

# Y2K AND MEDICAL DEVICES: SCREENING FOR THE Y2K BUG

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## JOINT HEARING BEFORE THE SUBCOMMITTEES ON HEALTH AND ENVIRONMENT AND OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTH CONGRESS

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## **Y2K AND MEDICAL DEVICES: SCREENING FOR THE Y2K BUG**

**TUESDAY, MAY 25, 1999**

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

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

Members present Subcommittee on Health and Environment: Representatives Bilirakis, Upton, Sterans, Burr, Bilbray, Ganske, Bryant, Bliley (ex officio), and Brown.

Members present Subcommittee on Oversight and Investigations: Representatives Upton, Burr, Bilbray, Ganske, Blunt, Bryant, Bliley (ex officio), Klink, and McCarthy.

Staff present: Lori Wall, majority counsel; John Manthei, majority counsel; Michael Flood, legislative clerk; Chris Knauer, minority professional staff member, and John Ford, minority counsel.

Mr. BILIRAKIS. The hearing will come to order. Good morning.

I am pleased that our two subcommittees, the Health and Environment Subcommittee and the Oversight and Investigations Subcommittee under Mr. Upton, have convened today to ensure, or at least to try to help to ensure, that healthcare delivery is not interrupted by the Y2K computer problem.

Specifically, we want to guarantee that medical devices using computer software will function properly after the 1st of January of the year 2000. Any failure, by any device, caused by the Y2K problem is one failure too many; I am sure we all agree with that. There is no room for error because human lives are at risk.

Today, we will hear what steps have been taken by the Food and Drug Administration, the medical device industry, and individual hospitals on medical device Y2K compliance.

Medical devices play a critical role in the daily delivery of healthcare, and can range from basic thermometers to more complex devices such as electrocardiograms and infusion pumps. Certainly, if devices that utilize computer software fail to operate, or give improper readings, patients all over the country, and indeed the world, may be put at an unnecessary risk.

The FDA has testified before Congress on this subject over the last couple of years. Unfortunately, in some instances, the FDA has

not had positive news to report. Today, I look forward to hearing the progress that the agency has made toward addressing this very pressing health concern.

The General Accounting Office will offer additional testimony on the FDA's efforts. In particular, the GAO will provide Congress with recommendations on its thorough audit of FDA's activities and the Y2K problem.

With respect to our second panel, we will hear about the steps individual hospitals and medical device manufacturers are taking to address the unique challenges resulting from the Y2K problem. Only the medical device manufacturers have complete access to a device's design, operating details, and manufacturing parameters. Therefore, their testimony is particularly important.

We look forward to hearing about the steps that the industry is taking to guarantee the safety of patients. With respect to the hospital industry witnesses, we are interested in specific examples of initiatives being undertaken to provide hospitals with the most up-to-date information and products.

On behalf of Mr. Upton and myself, I would like to welcome all of our witnesses and thank them for taking time out of their very busy schedules to join us this morning, and we all look forward to hearing your testimony. Mr. Bliley, the chairman of the full committee, for an opening statement.

[The prepared statement of Hon. Michael Bilirakis follows:]

PREPARED STATEMENT OF HON. MICHAEL BILIRAKIS, CHAIRMAN, SUBCOMMITTEE ON  
HEALTH AND ENVIRONMENT

Mr. Chairman, I am pleased that we have convened our two Subcommittees today to ensure that health care delivery is not interrupted by the Y2K computer problem.

Specifically, we want to guarantee that medical devices using computer software will function properly after January 1, 2000. Any failure, by any device, caused by the Y2K problem, is one failure too many. There is no room for error because human lives are at risk.

Today, we will hear what steps have been taken by the Food and Drug Administration, the medical device industry, and individual hospitals on medical device Y2K compliance.

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I look forward to hearing about the steps that the industry has taken to guarantee the safety of patients. With respect to the hospital industry witnesses, I am interested in specific examples of initiatives being undertaken to provide hospitals with the most up to date information on products.

Finally, I want to welcome all of our witnesses and thank them for taking time out of their busy schedules to join us this morning. I look forward to hearing your testimony.

Chairman BLILEY. Thank you, Mr. Chairman.

Several months ago, this committee began an in-depth look at the healthcare industry and its efforts to become ready for the year 2000. Letters were sent to the Health Care Financing Administration and healthcare associations representing Medicare contractors and Medicare providers, asking them about their progress in becoming year 2000 ready, or Y2K compliant.

Over the past year, this committee has received regular updates on the progress of the Department of Health and Human Services and what progress they have made in addressing their Y2K problems. Just last month, this committee held a hearing on the Y2K problem as it relates to billing and financial systems.

However, the issue of Y2K readiness includes not only billing and financial services, but also products associated with healthcare delivery, such as medical devices.

Today, we will hear about how medical devices and biomedical equipment are in terms of Y2K readiness. Medical devices are critical to medical treatment and research in both Federal as well as private sector healthcare facilities. Any equipment that performs a date or time calculation is potentially susceptible to the Y2K bug.

Since 1997, the Food and Drug Administration of FDA, as well as the Veterans' Health Administration, and others, have attempted to collect information from manufacturers of medical equipment regarding any Y2K problem a device or piece of equipment may have. A data base clearinghouse was established that would allow providers to find out whether a particular piece of equipment was Y2K compliant.

Since this process began over 2 years ago, progress has been made. Unfortunately, there are still device manufacturers who have not responded to repeated requests from the FDA to provide information on the Y2K status of their equipment. Therefore, Medicare providers are often left wondering whether or not their equipment will be safe as we enter the new year.

I hope this hearing will allow us to gain a better insight into the process that medical device manufacturers, Medicare providers, and FDA have undertaken in order to ensure that medical devices and equipment will be Y2K compliant. The health and safety of Medicare patients is of the utmost importance.

I would like to welcome all our panelists here today and thank you all for coming and testifying before us. Mr. Chairman, thank you.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Mr. Klink.

Mr. KLINK. Thank you, Mr. Chairman, for having this hearing today.

This hearing is about whether medical devices we use in the everyday practice of medicine are Y2K compliant and, if not, what corrective actions we must take to make them so.

In short, today's hearing has both good news and bad news. The good news is that today, we now have much more information on the Y2K problem and how it may affect certain medical devices than we had only a couple of months ago. The bad news, though, is that we still have a significant amount of information to gather and much more work ahead of us, and the clock and the calendar are running out on us.

Here is what we know so far about the biomedical side of the Y2K problem: Within the past several months, thanks to the help of the GAO, the FDA finally created a single, Internet-accessible clearinghouse, so that providers could determine the status of their existing inventories of medical equipment. To complete this data base, the FDA identified about 2,300 companies that they believe might have a Y2K problem, and so should be part of this data base.

The FDA then sent letters to, and attempted to contact directly, as many as of the 2,300 potentially susceptible companies as they could locate. Most of those responded to the FDA in one form or another. But, about 200, for reasons unknown, have yet to respond.

In discussions with the FDA and industry officials, committee staff were told that none of the non-reporting 200 companies appear to be major equipment manufacturers; that is, that they make medical equipment that could be life-threatening if a Y2K problem exists.

FDA reported, in fact, that many of the companies may have merged with others and, thus, may no longer exist, or may really never have existed at all, and were placed in error on the original list. Nevertheless, I would ask the FDA and the device industry to continue to identify all of the companies on this list, to try to determine with certainty that we are not, somehow, missing any companies that may be making critical equipment.

Of those that did report to the FDA's data base, some seem to have few, or no, Y2K-related equipment problems, while others have reported that some of their devices are affected by the date change. For example, while a number of the original 2,300 companies reported that none of their products were Y2K-susceptible, and thus, the FDA did not have to worry about their status, about 300 companies have reported that about 1000 biomedical devices that they collectively manufacture do have a Y2K problem.

Still another group, rather than listing information in the FDA data base, has opted instead to link to each of their own websites, where their equipment status can be identified. This group of about 400 companies will most certainly report at least some equipment requiring a Y2K fix.

What does this all mean? I believe that the group of approximately 300 companies reporting about 1000 problems, and the approximately 400 companies linking the FDA clearinghouse to their own websites, must be the major focus of these subcommittees' attention. What we can determine is that there exists a rather sizable group of companies, and thus devices, that do have Y2K problems. What we have not yet determined, however, is the exact nature of this equipment and how it may affect the healthcare delivery system of our Nation.

Quite simply, Mr. Chairman, we have begun to collect decent Y2K data, but I don't think we have made full use of it. I believe that this committee must work with the FDA and the GAO and the device industry to make further sense of this data. We presently know only that there are at least some Y2K problems affecting some medical devices. We must go beyond this general statement and place this problem into context. At a minimum, I would like to know, No. 1, the nature of the equipment being reported as having Y2K problems; No. 2, how the problem could affect each piece



of equipment, and No. 3, exactly how, and when, the problem will be dispositioned by the manufacturer. This is very achievable, I believe, in the limited months remaining before the year's end.

So, Mr. Chairman, I don't think the sky is falling regarding the Y2K safety of biomedical equipment but, nevertheless, I am not fully comfortable with the present status of this industry. In order to fully gain public confidence, I think we must go further and truly attempt to assess existing data to determine what areas are fully safe and where we need to pay additional attention.

Let me conclude by saying that I will split the difference between my good friends from GAO and what they have recommended and what the FDA has approved, or has proposed.

Frankly, I don't think there is enough time or the technical resources available at the FDA to undertake the kind of verification measures the GAO advocates. Quite simply, I don't believe the FDA is equipped to systematically review all of the Y2K assessments made by the device manufacturers reporting to the FDA's data base. Nevertheless, I do welcome at least some additional checks on behalf of the FDA, particularly in those areas where a serious Y2K problem has been identified in a medical device that could cause life-threatening failure.

Scrutiny in such areas cannot be overdone, and I am willing to work with our friends at both the GAO and the FDA and the device industry itself to reach some accommodating measures.

So, Mr. Chairman, we have made significant progress in these areas, but we have much more work ahead of us in the few months ahead. I look forward to working with you and other members of this committee and the witnesses before us today to continue our efforts.

I would just like to mention my friend, Mr. Upton, and I have been discussing, and I just bring this up publicly, we also have grave interest, as technology moves forward, talking about computers, and we would like subcommittee chairman Bilirakis to work with us also, it has come to our attention about the difficulties, right now, in reining in the sale of some pharmaceutical problems over computers, some of them without prescriptions, some of them being sold that are drugs that are illegal in this country. We have talked about it, and we want to bring you into that conversation. It is something that both the majority and the minority have great interest in, and we would like to be able also to pursue this together at some future time, Mr. Chairman. With that, I yield back.

[The prepared statement of Hon. Ron Klink follows:]

PREPARED STATEMENT OF HON. RON KLINK, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF PENNSYLVANIA

Thank you Mr. Chairman for having this hearing.

Today's hearing is about whether the medical devices we use in the everyday practice of medicine are Y2K compliant, and if not, what corrective actions we must take to make them so. In short, today's hearing has both good news and bad news: the good news is that today, we now have much more information on the Y2K problem and how it may affect certain medical devices than we had only a few months ago. The bad news is that we still have a significant amount of information to gather, and much more work ahead of us.

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Within the past several months, thanks to the help of the GAO, the FDA finally created a single Internet-accessible clearinghouse, so that providers could determine the status of their existing inventories of medical equipment.

To complete this database, the FDA identified about 2,300 companies that they believed might have a Y2K problem, and so should be part of this database. FDA sent letters to, and attempted to contact directly, as many of the 2,300 potentially susceptible companies as it could find. Most of these responded back to the FDA in one form or another. Nevertheless, approximately 200, (for reasons unknown) have yet to respond.

In discussions with FDA and industry officials, Committee staff were told that none of the non-reporting 200 companies appear to be major equipment manufacturers that make medical equipment that could be life threatening if a Y2K problem exists. FDA reported, in fact, that many of the companies may have merged with others and thus no longer exist or may have never existed at all and were placed in error on the original list.

Nevertheless, I would ask that the FDA, and the device industry continue to try to identify all of the companies on this list to determine with certainty that we are not somehow missing any companies that may make critical equipment.

Of those that did report to FDA's database, some seem to have few or no Y2K-related equipment problems while others have reported that some of their devices are affected by the data change.

For example, while a number of the original 2,300 companies reported that none of their products were Y2K susceptible, and thus the FDA did not have to worry about their status, about 300 companies have reported that about 1,000 biomedical devices they collectively manufacture, have a Y2K problem. Still another group, rather than listing information in FDA's database has opted instead to link to each of their own websites where their equipment's status can be identified. This group of about 400 companies will, with almost certainty, report at least some equipment requiring a Y2K fix.

What does this all mean, Mr. Chairman?

I believe that the group of approximately 300 companies reporting about 1,000 problems, and the approximately 400 companies linking the FDA clearinghouse to their own websites, must be the major focus of our attention. What we can determine is that there exists a rather sizeable group of companies, and thus devices, that have a Y2K problem. What we have not yet determined, however, is the exact nature of this equipment and how it may affect the health care delivery system.

Quite simply, Mr. Chairman, we've begun to collect decent Y2K data, but I don't think we've made full use of it.

Mr. Chairman, I believe that this Committee must work with the FDA, the GAO, and the device industry, to make further sense of this data. We presently know only that there are at least some Y2K problems affecting some medical devices. We must go beyond this general statement and place this problem into context. At a minimum, I would like to know: (1) the nature of the equipment being reported as having a Y2K problem; (2) how the problem could affect each piece of equipment, and (3) exactly how and when the problem will be dispositioned by the manufacturer.

This is very achievable in the limited months remaining before the year's end.

Mr. Chairman, I don't think the sky is falling regarding the Y2K safety of biomedical equipment. Nevertheless, I'm not fully comfortable with the present status of this industry. In order to fully gain public confidence, I think we must go further, and truly attempt to assess existing data to determine what areas are fully safe, and where we need to pay additional attention.

Finally, let me conclude by saying that I will split the difference between what my good friends from GAO have recommended, and what the FDA has proposed. Frankly, I don't think there's enough time, nor the technical resources available at the FDA to undertake the kinds of verification measures the GAO advocates. Quite simply, I don't believe the FDA is equipped to systematically review all of the Y2K assessments made by the device manufacturers reporting to FDA's database. Nevertheless, I do welcome at least some additional checks on behalf of the FDA, particularly in those areas where a serious Y2K problem has been identified in a medical device that could cause a life threatening failure. Scrutiny in such areas cannot be overdone and I am willing to work with my friends at the GAO, the FDA, and the device industry itself, to reach some accommodating measure.

Mr. Chairman, we've made significant progress in this area, but we have much more work ahead of us. I look forward to working with you, the other members of this Committee, and our witnesses before us today to continue our efforts.

With that, I yield back.

Mr. BILIRAKIS. Thank you. Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman. I would ask unanimous consent that my lengthy opening statement be made part of the record.

Mr. BILIRAKIS. With unanimous consent, all the lengthy opening statements of the members of the two subcommittees will be made a part of the record.

Mr. UPTON. I would just like to add that I appreciate this hearing by both of our two subcommittees and it stems from an earlier hearing that we had about a month ago with regard to billing within the health community and the Y2K problem.

This is a daunting task. In fact, a number of hospitals across the country are spending perhaps as much as \$1 million to comply, to make sure that things work when the calendar page turns.

Since FDA's clearinghouse began in 1998, they have heard from some 4000 manufacturers regarding compliance, but there are still hundreds that they have not heard from. As we all know, there is no room for error. I recently spent the day with one of my hospitals in Berrien County, Michigan, and looked at virtually every sector of what they do to provide good healthcare in our region. I can remember well a visit to the renal dialysis facility where virtually every single one of the booths was occupied. In fact, they said that they are occupied for the complete day, 24 hours a day, 6 days a week, providing assistance for folks, and there was no room even for visitors to come in from other parts of the country that might be visiting friends or families in our part of the State. If they had a reason, or need, for renal dialysis, the answer would be no.

With that type of occupancy, it is pretty clear that we have to make sure that these machines and other devices work within the hospitals and to try and get a better gauge of that.

I appreciate the hearing today and look forward to the testimony from the witnesses, and I yield back the balance of my time.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, CHAIRMAN, SUBCOMMITTEE ON  
OVERSIGHT AND INVESTIGATIONS

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 several months, the Committee on Commerce has undertaken an extensive review of the progress the Health Care Financing Administration, or H-C-F-A, its Medicare contractors and its hospitals, nursing homes, doctors and other providers have made in becoming Y-2-K compliant. Last month, these two subcommittees held a hearing on the Y-2-K status of Medicare providers and their billing and financial systems.

Today, our hearing will focus on the status 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 of life support device.

Several weeks ago, the importance of ensuring that medical devices and equipment are Y-2-K compliant really came home to me in a powerful way. I toured a renal dialysis unit in St. Joseph/Benton Harbor, Michigan, my home community, with a population of about 50,000. The dialysis center operates 6 days a week, 24 hours a day, at full capacity. It was during that visit that I learned that there was no room for visitors to use this facility. Obviously, should this unit and others in other communities across the nation fail to operate properly on January 1, 2000, lives would be put in serious jeopardy.

I have been talking with hospitals in my Congressional district about their Y-2-K efforts to ensure that their medical devices and equipment are compliant, and I

have learned a lot. First, the magnitude of the effort is daunting. All of the hospitals inventoried their devices as an initial step—one hospital system had 8000; another 5000. The direct costs of reviewing critical devices and upgrading or replacing those which are not compliant are also significant—\$½ to \$1.0 million.

As a second step, each hospital contacted device manufacturers for information on the device's Y-2-K compliance. All reported that initially, they often had difficulty getting information, particularly from smaller manufacturers. However, all have seen improvement and greater cooperation in meeting the challenges of Y-2-K, particularly with the creation of the FDA's central data base.

In 1997, the Food and Drug Administration, or F-D-A, began collecting data from device manufacturers regarding the Y-2-K compliance status of their devices. After several letters and a small response rate from manufacturers, the F-D-A joined in partnership with the Veterans Health Administration, the Department of Defense and the 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 Y-2-K compliance status of biomedical equipment in the United States.

Since F-D-A's data clearinghouse began in September of 1998, they have heard from 4,116 manufacturers regarding the compliance status of their equipment. They are still awaiting information from another 232 manufacturers. Since F-D-A began its database, the flow of information has increased significantly. However, the F-D-A has stated that they are in no way 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 F-D-A that the data provided is accurate or complete.

While information regarding medical devices continues to increase, recent surveys conducted show that Medicare providers are still expressing concern over the compliance status of their equipment. I hope this hearing will demonstrate the need for all manufacturers to release information to providers regarding the Y-2-K status of their devices and equipment. It is crucial at the turn of the century that service to Medicare beneficiaries is uninterrupted and patient safety is not jeopardized.

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

Mr. BILIRAKIS. I thank the chairman. Mr. Brown.

Mr. BROWN. Thank you, Mr. Bilirakis.

I would also ask to enter to my written statement into the record.

I just have a couple of comments that are a bit off the subject but I have not really heard much said during this whole Y2K debate and I find it interesting that in our much vaunted private sector in this country, where all wisdom begins and ends, that all of the computer geniuses, in all of the large companies that bought computer systems in the last 20 to 30 years, really did not anticipate this whole Y2K problem.

That companies that made billions of dollars, computer executives that are worth hundreds of millions, billions of dollars, in some cases, that companies where the purchasing agents, and the vice presidents in charge of putting in these computers, and buying these computers, made these purchases without really anticipating what was going to happen in the year 2000.

If that had been a government decision we would see newspaper article after newspaper article criticizing big government and telling us how government does nothing right in this country, but since it was the much vaunted private sector we have not really seen those kinds of newspaper articles.

I would imagine that that computer company executives that created this problem, and did not foresee this problem until not very many years ago, still got their bonuses and I would imagine large companies that have had this, that bought these computer systems and that installed them and did not warn their CEOs about the

Y2K problem until only a small number of years ago still got their bonuses and were still doing very well, thank you.

I just think it is important that as this country has begun, in the last small number of years, to deal with Y2K, and this Congress has been involved, that we are aware of some of the history of this and we are aware that this problem is one that has cost us so much money and has cost us so much time in this Congress, and in the private sector, and the public sector all over in dealing with it.

So, I thank the Chair and yield back the balance of my time.

[The prepared statement of Hon. Sherrod Brown follows:]

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF OHIO

Thank you, Mr. Chairman. I'm pleased to participate in our second joint hearing on Y2K issues, and I thank our distinguished panelists for joining us.

Today's hearing is important from a number of perspectives: to the extent the Year 2000 transition disrupts medical devices and the production and distribution systems supporting them, health care access, quality and continuity could all be affected.

According to FDA, there are more than 100,000 medical devices, equipment ranging from tongue depressors to MRIs.

Fortunately, the great majority of these devices are not date-dependent, and medical device manufacturers have been working hard to ensure that the production and distribution systems around these devices experience no disruption as we transition into the next century.

I commend FDA, which has worked with the Department of Veterans Affairs, the Department of Defense and the Health Industry Manufacturers' Association to develop a clearinghouse for compliance information.

One of the areas I hope today's witnesses will address involves devices made by manufacturers who are no longer in business or who have otherwise refused or have been unable to reply to FDA's request for information. How do we ensure that there will be no harm done to patients or disruption in the delivery of care?

I understand the response rate to FDA's clearinghouse information request was strong—about 90%—but that some 399 device manufacturers have not provided FDA any information.

I hope our witnesses also touch on areas we didn't explore during the last hearing, including the implications of the Y2K transition for non-hospital providers and their patients—areas such as home health care and setting such as skilled nursing facilities and community health clinics.

Today's hearing will provide valuable information in our continuing examination of Y2K transition issues. I look forward to hearing your comments.

Mr. BILIRAKIS. I thank the gentleman. Let's see, do we have an order here? Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. Good morning.

I want to thank you and Chairman Upton, as well as Mr. Brown and Mr. Klink, for holding this second hearing on the Y2K bug and its potential effects on medical care.

As we are all aware, the clock is ticking. The countdown continues to January 1, 2000. To be frank, I am concerned about what is going on and what is going to happen with my friends, relatives, and constituents who will need medical care at that time. Will we be prepared?

For some people, the answer to that question will mean the difference between life and death. For that reason, I am looking forward to the hearing today and the testimony that we will hear about the efforts of the manufacturers, and healthcare providers, and those in government, to assess the Y2K compliance of medical devices.

I sincerely hope that the news is encouraging, and taking leave of my prepared statement just briefly, for those of you who are prepared to testify, I would also like to hear testimony about the potential liability issues out there. I know in the Judiciary Committee we have looked at a Y2K liability bill that, in fact, has been passed out of the House of Representatives. And when it will be signed into law, I don't know, but I have talked to some people in the medical industry, particularly about the services in terms of their potential exposure as to whether or not medical devices, whether they take the assurance of the manufacturer, that it is going to work. Should they, themselves, test it independently of that and would they then incur liability for doing that testing?

There are lots of intriguing issues, and I realize that you did not come to testify specifically about that, but if you have any statements that you would like to make public on the potential impact of liability, I certainly would welcome those.

I would like to take a moment to welcome one of the witnesses who will appear on the second panel, and I want to particularly welcome her, Ms. Noel Brown Williams, of Columbia HCA Healthcare Corporation, who is here this morning representing the Federation of American Health Systems. I am particularly pleased she is here because we have two hospitals in my district from the Columbia system. One of those serves the good people of Cheatham County. It is the Cheatham Medical Center in Ashland City in Cheatham County, and the Horizon Medical Center in Dickson, and I am very interested and pleased with the progress that Columbia HCA hospitals have made, and will continue to make, to ensure that patient care is not compromised as we reach the turn of the century.

Again, Mr. Chairman, I want to thank all the witnesses for their testimony and you for having this hearing, and I would yield back.

Mr. BILIRAKIS. I thank the gentleman. Mr. Burr, for an opening statement.

Mr. BURR. Thank you, Mr. Chairman. I will be brief.

I want to take this opportunity to thank all of the witnesses who are here today.

A couple of the areas I want to concentrate on are the distinction between urban and rural. Do we have the same assurances with some of the rural facilities that their equipment is as up-to-date, even though it may be much older than equipment that we currently asked manufacturers about?

Another area of concern is, whose responsibility is it for the end-to-end testing, if it is needed, for this equipment? And, could this equipment be interconnected with other devices where end-to-end testing becomes extremely important as to who goes first?

I think that, Mr. Chairman, we all share the same common goal, that is, to give America the assurance that healthcare will go on uninterrupted. I have every reason to believe that we have very capable people working on this, and the clearinghouse certainly has produced good work.

