YEAR 2000 (Y2K) MEDICAL DEVICE ISSUES AND THEIR IMPACT ON THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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YEAR 2000 (Y2K) MEDICAL DEVICE ISSUES AND THEIR IMPACT ON THE DEPARTMENT OF VETERANS AFFAIRS

THURSDAY, SEPTEMBER 24, 1998

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:34 a.m., in room 334, Cannon House Office Building, Hon. Terry Everett (chairman of the subcommittee) presiding.

Present: Representatives Everett, Evans, Snyder, and Mascara.

Mr. EVERETT (presiding). Good morning. The hearing will come to order. The purpose of this morning's hearing is to examine the preparations of the Department of Veterans Affairs and the Food and Drug Administration for the Year 2000, Y2K, as we call it, compliance of medical devices used for the health care of veterans.

The basic question we want an answer to is can veterans be confident that the VA's medical equipment will work right on January 1, 2000. The answer to this very serious question is the same for the general public as it is for veterans.

This is the subcommittee's third hearing on Y2K issues. The last hearing was one year ago on September 25, 1997, also with GAO, VA, and FDA witnesses. I first publicly raised this medical equipment Y2K compliance issue at that hearing, and this hearing is to follow up on the specific issues and review progress.

As one of the largest health care systems in the country and the largest Federal system, the VA is one of the largest users of medical equipment, about $3 billion worth at 711 facilities. Obviously, the VA uses much of the same medical equipment for treating veterans that other public and private hospitals, clinics, and doctors' offices use for treating every American.

This subcommittee has been concerned for more about a year about the Y2K question relating to the VA's medical equipment. Because of our concern, in July 1997 I asked the General Accounting Office to do a careful study of the VA's health care delivery systems and Y2K. I asked GAO to include the Food and Drug Administration in the study because the FDA regulates the manufacturers of medical devices, including those used by the VA. Today, I am releasing the report, "Year 2000 Computing Crisis: Compliance Status of Many Biomedical Equipment Items Still Unknown." The title of this report tells us what it has found. (See p. 33.)

With only 464 days left until January 1, 2000, I find this information profoundly unsettling. We are running out of time to identify the medical equipment manufacturers who have produced equipment that has Y2K problems and get the critical equipment fixed or get it out of service. Some of these manufacturers are out of business. This is a very complex picture, because of the large number of and many kinds of medical devices in use.

We are confronted with a major public safety issue. It can't be left to chance or the hope that everyone will do the right thing. Of the thousands and thousands of medical devices out there, it only takes one critical noncompliant device to cause injury or perhaps even death. We can't tell veterans and the public, "Don't worry, you and your family can sue."

The VA and the FDA's jobs are to enforce or ensure safe health care for veterans and the public. We don't want to know if they are going to do it; we want to know how and when. Nothing less is acceptable. The objective should be coming as close as humanly possible to 100 percent certainty on the critical medical issue of compliance.

This morning, the first scheduled witness is our distinguished colleague, Senator Charles Grassley who has just been notified that they have back-to-back votes over in the Senate, and he is going to submit his comments for the record. I urge all here today to read those comments. They are very, very good. They are short, but very much to the point.

[The statement of Senator Grassley appears on p. 79.]

Mr. EVERETT. In addition to that, we have representatives of GAO, the VA, and FDA, and the Health Industry Manufacturers Association. I appreciate the cooperation of all to discuss this serious topic. They are all here voluntarily, and I welcome them.

Mr. Clyburn hasn't arrived yet, but I would recognize Mr. Mascara.

Mr. MASCARA. Thank you, Mr. Chairman. I would ask unanimous consent that the *Washington Post* article be placed into the record.

Mr. EVERETT. Without objection.

[The information follows:]

THURSDAY, SEPTEMBER 24, 1998 A23

Dodd Faults Firms' Year 2000 Reports

Medical Device Manufacturers Cited

By STEPHEN BARR
Washington Post Staff Writer

In a stern rebuke to manufacturers of medical devices, Sen. Christopher J. Dodd (D-Conn.) yesterday disclosed the names of companies that have not said whether their products are free of Year 2000 computer defects.

Dodd, who serves on a special Senate committee assessing potential threats caused by the so-called millennium bug, said the medical device industry has an "unacceptable" low response rate to letters sent by the Food and Drug Administration seeking Year 2000 data.

Because of the slow response, Dodd said he would submit a list of manufacturers that have not replied to the FDA for publication in the Congressional Record "for all Americans to see. . . . It is also my hope that this will serve as a wake-up call to other industries."

Some lawmakers and Clinton administration officials have expressed concern over the last few months about the lack of information from companies about the risks they face because of the computer problem, known as Y2K. At a July Senate hearing, Dodd and Sen. Robert F. Bennett (R-Utah) expressed frustration with the slow pace of notification to patients, doctors and hospitals on what types of medical devices might malfunction on Jan. 1, 2000.

There have been no predictions that patients will die because of the Y2K glitch, but some federal officials fear some devices, such as heart monitors and blood pumps, might not work as intended and pose a hazard to patient care.

The problem stems from the use in many computer systems of a two-digit dating system that assumes that 1 and 9 are the first two digits of the year. Without specialized reprogramming, the systems will recognize "00" not as 2000 but 1900, a glitch that could cause computer shutdowns or produce erroneous data.

Yesterday, Dodd said the FDA had identified 1,935 manufacturers of medical devices that might be vulnerable to Y2K problems but that only 755 had responded to a June FDA letter seeking information. This initial response rate "was indeed irresponsible," he said.

Dodd's lengthy list of companies included medical product firms in virtually every state and in some foreign countries.

But industry officials said the response rate is improving. More recent figures show 962 companies have responded to the FDA request for information—a doubling of the number responding since the July hearing held by Bennett and Dodd.

Alan H. Magazine, the president of the Health Industry Manufacturers Association (HIMA), said Dodd's statements reflected "a genuine concern for patient safety, which we share. We think tremendous progress is being made toward getting companies to comply with FDA's requests."

Many companies do not release data until they complete all of their product assessments, while others have found it difficult to track down data because of corporate mergers, HIMA said.

"We also suspect it is taking time for company information to get onto the FDA list, so there may well be a backlog," Magazine said.

Dodd's scolding of the industry came on the same day the Veterans Affairs Department and the Health and Human Services Administration announced they will jointly establish an online database to provide doctors, hospitals and patients with timely Y2K information on biomedical equipment.

The new Federal Y2K Biomedical Clearinghouse, operated by the FDA, can be found at this Web address:

www.fda.gov/cdrh/yr2000/year2000.html.

Data posted on the Internet site will be restricted to publicly releasable information provided directly by manufacturers, the VA said.

Mr. MASCARA. And I also ask unanimous consent that I be given the right to submit an opening statement for the record.

Mr. EVERETT. Without objection. I was going to do it myself, but that is fine.

Mr. MASCARA. Thank you.

[The statement of Mr. Mascara appears on p. 88.]

Mr. EVERETT. Dr. Snyder, you are welcome to submit anything for the record you like.

We will just move to panel two, and at this time I will recognize Joel Willemssen, Director of Civil Agencies Information Systems, Accounting and Information Management Division of the GAO, and ask him to introduce his panel.

Mr. Willemssen, before you begin, I want to commend GAO's work in producing this important report on the Y2K compliance status of medical devices. The GAO has performed a valuable public service by documenting for Congress and the public the current lack of compliance information about many medical devices.

This is a public safety issue, and I believe your report has led in this issue, even before it is released, to redoubled and more effective efforts so that these critical devices will be ready on January 1, 2000, or they will be identified as noncompliant devices and removed from service. If you will, go ahead.

STATEMENT OF JOEL WILLEMSSEN, DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY HELEN LEW, ASSISTANT DIRECTOR, CIVIL AGENCIES INFORMATION SYSTEMS, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE, AND NABAJYOTI BARKAKATI, TECHNICAL ASSISTANT DIRECTOR, OFFICE OF THE CHIEF SCIENTIST, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE

Mr. WILLEMSSEN. Thank you, Mr. Chairman, Congressmen. Thank you for inviting us here today to testify on biomedical equipment and Y2K. Accompanying me are Helen Lew and Dr. Naba Barkakati. As requested, I am going to briefly summarize our statement, and in doing so, I will cover two areas. First the status of VHA's and FDA's programs, and second, our recommendations detailing what we believe needs to be done in this area.

As you noted, Mr. Chairman, our report is being released at your hearing today, and that provides additional details beyond our statement.

First, regarding VHA, it has made progress in implementing its Year 2000 strategy, but it still does not know the full extent of the Year 2000 problems for its biomedical equipment. This is because it has not received compliance information from many of the manufacturers on its list of suppliers.

For example, about 100 manufacturers from VHA's list are no longer in business. In addition, the Postal Service returned to VHA slightly over 200 letters that were marked with no forwarding addresses. Further, among the manufacturers who have yet to respond is one who supplies high dollar, high value equipment to VHA.

Like VHA, FDA has also issued letters to manufacturers. However, the response rate to these letters has been disappointing, only about 12 percent as of July 30. In addition, according to FDA, it does not perform technical evaluations of manufacturers' responses to determine their adequacy. Rather, it reviews the responses only to determine whether all questions posed in the letters were answered.

Further, FDA does not plan to request test results from manufacturers that have renovated medical devices. FDA's list of compliant equipment also does not contain information on the equipment's make and model. In contrast, VHA's list does contain such information. Further, the Year 2000 compliance information publicly available through FDA does not include responses from many of the manufacturers that have responded to VHA.

Given where VHA and FDA stand, we have several recommendations to offer. Let me summarize those briefly. First, because some noncompliant equipment could pose a risk to patient safety, and because the Year 2000 compliance status of many items in VHA's inventory is not known, it is critical that VHA finalize its Year 2000 Contingency Guidebook and ensure that its medical facilities complete Year 2000 business continuity and contingency plans for equipment in their inventories.

Second, it is imperative that health care providers and users have access to compliance information from manufacturers so that they can take action on noncompliant equipment in their inventories.

Therefore, we recommend that the Secretaries of VA and HHS work together in developing a single data clearinghouse that provides compliance information to everyone. Among the items that we believe should be in that clearinghouse are model-specific information, the names of manufacturers that have not responded to requests for information, the names of manufacturers that are no longer in business, and the names of those who have not provided test results certifying Y2K compliance.

Finally, because health care providers are relying on manufacturers to validate, test, and certify that their equipment is compliant, there are no independent assurances that manufacturers have adequately addressed the Y2K problem for noncompliant equipment.

To address this, we are recommending that the Secretaries of VA and HHS first determine what actions should be taken on those manufacturers that have not responded to requests for compliance information. Second, determine what actions are needed to address equipment produced by manufacturers no longer in business. Third, review test results for critical care and life support equipment once determined to be noncompliant, but now deemed by manufacturers to be compliant.

And finally, determine what legislative regulatory or other changes are necessary to obtain assurance that the equipment is indeed compliant, including performing independent verification and validation activities of manufacturers' assurances.

Mr. Chairman, that completes a summary of our statement, and we would be pleased to address any questions that you may have.

[The prepared statement of Mr. Willemssen appears on p. 89.]

Mr. EVERETT. Thank you very much. Again, I think your entire report is worth everybody reading, and I hope they will take the time to do so.

Do you consider medical device Y2K compliance to be a serious public safety issue?

Mr. WILLEMSSEN. Yes, we do, Mr. Chairman, and in large part, it remains a critical issue because of the significant amount of unknowns that are out there. We are in a better position today than we were when you held your hearing a year ago. But as you mentioned, with the limited amount of time left, we've got a long way to go and we've got to get better knowledge on exactly where we stand, especially for those critical life-support related devices.

Mr. EVERETT. I mentioned earlier that your report is very thorough, and it is also very disturbing in that the still-unknown Y2K compliance status of many medical devices should light a fire under government agencies and the country's health care equipment manufacturers to put their efforts on an urgent basis.

You referred to the relatively short amount of time left. Does the GAO believe that the focus of the government's efforts should be critical medical devices, and by that, I mean the devices which would cause harm to patients and users if the date-sensitive functions do not operate properly?

Mr. WILLEMSSEN. We would definitely go in that direction. It is very parallel and similar to the kind of message we have delivered at other agencies for their standard information systems. You have got to set priorities and focus on the most critical items. That, clearly, is the case with biomedical equipment also.

And as we are recommending, for those items which are in the critical care life support area, we don't think it's enough just to rely on the manufacturer's assurance that everything is okay. We believe that you need to take it one step further and have some independent assurance that indeed, those critical devices are going to be okay.

Mr. EVERETT. And from your report, I gather the FDA knows some of these devices, but more importantly, there are others out there that they don't know about, is that correct?

Mr. WILLEMSSEN. That is correct, Mr. Chairman.

Mr. EVERETT. The FDA does not believe that listing all compliance products is necessary or cost-effective. I believe I read that you differed with that. What does GAO recommend?

Mr. WILLEMSSEN. You are correct, Mr. Chairman. We do have a disagreement with FDA on that. We think, as VHA has done, listing specific make and model information for biomedical equipment is especially useful in making sure that providers and users are aware of the status of those particular items.

It is especially important where you have situations where a company may have merged or bought out another company, with those companies making a general statement of Y2K compliance. It raises questions as to whether they have actually thoroughly checked all their devices.

And what kind of time period are we talking about? Are they fully aware that they have dealt with everything that they have sold over a given period of time? I might point out as an analogy, what we see in many agencies as they initially went into their Y2K

programs, were initial declarations that we think everything is okay, we've got it under control. As they went into further depth and detail in their programs, they found out differently.

Therefore, statements, for example, on FDA's website that Y2K doesn't apply to us, or that there is just a general statement of compliance, I think that should give everyone cause for concern.

Mr. EVERETT. Thank you. Mr. Mascara.

Mr. MASCARA. Thank you, Mr. Chairman. I had to step out and there was a question here, I hope if I missed it, maybe you can repeat the answer. But your testimony briefly cites some examples of potential risks to patient safety if certain manufacturers fail to ensure that their products are not Year 2000 compliant.

Can you give me some examples?

Mr. WILLEMSSEN. The risks really vary quite a bit. If you look at lower level risk, you could have a situation where the date is printing out as 00, and the medical provider would know right away that that is just a nuisance issue. You could have another situation where the date would be in a series of dates and may be ordered or arrayed chronologically, and if the medical provider didn't look at that carefully, they may misread that.

And then taken to a greater extreme, you could have calculations that are actually part of providing care to the patient. For example, one that has been identified is a radiation-related device that calculates dosage based in part on the age of patients. If that age is wrong, then you might get a wrong dosage.

So there really is a range of potential impacts here.

Mr. MASCARA. Thank you. Thank you, Mr. Chairman.

Mr. EVERETT. I know our next speaker has a professional, as well as a legislative interest, in it. Dr. Snyder.

Dr. SNYDER. Thank you, Mr. Chairman. Actually, Mr. Chairman, I found out a couple of days ago I passed my Family Medicine Boards that I have to take every seven years. I had to take them back in July. So I can still call myself a family doctor.

Mr. EVERETT. Congratulations.

Dr. SNYDER. Thank you. I just had one question. I noticed Dr. Kizer is on the witness list and is in the audience. The title of our hearing is the Hearing on Y2K Medical Device Issues and their Impact on the Department of Veterans Affairs.

From your perspective as you have looked at this issue, is there anything inherently different in the challenges facing Dr. Kizer versus a head of a hospital, say, a private hospital chain or a hospital in a town, or even the challenge facing a practitioner that prescribes and uses some of these devices.

Mr. WILLEMSSEN. In giving you an answer from a lay perspective, I don't think the challenge in terms of the questions that need to be pursued, varies dramatically. In fact, that is one of the reasons that we want to push for a single clearinghouse nationwide.

I have been with Chairman Horn at a series of field hearings and one of the issues that has come up is in the health area. One of the unfortunate things you hear is that all the different providers or major health facilities are trying to reinvent the wheel and collect information from manufacturers, what we see VHA and FDA doing. So it is not the most efficient process that we have.

We need to make it clear and publicize that we have one single clearinghouse that everybody can access, and it will have as rich and comprehensive information as possible, so that all these separate efforts don't have to go on. I can imagine the manufacturers certainly don't want to get all these letters repeatedly from different organizations asking for the same information.

Dr. SNYDER. I suppose the response, in terms of the need for a clearinghouse like you are talking about, we have some hospitals in Arkansas as there are all across the country, very small hospitals that still face the same challenge. Obviously, they are going to have to rely on somebody. They are not going to be able to evaluate all this themselves.

Mr. WILLEMSSEN. That's right and that's why it's critical that the word get out to those kind of hospitals: here's where you can go to get the information you need. Now, given that VHA and HHS have concurred with our recommendation to establish a single clearinghouse, we'd like to see when they are going to actually put it up and what it is going to contain. And we need to get that going as quickly as possible.

Dr. SNYDER. And obviously, there is liability concerns here, not only for the manufacturers of the products, but also for those of us who may prescribe or use these products. In terms of looking at the impact or potential liability concerns, if something goes awry when the Year 2000 kicks in, have those concerns—in your opinion, are they helping the process or hurting the process of coming to a resolution? Or do you have an opinion?

Mr. WILLEMSSEN. My nonlegal view of that is, for the most part, they have impaired the free exchange of information, not only in the biomedical equipment area, but all the other areas where we have been doing Y2K work.

Dr. SNYDER. Give me some examples of that, if you would.

Mr. WILLEMSSEN. Well, there would be a concern, for example, if a manufacturer tells FDA that, well, all of our products are Y2K compliant. When January 1, 2000 hits, one isn't compliant, and it has a significant impact on patient safety. Company x said it was compliant. Obviously, whatever the legal term is, negligent or whatever the case, you did not state the exact nature of the status of that device. Those are among the concerns that might arise.

Dr. SNYDER. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you. Did your report request that VA and HHS create a Year 2000 biomedical equipment clearinghouse?

Mr. WILLEMSSEN. Yes, we did make that recommendation, and I understand that VA and FDA plan to do that.

Mr. EVERETT. I have a release here in my hand where they have done that now. Thank you very much for your testimony.

Mr. WILLEMSSEN. Thank you, Mr. Chairman. Thank you, Congressmen.

Mr. EVERETT. Now I would like to recognize Dr. Kizer, the Under Secretary for Health, Department of Veterans Affairs.

Dr. Kizer, before I ask you to introduce your colleagues, let me just say that you have a tough time running and modernizing the VA and I, for one, appreciate your efforts that you have made, and the association we have had and your willingness to cooperate with

this committee. We may not always agree on everything, but I certainly appreciate the job that you are doing.

I want to say, however, that often the focus of some of our hearings are on what's gone wrong and not what's gone right. With the Y2K compliance of medical devices, clearly, the VA has been out front, setting the example for the rest of the health care arena. In part, the VA has been doing a job it shouldn't have needed to do, because it wasn't VA's primary responsibility to find out what devices were going to be compliant.

But to protect veterans, under your leadership, the VA has compiled the best data base in existence on the subject. I shudder to think where this would be if the VA weren't a large department with the resources and expertise to have accomplished that task.

However, the job isn't finished. But I do want to say that I highly commend the VA for the efforts it has made and the progress that you have thus far. After that endorsement, I know that you won't let veterans down, that you will make sure we will get there on time.

STATEMENT OF KENNETH W. KIZER, UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY LEONARD BOURGET, YEAR 2000 PROJECT MANAGER, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS, AND STEVEN WEXLER, CHIEF BIOMEDICAL ENGINEER, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS

Dr. KIZER. Thank you, Mr. Chairman. Your kind words are very much appreciated.

Let me introduce the two gentlemen with me at the table. On my right is Mr. Len Bourget, the Y2K Project Manager for VHA. On my left is Mr. Steve Wexler, the Chief Biomedical Engineer for VHA.

I appreciate this opportunity to testify before the committee, and especially with regard to biomedical equipment and medical devices. I would underscore that we share the committee's, the chairman's, and the Congress' concern about this matter.

I have included in my written testimony much more detail about many of the things that VA is doing in this regard and the things that we will comment about this morning, and I would ask that that be included in the record.

Mr. EVERETT. Without objection.

Dr. KIZER. As a preface to my further comments, I must say that it is somewhat ironic that advanced technology, which is the basis for so many of the wonders of modern health care, now presents potential hazards to patient care when the 21st century begins.

The committee is very familiar with the genesis of the Y2K problem, so I am not going to comment on that aspect of the issue.

As has already been commented upon this morning, there are thousands of medical devices that may be affected by one or more of the Y2K-related problems presented by this technology. While many of the problems that have been identified to date are relatively minor and can be fixed, I would underscore some of the comments made already this morning that emphasized that the critical problem we face today is that too many health care institu-

tions across the country simply are not positioned to accomplish those repairs, and in too many cases, simply don't know the extent of the problem they may have.

We have been working on this problem since 1996. Many of the details are in my written testimony. With regard to biomedical equipment, as I believe you know, we identified about 1,600 manufacturers that we have done business with over the past years out of the universe of approximately 16,000 manufacturers of medical devices and goods.

I think we are typical of many institutions in American health care systems in that a typical hospital has some 7,000 to 8,000 different devices or pieces of equipment. These have been purchased over the last 20 or 30 years. Much of the equipment, at least that which has been purchased in recent years, is not subject to this problem, but older equipment that may still be very workable and that is being used, is subject to a Y2K problem.

Of the 1,600 manufacturers that we have contacted over the last two years, I can report to you at this time that 728 of those manufacturers have certified to us that their products are Y2K compliant, and at least, per the manufacturer's report, there should not be any problem with these products, although I would hasten to add that we will be doing some testing to verify compliance to ourselves.

Sixty-five manufacturers have reported that their devices are not compliant and that they will no longer be supported by the manufacturers, that their equipment or device is considered obsolete and won't be fixed, even though many of these devices are actually functional and commonly used.

There are 130 manufacturers who reported models that are currently not compliant, but that they anticipate making compliant. These manufacturers intend to repair or fix the problem, although one of the concerns that we have at this point is that we don't know exactly how they intend to do that or what the specific nature of the problem is that has to be fixed.

I would also note in this regard that the way the fix will be accomplished varies widely across the industry. In some cases, manufacturers will come to the facility and repair the device; for others we have to send the device back to the company to be repaired. In some cases manufacturers will charge for the repairs; in others they won't. The nature of how the fix will be accomplished varies widely.

Forty-six manufacturers have reported that they are still doing their analysis on their products and, at this time, cannot tell us whether their products will be compliant or not. As the GAO testified, we have not been able to contact over 200 manufacturers—222 to be precise—despite having attempted contact at least four times. At this point, as part of our contingency planning, we are assuming we are probably not going to be able to get information from them and will have to make specific plans to deal with those pieces of equipment.

We know over 100 manufacturers have either gone out of business or have merged or otherwise are no longer the entity that produced the piece of equipment in the first place.

And then finally, we have just a little over 100 manufacturers that have not responded to us, despite our multiple requests.

Overall, at this time, we know that we have more than 1,000 models of devices that are not Y2K compliant, and approximately 20 percent of these will not be made compliant by the manufacturer. We still, as I say, have a problem with getting responses from quite a number of manufacturers.

In response to questions that were raised earlier this morning, as far as VHA experience relative to the rest of the health care industry, it is worthwhile to keep in mind the size of customer that we are and the fact that good business practices would suggest that manufacturers would be compliant or responsive to an entity that purchases as much equipment as we do. We believe the only difference between manufacturers response to VA and the rest of the health care industry is that there may not be as much incentive to respond to small hospitals or individual practitioners as there are to large systems like VA.

Let me just conclude these opening comments by addressing two points that were made in the prior testimony. A comment was made about our contingency book. I would note that it has been promulgated and is currently in the channels of distribution of the VA system.

Secondly, as the chairman commented very briefly, and as I believe you know, a few months ago, VA joined with the American Medical Association, the American Hospital Association and several other entities of the National Patient Safety Partnership calling for a single national clearinghouse where information on these medical devices would be available. I should note that we have now reached agreement with FDA on this matter and the nature of the information that will be provided on the clearinghouse.

