases in April.

The Industry Perspective

MDMA is pleased to know that the FDA believes the medical technology industry is well prepared for the year 2000. MDMA has worked with its members and the FDA over the past two years to help the medical technology industry address Y2K concerns. For instance, MDMA has

- collected information from its members for inclusion in the FDA's Federal Y2K Biomedical Equipment Database;
- joined with fellow associations in publishing public-service announcements in trade publications to raise general industry awareness;
- worked with the FDA, hospitals, distributors, and other stakeholders to refine Y2K surveys and databases to improve the quality of Y2K information available to patients and users; and
- helped develop industry-wide guidelines to assure health facilities and professionals of a continual and reliable supply and availability of medical products throughout the Y2K transition period.

Nevertheless, we are concerned that hospitals, other health facilities, and health professionals are not using the resources available to them to find out information on the Y2K status of biomedical equipment. Furthermore, we are concerned that these same organizations and individuals may be conducting unnecessary testing of biomedical equipment that may create problems where none would otherwise exist.

The recent survey by the Office of the Inspector General (OIG) at the Department of Health and Human Services suggests that end-users are not taking advantage of the Federal Y2K Biomedical Equipment Database. While we are heartened to see that nearly every hospital responding to the survey believes that their biomedical equipment will be Y2K-ready by December 31, we are disappointed that only 79 per-

cent were aware of the FDA's database, and only 59 percent had visited the database for information about the Y2K status of their equipment. I hope that the FDA, the hospital associations, and other representatives of health facilities and professionals will redouble their efforts to inform the healthcare community about the FDA's Y2K clearinghouse.

The OIG's survey also found that 68 percent of hospitals have tested their biomedical equipment to verify Y2K readiness. MDMA is concerned that in many cases, this testing is not necessary and may cause problems with the equipment being tested.

An independent health services research agency, the Emergency Care Research Institute (ECRI), in its "Position Statement on the Testing of Medical Devices for Year 2000 Compliance," writes that "testing when complete compliance information is available is not necessary" for a variety of reasons. For example, ECRI believes that "healthcare facilities are not likely to have the expertise, the access, and the resources to perform testing at the level needed to provide a reasonable assurance that a device is compliant." ECRI also has received "only a few confirmed reports of hospital tests that contradict manufacturer compliance statements, and all these reports have involved minor problems such as devices displaying or printing incorrect date information." Finally, ECRI points out that "problems could be introduced during testing" of a device.

MDMA agrees with ECRI's findings and urges health facilities and professionals to consult the FDA's information clearinghouse and to contact manufacturers before conducting any further Y2K testing of biomedical equipment.

Summary

MDMA is confident that the safety, effectiveness, performance, and reliability of medical technology will be largely unaffected by the Y2K computer-date problem. This is a direct testament to the focus and commitment of Advanced Neuromodulation Systems and our colleagues in the more than 7,000 companies in the medical device industry, more than two-thirds of which have fewer than 50 employees. To ensure as smooth a Y2K transition as possible, MDMA encourages health facilities and professionals

- to consult the FDA's Y2K clearinghouse and to contact manufacturers for more detailed information if necessary;
- to refrain from unnecessary testing of biomedical equipment when complete compliance information is available; and
- to preserve the integrity of the supply chain by not hoarding or stockpiling medical supplies and equipment.

Finally, MDMA commends the FDA for its efforts to provide health facilities and professionals with the resources they need to certify the Y2K compliance of their biomedical equipment. We also commend your subcommittees for your reasoned and even-keeled oversight of this situation. Thank you again for this opportunity to appear before you.

Mr. UPTON. Mr. Neill?

TESTIMONY OF C. THOMAS NEILL

Mr. NEILL. Good morning, Mr. Chairman and members of the committee.

I am Tom Neill, Vice President, Corporate Services, of Quorum Health Group. During the past several years, I have served as the executive sponsor for our company-wide Y2K program. I am honored to appear before you today on behalf of my company, which is a member of the Federation of American Health Systems, and on behalf of the hospital industry.

Today I will discuss Quorum's activities and preparations concerning Y2K which are expected to cost approximately $20 million. Quorum Health Group, through its affiliates, operates acute care hospitals and health systems nationwide. Through its affiliates, Quorum currently owns 21 hospitals, manages 223 hospitals, provides consulting services to 122 facilities and has more than 20,000 employees in more than 40 States and the District of Columbia.