We are reliant on manufacturers to share with us their information as it relates to the Y2K problem. I remind all of us that, just 6 months ago, most people thought that Y2K was a spot remover. The reality is that we have all had a very steep learning curve, but

these agencies and this Congress must assure the American people that their healthcare will be of the same quality, and uninterrupted, as we head into the new millennium.

I hope that we are further down that road when we complete this hearing. I yield back.

Mr. BILIRAKIS. I thank the gentleman. Mr. Bilbray for an opening statement. Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman, for holding this hearing. I think this is an important hearing, and I want to build on the remarks that Congressman Bryant made related to liability.

Last week, the House passed a liability relief for Silicon Valley and for manufacturers. I voted against that bill because I had some concerns, particularly for the users of those products, many of whom are represented today whose patients are going to be on ventilators, life-support, run with computer chips.

Vern Ehlers tried to get an amendment made an order for that bill that basically would have restricted the liability relief for products made after 1995. That was not made an order.

I sincerely hope that, when that Y2K liability bill comes back from the Senate and from conference, that we take into account the fact that, within that liability bill that we passed, there is a 90-day moratorium on legal redress for products that are not working because of their Y2K computer chips. I mean, I don't think that a patient on a ventilator has 90 days.

I think the message should be to the manufacturers and to the software Silicon Valley folks that we are not going to give you liability relief. You know, we have about 8 months to get this fixed, and there are going to be a lot of patients that potentially could be harmed if we don't fix this Y2K problem.

So, I believe that we need to pass more wise legislation on Y2K than what we have looked at so far in the House, and I will also be interested, like Congressman Bryant, in comments from members of the panels today on this issue.

Thank you very much.

Mr. BILIRAKIS. I thank the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF FLORIDA

I want to thank Chairman Bilirakis and Chairman Upton for holding this important hearing today.

I believe we would all like to be assured that all medical devices will be Y2K compliant.

What many people may not realize is that computer software is frequently imbedded as a component of devices. For example, software contained on a microchip to control a devices operation could deeply impact individuals who rely upon their pacemakers, ventilators and other life saving equipment for survival.

There is also the question of non-embedded software which is usually operated on a personal computer. This would involve such equipment as MRI's, Sonograms, X-rays, and CAT scans to name a few.

There are those who say there is too much hype about the Y2K problem and that we don't need to worry. I disagree and look forward to hearing from our distinguished panels about what they have done to prevent any possible future catastrophes from occurring.

As Chairman of the VA Subcommittee on Health, I noted Mr. Hubbards' comments about the Department of Veterans Affairs testimony before the VA Subcommittee on Oversight and Investigations indicating they had been assured by manufacturers that all the critical care devices are expected to be in compliance by

the year 2000. This is good news for our nation's veterans. I was also pleased to learn about the partnership between the VA and the FDA to develop a single data clearinghouse for biomedical equipment year 2000 status information.

I also look forward to hearing Mr. Noel Williams' testimony since several hospitals in my district are Columbia Health Care facilities. In fact, Ocala Regional Medical Center is in my home town. The other two HCA facilities are Putnam Community Hospital and Orange Park Medical Center. It is very reassuring to know that Columbia/HCA began planning for the Y2K problem back in 1996. Their efforts are to be commended and should serve as a role model for those in the public and private sectors that are not yet fully in compliance.

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PREPARED STATEMENT OF HON. KAREN MCCARTHY, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF MISSOURI

Thank you Mr. Chairman. Today we are discussing the issue of medical device Y2K compliance. We must ensure that medical devices that are date sensitive are Y2K compliant, so that patients depending on these devices are not adversely affected when the new year begins. I would like to thank the witnesses who are testifying today. I look forward to hearing your ideas about how to bring all medical devices into Y2K compliance.

Many people do not realize the serious nature of the Y2K problem. Dates are important to the functionality of many medical devices that contain internal computer chips. Basically, anything that is electronic is at risk for noncompliance. For example, in a *Kansas City Star* article on May 23, 1999, Dr. Andrew V. Kaufman, a Kansas City neurosurgeon explains the importance of Y2K compliance for the gamma knife. The gamma knife is a device used to treat brain tumors. A computer chip in the knife determines the length of radioactive exposure to the brain that is needed. Dr. Kaufman states, "It has to be perfect. We don't want to undertreat, because if we do, we are inadequately treating the condition. Were we to overtreat, we run the risk of brain injury or other complications such as brain swelling." Fortunately, preliminary tests have shown this device to be Y2K compliant, but more tests will be conducted in the next 60 days to be certain.

The costs associated with bringing medical devices into Y2K compliance are high, and could be an insurmountable burden for smaller hospitals. For example, Health Midwest of Missouri expects to spend 10 million dollars to check 21,000 biomedical devices. Because of these high costs and also because of the potential crises that could arise as a result of the failure of medical devices, we must explore contingency plans for this issue. I look forward to hearing more about such contingency plans as we continue this discussion.

I am eager to work with our witnesses and with my colleagues to find a solution that will protect our nation's patients and provide a fiscally responsible solution for the medical providers. Thank you. I yield back the balance of my time.

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PREPARED STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM  
THE STATE OF CALIFORNIA

Mr. Chairman, thank you for holding this important hearing to gain insight on the Y2K compliance of medical devices. These devices, such as cardiac defibrillators, pacemakers, and cardiac monitoring systems, are all computer-run, and thus are subject to the Y2K bug. It is imperative that we take a proactive stance on this matter.

The importance of this hearing is clear. Millions of people rely on medical devices everyday, and the consequences of these machines not working on January 1, 2000 would be devastating.

Pursuant to the Federal Food and Drug Act, it is the responsibility of the FDA to ensure the safety and effectiveness of medical devices in the marketplace. I know the FDA has tried, through various mail campaigns and the Federal Year 2000 Biomedical Clearinghouse, to do this as thoroughly as possible. However, the FDA heard back from less than 10% of those doctors who were mailed these questionnaires, and the success of the clearinghouse is so far indeterminate. It is clear that there is much to be done.

I am eager to hear from our witnesses today, to see how we can all work together to make sure the medical community is properly prepared for the Year 2000. Again, I thank you, Mr. Chairman, for holding this hearing, and I look forward to working with you.

Thank you.



Mr. BILIRAKIS. The Chair will now call for the first panel: the Honorable William Hubbard, Acting Deputy Commissioner for Policy with the U.S. Food and Drug Administration; Dr. Thomas Shope, Special Assistant to the Director, Office of Science and Technology Center for Devices and Radiological Health, U.S. Food and Drug Administration, and Mr. Joel C. Willemssen, Director, Civil Agencies Information Systems, Accounting and Information Management Division of the General Accounting Office.

The Chair now yields to his co-Chair, Mr. Upton.

Mr. UPTON. Thank you. Panel, we have a longstanding tradition in the Oversight and Investigations Subcommittee of our witnesses being sworn under oath. Do any of you have any objection to that, or problem with that?

[All witnesses shake head indicating no.]

And we also provide, under House rules, if you desire to have counsel. Do you need to have a counsel for your questions?

[All witnesses shake head indicating no.]

If not, if you would stand and raise your right hand?

[Witnesses sworn.]

I yield back to the chairman. Thank you.

Mr. BILIRAKIS. I thank the chairman. Each of you is now under oath. I am going to set the clock at 5 minutes. Obviously, your written statement is a part of the record, and we would hope you would complement it in your oral remarks. I am going to set the 5-minute clock, but, obviously, if it takes a little longer for you to get your message across, I want you to feel free to do so. Let us see, I guess we will call on Mr. Hubbard first.

**TESTIMONY OF WILLIAM K. HUBBARD, ACTING DEPUTY COMMISSIONER FOR POLICY, ACCOMPANIED BY THOMAS SHOPE, SPECIAL ASSISTANT TO THE DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION; AND JOEL C. WILLEMSEN, DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE**

Mr. HUBBARD. Thank you, Mr. Chairman. As you said, Mr. Chairman, we have a written statement which I will not read today.

Let me first mention that I have Dr. Thomas Shope, from our Center for Devices, and expert legal help with me today. He is an expert in this matter.

What I will do, Mr. Chairman, is briefly give you some sense of the many things that we have done in the FDA on this issue thus far. We have sent a number of letters to the industry giving them advice and advising them of what they need to do on the worry about this problem, to make sure that their products are Y2K compliant. We have given written guidance to the industry that spells out certain procedures that they need to follow. Our field staff has asked the right questions; we have inspected device firms, and we believe we are helping in that way. We have done a substantial amount of outreach to the industry, Mr. Chairman, with press contacts and speeches and meetings and mailings and articles and lots

of other things to make sure that the industry and hospitals know what to look for here.

We have developed a rapid response plan so, as the year progresses, if there are problems with these devices, our field force and our headquarters' specialists will be able to jump in right away. As a matter of fact, that program will be staffed on a 24-hour basis beginning in the fall.

We have developed, as you know, a biomedical equipment clearinghouse, a website, which initially listed all of the non-compliant medical devices, and now is attempting to list on that website compliant devices, so that the public, the hospitals, the physicians, and others will be able to access it readily.

We have worked with the VA and the hospitals to help identify critical devices that, if they fail, would be a problem. We have tried to identify those devices that might present a high risk to patients if they were not compliant and fail for that reason. We are pursuing those most vigorously.

All of these activities, Mr. Chairman, have led us to a fairly high degree of confidence that no serious problems exist from medical devices and that, as the year progresses, and we go into the first of the year, there won't be a problem.

Nevertheless, Mr. Chairman, our colleagues at the GAO have recommended that we take an additional step, the auditing of manufacturers' records, demonstrating that they have verified that no problem will exist and that a fix has been properly implemented, if a problem did exist for a given device.

The GAO believes that this additional step will provide assurance to the agency, hospitals, and the public that certain potentially high-risk devices will function properly at the turn of the century. We, of course, respect that view and have the clue that such a program could, feasibly, be constructed. We believe somewhere over 300 firms make these so-called potentially high-risk devices, the sort of devices that, if they failed, could cause serious injury to patients.

So, we propose to begin in June an audit program that would have contractors, hired by the FDA, specialists in this area, go to manufacturers and review their records and ascertain that, in fact, they have asked the right questions, done the proper validation and verifications, and have the proper paperwork to demonstrate that that is the case; Where there was a device that was not compliant, that they have done the necessary upgrades and properly implemented those.

We would propose, Mr. Chairman, to phase this concept in. As I said, there are somewhere over 300 manufacturers. so the concept would be to perhaps do a representative sample of perhaps 60 manufacturers initially, and if we found no problems with those, we would then consult with others and reassess whether we should go do the entire universe of these particular manufacturers. and, of course, if problems were found in that representative sample, we would be prepared, of course, to go to all these manufacturers and do the same sort of audit for those.

With that, Mr. Chairman, briefly, I hope I have given you a sense of where we are, and I would be glad to answer any questions you have.

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

PREPARED STATEMENT OF WILLIAM K. HUBBARD, ACTING DEPUTY COMMISSIONER FOR  
POLICY, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN  
SERVICES

#### INTRODUCTION

Good morning, my name is William Hubbard. I am the Acting Deputy Commissioner for Policy, Food and Drug Administration (FDA or the Agency). I am pleased to be here today to provide information on the Year 2000 date issue as it relates to medical devices. FDA has taken a number of constructive actions to work with manufacturers and provide information to users about medical device Year 2000 compliance.

FDA promotes and protects public health by helping to ensure that medical devices are safe and effective. The Center for Devices and Radiological Health (CDRH) is the component of FDA that has responsibility for regulating medical devices. CDRH helps carry out the Agency's mission by evaluating new products to determine if they can be marketed; assuring quality control in manufacture through inspection and compliance activities; monitoring adverse events in already marketed products; and taking action, when necessary, to prevent injury or death. A device manufacturer must comply with all applicable requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act, including, but not limited to, establishment registration and device listing, premarket review, use of good manufacturing practices, and reporting adverse events.

#### WHAT IS A MEDICAL DEVICE?

According to the definition in the FD&C Act, a "device" is:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body and which does not achieve its primary intended purposes through chemical action and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

As this definition suggests, many different types of products are properly regulated as medical devices. Medical devices include over 100,000 products in more than 1,700 categories. The products regulated by FDA as medical devices range from simple everyday articles, such as thermometers, tongue depressors, and heating pads, to the more complex devices, such as pacemakers, intrauterine devices, diagnostic imaging devices, and kidney dialysis machines.

Any computer software which meets the legal definition of a medical device is within the scope of the law and must comply with applicable FDA regulations. Medical devices which use computers or software can take several forms including: products containing embedded microchips which are part, or components, of the devices; devices employing non-embedded software which is used with, or to control, the devices or to record data from the devices; or individual software programs that use or process patient data to reach a diagnosis, aid in therapy, or track donors and products.

#### A. *Embedded Computer Software*

Computer software frequently is embedded as a "component" of devices, i.e., software contained on a microchip to control device operation. Examples of such common, important devices are pacemakers, infusion pumps and ventilators. The majority of these products will not be affected by the Year 2000 problem since almost none of them require knowledge of the current date to operate safely and effectively. For example, pacemakers *do not* use the current date in their operation.

#### B. *Non-embedded Computer Software*

Non-embedded software is intended to be operated on a separate computer, often a personal computer or work station. Such software devices may be used to control or enhance the operation of another device or devices and, further, may use the two-digit year format. It is possible that non-embedded software devices may rely on date information for proper operation and might be affected by the Year 2000 date change if not designed appropriately.

An example of non-embedded software is a computer program used to plan radiation therapy treatments delivered using radioactive isotopes as the radiation

source (teletherapy or brachytherapy). These treatments possibly could be affected if the computer program that calculates the radiation dose parameters uses only a two-digit year representation. The calculation of the length of time since the source was last calibrated could be in error and thus lead to an incorrect treatment prescription.

Other examples of uses of non-embedded software devices include: conversion of pacemaker telemetry data; conversion, transmission, or storage of medical images; automated analysis and interpretation of ECG data; programming or control of rate response for a cardiac pacemaker; perfusion calculations for cardiopulmonary bypass; and calculation of bone fracture risk from bone densitometry data. Since there is a chance that the two-digit format may affect the performance of these software devices, FDA believes that the Year 2000 risk requires that healthcare facilities take steps to identify and mitigate such problems through proactively working with manufacturers.

#### FDA EFFORTS TO ADDRESS YEAR 2000 ISSUE

##### *Year 2000 Database*

In order to give the general public, government agencies, and the healthcare and research communities one comprehensive source of publicly available information on the Year 2000 compliance status of biomedical equipment, the Federal Year 2000 Biomedical Equipment Clearinghouse database was established in March 1998 and is available to facilities via the World Wide Web. The Biomedical Equipment Clearinghouse provides Year 2000 product status information in five categories including: products that are Year 2000 compliant; products that do not use a date; products that have a date related problem; products whose status is provided on the manufacturer's website; and identification of manufacturers for whom no information is available (nonrespondents to FDA requests).

The Biomedical Equipment Clearinghouse database is being maintained by FDA on its World Wide Web site at the request of the Interagency Biomedical Equipment Working Group. This Working Group was organized early in 1997 under the Subcommittee on the Year 2000 of the Chief Information Officers' Councils. The database can be found on the Internet at: <http://www.fda.gov/cdrh/yr2000/>. Manufacturers also may submit a World Wide Web link to their own website, if they so choose, where the requested information is provided to the public.

FDA and the Department of Veterans Affairs (DVA) have worked in partnership to develop a single data clearinghouse for biomedical equipment Year 2000 status information. DVA, as a purchaser of medical devices, collected information from its vendors as to the compliance status of the medical devices used in its facilities. This data, along with data from the Department of Defense, has been provided to FDA and following confirmation by FDA, has been added to the clearinghouse database. Both FDA and DVA are working with private sector associates, mostly professional associations and organizations such as the American Medical Association, the American Hospital Association, the Joint Commission on Accreditation of Healthcare Organizations, the Health Industry Manufacturers Association (HIMA), the Medical Device Manufacturers Association (MDMA), and the National Electrical Manufacturers Association (NEMA) that provide advice and assistance as requested.

#### RECENT LETTERS TO MANUFACTURERS

##### *A. March 29, 1999 Letter on Year 2000 Compliant Products*

Biomedical equipment users have expressed the need for specific information on all Year 2000 vulnerable products that are compliant and have urged the establishment of a single, comprehensive source for this information. On March 29, 1999, FDA issued a letter requesting that medical device manufacturers submit a complete list of individual product models that are Year 2000 compliant to the FDA-operated Federal Year 2000 Biomedical Equipment Clearinghouse. Many biomedical equipment users have told FDA that a single statement that all of a manufacturer's products are Year 2000 compliant does not meet their need to have affirmatively identified specific compliant equipment. Once information on compliant products is received from medical device manufacturers it will be made available, with improved search tools, as part of the Biomedical Equipment Clearinghouse.

This database of Year 2000 compliant products is intended to provide information on products that biomedical equipment users might consider to be vulnerable to date-related problems because these products could utilize software, a computer or microprocessor control. Accurate Year 2000 status information on these products is critical to these users as they evaluate their product inventory and plan any needed remedial actions.

*B. March 29, 1999 Letter on Interim Inspectional Policy Regarding Y2K Issues.*

On March 29, 1999, the Director, Division of Emergency and Investigational Operations, Office of Regulatory Affairs (ORA), issued a memorandum to the FDA field instructing investigators to raise the awareness of potential Year 2000 problems to firms during FDA inspections. In this letter, ORA expanded the Year 2000 activities to include asking questions regarding what the firm has done to assure themselves that their computer controlled/date sensitive products, manufacturing processes and distribution systems are Year 2000 compliant, and to include information on this subject in their Establishment Inspection Reports when relevant. In addition, if the investigators encounter serious problems or concerns, or find the firm is not taking appropriate steps to avoid serious Year 2000 problems, this information must be reported to appropriate District and Center personnel.

*C. January 13 and March 3, 1999 Letters on Non-Compliant Products*

On January 13, 1999, FDA issued a letter to device manufacturers announcing FDA's intent to expand the product information maintained on the FDA-operated Federal Year 2000 Biomedical Equipment Clearinghouse and requested the continued cooperation of biomedical equipment manufacturers in this effort. The letter requesting this information was issued on March 3, 1999. In this letter FDA indicated that in some of the manufacturer responses to the earlier requests the information on the FDA website was not sufficiently detailed to adequately assist facilities in assessing the impact of non-compliant products. FDA requested that 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.

PREVIOUS LETTERS TO MANUFACTURERS

*A. June 25, 1997 Notification to Manufacturers*

In light of the review of the impact of the Year 2000 on some medical device computer systems and software applications, FDA has been actively alerting the medical device industry through a series of letters to medical device manufacturers for approximately two years. The first alert letter was sent on June—5, 1997, to all CDRH registered medical device manufacturers (8,322 domestic and 5,085 foreign) indicating that manufacturers needed to address this issue and review both embedded and non-embedded software products. FDA reminded manufacturers that, in addition to potentially affecting the functioning of some devices, the two-digit year format also could affect computer-controlled design, production, or quality control processes. FDA requested that manufacturers review the software used in medical devices to determine if there is any risk.

Device manufacturers who identify products that have a date-related problem are required to take appropriate action to remedy the problem. An example of appropriate action in some instances would be notification to device purchasers so that their devices can be appropriately modified before the year 2000.

*B. January 21, 1998 Request for Information*

In a letter dated January 21, 1998, Department of Health and Human Services (DHHS) Deputy Secretary Kevin Thurm asked approximately 16,000 medical device and biomedical equipment manufacturers to voluntarily provide information on the Year 2000 compliance status of their products. Included in the mailing were all FDA registered manufacturers without respect to the specific kind of device produced, even though FDA estimates that only approximately 2,000 manufacturers make products listed in the categories which include computerized products potentially sensitive to Year 2000 problems. Approximately 3,000 of the manufacturers included in the mailing are not regulated by FDA; for example, scientific instrument manufacturers. The letter detailed instructions on ways to submit the data requested and explained that to be Year 2000 compliant products must function as intended regardless of the date. Manufacturers also were given the opportunity to certify that their products are not affected, if that is the case, or certify that none of their products use computers or date information.

*C. Targeted Follow-up with Manufacturers of Computerized Devices*

On June 29, 1998, FDA issued a targeted, follow-up letter to specific manufacturers of computerized devices urging them to respond to our January 21 request to submit product data. This list was derived from the names of those firms which have registered as manufacturers of devices in the categories where Year 2000 vulnerability is likely.

Then on September 2, 1998, FDA issued a follow-up to the June 29, 1998 letter, directed to the manufacturers of potentially computerized devices who had not re-

sponded to the previous requests to specific manufacturers for information on the Year 2000 status of their devices. In the letter, FDA requested that the manufacturers respond to FDA within two weeks with the Year 2000 compliance status of their devices, or at least indicate that a complete response was being developed.

On August 14, 1998, Dr. Bruce Burlington, then Director, CDRH, and on September 2, 1998, Dr. Friedman, then Acting Commissioner of the Food and Drug Administration, issued letters to HIMA requesting that HIMA take aggressive and immediate actions to encourage and assist medical device equipment manufacturers in providing information to FDA about the Year 2000 compliance status of their products.

In late September 1998, FDA decided that it would be useful to provide an indication of whether a particular manufacturer of computerized devices potentially susceptible to Year 2000 concerns has or has not provided information on Year 2000 compliance. To that end, FDA posted on the website those manufacturers of selected product categories which are likely to include vulnerable products that had not provided a response to FDA's inquiries. FDA will continue to work with manufacturers to obtain this data and report to Congress on the status of these Year 2000 requests.

#### ADDITIONAL OUTREACH AND GUIDANCE

In addition to the website and the letters, CDRH has been conducting extensive outreach to the device industry and to other consumers on this issue. CDRH's Division of Small Manufacturers Assistance provided an article 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. The guidance was published in the *Federal Register* on June 24 for greater dissemination. The guidance re-emphasizes the provisions in existing regulations that require manufacturers to address any date problems which may present a significant risk to public health.

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.

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 "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.

#### WHAT IS THE DATA TELLING US THUS FAR?

As indicated above, FDA believes that approximately 2,000 manufacturers may produce equipment that may be affected by the Year 2000 problem. As of May 18, 1999, FDA has entered a total of 4,133 responses from the 16,000 manufacturers originally contacted. The data from all of these manufacturers who have responded have been entered into the database on the FDA website. These numbers change daily as data are entered, corrected or even removed at the request of manufacturers. Of the 4,133 manufacturers who have responded, 3,401 have reported that their products do not use date-related data or all of their products are compliant. Six hundred and sixty-one manufacturers [312 manufacturers listed on the FDA website and 349 manufacturers listed on the manufacturer's website] have reported one or more products with date-related problems. Four hundred and twenty manufacturers have provided World Wide Web links (URLs) to data provided on their own manufacturer-operated websites. There are a few submissions in which the data were incomplete or unclear in some manner. FDA is communicating with these manufactur-

ers to obtain clarification before entering the information into the database. FDA will continue to post additional responses as they are received.

In reviewing the data received from the manufacturers so far, FDA sees no indication of widespread problems which will place patients at risk, if and only if the solutions being developed and offered by manufacturers are implemented as they have indicated. Of course, FDA can not make assurances about manufacturers who have not reported product status. FDA believes that the information received to date confirms our original expectation that the Year 2000 problems with medical devices will not be significant or widespread if facilities take appropriate actions to address this issue. There will be specific problems which need correction; however, the current assessment is that they are much more likely to disrupt patient care rather than be of direct danger to patients. Nonetheless, such disruption could be serious and the potential for it to happen certainly merits rigorous attention to the problem.

One indication of FDA's belief that Year 2000 problems are not significant or widespread has been borne out by DVA in their testimony and responses to questions before the House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations. The DVA indicated that they had received answers from manufacturers on all of the critical care device components and they expected to be ready for Year 2000.

#### *Legal Authority*

FDA's Quality System Regulation (QSR) (21 CFR 820) places on manufacturers an ongoing responsibility to take corrective and preventive actions that may include recall for problems with current production. Devices automated with computer software are subject to all requirements of Title 21, *Code of Federal Regulations* (CFR), Part 820, unless expressly exempted by regulation. The regulation puts in place a system whereby manufacturers must incorporate a set of procedures and processes in their design and manufacturing activities to assure that products being manufactured are safe, effective finished products. The QSR regulation does not require the submission of any reports to FDA, however, it does require firms to maintain internal procedures and documentation of corrective and preventive actions (21 CFR 820.100).