Quite simply, and I think I can speak for the other member organizations of the National Patient Safety Partnership in this regard, the idea is that both professional organizations and facility or system management should have access to this information; we also think that individual practitioners, whether it's a nurse in the intensive care unit or the physician or the technician using the EKG machine, should be able to access the Internet, look for the specific piece of equipment they are using, and assure themselves that indeed what they are using is compliant, or if it is not, what may be done to correct the problem.

With those comments, I will be happy to respond to your questions.

[The prepared statement of Dr. Kizer appears on p. 103.]

Mr. EVERETT. Thank you very much, Dr. Kizer. We are joined by our distinguished ranking member of the full committee and former chairman of this subcommittee, Lane Evans. Do you consider medical device Y2K compliance to be a serious public safety issue, not just a VA issue?

Dr. KIZER. I do, and let me just amplify on that a little bit. While the absolute proportion, or percent, of equipment that may be affected may be very small, or even tiny, I think that this figure may be misleading. When you consider the number of patients that are treated on any given day in this country—probably four million individuals will be treated in hospitals, clinics, nursing homes, et

cetera, every day, in addition to those treated in the home setting—and when you consider the fact that those patients may have anywhere from a handful to several hundred interactions with information systems, devices, or biomedical equipment, and then when you do the math, you will see the numbers become huge.

So even if it is a very tiny percentage of devices that are affected, the potential for harm, I think, is very real.

Mr. EVERETT. I read that in your statement. I was astonished. I had never thought about the interaction that would take place on just one patient. I think about 3.8 or 4 million patients a day are using health care services.

If I understand your testimony on page three correctly, some medical equipment Y2K malfunctions could have potentially dangerous consequences. Would you please elaborate on those dangerous consequences.

Dr. KIZER. In a couple of ways. For example, we did bring some devices with us. The committee staff had asked if we would bring some with us to exemplify this, and one device that brings that point to mind is the monitor like the one that we have here which is used in a critical care setting.

The software is such that come the Year 2000, the alarm may not sound when a patient develops a serious arrhythmia. And in the typical intensive care unit setting, the nursing staff and other staff rely on both the visual cues (i.e., looking at the monitor) as well as auditory cues, because they are often doing lots of things at the same time. Conceivably, if they are busy doing other things and the alarm does not sound, then one might miss the fact that the patient has developed a potentially life-threatening arrhythmia, such as ventricular fibrillation or ventricular tachycardia which, if not treated, literally within seconds or a minute or so, could have a fatal outcome.

Likewise, in a somewhat different scenario, a defibrillator like the one we have brought with us may simply print the date incorrectly on the rhythm strip that comes out of the machine. But if you are trying to decide what medication that you gave at a certain point in time and match it with the rhythm to see what the response to the drug was in an effort to determine the most effective drug to give the patient in one of these life-threatening situations, if you have the wrong date printed on it, then the physician may come to the wrong conclusion as far as what was effective in stopping the arrhythmia or what's being done. That could potentially lead to a serious adverse outcome.

Also, just as one last example, the GAO already commented on the radiation devices in which dates are critical to calculating dose because these materials decay over time and you need to know exactly the decay and the age of the patient, et cetera, to factor the right dose. If that information is computed incorrectly, then you may end up giving within an inadequate dose or one that is too large, both of which could have deleterious effects for the patient.

Mr. EVERETT. Does the VA health care system have significant authority and resources to be ready for Y2K?

Dr. KIZER. I believe we are exercising all of the authorities we have. We put language in our contracts, and we are trying to use

our market leverage. However, we do not have any specific regulatory authority per se over this area, if that is what you're asking.

Mr. EVERETT. I want to recognize Mr. Evans for a moment—he has another engagement—and let him make any comments he would like to.

Mr. EVANS. Thank you, Mr. Chairman, and I salute you for scheduling this all-important follow up to last year's hearing on the VA's efforts to achieve Year 2000 compliance.

And I would also like to note that this is the last hearing that Adam Sachs, our counsel for the subcommittee, will be attending in his capacity as a member of the professional staff here. We salute him for his several years of hard work and hope he will do well in the future.

Mr. EVERETT. Absolutely.

Mr. EVANS. Thank you, Mr. Chairman.

[The statement of Mr. Evans appears on p. 82.]

Mr. EVERETT. Let me continue. The bottom line is being ready. Will the VA health care system be ready for Y2K?

Dr. KIZER. It is certainly our intent and expectation to be ready. I think, in all candor, we are still working through some of the issues. Our goal is to have all the information available and start making contingency plans—I mean, they are already being worked on, but in January of 1999, to start making contingency plans based on all of the information that we have at that time so that we have a year to work through this to do whatever testing and independent verification we feel is necessary, so that when the clock rolls around on January 1, 2000, we will, in fact, be prepared.

Mr. EVERETT. Of the almost 400 nonresponding manufacturers, how many of their devices are in the VHA's inventory, and how many will be replaced or retired?

Dr. KIZER. I do not have that specific figure. I will be happy to provide it for the record.

(Subsequently, the Department of Veterans Affairs provided the following information):

VHA does not have an actual count of the devices from these manufacturers. we will survey all VA facilities and will provide the information to the Committee.

Mr. EVERETT. Do you have any idea how many of these devices are considered to be critical care devices?

Dr. KIZER. I believe all of our devices that are in critical care arenas, we have information on. Let me ask Mr. Wexler to comment on that.

Mr. WEXLER. That's true. In addition, we have created a high-profile list of manufacturers who provide equipment to us that are either critical care, high-dollar value, or high volume in the VA health care system. And we have heard from all those manufacturers. So we don't believe that any of those on that list of remaining manufacturers we haven't heard from represent anything in our critical care inventory.

Mr. EVERETT. Thank you. Mr. Mascara.

Mr. MASCARA. Thank you, Mr. Chairman. The GAO, Dr. Kizer, has estimated that it will take approximately $40 million to solve this problem within the VA. Do you think that is sufficient or underestimated? Do you have any idea what it would take in dollars to resolve this problem?

Dr. KIZER. I am not confident at this time that that is an adequate amount. I think it is a good place to start the discussion. Again, we haven't heard from everyone yet. We don't have the full extent of information.

So while I don't argue with that figure, I think it should be viewed as a floor and not the maximum amount that may be needed. I think, in fact, it may be substantially more than that.

Mr. MASCARA. Thank you. I was going to ask the question, and you sort of answered it, about being involved with and coordinating with the health care industry generally about the problem.

Isn't the problem the same regardless of where we are. It is the inability of the computer to recognize the change from, since we dropped the first two digits originally, to recognize the change at the year 2000. If someone could find a solution to that, wouldn't it be universal? Aren't we all looking, even though we might be going off in different directions as it related to the health care industry, whether it be the IRS or the issuing of pension checks or veterans' retirement checks, isn't the problem universal?

Dr. KIZER. The genesis of the problem is universal. The way that it may manifest and how it may affect a given device or information system varies widely. It is really all over the board.

But I think the more important point that you are asking is one that I would agree with. And it goes beyond Y2K. Many of the issues that VA is wrestling with in health care today are the same ones that are confronting the private sector.

That's one of the reasons why, about a year ago, we initiated efforts to establish this National Patient Safety Partnership with the American Medical Association, the American Hospital Association, the American Nurses Association, the Joint Commission on Accreditation of Health Care Organizations, the Association of American Medical Colleges, the Institute for Health Care Improvement and the National Patient Safety Foundation—I believe those are all the founding members—and why we have issued invitations to a number of other public and private entities to join with us as we try to maximize what we can do in the public sector with what is being done in the private sector to find solutions to these common problems.

Y2K happens to be an excellent example of that and one of the reasons why the National Patient Safety Partnership targeted this issue as one of the first issues it took on.

Mr. MASCARA. I see. So there is a coordination of some sort going on throughout the industry.

Dr. KIZER. We are trying. Not everyone is at the table yet, though.

Mr. MASCARA. What can you tell us about VA's progress towards implementation of facility by facility contingency plans for addressing the potential Year 2000 failures? And do you agree with GAO's view that individual contingency plans should be put in place, and how long do you believe it will take the VA to implement such plans?

Dr. KIZER. Yes, I do agree that this is something that does have to be done facility by facility. Indeed, it has to be done service by service within the facility. We have issued a guidebook to facilities in this regard. Efforts are underway across the entire VA system.

We have set the tentative date—and others in the industry agree—that by January 1999, we need to start contingency planning on all the information that we have at that point. We have set that, if you will, as a target date for the biomedical device and medical equipment industry to get all their information to us. We know in some cases that patches or fixes to the problems will be available by that time.

So while efforts are, in fact, underway now, we do want a full year to work through both contingency planning, as well as independent verification where we feel that's necessary.

Mr. MASCARA. Well, you've answered part of my next question, which was what, in your view, is the drop-dead date for receiving compliance information from manufacturers? Do you have some kind of a date?

Dr. KIZER. January 31, 1999.

Mr. MASCARA. Do you have an opinion concerning which noncompliant medical equipment provides the greatest Year 2000 risk to patient safety? And how big of a risk do other facility-related systems and equipment pose? For instance, what steps has the VA taken to ensure that elevators, heating and cooling systems, and disaster recovery systems will be operational when we ring in the next millennium.

Dr. KIZER. Thank you for the clarification. We have reviewed those. I am going to ask either Mr. Bourget or Mr. Wexler to comment further on that. We think we are in good shape in that regard, although we haven't finished everything that needs to be done.

Mr. BOURGET. That's right, Dr. Kizer. We are still in the process of assessing our facility-based systems. We have identified some noncompliant products that need to be replaced, repaired, or upgraded. We are seeking further information from manufacturers in that arena, working with the General Services Administration and with the Department of Defense to leverage our efforts so that we are not, as Mr. Willemssen said, duplicating efforts. We feel that that will be a management problem.

Mr. MASCARA. Thank you, Dr. Kizer. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you. Dr. Kizer, VA's Acting General Counsel informed manufacturers in June 1998 of plans to release Y2K compliance information. Has the release of that information occurred?

Dr. KIZER. We have released it to a variety of forums. Just in the way of background, we had made multiple queries to many manufacturers before June 1998, as you know. We felt that making this information public might help the response rate for some of those who had not been compliant. But we also felt we needed to give the industry, those who had not responded, notice that we were going to make the information publicly available, so we did notify them and gave them time to respond. Since, then, we have made this information available to a number of sources that have inquired about it. We also have provided all of our information to FDA for the clearinghouse that has been agreed upon.

Mr. EVERETT. Since the VA is one of the largest medical device customers, should the VA declare a procurement moratorium with all those nonresponding manufacturers?

Dr. KIZER. I think that is certainly possible.

Mr. EVERETT. Or should I say, where it is possible.

Dr. KIZER. I was going to say, there are a host of complexities involved there, and that is one of the options that would be available. Let me give you an example of how I look at it. Many people in the room here have had the experience of getting a notice from an automobile manufacturer that they are conducting a recall on a vehicle you have purchased, and you need to take it back to the dealer to get it serviced.

When you take it in, if you get good service and the dealer takes care of the problem, then you feel good about doing business with them. If you get a hassle, or if they don't want to fix it, then you are not as inclined to do business with them in the future.

I think that is in many ways the way I feel about this. This is a problem in which there is a flaw in the equipment. If the company fixes it, then that will probably make us feel good. If they don't, then we are probably not going to feel very good about doing business with that company in the future.

Mr. EVERETT. Finally, from my questioning, was the FDA invited to join the National Patient Safety Partnership? If they were, when were they invited, and did you receive any response?

Dr. KIZER. The FDA has been invited, as have essentially all the agencies in DHHS, as well as the DOD, the American Association of Retired Persons, and a number of other entities. To date, FDA has indicated interest in exploring the matter, and they may have a representative at an upcoming meeting at the end of this month. The National Institute for Occupational Safety and Health (NIOSH) has indicated that they would like to join with us, as has the Agency for Health Care Policy and Research (AHCPR). The DOD's health care program has indicated a desire to join the partnership. CDC has declined, as has AARP. We are continuing to invite and work with entities. We feel this is a great area for public-private interaction.

Mr. EVERETT. Can you tell us when the invitation was first issued to FDA?

Dr. KIZER. I don't know if I have it here. It was some months ago. I believe it was in early June, but I can get that for the record.

(Subsequently, the Department of Veterans Affairs provided the following information):

An invitation to join the partnership was sent to the Food and Drug Administration on May 26, 1998.

Mr. EVERETT. Dr. Kizer, thank you again for appearing before this subcommittee. Again, I appreciate the work you do and the difficult task you have and the service you perform for our veterans, and I look forward to our next meeting, whenever that may be.

Dr. KIZER. Thank you, Mr. Chairman, and I also again thank you for your kind words.

Mr. EVERETT. Thank you. I would now like to recognize Dr. John Callahan, Assistant Secretary for Management and Budget for the Department of Health and Human Services.

Dr. Callahan, if you would please introduce your colleagues and then proceed with your statement.

STATEMENT OF JOHN J. CALLAHAN, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET AND CHIEF INFORMATION OFFICER, DEPARTMENT OF HEALTH AND HUMAN SERVICES; ACCOMPANIED BY BRUCE BURLINGTON, M.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, AND WILLIAM BRISTOW, CHIEF INFORMATION OFFICER, FOOD AND DRUG ADMINISTRATION

Mr. CALLAHAN. Yes, Chairman Everett, I am accompanied by Dr. Bruce Burlington, who is the Director of the Center for Devices and Radiological Health of the FDA, and Mr. Bill Bristow, who is the Chief Information Officer of the Federal Food and Drug Administration.

Chairman Everett, and other distinguished members of the subcommittee, I am pleased to testify here today before you about the efforts of the Department of Health and Human Services to ensure that biomedical devices regulated by the FDA will by Year 2000 compliant.

At this point, I would like to offer my written testimony for inclusion in the record, and I will summarize.

Mr. EVERETT. Without objection.

Mr. CALLAHAN. I would summarize our testimony by making the following key points about FDA's actions to ensure Year 2000 compliance of biomedical devices.

First, the FDA has, since June of 1997, been notifying the biomedical device industry of the need for Year 2000 compliance for their devices. On five separate occasions, FDA has sent letters and action transmittals to the industry about the issue. I believe it is fair to say that the industry is fully aware, or should be fully aware of their need to have Year 2000 compliance for their biomedical devices.

Second, the FDA has operated a Year 2000 biomedical website since March of 1998. Recently, the Department has signed a formal agreement, as of three or four days ago, with the Department of Veterans Affairs to expand that website, populating it with additional data supplied by the Veterans Administration.

The website is also being expanded almost on a daily basis by further information that is now being received from biomedical device manufacturers. And we would like to submit for the record the agreement that we concluded between ourselves and the Veterans Administration.

Mr. EVERETT. Without objection.

(See p. 29.)

Mr. CALLAHAN. Third, the industry is on full notice that it is in their, and clearly, the public interest to comply fully with FDA's request for information to be posted on this new and expanded website. While the FDA cannot require or compel the submission of information to the website, it does intend to post all responses and nonresponses to its request for information.

Medical providers and the general public undoubtedly will take due notice of the failure of an equipment manufacturer to indicate the Year 2000 status of its equipment. Again, I would emphasize it is clearly in the economic and commercial self-interest of a

health equipment manufacturer to post all relevant information on this website.

Biomedical equipment manufacturers should also take due note of the fact that as of January 1, 2000, that if their devices prove in any way to be Year 2000 noncompliant and they prove to be a health hazard, they will be immediately subject to recall and other public health protections of the law. The FDA will move aggressively on this point. All biomedical device manufacturers should be fully aware of this fact.

FDA does report progress on posting Year 2000 biomedical device information, even though more progress has to be made. While there are a total of about 13,500 medical device manufacturers overall, FDA estimates that approximately 1,935 of these manufacturers produce equipment that may be Year 2000 date-sensitive.

Of these 1,935 manufacturers, over 50 percent or 1,019, as of last night, have responded to the website with Year 2000 information. FDA will continue to seek information from the other 916 biomedical device manufacturers who have not responded.

Some companies have indicated that they are still assessing their products and cannot supply information at this time. FDA has informed them to provide information in a timely fashion and to indicate when their assessments will be complete and when they will be able to provide information to the website. We will also post that information on our website.

Thus far, the Year 2000 website information that we have indicates that we believe that the Year 2000 problems are going to be manageable. Among the postings, most devices indicate that they have no Year 2000 date problem. Some devices will, in fact, show an incorrect display or printing of a date, and there are patchworks or work-arounds, as they say in the trade, to deal with that.

Other reported devices will work properly, provided that the connecting personal computer which works the device or which runs the device, is Year 2000 compliant. And I might add at this point, while the committee's concern is about the device itself, they should have appropriate concerns for the personal computers in these medical institutions which run these devices.

Yet there are reported incidents where the device will not work unless and until the Year 2000 date problem is corrected. That means that FDA, in cooperation with the VA and other health partners, will maintain a high vigilance about this problem. Through the Patient Safety Coalition, which Dr. Kizer has worked tirelessly on, and through such efforts as FDA's bulletin on the subject sent to 700,000 health care practitioners last summer, FDA will also continue its outreach to the American health industry.

In conclusion, the Department of Health and Human Services, in cooperation with its health care partners inside and outside of the government, intends to meet its responsibility to ensure that biomedical devices are Year 2000 compliant.

We believe that the industry fully understands our obligations in that regard and will again, for their own best interest, provide a full range of Year 2000 compliant biomedical devices in order to best serve the health care needs of our veterans and the American people.

Thank you, and I would be happy to answer any questions you may have.

[The prepared statement of Mr. Callahan appears on p. 111.]

Mr. EVERETT. I find some of your testimony, frankly, puzzling. You are responsible for regulating this industry, yet you are willing to sit there and tell me that you don't have the authority to tell some manufacturer to respond to a request.

Mr. CALLAHAN. I will defer to Dr. Burlington for a further answer on this, but by law, by legal authority, we cannot compel them to require the information.

Mr. EVERETT. Have you asked for that authority? Have you asked the Congress for that authority?

Mr. CALLAHAN. Let me defer to Dr. Burlington on that.

Dr. BURLINGTON. We have not made a specific request for that authority.

Mr. EVERETT. Why not, considering the seriousness of this? Well, first of all, do you think this is a serious problem?

Dr. BURLINGTON. Mr. Chairman, I certainly think this is a serious problem. Hopefully, it will be manifest in a very small number of cases, because of the steps taken by this committee, by the Veterans Administration, and by FDA, among others, to deal with the problem, to understand it.

We have been working with the manufacturers. We have asked them repeatedly for this information, and we have started down the track of saying let's find out where the problem is and let's provide this clearinghouse of information.

Mr. EVERETT. In other words, you are responsible for regulating the industry, yet you are essentially toothless to do so. Is that your testimony?

Dr. BURLINGTON. We have many authorities which are effective. We are not in a position today where we can compel the sorts of reports that would require advance posting of compliance status.

Mr. EVERETT. Let me ask you, testimony has been given that you are not a member of the National Patient Safety Partnership. Why on earth would you not want to be at the table to discuss these issues?

Dr. BURLINGTON. Mr. Chairman, we are founding members of the National Patient Safety Foundation, the AMA body that started this. Dr. Kizer——

Mr. EVERETT. I didn't ask you about that. I asked you about the National Patient Safety Partnership that Dr. Kizer referred to. I am not interested in what you are a founding member of. I want to know why you are not a member of that, and why you are not at that table.

Mr. CALLAHAN. Mr. Chairman, if I may.

Mr. EVERETT. Yes.

Mr. CALLAHAN. I can assure you that we will be a member of the Patient Safety Coalition, and that will be done forthwith, sir.

Mr. EVERETT. And I can assume that you do consider the medical device Y2K compliance to be a serious public safety issue?

Mr. CALLAHAN. Absolutely, sir.

Mr. EVERETT. While we all recognize that the VA committee is not the authorizing committee for HHS and FDA, do HHS and FDA have sufficient authority and resources to do the job—never

mind authority, I think we have already discussed that. Sufficient resources to do the job for Y2K?

Mr. CALLAHAN. Let me respond to that, Chairman Everett. As you know, currently, in the Senate Treasury and Postal Appropriations Bill there is an emergency appropriation which is being set forth for approximately $3.25 billion for Y2K work across the government, affecting all departments.

We would intend to participate in that appropriation once it is passed by the Congress.

Mr. EVERETT. But do those funds include looking at the biomedical devices?

Mr. CALLAHAN. Yes, sir, they do.

Mr. EVERETT. Are there medical devices that could have potentially dangerous Y2K malfunctions?

Mr. CALLAHAN. Let me defer to Dr. Burlington on that.

Dr. BURLINGTON. Mr. Chairman, there certainly are. We would agree with the testimony that has already been heard this morning that there are some devices that, if a fix is not put in place, could endanger patients. And there are many devices where there could be confusion in medical practice about dates and about other information in patient records unless fixes are put in place.

Mr. EVERETT. Does the FDA have a contingency plan if, as Y2K approaches, compliance status of some or much medical equipment remains still unknown?

Mr. CALLAHAN. Let me offer one part of the answer to that question, Chairman Everett. As Dr. Kizer has indicated—and he is on the right track, since he is servicing the facilities—the facilities themselves have to have the contingency plans in place for replacing or repairing or discarding biomedical equipment.

That would be the same case for the Department of Health and Human Services, for example, in its Indian Health Service facilities. We will, as part of the FDA's effort with the biomedical website, move as aggressively as we can, as I indicated earlier, in populating that website with the best information possible so that the providers will be able to take appropriate action to remedy any biomedical device problem.

Mr. EVERETT. But if we don't have the information on what devices may malfunction, then how can we put a contingency plan out?

Mr. CALLAHAN. Let me say this, Chairman Everett. As I indicated today, as of last night, we now have responses from 1,019 biomedical equipment device manufacturers. You are correct, and this committee is correct, that in the past we have not received sufficient response from the industry with that regard.

Your efforts, and certainly efforts of your colleagues in the Senate side, have, I believe, raised the temperature, if you will, for the manufacturers, and they are supplying our website with further information. We will move as aggressively as we can to get that information into the website for all the providers.

Mr. EVERETT. How does FDA plan to address medical devices that were made by the nearly 100 manufacturers that are not even in business, so there's nobody to find?

Dr. BURLINGTON. Mr. Chairman, the issue about devices that were put into service and for which there is no company continuing

in business, or for which a company continuing in business has declared them obsolete, is a problem that we believe the institutions who own that equipment are going to have to take the responsibility in assessing what do they do.

The agency is not in a position for equipment which is obsolete or where the entity has gone out of business, to direct an action, and it does pose a real and significant problem for many hospitals.

Mr. EVERETT. I haven't any idea how small companies are supposed to do that. Let me just get one final question here and then I will go to my colleague.

As I mentioned to Dr. Kizer, the bottom line is being ready. Will HHS and FDA know the Y2K compliance status of medical equipment and be in position to assure American veterans and the public that medical equipment in use on January 1, 2000 will be safe and effective?

Mr. CALLAHAN. We believe that we will, but obviously, as you have indicated here, it will require our continued aggressive efforts with the manufacturers to make sure they give us that information and populate this biomedical website which we have now combined forces with VA with.

Mr. EVERETT. Mr. Mascara.

Mr. MASCARA. I'd like to go off in a different direction and perhaps engage in some conjecture. How much of the reluctance of the manufacturers is driven by greed? That is, it costs money to solve the problem. On the other hand, they can have new equipment that doesn't have the problem, the Year 2000 problem. Are they dragging their feet because they would rather sell new equipment that doesn't have the problem than spend the money to solve the problem?

And if so, Mr. Chairman, I think an investigation—let's drag those manufacturers in here and find out what's really going on, because if that's the case, that is an utter disgrace to think that manufacturers of this biomedical equipment would intentionally drag their feet so as to hopefully be able to sell when the Year 2000 is right around the corner. We are all going to be desperate and spend a lot of money buying their new equipment that doesn't have the problem. I think we need to investigate that.