Through great effort and a significant commitment of time, resources and money, we are pleased to say that over 98 percent of our Tier 1 clinical equipment at our own hospitals has been assessed and remediated for Y2K readiness. While our primary focus has been on equipment and systems that affect our ability to continue to deliver quality patient care, we recognized early on that a complete program involves addressing all aspects of the operation of a hospital.

In 1997, we began educating the hospital base chief information officers of our own hospitals about the year 2000 issue. They subsequently began working with their primary vendors that developed and supported our core information systems. In July 1998, the company hired outside consultants to form a program management office to assist our own hospitals even further in their preparations for the year 2000.

We have adopted a three tier approach for Y2K project completion. For instance, Tier 1 addresses applications and equipment that have a direct impact on patient safety and health care, or are essential to our daily operations. We are also using an outside vendor's database to gather and monitor manufacturer year 2000 compliance information for biomedical devices, building infrastructure components and information technology systems.

Our own hospitals' year 2000 strategy includes phases for education, inventory and assessment, validation and conversion, and remediation or replacement. We are also developing contingency plans to address potential disruption of operations arising from the year 2000 problem. Quorum estimates that it will spend approximately $20 million on Y2K activities for its 21 own hospitals.

Simply put, our policy is, we will not deploy any Tier 1 biomedical device for patient care without reasonable assurance that it will perform properly in light of the year 2000 problem. Quorum has substantially completed testing and validation of all Tier 1 biomedical equipment. We have not tested devices where the manufacturer has advised us against testing such equipment, and represented year 2000 compliance in writing. We currently expect to complete remediation of the remaining 2 percent or approximately 400 items by the end of 1999.

To restate, our policy is that we will not deploy any Tier 1 biomedical device for patient care without reasonable assurance that it will perform properly in light of the year 2000 problem. Further, our policy is to test all equipment that we have identified as Tier 1 regardless of the manufacturer's stated Y2K status.

While Quorum has taken a very conservative approach to testing all Tier 1 biomedical equipment, even those that the manufacturer states is compliant, responsibility of compliance still remains with the equipment manufacturer. Despite our best efforts, we are unable to test to the same degree that a manufacturer of that device could test.

Each of our hospitals' disaster plans form the foundation for our year 2000 contingency planning, but we have gone beyond this. Quorum's Y2K contingency planning training has been performed and best practices reviewed and shared with all hospitals. In fact, Y2K drills are being conducted now with a company-wide drill planned for November.

In conclusion, the comprehensive approach that we have taken on Y2K demonstrates the level of Quorum's commitment to the delivery of quality patient care in our hospitals. The approach to testing all Tier 1 biomedical equipment, coupled with our commitment to restrict the use of any device that is not Y2K ready, increases our confidence that patient safety and quality care will not be compromised in our hospitals.

To address the year 2000 issue to this degree has required a significant amount of resources, from our hospitals and business partners alike. However, Quorum is committed to working with our business partners and communities to ensure a safe transition into the next millennium.

Thank you for this opportunity to testify before you today, Mr. Chairman, and I welcome your questions.

[The prepared statement of C. Thomas Neill follows:]

PREPARED STATEMENT OF C. THOMAS NEILL, VICE PRESIDENT, CORPORATE SERVICESQUORUM HEALTH GROUP, INC. ON BEHALF OF THE FEDERATION OF AMERICAN HEALTH SYSTEMS

INTRODUCTION:

Good morning Mr. Chairman and Members of the Committees. I am Tom Neill, Vice President, Corporate Services, of Quorum Health Group, Inc. During the past several years, I have served as the executive sponsor for our company-wide Y2K program. I am pleased to appear before you today on behalf of my company, which is a member of the Federation of American Health Systems, and on behalf of the hospital industry. The Federation of American Health Systems represents nearly 1,700 privately owned and managed community-based hospitals and health systems that offer traditional acute care, ambulatory care, rehabilitative care, and allied companies involved in health care systems.

For purposes of today's hearing, I will discuss Quorum's activities and preparations concerning Y2K, which are expected to cost more than $20 million. Quorum Health Group, Inc., through its affiliates, operates acute care hospitals and health systems nationwide. Through its affiliates, Quorum currently owns 21 hospitals, manages 223 hospitals, provides consulting services to 122 facilities and has more than 20,000 employees in more than 40 states and the District of Columbia.