The Removals and Corrections Regulation (21 CFR 806) requires manufacturers to submit reports to FDA. In order to be reportable, a Year 2000 problem must pose a "risk to health" as defined in section 806.2(j). Many of the problems reported in the Biomedical Equipment database or on manufacturers' Year 2000 Web pages concern date recording or display problems that are readily apparent to the user and are unlikely to pose a risk to health. In the Year 2000 context, a decision to correct a problem may occur long before the correction itself is actually announced to customers. Once the decision for action is made, however, and if the action is to correct a risk to health, then the firm has 10 working days to notify the Agency through a report of correction or removal. A firm that previously notified FDA about a removal or correction through a Medical Device Report (under 21 CFR 803) does not have to submit an additional report under 21 CFR 806.

FDA will continue to emphasize to manufacturers the importance of reporting on the Year 2000 compliance status of their products and take additional steps to boost the response rate. Healthcare facilities need information from all manufacturers to properly prepare and plan for any actions they need to take to assure their devices needing corrections or updates receive these well before the Year 2000.

#### CONCLUSION

Thank you for the opportunity to update you about the issue of the Year 2000 and medical devices. Let me assure you that FDA takes this issue very seriously and is committed to a scientifically sound regulatory environment which will help provide Americans with the best medical care. In the public interest, FDA's commitment must be coupled with a reciprocal industry commitment: that medical device firms will meet high standards in the design, manufacture, and evaluation of their products. FDA recognizes that this can only be attained through a collaborative effort—between government and industry—grounded in mutual respect and responsibility. The protections afforded the American consumer, and the benefits provided the medical device industry, cannot be underestimated.

FDA will continue to provide any assistance it can to address specific problems that any other agency, such as the DVA, identifies. FDA also is working with other agencies, patient groups, medical associations and industry to optimize data collection and information sharing. FDA will continue urging manufacturers to ensure the continued safety and effectiveness of their medical devices by ensuring that their devices can perform date recording and computations that will be unaffected by the Year 2000 date change.

Thank you for the opportunity to testify.

Mr. BILIRAKIS. Thank you very much, sir.

Dr. Shope, I know you are not prepared to give an opening statement, but do you have anything you would like to add to what Mr. Hubbard has said, at least at this point?

Mr. SHOPE. No, Mr. Chairman, I think we will just respond to questions.

Mr. BILIRAKIS. Okay. Mr. Willemssen, please proceed, sir.

#### TESTIMONY OF JOEL C. WILLEMSSEN

Mr. WILLEMSSEN. Thank you, Mr. Chairman, Chairman Upton, Ranking Member Brown, members of the subcommittees. Thank you for inviting us to testify today. As requested, I will briefly summarize our statement.

As you have noted, biomedical equipment that uses a computer or embedded chip to perform date or time calculations can be susceptible to a Y2K problem. The significance of that problem can range from a nuisance to the more serious, with a potential to decrease patient safety.

FDA has made progress in obtaining Y2K compliance information from manufacturers in establishing its biomedical equipment clearinghouse. As of May 10, over 4,000 biomedical equipment manufacturers have submitted data to that clearinghouse. About 60 percent reported having products that do not use a date, while about 8 percent reported having date-related problems. FDA is now in the process of getting more detailed information that is product-specific and plans to put that on its website.

Less progress has been made in reviewing biomedical equipment test results. Last year, we recommended that HHS take steps to review manufacturers' compliance test results for critical-care and life-support biomedical equipment, to give the public additional assurance that these items would work as expected, come January 2000. However, at that time in response to our report, HHS had said that submitting compliance certifications alone was sufficient.

What we have found, in contrast to that position, was that some hospitals were actually going out and testing their own biomedical equipment. They felt it was necessary to prove that they had exercised due diligence in the protection of patient health and safety. Hospital officials, in some cases, have told us that their testing has identified some non-compliant equipment that manufacturers had certified as compliant.

We recently met with HHS and FDA to discuss options for reviewing test results, and we are pleased to hear in its testimony today that FDA is moving out in this regard. I think it will provide you, the Congress, and the American public with greater assurance that biomedical equipment items, especially critical-care and life-support items, will work as intended come the turn of the century.

Now, while there is much information now available on biomedical equipment, it is still not clear how extensively healthcare providers are using this available information. According to the FDA, it has taken steps to make users aware of the clearinghouse. More than 100,000 inquiries have been made. However, according to FDA it is not possible to determine the source of the inquiries.



Further, of the Y2K health surveys we reviewed, only the AMA survey mentioned the FDA clearinghouse, and for the AMA survey only 11 percent of the respondents indicated they were aware of the FDA clearinghouse.

Other information contained in available surveys is also not encouraging. For example, less than one-third of hospitals responding to the survey of the HHS Inspector General stated that the biomedical equipment was compliant, while only 6 percent of hospitals responding to an American Hospitals Association survey said their equipment was compliant. It is, therefore, quite apparent that there is a great deal of work remaining in a relatively short amount of time. That concludes the summary of my statement, and I would be pleased to address any questions you may have.

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

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

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

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

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

#### BACKGROUND

Biomedical equipment is indispensable; it plays a central role in virtually all health care. It is defined as any tool that can record, process, analyze, display, and/or transmit medical data—some of which may include medical devices, such as pacemakers, that are implanted in patients—and laboratory research instruments, such as gas chromatographs<sup>4</sup> and microscopes. Such equipment may use a computer for calibration or for day-to-day operation. If any type of date or time calculation is performed, susceptibility to a Y2K problem exists, whether the computer is a personal computer that connects to the equipment remotely, or a microprocessor chip embedded within the equipment itself. This could range from the more benign—such as incorrect formatting of a printout—to the most serious—incorrect operation of equip-

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

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

<sup>3</sup>A component of the Department of Veterans Affairs (VA).

<sup>4</sup>Such instruments are used to separate the components of a solution with heat and measure their relative quantities.

ment with the potential to decrease patient safety. The degree of risk depends on the role of the equipment in the patient's care.

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

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

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

#### MUCH BIOMEDICAL EQUIPMENT STATUS INFORMATION AVAILABLE IN FDA CLEARINGHOUSE

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

To provide more detailed information on the compliance status of biomedical equipment, as well as to integrate more detailed compliance information already gathered by VHA, we recommended that HHS and VA jointly develop a single data clearinghouse to provide such information to all users. We said development of the clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Office of the Assistant Secretary of Defense (Health Affairs) and the Health Industry Manufacturers Association. We recommended that the clearinghouse contain compliance status information by product make and model, and identify manufacturers that are no longer in business. Finally, we recommended that FDA and VHA determine what actions should be taken regarding biomedical equipment manufacturers that had not provided compliance information.

In response to our recommendation, FDA—in conjunction with VHA—established the Federal Y2K Biomedical Equipment Clearinghouse.<sup>8</sup> With the assistance of VHA, the Department of Defense, and the Health Industry Manufacturers Association,

<sup>5</sup> Such equipment allows therapeutic apheresis—the exchange or purification of blood plasma. Therapeutic apheresis is recognized as a successful treatment for more than 40 autoimmune diseases.

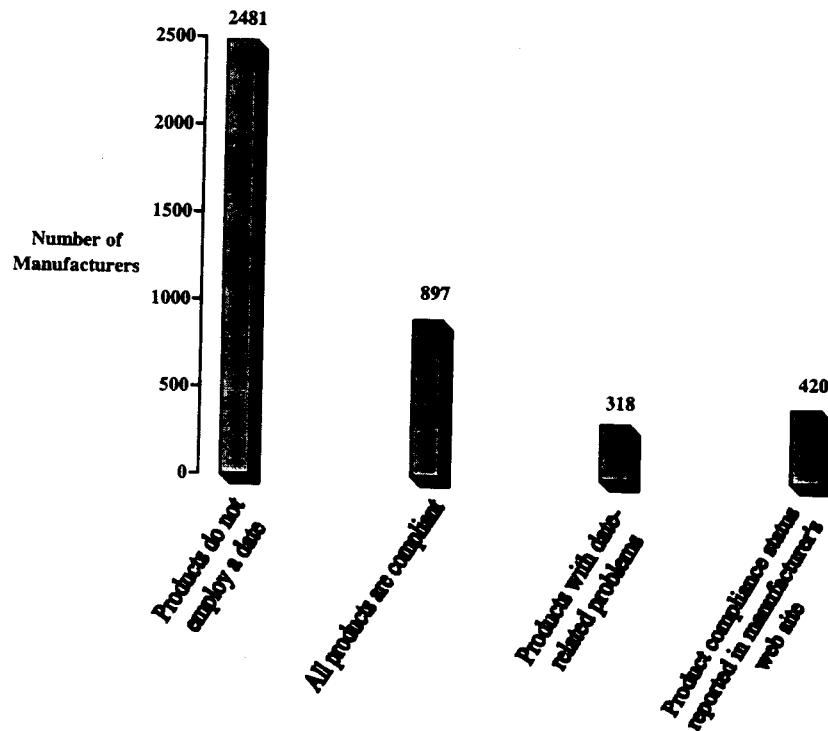
<sup>6</sup> Devices that use computer calculations of gestational status to help assess the risk of neural tube defects in the fetuses of pregnant women.

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

<sup>8</sup> The clearinghouse can be found on the World Wide Web at <http://www.fda.gov/cdrh/yr2000/year2000.html>.

tion, FDA has made progress in obtaining compliance status information from manufacturers. For example, according to FDA, 4,116 biomedical equipment manufacturers had submitted data to the clearinghouse as of May 10, 1999. As shown in figure 1, about 60 percent reported having products that do not employ a date, while about 8 percent reported having date-related problems such as incorrect display of date/time. Also, according to FDA, 232 manufacturers have not yet responded.

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



Note: Total number of manufacturers = 4,116.

Source: FDA.

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

Also, in response to our recommendation, FDA has expanded information in the clearinghouse; users can now find information on manufacturers that have merged with or have been bought out by other firms. Further, in collaboration with the National Patient Safety Partnership,<sup>9</sup> FDA is in the process of obtaining more detailed information from manufacturers on noncompliant products, such as descriptions of the impact of the Y2K problem on products left uncorrected. FDA also sent a March 29, 1999, letter requesting that medical manufacturers submit to the clearinghouse a complete list of individual product models that are Y2K compliant.

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

## FDA IS NOW CONSIDERING REVIEWING MANUFACTURERS' CERTIFICATIONS

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

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

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

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

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

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

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

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

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

INFORMATION ON BIOMEDICAL EQUIPMENT COMPLIANCE OF HEALTH CARE PROVIDERS  
INCOMPLETE

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

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

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

In addition, the Y2K readiness status of biomedical equipment at health care providers is not known because a significant number of providers did not respond to the surveys. As shown in table 1, the response rates to a survey from the HHS Office of the Inspector General to urban hospitals, nursing facilities, home health agencies, and physicians were all less than 50 percent. The response rates to surveys from the AHA and the AMA on this subject were even less, at 29 and 7.5 percent, respectively. Lastly, the response rate to a survey from the American Health Care Association (AHCA)<sup>14</sup> was very disappointing, at less than 3 percent.

Table 1: Survey Results of Y2K Readiness of Biomedical Equipment

Entity Performing Survey/Group Surveyed	Number Surveyed	Number of Responses	Percentage Responding Currently Compliant	Percentage Responding Not Applicable
<b>HHS Office of the Inspector General<sup>1</sup> (December 1998)</b>				
<b>HOSPITALS</b>				
Rural .....	500	281	31	3
Urban .....	500	208	23	4
<b>NURSING FACILITIES</b>				
Rural .....	500	221	21	31
Urban .....	500	191	21	27
<b>HOME HEALTH AGENCIES</b>				
Rural .....	500	136	26	41
Urban .....	500	133	21	39
<b>PHYSICIANS</b>				
Rural .....	500	124	30	36
Urban .....	500	95	20	52
<b>American Hospital Association (AHA) (February 1999) .....</b>	2,000	583	6	n/a
<b>American Medical Association (AMA) (February 1999) .....</b>	7,000	522	2	n/a
<b>American Health Care Association (AHCA)<sup>1</sup> (March 1999) .....</b>	12,000	342	24	28

<sup>1</sup> The survey instructions directed respondents to mark N/A if a question did not apply.

<sup>2</sup> According to the survey results, 65 percent of responding physicians rent or lease biomedical equipment that will be affected by Y2K; 41 percent of them were confident that their vendors have prepared the equipment for Y2K. Data were not provided on the remaining 35 percent of responding physicians.

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

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

In summary, while compliance status information is available for biomedical equipment through the FDA clearinghouse, FDA has not yet reviewed test results

<sup>13</sup> These include HHS' Office of the Inspector General, the AHA, and AMA.

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

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

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

Mr. BILIRAKIS. Thank you, Mr. Willemssen.

I have a couple of generic questions, but before I go into that, I would like to ask the FDA if FDA is concerned, was concerned, will be concerned about the safety of the medical device to operate properly after January 1?

Do you feel, Mr. Hubbard, that the agency presently has adequate legal authority to pull a product from the market and take steps to ensure that the patients will not be at risk, or will it require something from the Congress to be helpful in that regard?

Mr. HUBBARD. Well, certainly, we have written regulations based on the statutory authority we have been given, Mr. Chairman, to do that. If we determine that a medical device has not been properly made compliant, and could fail, and could cause patient harm, yes, we could order that—

Mr. BILIRAKIS. You do have that authority now, you feel?

Mr. HUBBARD. Yes, sir, we believe we do.

Mr. BILIRAKIS. You won't need any help from the Congress in that regard, any—

Mr. HUBBARD. On that particular issue, I don't believe so.

Mr. BILIRAKIS. Are there other issues, on that particular issue, but are there other issues involving this where you feel that you need more legislative authority in order to be able to do your job better?

Mr. HUBBARD. I think funding has really been the issue, to some extent, because the program that is doing this, Dr. Shope's program, and the other folks, they are working very hard, as you know, to get new medical devices on the market because we are a gateway to this new technology. It is very important and we are putting a huge amount of effort into getting all these new products on the market and to take those people away to do Y2K has been a stressful situation. But we have been seeking additional money through the appropriations process, and some has been coming forward.

Mr. BILIRAKIS. Thank you. Mr. Hubbard.

Dr. Shope, based on your experiences at FDA on this issue, are you confident that the medical technology industry will be ready on January 1?

Mr. HUBBARD. I think we are, Mr. Chairman. I would ask Dr. Shope to elaborate on that, if I may.

Mr. BILIRAKIS. Doctor?

Mr. SHOPE. Yes, sir. I think from my reading of the information we have received in our data base and discussions with manufacturers, and knowing our regulatory process, that manufacturers are taking the necessary steps to evaluate and assess their products,

to provide information to customers about the status of those products, and the steps to remediate products, the upgrades, or the fixes that the manufacturer can make available for those products.

So, I am rather sanguine about the situation with regard to the manufacturers' actions. I think the question, if there is one, is the extent to which hospitals, who own this equipment, and use it, are taking advantage of the information and taking the necessary steps to ensure that the products they have in their inventory have been checked, have been verified as having—

Mr. BILIRAKIS. All right, that is certainly a significant question, I agree with you, but are we taking steps to be sure that that is taking place on a timely basis, in the hospitals?

Mr. SHOPE. Certainly, FDA has taken as many steps as we can to inform the hospitals about this issue, working with the American Hospitals Association, the American Medical Association, very active participants in our healthcare sector working group under Mr. Koskinen's Y2K Conversion Council out of the White House. So there is a lot of communication going on there.

FDA took steps such as publishing in the Journal of the American Medical Association, mailings of our FDA medical bulletin, and other kinds of trade press, and other types of announcements, to make people aware of this issue.

Controlling hospitals is a little bit out of FDA's purview. Typically, we are dealing with the manufacturers and the manufacturers' responsibilities to provide good products, and get those into the hands of the users.

So, I think that this is an issue that we at FDA have not seen as our prime role, as far as actually ensuring that hospitals are doing this.

Mr. BILIRAKIS. Who has that prime role?

Mr. SHOPE. Well, I think that it is the responsibility of each hospital to make sure that their patients are treated with equipment that is going to work and do the right job.

Mr. BILIRAKIS. Let me go to Mr. Willemssen. Mr. Willemssen, of course, you and Mr. Hubbard both testified to the fact that the GAO has made certain recommendations to them. Taking all that into consideration, do you agree with the positive answers that we have received from the FDA to my question?

Mr. WILLEMSSEN. As of today, I am more optimistic than I would have been even at the hearing that you held a month ago. However, there is still a great deal of work remaining. What I heard in the oral statement today was very reassuring, that FDA intends, for those critical-care and life-support items, to get additional information, making sure they do work as intended.

I will also point out that, if you look at the kind of response rate that FDA has gotten compared to where it was less than a year ago, that has gone up tremendously, and they should be given credit for this. There still are a couple hundred manufacturers outstanding who have not yet responded, but this is a tremendously better rate than it was. So, bottom line, I am more optimistic, but there is a lot left to do, and relatively little time to do it.

Mr. BILIRAKIS. So, what you are saying is that we are in danger of not being ready, as far as GAO is concerned, on January 1?

Mr. WILLEMSSEN. I think what is critical right now is that FDA follow through on some of the steps that they have mentioned here today, and very importantly, to publicize the results of those steps, and make it clear to the public, what we know and what we don't know. As we move closer to the turn of the century and to the extent that we can, increasing the percentage of what we do know will go a long way to reducing any potential panic that could result.

Mr. BILIRAKIS. With the indulgence of the subcommittee, the question of whether the hospitals are ready, that Dr. Shope mentioned, I mean that is a very significant question, and certainly at least the patients of those hospitals ought to know whether they are going to be ready, God knows. But, do you have any suggestions as to how that can be done, what can be done there?

Mr. WILLEMSSEN. I would concur with you, the available data are not reassuring on the extent to which hospitals appear, or are saying they are checking this. So, I think that FDA can step-up its publicity campaign a few more degrees. For example, it could make sure this is a major agenda item—and you might want to address this with the second panel—at some of the major conventions, health-related conventions.

Also, I think, that when FDA plans to come out on June 1—I believe that is the date they are listing the critical-care and life-support items they will be checking for Y2K—it should be publicizing this list and letting the public know, “We are going to take an extra step for these kinds of items, and give you added assurance of what the Y2K issues are, and what we have found.”

So, I think, again, that the FDA has done some good things in putting the word out. They can do more, though, especially as we get closer to the date.

Mr. BILIRAKIS. Well, you know, I can't get over how we have gotten into this fix. We have put people on the moon; we have done so many great things technologically, and we all knew that the year 2000 was coming up. I am certainly not computer literate, I am ashamed to say, but most people are, certainly the experts and the agencies, departments, and with the various companies out there in the industry are. They have all known this was coming up, and yet we are running into this problem. If we have got to put ourselves into the shoes of that patient out there who reads about this, and maybe unduly so, is being really shook up—well, all right, Mr. Brown.

Mr. BROWN. Mr. Chairman, thank you. I would first like to ask unanimous consent to keep the record open for 3 days, say, for questions to be submitted.

Mr. BILIRAKIS. By all means and, of course, we always ask the witnesses if they are willing to receive additional questions, and are willing to respond to them. By all means, without objection.

Mr. BROWN. Mr. Willemssen, you have made the argument several times that FDA should require manufacturers to submit test results certifying compliance because, unless they do so, the agency really has no assurance that those manufacturers have adequately addressed the Y2K problem. Why should the FDA do that?

Mr. WILLEMSSEN. We recommended this, for a subset of biomedical equipment items, those considered to be in the critical-care and life-support areas. So, we don't recommend that for all items,



but just a small subset where the impact of a Y2K failure would have resulting effects on patient safety. We think this additional step is necessary to provide the public with added assurance that these items are going to work as anticipated.

As I mentioned in my testimony, we have identified some hospitals who told us that in some cases their own testing has identified items thought to be compliant that were not compliant. Now, in those cases, none of those, to date, that we are aware of have had a safety impact. They have primarily been display problems. But I think that because of the criticality of the issue, we think for that subset of items, that the additional step is warranted.

Mr. BROWN. What form would the data take? Would it be in great detail, in binders, and hundreds of pages or would it be a study or sort of outline of the methodology and then a concise report of the results?

Mr. WILLEMSSEN. It would not entail, or should not entail, any additional work on the part of the manufacturers because they should already have those results available in order for them to come to a conclusion that the item, is indeed, compliant. I would say, the process would work along the lines of FDA asking to look at the information to see if there is support behind the determination that the item was compliant.

Mr. BROWN. What kind of resources would it take for FDA to do that? Have you conducted any analysis to determine if the FDA even has the resources to implement your recommendation, even if, in fact, it agreed with it?

Mr. WILLEMSSEN. In talking with FDA on this issue, we suggested that they not just look internally, but they also look at other available resources, both private and public. You may or may not know, one of the leaders in this area has been the Department of Veterans Affairs, who actually was on board first in putting together quite a bit of information on biomedical equipment items. FDA then came on board with VA, but VA also has some expertise in this area. So, I think in looking at the resource question, FDA needs to go outside of its own boundaries and look at what available expertise there is.

Mr. BROWN. Dr. Shope or Mr. Hubbard, do you think that FDA has the technical expertise internally and in other parts of the government into which it can reach to do that?

Mr. HUBBARD. Well, not in any great numbers, Mr. Brown. We have a small staff of physicists and other biomedical engineers in Mr. Shope's office. It is a handful of people. They probably do have the technical expertise. Beyond that, I don't think so, because the kinds of data that you would get from a company, you know, probably large stacks of verification data and test data results would require someone with some knowledge of the product and the way that the software was designed and the way it operates. In the case of a fix of a non-compliant product, how that was done, and how that was tested and verified to be sure.

There may be the technical talent out in the country that could be contracted with to do that, of course, understand that the numbers could be perfectly enormous at a 100,000 different medical devices and 1,700 different categories. But only around 2,000 perhaps, have some date issue. We think, perhaps, in range of 300 to

600 actually are of the type, so called, critical care devices that Mr. Willemssen is talking about that might be in that category. So the number that would be most concerned is a much more manageable number. We believe that it would be possible to contract with professionals in the IT area, and perhaps, engineers to go to firms to look at this data. It would cost some millions of dollars, however, to do that. And I think there is a question as to whether or not the taxpayers' funds should be spent to do that sort of thing. That is why we are proposing our sampling proposal, which could be done much more cheaply, to build additional confidence, and then determine if, in fact, we need to do more than that.

Mr. BROWN. Mr. Willemssen, you note in your testimony, FDA saw no need to question manufacturers certifications regarding Y2K compliance status. Is GAO taking the position that FDA should question the reliability or truthfulness of manufacturers certificates?

Mr. WILLEMSSEN. What we are saying is for those critical care and life support items, added assurance is needed to the American public to make sure that they work as intended. Some hospitals have told us that their own testing has identified some equipment that was thought to be compliant that wasn't. It is not to say that organizations are not to be trusted, but where the criticality is high, an extra pair of eyes could be very useful.

Mr. BROWN. Mr. Chairman, could I ask for 60 additional seconds?

[Mr. Upton nods head to indicate yes.]

Mr. BROWN. Thank you.

So, Mr. Willemssen, if the FDA does certify that a manufacturer has undergone Y2K compliance testing, in taking into play, into consideration, the comments of Mr. Hubbard about a possible lack of resources, including technical expertise in the agency, does the Government run the risk of becoming liable if a serious Y2K problem develops with equipment that the FDA reviewed?

Mr. WILLEMSSEN. I think there can be no absolute guarantee that equipment will work as intended, even with additional checks being made. What you have done is closed the gap on the risk and made it more manageable for those especially critical items.

Mr. BROWN. You have closed the gap on the risk that have you, in fact, shifted some of the responsibility then to a Government agency from the private sector, who ultimately should, in fact, be responsible for compliance and for success.

Mr. WILLEMSSEN. Well, under this recommendation, FDA would not be independently testing items themselves. They again, would be relying on the work that has been done by the manufacturers.

Mr. BROWN. But FDA technical experts would review the methodology, look at the results, and ultimately have to make \*\*\*, and put a stamp of approval on it. Correct?

Mr. WILLEMSSEN. Under that process, it ultimately come to some judgment as to the risk involved, and whether all appropriate good manufacturing practices have been followed in assuring themselves that this a Y2K compliant item.

Mr. BROWN. So, are they shifting some of the reliability on the FDA? This recommendation?

Mr. WILLEMSSEN. I will, in part, defer to the record on that because I am not an attorney by training. I would defer to Dr. Shope and Mr. Hubbard, but we did not, on the face, see it in that way.

Mr. BROWN. Could Dr. Shope answer the question and then I will yield back? Dr. Shope.