Mr. EVERETT. We've dragged them in here now. You will have your opportunity with the next panel to pose those questions.

Mr. MASCARA. All right. Maybe that's why I see some smiles out there.

The other subject I would like you to briefly explain is—and you spoke to it just a few moments ago, about the agreement with the VA to provide an Internet clearinghouse for medical equipment Year 2000 compliance information. Is that going on, and how soon will that site be available?

Mr. CALLAHAN. Yes, we signed that agreement, as I indicated, several days ago. We are now in the process with the Veterans Administration of having their data transmitted and put up on our website. That will take approximately, we believe, another two or three weeks to get that done. So the website will be expanded within that time.

And again, as I say, we have increased the number of responses from manufacturers who we have asked for information, from ap-

proximately 300 or 400 responses several weeks ago to now over 1,000. These are among the biomedical device manufacturers which we feel are most Year 2000 date-sensitive. So over half of the targeted manufacturers have provided us that data, and we will continue to work aggressively and cooperatively with the industry to get that additional information.

Mr. MASCARA. Thank you, Dr. Callahan. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you. Counsel for the minority would like to ask a couple of questions.

Mr. SACHS. Dr. Callahan, your own testimony has indicated that so far the overall response from manufacturers has been, in your words, disappointing and incomplete. If you were to strip away all the resource concerns and the personnel concerns within your department, would you at least agree that some authority from Congress to mandate that the manufacturers respond would perhaps help push these manufacturers along, or is it your position that that is just not necessary.

Mr. CALLAHAN. I think clearly, since the committee has raised it, we should engage in direct consultation with the committee about that matter. But whether that legislation comes to pass in the near or the short term, we intend to be as aggressive as we can under our current authorities with the manufacturers.

I think they are showing a greater level of responsiveness, again, in no small part to the efforts of this committee and committees in the Senate, as well. I just clearly don't think, in the broad vein, if you will, it is in the economic or commercial self-interest of biomedical device manufacturers not to give us this information and not to cooperate, not only with this committee, but with other committees, to ensure that their devices are safe and effective. I just don't understand a business that would not want to operate in a safe and effective fashion in this area.

Mr. SACHS. Without dwelling on this point too much, can you provide some explanation for the hesitancy of your department in the past to support one-time authority in this area to give some more teeth to your enforcement power? Is it a resource and personnel issue, or is there some other explanation?

Mr. CALLAHAN. There are clearly, as in the case with any agency—and you have seen it in your own jurisdiction when you deal with the Veterans Administration—there are some resource constraints. This year, for example, in our appropriations process, for FDA, we have not received the President's budget request for all the operations of the FDA. They have another whole variety of other operations beyond biomedical device operations, food safety, a whole variety of other things. And we have not received as much resources, obviously, as we would like, for the variety of our concerns. So there is a resource dimension that would come into play.

Mr. SACHS. Thank you, Dr. Callahan. Thank you, Mr. Chairman.

Mr. EVERETT. Certainly. Dr. Callahan, let me give you that I recognize the universe that you have to operate in is much larger and perhaps more complex in some ways than that of the VA. But I feel compelled to say that I don't understand why HHS did not take the lead in putting a database together and perform the service that

VA has been compelled to perform, not only for the VA, but for the public safety.

As I said, I give you the fact that your universe is a lot larger, but I do think that HHS or FDA was remiss in not taking the lead in this. I do, however, thank you for your testimony today and for appearing here before the subcommittee. Thank you very much.

Mr. CALLAHAN. Thank you very much, Chairman.

Mr. EVERETT. I would like to now call Dr. Alan Magazine, President of the Health Industry Manufacturers Association.

Dr. Magazine, I would ask you to hold your comments to five minutes and we will submit your complete comments for the record. You may proceed, sir.

STATEMENT OF ALAN H. MAGAZINE, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Mr. MAGAZINE. Thank you, Mr. Chairman. My name is Alan Magazine. I am President of the Health Industry Manufacturers Association, a D.C. based trade association representing more than 800 manufacturers of medical devices, diagnostic products, and medical information systems, whose members make nearly 90 percent of the $58 billion in device products purchased annually in the United States.

Thank you for this opportunity to speak about the readiness of our industry to ensure the safe and reliable operation of medical devices in the Year 2000. It goes without saying that the health and safety of patients constitute the paramount concerns of our industry.

Mr. Chairman, let me begin by answering a question that you have asked previous witnesses. I think I can safely say on behalf of the entire industry that we believe the Y2K issue is a potentially serious public safety issue. That is why we have taken the many steps and actions we have taken to try to assure industry compliance.

Mr. Chairman, I want to make three points today. First, the device industry is extremely concerned about the potential hazards associated with the Year 2000 problem and has put substantial effort into assuring that devices function safely after the century change.

Second, HIMA strongly supports the interests of HHS, FDA, the VA and others in determining the Year 2000 compliance status of device manufacturers.

And three, HIMA members recognize that timely access to Year 2000 compliance information about their products is integral to the solution of the problem.

Earlier this year, we pledged before Congress to work with the Federal Government and other concerned parties to make industry Year 2000 compliance information publicly available. I am here today to renew that pledge and to report to you on our efforts so far.

We are as conscious as anyone that the clock continues to tick toward January 1, 2000, and we will do whatever patient health and safety require. HIMA continues to encourage our members to work to ensure their devices are Year 2000 compliant, to use the FDA website to communicate their compliance status, and to en-

sure that information about their compliance status is available to their customers.

And we have created a Year 2000 section on HIMA's website which includes instructions on how to submit information to the FDA website. HIMA has also communicated its Year 2000 messages to more than 6,000 nonmember companies.

I am pleased to report that these efforts are beginning to bear fruit. Of the thousands of FDA-registered device companies, the Agency has identified 1,935 whose products likely have a date-dependent function, as you have heard. We are encouraged that over 1,000 device companies have now responded to FDA's request for compliance information. That number has doubled since mid-July and is growing by 30 to 40 companies per day.

Nonetheless, we still have a ways to go. I should point out that in the current mergers and acquisitions environment, it is quite complicated to track compliance information. For example, HIMA's membership of slightly more than 800 companies actually consists of 300 parent companies and their more than 500 subsidiaries. It is difficult for anyone to determine whether a corporate headquarters has responded for all of its subsidiaries or whether each subsidiary has provided compliance information just for itself.

Thus, as a second phase of our Year 2000 campaign, HIMA is publicly committing today to contact each of our 300 parent companies at the senior executive level to facilitate their corporate and subsidiary compliance efforts.

We are going to work with the FDA and the VA to identify and contact companies that have not responded to their inquiries, and to ensure their communications are going to the appropriate company contacts. And we are organizing educational seminars for our members to help provide guidance in assessing and addressing Year 2000 issues.

Earlier this year, the National Patient Safety Partnership referred to by Dr. Kizer and others—a coalition comprising the VA, the American Hospital Association, the AMA, and others concerned about the impact of the Year 2000 problem on patient safety—suggested that a central clearinghouse be established to make Year 2000 information publicly available. I am pleased to say we have been working closely with the FDA to make this happen.

We also applaud the recent VA and HHS agreement to use the FDA website as the central Year 2000 biomedical equipment clearinghouse.

The Year 2000 problem for our industry is not simple. Each company faces unique technological circumstances involving its products, and solutions developed by one firm will not be applicable to, or feasible for, others.

The device industry encompasses more than 50 scientific and engineering disciplines, including such diverse fields as solid state physics and holography in the development of its products. Our products are used in applications throughout the human body, and in more than 50 different medical specialties, such as orthopedics, cardiology, and ophthalmology. There are more than 3,000 major product lines and approximately 84,000 individual products.

Nonetheless, we agree with FDA's assessment that most medical devices will not prove to be date-dependent.

In closing, I would like to say that the Year 2000 problem for our diverse industry cannot be resolved with an easy one-size-fits-all solution. But we are confident that by working together we can achieve what we all want, which is that on January 1, 2000, medical technologies on which millions of patients depend, function safely and effectively.

We are open to your suggestions and look forward to working with the members of this committee to achieve our shared goal.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Magazine appears on p. 118.]

Mr. EVERETT. Thank you, Dr. Magazine. Let me ask, does Senator Bob Bennett's bill, S. 2392, the Year 2000 Information Readiness and Disclosure Act, address the liability issue for the medical device manufacturers to disclose noncompliance?

Mr. MAGAZINE. Sir, I think it goes a long way towards solving a problem that really, in fact, has slowed down the compliance by manufacturers. We did hear from many manufacturers that they were very concerned about sharing the information because of liability concerns.

For example, putting information on the Web that indicates that something is Y2K compliant, and then if something should happen, they'd be wiped out. So sharing the information really does help.

I think the committee should understand that approximately 80 to 85 percent of the companies in the industry are very small and have less than 50 employees. Many of them have one or two products. And all it takes is one lawsuit to wipe out the company. And as we all know, some of these lawsuits, many lawsuits, can be frivolous.

So there really was a concern about liability issues and I think this bill will go a long way towards resolving those concerns.

Mr. EVERETT. Having said that, you know from our conversation that I really feel that the industry perhaps did not take the lead in this when it should have. As I commented to you, after all, this is not brain surgery. This could have been looked at and predicted some time ago by industry that has, what, I think some $83 billion worth of business a year, or whatever that figure might be.

Let me ask you, the National Patient Safety Partnership recommends that all U.S. medical equipment manufacturers take immediate action to identify their devices' compliance and make the information freely available to the public. This manufacturers' information should be provided no later than January 31, 1999. Do you think that's doable?

Mr. MAGAZINE. Mr. Chairman, we represent about 800 companies. There are about 12,000 or 13,000 companies on the FDA registration list. What I can tell you is that we are making every effort to make sure that at the very least, our membership complies with those requests.

We have made efforts as well and will continue to make efforts to try to get the rest of the industry to comply. And we are certainly open to any suggestions this committee would like to make for other actions that we could take.

Mr. EVERETT. Well, we are kind of at the eleventh hour. Mr. Mascara.

Mr. MASCARA. Thank you, Mr. Chairman.

Perhaps, Dr. Magazine, you can try to respond to my earlier question to the previous panel. Did you say there was only 800 in your organization out of 12,000?

Mr. MAGAZINE. Eight hundred companies that manufacture——

Mr. MASCARA. That belong to your organization.

Mr. MAGAZINE. That's right.

Mr. MASCARA. So we have 11,200 out there running around that belong to no organization or other organization? So you represent really a small portion of the manufacturers who make medical equipment.

Mr. MAGAZINE. In numbers of companies, yes. In volume of production sales, it is over 90 percent.

Mr. MASCARA. Okay. Today's testimony from the Department of Health and Human Services indicates concern over the apparent unwillingness of health industry manufacturers to respond to repeated inquiries concerning the 2000 compliance.

In fact, the testimony states that so far the overall response from manufacturers has been disappointing and incomplete. How do you respond to this concern and how do you explain the spotty and often incomplete responses by members of your industry to these inquiries? In your view, would manufacturers be more inclined to respond if their future ability to contract with a Federal agency such as the VA were at risk?

Mr. MAGAZINE. Congressman, admittedly, the industry got off to a slow start. And we were certainly taken to task by Senators Dodd and Bennett on the Senate side for that, and it clearly got our attention.

But I would also say that there are many companies that have been working on this problem for years, literally, for years, solving the problems that do exist. First they had to find out whether their products were date-dependent. For those that are date-dependent, solving the problem is not something that can be done overnight.

And in fact, there are many companies still working on the problem that have not reported to FDA, and we are asking them to do that and let FDA know the status of their situation. So I think it is a very complex issue that has taken time to get industry attention.

However, you also heard, I think, Dr. Kizer or one of his colleagues indicate that they didn't see any problems in any of the cardiac care areas, that those products seemed to be in compliance and the companies are working on it. So I think you have to sort of break down the industry, you have to stratify the industry and look at size of company, product line, etc. It is a very complicated situation.

However, having said all that, I really think it's headed in the right direction. FDA has identified about 1,900 companies. More than 1,000 have complied; 30 to 40 are sending in information on a daily basis. I think that is very positive. I understand the concern and we share the concern, but I do think the glass is half full. We have seen a tremendous increase in compliance just in the last 60 days.

Mr. MASCARA. So do you think it might be an incentive if these manufacturers could not contract with agencies like the VA if they didn't come to the table or didn't provide the information that they

have, either their company or jointly with other manufacturers, to solve the 2000 problem.

Mr. MAGAZINE. Well, let me put it this way, Congressman. These companies are very concerned about their customers. These companies are going to do whatever it takes to make sure that they don't lose customers. Clearly, the VA is a very large purchaser for many companies.

But I would say this: I think we do now have the attention of the companies. I am not sure actions like that really are warranted. I would ask the committee to give it a little more time and to see what kind of compliance you see. As I said, in the last 60 days, it has increased significantly, and I think that will continue.

Mr. MASCARA. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you. And thank you, Dr. Magazine.

The House schedule today is very busy. It is very crowded and many of the members of the subcommittee could not be here today. Much media attention is obviously focused on another committee. But this hearing has raised a matter that should be of concern to every American.

On January 1, 2000, almost 4 million Americans will get sick or hurt, just as they do every other day, and they will need medical treatment. You heard Dr. Kizer say that each of these 4 million Americans will interact with devices maybe as much as 8, 10, 12 times. The FDA's effort on Y2K compliance for medical equipment appears to be finally coming together at what amounts to the eleventh hour, however. I just hope and pray that the database work can be done in time and if it can't, adequate contingency plans can be in place.

The VA's health care system, by contrast, now seems to be a leader on Y2K for health care providers. And I know that the VA will cooperate with the FDA and share its information with everyone to the greatest extent possible.

Medical equipment manufacturers have their work cut out for them also. They are in the best position to know or find out what is in Y2K compliance and what is not. The manufacturers have a public responsibility, as well as a legal obligation, to have safe products for health care and to disclose if any products may become unsafe on January 1, 2000. These manufacturers have put so many wonderful, life-saving devices on the market that I cannot believe they would not live up to their responsibilities and their obligations to the veterans of this country and to the American public.

But if they do not, I support listing these manufacturers not disclosing Y2K status of their products on the FDA's website for the whole world to see. Further, the Federal Government should stop doing business with them, where and when possible.

Finally, there is still time for another hearing or two, and no matter what happens in the November elections and the results of those elections, I would just guarantee you this subcommittee will continue to monitor the Y2K situation very closely next year regardless of who is in this chair.

Thank you all for attending today. The hearing is adjourned.

[Whereupon at 11:01 a.m., the subcommittee adjourned subject to the call of the chair.]

APPENDIX

Federal Y2K Biomedical Equipment Clearinghouse Collaborative Agreement

BETWEEN:
Partner Agencies and Associates

STATEMENT OF NEED:
There is a risk for serious adverse impact on patient health and safety due to the year 2000-date change and its potential effect on some biomedical equipment. The adverse impact is either real, resulting from improper operations of medical equipment upon the date change and/or perceived, because of the lack of adequate, timely and easily obtainable information about this issue for both health care providers and the patients they serve.

PURPOSE OF THE DOCUMENT:
This document establishes the collaboration between the Partners and Associates in the development of a Federal Y2K Biomedical Equipment Clearinghouse (referred to herein as the Biomedical Equipment Clearinghouse). The Biomedical Equipment Clearinghouse will be an on-line database on the FDA web site, operated and maintained by FDA. Data included in the Biomedical Equipment Clearinghouse will be restricted to publicly releasable information provided directly by manufacturers to Partners or Associates.

BIOMEDICAL EQUIPMENT CLEARINGHOUSE STEERING COMMITTEE:
The Biomedical Equipment Clearinghouse Steering Committee will be comprised of Partners, as defined below. The Steering Committee will review and approve deliverables, and monitor and evaluate the performance of the project. In addition, the Steering Committee shall review and discuss additional data sources to determine whether or not they should be included in the system and their impact on the timelines, costs, and requirements. The Steering Committee and its responsibilities will be more fully defined in the Steering Committee charter.

PARTNERS:
Partners are government organizations who will provide data to the Biomedical Equipment Clearinghouse, establish funding mechanisms, and designate members to the Steering Committee that provides oversight to the Biomedical Equipment Clearinghouse project. There are two designations of Partners -- Strategic and Technical. Strategic Partners are those partners who are voting members of the Steering Committee and provide input and recommendations to the Technical Partners. Technical Partners are those partners who are voting members of the Steering Committee and who are responsible for the design, development, implementation, and maintenance of the Biomedical Equipment Clearinghouse. Specific responsibilities of the Partners are below.

Strategic Partners include:

- Department of Health and Human Services (DHHS)

- The Department of Veterans Affairs (VA)

Technical Partners include:
- Food and Drug Administration (FDA)
- Veterans Health Administration (VHA)

ASSOCIATES:
Associates are non-governmental organizations, such as professional and trade associations, who will, upon request, advise the Partners on matters concerning the Biomedical Equipment Clearinghouse. Associates may also, upon request, provide data to the Biomedical Equipment Clearinghouse. Associates will not serve on the Steering Committee.

FUNDING:
Funding for this project is pending the enactment of the Government-wide Y2K emergency fund. If that is forthcoming in the amount requested by FDA, funding issues will be resolved. If not, the Partners shall establish funding mechanisms to support the development, implementation and operation of the Biomedical Equipment Clearinghouse. This shall be accomplished within forty five days from the signing and approval of this document.

STRATEGIC PARTNER RESPONSIBILITIES:

1. The Partners shall participate in the Biomedical Equipment Clearinghouse Steering Committee. The Steering Committee shall be responsible for accepting new Strategic and Technical Partners.

2. In conjunction with FDA, Partners shall provide draft requirements for modifying the FDA's Biomedical Equipment Y2K Status database to meet the needs of the Biomedical Equipment Clearinghouse. The Steering Committee shall approve the final requirements.

3. The Partners shall contact other potential Partners and Associates, and obtain additional data for the Biomedical Equipment Clearinghouse, subject to approval by the Steering Committee.

4. The Partners shall provide assistance to FDA in follow-up with manufacturers including reconciling conflicting and duplicative information.

5. The Partners shall provide data that FDA can make publicly available with the consent of the manufacturer or by legally making it public under their regulations prior to providing it to FDA.

6. The Partners shall prepare cost estimates for their tasks under this project and submit them to the Steering Committee.

TECHNICAL PARTNER RESPONSIBILITIES:

VHA

1. VHA, as a technical expert in the development of the Federal Y2K Biomedical Clearinghouse, shall participate as a voting member in the Biomedical Equipment Clearinghouse Steering Committee.

2. VHA shall be responsible for inviting additional Strategic Partners and Associates to participate in the Clearinghouse.

3. In conjunction with FDA, VHA shall provide draft requirements for modifying the FDA's Biomedical Equipment Y2K Status database to meet the needs of the Biomedical Equipment Clearinghouse. The Steering Committee shall approve the final requirements.

4. In conjunction with the Partners, VHA shall prepare cost estimates for VHA's tasks under this project and submit them to the Steering Committee.

5. VHA shall work with Partners and Associates to identify additional data sources.

FDA

Because the FDA has been tasked to develop, operate and maintain the Biomedical Equipment Clearinghouse, it has the following responsibilities

1. FDA, as a technical expert in the development of the Federal Y2K Biomedical Clearinghouse, shall participate as a voting member in the Biomedical Equipment Clearinghouse Steering Committee.

2. In conjunction with the Partners, FDA shall prepare a draft charter for approval by the Steering Committee. This shall be accomplished within thirty days from the signing and approval of this document.

3. In conjunction with the Partners, FDA shall prepare and maintain a project plan with milestone schedule and shall present this document to the Steering Committee for approval. This shall be accomplished within thirty days from the signing and approval of this document.

4. In conjunction with the Partners, FDA shall prepare cost estimates for the FDA's tasks under this project and submit them to the Steering Committee. This shall be accomplished within thirty days from the signing and approval of this document.

5. In conjunction with the Partners, FDA shall provide draft requirements for modifying the FDA's Biomedical Equipment Y2K Status database to meet the needs of the

Biomedical Equipment Clearinghouse. The Steering Committee shall approve the final requirements. This shall be accomplished within thirty days from the signing and approval of this document.

6. FDA shall expand the FDA Biomedical Equipment Y2K Status database to include mutually agreed upon data and fields from the Partners.

7. FDA shall maintain the Biomedical Equipment Clearinghouse until March 31, 2000 or to such date as mutually agreed upon.

8. As mutually agreed upon, FDA shall generate follow-up questions and correspondence for non-response, data verification, and/or reconciliation.

SIGNATURES:

Kenneth W. Kizer, M.D., MPH, Under Secretary for Health, VHA, VA — Date 09/15/98

John J. Callahan, Assistant Secretary for Management and Budget, DHHS — Date 9/16/98

United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

September 1998

YEAR 2000 COMPUTING CRISIS

Compliance Status of Many Biomedical Equipment Items Still Unknown

GAO/AIMD-98-240

GAO

United States
General Accounting Office
Washington, D.C. 20548

Accounting and Information
Management Division

B-280584

September 18, 1998

The Honorable Terry Everett
Chairman, Subcommittee on Oversight
and Investigations
Committee on Veterans' Affairs
House of Representatives

Dear Mr. Chairman:

Biomedical equipment is important to the Veterans Health Administration's (VHA) role of providing health care services to the nation's veterans. This equipment includes medical devices, such as cardiac defibrillators, cardiac monitoring systems, and pacemakers, which can record, process, analyze, display, and/or transmit medical data, and some of which may be implanted in patients, as well as scientific and research instruments, such as blood gas and glucose analyzers. Biomedical equipment may employ computers or computer chips to operate and/or may be adversely affected by the Year 2000 problem.[1] In addition, the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) has responsibility for oversight and regulation of medical devices, including the impact of the Year 2000 problem.[2]

As you requested, and based on subsequent discussions with your office, we assessed the status of VHA's and FDA's Year 2000 biomedical equipment programs. Our assessments of other aspects of the Veterans Benefits Administrations' and VHA's Year 2000 programs, including their mission-critical systems, locally developed software applications, commercial off-the-shelf software products, and facility systems, were reported to you separately.[3]

[1]The Year 2000 problem is rooted in how dates are recorded and computed. For the past several decades, many existing computer systems have used a two-digit date field to represent the current year—such as "98" for 1998. However, such a format does not distinguish between 2000 and 1900. Computer programs that are not corrected to accommodate the 2000 date could process information incorrectly, possibly affecting the medical care and safety of patients.

[2]The Federal Food, Drug and Cosmetic Act grants FDA authority to regulate medical devices. The term medical "device" is defined in 21 U.S.C. section 321 (h). For purposes of this report the term biomedical equipment includes both medical devices subject to FDA regulation and scientific and research instruments which are not subject to FDA regulation.

[3]Year 2000 Computing Crisis: Progress Made in Compliance of VA Systems, But Concerns Remain (GAO/AIMD-98-237, August 1998).

Results in Brief

Since our September 1997 testimony,[1] VHA has made progress in implementing its Year 2000 strategy for biomedical equipment, which relies on compliance information from the manufacturers. As of July 29, 1998, VHA had received information on biomedical equipment compliance from 73 percent of the 1,490 manufacturers on its list of suppliers; 701, or 47 percent, of these manufacturers, reported that their products are Year 2000 compliant.

In spite of this, VHA does not yet know the full extent of the Year 2000 problem on its biomedical equipment and the associated costs to address this problem. This is because, as of July 29, 1998, it had not received compliance information from 27 percent of the manufacturers on its list of suppliers, as well as the nearly 100 additional manufacturers that VHA determined are no longer in business. Among the manufacturers that had yet to respond or complete their assessments is one that supplies high-dollar value equipment, such as radiology systems and electronic imaging systems equipment, to VHA.[5] Because VHA, like other health care providers, relies on the manufacturers to validate, test, and certify that their equipment is compliant, it is critical that they provide this information to VHA so that it may take prompt action on noncompliant equipment in its inventory.