Year 2000 Plan

Through great effort and a significant commitment of time, resources and money, we are pleased to say that over ninety-eight percent of our Tier 1 clinical equipment in our owned hospitals has been assessed and remediated for Y2K readiness. While our primary focus has been on equipment and systems that affect our ability to continue to deliver quality patient care, we recognized early on that a complete program involves addressing all aspects of the operation of a hospital.

In 1997, we began educating the hospital-based chief information officers (CIOs) of our owned hospitals about the Year 2000 issue. They subsequently began working with their primary vendors that developed and supported our core information systems. In July 1998, the Company hired outside consultants to form a Program Management Office (PMO) to assist our owned hospitals even further in their preparations for the Year 2000. The PMO's integrated, team-oriented approach brought together a team of experienced players into one centralized office. The group included numerous associates from Quorum, consultants from Keane, the law firm of Rudnick & Wolfe of Chicago, and third party management service providers who took the unique project very seriously from day one.

Year 2000 Approach

We have adopted a "tier approach" for Year 2000 project completion. Tier 1 addresses applications and equipment that have a direct impact on patient safety and health or are essential to our daily operations. Tier 2 represents applications and equipment that are critical to continued business operations, but not required to provide day-to-day service to the patients and for which a viable alternative exists. Tier 3 relates to applications and equipment that are not essential to our daily operations.

To date, we have given first priority in our testing and remediation efforts to Tier 1 applications and equipment. We are also currently validating and remediating Tier 2 devices, components and systems. We currently expect to substantially complete validation and remediation of Tier 2 devices, components and systems by the end of 1999. In addition to our own testing, we are using an outside vendor's database to gather and monitor manufacturer Year 2000 compliance information for biomedical devices, building infrastructure components and information technology systems. In general, we are relying on vendor verification of Year 2000 compliance for Tier 2 devices, components and systems, rather than testing these items ourselves.

Process Overview/Phases

The PMO developed a multi-phase approach to help Quorum-owned hospitals quickly address their Y2K mission critical issues. While not directly a part of the PMO, hospitals managed by Quorum Health Resources, LLC, have been provided education and suggested guidelines for their own readiness efforts. Best practices are shared with managed facilities to assist their independent efforts.

Our owned hospitals' Year 2000 strategy includes phases for education, inventory and assessment, validation (including testing) and conversion, remediation or replacement. We are also developing contingency plans to address potential disruption of operations arising from the Year 2000 problem.

- **Awareness:** This is truly an ongoing function. We are continually raising the level of awareness and education of the hospitals' Y2K projects throughout the Company and communities.
- **Inventory:** We have taken action to ensure thorough and comprehensive inventory identification.
- **Assessment and Impact Analysis:** We have made a comprehensive assessment of all hospital systems, equipment and vendors, utilizing a tier approach where priorities are based on impact and criticality.
- **Testing:** Quorum's testing strategy for biomedical equipment involves setting the date to one of four potentially problematic dates (e.g., 1/1/2000, 2/29/2000, etc.). Quorum has taken a conservative approach by establishing a policy to test all Tier 1 biomedical equipment where feasible.
- **Remediation:** Quorum has undertaken the remediation process and is correcting Y2K problems in biomedical equipment, computer systems, or other hospital equipment. This action may include replacement, upgrade, elimination, or performing a workaround.
- **Contingency Planning:** Our hospitals are preparing for potential Y2K problems by first reviewing existing hospital disaster recovery plans, then developing Year 2000 specific contingency plans.
- **Documentation:** Our hospitals are implementing a process to ensure that the hospitals' Y2K project efforts and activities are properly recorded and well preserved.

Costs & Impact

Quorum estimates that it will spend approximately $20 million dollars on Y2K activities for its 21 owned hospitals. Specifically, the total resources necessary to manage an inventory of 32,000 devices and systems towards Y2K readiness will cost approximately four million dollars. Capital costs for replacing, upgrading, and fixing Y2K issues are estimated to total approximately $16 million dollars of the $20 million dollars. This includes replacing the core information systems in six (6) owned hospitals.

Approximately fifty percent (or 16,000) of Quorum's Y2K inventory was given the highest priority rating of Tier 1 based upon possible impact to patient care and hospital operations. Seventy-five percent, or approximately 12,000 of that 16,000, were clinical devices. We discovered that approximately forty percent of our clinical devices have no Y2K sensitivity, meaning the device has no clock chip. Therefore, we tested approximately 7,000 clinical devices in our owned hospitals.