Mr. SHOPE. I just wanted to make a comment on the issue of the testing, or not so much testing, but the verification of manufacturers activities. What we are talking about here is really exactly the same kind of activities that FDA undertakes on a routine basis in our inspection of manufacturers quality systems. It is the quality system that a manufacturer has in place that gives us the assurance that they are developing, designing, producing, evaluating medical devices in a way that gives us assurance about their safety and effectiveness. And what we are talking about here is focusing some additional effort, if we were to do it, on those changes related to Y2K. We rely on this quality system for the initial development of medical devices. We rely on it when we clear them for pre-market and we rely on them for any other kinds of changes.

Medical devices frequently are found to have problems; those problems get corrected. Particularly with software control products, new features are added, those are done under the quality system and the design control process. All of that is done by the manufacturer, using the quality system that they have in place.

I think that the issue here is that whether something additional is needed for dealing with these Y2K upgrades. I think, strongly, that our regulatory system that we have, with the quality systems that manufacturers use, and that FDA exercises oversight to verify that are in place and are being used gives us a high level of confidence that these activities are being conducted and they do give us this kind of assurance. The question is, do we need to do something more and additional and special just for the Y2K issues?

Mr. BROWN. Thank you, I thank the chairman for his indulgence.

Mr. UPTON. Thank you.

Mr. Hubbard, I was very interested in seeing that there were, I guess, 232 companies that did not respond to the inquiry from FDA. What is happening to these companies? What is the level of your concern?

Mr. HUBBARD. All right, that is a subset of the firms that we believe might make products that are date dependant, as opposed to the large universal products that have no computer issue involved in them. We are continuing to pursue those companies. We have a contractor of calling and trying to identify those companies. By and large, we believe that they are companies that are, perhaps, foreign companies that have gone out of business or we can't find, otherwise, and perhaps, aren't marketing a product in this country anymore. Even though that is our suspicion, we are trying to confirm that, that is in fact true, and that none of those 232 are marketing any products. I believe, Tom, that it is actually 199 now, it is down to 199, we have found a few more in the last 3 days.

Mr. UPTON. Well, that is good to hear. In your statement, your written statement, you didn't talk about the statistical sampling that you have now decided to embark on that you talked about in your verbal statement. As I recall, you said something like, you are going to survey about 60 firms, is that right?

Mr. HUBBARD. Our belief is, we have asked various experts at the device program to look at the sorts of devices that the GAO has identified, as perhaps, what they call critical care devices. But devices that have a potentially high risk to patients if they were to fail due to a date dependency. We believe there is somewhere over 300 manufacturers of such devices. So, the concept would be to develop a representative sample of that 300-plus device manufacturers and then go out and audit that sample. And 60 sounded like, we are looking around 60 as being a good representative sample to feel that we have covered the range of these kinds of products.

Mr. UPTON. Is there a reason why you might have waited so long, the end of May, to sort of begin to do that?

Mr. HUBBARD. I think, as we have said earlier, Mr. Upton, we do have a fairly high confidence level that there is not a problem here with these products. Every time that there has been an allegation that a device has failed, we have followed up on it, stringently, and we have not been able to find the sorts of life-threatening concerns that exists. But that is not to say that, as Dr. Shope just said, that perhaps we can do more. The GAO is saying, take it to one more level and go into the firms and look at their data and quiz them more and develop yet an additional layer of confidence for the hospitals and the public and the Congress that, in fact, things are okay. We have a fairly high degree of confidence now that these devices have been attended to.

Mr. UPTON. Mr. Willemssen, have GAO's efforts primarily been focused on the manufacturing end and the FDA end? Have you at all looked at the degree of communication between the hospitals and their communication, their networking among themselves?

Mr. WILLEMSSEN. We have to some degree, but most of our audit effort in this area has been focused primarily at what FDA actions have been taken and less so in the other areas.

Mr. UPTON. Do you think that that would be a wise approach, to talk to some of the hospitals to see how they are fairing?

Mr. WILLEMSSEN. Yes. One thing, because of our concern on what the data was showing about the apparent lack of use by some of the healthcare providers of the FDA data base, we were pondering whether some independent organizations do spot checks of major healthcare providers to ask them, "Have you checked the data base?", and "Oh, by the way, did you know that these particular items are considered non-compliant? Do you have any of these items in your inventory? You should probably go check." We don't have a high degree of confidence as to whether those kind of activities have been done or not. They may, in fact, have been done to large degree, but the data doesn't show this. And that is the reason for our concern.

Mr. UPTON. Thank you. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. I have just a question for, I guess, the FDA, Mr. Hubbard. I missed your testimony, I had to run to another committee meeting. So, you may have talked about this, and this may be a real basic question, a simple question, if you will. Regarding the FDA approval process for medical devices, has that been a standard, is that a standard now for approval of a medical device, that it be Y2K compliant?

Mr. HUBBARD. Well, it certainly is now. We have been identifying it, as you know, we have review staff, physicians and others that review new medical devices for their safety and efficacy. And, of course, a different process for changes in approved devices that are already on the market. Certainly, our reviewers are now making that one of the things that they look at. Obviously, the companies have great incentive to make sure that that is not a problem, but as an additional check, our reviewers are asking that question and making sure that there is not a date dependency issue with new devices going on the market, now.

Mr. BRYANT. How long has that been a standard? I understand that your testimony is that it is a standard of FDA before it approves a medical device, that it be Y2K compliant. How long has it been the standard?

Mr. SHOPE. If I might answer that. We focused on this issue early in 1996, and I think we got a general agreement in our Office of Device Evaluation that, for those types of devices where this date issue could be a critical aspect to their functionality, those pre-market review staff were sensitized to this issue in late 1996, early 1997. We have to note, however, that there are two routes to market. One is a new device, the pre-market approval process, which gets a high level of scrutiny. The second is substantial equivalence. Back at the end of the 1997/98 timeframe, we actually had a few products come to market that had been under development through the 510(k) process, that the manufacturer said, "I realize this product is not Y2K compliant today, but by the time it is an issue for this particular product, we will have a software upgrade." So, based on the issue of substantial equivalence determination, those products were allowed to go to the market. But, the manufacturer had the understanding that he needed the software upgrade in the next couple of years, and to get that into the hands of the users. And that those products will be misbranded and adulterated as of year 2000, if that hadn't been remediated.

Mr. BRYANT. How do we catch and correct those instances now?

Mr. SHOPE. Those are, again, products——

Mr. BRYANT. The manufacturer?

Mr. SHOPE. The manufacturer knows about it already. He has communicated to the users of those products, if they are still out there, and those early software versions should be listed in our website as a non-compliant version that the hospital needs to check to make sure that they have gotten the upgrade. So I think the information about that is there. Again, a big part of the responsibility here is on the healthcare users to compare what they have to what has been demonstrated to have issues, then to take the remediation steps that are necessary.

Mr. BRYANT. Thank you. I will yield the balance of my time to my colleague from Iowa.

Mr. GANSKE. Thank you.

Mr. Willemsen, I want to be sure that I heard you correctly. I think you quoted some study that said only 6 percent of hospitals say that their equipment is Y2K. Was that correct?

Mr. WILLEMSSEN. I believe so, yes, sir.

Mr. GANSKE. Six percent?

Mr. WILLEMSSEN. Yes, the table on page 14 of our statement reflects that 6 percent statement.

Mr. GANSKE. Okay. Well, then, coupled with your other statement that said that you know of some hospitals that are doing their own testing of equipment where they say the manufacturers say they are compliant but then when the hospitals do their testing, they aren't, can you give me some examples of what type of equipment they have checked?

Mr. WILLEMSSEN. Yes. There were equipment such as a cardiac catheterization unit, a pulse oximeter, medical imaging equipment, and ultrasound equipment. Now, what the hospitals that we talked to said, that the issues they found were display problems that didn't appear to have immediate health impacts.

Mr. GANSKE. Except that if you have a pulse oximeter and it is not reporting correctly, that can be a pretty serious problem.

Mr. WILLEMSSEN. Yes.

Mr. GANSKE. Like if you had a pulse oximeter on a patient during anesthesia and it is incorrectly reporting. Now, Dr. Shope, you are shaking your head no?

Mr. SHOPE. I would just say that most of these kinds of issues have to do with recording a record of what the device has done; and, typically, do not impact the actual functionality of the device. The pulse oximeter, I don't know the specifics of this one, but my information would be that that pulse oximeter would work as intended; it will give the display as intended. What might be the problem here is either the display on its face or a readout showing the day's date and time or a record of what was occurring and the date and times associated with that record of what the device did. Typically very few medical devices have a date dependency in their functionality. Many of the problems that we have that are listed as non-compliant problems are problems associated with keeping a record of what the device did, or the way in which that date is displayed.

Mr. GANSKE. But, some do have time-dependent functions, such as ventilators, where you set the rates and things like that, or dialysis machines and things like that. Is it possible that those could be affected by chips as well?

Mr. SHOPE. It is not out of the realm of possibility. However, most medical devices are kept as simple as possible, and therefore, I can't think of very many of these issues where the day of the week or the day of the month, that kind of date record is relevant to the operation of the device. What is relevant perhaps is time intervals, and there are other ways of keeping track of that than having to record date and time information.

So, we think manufacturers, the vast majority of these approaches, keep it as simple as possible; use only the timing that is necessary; don't depend on date, month, year kind of information when that is not necessary. So, it is not out of the realm of possibility that a system could be so designed.

One of the very large issues is many medical devices are either controlled by, or provide data to, or through, a PC-type system. So if that associated PC can't keep good records of the date and time, any recording that it does, files that are stored, dates associated with that information, gets corrupted because of the Y2K problem.

It really doesn't impact the functionality of the device. The service that you want from that device gets delivered. It is the record-keeping associated with what happened that may not be as you would desired.

Mr. BRYANT. Mr. Chairman, the time is out. I will come back. I will try to be back for additional questions.

Mr. UPTON. Thank you. Ms. McCarthy.

Ms. MCCARTHY. Thank you, Mr. Chairman. Dr. Shope, I note in a article from Healthcare Today last November/December, Joseph Jorgen's piece that states, "Since Y2K non-compliant products function appropriately at this time, the Center for Devices and Radiological Health will clear and approve Y2K non-compliant devices. However, manufacturers will be informed that if these devices are not upgraded, they will be considered adulterated as of January 1, 2000."

You can recall products. Are there any products that you intend to recall because of Y2K? If, for example, some manufacturers face this dilemma described in this article in their projects, or products under investigation, you know, don't comply, at what point should healthcare providers go into contingency plans? And would you expand upon what those should be?

Mr. SHOPE. We have no plans right now, or no products identified that would merit a recall as far as our authorities go, because, by and large, all of the products that have problems, those problems have been identified and the manufacturer is providing a route to upgrading or correction of that problem. It is only if there were a product which presented a very serious risk to injury and there was no action being taken by the manufacturer, there was no upgrade available, then our regulatory authority to do a recall would come into play.

I think the contingency for hospitals, or for healthcare facilities, is not so much a contingency, but what they need to be doing now. Which is doing their inventory, assessing their products, determining which of the inventory might be susceptible to a problem, availing themselves of the solution that the manufacturer has provided for that problem, and remediating their inventory. If there are products for which they cannot find the manufacturer because there are a few manufacturers that do go out of business—I don't think this is a very large issue—but should they not be able to find the original manufacturer, and they can't obtain any technical information about that product, then the hospital has to make a decision based on what that product is and the way it could impact patient care as to whether they can somehow evaluate it themselves, have a third party evaluate it for them, or take it out of service. Probably the best thing is to take it out of service and find a replacement for that device.

Ms. MCCARTHY. But, you are approving Y2K non-compliant devices now, correct, or is this article factually incorrect?

Mr. SHOPE. Well, I think at the time that the article was written, back in November, we were still anticipating that we could get 510(k) submissions which would come in and say, I have a problem, I want to get clearance for the software as I have designed it now, but it has got to have an upgrade to be Y2K compliant 1½ years

from now, or 2 years from now. We had no mechanism to deny access to market for that kind of product.

Ms. MCCARTHY. But you do have the power of recall. So if you find, having taken that step that was appropriate, that recall is needed, because the next step, per your request, was not met, will you take action of recall?

Mr. SHOPE. Oh, certainly, if we find any product where there is a potential risk to health that would rise to the threshold that is contemplated for the recall authority, we would certainly vigorously pursue that issue.

Ms. MCCARTHY. Well, on a second point that you raised to my question on the hospitals taking necessary steps, Health Midwest, which is a very huge presence in my congressional district in Kansas City, expects to spend about \$10 million to check the 21,000 biomedical devices that they have. This was in a big piece over the weekend in the Kansas City Star. How are the smaller hospitals going to pay for these activities, my teaching hospitals, Children's Mercy and others?

Mr. SHOPE. If they are going to attempt to test all of their inventory, they have a rather tremendous undertaking. However, I think there is real question about whether hospitals need to do this kind of testing. There are a number of groups that have weighed in on this issue, FDA has not taken an official position, but I think our knowledge of the medical device industry and the medical device designs would say that the manufacturers is really the only one in a good position for a complex medical device to do an adequate evaluation and testing of that product. So, my advice to a hospital would be to rely on the information from the manufacturers about the compliant status of the device and I would question a massive undertaking to test medical devices on the part of hospitals.

Ms. MCCARTHY. With all due respect, your organization having approved non-compliant Y2K products, appropriately at the time, and then relying on the companies to come forward and assure hospitals, indeed, that all of that has been addressed, what does that do for the risk of the hospital if that is somehow factually wrong? I can see why hospitals want to do their own testing. They have a stake in this, too. They will be responsible to the patients that they serve. Do you see the sort of argument going round and round.

Mr. SHOPE. Right, and it is the same kind of argument that would apply, I think, in a much bigger issue, which are the products that were approved without knowing they were non-compliant. Now, we have many of those that are, in fact, non-compliant, and the manufacturers are developing upgrades. So, the situation, I don't see much difference between the situation there. The issue is the manufacturers have assessed their products; they know which ones have problems; they are providing solutions for those. If it comes to our attention that there is a product that is out there and it is a type of product that could present such a risk to a patient and no action is being taken, that is the kind that we would be able to exercise our recall authority. I have to say that, there are very few products that I can contemplate that would rise to that level of risk-to-patients that the manufacturers haven't addressed and provided a fix for.



Ms. MCCARTHY. I see that I have gone beyond my time, Mr. Chairman, and I apologize, but I wanted to pursue this issue, and I thank you.

Mr. UPTON. Mr. Burr.

Mr. BURR. Dr. Shope, let me just say that your answer to Dr. Ganske was the most reassuring thing that I have heard in this hearing so far, when you answered Dr. Ganske earlier. Let me stick with you for just a second. Do I take from your answer to Ms. McCarthy that, from a standpoint of a rural versus urban, we shouldn't have a concern that rural America is more at risk than urban America?

Mr. SHOPE. No, I wouldn't conclude that, because I think one could anticipate the amount of resources being available to the smaller, rural facilities and the kinds of expertise available to them to simply do the inventory, to do the evaluation, to do the followup, and perhaps, if there are items that need to be replaced, to make those replacements. I think the facilities have work to do.

Mr. BURR. We are still very reliant on the facilities to make determinations as well?

Mr. SHOPE. Yes.

Mr. BURR. Let me ask you, Mr. Hubbard, 16,000 manufacturers originally contacted; we heard, from 4,100, you said that there are roughly 200 that you are chasing. That is 4,400. Clarify for me, if you will, where the other 12,000 are. Are they hospitals, doctors, what?

Mr. HUBBARD. Right, the numbers can get confusing. Our initial letter went to 16,000. There are about 13,500 device manufacturers; we added in, at the request of the White House, 2,500 instrument manufacturers, so that the larger world of biomedical products would be covered, even though some of those are not devices that FDA regulates. Then, I think the important number is that about 2,000 are manufacturers of products that might have a date-dependency issue. Things like tongue depressors, obviously, aren't a problem, so they are in that 16,000, but they are not a problem. They got a letter, but they either didn't write back or we don't care if they don't write back.

Mr. BURR. Do we know all the medical devices that have a chip or software problem?

Mr. HUBBARD. Well, as I said, if you take the 2,000, roughly, that might have a date-dependency issue, we have heard from all but about 200 of those. So, it is those 200 that we haven't heard from we are trying to trace down. As I said earlier, they seem to be firms that aren't doing business here any longer, and they are not a problem, but we don't want to just assume that; we are continuing to try to find them.

Mr. BURR. Based upon what we know today, how many medical devices have a potential chip or software problem?

Mr. SHOPE. FDA does not, per se, have a list of all medical devices by make and model number. What we have are manufacturers who have gotten an approval for a particular type of device, one of our classification regulation types. We have 1,700 classifications, different generic types of devices.

Mr. BURR. Wasn't one of the recommendations of GAO that we track this based upon model serial number as far as the clearing-

house purposes of listing, so that people would know the classification?

Mr. SHOPE. Right, we, in fact, have done that. We have gone—let me just make the point. We don't have this list of make and model because manufacturers design many different models, many different makes. So we don't have that list of inventory. What we have done, though, is look at the manufacturers that make the generic types of products that we think are susceptible to being computerized or having computer control, or having microprocessor control. It was that activity that identified the roughly 2,000 manufacturers that we wanted to focus on because they make the types of products that are likely to be susceptible, even though we don't know for a fact that each one of those has computerized their particular versions. There can be computerized and non-computerized versions of the same equipment. Our data base doesn't get to that level of specificity.

So, to address this issue of specific information about products that could be vulnerable, we have asked the manufacturers, that same universe of roughly 2,000 manufacturers, to give to us a list by make and model number of the devices that they have verified do not have a Y2K problem. And we are in process now of collecting that information.

Mr. BURR. That do not?

Mr. SHOPE. Do not have a problem. We already had information on the products that have problems.

Mr. BURR. And there are how many that have a problem?

Mr. SHOPE. We don't have that exact number. I can tell you that in our data base we have heard from roughly 310 manufacturers that have described 800 or so products that have specific problems.

Mr. BURR. So the number is, from the respondents so far, 800-plus?

Mr. SHOPE. Plus, and the plus is because we have 350 manufacturers that haven't given us the list of problem products. They have posted it on their website, and we haven't enumerated those.

Mr. BURR. And what was the deadline that the FDA gave these manufacturers for reporting this information?

Mr. SHOPE. This is a voluntary effort, and we didn't give them a deadline. We asked them, as soon as you have finished assessing all of your products, because one of the issues here is that manufacturers with extensive inventory had to have assessed all their current and previously manufactured products that might be in use in order to submit this information, and a conclusive list of any product that could have a problem, and I think the rate of submissions of that have slowed down considerably around the first of the year.

In March, we asked some of the manufacturers who hadn't given us sufficient detail to provide additional detail on the nature of the problems. So a hospital going to our data base would see, not just the product as non-compliant, but why it is non-compliant and how that would affect the functionality of the product.

Mr. BURR. Does the FDA have any contact with hospitals relative to this list of 800-plus pieces of equipment that might or might not have a problem?

Mr. SHOPE. I am not sure I understand your question.

Mr. BURR. Well, I take it for granted that Mr. Hubbard's answer earlier that, in the 16,000 people contacted, that did not include hospitals or doctor's offices——

Mr. SHOPE. No, that's just manufacturers' devices.

Mr. BURR. My question is, now that we have identified 800-plus possible devices that might have a date-sensitive or software-sensitive problem, has there been any correspondence from the FDA to hospitals saying, "Here is what we have found so far." Or are we relying on hospitals to go into the website to look up this information?

Mr. SHOPE. Right, we are making the website our mechanism of disseminating this information. I will add that the Health Care Financing Administration and several mailings to all of their practitioners and healthcare facilities have emphasized the need, not just to address their financial systems and their payment issues, but also their hospital equipment inventories, and have given the hospitals the reference of how to find the FDA data base and the kind of information that is there. So, there has been a lot of notification to hospitals about this issue.

Mr. BURR. Does HHS look at HCFA as their conduit to hospitals and rural health clinics and community health centers and doctors' offices? Is that our line of communication?

Mr. HUBBARD. Well, certainly not solely; I think, in fact, that they have that conduit; that has been very helpful. But, as we said earlier, we have also tried a number of direct means through the press, mailings directly to physicians and others, articles in various professional journals that we know these people read and other things.

Mr. BURR. Is there a primary part of HHS that is responsible for hospitals and community health centers and rural health clinics and doctors' offices?

Mr. HUBBARD. Certainly HCFA is in the sense of payments, and has regular contact with them and knows who they are and how to reach them. We do not; we do not regulate the practice of medicine or these facilities.

Mr. BURR. Are we the first one to ask that question?

Mr. HUBBARD. I am sure that you are not.

Mr. BURR. I see that my clock has run out, and I hope that we will be the last ones to ask the question of whose responsibility it is.

And I will yield back.

Mr. UPTON. The gentlemen's time has expired. Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman.

Dr. Shope, can you provide us with that list of 800-plus products?

Mr. SHOPE. Yes, sir, that is on our website. It can be downloaded by any citizen that wants it, and we can provide it.

Mr. GANSKE. Okay. Please send that directly to my office.

Now, we were having a discussion before where I think you were basically saying that a lot of this is equipment with the timer function related to readout data. Congressman Vern Ehlers, who I respect a lot on his knowledge on these issues, has pointed out that, for instance, with household appliances—i.e., let's say thermostats that run off of computer chips that have timer functions, they don't necessarily have a year on your readout, but the chips that are in

there may be older chips or chips that are not Y2K compliant. And he has speculated that there could be problems with the functioning of the rest of the chip if it is not Y2K compliant, even though you may not get the readout. Do you have any perspective on that?

Mr. SHOPE. I think in our discussions with our design engineers about this issue, our conclusion is that we would be very surprised if a medical device designer inserted into a medical device, particularly a medical device that had any critical life-supporting, life-sustaining kind of functionality, that kind of a timing chip or device that was unnecessary to the design. So, I think this is an issue that has been speculated a lot about, but I have really no hard evidence that, in fact, is an issue.

Mr. GANSKE. Except for the fact that the hospitals that have done some of their own testing have shown that some of those devices that were supposed to be Y2K compliant are not.

Mr. SHOPE. That's right, and to the ones that I am aware of, it has not been the kind of problem that you have just described. It was usually an oversight between a manufacturer and a parts supplier about a functionality for some accessory device used with the device, and missing the fact that there was a minor date issue there that needed to be addressed and didn't get addressed in the initial assessment.

Mr. GANSKE. Dr. Shope, I see that you are with the Center for Devices and Radiological Health, so I want to go to ask you a question specifically I think that is from Mr. Willemssen's testimony on page 4, where he talks about radiation treatment delivery devices using a radio isotope as a source and that an error in the calculation in the radiation source strength on the day therapy is to be delivered could result in a dose that is either too high or too low. Are you familiar with this particular device and potential problem?

Mr. SHOPE. Yes, sir.

Mr. GANSKE. Could you describe that in a little bit more detail?

Mr. SHOPE. Okay. Radiation treatment planning systems are basically software programs, or computer programs, and often they come with a workstation interface that the medical physicists in the hospital or the radiation therapists in the hospital use. These are programs that use imaging data that is acquired, either from something like a computer tomography x-ray machine or a MRI scanner, where you delineate the patient's anatomy. You then take that information, import it into the computer program that plans the radiation treatment, and the radiation therapist, in consulting with the medical physicist, develops the plan for the direction of the radiation beams and the intensity of the beams and the number of them and frequency with which they will be used to treat a tumor volume and to spare radiation damage to the surrounding tissues. So, these are very complex calculational programs.

This kind of therapy is typically delivered, for the most part, currently, by a device called a linear accelerator. That is a big machine; you turn on the switch, and it emits radiation or electrons, and you turn it off and it stops.

There are some older versions of radiation therapy, however, that don't use an electronic means for the source of the radiation; they use radioactive isotopes. This is referred to as teletherapy when it

is a cobalt-60 unit, which is a source of the radiation. You open the shutter, and let the beam out for the radiation.

Another type of treatment is called brachytherapy, which is when the isotopic source is either inserted into the patient or applied directly to the patient. In either of those types of planning, if you are planning brachytherapy or teletherapy, one of the calculations that has to be made about the therapy is what is the strength of that radioactive source on the day you use it, compared to the day in which it was calibrated initially, which may be 6 months ago. And so there is a date calculation involved. Some of the earlier versions of software that incorporated brachytherapy or teletherapy features for planning that kind of therapy did, in fact, use two digits to represent the year. So this calculation of source strength on the day of use could be an error, if that wasn't corrected.