According to VHA's Year 2000 Project Manager, most of the manufacturers reporting that they had noncompliant equipment cited incorrect display of date and/or time as problems. Date and/or time display problems should not present a risk to patient safety because health care providers can work around them. However, some manufacturers cited problems that could pose a risk to patient safety. For example, a radiation therapy planning computer may miscalculate the radiation source strength on or after January 1, 2000, and the resulting radiation dose may be hazardous or ineffective for the patient.

To the extent that noncompliant biomedical equipment has to be replaced or repaired, the cost estimate reported by the Department of Veterans Affairs (VA) to the Office of Management and Budget (OMB) is incomplete. This is because (1) the estimate is not based on updated cost information from the medical facilities, (2) some manufacturers have not provided compliance and cost information to VHA, and (3) nearly 100 manufacturers are no longer in business. Furthermore, VHA's medical facilities have not

[1]Veterans Affairs: Action Underway Yet Much Work Remains to Resolve Year 2000 Crisis (GAO/T-AIMD-97-174, September 25, 1997).

[5]High-dollar value equipment has a purchase price in excess of $250,000.

yet completed development of business continuity and contingency plans to help ensure the health and well-being of VHA patients in the event that some biomedical equipment items fail to operate at the turn of the century, which poses a risk to patient safety.

To assist health care facilities in the public and private sectors, HHS, on behalf of the Chief Information Officer (CIO) Council's Subcommittee on the Year 2000 for Biomedical Equipment, and FDA issued a letter in January 1998 to biomedical equipment manufacturers, requesting information on products affected by this computer problem. In contrast to VHA, as of July 30, 1998, FDA had only received responses from 1,975, or about 12 percent, of the approximately 16,000 biomedical equipment manufacturers[6] to which its letter was sent. According to an FDA official, many of these manufacturers do not produce any computerized products. He said most of these respondents indicated that there are no Year 2000 problems with their products, but about 100 indicated that at least one of their products is not compliant. FDA, like VHA and other health care providers, relies on the manufacturers to validate, test, and certify that their equipment is compliant. Accordingly, failure to obtain timely compliance information from the manufacturers increases the risk to health care providers and biomedical equipment users that their equipment may not operate properly on and after January 1, 2000.

FDA has made information from the biomedical equipment manufacturers available through an Internet World Wide Web site. VHA, however, has not yet done so because (1) when VHA requested the information from the manufacturers, VHA did not tell them that it intended to release the information outside the federal government and (2) VHA said it had concerns regarding whether it would be proper for it to release some of the information provided by the manufacturers because the information may be proprietary. VHA, on the advice of VA's Acting General Counsel, informed manufacturers in June 1998 that it plans to release information that VHA has determined is not confidential commercial information. This is an important step because compliance information from biomedical equipment manufacturers is of interest to all health care providers and users of biomedical equipment.

Background

Biomedical equipment, such as magnetic resonance imaging (MRI) systems, X-ray machines, cardiac monitoring systems, cardiac defibrillators, and

[6]Biomedical equipment refers to both medical devices regulated by FDA and scientific and research instruments not regulated by FDA.

various other tools for laboratory analysis, are critical to health and medical treatment and research in federal and private sector health care facilities. This equipment may use a computer for calibration or day-to-day operation. The computer could be either a personal computer that connects to the equipment remotely or a microprocessor chip embedded within the equipment. In either case, the controlling software may be susceptible to the Year 2000 problem if any type of date or time calculation is performed. This could range from the more benign—such as incorrect formatting of a printout—to the incorrect operation of the equipment with the potential to adversely affect patient care or safety. The degree of risk depends on the role of the biomedical equipment in the patient's care.

VHA manages health care delivery to veterans within 22 regional areas known as Veterans Integrated Service Networks (VISN). These VISNs encompass 172 VHA medical centers, 376 outpatient clinics, 133 nursing homes, and 30 domiciliaries—a total of 711 facilities. VHA's biomedical equipment inventory—with its acquisition cost valued at almost $3 billion—can be found at these facilities. As the largest centrally directed civilian health care system in the United States, VHA is a key stakeholder in determining the Year 2000 compliance of biomedical equipment. VHA's CIO has overall responsibility for planning and managing the Year 2000 compliance program. The CIO created a VHA Year 2000 Project Office, which directs and oversees the Year 2000 assessment and renovation activities in the VISNs.

Another key player in determining the Year 2000 compliance of biomedical equipment is FDA. Under provisions of the Federal Food, Drug, and Cosmetic Act,[7] as amended, FDA protects public health through oversight and regulation of medical devices. FDA regulates medical devices that use computers or software pursuant to applicable FDA medical device regulations.

In September 1997, we testified that both VHA and FDA had just begun efforts to assess biomedical equipment for Year 2000 compliance.[8] VHA had sent letters to approximately 1,600 biomedical equipment manufacturers that supply VHA, requesting compliance information for their products. We also testified that FDA had sent a letter to about 13,000 medical device manufacturers in July 1997, reminding them of their responsibility to ensure that their products will not be affected by the century change.

[7] 21 U.S.C. sections 301 et. seq.

[8] GAO/T-AIMD-97-174, September 25, 1997.

Objective, Scope, and Methodology

The objective of this review was to assess the status of VHA's and FDA's Year 2000 biomedical equipment programs. In performing this review, we applied criteria from our Year 2000 Assessment Guide[9] and Year 2000 Business Continuity and Contingency Planning Guide.[10] In assessing the status of VHA's Year 2000 biomedical equipment program, we reviewed and analyzed VHA documents, including the March 25, 1998, VISN Assessment Feedback Reports; the January 30, 1998, Assessment Phase Report; the July 1997 Year-2000 Product Risk Program; the April 30, 1997, and October 31, 1997, versions of the Year-2000 Compliance Plan; and the May 15, 1998, and August 15, 1998, quarterly reports to OMB. We did not independently verify data contained in these documents. We met with Year 2000 project teams in three VISNs—VISN 4, VISN 5, and VISN 12—and in VHA medical facilities in Pittsburgh; Philadelphia; Wilmington, Delaware; Washington, D.C.; Baltimore; Martinsburg, West Virginia; and Chicago. We also discussed VA biomedical equipment assessment and renovation plans and efforts with members of the Year 2000 Project Office at VHA headquarters in Washington, D.C.

To assess the status of FDA's Year 2000 biomedical equipment program, we reviewed FDA documents on this issue, including those on its Internet World Wide Web site. We met with HHS' Director of Policy and Evaluation in Washington, D.C., and the Director of FDA's Division of Electronics and Computer Science at the Center for Devices and Radiological Health, located in Rockville, Maryland.

We also met with biomedical engineers, who were attending the 1998 annual meeting of the Association for the Advancement of Medical Instrumentation. At this meeting, both VHA and FDA officials presented their respective Year 2000 biomedical equipment programs.

We performed our work from July 1997 through June 1998, in accordance with generally accepted government auditing standards. We requested written comments on a draft of this report from the Secretary of Veterans Affairs and the Secretary of Health and Human Services. These comments are reprinted in appendixes I and II.

[9]Year 2000 Computing Crisis: An Assessment Guide (GAO/AIMD-10.1.14, September 1997).

[10]Year 2000 Computing Crisis: Business Continuity and Contingency Planning (GAO/AIMD-10.1.19, August 1998).

VHA Has Made Progress in Implementing Its Year 2000 Strategy

Since our September 1997 testimony, VHA has made progress implementing its Year 2000 strategy for biomedical equipment. This strategy, which depends on compliance information from the manufacturers, consists of five steps. These are (1) increase awareness and continually educate VHA CIOs, VISNs, and health care facilities on biomedical issues, (2) establish an expert working group to provide guidance, (3) develop a database of biomedical equipment manufacturers that supply equipment to VHA, (4) survey these manufacturers to identify the compliance status of biomedical equipment and solutions for noncompliance, and (5) communicate survey results to the field for use in determining the compliance status of biomedical equipment at the medical facilities. Each month, these facilities are expected to report to the VHA Year 2000 Project Office their strategies for dealing with noncompliant and conditional-compliant equipment in their inventories and the cost to accomplish this.

To increase awareness, VHA has established an intranet web site containing compliance information from the manufacturers. This web site is also used to educate VHA CIOs, VISNs, and health care facilities on biomedical issues. VHA has also established an expert working group[11] to assist the Year 2000 Project Office in identifying, assessing, and evaluating biomedical equipment at risk from the Year 2000 problem.

VHA developed a database of biomedical equipment manufacturers by using an existing database, which tracks service manuals of both medical devices and scientific and research instruments purchased by its medical facilities. The expert working group reviewed the database to ensure that key manufacturers in specialty areas were included.

To survey biomedical equipment manufacturers, the VHA Year 2000 Project Office sent a series of letters to them requesting information on the Year 2000 compliance status of their products. The first letter was sent to approximately 1,600 manufacturers on September 9, 1997. Two follow-up letters were sent to those that did not respond on October 6, 1997, and November 12, 1997. Upon receipt of responses to these letters, VHA categorized the compliance status provided by the manufacturers for the equipment, as illustrated in table 1.

[11]This group consists of physicians and engineers from the fields of radiology, nuclear medicine, pathology and laboratory, cardiology, surgery, biomedical engineering, acquisition and materiel management, medical research, prosthetics, and the Year 2000 Project Office.

Table 1: VHA Biomedical Equipment Compliance Categories

Category	Explanation
Compliant	Equipment will function properly in all aspects upon the change to the year 2000 without any modification or revision.
Noncompliant	Equipment will not function properly upon the change to the year 2000, and no manufacturer remedy is available. In some cases, improper function involves an incorrect date-time stamp on the output of the equipment, but the equipment's clinical function is not impaired.
Conditional-compliant	Equipment requires some form of user intervention to function properly after the year 2000. Such intervention includes the installation of manufacturer-provided software or hardware or a one-time user action (such as turning the equipment on and off after the year 2000).
Pending	Manufacturers reported to VHA that they have not completed the Year 2000 assessment of their product line.

Source: Veterans Health Administration.

Of the nearly 1,600 manufacturers in VHA's initial mailing, VHA determined that about 100 were no longer in business. Accordingly, VHA revised its list of manufacturers to 1,504 as of June 1, 1998, and reported that it received compliance information from 1,070, or 71 percent, of these manufacturers. Just under half of the 1,504 manufacturers reported that all of their devices are Year 2000 compliant.

As shown in table 2, the manufacturers have provided VHA with compliance information on a wide range of biomedical equipment. VHA's data, as of June 1, 1998, indicated that for those manufacturers that reported, at least 80 percent of the equipment types are compliant. According to VHA's Year 2000 Project Manager, the expert working group reviews the information provided by the manufacturers for reasonableness. The Year 2000 Project Office has provided this information to its medical facilities through VHA's intranet web site, and the facilities are to use the information to assess the compliance status of their equipment.

Table 2: Reported Biomedical Equipment Year 2000 Compliance Categories, as of June 1, 1998, and Examples

Compliance category	Number of manufacturers	Number of equipment types within this category	Examples of equipment types within this category[a]
Compliant	694	3,873	Intra-aortic balloon pump, dialysis machine
Noncompliant	34	182	Defibrillator monitor, cardiology monitor
Conditional-compliant	102	673	Electrocardiograph machine, defibrillator
Pending	53	157	Ultrasound system, ventilator
Manufacturer merged or bought out	187	[b]	
Total	**1,070**	**4,885**	

[a]Inclusion of a specific type of biomedical equipment in the compliant, noncompliant, conditional-compliant, or pending category does not necessarily mean that all equipment of this type in VHA's inventory was reported by the manufacturer; similar equipment made by other manufacturers could fall into different categories.

[b]The biomedical equipment reported by these manufacturers have already been accounted for in one of the above compliance categories.

Source: Veterans Health Administration. We did not independently verify these data.

According to VHA officials, most of the manufacturers that reported one or more of their biomedical equipment products as noncompliant cited incorrect display of date and/or time as problems. 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 the Diagnostic Services Chief of VHA's Technology Division, these cases do not generally lead to the equipment 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 this problem. For example, a physician or technician would note the correct year on the printout from the electrocardiograph machine when the equipment imprints "1900" on the printout.

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 is sorted automatically to present a patient's condition, over a period of 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 example, the case of blood sugar readings. If readings were taken on December 25, 27, and 30, 1999, and again on January 1, 2000, for example, the ordering might appear with the last entry first, if it were abbreviated as "00" and read as January 1, 1900. If the physician or other clinician did not pay close attention, a faulty diagnosis or treatment decision could be made based on a misreading of the data.

VHA also recognizes that an equipment function that depends on a calculation involving a date and that is performed incorrectly as a result of a date problem, could present a risk to the patient. One example reported by a manufacturer is 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 could result in inappropriate treatment—either too low or too high a dosage—and could have an adverse effect on the patient on or after January 1, 2000. This noncompliant equipment is currently in the inventory of several VHA medical facilities. In commenting on a draft of this report, VA noted that VHA has identified three facilities that use this specific equipment, and the noncompliant equipment will be taken out of service.

Given the above case scenarios, it is crucial that biomedical equipment manufacturers provide VHA with information on the compliance status of their equipment. This information is necessary for VHA medical facilities to formulate safe and effective solutions to address Year 2000 problems.

Between November 1997 and January 1998, VHA's medical facilities completed inventories of their biomedical equipment and reported the results to the Year 2000 Project Office. Using data on the facility's biomedical equipment inventory from VHA's equipment database, each facility was to conduct a physical inventory of its biomedical equipment and check this inventory against compliance information submitted by the manufacturers, which the Year 2000 Project Office had posted on the VHA intranet web site.

According to VHA's January 30, 1998, Year 2000 Assessment Phase Report, the medical facilities noted that based on the information from the manufacturers, some of the noncompliant biomedical equipment at VHA sites included defibrillator monitors, noninvasive blood pressure machines, vital signs monitors, and cardiology monitors. VHA officials have stressed that noncompliant equipment of one type reported by certain manufacturers does not indicate that all equipment of the same type in use

at its medical facilities is noncompliant. VHA officials told us that there are other manufacturers of this equipment type that have reported that their equipment is compliant.

The VHA Year 2000 Project Office has directed VHA medical facilities to regularly check the web site for updates on the compliance status of biomedical equipment reported by manufacturers. This is important for the medical facilities because, in some cases, the manufacturers have subsequently changed the compliance status of their equipment after their initial reports to VHA. The changes have ranged from some equipment previously reported as conditional-compliant that is now being reported as compliant to equipment previously reported as compliant that is now considered noncompliant. According to VHA's Year 2000 Project Manager, the project office monitors the medical facilities' Year 2000 activities through periodic reports and site visits.

VHA officials have informed us that they will be relying on the biomedical equipment manufacturers to validate, test, and certify that replacement equipment is Year 2000 compliant. This is because some manufacturers have informed them that VHA should not attempt to conduct in-depth testing by manipulating the software embedded inside the equipment. According to the Diagnostic Services Chief of VHA's Technology Division, such testing may void the manufacturer's certification to FDA that the equipment is safe for use on patients, thereby exposing VHA to legal liability in the event that a patient's health is harmed by equipment that malfunctions following VHA testing. VHA's Year 2000 Project Manager told us that the medical facilities will perform limited functional testing of replacement equipment and of manufacturer modifications to conditional-compliant equipment. He stated that the medical facilities will test equipment performance in accordance with locally established acceptance testing procedures for new equipment.[12]

Uncertainty Over Year 2000 Compliance Status Increases Risk

Despite VHA's progress in implementing its Year 2000 strategy, as of July 29, 1998, it still did not know the full extent of the Year 2000 problem on its biomedical equipment because it has not received compliance and cost information from 27 percent of the manufacturers on its list of suppliers, as well as from nearly 100 additional manufacturers that are no longer in business. This situation impedes VHA's medical facilities from promptly developing strategies to deal with equipment with potential

[12]These procedures generally prescribe that a systematic examination be performed to determine if the equipment meets the electrical safety requirements of the medical facility and the manufacturer's performance specifications for the equipment.

patient safety problems. In addition, the current cost estimate of $40 million[13] reported to OMB to replace or repair noncompliant equipment is incomplete. Also, given the uncertainties surrounding the compliance status of many VHA biomedical equipment items, it is critical that medical facilities develop contingency plans to ensure patient care in the event of Year 2000-related failures. However, the medical facilities have not completed such plans.

Some Manufacturers Have Not Provided Compliance Information on Their Equipment

VHA does not currently know how much of its biomedical equipment is Year 2000 compliant because, as shown in table 3, it has not yet received compliance information from 398 manufacturers. This information is critical to VHA because, like other health care providers, it relies on the manufacturers to validate, test, and certify that their equipment is compliant.

Table 3: Status of Manufacturer Responses as of July 29, 1998

Status of manufacturer response	Number of manufacturers
Compliant manufacturers[a]	701
Noncompliant manufacturers[b]	43
Conditional-compliant manufacturers[c]	106
Pending manufacturers[d]	47
Manufacturer merged or bought out	195
Nonresponsive manufacturers[e]	398
Total	**1,490**

[a]For inclusion in this category, 100 percent of a manufacturer's products had to be considered compliant.

[b]For inclusion in this category, only one of a manufacturer's products had to be considered noncompliant.

[c]For inclusion in this category, the manufacturer has no noncompliant equipment, no pending equipment, and at least one conditional-compliant equipment item.

[d]For inclusion in this category, the manufacturer has no noncompliant equipment and at least one equipment item that is pending.

[e]For inclusion in this category, VHA had not received compliance information from the manufacturer.

Source: Veterans Health Administration. We did not independently verify these data.

Letters sent to more than half of the nonresponsive manufacturers—227 out of 398—were returned to VHA by the U.S. Postal Service marked with no forwarding addresses. In addition, as noted in table 3, an additional 47

[13]We did not independently verify the $40 million cost estimate.

manufacturers that did respond are in the pending category because they reported that they had not completed their assessments, and, therefore, did not yet know if their products were compliant. Among the manufacturers that had not yet responded or completed their assessments as of July 29, 1998, is one that supplies high-dollar value equipment, such as radiology systems and electronic imaging systems equipment, to VHA.

According to the Year 2000 Project Manager, VHA will continue its efforts to obtain compliance information from nonresponding manufacturers. Consistent with this strategy, on June 24, 1998, VHA sent another letter to nonresponsive manufacturers requesting that they provide VHA with Year 2000 compliance information on their products. The Project Manager said VHA will continue to work through October 1998 to obtain compliance information from the manufacturers. Further, he said at that time, VHA's medical facilities must be ready to put contingency plans into effect for noncompliant and conditional-compliant equipment and for that equipment, the status of which is unknown.

Year 2000 Cost Estimate for Biomedical Equipment Is Incomplete

VHA's Year 2000 cost estimate for replacing and/or retiring noncompliant biomedical equipment is incomplete. In its August 15, 1998, quarterly report to OMB, VA estimated the Year 2000 cost to replace or repair this equipment at $40 million. It also reported that VA expects the costs to replace or repair noncompliant biomedical equipment to increase as manufacturers continue to disclose their compliance status. The VHA Year 2000 Project Manager told us that VHA expects to manage these costs within the department's budget. However, the $40 million estimate is not based on updated cost information from the medical facilities, and VHA does not know the replacement and repair cost for biomedical equipment for the manufacturers that have not reported compliance and cost information, as well as the nearly 100 manufacturers that are no longer in business.

VHA's Year 2000 Project Manager informed us that three quarters of the $40 million estimate was calculated based on cost information provided by the VISNs and medical facilities. Specifically, the VISNs and facilities reported to the Year 2000 Project Office the number of noncompliant and/or conditional-compliant equipment items in their inventories and the replacement or repair cost for this equipment using information provided to VHA by the manufacturers and posted on its intranet web site in January 1998. The remaining $10 million was calculated based on the VHA Year 2000 Project Office's estimate of the number of such equipment items

at VHA medical facilities and any cost information provided by manufacturers during the period February through April 1998.

VHA's Year 2000 Project Manager has acknowledged the shortcomings of the current cost estimate. Accordingly, the VISNs were to begin using a new reporting process, effective July 31, 1998. The new process will use a recently developed software package to track the status of noncompliant and conditional-compliant equipment at the medical facilities and the associated costs to replace, repair, or retire it. In commenting on a draft of this report, VA stated that this software was released on July 10, 1998, and the Under Secretary for Health signed an information letter, providing direction and instruction on the software to VHA medical facilities on July 20, 1998.

VHA Has Not Yet Completed Business Continuity and Contingency Plans for Biomedical Equipment

To assist agencies in their business continuity and contingency planning efforts, we have prepared a guide[14] that discusses the scope of the Year 2000 challenge and offers a step-by-step approach for reviewing an agency's risks and threats as well as how to develop backup strategies to minimize these risks. This business continuity and contingency planning process safeguards the agency's ability to produce a minimally acceptable level of outputs and services in the event of failures of internal or external mission-critical information systems and services. A business-level contingency plan would address how each VHA medical facility would handle various types of Year 2000 problems caused by business partner problems, such as nonresponsive manufacturers and the nearly 100 manufacturers that VHA determined were no longer in business.

Despite the uncertainties surrounding the compliance status of many of VHA's biomedical equipment and the potential health risks to patients of certain equipment, VHA medical facilities have not yet completed business continuity and contingency plans on actions they must take to address potential Year 2000-related failures. The Year 2000 Project Manager informed us that these plans need to be ready for implementation by October 31, 1998. He did not know the status of these plans because the project office had not reviewed them. The Project Manager told us that he expects to review these plans when Year 2000 Project Office representatives visit the VISNs and medical facilities later in 1998.

[14]GAO/AIMD-10.1.19, August 1998.

Our review of the March 25, 1998, VISN Assessment Feedback Reports[15] for the three VISNs we visited showed that these VISNs had reported that they did not have business continuity and contingency plans to deal with 76 of the 89 noncompliant biomedical equipment items identified in their inventories. The CIOs at two of these VISNs informed us that they are currently in the process of developing these plans. The third CIO said the VISN's medical facilities have prepared business continuity and contingency plans. However, our review of four of the five plans for this VISN disclosed that these plans did not specifically address Year 2000-related failures of biomedical equipment. Instead, they focused on preventative maintenance inspections and general system and equipment failures.

In light of the uncertainties surrounding the compliance status of VHA's biomedical equipment and their potential effect on patient health and safety, it is crucial that medical facilities be prepared in the event of Year 2000 failures. An official in VHA's Year 2000 Project Office told us that the office is in the process of developing a guidebook to assist the VISNs and medical facilities in addressing Year 2000 business continuity and contingency planning for biomedical equipment and other related issues. The Year 2000 Project Manager said the guidebook will discuss VHA's strategy for obtaining information from nonresponsive manufacturers and address issues such as replacing, repairing, and/or retiring noncompliant biomedical equipment and equipment produced by the nearly 100 manufacturers no longer in business; using the new reporting software for biomedical equipment; procuring compliant biomedical equipment; and having adequate facility staff available on the weekend of January 1, 2000. In commenting on a draft of this report, VA noted that a draft of the guidebook was completed on August 6, 1998, and it expects to issue a final guidebook by September 1998.

FDA Is Also Relying on Biomedical Equipment Manufacturers for Compliance Information

FDA, the agency with oversight and regulatory responsibility for domestic and imported medical devices, is also trying to determine the Year 2000 compliance status of these devices, as well as some scientific and research instruments. Its goal is to provide a comprehensive, centralized source of information on the Year 2000 compliance status of biomedical equipment used in the United States and make this information publicly available on an Internet World Wide Web site.

[15]These reports, prepared by VHA's Year 2000 Project Office, provide feedback to each VISN on its reported January 1998 assessment results and suggest actions that should be taken to enhance the Year 2000 assessment and renovation process at the facility and VISN level.

On January 21, 1998, HHS, on FDA's behalf, issued a letter to approximately 16,000 domestic and foreign biomedical equipment manufacturers[16] requesting information on the Year 2000 compliance of their complete product line.[17] The letter stated that all information received would be made available to the public through FDA's web site. Manufacturers were asked to identify any noncompliant products by type and model number and provide a brief description of the date-related problems and the solutions for mitigating the problems. If all the manufacturer's products were considered compliant, the manufacturer was asked to provide a statement certifying such compliance. In this case, the manufacturer did not have to provide information on the compliant device's make and model. Manufacturers were instructed to forward their responses in writing or electronically to FDA's Center for Devices and Radiological Health.