Hospital Medical Device Testing

We have substantially completed testing and validation of all Tier 1 biomedical equipment. We have not tested devices where the manufacturer has advised us against testing such equipment and represented Year 2000 compliance in writing. We believe that approximately ninety-eight percent of the Tier 1 devices requiring Year 2000 validation are now Year 2000 compliant. We currently expect to complete remediation of the remaining two percent, or approximately 400 items, by the end of 1999. **Our policy is that we will not deploy any Tier 1 biomedical device for patient care without reasonable assurance that it will perform properly in light of the Year 2000 problem.** Such assurance may take the form of testing,

vendor assurances of Year 2000 compliance or, where feasible, developing a work-around procedure for the device in case of a possible malfunction.

Y2K Readiness Validation

Quorum has taken a dual approach to determining the Y2K readiness of our hospitals' medical devices. First and foremost, we look to the manufacturer for the status, knowing that they are the ultimate authority on their own equipment. We contracted with an outside service provider to manage and update the compliance status from manufacturers. This service provider gathered information from the FDA web site, manufacturer web sites, or directly from the manufacturer.

Second, our testing program provides additional verification of the information from the manufacturer. **Our policy is to test all equipment which we've identified as Tier 1, regardless of the manufacturers' stated Y2K status.** The only exception to this policy is granted when the vendor provides written assurance that the device is Y2K compliant and states that field testing would or could damage the equipment.

Responsibilities

While Quorum has taken a very conservative approach to testing all Tier 1 biomedical equipment, even those that the manufacturer states as compliant, responsibility of compliance still remains with the equipment manufacturer. As a user of the equipment, we believe we can only reasonably perform tests of the rollover from one date to another. Despite our efforts, we are unable to test to the same degree that a manufacturer of that device could test.

Contingency Planning

We developed contingency plans in all of our owned hospitals that we believe will reduce disruption in service that could be caused by the Year 2000 problem. As part of our contingency plan, each of our owned hospitals has a disaster plan, which we review regularly. These disaster plans are designed to enable the hospital to continue to function during natural disasters and other crises. Y2K contingency planning training has been performed and best practices reviewed and shared with all hospitals. Minimum standards for the plans were set and a review of every hospital's plan is under way. Y2K drills are being conducted with a company-wide drill planned for November.

Industry Status Observations

Overall reports from the Department of Health & Human Services indicate that the majority of hospitals will be ready for the Year 2000. Also, the recent survey by the American Hospital Association on "Y2K Readiness of Fee-For-Service Providers as of July 1999" made the following points:

- Twenty-seven percent of responding hospitals say that ALL their biomedical equipment is ready. Of those whose biomedical equipment is not ready, the majority (357) say that they have completed eighty-six percent or more.
- Nearly all hospitals (513) predict that ninety-nine percent of their equipment will be ready by the end of the year.

Another recently released report on the Y2K readiness of healthcare providers from the Office of Inspector General (OIG) indicates that most hospitals will be ready for Y2K. As quoted:

- Hospitals had the highest survey response rate which "shows their willingness to be forthcoming about the work that is still needed to be completely Y2K ready."
- "Clearly, the survey indicated that the vast majority of hospitals are doing everything it takes to be Y2K ready."

Conclusion

In conclusion, the comprehensive approach that we have taken on our Year 2000 program demonstrates the level of Quorum's commitment to the delivery of quality patient care in our hospitals. The approach to testing all Tier 1 biomedical equipment, coupled with our commitment to restrict the use of any device that is not Y2K ready, increases our confidence that patient safety and quality care will not be compromised in our hospitals. To address the Year 2000 issue to this degree has required a significant amount of resources from our hospitals and our business partners alike. However, Quorum is committed to working with our business partners and communities to insure a safe transition into the next millennium. Thank you for this opportunity to testify before you today. I welcome your questions.

Mr. UPTON. We've appreciated the testimony of all of you. As you have heard from these buzzers and lights, we have a vote on. We

are going to try to keep the committee moving as we did in the first panel. Mr. Bryant has gone over, he has the fast legs, so he will be back soon, and Mr. Brown will be back as well, and obviously Mr. Bilirakis.