There were products on the market that did that incorrectly. The manufacturers have identified those, and have either said, this is the upgrade, the software fix needed to address that issue, or this product is so old, there are so many new features in our current version of product, that we aren't going to upgrade the old product; we suggest you buy a new replacement. In fact, the Department of Veterans' Affairs, I think, had seven of those types of systems that they had to replace, at no small expense. But they chose to do the replacement.

Mr. GANSKE. Do you know where all of those machines are?

Mr. SHOPE. No, sir. These are software programs that are purchased by hospitals.

Mr. GANSKE. Right. So you do not know, then, whether the hospitals that have those software programs have received data warning them of that?

Mr. SHOPE. No, sir, we don't have specific knowledge of that.

Mr. GANSKE. So, it is possible, then, that on January 1, 2000 a patient could get an inappropriate calculation?

Mr. SHOPE. If the hospital has paid no attention to this issue and ignored all of the information that has been presented, I have to—

Mr. GANSKE. And what would be the consequence of a patient receiving an overdose?

Mr. SHOPE. It could be either an overdose or an underdose; one would be—

Mr. GANSKE. Underdose, they don't get treated enough.

Mr. SHOPE. Complications to the therapy used.

Mr. GANSKE. Could a patient die if they get an overdose?

Mr. SHOPE. It depends on the level of the overdose, sir.

Mr. GANSKE. Possible?

Mr. SHOPE. It is certainly possible.

Mr. GANSKE. Thank you.

Mr. UPTON. Thank you. We will go to a second round for those that have additional questions, and I do have one.

You know, when I think about my own purchase habits, whether it is a gas grill, or certainly an automobile, even an alarm clock, you get a little warranty card and they ask for your name and address, and if something is wrong, I suspect that they come back to you. The fact is that I have had problems with even seatbelts and that type of thing; I hear back from the manufacturer, and when

I take that car back in to the facility, it is on record there, so if I happen to forget that was a cause, then they remind me and they take care of it.

Is there any such, when you talk about the 800 devices that are, in fact, could be a problem with the date, is there any, other than checking the website—and I appreciate that, and we are going to get that information out to my providers in our State for sure—but is there any way that the hospital would hear or that the provider would hear directly from the manufacturer that their product is on that list of 800 products, directly from the manufacturer versus them taking the initiative?

Mr. SHOPE. Yes. There has been a tremendous amount of communication from manufacturers to their purchasers, particularly for products that the manufacturer has identified as being non-compliant. We can't say 100 percent that every manufacturer of every one of those 800 products has mailed a letter to each one of their purchasers, if they know them. But, I think manufacturers have a very large interest in communicating with those purchasers. If it is known that a purchaser has a product that needs replacement, it certainly makes a lot of good business sense that the company would want to be there and be involved in that purchaser's mind about replacement activity. So, I think the original manufacturer has lots of incentive to communicate to their purchasers problems about products they may have in the past purchased. This is a very common activity.

Mr. UPTON. So, to your knowledge, what would you say, 90 percent, a 100 percent of the providers have been contacted if they are on the list of 800?

Mr. SHOPE. I couldn't put a number on it, sir. But, I think it is not uncommon. You might ask the representative from the manufacturers about this. But, I think the vast majority of manufacturers do communicate with their customers about these issues.

Mr. UPTON. But, probably not 100 percent?

Mr. SHOPE. No, sir.

Mr. UPTON. Okay. Mr. Brown.

Mr. BROWN. Dr. Shope or Mr. Hubbard—Dr. Shope, you mentioned, in response to a question I believe from Mr. Burr—I am not sure—that you had some information on which specific companies have Y2K problems. Talk through that again. I mean, the overall feeling that I am getting from this hearing is neither of you, Dr. Shope or Mr. Hubbard, seems real concerned that there is any significant problem here yet. When I hear some of your answers to which companies, how many companies making how many products, have problems, I am a little concerned. So, run through. Does the FDA have a list of medical equipment, one, that presently has a Y2K problem; second, presently has a Y2K problem that might actually be life-threatening? Tell me what you know about that.

Mr. SHOPE. We have two kinds of information about products with problems. We have the information that the manufacturers have voluntarily provided to us, and that is posted on our website. That is currently on the order of 900 specific products.

Mr. BROWN. That is some 300 companies, you said?

Mr. SHOPE. Yes. The second kind of information is information from roughly 350 companies that are posted on their own websites.

I can't say that I have looked at every one of those companies, but I have reviewed a large number of that 350 to see what kind of information is there, what kind of products are being described, what the nature of the problem is. I have also looked at our own website, probably when the number was more like 600, instead of 800, and gone through that list and looked and tried to gather some impressions of the kind of products that were there, the nature of the problems, and whether any of those presented a very significant risk.

There are a few products there that one would be concerned about if the hospital didn't take action. The vast majority of them are date display or recording in a way that, I think, would be rather insignificant in terms of patient-immediate impact. It could lead to some potential confusion and hospital records later on and after the fact. Is that—

Mr. BROWN. That is the start. Can you tell me, can you tell these subcommittee, No. 1, how many companies there are that have not reported to you—you have looked at their website perhaps—but how many there are that haven't reported to you and how many products those companies make and how many of those products might be life-threatening?

Mr. SHOPE. We can do some arithmetic. We certainly know, of our original estimate of roughly 2,000 companies, there are less than 200 that we haven't heard from, and we don't expect that they are manufacturers of any significant volume in that sample. We have not gone and done an individual company-by-company comparison to see what kind of product those non-responding companies make. However, that is something that is on our plate to take a look at as we continue our effort to analyze this information.

We don't have a list of the products manufactured by every company by make and model. We just don't have that information.

Mr. BROWN. Don't you need that? Some of them might be life-threatening perhaps.

Mr. SHOPE. We can identify by manufacturer if they make a life-threatening-type product. We are currently developing that list of manufacturers which would be the focus of our extensive follow-up effort that we are talking about here.

Mr. BROWN. Mr. Willemssen, what should they be doing?

Mr. WILLEMSEN. Well, I want to express one caveat to some of the numbers that have been discussed. That has to do with, as of May 10, we show that for about 420 manufacturers, FDA relies on their web sites to provide information on non-compliant products. Usually those manufacturers are larger companies. So in terms of the number of 800 or 900 devices that are non-compliant, the actual number is significantly higher than that.

For example, I went on the web site this morning and pulled up one company, and just within the digital imaging sub-systems area of that one company, it listed 11 products with a Y2K issue. So I want to caution you on the numbers that have been discussed, that the numbers are probably, quite a bit higher, because we haven't been talking about all of these web sites that give you an avenue into another whole wide range of products.

Mr. BROWN. Isn't this a pretty serious problem? There are 400 companies on the website; you have spent some time looking at one

and found 11 products. I mean, obviously, you don't necessarily multiply 400 by 11, but you have a significant number, some of them probably, life-threatening. Don't we need to know a lot more than what we know?

Mr. WILLEMSSEN. That is why we agree with what FDA is doing now. You have got to have a list of critical care and life support items and, based on that list, take the additional actions that we have talked about earlier. We think that is a step in the right direction.

Mr. BROWN. How do you define critical care? Does FDA define it? Do you define it? What do you mean?

Mr. WILLEMSSEN. I would rely on Dr. Shope's medical expertise to come up with that definition, but during the course of work it is clearly something that has come up. Our overriding criterion is patient safety and where that patient safety can be degraded because of a Y2K issue in a biomedical equipment device. We feel that needs to be addressed.

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

Mr. UPTON. Mr. Bilirakis?

Mr. BILIRAKIS. Well, and I really planned to go into this with the next panel, too, but we have asked a lot of questions, and of course, a lot of statistics have been thrown out and that sort of thing. How difficult would it be for the Congress, for this committee, to receive the hard data supporting some of the statements that you have made and some of the responses that you have given us, Dr. Shope? I mean, you know, the particular companies that you have contacted and communicated with; the critical medical devices associated with those companies, things of that nature. I mean, is that something that is available that you could just push a button and, in effect, give us a copy of all of that?

Mr. SHOPE. Certainly, the data that is on our website is available in that fashion. We are continuing to work on our list of these, what we call, high-risk devices, and we expect to complete that list very shortly. We will use that list, then, to identify the manufacturers of those types of products. So, any of the information that we have with regard to what we know about manufacturers is certainly available. It would be difficult to produce lists of the products that are on the manufacturers' websites. We haven't downloaded that information.

We have to go back and look at the intended purpose of this website, initially, which was the outgrowth of a joint Federal agency activity to determine which products would have negative impacts from the year 2000 and how to get information out to the Federal purchasers and to the public purchasers of that equipment. The website was seen to be a convenient method for doing that. We relied on manufacturers to voluntarily provide this information because we didn't have a regulatory authority or regulation on the books that would require that kind of information to be provided to us.

Mr. BILIRAKIS. You know, Doctor, with all due respect, I really don't feel any better about everything. You know, you and Mr. Hubbard flat out said that you feel that we will be ready, insofar as the medical devices are concerned, insofar as the FDA jurisdiction area is concerned. But you can't be very much help, appar-



ently, as far as hospitals are concerned, the use of those devices, so to speak, down at that level. And again, how in the hell did we get ourselves into this kind of a situation, knowing darn well that the year 2000 was coming, et cetera, et cetera?

You have enough to know, and I don't want to add anything additional to your workload, when you can better be using your time getting ready, rather than giving us any of this hard data. And I don't know, Mr. Chairman, whether getting that hard data would be of any consequence as far as help is concerned to this subcommittee. Maybe we can talk about that rather than request it now; we can always request it if we feel that it would be.

But, Mr. Willemssen, you have been kind of chomping at the bit when Mr. Burr was asking you a question, and Dr. Ganske. Is there anything more that you want to add? I just want to kind of give you the rest of my time.

Mr. WILLEMSSEN. The issue that I was concerned about was when some of the numbers were being discussed, and I wanted to make sure there was some context for those numbers, and that the numbers that weren't talked about were all of those items on large companies' web sites, which increases the number exponentially. So, I just wanted to make sure that item was out on the table.

Mr. BILIRAKIS. Yes, sir, Doctor.

Mr. SHOPE. I just make the comment, the fact that those items are on the manufacturer's website normally means the manufacturer has assessed that product; he has looked at the vulnerability of that product, and he has provided the solution for that product, or a description of what kind of solution he is going to provide for that product. So, I think one needs to know that piece—I think the concern that may still be there is, how well has the manufacturer done that? That is the kind of thing that we depend on our quality system for and our potential follow-up activities to address and get some additional assurance.

Mr. BILIRAKIS. Thanks, Mr. Chairman. I still don't really feel very good about it.

Mr. UPTON. Well, make sure you get the end-of-the-year checkup.

I would just like to note, for those in the audience that those that don't have the testimony, that the website is [www.fda.gov](http://www.fda.gov).

Mr. Bryant, do you have additional questions?

Mr. BRYANT. Just a couple of quick questions. I hope that they have quick answers.

I know all of you have been working very diligently trying to assess this situation and remediate it, but I am still unclear—there appear to be some 200 to 400 people out there who have manufactured medical devices that have not responded to this survey. Am I understanding your testimony, that the FDA is going to be more aggressive in contacting these people, affirmatively contacting them, to determine if they are bankrupt, if they have merged, if they have disappeared, but trying to get together this information?

Mr. HUBBARD. That is right, Mr. Bryant. We have been doing that. Our contractors are trying to find them, call them, whatever way we can contact them, to find out if, in fact, they still exist, if they are still manufacturing medical devices, if those medical devices are being sold in the United States or exist anywhere in the United States. You know, our suspicion is, as I said, that they are

perhaps not marketing products any longer; they are foreign companies that planned to market here, never did, or companies that have gone out of business, or such things as that. We think the vast majority of manufacturers we have been able to find and asked the questions and gotten the answers. But, we are not giving up on those 200, either; we are continuing to look for them.

Mr. BRYANT. Are you trying to get help from the hospitals and the doctors and the people who—

Mr. SHOPE. We haven't pursued that kind of assistance to locate these manufacturers. It usually works the other way around. We hear from the hospitals, "Can you tell me how to find this manufacturer," as opposed to, "I found one for you; here he is." I think a comment needs to be made about the source of our list of manufacturers. That comes from our registration and listing data base, and that data base oftentimes can have in it people who are no longer in business at the time that we use that address list, people who had an intention when they registered with us that they were going to go into business, but that never came to fruition, people who maybe submitted a pre-market submission, but, for one reason or another, had a clearance for a product but never took that product to market. So there are a lot of business kinds of problems that arise that prevent someone who actually registered and listed with us from continuing in business.

I suspect the large number of the ones that we are trying to track down now are that type of company that really never brought a product to market. The other issue is that they may have a product that they brought to market, but it may not be a computerized device. It got flagged because they make an accessory or supply used with the computerized device. So, when we ask them about computerized device status, they have no real incentive to respond to us.

In fact, just a couple of days ago, I got a list of 20 companies that our contractor had tried and failed on three different occasions to try to contact. We will now take that list and see if there are any products that we can associate with any of those companies that would raise concern. If not, we will have to say this is a list of 20 that we are writing off as non-contactable and products of non-concern.

Mr. HUBBARD. So, if it is any consolation, Mr. Bryant, it is unlikely that these manufacturers, if they exist at all, are making any large number of products where there is a very large problem. But, again, even if there is a small problem, we would like to track them down.

Mr. BROWN. Okay. Mr. Willemsen, do you have any comments.

Mr. WILLEMSSEN. One thing that I would add related to that is to the extent that, if FDA cannot get that information, then they need to consider publicizing that list of non-respondents on its web site, so that hospitals are aware of who those manufacturers are, and if they have equipment from those manufacturers in their inventory, they will want to think twice about whether to use it or not.

Mr. BROWN. Very good. Thank you.

Mr. UPTON. Dr. Ganske? Okay. Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Let me ask you, Mr. Hubbard, somebody earlier asked about the possible 510(k)'s that were in process now.

Mr. HUBBARD. Right.

Mr. BURR. What process do you go through to assure of compliance?

Mr. HUBBARD. I will have to ask Dr. Shope to answer that.

Mr. BURR. Okay. Dr. Shope.

Mr. SHOPE. The process for 510(k), and basically for software products, they are very similar between a 510(k) and a pre-market approval application. That is, the manufacturer, if they are making a computerized device, will provide to us, based on what we call our level of concern or the level of risk that device could present to a patient, varying levels of information and documentation about the software development process used in developing that device. What we would see are artifacts of that software development design process, such things as the overall description of the design process, the types of verification and validation activities the manufacturer undertook, and perhaps some sample test records and test data for the very-high-risk devices. That comes in as part of the application and is reviewed by the pre-market reviewer or sometimes by some of our software specialists. It is not a line-by-line review of the code.

Mr. BURR. In your estimation, is it possible for a device that is non-compliant to be approved today?

Mr. SHOPE. It is probably possible if a manufacturer makes a good case to us that, "I have been working on this product for 2 years."

Mr. BURR. The manufacturer makes the case that it is compliant, and in fact, the product is not compliant in some fashion?

Mr. SHOPE. Certainly, that is possible. Our review process is not foolproof.

Mr. BURR. You mentioned earlier, Mr. Hubbard, resources.

Mr. HUBBARD. Yes, sir.

Mr. BURR. I won't dispute it with you. I will only ask, did the FDA make a line-item request in the 1999 budget for specifically the compliance resources needed for this?

Mr. HUBBARD. Well, what we have done, Mr. Burr, is I believe Congress appropriated a sum of funds for Y2K across the administration as being the funds that have been managed by the Office of Management Budget at the White House, and agencies have gone to that, to the OMB, for specific Y2K-related activities. We have done so for our internal systems correction and had some money funded. We have done some of our emergency response process, so to have our field prepared if problems occur later in the year, and there has been funding for that. We are preparing now to survey drug and device manufacturers to ask more questions about the compliance.

Mr. BURR. So, you do have sufficient resources?

Mr. HUBBARD. Well, certainly funding is coming. The activity we describe today has not been funded, and we will have to go back to the OMB and ask to release some of those funds for that activity.

Mr. BURR. But, you have never made a line-item request from Congress for money for compliance?

Mr. HUBBARD. Not to my knowledge, but, again, because there was this money appropriated by Congress for all of the agencies across—

Mr. BURR. How about in the 2000 budget, even though that doesn't kick in until extremely late in the year; there wasn't a specific line item in the request?

Mr. HUBBARD. Again, I think the reliance has been on these funds already appropriated, Mr. Burr.

Mr. BURR. May I ask you—let us assume for a minute that you ID an non-compliant device. What happens?

Mr. HUBBARD. Depending on the risk, obviously, if we found one today, we would be advising the manufacturer that they need to do to make it compliant. We have the authority, if we believe that device poses a risk to health and could fail some way, we have authority to have it seized or the manufacturing might be stopped, or to have it recalled if it is out in the marketplace.

Mr. BURR. How do you go through that market recall?

Mr. SHOPE. The market recall process is in section 518 of the act.

Mr. BURR. No, I am asking specifically, what process kicks in where you ask or request the recall? The actual products to go back to the manufacturer to be pulled off of the market, not to be used, what process does the FDA go through?

Mr. SHOPE. We would be working with the manufacturer to identify purchasers of those products.

Mr. BURR. Manufacturer would supply you with the list of people that purchased?

Mr. SHOPE. Yes, sir. I am not an expert on these compliance-type operations. So, I am getting into unknown territory from my personal knowledge to describe this compliance activity.

Mr. BURR. I hope you understand, what I am trying to determine is, to what degree do we search for the relevant information when we identify we have a potential health risk in the marketplace versus what are we doing now with our ability to identify equipment that may or may not have a Y2K compliant problem? It seems like the two processes are significantly different. Would you agree?

Mr. SHOPE. I am not sure I can compare the processes.

Mr. BURR. Well, let me put it this way: Have we in any of the Y2K-compliant activities at FDA sought from the manufacturer every location that purchased a specific device and contacted to say, "You purchased this. We understand it is non-compliant to Y2K. We would advise you to go through this process."?

Mr. SHOPE. No, sir. We haven't done that because I think it is a little premature for that decision. What would be happening now would be manufacturers—

Mr. BURR. How close to January 1 do we get before it is no longer premature?

Mr. SHOPE. I think it has to be pretty close if the manufacturer is working on a fix and is going to make that available.

Mr. BURR. Define "pretty" for me, because I need to know at what time do we cry "wolf" and start notification, and how long does it take you to notify?

Mr. SHOPE. I can give you a personal view here. If it is after October 1 and we come across a device that could present a significant risk to patient health, and the manufacturer hasn't taken the

appropriate action to make a solution available, I think we would get very engaged with that manufacturer about his intentions.

Mr. BURR. Now, let me ask you, because there is still a discrepancy today about whose responsibility it is about oversight, can I safely assume there are some non-compliant devices in hospitals and non-compliant devices in doctors' offices?

Mr. SHOPE. Yes, sir.

Mr. BURR. Private homes?

Mr. SHOPE. Possibility.

Mr. BURR. Okay. There is still a disagreement over whose primary responsibility it is for hospitals, doctors' offices, and I don't even think we have discussed private homes. Who will take the lead if we get to October 1, you identify a piece of equipment or several pieces of equipment, the alarm goes off, who takes the primary lead on hospitals? You, HCFA, who?

Mr. SHOPE. I think the realistic scenario would be, if there is a product that has a problem that is not being appropriately addressed and it rises to the level, we could do a mandatory recall-type activity. Typically, before we get to that level, the manufacturer has exercised the voluntary recall and has notified purchasers and had that product removed—either a product withdrawal or some kind of voluntary recall, offering a solution or an alternative to that solution.

Mr. BURR. Mr. Chairman, could I ask for unanimous consent for 2 additional minutes?

Let me skip over to the in-home use. Has FDA determined the amount of time it would take, once you have requested of a manufacturer to contact every person who had a specific non-compliant devices if it were in people's homes, how long would it take a manufacturer to go through the process of notification and for the FDA to receive assurances that everybody had been contacted and that these devices had been taken care of? Is that something that you feel could be done in 90 days?

Mr. SHOPE. It is a little bit beyond my expertise, but I suspect that a critical-type device like that manufacturers could do a reasonable job of identifying and providing information in a 90-day timeframe.

Mr. BURR. So, the likelihood is that they would have to contact a distributor of medical devices or something, who then sold that or has it out on rent or loan or something to an individual, and that whole chain is going to work, and they are going to contact that individual and have all of that information back in a 90-day timeframe? Do you feel like that is possible?

Mr. SHOPE. I am a little beyond my expertise here in terms of how fast these compliant recall-type activities work. I am sure we can provide some information on that.

[The following was received for the record:]

FDA routinely oversees recalls of all products regulated by the Agency under its voluntary recall authority, and, less frequently, has required recalls of medical devices under the authority of the Federal Food, Drug and Cosmetic (FD&C) Act. The Agency's recall authority provides FDA with a highly effective and expeditious means of protecting the public from potentially harmful products. The length of time the entire recall process takes can vary widely based on the device and the extent to which it has been distributed.

Although the ultimate goal of any recall is to repair a dangerous product or remove it from distribution, the primary public health goal of the recall authority—halting the use of a product that poses a health risk—can be accomplished during the initial stages involving notification and publication of information concerning the device. Under the mandatory recall requirements, the individual or firm to whom FDA issues the order must immediately issue notifications and instructions to cease use. This is accomplished through directed notification to the manufacturers, distributors, purchasers, etc., and also through press releases. These actions ensure that health care workers can make informed decisions about patient care.

FDA's mandatory recall authority is reserved for medical devices that pose a high degree of risk to the public health. Section 518(e) of the FD&C Act requires that the Agency first order an appropriate individual to issue notification of the risk of the device to user facilities and health professionals, along with instructions to cease use of the device. The appropriate individual is the individual most well-situated to locate the device and contact those responsible for its use. This person frequently will be the manufacturer, although FDA may use its authority under 518(e) to impose orders on distributors, importers, or other individuals the Agency determines are best able to respond to the requirements of the order. Most mandated notifications can be completed within 48 hours.

The procedures under FDA's voluntary recall regulation are more flexible. Under its procedures for voluntary recall, the Agency can work with manufacturers to initiate a variety of actions, including notifications and recommendations concerning discontinuation or modification of use of the product. Voluntary recall procedures are available for all levels of product risk.

The length of time it will take to remedy the device or remove it from distribution will depend on the number of devices in distribution and other factors; FDA cannot predict this time period in the absence of a particular set of facts. FDA's mandatory recall regulations, however, provide authority for the Agency to respond with immediacy to serious threats. Although the mandatory recall regulations require that FDA provide an opportunity for a hearing before amending a notification order to include recall, the preamble to the regulation makes clear that FDA may issue its notification order, hold its hearing, and amend the order to require recall all in a single day when the public health requires immediate action. 61 FR 59004, 59007 (November 20, 1996). Only an extreme risk would dictate such an urgent response. FDA's recall authority was designed to empower the Agency to respond with Urgency to significant health threats. FDA anticipates this authority will enable the Agency to control health risks it identifies by October 1, 1999, (or an earlier date) within 90 days.

Mr. BILIRAKIS. If the gentleman would yield?

Mr. BURR. Yes, back to you.

Mr. BILIRAKIS. So this gets back to your "pretty close," "pretty close" point, Doctor. The discussion here is 90 days, and I guess I am not sure where the 90 days came from; maybe I wasn't paying attention. I was ordering something to eat.

Mr. BURR. There is a lead time in any case, particularly if we are going to go to the private homes.

Mr. BILIRAKIS. And that sort of thing—I don't know, I hope we are not really making a mountain out of a molehill here. I think it is just significant that we not leave anything unlooked at. But keeping in mind the timeline, you know, there is a period of time here for recall and getting into the private homes and getting into the hospitals, et cetera, et cetera. When you say, "pretty close," what are we talking about there? You are certainly not talking December, are you? Are you talking December or are you talking November or are you talking October? October is 30 days; September is really 30 days.

Mr. SHOPE. I think we would be wanting to have some good understanding of the situation by October 1 in order to be realistic about taking care of a significant problem. I would like to add that I have a very hard time thinking about a device used in the home that is date-dependant in a way that it would present a significant

risk to the patient. There are blood glucose monitors that are used in home use, and some of those do trending of readings, and there is a potential for problems there with some models of that type of device. But, I am hard-pressed to think of other products used in the home where a date functionality is critical to the use of the device. But, that is not to say there may not be something.

Mr. BURR. Doctor, have we ruled out every implantable device possibly having a Y2K-compliant problem?

Mr. SHOPE. We know of no implantable devices that have Y2K-date dependencies.

Mr. BURR. I appreciate the answer, but I asked it in a different way. Are we assured that there are no implantable devices that might have a Y2K problem?