FDA acknowledges that the response rate to date to the January 1998 letter is disappointing. As of July 30, 1998, FDA had received 1,975 responses from biomedical equipment manufacturers and posted them on its web site. The Director of FDA's Division of Electronics and Computer Science cited several reasons for the low response rate, including manufacturers not yet completing their assessments and the manufacturers' responses to FDA's request being voluntary. He also indicated that the vast majority of manufacturers that received letters from FDA do not make products with any sort of electronic components, and he believed that many of these manufacturers chose not to respond because the request did not pertain to them.

On June 29, 1998, FDA sent a second request to 1,935 medical device manufacturers that had not previously responded to its inquiry and that FDA believes have products that might employ computers or embedded systems. According to the Director, as of July 30, 1998, 628 manufacturers reported that their products employ a date/time function. Of these, about 100 indicated that one or more of their products were not compliant.

[16]FDA developed its mailing list from the manufacturers that have registered their products with the FDA and also the mailing lists of two scientific and research instrument manufacturing associations. Accordingly, this list included manufacturers that do not employ computers or embedded systems in their products, e.g., products such as rubber gloves, tongue depressors, and eyeglasses.

[17]For FDA, compliance means that the product will accurately process and store date/time data (including but not limited to calculating, displaying, recording, and sequencing operations involving date/time data) during, from, into, and between the 20th and 21st centuries, including the correct processing of leap year data.

According to the Director of FDA's Division of Electronics and Computer Science, FDA does not perform technical evaluations of the manufacturers' responses to determine their adequacy. Rather, the Director, his secretary, and a biomedical engineer review the manufacturers' submissions to see if the responses included answers to the questions in the January 1998 letter. He said that FDA relies on the manufacturers to certify whether their products are Year 2000 compliant. FDA's web site includes the statement that

"Inclusion of information in this database indicates that the manufacturer has certified that the data is complete and accurate. The Food and Drug Administration, however, cannot and does not make any independent assurances or guarantees as to the accuracy or completeness of this data."[18]

The Director informed us that except for diagnostic X-ray equipment, FDA does not test new medical devices entering the market. In addition, he said that FDA has performed about 8 to 10 tests per year involving forensic investigations of problem devices. In commenting on a draft of this report, HHS stated that FDA tests this equipment during the premarket review process to ensure that it is in compliance with a mandatory federal performance standard for X-ray equipment. It also indicated that the testing of this equipment does not include compliance with Year 2000 requirements.

According to the Director, FDA reviews the test results submitted by manufacturers requesting premarket approval of their medical devices to see if the manufacturers have demonstrated that products are safe and effective for intended use. When asked if FDA will request test reports from manufacturers that have renovated medical devices that are not Year 2000 compliant, the Director informed us that FDA will not. He said that correcting a date problem does not change the design of the device, and it is the manufacturers' responsibility to ensure proper device design. We disagree with the Director that the date change will not change the design of the device. Correcting the date problem will change the software design of the device and may alter the internal logic of the software. The Director also cited staff limitations as another reason for not requesting and reviewing test results from the manufacturers.

[18]Food and Drug Administration, Year 2000 Impact on Biomedical Equipment, (Washington, D.C., FDA), *http://www.fda.gov/cdrh/yr2000/y2kintro.html*, (cited March 19, 1998).

Some Users Question Usefulness of Current FDA Biomedical Equipment Web Site

While FDA is making an effort to assemble information on biomedical equipment compliance and making this information available to the public, some biomedical engineers attending a June 1998 meeting of the Association for the Advancement of Medical Instrumentation expressed concern that information on the FDA web site is not detailed enough to be useful. Specifically, as mentioned earlier, FDA's list of compliant equipment contains no information on the equipment's make and model. In contrast, VHA's list of compliant equipment generally contains such information.

Also, a review of the FDA database for noncompliant equipment disclosed that some manufacturers have reported that they will have solutions for their equipment in late 1999. Putting off solutions until this late date is risky. However, making this information publicly available does provide hospitals and other users of biomedical equipment with the opportunity to plan alternative solutions.

Further, the Year 2000 compliance information publicly available through FDA does not include responses from many of the manufacturers that have responded to VHA. For example, we selected, on a random basis, a sample of 53 manufacturers in VHA's database that reported their products to be Year 2000 compliant and found that 48 of them were not listed in the FDA database. We, likewise, selected a sample of 13 manufacturers in VHA's database that reported that their products are not Year 2000 compliant, and found that 12 of them were not listed in the FDA database. These manufacturers' products include cardiology equipment, defibrillator monitors, and ultrasound equipment.

The Director of FDA's Division of Electronics and Computer Science acknowledged that the manufacturers were more responsive to VHA's requests, and the VHA database, therefore, contains a higher percentage of responses. He said that he believed the primary reason for this was VHA's position as a large volume customer that could take future action toward the manufacturer if the information was not forthcoming. He also noted that FDA requested information on the complete product line of the manufacturers, while VA requested information from the manufacturers on its list of suppliers.

New Reporting Requirements Identify Medical Devices Posing Health Risk

FDA implemented a new rule[19] on May 18, 1998, requiring medical device manufacturers and importers to report promptly to FDA action to correct and remove devices that pose a health risk or that are in violation of the Federal Food, Drug, and Cosmetic Act.[20] This rule protects public health by ensuring that FDA has current and complete information regarding actions taken on medical devices. These reports are expected to improve FDA's ability to evaluate device-related problems, as well as enable it to take prompt action regarding devices, that pose a health risk. Under the new rule, the affected manufacturer is required to submit a report of action taken to correct the problem or remove the device from service.

According to the Director of the Center for Devices and Radiological Health, under the new rule, FDA has a better chance of learning what corrective actions, including those to address the Year 2000 computer problem, are taken by the manufacturers on medical devices that could pose health risks. The Director said that no manufacturers have yet submitted any reports under this new reporting requirement.

VHA Plans to Make Compliance Information Available to the Public

In contrast to FDA, VHA had not been making information obtained from biomedical equipment manufacturers on the Year 2000 compliance status of their products available to the public through an Internet World Wide Web site. VHA has not yet done so because (1) when VHA requested this information from the manufacturers, VHA did not tell them that it intended to release the information outside the federal government and (2) VHA said that it had concerns regarding whether it would be proper for it to release some of the information provided by the manufacturers because the information may be proprietary. The VHA Year 2000 Project Manager told us that VHA believed it would need the manufacturers' permission before it could share this information. He said that VHA is concerned about the proprietary nature of the products, potential legal issues, and manufacturers' price structure for Year 2000 compliant products. VHA had shared some of Year 2000 compliance status information provided by manufacturers with federal agencies, such as the Department of Defense and the National Institutes of Health (NIH), with the caveat that it was for federal use only. NIH then shared this information with FDA.

VHA, on the advice of the VA Acting General Counsel, has recently informed the manufacturers of its plans to make this information available to the

[19] 21 CFR part 806. The regulation implements provisions of the Safe Medical Devices Act of 1990 (P.L. 101-629).

[20] 21 U.S.C., sections 301 et seq.

public through an Internet World Wide Web site. Specifically, on June 17, 1998, VHA mailed letters to manufacturers that had responded to VHA's previous requests for compliance information. It informed the manufacturers that it intended to place information they provided to VHA on a publicly-available World Wide Web site unless the manufacturers informed it otherwise. VHA included similar language in a June 24, 1998, letter to manufacturers that had not yet provided compliance data. The VHA Year 2000 Project Manager said the response from the manufacturers as of June 30, 1998, has been positive. He added that two manufacturers objected to disclosing this information to the public, citing proprietary reasons. These responses have been referred to VA's legal department.

VA has not yet decided how and when a clearinghouse of compliance information provided to VHA from manufacturers will be made available to the public. According to VHA's Year 2000 Project Manager, the FDA web site is one of the options being considered for the clearinghouse. The Director of FDA's Division of Electronics and Computer Science informed us that FDA and VHA have discussed using FDA's web site as such a clearinghouse.

VA's Under Secretary of Health recognizes the importance of gathering compliance data and sharing them publicly. Specifically, in a July 9, 1998, press conference sponsored by the National Patient Safety Partnership,[21] he called on biomedical equipment manufacturers to identify and address potential patient safety problems resulting from the Year 2000 problem. On behalf of the partnership, he called for (1) all health care practitioners and medical treatment facilities to survey their equipment and seek information from their relevant biomedical equipment manufacturers about their products' Year 2000 compatibility, (2) all health care consumers who use biomedical equipment at home to check with their health care providers about the products' Year 2000 compatibility, (3) the medical equipment manufacturers to take immediate action to determine the compliance status of their equipment, and (4) the establishment of a single, national clearinghouse from which compliance information from manufacturers can be readily accessed by the public. The Under Secretary reiterated these four items in a July 23, 1998, hearing before the Senate Special Committee on Year 2000.

Conclusions

Prompt correction of the Year 2000 problem for biomedical equipment is critical to VHA's role as a health care provider. Although VHA has made

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

progress in assessing its biomedical equipment, it does not yet know the full extent of the Year 2000 problem with this equipment and the associated costs to address this problem because it has not received compliance information from many of the manufacturers. This information is important because VHA relies on the manufacturers to validate, test, and certify that their equipment, including replacement equipment, is compliant. Despite these uncertainties, VHA medical facilities have not yet completed business continuity and contingency plans on actions they must take to address Year 2000-related failures. The Year 2000 Project Office also has not yet completed a Year 2000 contingency guidebook for biomedical equipment to assist the VISNs and medical facilities in their business continuity and contingency planning and other activities. Until these issues are resolved, VHA lacks adequate assurance that its delivery of medical care through the use of biomedical equipment will not be adversely affected by the Year 2000 problem.

FDA's goal is to provide a comprehensive, centralized source of information on the Year 2000 compliance status of biomedical equipment used in the United States, and make this information publicly available on an Internet World Wide Web site. FDA, like VHA, relies on the manufacturers to validate, test, and certify that the equipment is Year 2000 compliant. However, FDA has no assurance that the manufacturers have adequately addressed the Year 2000 problem for noncompliant equipment because it does not require manufacturers to submit test results to FDA certifying compliance. Also, FDA does not have as much information in its database on the compliance status of biomedical equipment as VHA.

Finally, VHA, which currently does not make compliance information obtained from the manufacturers available to the public, now plans to do this through an Internet World Wide Web site. The sharing of this information could greatly assist all health care providers and other users of biomedical equipment in identifying noncompliant and conditional-compliant equipment in their inventories and taking prompt action to make them compliant. Sharing also could provide users with a mechanism to overcome the deficiencies in the FDA database, such as the lack of detailed information on the make and model of compliant equipment and the disappointing response rate from manufacturers to FDA's request for compliance information.

Recommendations to the Secretary of Veterans Affairs

We recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to take prompt action to:

- Ensure that the VISNs and medical facilities use the new reporting system to provide the VHA Year 2000 Project Office with up-to-date and more complete information on the cost to replace and/or repair noncompliant and conditional-compliant biomedical equipment.
- Complete and issue as soon as possible to the VISNs and medical facilities a Year 2000 guidebook on how to address contingency planning and other related issues for biomedical equipment for incorporation in their individual Year 2000 plans.
- Require that each VISN director ensure that medical facilities within the VISN complete development of a Year 2000 business continuity and contingency plan for biomedical equipment in its inventory. This plan should address steps the facility will take on (1) biomedical equipment produced by the manufacturers from which VHA has not received compliance information and the nearly 100 manufacturers no longer in business, (2) noncompliant equipment that have date-time problems but can still be safely used on and after January 1, 2000, and (3) equipment that manufacturers have certified as compliant but that may cease to function or malfunction on and after January 1, 2000.

Recommendations to the Secretary of Veterans Affairs and the Secretary of Health and Human Services

We recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain (1) information on the compliance status of all biomedical equipment by make and model, (2) the identity of manufacturers that are no longer in business, including the types of equipment, makes, and models produced by these manufacturers, (3) the identity of manufacturers that have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant, and (4) the identity of manufacturers that have not provided compliance information to VHA and/or FDA.

We also recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under

Secretary for Health and the Commissioner of the Food and Drug Administration,

- determine what actions, if any, should be taken regarding biomedical equipment manufacturers that have not provided VHA and/or FDA with compliance information;
- determine what actions, if any, are needed to address biomedical equipment produced by manufacturers no longer in business;
- take prudent steps to review the test results for critical care/life support biomedical equipment, especially equipment once determined to be noncompliant but now deemed compliant, and that for which there are concerns about the determination of compliance, and make the results of these reviews publicly available through the single data clearinghouse; and
- determine what legislative, regulatory, or other changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturers' certification.

Agency Comments and Our Evaluation

In commenting on a draft of this report, VA generally concurred with our recommendations to the Secretary of Veterans Affairs and the first of two joint recommendations to the Secretary of Veterans Affairs and the Secretary of Health and Human Services to develop a single data clearinghouse. VA stated that VHA is working closely with other federal agencies, such as the Department of Defense and FDA, to address common problems with biomedical, clinical, and laboratory equipment and facilities. VA also noted that it has joined with the American Hospital Association, the American Nurses Association, and the Joint Commission on the Accreditation of Healthcare Organizations in calling for a joint effort to create a national clearinghouse for Year 2000 information.

VA stated that the percentage of manufacturers not responding to VHA's inquiries is now 14 percent, meaning an 86 percent response rate. However, VHA counted letters returned to VHA by the U.S. Postal Service marked with no forwarding address as responses. Because these manufacturers did not provide VHA with information on the compliance status of their products, the response rate from manufacturers, based on updated information provided to us by VA as of July 29, 1998, is 73 percent, only slightly above the 71 percent rate cited in our draft report.

VA also described actions taken and planned to implement our recommendations, as well as a number of suggested changes to this

report. These comments have been incorporated into the report as appropriate and are reprinted in appendix I.

Regarding our second joint recommendation to the Secretary of Veterans Affairs and the Secretary of Health and Human Services, VA stated that it has no legislative or regulatory authority to implement this recommendation and defers to HHS. VA, however, stated that it will provide consultation or other appropriate assistance to HHS in implementing this recommendation.

HHS, in commenting on a draft of this report, also concurred with the joint recommendation to the Secretary of Veterans Affairs and the Secretary of Health and Human Services to develop a single data clearinghouse. It stated that HHS and VA are merging their efforts to provide complete information to the health care community and the general public regarding the Year 2000 compliance of biomedical equipment. It also stated that FDA will post on the web site the names of manufacturers that have not provided compliance certification. However, HHS did not believe that it is necessary or cost-effective to list all compliant products. It believed that information at the individual model level is only needed for noncompliant products. We disagree with HHS. The make and model information will provide users with detailed data on the reported compliance status of their products, especially for those 195 manufacturers that VA has determined to have merged or been bought out by other manufacturers as of July 29, 1998.

In addition, HHS concurred with two of the three components of the second joint recommendation. Specifically, it concurred with the component of the recommendation to determine the actions that should be taken regarding manufacturers who fail to respond to requests for compliance information. HHS also stated that under current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant.

HHS also concurred that the identity of defunct manufacturers, along with the known types, makes, and models of devices they manufactured should be included in the clearinghouse database. It further stated that it would explore possible approaches to acquiring additional information regarding defunct manufacturers' products.

HHS did not concur with the component of the recommendation to review test results supporting the medical device equipment manufacturers'

certifications that their equipment is compliant. It believed that the submission of appropriate certifications of compliance is sufficient to ensure that the certifying manufacturers are in compliance. We disagree that this is sufficient. Through independent reviews of the manufacturers' test results, users of the medical devices are provided with a level of confidence that the devices are Year 2000 compliant. HHS also stated that it did not have the resources to undertake such a review, and there is insufficient time to complete a review of this nature. In this regard, if HHS lacks sufficient resources to review the manufacturers' test results, it may want to solicit those of federal health care providers and professional associations, such as VA and the National Patient Safety Partnership. Additionally, to make effective use of limited resources, FDA and the health care community, at a minimum, should focus their review efforts on critical care/life support biomedical equipment that was determined to be noncompliant but is now deemed compliant and that for which there are concerns about the determination of compliance.

Regarding our recommendation on legislative or regulatory changes necessary to obtain assurances that manufacturers' biomedical equipment is compliant, HHS believed that the solutions to the Year 2000 problems can be reached through approaches such as the clearinghouse. HHS also clarified FDA's testing of diagnostic X-ray equipment. We have revised the report to reflect this.

Finally, HHS described actions it has taken and planned to implement our recommendations, and these are reprinted in appendix II. HHS also provided a number of technical suggestions to this report, and these comments have been incorporated into the report as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to the Ranking Minority Member of the Subcommittee on Oversight and Investigations, House Committee on Veterans' Affairs, and the Chairmen and Ranking Minority Members of the Subcommittee on Benefits, House Committee on Veterans' Affairs, and the Subcommittee on Health, House Committee on Veterans' Affairs. We will also provide copies to the Chairmen and Ranking Minority Members of the Senate and House Committees on Veterans' Affairs; the Senate Committee on Appropriations; the Senate and House Subcommittees on VA, HUD and Independent Agencies, Senate and House Committees on Appropriations; the Subcommittee on Labor, Health and

Human Services, Education and Related Agencies, Senate Committee on Appropriations; the Senate Committee on Labor and Human Services; the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs; the Subcommittee on Public Health and Safety, Senate Committee on Labor and Human Resources; House Committee on Appropriations; the Subcommittee on Labor, Health and Human Services, and Education, House Committee on Appropriations; the House Committee on Government Reform and Oversight; the Subcommittee on Human Resources, House Committee on Government Reform and Oversight; and the Subcommittee on Oversight and Investigations, House Committee on Commerce; and the Secretary of Veterans Affairs; the Acting Commissioner of the Food and Drug Administration; the Director of the Office of Management and Budget; and the Chair of the President's Council on Year 2000 Conversion. Copies will also be made available to others upon request.

Please contact me at (202) 512-6253 or by e-mail at *willemssenj.aimd@gao.gov* if you have any questions concerning this report. Major contributors to this report are listed in appendix III.

Sincerely yours,

Joel C. Willemssen
Director, Civil Agencies Information Systems

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Abbreviations

CIO	chief information officer
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
MRI	magnetic resonance imaging
NIH	National Institutes of Health
OMB	Office of Management and Budget
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Appendix I

Comments From the Department of Veterans Affairs

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF VETERANS AFFAIRS
ASSISTANT SECRETARY FOR POLICY AND PLANNING
WASHINGTON DC 20420

AUG 25 1998

Mr. Gene Dodaro
Assistant Comptroller General
Accounting and Information Management Division
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

See comment 1.

This is in response to your draft report, ***YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown*** (GAO/AIMD-98-240). We are pleased that GAO recognizes the progress the Department of Veterans Affairs is making in implementing its Year 2000 (Y2K) strategy for biomedical devices. However, although it is not GAO's intent, the draft report infers that Y2K compliance issues with biomedical equipment are unique to VA when in fact, they are industry-wide problems. Moreover, the Veterans Health Administration (VHA) has used its own resources to gather more information than anyone else in the healthcare industry has on biomedical devices. VHA is also ensuring that this information is available to other healthcare providers and consumers. We concur in the recommendations, and have several comments, many of which serve to update information presented in the draft report.

See comment 2.

See comment 1.

VA, like the Food and Drug Administration and many private hospitals and other hospital organizations, bases its Y2K strategy for biomedical devices on obtaining compliance information from the original equipment manufacturers (OEMs) of the devices. This is because the OEMs are the only parties with full access to all design and operating parameters that may have Y2K implications and are, therefore, the most reliable sources of information. VHA has aggressively pursued OEM compliance information, and, although it is still tracking manufacturers who have not responded to its inquiries, of the 55 OEMs with extensive representation at VA facilities with high cost ($250,000 or more), high volume (multiple pieces of equipment at a site) or critical care/life support equipment, only 1 manufacturer remains unresponsive, not the 19 cited in the report. GAO correctly notes that VHA has found only one device posing a serious risk to patient safety. We hasten to add that VHA has already notified the three facilities with this device of its Y2K problem. In addition, the percentage of manufacturers not responding to VHA's inquiries is now 14 percent, not the 29 percent cited in the report. This raises VHA's total response rate to 86 percent. The enclosure presents a table that provides the most recent data on the status of VHA's efforts.

2. Mr. Gene Dodaro

See comment 1.

As stated in our response to your recent report, ***YEAR 2000 COMPUTING CRISIS: Progress Made in Compliance of VA Systems, But Concerns Remain*** (GAO/AIMD-98-237), VHA is working closely with the Department of Defense (DoD), the National Institutes of Health, Centers for Disease Control and Prevention, and the Food and Drug Administration to address common problems with biomedical, clinical and laboratory equipment and facilities. VHA is also working with the National Patient Safety Partnership to increase awareness of compliance problems and has joined the American Medical Association, the American Hospital Association, the American Nurses Association, and the Joint Commission on the Accreditation of Healthcare Organizations in calling for a joint effort to create a national clearinghouse for Year 2000 information. This clearinghouse is intended to meet the needs of health care providers and consumers who face the same set of issues for medical devices that VA faces.

Finally, as we previously stated in the above cited Y2K report, the reluctance by business entities to disclose compliance information may be resolved by the Administration's proposed "Good Samaritan" law. This law will encourage vendors to disclose their compliance activities.

The enclosure describes our actions taken and planned to implement your recommendations. It also contains recommended corrections to the draft. I appreciate the opportunity to review the draft of your report.

Sincerely,

Dennis Duffy

Enclosure

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)

GAO recommends that the Secretary of Veterans Affairs direct the Under Secretary for Health to take prompt action to

- **Ensure that the VISNs and medical facilities use the new reporting system to provide the VHA Year 2000 Project Office with up-to-date and more complete information on the cost to replace and/or repair noncompliant and conditional-complaint biomedical devices**

Concur - With input from field-based Biomedical Engineers, VHA has developed software to enhance its equipment tracking module AEMS/MERS (Automated Engineering Management System/Medical Equipment Reporting System) to provide for Y2K tracking, documentation and reporting. VHA released this module on July 10, 1998. To provide direction and instruction, the Under Secretary for Health signed an Information Letter, "VISTA Patch for Year 2000 Tracking and Reporting" (IL 10-98-17). VHA released the information letter to all its medical facilities on July 20, 1998.

- **Complete and issue as soon as possible to the VISNs and medical facilities a Year 2000 guidebook on how to address contingency planning and other related issues for biomedical devices for incorporation in their individual Year 2000 plans.**

Concur - A special task group of Biomedical Engineers completed a draft of a "VHA Year 2000 Guidebook for Medical Equipment" on August 6, 1998. The guidebook illustrates available tools and resources within VHA for use by medical facility staff to address Year 2000 compliance for medical devices. The topics include Awareness, Assessment, Renovation/Implementation, and Validation (which addresses contingency planning and testing principles).

- **Require that each VISN Director ensure that their medical facilities complete development of a Year 2000 business continuity and contingency plan for the biomedical devices in its inventory. This plan should address steps the facility will take on (1) biomedical devices produced by the 29 percent of the manufacturers from whom VHA has not received compliance information and the nearly 100 manufacturers no longer in business; (2) noncompliant devices with a date-time**

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

problem, which can still be safely used on and after January 1, 2000; and (3) devices that manufacturers have certified as compliant but which may cease to function or malfunction on and after January 1, 2000.

Concur with modification - The publication of the guidebook (discussed above) will enable facilities to develop local contingency plans tailored to their needs and their unique Y2K compliance position. The book discusses scenarios to be considered for contingencies, should specific vulnerabilities materialize. This GAO recommendation is based on developing contingency plans, in part, based on "the 29 percent of the manufacturers from whom VHA has not received compliance information..." As discussed earlier in this response, the percent of manufacturers has been reduced to 14 percent. We expect this trend to continue as we aggressively pursue manufacturer compliance information. The recommendation should reflect this change.