Before I need to go and vote, I have a couple of questions for sure. The HHS inspector general report indicated that about 60 to 70 percent of providers rely on manufacturers' assurances that the equipment will be Y2K compliant. But about half of the hospitals apparently reported problems getting information from those manufacturers. Any reason why? Any thoughts between the three of you?

Mr. NEILL. Mr. Chairman, if I might respond, initially——

Mr. UPTON. I mean, it sort of goes back to the series of questions that I asked, as well, that the manufacturers ought to be the first ones on the scene to report back to the providers in terms of problems that they might experience.

Mr. NEILL. I agree with your assessment, Mr. Chairman. Early on in the Y2K agenda, and when I say early on, 18 months ago, there was a huge cloud of liability over the entire concept of Y2K. And that cloud of liability still remains today.

But early on, in response to your question, there was some apprehension on behalf of the manufacturers to come forth and be totally forthright and candid regarding the Y2K compliance of their equipment. But we have not found that to be the case this year.

The FDA has done a commendable job in pulling that information together. Other organizations, such as the VHA out in Dallas, likewise, working with FDA, has pulled the manufacturers' information together. And we have found that information to be readily attainable.

Mr. UPTON. I would just note from my own personal observations, I have a large employer in my district called Stryker. I know you recognize it. I know those folks very well. And as I went in, and kicked the tires, as one might say, I found that their attitude was very responsible in making sure that everything was compliant and full notice was given, and a concern to no end to make sure that literally every rock and stone was unturned just to make sure that they would not experience problems.

Would you say that in general, most other device manufacturers, particularly in your membership, Mr. Benson and Mr. Horowitz, followed the same type of lead that the Stryker folks have?

Mr. BENSON. Absolutely.

Mr. UPTON. Is that indicative of the entire industry?

Mr. BENSON. Absolutely. I think common sense, if you just look at it from a common sense standpoint, these companies are in business to help patients, to make sure patients are treated safely, that the quality of health care is very positive, the quality of their lives is very positive.

And of course, there is a profit motive. It does not make sense for them to not put that information out. I think the example you gave from Stryker is a good one, and I think that is the model that companies have followed.

In answer to your question, the only reason I can think of, perhaps in addition to Mr. Neill's explanation, is simply just volume of requests. I am a little doubtful of that data. I would think that

if you look back over the past several months, over the past year or so, that the vast majority of questions have been answered, and probably answered promptly.

Mr. UPTON. Okay. I am getting a little nervous, I have not missed a vote this year or last year, and I want to make sure I get there. I know Mr. Bryant will be back momentarily and we will continue at that point.

Thank you.

[Brief recess.]

Mr. BRYANT [PRESIDING]. We will reconvene.

I left early and raced over there to vote so I could relay back and catch the chairman, but we did not quite make the time pass exactly. But in the interest of saving you folks some time, you have been here a long time, we try to do that occasionally and make it work.

Mr. HOROWITZ. He complimented your legs.

Mr. BRYANT. I did not have my cape on, I might have flown over there today.

I understand we are at that point where we have finished our statements. Mr. Neill, I think you were testifying when I left. Again, it was nothing you said that caused me to leave.

But let me start the questioning, if I could. I think I wanted to ask Mr. Neill, I understand perhaps you have conducted some testing, is that right?

Mr. NEILL. Yes, sir, we have.

Mr. BRYANT. As part of your testing that you have done for the Tier 1 devices, were there any occasions where your own testing showed non-compliance of the device and the manufacturer had previously stated that the device was in fact Y2K complaint?

Mr. NEILL. No, sir, I do not recall any of that at all. Our testing of Tier 1 indicated a failure rate overall of around 2 to 4 percent, it just depended on which line of the equipment. But we did not, to the best of my knowledge, discover any malfunctions that had not already previously been reported by the manufacturer.

Mr. BRYANT. Would you again, for the people who might later see this program or might be in the audience, distinguish between Tier 1 and Tier 2?

Mr. NEILL. Tier 1, Mr. Chairman, is any device by our definition that touches a patient that is related to patient safety. A more prevalent definition throughout the health care industry has been to call it a mission critical device. A Tier 2 is something other than a Tier 1. It does not touch a patient. It is not patient safety related. It is primarily hospital operations and business systems oriented.

Mr. BRYANT. I wonder if all three of the members, and Mr. Liebler, if you are aware that the FDA has hired outside contractors to help in assessing the Y2K problem? Has that been of any help? Was that of any help to you in your own involvement with this issue?