Mr. SHOPE. I am not sure that I can answer it in any other way than the fact that we are not aware of any product like that. We have been in touch with the manufacturers of such things as pace-makers, implantable infusion pumps, implanted defibrillators. It just doesn't make sense to design those with an unneeded date dependency. And none of those products work in a way that requires them to have knowledge of the date. Those things use timing circuits, but when they use timing circuits, they are using a register counting oscillations of a oscillator. It is the external device that maybe interrogates that device that adds the date-time type of information to the record that it brings out from that device.

Mr. BURR. Well, I thank all of you. This has been enlightening. Just as a personal observation, I think we still have quite a bit of work to do. I don't think that I would find disagreement from any of our panelists. I would also urge my colleagues that we, as a committee, try to work with the FDA and with all the agencies that have some oversight. I would encourage the FDA to encourage HHS to draw a little clearer lines of responsibility as it relates to hospitals and rural health centers and doctors' offices. I think it is important that at least that question have an answer versus to pass it off on the manufacturers. It may be their responsibility. If it is, then let us make sure that we clearly communicate it. If it is not, let us make sure that we know which arm of the Federal Government is going to be responsible for notification.

I yield back.

Mr. HUBBARD. We will follow up on that, Mr. Burr.

Mr. BILIRAKIS. I would hope, Mr. Chairman, if I may, I would hope that we get our heads together and schedule another hearing, maybe like in September, something of that nature, as we get closer to these timelines.

Mr. UPTON. I think that would be a very good idea.

If no other members have questions—

Mr. BROWN. I would just add, thank you, Mr. Chairman. If we do another hearing in September, as Chairman Bilirakis suggests, and we do find ourselves continuing to give more responsibility and expect more responsibility to and expect more from the FDA, that we look at their funding also. That is something that, at least, we should consider because Mr. Hubbard's comments on the technical expertise, in response to my question, sound like partly a paucity of resources, in addition to a lack of technical expertise. I think we

should at least consider that in an emergency situation, if it comes to that.

Mr. UPTON. Thank you. Panel, you are excused. Thank you very much for your testimony, and you may be getting some questions further down the road from us as well.

Our next panel includes Mr. Kent Smith, who is the global project manager of Baxter Health Care Corporation. He is the spokesperson for the Health Industry Manufacturers Association, HIMA. Mrs. Noel Brown Williams, senior vice president at Columbia HCA Health Care Corporation, spokesperson for the Federation of American Health Systems. And Mr. John C. Nunn, vice president for patient care services from Henry Ford Hospital, representing the American Hospital Association.

We are delighted that you are here this morning, and we appreciate you listening, certainly, to the first panel. And as you heard me say to the first panel, we have a long tradition in the Oversight and Investigations Subcommittee of taking testimony under oath. Do you have any objection to that?

[No response.]

Seeing none, also, under House rules, you are allowed to have counsel, if you prefer that. Do you have a need for a counsel?

[No response.]

Then if you would stand and raise your right hand?

[Witnesses sworn.]

You are now sworn in, and as we did with the first panel, your entire statement will be made part of the record. If you would like add or summarize, but try and observe the 5-minute rule, that would be terrific. We will start with you.

**TESTIMONY OF KENT T. SMITH, GLOBAL PROJECT MANAGER, BAXTER HEALTHCARE CORPORATION, ON BEHALF OF THE HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; NOEL BROWN WILLIAMS, SENIOR VICE PRESIDENT, COLUMBIA HCA HEALTH CARE CORPORATION, ON BEHALF OF THE FEDERATION OF AMERICAN HEALTH SYSTEMS; ACCOMPANIED BY DON WORKMAN, COLUMBIA HCA HEALTH CARE CORPORATION; AND JOHN C. NUNN, VICE PRESIDENT FOR PATIENT CARE SERVICES, HENRY FORD HOSPITAL, ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION**

Mr. SMITH. Thank you, Mr. Chairman. As mentioned, I am the chairman of Baxter Healthcare Corporation.

Mr. BILIRAKIS. Will you pull the mike closer?

Mr. UPTON. Yes. Pull the mike up a little bit closer.

Mr. SMITH. That is the first time I have ever heard somebody tell me I couldn't speak loud enough, by the way.

I am the chairman of Baxter Healthcare Corporation's committee on the year 2000. And just for your information, Baxter is a global medical products and services company that provides critical therapies for patients' life-threatening conditions. I am very pleased to testify today on behalf of HIMA and the medical device industry's Y2K readiness.

The device industry shares the concern of healthcare providers and patients regarding the year 2000 date problem. Over the past year, HIMA has stepped up the challenge and worked effectively



with the FDA, the Veterans' Administration, and the National Safety Patients' Partnership, as well as others, to identify critical issues, communicate Y2K compliance, and ensure patient access to safe and effective devices on January 1, 2000.

To date, HIMA members are at different levels in their Y2K-compliance process. Most are now focused on the Y2K business contingency planning process. And I want to emphasize the point that all HIMA members have a year 2000 process in place today. On device compliance, HIMA has worked closely with the FDA and the Veteran's Administration to ensure the FDA's year 2000 clearinghouse is an effective central data base for Y2K device compliance information.

HIMA has also ensured a 100 percent response rate from its 800 member companies who manufacture 90 percent of the devices sold in the country in the US. They communicated with 6,000 non-member companies, urging them to respond to the FDA to ensure their devices were Y2K compliant, which we have heard from. They have made phone calls to non-HIMA member companies who did not respond to the FDA or the VA request for this information. And they have sponsored advertisements with the FDA and the VA in industry trade magazines, urging companies to respond to the FDA request on the Y2K status information. So, in summary, I believe the device industry has risen to the challenge of coordinating and effectively communicating the medical device industry's progress toward Y2K compliance, though we still have some work to do.

As a window into the activities of a large company with a diverse product line, let me quickly highlight elements of Baxter's comprehensive Y2K program which have been in place since early 1997. Our product compliance checking is complete, and it identified fewer than 20 products with Y2K issues. Modifications and replacements for these products will be complete by mid-1999. Information regarding our Y2K-compliance status and implementation solution has been available since December 1, 1998. We have sent out over 30,000 compliance letters to customers worldwide, describing product issues and the process for implementing product fixes.

To evaluate our suppliers, we have required each supplier to communicate its Y2K compliance. We have over a 95 percent response rate to questionnaires sent to 7,000 critical suppliers. We are conducting face-to-face as well as telephone audits with these targeted suppliers.

With respect to our manufacturing plants, 80 percent of our manufacturing and facility systems have been fixed. Implementation will continue through the mid-part of this year for that piece. And finally, we have a very extensive business contingency planning process in place for all of our businesses and regions around the world, focused on customer communication, human resource planning, and inventory management.

With respect to contingency planning that I just mentioned, I participated in a HIMA-wide teleconference to educate the other HIMA members on Y2K contingency planning. And while these are a normal course of business, in this particular case, we happen to know when the year 2000 transition will occur, and so it is easier to plan from a contingency planning perspective.

HIMA has now turned its attention to the serious issue of potential or provider stockpiling, if you will, or provider hoarding. As a member of the healthcare sector of the President's Council on the Year 2000 Conversion, HIMA is working with the American Hospital Association, the Health Industries Distributors Association, the FDA, HCFA, and others on a White House-sponsored roundtable on hospital supplies to be held in early June.

In closing, we are encouraged by the progress of our industry in achieving Y2K readiness. However, we cannot achieve success alone. The government must play an integral role in helping the diverse and segmented healthcare sector coalesce in responding to Y2K. You can help us by supporting any consensus that is developed in the forthcoming White House roundtable. In so doing, you will help every patient in America. Working together, we can assure patients that the healthcare sectors will continue to provide value and safety into, during, and beyond January 1, 2000.

And obviously, I would be glad to take any questions you may have.

[The prepared statement of Kent T. Smith follows:]

PREPARED STATEMENT OF KENT T. SMITH, CHAIRMAN, YEAR 2000 COMMITTEE, BAXTER HEALTHCARE CORPORATION ON BEHALF OF THE HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

My name is Kent Smith. I am Chairman of Baxter Healthcare Corporation's Committee on Year 2000. Baxter is a global medical products and services company that provides critical therapies for patients' life-threatening conditions. The company's products and services in blood therapies, biopharmaceuticals and blood collection, separation and storage devices, cardiovascular medicine, medication delivery and renal therapy are used by health care providers and their patients in 112 countries.

I am pleased to testify today on behalf of the Health Industry Manufacturers Association (HIMA) on the status of the medical device industry's Year 2000 readiness. 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.

The medical device industry recognizes and shares the concerns of health care providers, patients, and the general public regarding the possible effects of the Year 2000 computer date problem. The American medical technology industry has built a reputation for leadership and excellence that is recognized worldwide. It goes without saying that the health and safety of patients constitute the paramount concerns of our industry.

Over the past year, I believe that the device industry has stepped up to the challenge and has worked closely and effectively with key constituencies including the FDA, the Department of Veterans' Affairs, the National Patient Safety Partnership and others to identify critical issues, communicate the industry's compliance, and ensure patient access to safe and effective medical devices on January 1, 2000 and thereafter. I can speak directly for Baxter Healthcare Corporation when I say that we are devoting significant resources to assure the Year 2000 compliance of our devices and to communicate our compliance status to interested parties. I am personally aware of numerous other companies that are acting similarly. I am confident that the medical technology industry will do whatever is necessary to maintain the health and safety of our patients.

In my testimony today, I will outline for the Subcommittee the numerous activities, both past and present, that HIMA has undertaken to ensure that both HIMA member and non-member companies fulfill their responsibility to provide compliance information to appropriate government entities as well as their customers. I will also share with you the comprehensive Year 2000 compliance program that Baxter Healthcare has developed.

I would be remiss, however, if I did not express to you the legitimate liability fears of the medical technology industry—fears that are shared by other industries.

Congress recognized these in enacting the Year 2000 Information and Readiness Act that has helped tremendously to encourage all industries to disseminate Year 2000 compliance data without fear of liability. The House has now taken the second step of passing liability legislation that will help create an environment that will encourage remediation and discourage frivolous lawsuits. It is our hope that the House, the Senate, and the Administration will be able to reach a compromise to ensure that liability legislation is passed as soon as possible.

#### *A Diverse Industry Poses Unique Challenges*

The medical device industry is extremely concerned about the potential hazards associated with the Year 2000 problems and has put substantial effort into ensuring that medical devices function properly and safely during and after the century change. We have committed to Congress to work with the federal government and other concerned parties to ensure that information about Year 2000 medical device compliance is publicly available. While we remain confident that there will be few disruptions to patient health care as a result of non-compliant medical equipment, it might be useful to understand the true diversity of the medical technology industry.

More than 50 scientific and engineering disciplines, including such diverse fields as solid state physics and holography, are involved in the development of our products. Over 50 different medical specialties, such as orthopedic surgery, cardiology and ophthalmology, utilize the industry's products in applications throughout the human body. There are more than 3,000 distinct, major product lines, and approximately 84,000 individual products. For these reasons, the challenge posed by the Year 2000 bug does not represent a single problem that will yield to a single solution. For the majority of cases, solutions developed by one firm likely will not apply to, or be feasible for, others. Rather, each company faces a unique set of circumstances involving its own technologies.

Further, while the number of electrical medical devices containing software has been rising, it is important to understand that many of the highest risk devices vital to keeping patients alive are not date sensitive. For instance, many have cited the potential Year 2000 risks associated particularly with pacemakers and implantable defibrillators. Pacemakers and implantable defibrillators are required to operate at all times regardless of the day or date. We know of no pacemakers or defibrillators that are date dependent.

#### *HIMA's Year 2000 Activities*

As a matter of course, HIMA has strongly encouraged its members to work to ensure that their devices are Year 2000 compliant and to communicate Year 2000 compliance status to their customers. We have developed and executed a comprehensive program to advise HIMA member and non-member companies regarding their responsibility to provide compliance information to the government and have worked closely with the FDA and others to disseminate necessary information.

HIMA has also:

- Established a member committee to advise on and oversee the Association's efforts to successfully address Year 2000 issues.
- Created a Year 2000 section on HIMA's Web site to communicate with the public and our members on Year 2000 issues.
- Consistently reached out to all segments of the industry including the National Electrical Manufacturers Association (NEMA), and the Medical Device Manufacturers Association (MDMA) to coordinate our efforts and to help ensure that critical Year 2000 messages reach virtually all device manufacturers.

Early in the Year 2000 debate, an important coalition—the National Patient Safety Partnership—comprising the Department of Veterans' Affairs, the American Hospital Association, the American Nurses Association, and others concerned about the impact of the Year 2000 problem on patient health, proposed the development of a central clearinghouse on the compliance status of medical technology. Other private organizations, such as Rx2000 Solutions Institute, also called for centralized databases.

HIMA has worked diligently and closely with the Food and Drug Administration (FDA) and the Department of Veterans' Affairs to help the FDA's Year 2000 Biomedical Equipment Clearinghouse become a 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:

- Ensured a 100-percent response rate from HIMA's 800 member companies who together manufacture 90 percent of the medical technology products sold in the U.S. market.

- Communicated with more than 6,000 primarily small non-HIMA 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 industry trade magazines urging device companies to respond to FDA's request for Year 2000 status information.

It is important to note that in the current device industry environment of mergers and acquisitions, it is not always obvious how one company may be affiliated with another, or which corporate entity should be the responsible reporting entity for a particular product. It is accurate to describe our industry as something of a corporate maze. For example, HIMA's membership of more than 800 companies actually consists of 300 companies and parent companies and their more than 500 separate subsidiaries and divisions. For these reasons, HIMA also:

- Asked each member company to designate an individual who is responsible for coordinating Year 2000 activities.
- Worked with the FDA and the VA in an effort to ensure that their communications were going to Y2K coordinators, especially in instances where they were receiving no response.
- Made calls to non-HIMA 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 the FDA Biomedical Equipment Web site.

Of the more than 13,000 FDA-registered device companies, the FDA identified 1,935 whose products are likely to have a date-dependent function. We understand that FDA's non-response rate is now just over 200 companies. We can probably assume that many of these companies are no longer in business.

More recently, in an effort to provide "one stop shopping" for health care providers on Year 2000 compliance information, the FDA has expanded their Web site to include information on Year 2000 *compliant* devices. HIMA worked closely with the FDA to help develop a workable template in order 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, in a memorandum, to provide the requested information. HIMA also used its Web site to promote compliance with the request.

#### *Baxter Healthcare Corporation Year 2000 Actions*

As a window into the activities of a large medical technology corporation with a diverse product line, I would like to highlight the Year 2000 progress and awareness initiatives Baxter Healthcare Corporation has undertaken. Given our goal of providing quality care for patients, Baxter has since early 1997 been actively addressing Year 2000 issues relating to our customers, employees, suppliers, manufacturing and facility systems, products, services and internal systems. We have made tremendous progress and we anticipate that we will meet our goal of being Year 2000 compliant by September 30, 1999. To date, we have spent approximately 85 percent of our \$135 million Year 2000 budget to address our role in the health care supply chain. Baxter's Year 2000 initiatives are comprehensive and include a variety of activities.

*Products*—Baxter delivers critical therapies for life-threatening conditions. It is important work. Important to patients whose lives depend on our products and services. Important to health care professionals who count on us to help them treat their patients. Consequently, providing timely information regarding the status of Year 2000-affected products and services is one of the Year 2000 team's top priorities. Baxter's product and software engineers have identified fewer than 100 electronic medical products that *could have been* affected by Year 2000 issues. Information regarding the Year 2000 compliance status and implementation solutions for Baxter's electronic date-dependent products was available December 1, 1998. Our compliance checking has been completed and identified *fewer than 20 products* with Year 2000 issues. Product modifications and replacements are expected to be complete by mid-1999.

*Customers*—The Year 2000 challenge isn't just about rewriting computer code, it's about being responsive to customers. We are actively working with customers to address various Year 2000 issues, including medical device compliance, viability of the supply chain, and Electronic Data Interchange (EDI). Beginning in June 1998, Year 2000 certification documentation (letters, compliance certificates, and Baxter's compliance definition) began to be distributed to customers we identified as having date-dependent products.

Also in June 1998, Baxter launched its Year 2000 Web site, which includes a complete list of Baxter's electronic medical products, detailed information regarding Year 2000-affected products, a customer inquiry form, compliance definition, product

supply requirement information and other information on Baxter's Year 2000 Program. To date, we have responded to over 4,500 Year 2000 customer inquiries and have mailed over 25,000 compliance letters to customers worldwide. 40,000 Baxter brochures in 10 languages were distributed to customers, suppliers, and employees to help increase global Year 2000 awareness.

In early 1999, all customers who communicated with Baxter through EDI were notified about Baxter's implementation of the newest EDI standards that are Year 2000 compliant. While a change to a newer version may not have been required in all cases, it is the preferred way to communicate with Baxter.

*Suppliers*—Suppliers in the broadest sense include all those parties that provide material, products, or services to Baxter. One of the biggest risks facing our global company is the potential failure of key strategic business partners, suppliers, and third parties on which we depend to address Year 2000 issues. To evaluate our suppliers, we have a coordinated effort through Baxter's Purchasing Council to address our raw materials/finished goods and maintenance, repair and operations (MRO) suppliers. Each Baxter facility is also requiring their local suppliers to communicate their progress toward Year 2000 compliance. These suppliers may include utilities, telecommunications, third-party logistics providers, distributors, service providers, property managers and any other critical business supplier. We have received an over 90 percent response rate from questionnaires sent to our identified 7,000 critical suppliers asking for their Year 2000 readiness information. We are also conducting face-to-face and telephone audits with targeted suppliers. Our goal is to complete these audits by mid-1999.

*Manufacturing*—Baxter manufacturing worldwide adheres to high standards of quality. Our manufacturing plants are consistently recognized for their dedication to total quality and manufacturing excellence. As a health care manufacturer, Baxter has over 70 manufacturing facilities, distribution centers and replenishment centers around the world. To date, 80 percent of Year 2000 manufacturing and facility systems have been fixed and implementation will continue through mid-1999 according to plan.

*Internal Systems*—As a global company, Baxter has literally thousands of internal interconnections and interactions amongst and between computer operating systems. In an effort to make it easier for our customers to do business with us, enhance our employees' ability to respond to customers, as well as improve our overall economic efficiency, we are implementing a global integration project. This project will implement software upgrades that are certified as Year 2000 compliant as well as integrate our operational processes. To date, Baxter has achieved all major milestones relating to systems initiatives with approximately 75 percent of systems implementations complete as of March 1999.

*Contingency Planning*—As part of its contingency planning and awareness efforts, Baxter is:

- meeting with customers to discuss their requirements and obtain key information as input into our contingency plans;
- contacting customs officials to identify potential Year 2000 issues;
- monitoring the Year 2000 progress of its key distributors and suppliers;
- assessing the viability of the entire supply chain and developing appropriate contingency plans at each of its manufacturing facilities worldwide;
- upgrading, replacing or modifying all major computer-based business and finance systems where necessary to enhance interactions with customers; and
- developing strategies for communicating with customers during the Year 2000 transition.

We are confident our comprehensive Year 2000 plan and implementation strategy will help us continue our mission of providing critical therapies for life-threatening conditions.

#### *HIMA Contingency Planning Activities*

With respect to company operations' contingency planning, HIMA has helped to educate its membership on the importance of Year 2000 contingency planning and the various components involved. For example, I participated in an association-wide teleconference to educate my colleagues on the many aspects of the contingency planning process in order to avoid critical interruptions of the supply chain and to enhance communications with customers. Year 2000 contingency planning is focused on developing alternate operating procedures that support business continuity. It should be noted that contingency plans are part of a company's normal course of business. Prudent companies must protect their operations during storms, strikes and other potential disruptions. In the case of Year 2000, these plans could range from taking customer orders by hand instead of by computer to establishing a Year 2000 command center for critical communications during the Year 2000 transition.

The President's Council on Year 2000 Conversion is working to evaluate the readiness of critical industries. To support the Council's initiative, HIMA circulated to its members a survey based on a template prepared by the President's Council. While we have not completed our analysis of the survey, our initial work indicates that the companies that supply the bulk of the country's medical devices are well on the way to complete Year 2000 readiness before the end of the year. The results collected thus far have given us a handle on general industry trends. For instance, we believe the companies that sell the vast majority of medical devices sold in the U.S. are communicating with their suppliers and their customers using multiple means such as face-to-face meetings, 800 numbers, Web sites, e-mail, etc. In addition, the preliminary results indicate that these same companies expect to be Year 2000 compliant with respect to both their products and their operations.

#### *Preemptive Buildup of Supplies*

On another equally important front, HIMA has recently turned its attention to the more serious issue of the potential for preemptive inventory build-up or stockpiling. As January 1, 2000 nears, serious concerns have been expressed throughout the supply chain that some providers may, as part of their contingency planning, preemptively hoard supplies. As a member of the Health Care Sector of the President's Council on Year 2000 Conversion, HIMA is working closely with the American Hospital Association, the Health Industry Distributors Association and others on a White House-sponsored Roundtable on Hospital Supplies to be held in early June.

We expect the Roundtable to be a major source of valuable information and policy development that will relieve the pressure related to concerns over potential hoarding of hospital supplies. For instance, a possible outcome could be an industry/health care provider consensus that would, in effect, limit the amount of inventory providers would purchase to previous historical levels plus some minimal additional amount.

#### *Proposals for Independent Verification of Industry Test Protocols*

A number of parties, including the General Accounting Office, have called for third-party verification of medical technology Year 2000 test protocols. Others have advocated user or third-party testing of devices. Some have argued that FDA should properly take on such responsibilities. Still others have called on industry to make public its test protocols as well as detailed testing results. We would like to highlight a number of concerns with such approaches:

- It is unlikely that enough independent third-party test organizations exist to analyze and process the highly complex test protocols associated with thousands of devices in the available time.
- It would take tremendous resources and staffing for any organization, including the FDA, to begin to verify independently the numerous testing protocols involved for each model of each device, some of which for complex devices can approach 100 pages.
- Making public test protocols assumes that the provider technicians responsible for such testing would be able to properly and safely use and understand the protocols.

We believe that at this late date, such activity would be a misdirection of resources. We understand that this view is shared by ECRI, a leading independent, non-profit research agency for health care technology and the Department of Veterans' Affairs, which expressed this opinion in several of our meetings with them. We have attached a slide prepared by the chief biomedical engineer of the Department of Veterans' Affairs describing the reasons for not entering into a major program to retest medical devices.

Medical device manufacturers are strictly required by the FDA to verify and validate all product changes affecting patient safety. These activities are undertaken as part of each company's Design Control program under the FDA Quality Assurance regulation. These rules require written procedures for design change validation and verification, and independent internal audits of quality assurance activities. There are severe sanctions for failure to validate changes, and FDA has significant inspection authority to assure compliance. It is difficult to conceive that either users or third parties can more effectively verify device Year 2000 readiness than the manufacturers who originally designed the devices.

#### *Conclusion*

In closing, HIMA will continue to work on a variety of fronts to ensure that the medical technologies on which millions of patients depend continue to function safely and effectively as we move into the next millenium. We want the patients who

we serve as an industry to have confidence in us, and we will continue to do whatever we must to deserve their trust. We are committed to working cooperatively with anyone who shares this goal. We are open to suggestions and look forward to working with members of the Subcommittees.

Mr. UPTON. Thank you very much.

Mrs. Williams.

#### **TESTIMONY OF NOEL BROWN WILLIAMS**

Ms. WILLIAMS. Good afternoon, Mr. Chairman and members of the subcommittee.

Mr. UPTON. Could you just put the mike just a little bit closer?

Ms. WILLIAMS. A little bit closer. How is that?

I am pleased to appear before you today on behalf of Columbia HCA Health Care Corporation, who is a member of the Federation of American Health Systems. The federation represents nearly 1,700 hospitals. I am here today to discuss Columbia HCA's activities and experience concerning year 2000 and the medical devices.

Columbia HCA is one of the leading healthcare service companies in the United States. We currently operate 236 hospitals throughout the country and employ approximately 225,000 workers, each of whom is committed to the care and improvement of human life. Columbia HCA estimates that we will spend approximately \$86 million on Y2K, which does not include capital costs related to replacing non-compliant equipment.

Columbia HCA began planning for the year 2000 in 1996. We established a year 2000 executive committee and have formed a multi-disciplinary Y2K support team. This team is monitoring over 1.4 million medical equipment information systems and physical plant assets. Our Y2K efforts have included activities such as contingency planning, coordination with our fiscal intermediaries, and medical equipment planning.

Medical equipment planning has been, and continues to be, one of the key areas in our Y2K planning effort. The first thing we did was an inventory of our medical equipment assets. With few exceptions, this included anything that had a battery or power cord. The current medical equipment inventory includes over 450,000 pieces of equipment.