GAO also recommends that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and the Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain: (1) information on the compliance status of all biomedical equipment by make and model; (2) the identity of manufacturers who are no longer in business, including the types of devices, make and model produced by these manufacturers; (3) the identity of manufacturers who have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant; and (4) the identity of manufacturers who have not provided compliance information to VHA and/or FDA.

Concur - VA is addressing this recommendation. Representatives from both VA and Health and Human Services met to plan a common database to serve the needs of the public. We developed a draft charter for the federal partners in this effort, which will include the Department of Defense (DoD). We expect our weekly meetings to continue

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

until the working group adequately identifies resources, database definition, and database integrity, among other details. The final product is intended to meet the needs of all healthcare providers and consumers who face the same set of issues for medical devices and the Year 2000 problem.

GAO also recommends that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under Secretary for Health and the Acting Commissioner of the Food and Drug Administration:

- **determine what actions, if any, should be taken toward biomedical equipment manufacturers who have not provided VHA and/or FDA with compliance information;**
- **take prudent steps to review the test results supporting the biomedical equipment manufacturers' certifications that their equipment is compliant, and make the results of these reviews publicly available through the single data clearinghouse; and**
- **determine what legislative or regulatory changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturer's certification, similar to the current process for reviewing radiological equipment.**

See comment 1.

VA has no legislative or regulatory authority to implement this recommendation and defers to the Department of Health and Human Services. We will, however, provide consultation or other appropriate assistance to HHS in implementing this recommendation.

Specific Comments:

See comment 3.
Now on pp. 2 and 9.

1. GAO makes several references (page 3 and page 15) to a radiation therapy planning computer that is noncompliant. GAO should note in the report that VHA has already identified the three VHA facilities that use this specific device and the noncompliant device will be taken out of service at these facilities.

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

2. On page 3, paragraph 1, and page 4 paragraph 2:

Now on pp. 2 and 3.
See comment 3.

We suggest inserting the words "like other health care providers" when referring to VHA's reliance on manufacturers to validate, test and certify that their devices are compliant. This recommended change is consistent with the report's language on page 18.

3. On page 5, paragraph 1:

Now on page 3.
See comment 3.

Suggest changing the second and third sentences to read:

> VHA, however, has not yet done so because (1) when VHA requested the information from the manufacturers, VHA did not tell them that it intended to release the information outside the Federal government, and (2) as a result, VHA believes that some of the information provided by the manufacturers may be proprietary information, which VHA could not legally release to the public. In order to resolve this issue, on advice of the Acting General Counsel, VHA recently asked manufacturers to advise the agency if they considered any of the information provided to VHA to be confidential commercial information. VHA will then consider the response of each manufacturer in light of all the information available to VHA to determine whether the information provided by that manufacturer is confidential commercial information. If VHA determines that the information is not confidential commercial information, subject to notice to the manufacturer in indicated instances, VHA will release the information. If VHA determines that the information is confidential commercial information, absent consent from the manufacturer, VHA legally may not release the information.

4. On page 7, paragraph 1:

Now on page 4.
See comment 3.

Suggest changing sentence to "...to approximately 1,600 device manufacturers who supply VHA..."

Enclosure

DEPARTMENT OF VETERANS AFFAIRS COMMENTS
TO GAO DRAFT REPORT,
YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown
(GAO/AIMD-98-240)
(Continued)

Now on pp. 11 and 12.
See comment 3.

5. On page 18, paragraph 1 and page 21, paragraph 1:

In our May Year 2000 quarterly report to OMB, VA noted that we expect costs to replace or repair non-compliant biomedical equipment to increase as manufacturers continue to disclose their compliance status.

Now on page 14.
See comment 3.

6. On page 24, paragraph 2:

A special task group of biomedical engineers completed a draft "VHA Year 2000 Guidebook for Medical Equipment" on August 6, 1998. The final guidebook will be released by September 1998.

Now on page 18.
See comment 7.

7. On page 30, paragraph 3:

The language should be modified to be consistent with the new language we suggested for page 5, the first paragraph.

Now on page 18.
See comment 3.

8. On page 31, paragraph 1:

Change end of last sentence from "internal use" to "Federal use."

Updating Information:

Original Equipment Manufacturer's Response to Year 2000 Compliance Inquiry by Category

See comment 3.

June 1, 1998	July 29, 1998	Category	Difference
694	701	Compliant	+7
34	43	Non-Compliant	+9
102	106	Conditionally Compliant	+4
53	47	Pending	-6
187	195	Mergers/Buyout	+8

The following are GAO's comments on the Department of Veterans Affairs' letter dated August 25, 1998.

GAO Comments

1. Discussed in "Agency Comments and Our Evaluation" section of report.

2. Report updated to reflect that only 1 of 19 manufacturers remains unresponsive.

3. Report changed to reflect agency comments.

Appendix II

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP - 2 1998

Mr. Gene L. Dodaro
Assistant Comptroller General
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Dodaro:

Enclosed are the Department's comments on your draft report entitled, "Year 2000 Computing Crisis: Compliance Status of Many Biomedical Devices Still Unknown." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

June Gibbs Brown
Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services on the General Accounting Office Draft Report Entitled, YEAR 2000 COMPUTING CRISIS: Compliance Status of Many Biomedical Devices Still Unknown GAO/AIMD-98-240

We are grateful for the visibility that the Congress and this General Accounting Office (GAO) report have provided on behalf of the Department of Health and Human Services' Food and Drug Administration's (FDA) national clearinghouse on biomedical equipment (includes medical devices regulated by FDA as well as other computerized equipment used in the medical field). We share your concerns and will do our utmost to protect the uninterrupted provision of safe and effective patient care by the health care community, and continuation of our Nation's medical research activities.

General Comments

Because it is imperative to ensure that biomedical equipment systems with embedded microchips function properly in the next century, the Department of Health and Human Services (the Department or HHS) has been involved in an effort to ensure the compliance of biomedical equipment for over a year. As noted in the report, on January 21, 1998, the Department issued a letter to 13,000 manufacturers of medical devices and, working through professional associations, approximately 3,000 manufacturers of scientific laboratory equipment. This letter asked the manufacturers to provide information concerning the compliance status of their products.

See comment 1.

As also noted in the report, on June 29, 1998, FDA issued a follow-up letter to 1,935 manufacturers. In considering this follow-up strategy, FDA targeted particular manufacturers that, based on their FDA registration information, appeared to produce medical devices that could have a date problem. The follow-up letter has resulted in a number of new submissions from manufacturers, but the Department believes more efforts are needed to ensure the compliance of biomedical equipment.

See comment 2.

To improve our ability to provide complete information to the health care community and to the general public regarding the Year 2000 compliance of medical devices and biomedical equipment, the Department and the Department of Veterans Affairs (VA) are merging our efforts on biomedical equipment. We have convened a steering committee to develop a charter, action milestones, and funding mechanisms. The charter and a collaborative agreement are in the final stages of development, and a high level action plan, along with a funding estimate, has been drafted. We will work through the Health Care Sector Outreach Committee and the White House Year 2000 Conversion Council to enhance our ability to make more information available to the public. We also will take steps to include additional data elements as mutually decided by the participating Departments. In addition, FDA has requested a supplemental appropriation in order to fund the collection, verification, and posting of information by the biomedical equipment clearinghouse.

The Departments' objective remains the uninterrupted provision of safe and effective patient care and the continuation of our Nation's medical research activities through the provision of a comprehensive, centralized national source of information on the Year 2000 compliance status of medical devices used in the United States and making this information publicly available through our web site. Our joint efforts with the VA are designed to better leverage our collective information and influence. As noted above, we already are working together to enhance the existing website to be the national biomedical equipment clearinghouse by adding equipment inventories from other organizations and by conducting additional follow-up activities.

The National Institutes of Health (NIH) works directly with grantees on the Year 2000 compliance issue, which is critical for accomplishing the NIH medical research mission. The grantees will greatly benefit if, by joining together with the other agencies, we are able to gather sufficient, publicly available data to inform them of the compliance status of medical devices and scientific laboratory equipment. The Department is working with NIH to assure that their needs are met, as well as those of the other government agency and the general public.

These activities include checking whether a medical devices manufacturer has met a planned date for availability of a compliant product version and inspecting records relating to the Year 2000 compliance of computerized medical devices during FDA inspections. Additional enhancements are also under consideration. For example, we are considering how to provide the ability for manufacturers to update their product information when the compliance status of the product changes, without eliminating the existing information, as well as many of the changes recommended by GAO.

See comment 3.

There are several areas of concern regarding the text of the report, its conclusions and recommendations that we wish to bring to GAO's attention. First, the report's premise regarding how FDA tests diagnostic x-ray equipment (*only* diagnostic x-ray equipment, *not* "radiological equipment") is not correct. This premise appears to be the basis for much of the report and the recommendations, and therefore, needs to be corrected. The tests FDA conducts on diagnostic x-ray equipment are very limited and are the only routine tests of medical devices by FDA. FDA tests these systems during the premarket review process only to ensure that they are in compliance with a mandatory Federal performance standard for x-ray equipment. The tests are run on a single piece of new equipment that is provided by the manufacturer just for the purpose of being tested. The testing is limited to well-defined tests that are measured against well-defined criteria set by the Federal Performance Standard. The testing of equipment for compliance with Year 2000 requirements would require testing most, if not all, devices currently in use. Furthermore, there are no broadly applicable tests and criteria for determining Year 2000 compliance; every product would require its own unique testing regimen to reflect the unique characteristics and operating environment of the particular device. Contrary to the draft report, testing devices for compliance with Year 2000 requirements is not "similar" to any current FDA practice, and would create a very significant additional burden on FDA's resources.

See comment 4.

The report sometimes refers to biomedical devices and sometimes to biomedical equipment. GAO needs to distinguish between "medical devices", which FDA regulates, and "biomedical equipment" which includes not only medical devices, but also many other products (for example,

laboratory equipment) that FDA does not regulate, and indeed has no authority to regulate. FDA can take action only where there is statutory authority to do so. The report should be precise in its discussion and in the final recommendation to avoid confusing the reader regarding the extent of FDA's authority. If GAO believes FDA needs additional authority to take action with regard to the Year 2000 problem, their recommendation should be directed to Congress.

Finally, the report should explicitly acknowledge that Federal Government action, including legislative or regulatory action, cannot be expected to resolve all Year 2000 concerns with medical devices or other biomedical equipment and that manufacturers and users must accept responsibility for addressing the specific concerns that arise in their facilities.

GAO Recommendation

We recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services work jointly to develop immediately a single data clearinghouse that provides compliance information to all users of biomedical equipment. Development of this clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs, American Hospital Association, American Medical Association, and the Health Industry Manufacturers Association. At a minimum, the clearinghouse should contain: (1) information on the compliance status of all biomedical equipment by make and model; (2) the identity of manufacturers who are no longer in business, including the types of devices, make and model produced through by these manufacturers; (3) the identity of manufacturers who have and have not provided VHA and/or FDA with test results certifying that their equipment is Year 2000 compliant; and (4) the identity of manufacturers who have not provided compliance information to VHA and/or FDA.

Department Comment

See comment 2.

We concur. The Department and VA already are working as a Federal partnership to develop a single data clearinghouse. Our private sector associates, mostly professional associations such as the American Medical Association, the American Hospital Association, and the Joint Commission on Health Care Accreditation, will provide advice and assistance as requested. We also agree that it would be useful to provide an indication of whether a particular manufacturer has or has not provided information on Year 2000 compliance for manufacturers of electronic products that are susceptible to Year 2000 concerns. To that end, FDA will post on the web site the identity of manufacturers who have not provided compliance certification.

See comment 2.

We do not believe, however, that listing all compliant products is either necessary or cost-effective. The FDA web site already includes a certification statement assuring total compliance from those manufacturers who report that all of their products are compliant. Information at the individual model level is needed for noncompliant products only. If a manufacturer's entire product line is compliant, users of the clearinghouse would receive no additional benefit from the model-level information, which would be quite expensive to obtain and enter into the database. Furthermore, manufacturers could be expected to cooperate more fully with the clearinghouse if reporting burdens are kept to a minimum and only essential information is requested.

Because we believe there is redundancy between this recommendation and those that follow, we will address the remaining elements of this recommendation in our responses below.

GAO Recommendation

We also recommend that the Secretary of Veterans Affairs and the Secretary of Health and Human Services, in conjunction with VA's Under Secretary for Health and the Acting Commissioner of the Food and Drug Administration:

> determine what actions, if any, should be taken toward biomedical equipment manufacturers who have not provided VHA and/or FDA with compliance information;

Department Comment

See comment 2.

The Department concurs that it will be necessary to determine what further action should be taken regarding manufacturers which fail to respond. FDA already notes on its web site that there is no assurance that manufacturers which have not responded to FDA's survey request are Year 2000 compliant. Under current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant, although FDA can communicate with firms and encourage cooperation with the clearinghouse.

GAO Recommendation

> determine what actions, if any, are needed to address biomedical equipment produced by manufacturers no longer in business;

Department Comment

See comment 2.

We concur that the identity of manufacturers known to be defunct, along with the known types, makes, and models of devices they manufactured should be included in the clearinghouse database, and will explore possible approaches to acquiring additional information regarding defunct manufacturers' products. At this time, however, appears that obtaining this information would be very difficult and costly, and might not be possible for the majority of the defunct manufacturers. When a corporate entity goes out of existence, usually there remains no legally responsible party to whom a request for information could be addressed, nor is there any assurance that such detailed information would still exist. One approach that should be considered is to advise hospitals and other users of devices manufactured by a defunct firm that they will need to develop alternative strategies for assuring their equipment will continue to function appropriately after the Year 2000 problems. These alternative strategies could include examination of the device and any manuals or other documents, testing by internal staff or a consultant, or replacing the device with one known to be Year 2000 compliant.

GAO Recommendation

> take prudent steps to review the test results supporting the biomedical equipment manufacturers' certifications that their equipment is compliant, and make the results of these reviews publicly available through the single data clearinghouse; and

Department Comment

See comment 2.

We do not concur. Resources to undertake such a review are not available, and there is insufficient time before the Year 2000 to complete a review of this nature.

We believe that submission of appropriate certifications of compliance is sufficient to assure that the certifying manufacturers are in compliance. Certifications submitted to any Federal agency must be truthful. Certifiers are subject to criminal prosecution under 18 USC 1001 if they submit false information. Furthermore, the responsibility for truthfully assuring the compliance of medical devices must rest primarily with those who manufacture and market such devices, and are best able to assess and correct Year 2000 problems.

GAO Recommendation

> determine what legislative or regulatory changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturer's certification, similar to the current process for reviewing radiological equipment.

Department Comment

See comment 2.

While we would welcome any assistance the Congress could give, the Department believes that the solutions to Year 2000 problems relating to medical devices can be achieved through other approaches, such as the clearinghouse and other educational efforts that are already underway. Also, as noted in the general comments above, GAO appears to have misunderstood FDA's role in approving new medical devices. FDA does not independently verify and validate test data provided by manufacturers except in the one instance cited above. As noted above, we do not have the resources to undertake such a program at this time.

The following are GAO's comments on the Department of Health and Human Services' letter dated September 2, 1998.

GAO Comments

1. Report modified to include "1,935 manufacturers."

2. Discussed in "Agency Comments and Our Evaluation" section of report.

3. Report revised to reflect agency comments.

4. Report revised to clarify the terms "biomedical equipment" and "medical devices." The term biomedical equipment includes both medical devices subject to FDA regulation and scientific and research instruments which are not subject to FDA regulation.

Appendix III

Major Contributors to This Report

Accounting and Information Management Division, Washington, D.C.

Helen Lew, Assistant Director
Nabajyoti Barkakati, Technical Assistant Director
Tonia L. Johnson, Senior Information Systems Analyst
J. Michael Resser, Business Process Analyst-in-Charge

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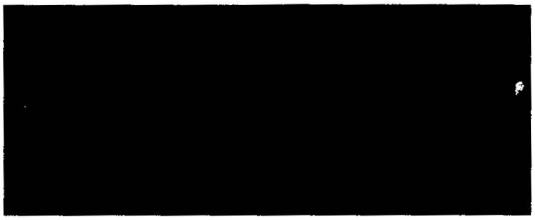

Statement of Senator Charles E. Grassley
Chairman, Special Committee on Aging
before the
House Committee on Veterans' Affairs
September 24, 1998

Chairman Everett and Members of the Committee, thank you for your graciousness in extending an invitation to me to appear at this critically important hearing addressing biomedical devices and the Year 2000 problem. In addition, I apologize for the fact that I will be unable to stay and respond to any questions after my statement. I have to leave to chair a Judiciary Subcommittee hearing.

Over the past 18 months or so, as Chairman of the Senate Special Committee on Aging, I have been actively involved in monitoring the progress, or lack thereof, by the Social Security Administration (SSA) and the Health Care Financing Administration (HCFA) to address the Y2K problem. I am confident that we all agree that ensuring the continued operation of SSA and HCFA, without a stumble, is imperative. At this time, I am happy to note that SSA recently demonstrated that it is likely to meet its Y2K goals. Unfortunately, I am deeply troubled by the continuing lack of progress at HCFA, especially in terms of its management of Medicare.

At the same time, ensuring that the "check is in the mail" pales in comparison to the issue before us today — are biomedical devices like dialysis machines, radiological equipment and patient monitors, just to name a few, going to be affected by the Y2K bug in a big way, little way or not at all?

There was a time when the term micro-chip was heard only in the lecture halls of MIT. Today, micro-chips are embedded in countless biomedical devices. In fact, the FDA says that there are more than 10,000 medical devices being used today alone. These devices are manufactured by thousands of corporations and have become essential to the practice of medicine.

Because of our dependency on the micro-chip and the devices containing them, a number of critical questions arise. Will innocent, and often vulnerable and uninformed, people throughout the United States be subjected to some unexpected or even life-threatening situations by non-compliant biomedical devices? Unfortunately, the answer to this and many other questions are not within our grasp. But they should be. The answer to this and other related questions should be available to every consumer and provider including every physician, every hospital and every nursing home.

There is a serious problem lurking in each and every device containing a micro-chip or real-time clock. These devices are suspect simply because they contain a micro-chip. We don't know that these devices will fail and we don't know that they won't.

We as legislators have a duty to our constituencies, our families, our friends and ourselves to ensure that the government:

1. Promotes communication and a meeting of the minds among all members in the health care industry so that they can embrace the magnitude and seriousness of the Y2K problem, and recognize its implications for the people they serve;

2. Possesses a reliable list of corporations that manufacture devices containing a micro-chip;

3. Creates and maintains a reliable list of devices that contain a micro-chip or real time clock;

4. Continues asserting pressure on the health care industry to deal with the Y2K problem swiftly, deliberately and cooperatively;

5. Ensures that the federal government in each and every acquisition contract executed with a biomedical device manufacturer require that the device sold is Y2K compliant;

6. Encourages the health care industry to communicate and educate physicians, nurses and others to be aware of the depth and scope of the Y2K problem in medical devices; and

7. Promotes public awareness and access to information that could impact their lives or the life of someone dear to them.

These actions are imperative because, as we sit here today, we do not yet have a list of the companies that manufacture biomedical devices or a comprehensive list of the biomedical devices containing a micro-chip. Without this basic information we cannot move forward.

I understand that the reasons for this lack of information are many and a great deal of finger pointing has gone on in the past. Well, that finger pointing must stop and it must stop now. The key players — the hospitals, the doctors, the biomedical device manufacturers, the Food and Drug Administration, the Health Care Financing Administration, the Veterans Administration and the Congress must work collaboratively to prevent the occurrence of Year 2000 problems.

Before closing I want to address the American public and say:
Your Safety Could be At Risk. Wake Up, Be Alert, Ask Questions, Check it Out and Don't Assume Everything's Alright. It May Not Be.

Again, Chairman Everett and other members of the Committee, thank you for your leadership on this critically important issue and thank you again for the honor of appearing before this distinguished panel.

STATEMENT OF HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
HOUSE COMMITTEE ON VETERANS AFFAIRS

HEARING ON BIOMEDICAL EQUIPMENT AND STATUS OF YEAR 2000 COMPLIANCE EFFORTS

SEPTEMBER 24, 1998

I AM PLEASED THAT CHAIRMAN EVERETT AND RANKING DEMOCRAT CLYBURN HAVE SCHEDULED THIS ALL-IMPORTANT FOLLOW-UP TO LAST YEAR'S HEARING ON THE VA'S EFFORTS TO ACHIEVE YEAR 2000 COMPLIANCE.

TODAY'S HEARING FOCUSES ON Y2K ISSUES IMPACTING BIOMEDICAL EQUIPMENT, AND I AM PLEASED TO SAY IT HAS ALREADY PRODUCED TANGIBLE RESULTS. THIS PAST TUESDAY, THE VA ANNOUNCED IT HAD

REACHED AN AGREEMENT WITH THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) TO ESTABLISH A Y2K CLEARINGHOUSE FOR MEDICAL EQUIPMENT.

IF PROPERLY IMPLEMENTED, THIS JOINT PLAN WOULD ESTABLISH AN INTERNET SITE THAT WOULD ALLOW PATIENTS AND MEDICAL PROFESSIONALS ALIKE TO DETERMINE WHAT Y2K PROBLEMS STILL EXIST. IT WOULD ALSO HELP VA, HHS, AND PRIVATE INDUSTRY TO DETERMINE WHAT ADDITIONAL STEPS NEED TO BE TAKEN TO ENSURE THE VA IS ABLE TO PROVIDE UNINTERRUPTED, HIGH QUALITY HEALTH CARE TO ITS VETERANS IN THE YEAR 2000 AND BEYOND.

GAO'S EXTREMELY USEFUL TESTIMONY THIS MORNING POINTS OUT SOME CRITICAL AREAS REQUIRING IMMEDIATE FOLLOW UP IF Y2K PROBLEMS ARE TO BE RESOLVED. I URGE BOTH VA AND HHS, AS WELL AS PRIVATE INDUSTRY, TO HEED GAO'S WARNING SIGNALS, AND TO PLACE RENEWED ATTENTION AND COMMITMENT TO ADDRESSING THESE CRITICAL PROBLEMS.

THANK YOU, MR. CHAIRMAN.

STATEMENT OF HONORABLE JAMES E. CLYBURN
RANKING DEMOCRATIC MEMBER
SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS
HOUSE COMMITTEE ON VETERANS AFFAIRS

HEARING ON BIOMEDICAL EQUIPMENT AND STATUS OF YEAR 2000 COMPLIANCE EFFORTS

SEPTEMBER 24, 1998

THANK YOU CHAIRMAN EVERETT FOR CALLING THIS CRITICAL HEARING FOCUSING ON RECENT EFFORTS TO ADDRESS YEAR 2000 UNCERTAINTIES WITH REGARD TO BIOMEDICAL EQUIPMENT ESSENTIAL TO PROVIDING HIGH QUALITY HEALTH CARE TO OUR NATION'S VETERANS.

AS MEMBERS OF THE SUBCOMMITTEE WITH DIRECT OVERSIGHT RESPONSIBILITY OF THE VA, AND AS MEMBERS OF CONGRESS WHO OFTEN FIND IT EASIER TO SECOND GUESS RATHER THAN PRAISE FEDERAL AGENCY ACTIONS, WE RARELY HAVE THE CHANCE TO SAY ANYTHING GOOD ABOUT

THE DEPARTMENT DURING SUBCOMMITTEE HEARINGS.

IN THIS CASE, HOWEVER, I AM MORE THAN HAPPY TO COMMEND THE VA FOR WHAT EVEN GAO'S TESTIMONY SUGGESTS IS A RENEWED AND REAL COMMITMENT TO RESOLVING Y2K PROBLEMS WITHIN THE VHA.

SINCE I AM IN A FAIRLY CHARITABLE MOOD THIS MORNING, I WON'T SPEND A LOT OF TIME DWELLING ON WHAT SOME WOULD REGARD AS A LESS-THAN-FULL COMMITMENT ON THE PART OF THE FDA TO DEAL WITH THESE PROBLEMS.