Mr. HOROWITZ. From the perspective of the manufacturer, we would have taken any action that we have taken anyway. Just from the perspective that the devices have to be safe and effective, we have customers that rely on them. And the fact that FDA hired consultants to check up on us, really did not factor into our compliance in any way.

Mr. BRYANT. Mr. Benson or Mr. Liebler?

Mr. LIEBLER. I have spoken with a number of our manufacturers who did volunteer for these examinations. I asked them to tell me how they went, and they were very pleased with them.

And I think the most important point they had to mention was, this is a unique event and a unique situation. They all had worked very hard and felt that they had done as well as they could. And this served as a good independent third party who came in and at least told them they believed they were doing things in the right way. So I think that was an overall benefit to the industry.

Mr. BRYANT. Mr. Benson, I understand your association represents about 1,000 manufacturers. I think the total number of manufacturers registered with the FDA is, I don't see the figure but it is something like 17,000. I am wondering, too, Mr. Horowitz, do you represent 100, I think it is——

Mr. HOROWITZ. It's 130.

Mr. BRYANT. I assume they are some of the same people, perhaps cross-pollinating there. But what that tells me is the two of you represent, in your associations, I don't know where all these other people go for their representation, but it is a substantial minority.

Is there concern in the industry as a whole on either of your parts, and Mr. Liebler, I will add you, too, about compliance with the other manufacturers, non-members?

Mr. BENSON. Let me mention first that HIMA's, if you look at the HIMA membership in terms of sales, it is almost 90 percent of the medical device industry.

Mr. BRYANT. I am sorry, you did mention it was 90 percent.

Mr. BENSON. You've got a slug of MDMA and some of the other trade associations, NEMA, into that, you're pushing 100 percent.

But there are a lot of small manufacturers, there are a lot of manufacturers that are classified as startups, or they may not even have a product on the market. We went out of our way, not only to push our own members, as did the other associations, but also to contact non-members. Because we wanted to be responsible citizens and make sure that the industry was in fact doing what it should do to make sure there was not a Y2K problem.

So I personally feel very strongly that the device industry is in great shape when it comes, I am not concerned about the fact that we do not have 100 percent of the companies.

Mr. HOROWITZ. MDMA has done similar things to what HIMA does. Obviously, membership of MDMA has consisted mostly of small and startup companies. But we feel the same way that HIMA does, that in general, these are very highly technologically oriented companies. And this is not a secret, we have been aware of this for quite a while and have taken steps to address the problem.

Mr. BRYANT. Since Mr. Brown is here, I am going to go ahead and ask one or two other questions. We have seized control of the Chair, so I am very liberal with myself in time.

Could I ask you one general follow-up, to all of you? You were here when the first panel testified and the inspector general for HHS, and to some extent the GAO representative testified about their concern with the, not only liability, but here we are talking about human lives, their concern at the provider level, where your product may be testified. And Mr. Neill, you can give us some more

light on this, because you are kind of at the downstream end of this more so. But the manufacturer's product may testify fine in a lab setting, but hooked up to everything else in a real world setting, there might be some problems there.

I would love to have your opinions and your thoughts on those kinds of comments in the way of giving us some assurance, one way or the other.

Mr. HOROWITZ. Well, the devices that ANS makes, and the actually probably the majority of devices that are made by our members, are pretty much stand alone devices. They do not interface with computers or other people's devices. So the testing that we conducted would assure the fact that the devices will function as intended.

To address the other problem, it seems reasonable that if a device is going to be Y2K compliant, that the output from that device to another one would also have to be Y2K compliant as well. It would certainly be prudent on the hospitals' part to confirm that, because there is really no way that the manufacturer of one device can predict what the product of another manufacturer's device will do, once they interface it. And they are really the only ones that know how they are using the device.

Mr. NEILL. Mr. Bryant, our organization has elected to confirm Y2K compliance in the operational environment as opposed to the lab test environment for the reasons you suggest.

Mr. BRYANT. Thank you. Mr. Benson or Mr. Liebler, any comment?

Mr. LIEBLER. Well, again, I would like to refer to a discussion I was having yesterday with one of our larger members and the person running their program. He noted that they have structured their testing as far as they could to make it real world testing. They understand the concept, you can't put it in a black box and then say it works when you drop it in the world. So they understand the environments where they are used, and the testing was designed to make sure that it would work in that environment, and I am very confident that we are not alone among our companies doing that.