In an attempt to prioritize our medical equipment and device planning efforts, we developed a classification system. This classification system enables us to focus our efforts on medical equipment that is essential to providing patient care. The classification has five impact ratings. However, our focus is mission-critical equipment, which includes life-support equipment such as ventilators and anesthesia machines.

Next, we identified almost 900 prevalent vendors in the Columbia HCA medical equipment network. We then surveyed each of these vendors for compliance information. Ninety-five percent of those vendors have responded to our request.

Next, vendor responses were evaluated by our survey teams, subject matter experts, and then risk management experts before being published in our internal data base. We now have compliance information on over 28,000 items in this data base, including 11,000 in the medical equipment category. Our facilities can now

match their equipment inventory back to this data base to determine if it is compliant or non-compliant.

The final step is facility decisions and remediation. Once our facility has completed an equipment match to an item to our internal data base and have identified that the equipment is non-compliant, they can plan accordingly—to use the equipment as is, where the Y2K impact does not affect how the equipment is used in a patient care setting, plan a workaround, consider an upgrade, replace the equipment, or retire the equipment. The facility evaluation is based on the equipment classification and how this equipment is being used in the facility.

Our research and evaluation of medical equipment varied based upon the equipment's classification. For example, stricter acceptance criteria from vendors was required for mission-critical devices. Of approximately 450,000 medical equipment assets, over 190,000 are mission-critical or impact level one. We have identified approximately 8 percent of these as limited or non-compliant and will require remediation. In addition, we have identified over 800 pieces of mission-critical or impact level one medical devices which we have placed in a status of unknown, because the manufacturer has indicated that they are not evaluating the compliance status of the devices or for which we have not received acceptable vendor information. And I might add, that represents 18 companies.

There are several issues we feel might be of particular significance to the subcommittees, which we have discussed in our written testimony. They are proof of compliance, the FDA clearinghouse, hospital medical device testing, and supply chain issues. We believe that the healthcare providers, the equipment manufacturers, and the FDA all have responsibilities in this process. The provider must identify their medical equipment, obtain the compliance information from the manufacturer, and then determine if the Y2K impact requires remediation. The manufacturer should be responsible for accurately determining the Y2K status of its equipment, communicate that status, including specific details about what makes the device compliant or non-compliant to the healthcare community.

The FDA can support these initiatives by requiring the manufacturers to determine the compliance status of all of the equipment, what the impact is, the availability of upgrades, replacements, or workarounds, and ensuring that there is an easily accessible mechanism for all healthcare providers to get the information, including updates. Of special interest is the need for manufacturers to provide compliance information for all of their devices, as some have chose not to test obsolete or retired devices.

Columbia HCA has taken the initiative to manage the year 2000 issue in order to protect the safety of our patients and to continue providing quality health services. This effort requires the support and cooperation of public and private sectors. We appreciate the opportunity to testify today and I would be happy to answer any questions you have. Thank you.

[The prepared statement of Noel Brown Williams follows:]



PREPARED STATEMENT OF NOEL BROWN WILLIAMS, SR. VICE PRESIDENT & CHIEF  
INFORMATION OFFICER, COLUMBIA/HCA HEALTHCARE CORPORATION

INTRODUCTION

Good morning Mr. Chairman and Members of the Subcommittees. I am Noel Williams, Senior Vice President and Chief Information Officer of Columbia/HCA Healthcare Corporation. I am pleased to appear before you today on behalf of my company who is a member of the Federation of American Health Systems. 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 specifically discuss Columbia/HCA's activities and experience concerning Y2K and medical devices. I will also refer to Columbia/HCA Healthcare Corporation and its affiliates as simply Columbia/HCA. Columbia/HCA is one of the leading health care service companies in the United States. We currently operate 236 hospitals throughout the country and employ approximately 225,185 workers, each of whom is committed to the care and improvement of human life.

Let me begin by thanking you for the dedication and interest you have shown for the Year 2000 issue. Columbia/HCA recognizes and shares your concern and I appreciate the opportunity to explain how we, as representatives of the medical industry, are preparing for Y2K.

Columbia/HCA estimates that we will spend approximately \$86 million on Y2K, which does not include capital costs related to replacing non-compliant equipment.

COLUMBIA/HCA'S Y2K PLANNING EFFORT

Columbia/HCA began planning for the Year 2000 in 1996. We established a Y2K Executive Committee that includes our CEO and other senior managers, and we periodically update our Board of Directors on our progress. In addition, we have formed a multi-disciplinary Y2K support team made up of physicians and other health care professionals, information systems (IS), engineering, risk, financial, audit and other experts to provide guidance, oversight and support for our facilities. This team is currently monitoring over \$1.4 million assets in our medical equipment, IS infrastructure and facility and physical plant tracks.

We have also worked closely with other groups and organizations on the Y2K issue. These include the American Hospital Association and the Odin Group. The Odin Group is a collection of healthcare-related companies that include equipment manufacturers, hospitals, pharmaceuticals, health equipment manufacturers and others involved in the healthcare process.

Our Y2K efforts have included activities such as contingency planning, coordination with our fiscal intermediaries, medical equipment and device planning. I would like to talk briefly about our activities in the medical equipment and medical device area.

MEDICAL EQUIPMENT PLANNING

Medical equipment planning has been and continues to be one of the key areas in our Y2K planning effort. Our process for the evaluation and remediation of medical devices includes the following:

1. *Inventory.* This involved an inventory of all of our medical equipment assets. With few exceptions, this included anything that had a battery, electrical power or power cord. The current medical equipment inventory includes over 450,000 pieces of equipment. Our next step in this process was to classify the equipment.
2. *Classification.* In an attempt to prioritize our medical equipment and device planning efforts, we developed a classification system. This classification system enables us to focus our efforts on medical equipment that are essential to provide patient care. The classification system includes mission critical equipment, which includes life-support equipment such as ventilators and anesthesia machines, and impact ratings one through four. The next step in our process was vendor research.
3. *Vendor Research.* We identified approximately 880 prevalent vendors in the Columbia/HCA medical equipment network. We then surveyed each of these vendors for compliance information. I am pleased to say that 95% of these vendors have responded to our request for compliance information.

4. *Evaluation.* After the research component was completed, we analyzed the survey results using a 3-step process. Vendor responses were evaluated by our survey teams, subject matter experts and then risk management experts, before being published in our internal database. We now have compliance information on over 28,000 items in this database, including 11,000 in the medical equipment track. Our facilities can now match their equipment back to this database to determine if it is compliant or non-compliant.
5. *Facility Decisions/Remediate.* Once our facilities complete an equipment match to an item in our internal database and have identified the equipment that is non-compliant, or has a limited compliance status, they can plan accordingly. Their options include:
  - 1) use the equipment “as is” where the Y2K impact does not affect how the equipment is used in a patient care setting,
  - 2) plan a “workaround”,
  - 3) consider an upgrade,
  - 4) replace the equipment or,
  - 5) retire the equipment. The facility evaluation is based on the equipment classification and how this equipment is being used in the facility.

Our research and evaluation of medical equipment varied based on the equipment's classification. For example, stricter acceptance criteria from vendors were required for mission critical and impact level one devices.

Of approximately 450,000 medical equipment assets, over 190,000 are “mission critical” or “impact level one.” Approximately 92% of these mission critical or impact level one devices are compliant, while approximately 8% of these have been identified by us as limited or non-compliant and will require remediation.

In addition, we have identified 51 models, representing over 800 pieces of mission critical or impact level one medical devices, which we have placed in a status of “unknown” because the manufacturer has indicated they are not evaluating the compliance status of the devices or for which we have not received acceptable vendor information.

There are several issues we feel might be of particular significance to the Subcommittees. I'd like to take a moment to discuss these with you.

#### PROOF OF COMPLIANCE

The General Accounting Office (GAO) has indicated that medical device manufacturers should provide to the FDA and VHA documentation of the tests they have conducted on their devices, so they can determine whether or not the equipment was compliant. As I have previously stated, we required different levels of information from our manufacturers, based on the impact level of the equipment.

For mission critical and impact level one medical devices, we asked the manufacturers for version specific compliance information, as well as documentation to prove that they had performed testing. We also required them to provide testing documentation, or testing scripts and protocols indicating appropriate due diligence was exercised. There are some obvious advantages in having the FDA manage and standardize such a process, but unfortunately it is probably too late to initiate this effort.

#### FDA CLEARINGHOUSE

Although we understand that the FDA has established a clearinghouse of medical devices, our approach has been to gather information directly from the manufacturers. While the clearinghouse provides a source of information for hospitals, there are areas for enhancement of the site, which would make it more user friendly. These include consistency in the presentation of compliance data, a mechanism for tracking manufacturer's compliance updates or changes and standardized requirements for compliance information acceptance criteria.

#### HOSPITAL MEDICAL DEVICE TESTING

To summarize our process at Columbia/HCA, we begin with a detailed inventory of our medical devices, including model, version and in some cases serial number.

Next, we match compliance information from the manufacturer with the specific device in our inventory. We rely on the manufacturer to be the authoritative source for compliance information, and have adopted a testing policy based on the ECRI recommendations that testing should not be performed by any one other than the manufacturer, except in cases where insufficient information is available from the manufacturer.

## RESPONSIBILITIES

We believe that the healthcare providers, the equipment manufacturer and the FDA all have responsibilities in this process. The provider must identify all their medical equipment, obtain the compliance information from the manufacturer, and then determine if the Y2K impact requires remediation. The manufacturer should be responsible for accurately determining the Y2K status of its equipment and communicate that status, including specific details about what makes the device compliant or non-compliant to the healthcare community. The FDA can support these initiatives by requiring the manufacturers to determine the compliance status of all of their equipment, what the impact is, the availability of upgrades, replacements or workarounds, and ensuring that there is an easily accessible mechanism for all healthcare providers to get the information, including updates.

Of special interest is the need for manufacturers to provide compliance information for all of their devices, as some have chosen not to test obsolete or retired devices.

## SUPPLY CHAIN ISSUES

There are several supply chain issues related to medical equipment. These are:

- 1) availability of upgrades and service personnel to fix the non compliant equipment, and
- 2) availability of disposable supply items and reagents that are required for operating the medical devices.

Hoarding of hospital supplies has recently become a concern in the industry. We are working closely with our peers, the American Hospital Association, our suppliers and distributors to evaluate the supply chain and put safeguards in place to ensure uninterrupted supply availability. In our opinion, hoarding or stockpiling of additional supplies could create shortages well ahead of the Year 2000 transition. We encourage all parties to work collaboratively on this critical issue.

## CONCLUSION

Columbia/HCA is taking the initiative to manage the Year 2000 issue in order to protect the safety of our patients and to continue providing quality health services.

There are serious challenges ahead of us, but we are confident that the healthcare industry will meet these challenges. This effort requires the support and cooperation of both public and private sectors. We appreciate the opportunity to testify today and welcome any questions you may have at this time. Thank you.

Mr. UPTON. Thank you.

Mr. Nunn.

**TESTIMONY OF JOHN C. NUNN**

Mr. NUNN. Good afternoon. I am John Nunn, vice president for Patient Care Services at Henry Ford Hospital, part of the Henry Ford Health System in Detroit. I also co-chair the Systems Y2K Contingency Planning Committee. I am here on behalf of the American Hospital Association's 5,000 hospitals, health system networks, and other providers of care.

Most of the Nation's hospitals expect to be Y2K compliant by January 1, 2000, based on the results of the nationally representative AHA survey. Of the remainder, almost all expect to be sufficiently prepared that critical operations will not be affected. Approximately 2,000 hospitals responded to the AHA survey which was conducted in February: 5.7 percent of the hospitals said that their medical devices were compliant, 90.4 percent expected their devices to be compliant by the year end or expected no problems in their operations, and only .5 percent expected compliance with possible adverse effects.

Henry Ford Health System is in the middle category. Our devices are not 100 percent compliant, but like the great majority of hospitals, we expect no problems as a result. Put another way, all of

our devices may not be compliant, but our hospitals themselves will be.

At Henry Ford we have about 25,000 medical equipment devices; we have completed the Y2K assessment in all but 7,800. Those are held up largely because the communication process between us and the manufacturers is ongoing. Some cases, especially in older devices, simpler devices, or where manufacturers are out of business or merged and no longer servicing their devices, we are having difficulty getting devices declared or certified compliant.

Of the items we have assessed, only about 3 percent, or about 500 devices, required action. Of those, 60 percent required a software upgrade; 20 percent will be subject to what we call a workaround, which means that staff can work around the problem without modification of the device; 18 percent of the equipment will need to be replaced. Remediation is required if the two-digit date in the medical device's computer chip is used in a calculation, archiving or sent to another computer. The decision to upgrade or replace the device depends on availability and cost. If the data is not critical used in one of these calculations, the workaround solution may be used.

For example, we are replacing or upgrading some of our EKG machines because they report to a central reporting computer. We will upgrade that equipment. Our standalone EKG equipment, on the other hand, may show the wrong date and be technically not compliant, but we will work around by striking that date, writing in the correct date on the report, and signing the correct date.

Most devices that we still need information on are not critical care or the life support area. We have machines in our labs that mix—shake blood samples, for example; it monitors other equipment that do not have a safety hazard associated with them. While we are convinced that many of these devices which are electric will not be affected, until we hear from the manufacturer, we are hesitant to declare them compliant. As January 1 approaches, we will make those decisions and are prepared to move ahead without manufacturer information.

We do rely heavily on the manufacturer testing and information, and the information we have been receiving appears to be reliable. As the new year approaches, if we cannot get the information we need, we will have four options: Try to do limited testing ourselves; hire a third-party tester; wait until the date change and then recalibrate the device to make sure it works, using our normal QC processes, or ultimately retire or replace specific devices.

No matter how hard we prepare, surprises happen. Fortunately, hospitals are experienced in and ready for surprises. Whether it is Oklahoma, Kansas, Colorado, Georgia, forces of nature, failures of man, hospitals expect the unexpected. Last summer a construction company dug through our hospital's main power line. Ultimately, we lost two-thirds of the power to our hospital, and we were able to manage that situation without harm to our patients.

I note that my time is up and am just entering my conclusion. Of course, Y2K could be different, but then, again, we plan for the unexpected. Y2K is not unexpected. It is something that we know will happen; it is at a known time in a controlled environment. We have identified the contingencies we need to prepare for and are

preparing for them. I believe the hospitals and the health systems will succeed because of the people inside of them. Emergency department personnel to the CEO do this type of work and are prepared to make the decisions that will be required.

I would be glad to answer any questions.

[The prepared statement of John C. Nunn follows:]

PREPARED STATEMENT OF JOHN C. NUNN, VICE PRESIDENT FOR PATIENT CARE SERVICES, HENRY FORD HOSPITAL ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. Chairman, I am John C. Nunn, vice president for patient care services at Henry Ford Hospital, part of the Henry Ford Health System in Detroit. I am here on behalf of the American Hospital Association's (AHA) nearly 5,000 hospitals, health systems, networks, and other providers of care.

The AHA and its members are committed to continuing the smooth delivery of high-quality health care, at the turn of the century and beyond, uninterrupted by the calendar change that will occur at midnight December 31. We appreciate this opportunity to update you on our efforts, to outline the role that the AHA has taken in aiding the health care field, and to focus on what hospitals are experiencing as they work to assure themselves, their patients, and their communities that the medical devices and equipment they rely on will operate safely.

#### PROGRESS ON Y2K COMPLIANCE

The majority of the nation's hospitals expect to be completely "Y2K compliant" by January 1, 2000, based on the results of a nationally representative survey we conducted. Of the balance, almost all expect to be sufficiently prepared that critical operations will not be affected. The survey occurred in February 1999, and medical device readiness was one of the focuses. Respondents represented not-for-profit and investor-owned hospitals in urban and rural areas. Following are highlights from the medical devices portion of the survey:

- 5.7% of hospitals said their devices were compliant when they responded in February.
- Another 90.4% of hospitals expected their devices to be Y2K compliant by year end or expected no problems in their operations.
- 0.5% expected non-compliance with possible adverse effects.

In the survey, hospitals were asked whether their medical devices would be compliant, or noncompliant with no adverse effects. This is important, because some medical devices could technically be labeled non-compliant, even though they will not fail to operate as a result of the date change.

For example, an EKG machine may provide accurate heart rate information, while the strip recording the test information notes the date of the test incorrectly. In such cases, medical personnel would simply write the correct date onto the read-out. In no way would this machine be a danger, but it technically would be labeled non-compliant because it did not recognize the date change.

#### HOW HOSPITALS ARE PREPARING

In general, hospitals have been taking the following steps to ensure the safety and reliability of their medical devices at the turn of the century:

- Taking inventory of all equipment and devices—identifying which may be potentially affected by Y2K.
- Determining which are actually affected and how their functioning will be altered—this is done through contact with the manufacturers to get the results of their assessments and testing.
- Taking follow-up action if those devices or equipment are affected by Y2K—depending on the device or equipment, this may mean repairing, taking out of service, or training staff on how to use the equipment going into the new year.
- Developing contingency plans—even with all the advance preparations. Hospitals still need to anticipate the unforeseen.

#### CONTINGENCY PLANNING

America's hospitals and health systems are in the business of dealing with the unexpected. They are used to mobilizing quickly in the face of floods, hurricanes and potentially disastrous events that are an unfortunate fact of life. There is no reason to believe that they will not also be ready for the Year 2000, whether or not every medical device in the hospital is Y2K-compliant.

Patient safety is the highest priority for hospitals and health systems. Our ultimate contingency plan is to take care of patients at the bedside—as we do 24 hours a day, seven days a week, 365 days a year. Should a medical device turn out to be non-compliant, it is very likely that the ramifications will be limited, because it is a hospital's people who take care of patients, not a hospital's medical devices.

Hospitals are examining a range of options, such as having extra staff available for the date change and for the few days after, and not scheduling elective surgeries, thus ensuring that only people who absolutely need to be in the hospital are there.

This is not being done out of a sense of panic, but to provide the broadest latitude for dealing with the unexpected. Some devices and equipment can only be operated in real-time—that is, after the clock turns from Dec. 31 to Jan. 1—and hospital personnel will literally watch this equipment's clock change to ensure that it works properly before allowing it to be used for patient care. The ultimate contingency plan is to provide care the old-fashioned way in the unlikely case of a modern medical device impeding care.

Some outside factors could also have an indirect effect on how our people deliver care. Specifically, it is incumbent upon hospitals to prepare now to respond to the potential loss or disruption of *any* essential hospital processes or services, and our survey indicates that our members are doing just that. They are directing their efforts both internally across hospitals' facilities, and externally within communities. This includes working with such entities as utility companies, emergency medical services, and other health care providers.

According to the AHA's survey, 66 percent of hospitals have initiated contact with utilities in their area; 44 percent have initiated contact with other hospitals; 38 percent have initiated contact with fire and police authorities; 36 percent have initiated contact with ambulance services; and 35 percent have initiated contact with their local governments.

#### RELYING ON MANUFACTURERS

Hospitals have historically relied on manufacturers' representations of the fitness and safety of their products. There is a sound reason for this: Manufacturers are in the best position to analyze and test their products, and they have a regulatory obligation to do so. Absent some bona fide basis for believing that a manufacturer's compliance statement is inaccurate, hospitals need to rely on the longstanding presumption that manufacturers are acting in good faith and issuing information backed up by proper analysis and research.

The FDA's Y2K guidance to manufacturers emphasizes the responsibility of manufacturers for their products' Y2K compliance and safety. FDA has stressed that the technical know-how for determining the compliance status of devices rests with the manufacturers.

A complex question that hospitals face is whether to undertake independent testing of their medical devices and equipment. This is a decision that ultimately must be made using the judgement of the leaders of each individual hospital or health system.

ECRI, an international nonprofit health services agency that is recognized as the "Consumer Reports" for biomedical devices, recently published its position recommending how health care organizations should address the Y2K medical device testing issue. At AHA's request, this position statement was reviewed and discussed by a number of health care systems and biomedical manufacturers. Considerations for evaluating the thoroughness of a manufacturer's compliance disclosure statement also were discussed. The AHA has made the ECRI paper available on the AHA Web site and issued a companion advisory.

The ECRI statement cautions that a program of testing is not a panacea for health care providers. Rather, ECRI recommends that health care facilities address the Y2K medical device problem in the following way:

- Obtain manufacturer information regarding Y2K compliance status of any susceptible medical devices in their inventories either directly from the manufacturer or through the Food and Drug Administration (FDA) or a commercial data base.
- If a facility has received complete compliance information for a device, testing of that device by the health care institution is not necessary.
- If clear and complete information on a device's Y2K compliance status cannot be obtained, the facility should perform Y2K testing or take other appropriate action.

The ECRI position identifies reasons why health care institutions should proceed cautiously when considering a testing program, including the lack of expertise and information at most institutions to perform an adequate level of testing. ECRI argues, in fact, that the testing a provider can accomplish is superficial and may pro-

vide false assurances about compliance and introduce a wholly different set of problems.

Although a few hospitals have identified discrepancies between what some manufacturers have reported and their own tests of medical equipment, ECRI believes that the total number of these occurrences is extremely small and none are mission critical.

The ECRI position separately addresses situations in which testing is warranted: devices that are interfaced as a system, those with replacement parts, and those user-modified.

#### THE ROLE OF THE FDA

The AHA, as part of the National Patient Safety Partnership, has been collaborating with the FDA to ensure that its Federal Year 2000 Biomedical Equipment Clearinghouse is receiving accurate and useful information from manufacturers. This information, easily available on the agency's Web site at [www.fda.gov](http://www.fda.gov), has been improved significantly.

As the General Accounting Office recently testified before these subcommittees, "In collaboration with the National Patient Safety Partnership, FDA is in the process of obtaining more detailed information from manufacturers on noncompliant products, such as make and model and descriptions of the impact of the Y2K problem on products left uncorrected. For example, FDA sent a March 29, 1999, letter requesting that medical device manufacturers submit to the clearinghouse a complete list of individual product models that are Y2K compliant."

It is critical that the FDA continue to closely monitor the reporting of manufacturers about their medical devices and equipment. FDA has the expertise, the resources, and the authority to ensure that products are safe and reliable.

At the same time, we believe that the FDA should play a "rumor control" role, monitoring such arenas as the Internet and the media to make sure that information that circulates about the effects of Y2K on medical devices and equipment is accurate, and correcting it when it is wrong.

#### Y2K LIABILITY

Hospitals cannot meet the Y2K challenge alone. We depend not only on medical device manufacturers, but also on vendors and suppliers, software companies, even the companies that maintain the elevators we use to transport patients, to name a few. Hospitals have made hundreds of thousands of contacts through letters and phone calls to learn whether manufacturers' and vendors' products are Y2K compliant and, if not, what modifications may be necessary to bring them into compliance.

In most cases, hospitals depend on manufacturers and vendors for information and support; hospitals cannot make the changes themselves. Unless hospitals are provided the necessary information, they will not be able to take appropriate action, including the development of responsible contingency plans. Vendors and manufacturers must take the initiative for several reasons. From a legal perspective, license agreements, warranties and other protections will be at risk if the hospital takes action on its own. From a practical perspective, only the vendors and manufacturers have the know-how needed to make technical evaluations and recommendations.

In spite of all that is being done, some problems may still arise. The AHA and its member hospitals understand and appreciate the desire to avoid litigation. Dollars diverted from the delivery of health care are dollars lost to the mission of hospitals. In considering any proposal for Y2K liability reform, hospitals and health systems have one overriding concern: that their ability to deliver high quality care will not be hurt in any way.

We want to ensure that hospitals remain on a level playing field when defending personal injury cases. Hospitals must retain all of their current rights to take legal action against a vendor or manufacturer whose product is involved in a claim. While we believe that the legislative proposals do not intend to create a disadvantage for hospitals, it is essential that, if a hospital is sued by a patient for a Y2K related event, explicit language be included in any proposal to ensure that the hospital has the same recourse against a vendor or manufacturer as it has today. H.R. 775, recently passed by the House does this. We are working to assure that the Senate includes a similar provision in their Y2K legislation.