INSTEAD, I'LL PRAISE THE FDA AND HHS FOR ITS AGREEMENT TO SET UP A JOINT VA-HHS INTERNET SITE THAT WILL SERVE AS A CLEARINGHOUSE FOR INFORMATION CONCERNING Y2K COMPLIANCE AMONG MEDICAL EQUIPMENT MANUFACTURERS.

THERE CONTINUES TO BE GREAT UNCERTAINTY ABOUT THE POTENTIAL IMPACT OF THE YEAR 2000 BUG ON VETERANS' HEALTH CARE. AND WHILE TODAY'S HEARIING SHOULD DRAW FAVORABLE ATTENTION TO THE VA'S EFFORTS IN THE PAST YEAR TO ADDRESS THESE PROBLEMS, IT SHOULD ALSO SERVE AS A WARNING SIGN THAT MUCH HARD WORK HAS YET TO BE DONE BY VA, HHS AND PRIVATE INDUSTRY IF YEAR 2000 OBSTACLES ARE TO BE OVERCOME.

AGAIN, I THANK THE CHAIRMAN FOR DEVOTING THE LAST FORMAL SUBCOMMITTEE HEARING OF THE SESSION TO THIS EXTREMELY IMPORTANT TOPIC, AND I LOOK FORWARD TO THIS MORNING'S TESTIMONY.

Opening Statement for Rep. Mascara
on the Year 2000 Bug
Before the Oversight Subcommittee Hearing
September 24, 1998

Thank you Mr. Chairman, I want to thank you and the Ranking Member of this Subcommittee, Mr. Clyburn, for your continued vigilance and hard work in keeping this important subject as a priority.

My first hearing after joining this subcommittee dealt with this issue, and at the time I was not very impressed with the level of interest in solving this problem. I am still not impressed with the work that is being done. It has been over a year since we discussed this situation, and only on this past Tuesday did the VA and HHS decide they were going to work seriously on this issue together.

While I am very concerned with whether the veterans in Southwestern Pennsylvania and elsewhere around the country will receive their checks on time, and whether the government will by shut down or not, I am even more concerned with those people who use these medical devices in order to survive. A check can be reissued and will be more an annoyance than anything else for the recipient. However, a dose of medicine cannot taken back once it is given to the patient. An improper medical treatment has a significant risk to the patient. No one should die because of this issue.

Waiting until two days before this hearing to announce a new initiative to help solve this problem only makes me wonder what else is not being done.

I look forward to hearing from all the witnesses today.

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

YEAR 2000 COMPUTING CRISIS

For Release on Delivery
Expected at
9:30 a.m.
Thursday,
September 24, 1998

Leadership Needed to Collect and Disseminate Critical Biomedical Equipment Information

Statement of Joel C. Willemssen
Director, Civil Agencies Information Systems
Accounting and Information Management Division

GAO/T-AIMD-98-310

Mr. Chairman and Members of the Subcommittee:

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

The Department of Veterans' Affairs (VA)--specifically, the Veterans Health Administration (VHA)--is attempting to determine the Year 2000 compliance status of biomedical equipment in use in its medical centers, outpatient clinics, nursing homes, and domiciliaries. Within the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) oversees and regulates medical devices in the private sector. Both organizations are employing the same strategy: relying on information provided by equipment manufacturers. Our report being released at this hearing details the status of VHA's and FDA's biomedical equipment programs.[3]

In brief, VHA has made progress in implementing its Year 2000 strategy for biomedical equipment, but it still does not know how pervasive the problem is. This is because it has not received compliance and cost information from many of the manufacturers on its list of suppliers, as well as from the nearly 100 additional manufacturers no longer in business. Like VHA, FDA has sent letters to biomedical equipment manufacturers, requesting information on products affected by the Year 2000 problem. The response rate to FDA has been disappointing. Failure to obtain timely compliance information from the manufacturers increases the risk to health care providers and biomedical equipment users that such equipment may not operate properly after the turn of the century. It is critical that such information be obtained and publicized; while many reported noncompliant equipment items do not present a risk to patient safety, some could present such risks.

My testimony today will discuss (1) the progress that VHA and FDA have made in determining the compliance status of biomedical equipment, and (2) further actions they need to take to minimize associated Year 2000 risks.

BACKGROUND

Biomedical equipment is indispensable; it plays a central role in virtually all health care. It can be defined as any tool that can record, process, analyze, display, and/or transmit medical data--some of which may even be implanted in patients--and laboratory research instruments such as blood gas and glucose analyzers. Such equipment may use a

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

[2]The Year 2000 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. A listing of our publications on the Year 2000 problem is included as an attachment to this statement.

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

computer for calibration or for day-to-day operation. If any type of date or time calculation is performed, susceptibility to a Year 2000 problem exists, whether the computer is a personal computer that connects to the equipment remotely or a microprocessor chip embedded within the equipment. This could range from the more benign--such as incorrect formatting of a printout--to the most serious--incorrect operation of equipment with the potential to decrease patient safety. The degree of risk depends on the role of the equipment in the patient's care.

As a health care provider, VHA is a key stakeholder in determining the potential effect the Year 2000 computer problem could have on its biomedical equipment. Because VHA, like other health care providers in the private and public sectors, relies on manufacturers to validate, test, and certify that their equipment is compliant, it is critical that manufacturers provide this information so that VHA may take prompt action on noncompliant equipment in its inventory. Another key stakeholder in determining the status of equipment compliance is FDA, which has oversight and regulatory responsibility for domestic and imported medical devices.

VHA: PROGRESS, BUT SIGNIFICANT RISKS REMAIN

VHA's strategy for identifying and remedying noncompliant biomedical equipment comprises five steps: (1) increased awareness and continual education of VHA chief information officers (CIOs), the Veterans Integrated Service Networks (VISNs),[4] and health care facilities on biomedical issues; (2) establishment of an expert working group to provide guidance; (3) development of a database of biomedical equipment manufacturers that supply equipment to VHA; (4) surveying of these manufacturers to identify compliance status and solutions for noncompliant items; and (5) communication of survey results to the field for use in determining the compliance status of biomedical equipment at medical facilities.[5]

Much of the rationale behind VHA's reliance on biomedical equipment manufacturers to validate, test, and certify that their equipment is Year 2000 compliant stems from the position taken by some manufacturers that VHA should not attempt to conduct in-depth testing by manipulating the software embedded inside the equipment. According to a VHA official, such testing could void the manufacturer's certification to FDA that the equipment is safe for use on patients, thereby exposing VHA to legal liability in the event that a patient's health is harmed by equipment that malfunctions following VHA testing.

As part of VHA's strategy, its Year 2000 Project Office sent a series of letters to biomedical equipment manufacturers requesting Year 2000 compliance status information. The first letter was sent on September 9, 1997, to approximately 1,600 manufacturers in VHA's database of suppliers. Follow-up letters were subsequently sent in October and November 1997 and June 1998 to those not previously responding. Upon receipt of responses to these letters, VHA categorized the compliance status provided by the manufacturers for equipment items, as illustrated in table 1.

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[4]There are 22 VISNs, which encompass 172 VHA medical centers, 376 outpatient clinics, 133 nursing homes, and 30 domiciliaries--a total of 711 facilities.

[5]Each medical facility, on a monthly basis, is expected to report to VHA's Year 2000 Project Office its strategies for dealing with noncompliant and conditional-compliant equipment in their inventories (see table 1 for definition), and the cost to accomplish this.

Table 1: VHA Biomedical Equipment Compliance Categories.

Category	Explanation
Compliant	Equipment will function properly in all aspects upon the change to the year 2000, without any modification or revision.
Noncompliant	Equipment will not function properly upon the change to the year 2000, and no manufacturer remedy is available. In some cases, improper function involves an incorrect date-time stamp on the output of the equipment, but the equipment's clinical function is not impaired.
Conditional-compliant	Equipment requires some form of user intervention to function properly after the year 2000. Such intervention includes the installation of manufacturer-provided software or hardware or a one-time user action (such as turning the equipment on and off after the year 2000).
Pending	Manufacturers reported to VHA that they have not completed the Year 2000 assessment of their product line.

Source: Veterans Health Administration.

As shown in table 2, manufacturers have provided VHA with compliance information on a wide range of biomedical equipment.

Table 2: Reported Biomedical Equipment Year 2000 Compliance Categories, as of June 1, 1998, with Examples.

Compliance category	Number of manufacturers	Number of equipment types within this category	Examples of equipment types within this category[a]
Compliant	694	3,873	**Examples:** intra-aortic balloon pump, dialysis machine
Noncompliant	34	182	**Examples:** defibrillator monitor, cardiology monitor
Conditional-compliant	102	673	**Examples:** electrocardiograph machine, defibrillator
Pending	53	157	**Examples:** ultrasound system, ventilator
Manufacturer merged or bought out	187	[b]	
Total	**1,070**	**4,885**	

[a]Inclusion of a specific type of biomedical equipment in the compliant, noncompliant, conditional-compliant, or pending category does not necessarily mean that all equipment of this type in VHA's inventory was reported by the manufacturer; similar equipment made by other manufacturers could fall into different categories.

[b]The biomedical equipment reported by these manufacturers has already been accounted for in one of the above compliance categories.

Source: Veterans Health Administration. We did not independently verify these data.

Of the nearly 1,600 manufacturers in VHA's initial mailing over a year ago, about 100 were no longer in business, and a small number responded that the Year 2000 issue did not apply to their products. Accordingly, VHA revised its list of manufacturers to 1,490 as of July 29, 1998; it received compliance status information from about 1,100 (73 percent) of these manufacturers. As shown in table 3, just under half of the 1,490 reported that all of their devices were Year 2000 compliant.

Table 3: Status of Manufacturer Responses as of July 29, 1998.

Status of response	Number of manufacturers
Compliant manufacturers[a]	701
Noncompliant manufacturers[b]	43
Conditional-compliant manufacturers[c]	106
Pending manufacturers[d]	47
Manufacturer merged or bought out	195
Nonresponsive manufacturers[e]	398
Total	**1,490**

[a]For inclusion in this category, 100 percent of a manufacturer's products had to be considered compliant.

[b]For inclusion in this category, only *one* of a manufacturer's products had to be considered noncompliant.

[c]For inclusion in this category, the manufacturer had to have no noncompliant equipment, no pending equipment, and at least one conditional-compliant equipment item.

[d]For inclusion in this category, the manufacturer had to have no noncompliant equipment and at least one equipment item pending.

[e]For inclusion in this category, VHA had to have received no compliance information from the manufacturer.

Source: Veterans Health Administration. We did not independently verify these data.

VHA did not receive responses from 398 manufacturers. According to a VHA official, letters sent to 227 of these manufacturers were returned by the U.S. Postal Service marked "no forwarding address." Further, as noted in the table, an additional 47 manufacturers that did respond are in the pending category because they reported that they had not completed their assessments and therefore did not yet know if their products were compliant. Among the manufacturers who have yet to respond or complete their assessments is one who supplies high-dollar, high-value equipment, such as radiology systems and electronic imaging systems, to VHA.

According to VHA officials, most of the manufacturers that reported one or more of their biomedical equipment products as noncompliant cited incorrect display of date and/or time as the main problems. For example, a noncompliant electrocardiograph machine, used to monitor heart signals, would print charts with 2-digit dates, showing the year 2000 as "00." According to a VHA official, these cases do not generally lead to

the device's 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 problems such as this.

Conversely, 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 patient's condition, over a period of 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 example, 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 as "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 a result of a date problem, could present a risk to the patient. One example reported by a manufacturer is 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 inappropriate treatment--either too low or too high a dosage --and could have an adverse effect on the patient. Therefore, until VHA receives compliance information from all of its manufacturers, it will be stymied from making decisions as to whether to replace, retire, or continue to use certain biomedical equipment items in its inventory.

Another area of concern is the lack of complete cost information for the replacement or retirement of noncompliant equipment. Last month, VA estimated this cost at $40 million.[6] This estimate, however, was not based on updated cost information from medical facilities, and VHA did not know the replacement and repair cost for biomedical equipment for the manufacturers that have not yet reported compliance and cost information, as well as for the nearly 100 manufacturers no longer in business. VHA has acknowledged the shortcomings of its cost estimate, and just recently began using a new reporting process to capture the cost to replace or repair its noncompliant equipment.

In light of the uncertainties surrounding the compliance status of VHA's biomedical equipment and the potential effect on patient health and safety, it is crucial that VHA medical facilities develop business continuity and contingency plans to minimize risks associated with the Year 2000 problem. VHA's medical facilities have not completed plans of this type, and its Year 2000 Project Office has not finalized a contingency plan guidebook to assist the medical facilities in their attempts to come to terms with this risk.

FDA: LIMITED PROGRESS IN DETERMINING COMPLIANCE STATUS OF BIOMEDICAL EQUIPMENT

To assist health care facilities in the public and private sectors, HHS--on behalf of the CIO Council's Subcommittee on the Year 2000 for Biomedical Equipment and FDA--sent letters to approximately 16,000 biomedical equipment manufacturers[7] in January of this

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[6]We did not independently verify the $40 million cost estimate.

[7]FDA developed its mailing list from manufacturers that have registered their products with FDA and from the mailing lists of two scientific and research instrument manufacturing associations. Accordingly, this list included manufacturers that do not employ computers or embedded systems in their products (e.g., products such as rubber gloves, tongue depressors, and eyeglasses).

year, requesting information on the Year 2000 compliance of their complete product line. On June 29, FDA sent a second letter to 1,935 medical device manufacturers that had not previously responded to its inquiry and that FDA believed had products that might employ computers or embedded systems. After being provided to FDA, this information was to be made available to the public and to government purchasers and users of these products through an Internet World Wide Web page.

The response rate to these letters has been disappointing; as of July 30, 1998, only about 12 percent (1,975 out of 16,000 letters) had responded. Of the 628 manufacturers reporting that their products do employ a date/time function, about 100 indicated that one or more of their products was not compliant.

According to FDA, it does not perform technical evaluations of manufacturers' responses to determine their adequacy. Rather, it reviews the responses only to determine whether all questions posed in the letters were answered. This may explain why FDA's web page includes this disclaimer:

> *"Inclusion of information in this database indicates that the manufacturer has certified that the data is complete and accurate. The Food and Drug Administration, however, cannot and does not make any independent assurances or guarantees as to the accuracy or completeness of this data."*[8]

Further, except for diagnostic x-ray equipment, FDA does not test new medical devices entering the market. It also does not test devices for Year 2000 compliance. According to an FDA official, the agency does review the test results submitted by manufacturers requesting pre-market approval of their medical devices to see whether the manufacturers have demonstrated that their products are safe and effective for their intended uses. FDA does not, however, plan to request test results from manufacturers that have renovated medical devices and/or scientific and research instruments that are not Year 2000 compliant. Accordingly, no assurances exist that manufacturers' compliance certifications are accurate.

While FDA is making compliance information from biomedical equipment manufacturers available to the public, some users have expressed concern that information on the FDA web site is not detailed enough to be useful. Specifically, FDA's list of compliant equipment contains no information on the equipment's make or model. In contrast, VHA's list of compliant equipment generally contains such information.

Further, the Year 2000 compliance information publicly available through FDA does not include responses from many of the manufacturers that have responded to VHA. For example, we selected, on a random basis, a sample of 53 manufacturers in VHA's database that reported their products to be Year 2000 compliant; 48 of them were not listed in the FDA database. We likewise selected a sample of 13 manufacturers in VHA's database that reported that their products were not Year 2000 compliant; 12 of these were not listed in the FDA database. These manufacturers' products include cardiology equipment, defibrillator monitors, and ultrasound equipment.

An FDA official acknowledged that the biomedical equipment manufacturers were more responsive to VHA's requests for compliance information. He stated his belief that the primary reason for this was VHA's position as a large-volume customer that could take future action toward the manufacturer if information was not forthcoming. He also noted that FDA requested information on manufacturers' complete product lines, while VHA requested information from manufacturers only on its list of suppliers.

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[8]Food and Drug Administration, Year 2000 Impact on Biomedical Equipment, (Washington, D.C., FDA), *http://www.fda.gov/cdrh/yr2000/y2kintro.html* (cited March 19, 1998).

VHA PLANS TO MAKE COMPLIANCE INFORMATION AVAILABLE TO THE PUBLIC

Unlike FDA, VHA has not made information from biomedical equipment manufacturers available via the Internet. This is because (1) when VHA requested the information from manufacturers, it did not disclose its intention to release it outside of the federal government, and (2) VHA had concerns regarding the possibly proprietary nature of some of the information provided.

VHA is currently in the process of resolving these concerns. Specifically, on the advice of VA's Acting General Counsel, VHA informed manufacturers in a June 1998 letter that it plans to release information that the manufacturers provided and that VHA has determined not to be confidential commercial information. This is an important step, as compliance information from biomedical equipment manufacturers is of interest to all health care providers and users.

VA has not yet decided how and when a clearinghouse of compliance information provided to VHA from manufacturers will be made available to the public. FDA and VA have, however, discussed using FDA's web site as such a clearinghouse.

FURTHER ACTIONS NEEDED TO MINIMIZE RISKS OF YEAR 2000 FAILURES

Given that some noncompliant biomedical equipment items could pose a risk to patient safety and that the Year 2000 compliance status of many equipment items in its inventory is unknown, VHA may not be able to handle Year 2000 failures affecting its biomedical equipment. Because of this, in our report being released today we recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to provide a Year 2000 contingency guidebook for biomedical equipment to all VHA medical facilities, and ensure that they complete Year 2000 business continuity and contingency planning for all biomedical equipment in their inventories.

It is also crucial that all health care providers and users of biomedical equipment have access to compliance information from the manufacturers in order that they may take prompt action on noncompliant and conditional-compliant equipment in their inventories. Accordingly, we recommend that the Secretaries of Veterans Affairs and Health and Human Services work together in developing a single data clearinghouse that provides compliance information to all users of biomedical equipment. Model-specific information should be included, along with the names of equipment manufacturers that have not responded, manufacturers that are no longer in business, and those that have not provided test results certifying Year 2000 compliance. VA and HHS have generally agreed to implement this recommendation.

HHS, however, stated its belief that it is neither necessary nor cost-effective to list all compliant products. It asserted that information at the individual model level is only needed for noncompliant products. We disagree. Model-specific information will provide users with detailed data on the reported compliance status of their products, especially for those manufacturers that VA has determined to have merged or been bought out by other manufacturers. In this way, rather than taking it on faith that all of a manufacturer's equipment has been deemed compliant, users will have greater assurance by seeing the specific model number listed.

Last, because health care providers rely on manufacturers to validate, test, and certify that their equipment is compliant, there are no assurances that manufacturers have adequately addressed the Year 2000 problem for noncompliant equipment, especially since FDA does not require manufacturers to submit test results certifying compliance. To address this concern, we recommend that the Secretaries of Veterans Affairs and Health and Human Services, in conjunction with VA's Under Secretary for Health and

the Commissioner of the Food and Drug Administration, (1) determine what actions should be taken regarding biomedical equipment manufacturers that have not responded to their requests for compliance information, (2) determine what actions are needed to address equipment produced by manufacturers no longer in business, (3) take prudent steps to review test results for critical care/life support equipment once determined to be noncompliant but now judged by the manufacturers to be compliant, and (4) determine what legislative, regulatory, or other changes are necessary to obtain assurances that the manufacturers' equipment is compliant, including performing independent verification and validation of the manufacturers' certifications.

VA stated that it has no legislative or regulatory authority to implement the recommendation and deferred to HHS. HHS agreed to implement two components of the recommendation: specifically, to determine the actions that should be taken with respect to those manufacturers who fail to respond to requests for compliance information, and to include in the clearinghouse database the identity of defunct manufacturers, along with the known types, makes, and models of devices that they manufactured. It did not agree to reviewing test results supporting manufacturers' certifications. It stated that the submission of appropriate certifications of compliance is sufficient to ensure that the certifying manufacturers are in compliance. We disagree that this is sufficient. Through independent reviews of the manufacturers' test results, users of the medical devices are provided with a greater level of confidence that the devices are Year 2000 compliant.

In summary, VHA and FDA do not yet know the full extent of the Year 2000 problem with biomedical equipment because they have not received compliance information from many of the manufacturers. Further, they have not reviewed test results supporting manufacturers' certifications to provide the American public with a high level of confidence that biomedical equipment will work as intended. While some aspects of equipment noncompliance may not affect patient safety, some may; we do not know for sure. Therefore, VHA and FDA need to work together--along with others in the health care industry--to make this information available to the public quickly so that appropriate action can be taken to remedy any potential risks to patient safety.

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

GAO REPORTS AND TESTIMONY ADDRESSING THE YEAR 2000 CRISIS

Year 2000 Computing Crisis: Federal Reserve Is Acting to Ensure Financial Institutions Are Fixing Systems, But Challenges Remain (GAO/AIMD-98-248, September 17, 1998)

Year 2000 Computing Crisis: Federal Depository Institution Regulators Are Making Progress, But Challenges Remain (GAO/T-AIMD-98-305, September 17, 1998)

Year 2000 Computing Crisis: Progress Made at Department of Labor, But Key Systems at Risk (GAO/T-AIMD-98-303, September 17, 1998)

Year 2000 Computing Crisis: Significant Risks Remain to Department of Education's Student Financial Aid Systems (GAO/T-AIMD-98-302, September 17, 1998)

Year 2000 Computing Crisis: Severity of Problem Calls for Strong Leadership and Effective Partnerships (GAO/T-AIMD-98-278, September 3, 1998)

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STATEMENT
OF
THE HONORABLE KENNETH W. KIZER, M.D., M.P.H
UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE
THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

September 24, 1998

Introduction

Good morning, Mr. Chairman and members of the Committee, I appear before you today to comment on the impact of Year 2000 (Y2K) technology problems in medical devices in the Veterans Health Care System. Medical devices and biomedical equipment that will not function normally due to misinterpretation of dates in the next century pose significant health care issues and potential risks to patient safety. VHA is acutely aware of this potential and is highly motivated to identify and correct devices and systems that may be affected by this problem. Indeed, VHA has been working on this problem for nearly two years.

Background

Advances in computer technology have been responsible for many of the improvements in modern health care, so it is ironic that these same advances may now become a hazard to patient care as the 20th century comes to a close.

Most medical devices utilizing microprocessors or computers, like other information technologies, were designed when there was little concern about how year references were reflected in hardware or software. Historically, most dates programmed in computers and medical devices were based on a two-digit year – i.e., "97" rather than "1997." This was initially done in an effort to conserve costly data and program storage space. The practice of using two-digit years was continued until relatively recently.

The essence of the Y2K problem is that when the year changes from 1999 to 2000 and the date is entered as "00," systems and devices may not recognize this date as the intended or correct year. Several outcomes are possible. The device (i.e., its program) may fail to perform as designed; it may reject the legitimate date entry; or it may yield an erroneous result. Thousands of medical devices may be affected by one or more of these problems that constitute what I have called the "Millennium Bug Syndrome" or "MBS".

The MBS may occur within any date-related process, including such processes as sorting by date, performing comparisons by dates, or calculating age. For example, in the output of a blood gas analyzer an incorrect date in a time sequence of results could result in a misinterpretation of the data, causing an error in diagnosis or treatment. Likewise, MBS could cause an incorrect age calculation on an automated chest X-ray, and prompt unnecessary further testing or even result in a misdiagnosis.

Medical devices are not the only advanced technologies to be affected by the MBS. Hospital information management systems; building systems controlling heating, ventilation and air conditioning, security, and elevators; and billing and accounting systems also are subject to this problem. All such systems and devices must be thoroughly checked, and repaired or replaced, as required, before January 1, 2000.

While most of the Y2K problems identified to date are relatively minor and can be repaired, many healthcare institutions across the country are not prepared to identify or accomplish these needed repairs. At this time, many healthcare institutions do not yet know whether they have a Year 2000 problem, or how big it is.