Mr. BRYANT. Thank you. At this time, the Chair would yield my time to Mr. Brown, the ranking member.

Mr. BROWN. Thank you, Mr. Chairman.

I asked Mr. Willemssen a question of how he would grade providers and grade all participants, if you will, for Y2K readiness. I would like to ask each of you, starting with Mr. Neill, how you grade your members, your industry, A to F, for Y2K preparedness?

Mr. NEILL. Mr. Brown, it is difficult for me to grade other providers in the industry. But with your permission, I would be delighted to grade my own organization. We have quite a few hospitals scattered throughout the country. We have made a significant investment, as I reported in both written and oral testimony. We are spending around $20 million on Y2K within Quorum.

And I would give us an A plus. I appreciated the question when you asked it to panel No. 1. I do think that when you start getting some responses from the provider community that you are going to find that more work has been done than perhaps has been reported overall.

Mr. BROWN. Mr. Horowitz?

Mr. HOROWITZ. It is a bit difficult for me to speak for the other members of MDMA. I can speak for us. And obviously, I would give us an A. We have been at it for quite a while, and we are confident that everything is fine.

One thing I would like to point out, that we do have to operate under the quality system regulation which does include design controls. And any prudent medical device manufacturer would include this type of testing as part of the development and the validation and verification of any medical device.

So as long as we are following the regulations and our own procedures, I would feel confident that all of the devices would comply and would not have this problem.

Mr. BROWN. And your grade would be?

Mr. HOROWITZ. Well, if they were doing that, I would give them an A. But like I said, I do not have the information available to let you know exactly how the other companies feel about their process.

Mr. BROWN. Mr. Benson?

Mr. BENSON. I would give the industry a strong A, A plus.

Mr. BROWN. Because?

Mr. BENSON. Well, as I mentioned in testimony, $700 million has been spent. I think their reputations are at stake in this. They are concerned about patient safety. I have seen an enormous effort on their part to make sure that not only that individual companies, companies that we have, for example, one of our companies chaired a committee issue working group that addressed the Y2K, you know, that leadership has been strong. A lot of activity at the real working level to make sure that products are in fact compliant, and that that information is then communicated.

Mr. BROWN. Considering the grades that you each gave yourselves and your industries, obviously the public, and I guess this Congress, apparently, the majority, anyway, that scheduled this hearing does not believe that it is in quite that good a shape. But the public, in the media, you hear stories that the pacemakers will stop working after January 1. What message do you have for the public so that they rest more assured that any kind of tragedies like this will not happen? Mr. Benson?

Mr. BENSON. That is a good question. I actually think one of the main problems that has also been addressed that we have not talked about here is one of distribution. So I think I would reassure the public that in the medical community, I am not competent to speak in others, that they recognize that and relax and trust the system to work.

On a personal note, I do not particularly relish the idea of having to go to the hospital, but if that were to occur, if it were to occur to a member of my family, I would not be concerned. I think I would be very willing to say that.

I think Bernie wants to add something.

Mr. LIEBLER. I think that we are dealing with extremely complex technology. And I think the pacemaker example that you mentioned is an excellent example, because it was the first thing that I heard about when I started working on Y2K several years ago.

And it has been very hard to get the message to people that it is a technology that does not depend on dates. The way I respond to most reporter questions about that was, does your heart care the date? Your heart has to beat. And the pacemaker's job is to help your heart beat. And it better not care about what date it is either. As they refer to in computers, it's a 24/7 job.

And it is difficult, it is very difficult for all of us to understand how computers work, how cell phones work, how medical devices work. It is daunting. And I think that the best we can do is try to tell people that the people that work on these, the people that design these, are good people like they are, working for a good purpose, who want to keep doing it in the future. And they only have the good of the patient at heart.

Mr. BROWN. Thank you. Thank you, Mr. Chairman.

Mr. BRYANT. Let me thank the panel. You were all very competent and well versed in your expertise, you expressed it well to us. And you have been very helpful to us, as was the first panel also very helpful to us.

Since you have all traveled a long way, does anyone have any closing remarks related to this subject?

[No response.]

Mr. BRYANT. There being none, then, I would assume it is time to adjourn this hearing. And this hearing is adjourned. Thank you.

[Whereupon, at 12:18 p.m., the subcommittees were adjourned, to reconvene at the call of their respective Chairs.]