#### THE ROLE OF THE AHA AND OTHER ASSOCIATIONS

Mr. Chairman, all of the activities I've described above are part of an overall effort by the AHA and its state associations to help hospitals and health systems in their Y2K preparation. This effort includes:

- Working with state hospital associations to sponsor Security Third Millennium (SIHM), an Internet tool helping health care providers get information to minimize malfunction or failure of biomedical devices and equipment on January 1, 2000;
- Developing a members-only Y2K section of AHA's Web site with up-to-date news and resources to help manage the Y2K computer challenge;
- Using a toll-free 800 number to provide Y2K information to members on educational opportunities, peer and consultant referrals and speaker recommendations;
- Creating the "Y2K: Mission Critical" executive briefing, a notebook for hospitals that outlines the Y2K problem and offers information on how to deal with it;
- Using AHA's publications to provide members with information, including "The Clock's Ticking" column, devoted entirely to Y2K, in AHA's weekly newspaper;
- Developing the members-only "Y2K Communications Action Kit," a resource with tools to help communicate a hospital's Y2K progress with the public; and
- Distributing a contingency planning workbook with templates to help hospitals create internal and external back up plans.

The AHA, along with state, regional and metropolitan hospital and health system associations, is also working hard to make sure that America's hospitals and health systems are informed about, educated on, and assisted with Year 2000 contingency planning. We recently distributed to every AHA member a briefing on hospital contingency planning. This briefing emphasizes the interdependent nature of health care, and stresses the need for hospitals to plan in advance, with their key partners, how they will handle potential Y2K-induced losses or disruptions. This executive briefing was followed up by "how-to" materials for hospital contingency planning, including a business continuity planning guide.

In addition, the AHA will be working with the Federal Emergency Management Administration to coordinate emergency preparedness efforts at a national level with contingency planning taking place at individual hospitals in local communities. We recently brought together representatives of major health systems and health care manufacturing and supply companies to discuss how we can provide guidance to the health care field on issues related to Y2K preparedness and concerns about health care equipment and pharmaceutical and medical supply stockpiling. We are also participating in the President's Y2K Council's roundtables on the issue of stockpiling.

#### THE ROLE OF CONGRESS

As I have described, health care providers and the associations that represent them are devoting significant time, resources and energy to preventing potential Year 2000 problems from affecting patient safety. It is essential that we all look for ways to help prepare America's health care system for the turn of the century, and Congress can play an important role. Your attention to this issue, through hearings such as this, reflects your understanding of the gravity of the situation.

One major step toward Y2K compliance occurred when Congress passed its "Good Samaritan" legislation. By shielding from liability the sharing of information among businesses that provide it in good faith, this law encourages all parties—providers, suppliers, manufacturers, and more—to work together.

We ask you to help America's health care system avoid Year 2000 problems by taking several other steps:

- Congress should provide the FDA with any additional authority or resources it needs to ensure the necessary information is disclosed by medical device manufacturers, and to serve a "rumor control" function regarding devices.
- Recently, John Koskinen, chairman of the President's Council on Year 2000 Conversion, mentioned the possibility of creating a contingency fund from which states (in the case of Medicaid, for example) or hospitals could draw monies needed to continue operating in case of a Y2K disruption. We support that principle, and would be glad to be a part of any discussions concerning how such a fund should be set up.
- MedPAC has included in its hospital prospective payment system update recommendation for fiscal year 2000 an additional 0.5 percent to cover hospitals' costs of becoming Y2K compliant. We ask Congress to increase the congressionally mandated hospital update factor by 0.5 percent to reflect this MedPAC recommendation.

#### CONCLUSION

America's hospitals and health systems, their state associations, and the AHA are partners in the effort to prepare for the Year 2000. We believe that most manufac-



turers are being forthcoming and complete in their assessments of the medical devices they provide to hospitals. We look forward to continuing our work with you, the FDA, and medical device manufacturers in ensuring a smooth—and healthy—transition into the new millennium.

Mr. UPTON. Thank you very much.

I will recognize first the vice chair to the subcommittee, Mr. Burr, for 5 minutes.

Mr. BURR. Thank you, Mr. Chairman.

Mr. Smith, let me commend HIMA for I think going above and beyond what associations are set up, but with Y2K we have got somewhat of a circumstance we have never been faced with before. I think it is wise for the association to engage to the degree that they have, and I am hopeful that will be in a form of a partnership as well, but the Federal Government will do equally their share.

Let me just ask you, going back to this point where we begin to panic, if in fact we have a product in the marketplace that is non-compliant, can the manufacturers handle some type of recall in 90 days?

Mr. SMITH. As I listened to that earlier discourse, I was struck with the fact that perhaps one manufacturer could handle a recall in 90 days. I am not so sure that many, many multiple manufacturers could handle the recourse in that case.

Mr. BURR. And the fact is that we don't know whether we will have any problems, or whether we will have 10 problems, or whether we will have 100 problems. Is that a pretty safe assumption right now?

Mr. SMITH. It is a safe assumption that we don't know that. I think it is a safe assumption as well that we are all working to mitigate those problems such that we have many fewer than most.

Mr. BURR. And I think—

Mr. SMITH. I would like to add one more thing—I am sorry.

Mr. BURR. Yes, sir.

Mr. SMITH. And that is that I think we have lost, to some degree, the ideology that, as the year 2000 gets closer, there is much more focus and effort put on trying to solve issues associated with the year 2000. It is very common-sense to me that a year ago, having not been as focused on the problem, we see things in a certain way. A year later, 6 months later, the dynamic nature of this, we are making tremendous strides, I think, maybe exponential strides, to continue to address things. I think that is true throughout the healthcare arena, by the way.

Mr. BURR. I think one of the responsibilities of this committee is to instill the same sense of urgency—

Mr. SMITH. I agree.

Mr. BURR. [continuing] in all areas of the Federal Government.

Let me ask you, Ms. Williams, who do you think as far as Federal agencies has the oversight over this issue as it relates to hospitals? Who would you expect to contact you relative to Y2K-compliance issues from the Federal Government?

Ms. WILLIAMS. Probably the FDA. Possibly the HCFA, but primarily FDA.

Mr. BURR. Mr. Nunn?

Mr. NUNN. I think that the best source of communication will come from the manufacturer. The most effective source, if we do get communicative from the government, I think it is the FDA.

Mr. BURR. Do you see the FDA by design or just because nobody else wants to deal with it as the oversight agency?

Mr. NUNN. Yes.

Mr. BURR. It wasn't a yes or no, but I will take it by design.

I ask those specifically for Dr. Shope, because he is here, interested enough to stay, and I think it is important that they understand how hospitals look at FDA's role relative to the Y2K, when they go back and try to answer some of these questions.

Ms. WILLIAMS, for a hospital that has not done what Columbia has done, gone through, looked at the number of items, looked at contacting manufacturers, and asked for proof of compliance to determine how many potential problems you may have in your facilities, let us assume that today they got that sense of urgency; can they go through the process that Columbia has between now and January 1, 2000?

Ms. WILLIAMS. I would say it would depend on the size of the hospital. I mean, if they had a very focused effort. But again, it is going to depend on the size of the hospital, the number of—

Mr. BURR. You said for Columbia you started working in 1996, or at least you began to identify the problems in 1996. Is it realistic that there is a hospital that has the capabilities in a 7-month period now to actually go through and evaluate all their devices?

Ms. WILLIAMS. I would say it would be difficult, but if they applied proper resources and, you know, very focused efforts.

Mr. BURR. The smaller the hospital, the fewer the resources; the larger the hospital, the more the resources, but larger hospitals also have more equipment.

Ms. WILLIAMS. It would be difficult.

Mr. BURR. Okay. Let me ask you about the FDA clearinghouse real quick, because you made some statements, "although we understand the FDA has established a clearinghouse of medical devices." That statement leads me to believe that you haven't even looked at the website.

Ms. WILLIAMS. We have looked at it. We do not rely on it as our primary resource. We rely on the manufacturers.

Mr. BURR. Have you used it in any way as a resource?

Ms. WILLIAMS. Not as a primary resource. We have looked at it.

Mr. BURR. Have you used it as a secondary resource other than to just look at it? I would like you to be as honest as you can, because I think there is a tremendous reliance at the FDA on the clearinghouse as a search, and if it is not something that hospitals—I say that in a broad way—are utilizing today, I think it is important that we point it out to the FDA, so that they can plan accordingly.

Ms. WILLIAMS. As I said, we rely primarily on the manufacturers, and our primary use of the FDA website is for addresses of the manufacturers, and so forth.

Mr. BURR. Mr. Nunn, would you like to comment?

Mr. NUNN. We have used the FDA website. Talking to our clinical engineers, they do use it as an information source. They also

like that you can click into the manufacturer data bases when you are in and researching particular information.

Mr. BURR. If you identified something through the clearinghouse, is the likelihood that you would stop there if it expressed some concern, or would you then contact manufacturer?

Mr. NUNN. No, we are working directly with the manufacturers. We consider them to be our prime source of information.

Mr. BURR. So it is not a one-stop shop?

Mr. NUNN. That is correct.

Mr. BURR. I see that my time has run out. Let me just thank all three of our panelists today. I can ensure you that it is our intent to serve as a facilitator in making sure that sense of urgency, but also that the resources are available for that partnership between the private sector and the Federal Government. So that everybody can have the assurance, not just the size of Columbia, or your facility, Mr. Nunn, but also right down the rural health clinics that many of us have throughout our districts.

With that, Mr. Chairman, I yield back.

Mr. UPTON. Thanks. The Chair recognizes Mr. Klink.

Mr. KLINK. Thank you, Mr. Chairman.

Let me ask each of you, the GAO has argued that the FDA should not necessarily rely on medical device manufacturers' certification of Y2K compliance. Instead, the GAO has advocated the FDA itself certify such testing has been completed and then review the results themselves. So my question is, do you think that the manufacturers' certificate certifying Y2K compliance is enough or is it trustworthy, or do you think the FDA needs to go behind such certification and review the data itself? Let me start with you, Mr. Smith.

Mr. SMITH. From my perspective, I believe we have been doing this all along from an industry perspective for many years prior to Y2K. And therefore, I think the information that is there is sufficient and should be sufficient. I think the GAO request to go beyond that on behalf of Y2K, quite frankly, is another intervening step. I understand their concern, but at the same time I think there is a process in place that has been in place for a long time that has met both the industry's needs and, more importantly, met the needs of patients during that time as well.

Mr. KLINK. Thank you. Ms. Williams.

Ms. WILLIAMS. We agree with that.

Mr. KLINK. Mr. Nunn.

Mr. NUNN. Yes, I agree with that.

Mr. KLINK. You concur?

Is there a role that all—let me go back and ask each of you and maybe start with you, Mr. Nunn. Do you see a role for the FDA in reviewing any of these compliance certificates? What role would you think the FDA should have?

Mr. NUNN. I agree with Dr. Shope that the FDA's role is in the assurance that their process is appropriate rather than individually looking at equipment. And if there is some specific equipment, in terms of high-risk equipment, that it is felt that an additional level of diligence is required, I would be supportive of that.

Mr. KLINK. Ms. Williams, you concur? Mr. Smith?

Mr. SMITH. I would agree with Dr. Shope's comments that the issue is probably the critical items in that—again, while I don't think it is necessarily based on the process that goes on, the 60 categories that he referenced being critical, et cetera, if the FDA feels that is where they should go from a HIMA perspective, and certainly from a Baxter perspective, we would be very supportive of that.

Mr. KLINK. Ms. Williams, what particular types of equipment do you think, at the present time, we should be most concerned about regarding Y2K compliance?

Ms. WILLIAMS. I have my colleague, Don Workman, here with me who is very technically oriented in this regard. Might I defer that question to him?

Mr. KLINK. Mr. Chairman, is that fine?

Mr. UPTON. Sure.

Mr. KLINK. Pull a chair up, sir. Welcome to the committee.

Mr. WORKMAN. Kind of like Thanksgiving.

Mr. KLINK. If you are the turkey, right?

Invited to a party.

Mr. WORKMAN. If I understood the question or heard it correctly, what types of devices should we be concerned about?

Mr. KLINK. Yes, what devices should we be most concerned about concerning Y2K compliance?

Mr. WORKMAN. We have a classification system that has categorized approximately 700 medical device categories. We are focused on the mission-critical in level one. These are devices that would have some sort of impact on patient safety or patient care—either deliver care to a patient; they are electrically charged in some way, shape, or fashion, or a failure of these devices would impact patient safety or business continuity.

Mr. KLINK. Does anyone else, Mr. Smith or Mr. Nunn, have anything to add to that?

Mr. NUNN. No.

Mr. SMITH. No.

Mr. KLINK. You concur?

The GAO mentions in their testimony some hospitals have had their own in-house compliance engineers test biomedical equipment that they believe is the most susceptible to the Y2K bug. These hospitals reportedly told GAO that this was proper due diligence regarding Y2K testing. This seems to imply that hospitals not doing this type of in-house testing are somehow being negligent with regard to the public's health and safety. Do you believe that every user of a biomedical device should be doing their own testing? In other words, is there a certain group of providers such as hospitals that should be doing their own in-house testing?

I will start with you, Mr. Smith.

Mr. SMITH. I think, as I mentioned earlier Congressman, I don't think they do. I think the process is in place, and has been in place for quite a while for medical device manufacturers, per the FDA, to meet those standards. We follow good manufacturing practices; we have for a long time, and I think this has become an issue simply because we are dealing with the year 2000. Left to our own device, this would be going on as it has many years prior to this.

Mr. KLINK. Ms. Williams.

Ms. WILLIAMS. We agree with that.

Mr. KLINK. You don't have your own in-house biomedical engineers at Columbia?

Ms. WILLIAMS. We do, but we are not——

Mr. KLINK. Can you pull the microphone over a little bit?

Ms. WILLIAMS. We do have biomedical engineers, but we are not testing every piece of equipment ourselves. We are relying on the information that we got from the manufacturers.

We visited a number of manufacturers in order to understand the information that they are providing to us that we asked for their testing protocols when we did this compliance survey. So, we are, with the exception of those 800 pieces of equipment that we don't have answers on, we continue to try to get answers on that equipment, and if we don't, then we will make a determination what level of testing we need to do there. But, otherwise, we are relying on the manufacturer.

Mr. KLINK. Can you tell me how you determine what it is you test and how that is decided?

Ms. WILLIAMS. We have relied upon the manufacturers and an understanding of their testing protocols. The 800 pieces of equipment that we have not received information on we continue to try to go back to the manufacturer and receive information. If we don't, probably in the third quarter we will determine what level of testing we need to do on that equipment based upon the impact of the equipment on patient care.

Mr. KLINK. Let us forget about Y2K for 1 second. I assume that you didn't just hire these biotechnical engineers because the year 2000 is coming up; they work for you?

Ms. WILLIAMS. Right.

Mr. KLINK. At other times, how would you determine what you would have them test?

Ms. WILLIAMS. I need to defer that to——

Mr. KLINK. That is fine. Do they test everything that comes in or there is certain protocol as to what equipment they test?

Mr. WORKMAN. No, sir. When the manufacturers come in and do software upgrades or bring in new pieces of equipment, we depend on the manufacturer to certify that that equipment is ready for patient safety or patient care.

Mr. KLINK. Then, how do you determine what it is your people are going to test?

Mr. WORKMAN. We are following the ECRI guidelines. ECRI is a sort of the Consumer Reports for medical device testing. They came out with a position that said that, in the absence of adequate manufacturers' compliance information, a limited testing strategy should be put in place. Our program is focused on mission-critical and level one and we are going to follow a three-step process. Originally, we would hope that the original equipment manufacturer would test for us. If we are unable to do that, we are going to bring in an authorized service provider for that manufacturer, and if we can't get to that level, then we signed a contract with General Electric for their biomedical folks to come in and help test devices for us.

Mr. KLINK. What does this say about the hospitals that are not doing this testing? Do they count on hospitals the size of Columbia

to do this kind of testing? And is this information shared with other hospitals? And if other hospitals are doing tests, is that made available to you?

Mr. WORKMAN. I am not aware of a source for that type of information.

Mr. KLINK. Well, let me go back to the first part of my question. Does this make any statement about other hospitals that don't have the biotechnical engineers or biomedical engineers on staff, and aren't able to do the kind of testing that you do? I don't want to put you in a bad place; it just raises a question to me.

Mr. WORKMAN. I can express a personal opinion. I think some of those hospitals are going to have some problems meeting the deadline, given the 7 months that are left.

Mr. KLINK. Thank you very much.

Mr. Chairman, I see the red light is on also.

Mr. UPTON. Thank you.

Mr. Smith, first of all, I want to commend the work of HIMA, and with your testimony, congratulations certainly are deserved as you look at 100 percent compliance with your association and your ability to reach out. I think that is really terrific, and I want to thank you for that.

Mr. SMITH. Thank you.

Mr. UPTON. You know, as I think about my own congressional district, it is really a lot—it is a microcosm, I think, of the real Nation in terms of a blend between urban and rural. We have got small hospitals and larger ones like Bronson and Borges, which I certainly know, Mr. Nunn, you are familiar with. There has been a lot of association work, a lot of communication between the hospitals, whether they are affiliated or not, in terms of how to comply with a number of different things.

Do you feel that the State associations have done a pretty good job, and what relationship has Henry Ford had with some of the hospitals that it has on the other side of the State from me?

Mr. NUNN. We have been in communication with the State associations. There has been work on the issue and education around the issue, those kinds of things. We have met with hospital groups. In fact, we are meeting next week with a group of hospitals in the metropolitan Detroit area on this issue. Ultimately, though, I believe when it comes down to your devices and what your plans are for your devices, it becomes much more focused on the issues as they have been discussed here today, which is communication between the manufacturers, potentially FDA, and yourself, and what your plans are for your devices.

I think there has been, though, from what I can see, and in my discussions with our people who are involved in this, extensive communications with people outside of our hospital and other hospitals, whether it is trade groups, associations, at conventions. This has been on the agendas at conventions to be talking about it. So I think that communication has been there, but it won't drive the answer, which I think is between us and manufacturers.

Mr. UPTON. Do you think that the hospitals have had some feeling that they have had to reinvent the wheel, or do you think because of the association and the cooperation with other hospitals,

whether they be in the region or system that they might be affiliated with, that it has been a pretty good relationship?

Mr. NUNN. I think it has been a good relationship. It certainly was not our intention to reinvent the wheel, but to use the information that was out there and bring it into our organization and have it work for us. I think the information is there for people to do that.

Mr. UPTON. Ms. Williams.

Ms. WILLIAMS. We have worked actively with the federation members as well as the American Hospital Association and another group called ODEN, which is a research and advisory group dedicated to healthcare technology issues. Members of that group are equipment manufacturers, pharmaceutical companies, payers, and other providers, and we have worked within that group across the industry on the medical device issues as well as contingency planning. So we have been active in a lot of groups in terms of information-sharing and coordinated planning.

Mr. UPTON. You know, one of the questions that I have asked a number of my folks back home as they prepare for Y2K, they always seem to say we think we are going to be okay as long the power stays on or, you know, a variety of other units have made their successful effort. There has been talk about hoarding of supplies. You see that in the news media as well. Have the hospitals made any real effort, do you think, to hoard supplies in fear that the supply train may have some problem beginning January 1?

Mr. NUNN. Our pharmacy is working with the other pharmacy departments at other hospitals around the Detroit area, in conjunction with the manufacturers in the supply chain, to ensure that there is not a disruption in the supply chain for pharmaceuticals, because pharmaceuticals, in particular, the supply chain is long. If there is hoarding, there could be a problem. So we are working with the appropriate people to prevent that from happening. So I think there is recognition of the supply chain issues, and work is going on in those.

I think that one of the areas that support can be given is in helping manage the rumors and not having a panic situation going into the fourth quarter. If the public is convinced that the sky is falling, it will be very difficult, and there will be hoarding going on, and I think accurate information being distributed so that we are not a society in panic would be very helpful in this regard.

Mr. UPTON. Thank you. My light is on and I will recognize the chairman of Health and Environment, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

I did want to put into record that Dr. Shope is here to hear your testimony, and I think that is always very helpful. We appreciate your staying, Doctor.

Well, let us see, Baxter, your company is a global company—

Mr. SMITH. Yes.

Mr. BILIRAKIS. [continuing] and you have shared with us some apparently good work that your company is doing regarding addressing this issue. But you do business, as I understand it, in over 100 countries?

Mr. SMITH. We do.

Mr. BILIRAKIS. Yes, all right, and I don't want you to give me any details, but would you say that you are basically being prepared or are prepared insofar as the global is concerned?

Mr. SMITH. We have taken the same process in the other countries we have taken in the United States, which is from a business contingency plan perspective. We have gone out and contacted our customers and contacted all the elements, if you will, associated with making sure that we can provide consistent supply of products in that country. That could be something as broad as talking with the customs folks to making sure that the import/export activities don't go down as a result of a Y2K problem, or something as small as looking at a particular product that we only sell in that particular country.

Mr. BILIRAKIS. Well, how about a medical device that is manufactured in one of these other countries. I suppose maybe we could have asked FDA that, but in terms of, you know, their cooperation, compliance, and things of that nature, what can we anticipate there?

Mr. SMITH. From a Baxter—

Mr. BILIRAKIS. And I really don't know off the top of my head what device I could be referring to, but I would assume there are some out there that have been approved that are being used by Americans but manufactured elsewhere.

Mr. SMITH. I probably would defer that question to Dr. Shope, because I think he is probably better suited to answer it. From a Baxter perspective, those plants outside the United States where we do make medical devices fall into the same provisions as plants that we manage within the United States. So we run them just the same way.

Mr. BILIRAKIS. You run them?

Mr. SMITH. Meaning we follow the same manufacturing practices.

Mr. BILIRAKIS. If they are your plants, but if they are not your plants?

Ms. Williams, I know that, and I am not just referring to Columbia, but a lot of hospitals around the country, certainly many in my area, are having problems these days. What BPA 97 did to them—I know Herb Katz would want me to make that comment. And you know, in other words, they are having some problems. So, I know that this is an additional load, because obviously there is going to be some finances involved here.

With all that Columbia apparently has done, I think you have said that it has been done in cooperation with the American Hospital Association and with other groups. Is that right?

Ms. WILLIAMS. Right. That is right.

Mr. BILIRAKIS. Well, Mr. Nunn, you said that while all of your devices—I don't know that I am quoting you correctly—may not be compliant in your hospitals, but all of your hospitals will be, or words to that effect.

Mr. NUNN. Yes.

Mr. BILIRAKIS. What do you mean by that?

Mr. NUNN. If we have a device that we cannot get certified or determine that it is compliant, we will be prepared to either retire it from service or have a workaround. We know that some of our



EKG machines will not be technically compliant, and we will have a workaround in place, so that that does not impact the patient or our storage of information, which is really the——

Mr. BILIRAKIS. So, you are basically saying that you feel that your hospitals will be completely up to par by the year 2000, by January 1, 2000. So all of the medical devices may not be, but your hospitals will be——

Mr. NUNN. Yes.

Mr. BILIRAKIS. [continuing] will be alert, et cetera?

Mr. NUNN. Yes.

Mr. BILIRAKIS. That is what you are saying. Now, you know, I think I have kind of expressed it here; sure, we are concerned about the FDA role and things of that nature, but we also express, I think, maybe even more concern with devices at the hospital level, and rural healthcare, and, of course, in the homes, and that sort of thing.

What is the percentage of hospitals that belong to the American Hospital Association? I mean, they don't all belong to the AHA?

Mr. NUNN. No. There are 5,000 hospitals in the American Hospital Association.

Mr. BILIRAKIS. But there is a lot more than 5,000 hospitals out there.

Mr. NUNN. Yes.

Mr. BILIRAKIS. So you are working with your hospitals?

Mr. NUNN. That is correct.

Mr. BILIRAKIS. How about all the others that are not members of the AHA? In terms of being ready?

Mr. NUNN. I can't comment on their——

Mr. BILIRAKIS. This is not a pitch now for the American Hospital Association, although I would suggest probably a good idea that they all be members.

Well, all right, my time is up, but you know we are really concerned about this and I am not sure—I mean, frankly, I am a little more optimistic in listening to you all. I am not saying that FDA has lowered that optimism somewhat, but I guess I see a gap there, particularly when it involves the hospitals, home health, and what-not, which FDA apparently does not have overall jurisdiction responsibility for, and we not just really sure who is going to cover that gap. That is really what concerns me, I guess, more than anything else.

Well, we may have further questions. I was really going to ask these good people for some hard data on some of the things they have been telling us, but at this point, again, I don't want to add just make-work to their heavy responsibilities in this regard. If we request that, we will do so at another time and give you an opportunity to respond.

Thank you very much. Thank you, Mr. Chairman.

Mr. UPTON. Thank you, Mr. Chairman.

And I, again, appreciate the testimony from the witnesses, all the witnesses on both panels this morning. And we do have four votes in a row on the House floor, so we are going to be scurrying over there, but this hearing is now adjourned. Thank you.

[Whereupon, at 12:49 p.m., the subcommittees were adjourned.]