General Healthcare Y2K Issues

For the health care industry, the inability of many computers to process date information later than December 31, 1999, is more than just a computer or information management problem. For hospitals and health care systems, Year 2000 failures may, if unrecognized, threaten the entire institution, not just information systems departments. Uncorrected Year 2000 problems could compromise patient care, disrupt core business functions, and create substantial liability exposure.

I believe the health care industry is at greater risk than many of the other industries that are also grappling with the Y2K problem because there are so many information technologies in hospitals. Information systems such as: admissions, discharges, transfers, medical records, inventory control, clinical informatics and billing may be affected by Y2K problems and may have both direct and indirect effects. Delays in payments from third parties could delay cash flow. Similarly, a Year 2000-induced error could cause a piece of laboratory equipment to skip a function, or perform a function twice. A patient's lab result could be mistaken for the lab results of the patient who preceded or succeeded him or her, with potentially dangerous consequences in treatment. Likewise, without accurate dating systems, inventory reorder dates may be missed raising the risk of depleting needed supplies. This could be particularly problematic for hospitals, since they typically maintain a minimal depth of inventory for perishable items such as blood products.

Further, modern healthcare institutions interact with many external information technology systems. Simply resolving Y2K issues in a hospital's systems and biomedical equipment will not necessarily guarantee a smooth transition into the new millennium. Every health care system depends upon suppliers for goods and services. If the linen service, food suppliers, ambulance services, power management systems, oxygen suppliers and reference labs have problems in their systems, they may not be able to take orders, manage inventory, or deliver ordered supplies or services. Failure or malfunction of any of these services could disrupt or impair quality patient care.

Several manufacturer-related concerns have become evident as we have addressed this problem. Some equipment that we purchased is no longer supported because the manufacturer has gone out of business. Since the primary source of compliance information for these devices is not available, we must turn to local engineering knowledge to assess and remedy the devices. Similarly, we have received promises by some equipment manufacturers to deliver remedies for Y2K compliance problems. Information from the medical centers indicates that these dates are in some cases slipping dangerously close to fail dates for this equipment. With insufficient data about the correction of the Y2K problem, the risk of equipment failure could prompt medical centers to replace expensive equipment when an inexpensive repair might do. Lastly, Y2K 'upgrades' are becoming a more frequent response, especially from smaller companies. Companies selling device upgrades to defuse Y2K compliance issues are charging nominal fees, for example $100. While this seems like a small amount, it amounts to a large sum when VHA must 'upgrade' thousands of these devices.

VHA Size and Scope

As you are aware, the Veterans Health Administration (VHA) operates the largest fully integrated health care system in the United States. A wide range of electronic information systems, biomedical equipment, facility management systems and other computer-based system products provide vital support to the delivery of health care and other services to veterans at over 1,100 sites of care delivery. (VA medical care assets

include 171 hospitals, over 600 ambulatory and community-based clinics, 132 nursing homes, 40 domiciliaries, 206 counseling centers, and 75 home health programs, as well as various contract treatment programs.)

VHA currently has an installed inventory of over 125,000 models of medical devices with an acquisition value of several billion dollars. The inventory is diverse and ranges from rudimentary devices such as suction machines and sphygmomanometers to complex magnetic resonance imaging systems and extracorporeal lithotripters.

In addition to its medical equipment, VHA's diverse systems and equipment inventory affected by MBS include hospital information systems and applications, corporate information systems and databases, commercial off-the-shelf (COTS) hardware and software, communications systems and networks, laboratory and research systems, and computer-controlled facility systems. There are many data interfaces among these systems and thousands of types of equipment and devices in this extensive inventory. At the core of VHA's systems environment is the Veterans Health Information Systems and Technology Architecture (V*IST*A). V*IST*A is a critical element of the total systems environment that provides information management support to VHA healthcare facilities. It is continually reviewed, developed, and enhanced by our staff in Technical Services.

VHA Approach

To address potential Y2K problems, VHA established a Year 2000 Project Office in 1996. This office has been responsible for coordinating all Y2K compliance efforts within the agency. The Project Office prepared *The VHA Year 2000 Compliance Plan* in April 1997, which included a structured compliance plan for all categories of VHA's systems and equipment inventory, assigned responsibilities for all actions and provided performance tracking and reporting requirements. This plan is updated regularly to reflect current information and to address new issues as our efforts proceed.

Although my comments today are primarily focussed on biomedical equipment and medical devices, I wish to briefly describe our efforts outside the biomedical device area at this time.

To ensure coverage of all affected VHA medical devices, systems and software, we prepared plans tailored to specific classes of products, as follows:

> **V*IST*A software applications** - The Veterans Health Information Systems and Technology Architecture (V*IST*A) is the heart of information resource management activities at VHA medical facilities. VHA's V*IST*A application development requirements in effect since 1984 dictate a standard method of storing and deriving date information through the use of a pre-existing database management system known as VA File Manager.
>
> VA File Manager uses a seven digit date field that has three digits for the year (rather than the common two-digit year field in most legacy systems) and two digits each for the month and day (date format is YYYMMDD). The year is specified according to the number of years from the base year 1700.
>
> Because VHA decided to use the VA File Manager date standard, the core applications were expected to be able to support date information through the year 2699. This expectation was confirmed in our assessment phase. Our programming approach eliminated most of the two digit year issues for the majority of V*IST*A applications at VHA medical facilities. The databases used by and linked to these applications, interfaces between these applications and other

systems and equipment, and other system products that do not use the VA File Manager date format, have been carefully assessed for Year 2000 compliance.

Our VHA in-house technical staff assessed, repaired, and tested needed repairs to the applications. While assessment, repair and testing were done centrally, implementation is being done locally by each medical center's information management staff.

Local software applications - Many special purpose programs have been developed by VHA medical centers. Local Information Resource Management staff or other system users have written these programs on-site, or they have been acquired from other VA medical centers. These programs generally meet a local need or extend the functionality of nationally released **VISTA** applications. These applications have more non-compliant code than **VISTA**, but they have fewer users and less mission and financial impact. Such programs are being assessed and repaired at the local level. Many of these local applications have been discarded as a result of the Y2K assessment.

VHA corporate systems - These systems and databases involve a wider range of programming languages (including OS/VS COBOL, COBOL II, and ALC) than the **VISTA** application suite. VHA corporate systems are applications and databases that gather and store information from one or more field facilities. An example is the National Mental Health Database System, which runs on a PC at the Pittsburgh (Highland Drive) VA Medical Center. This system is used for performance measurement purposes, and it is updated weekly by 97 substance abuse treatment programs and 73 post-traumatic stress disorder (PTSD) programs that are located at 120 medical centers. These types of corporate systems are being assessed by their sponsors and repaired either by in-house staff or contractors.

Commercial Off-the-Shelf (COTS) software - There are over 3,000 COTS software packages in use at VHA facilities. These include various versions of PC operating systems, office automation products, communications software, desktop publishing software, and project management software. There are also clinical software packages for such applications as intensive care unit monitoring or nurse scheduling. In addition, there are server operating systems and utilities, Internet services packages, network management tools, database and software development environment tools, and operating systems utilities. While we have done some in-house testing of these software packages, VHA, like other organizations, is dependent on manufacturers to provide the Y2K compliance status of their products, because the number of products is so large.

Databases and data archives - There may be as many database files as there are application programs in the VHA inventory. Today's relational database structures encourage large numbers of interrelated files. If any file has a two-digit year field, then it must be thoroughly assessed. If one database must be changed in order to be made Year 2000 compliant, then databases and programs linked to it may also need to be changed. Data archives might have to be converted if the databases to which they refer are upgraded for Year 2000 compliance. Local owners of databases and files are responsible for their assessment, repair, validation, and implementation.

Computer and communications hardware - In addition to personal computers on employees' desks, there are servers for printer and file sharing, automated phone systems, voice mail and fax back services, computers for electronic mail, computers in fax machines and in-network hubs and switches, and computers that monitor system activity. These systems are often highly interlinked and interdependent.

Assessment of this equipment has been done through testing and from information from manufacturers. Repair and replacement is a local business decision.

Facilities-related systems and equipment - Facilities-related systems and equipment are fundamental to the operation of VHA in providing quality health care service. These include those systems that control elevators; heating, ventilating, and air conditioning equipment; lighting; security; and disaster recovery. Personnel from engineering, information resources, facilities management, acquisition and administration are coordinating to ensure that facility-related equipment will be Year 2000 compliant.

Biomedical equipment - Biomedical equipment includes an array of products that record, process, analyze, display and transmit medical data. Such equipment and devices include computerized tomographic (CT) scanners, and magnetic resonance imaging (MRI) systems, cardiac monitoring systems, tissue and blood gas analyzers, cardiac defibrillators and various laboratory analyzers, to name a few. Some devices interface and exchange data with *VISTA* application systems and other VHA system products. In addition to the medical devices used in clinical care, devices and equipment used in medical research facilities also are being inventoried and assessed for Year 2000 compliance.

Because manufacturers have been aware of the year 2000 problem in recent years, most currently manufactured medical devices should be unaffected by the Year 2000 problem. However, most hospitals and health care systems utilize a wide range of devices that have been manufactured over the past two or three decades. In an effort to define the extent of VHA's potential problem with biomedical equipment, early last summer we identified over 1,600 manufacturers from whom we had purchased equipment or devices over the years; this is out of a universe of over 16,000 medical supply and device manufacturers. During the past ten months, we have solicited data from these manufacturers with as many as four letters each (depending on the manufacturer's responsiveness). The communication continues with manufacturers who have not responded or who have advised us about non-compliant products.

VHA has met with General Electric, Hewlett Packard, and Picker International and is planning to meet with Phillips Medical Systems later this month. These meetings with some of the largest manufacturers of medical devices assist VHA, and other Federal and private consumers.

VHA has established multi-disciplinary oversight teams to investigate medical devices for compliance at each VA medical center. Each Medical Devices Integrated Product Team (MDIPT) includes a radiologist, a pathologist, a cardiologist, a surgeon, and a nuclear medicine physician, along with engineers, acquisition specialists and administrative personnel.

VHA has developed a process for identifying, inventorying, assessing, and evaluating VHA medical devices at risk of failure from the millennium bug. We have also developed a Year 2000 patch for the *VISTA* software module used by each medical center for equipment inventory and preventive maintenance programs. The software patch for Y2K compliance provides additional fields to store and report data associated with conducting assessment, renovation tracking, and estimating cost of device repairs or replacement.

VHA has produced a medical devices, Y2K guidebook to assist biomedical engineers and all VA facilities. VHA expects to customize this guidebook for users outside of VHA in order to assist these facilities to manage such a complex task.

VHA Results

Mission Critical Systems

VHA is currently on target to achieve Year 2000 compliance for its mission-critical systems within the schedule imposed by the Office of Management and Budget (OMB). This includes complete renovation of both **V*IST*A** and Corporate Systems by March 1999. The renovation of all **V*IST*A** and Corporate Systems applications is projected to cost less than $2 million.

The results of VHA's assessment revealed that approximately 8% of the total **V*IST*A** code required renovation to achieve compliance. Renovation was contained in 66 applications, with none of the renovation work being categorized as more than minor repair. Renovation is now 100% complete. Hospitals are currently averaging 77% implementation of the 68 enhancement or modification patches released to bring **V*IST*A** applications into compliance.

Y2K assessment of VHA's Corporate Systems identified 14 systems that required repair or replacement. Seven of these systems have completed renovation and validation and are implemented into production as compliant systems. Five systems are renovated and are currently being validated. The remaining two systems are finishing renovation this month and are expected to complete validation next month.

Biomedical Equipment and Medical Devices

In the biomedical equipment and medical device area we can report as of August 1998 that:

- 728 manufacturers (46%) have certified to us that their products are Y2K compliant or do not rely on date coding. (Many of these devices are items manufactured in recent years.)
- 65 manufacturers (4%) have reported that their models of equipment or devices are not Y2K compliant and are no longer supported by the manufacturer. These models are considered obsolete and will not be fixed by the manufacturer, even though in many cases the device is still functional and commonly used.
- 130 manufacturers (8%) have reported that they produce models that currently are not Y2K compliant, which they intend to repair. In most cases, the manufacturer has not stated what the failure of the device will be or exactly what will be done to fix it. The method by which the manufacturers will fix the problem — for example, will it be covered by warranty or will they charge for it, will they send a repair technician or require the product to be returned — varies widely among the manufacturers.
- 46 manufacturers (3%) reported that they are continuing to analyze their products, and thus VHA is still waiting for compliance information.
- Inquiries to 222 manufacturers (14%) were returned to VHA marked "Return to Sender." After four attempts over a 10-month period to determine their correct address, we have assumed that we will never know from them about the compliance of these devices, and we are making appropriate contingency plans for these items.
- 102 manufacturers (6%) have not responded to us despite our multiple inquiries.
- From the initial 1,600 manufacturers, we have identified 111 manufacturers (7%) who have gone out of business, are no longer manufacturing medical devices, or have been identified as manufacturing non-electronic devices. Additionally, 196 manufacturers (12%) have merged, were acquired by other entities, or are divisions or subsidiaries of manufacturers who have (or will) centrally report their Y2K compliance to VHA.

Other Efforts

VHA is working closely with the Office of the Assistant Secretary of Defense for Health Affairs to optimize the sharing of information with the DOD healthcare system. VA is also working closely with the National Institutes of Health, Centers for Disease Control, and Food and Drug Administration within the Department of Health and Human Services, who share common Year 2000 problems in the areas of biomedical and clinical equipment and laboratory facilities.

VHA has participated in national meetings and made presentations on our activities to the Association for Advancement of Medical Instrumentation, the American Society of Healthcare Engineers, and the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Seminars on Y2K Compliance Activities.

Two months ago, we joined with the American Hospital Association, the American Medical Association, the American Nurses Association and Joint Commission on Accreditation of Health Organizations in calling on the nation's healthcare industry to support our efforts in identifying and addressing potential patient safety problems resulting from MBS. Working with these members of the National Patient Safety Partnership (NPSP), we are calling for increased awareness of Y2K compliance within the healthcare industry represented by medical equipment manufacturers, medical equipment sales and retail companies, retail pharmacies and other organizations that use medical devices.

The NPSP has challenged medical device manufacturers, health care providers, and consumers with the following four actions:

> First, the Partnership called on all healthcare practitioners and medical treatment facilities to survey their equipment and seek information from their relevant medical equipment, devices or systems manufacturers about their products' Y2K compatibility.
>
> Second, the Partnership called on all healthcare consumers who use medical devices at home to check with the healthcare provider about the product's Y2K compatibility. As you know, a very large amount of healthcare is now provided at home.
>
> Third, the Partnership called upon the nation's medical equipment manufacturers to take immediate action—if they have not done so already—to identify their devices' compliance. We urge in the strongest possible terms that equipment and device manufacturers provide this information no later than January 31, 1999, so that there will be ample time to address identified problems.
>
> And fourth, the Partnership called for the establishment of a single, national clearinghouse from which this information can be readily accessed by anyone. I am pleased to report today that FDA and VA have signed a memorandum of understanding to create such a clearinghouse.

Finally, in August 1998, VA, FDA, and DOD met with representatives from the pharmaceuticals industry to discuss issues concerning supply and distribution as it relates to Year 2000. We will continue to address this issue on an interagency basis through the President's Council on Year 2000 Conversions.

Conclusion

In closing, let me reiterate that while the Millennium Bug Syndrome has implications for nearly every industry and many households nationwide, it is particularly critical for health care, since health care today is so dependent on the use of biomedical equipment and medical devices that rely on embedded, date-dependent information technology. Moreover, we now know that many medical devices are not Year 2000 compliant, and their manufacturers will not make a significant number of them compliant.

We also know that, when the clock rolls forward to the year 2000, 463 days from today, about 3.8 million Americans each day will receive healthcare. Whether at hospitals, clinics and nursing homes, or at home, each of these patients will typically have many different interactions with equipment, devices and information technology systems. When you consider the extraordinary number of such interactions, it becomes clear how large is the potential is for adverse events. Fortunately, there is still time to ensure that no patient suffers harm as a result of the Millennium Bug Syndrome, if concerted and aggressive action is taken in the months ahead.

We thank the Committee for its assistance in helping to resolve this technological problem.

STATEMENT

BY

JOHN CALLAHAN, Ph.D.

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and

CHIEF INFORMATION OFFICER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 24, 1998

I INTRODUCTION

Good morning, my name is John Callahan, Ph.D., Assistant Secretary for Management and Budget, and Chief Information Officer (CIO) for the Department of Health and Human Services (DHHS). I am pleased to be here today to provide information on the Year 2000 date issue as it relates to medical devices. The Food and Drug Administration (FDA) has taken a number of constructive actions to work with manufacturers and provide information to users about medical device Year 2000 compliance.

II WHAT IS A MEDICAL DEVICE?

According to the definition in the Federal Food, Drug, and Cosmetic (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: embedded microchips which are part, or components, of devices; non-embedded software used with, or to control, devices or record data from devices; or individual software programs which use or process patient data to reach a diagnosis, aid in therapy, or track donors and products.

FDA is responsible for promoting and protecting public health by helping to ensure that medical devices are safe and effective. FDA carries out its mission by evaluating new products before they are 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 FD&C Act, including, but not limited to, establishment registration and device listing, premarket review, use of good manufacturing practices, and reporting adverse events. The FDA Center for Devices and Radiological Health (CDRH) has responsibility for regulating medical devices.

As diverse as medical devices are, so are the range and complexity of problems which can arise from their use. These problems include mechanical failure, faulty design, poor manufacturing quality, adverse effects of materials implanted in the body, improper maintenance/specifications, user error, compromised sterility/shelf life, and electromagnetic interference among devices.

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. Based on FDA's discussions with the manufacturers, the majority of these products will not be impacted 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 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 the current date for proper operation and might be affected by the Year 2000 date change.

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 non-embedded software devices include: conversion of pacemaker telemetry data; conversion, transmission, or storage of medical images; off-line analysis of ECG data; automated analysis and interpretation of ECG data; calculation 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 needs to be mitigated through proactively working with manufacturers.

III DHHS and FDA efforts to address Year 2000 issue

A. June 25, 1997 notification to manufacturers

The impact of the Year 2000 problem on some medical devices containing embedded microchips and software applications clearly warrants the attention of FDA. Manufacturers of such products are the only reliable source of information as to the details of the methods used in the programming.

In light of the review of the impact of the Year 2000 on some medical device computer systems and software applications, FDA has been proactive in alerting the medical device industry through a series of letters to medical device manufacturers. The first alert letter was sent over a year ago on June 25, 1997, to 13,407 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.

FDA recommended specific actions to ensure the continued safety and effectiveness of these devices. For currently and previously produced manufactured medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the Year 2000 date change. If these analyses show that device safety or effectiveness could be affected, then appropriate steps should be taken to correct current production and to assist customers who have purchased such devices. For computer-controlled design, production, and quality control processes, manufacturers should assure that two-digit date formats or computations do not cause problems.

In the June 1997 letter to industry, FDA reminded manufacturers that under the Good Manufacturing Practices Regulation and the current Quality System Regulation (which describe the design and manufacturing processes that must be used to assure design and production of a safe, effective finished product), they must investigate and correct problems with medical devices. This includes devices which fail to operate according to their specifications because of inaccurate date recording and/or calculations.

FDA expects manufacturers who identify products that have a date-related problem to take the necessary action to remedy the problem. This might include notification to device purchasers so that their device can be appropriately modified before the year 2000. Provided appropriate corrections are made, FDA does not anticipate any significant problems to the patients with individual medical devices containing embedded microchips since these devices generally do not use the current date in their operation. At the same time, FDA wants to ensure the continued safety and effectiveness of these devices.

For future medical device premarket submissions, sponsors of devices whose safe operation could be affected by the Year 2000 date change will be required to verify that the products can perform date recording and computations properly (i.e., are Year 2000 compliant), or clearly label products, which are introduced and are not Year 2000 compliant as not to be used after December 31, 1999.

B. January 21, 1998 Request for Information

In the year since the first letter, there have been continuing efforts by DHHS and FDA to obtain and provide information on the Year 2000 status of medical devices. In a letter dated January 21, 1998, 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. Under its current regulations, FDA does not have the

authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant. Included in the mailing were all FDA registered manufacturers without respect to the specific kind of device produced, even though FDA estimates fewer than 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. Year 2000 Database

The Year 2000 product database was established in March 1998 and 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 under the Chief Information Officer's Councils' Subcommittee on the Year 2000. The web site is intended to give the general public, government agencies, and the healthcare and research communities one comprehensive source of information about this issue. The web site is found at: http://www.fda.gov/cdrh/yr2000/year2000.html. Manufacturers also may submit a World Wide Web link to their own web site where the requested information is provided to the public, if they so choose. FDA does provide a link to the site where the manufacturer presents complete product information.

The web site includes information at the individual model level only for non-compliant products, since this is the most useful information to a user of the web site. The decision to include only this information was based on the belief that if a manufacturer's entire product line is certified to be compliant, users would receive no additional benefit from posting of the specific model level information of compliant products.

In addition, the DHHS and the Department of Veterans Affairs (DVA) are working as a Federal partnership to develop a single data clearinghouse. DVA, as a purchaser of medical devices, has been collecting information from its vendors as to the compliance status of the medical devices used in its facilities. DVA is taking the steps necessary to make the product status information it gathers available to the public. FDA is working with DVA to merge this data with the FDA database and provide a single comprehensive source of information for the public. We have signed a collaborative agreement to accomplish this goal. To date, FDA alone has borne the cost of the web site database effort. Both HHS and DVA are working with private sector associates, mostly professional associations such as the American Medical Association, the American Hospital Association, the Joint Commission on Health Care Accreditation, and the Health Industry Manufacturers Association (HIMA), who will provide advice and assistance as requested.

D. Targeted Follow-up with Manufacturers of Computerized Devices

On June 29, 1998, FDA issued a targeted, follow up letter to 1,935 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. This letter is our second comprehensive request for voluntary submission of data.

On August 14, 1998, Dr. Bruce Burlington, Director, CDRH, and again on September 2, 1998, Dr. Friedman, 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.

Then on September 2, 1998, FDA issued a follow-up to the June 29, 1998 letter, directed to the approximately 1,400 manufacturers of computerized devices who had not responded to the previous requests 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. FDA will continue to work with manufacturers to obtain this data and report to Congress on the status of these Year 2000 requests.

In the past few weeks FDA has decided that it would be useful to provide an indication of whether a particular manufacturer of computerized devices that are susceptible to Year 2000 concerns has or has not provided information on Year 2000 compliance. To that end, FDA intends to post on the web site the identity of manufacturers of those selected product categories which are likely to include vulnerable products and have not provided a response to FDA's inquiries.

E. Additional Outreach and Guidance

In addition to the web site and the letter, CDRH has been conducting outreach to the device industry 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 web site database and to encourage the posting of data by manufacturers. The web site and database are 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 health care practitioners this past summer.

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 web site. 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. 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 web site. 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 staff organized, with the staff of the ECRI, a medical device consulting and testing organization, a half-day session on the Year 2000 date problem at the June 2, 1998 annual meeting of the Association for the Advancement of Medical Instrumentation. This meeting was attended by hospital clinical engineers, representing the device purchasers and users, medical device researchers and developers, and device manufacturers. The session permitted an exchange of information on all aspects of the Year 2000 problem as it relates to medical devices and the actions healthcare facilities should be taking to address this issue. In addition, a satellite video conference to discuss product compliance and manufacturers' Good Manufacturing Practices issues, including the Year 2000 issue, was held September 9, 1998 with medical device companies.

To reinforce its efforts, FDA intends to send additional follow-up letters to manufacturers informing them of Good Manufacturing Practices obligations with respect to Year 2000 compliance. FDA will continue periodically to send additional follow-up letters to manufacturers reminding them of the need to provide the Year 2000 status of their devices for posting on the web site.

Companies need to post the Year 2000 status of their devices quickly if the web site is to meet its objective -- to provide an information clearinghouse which will be valuable to the users, such as doctors' offices and hospitals. Users of medical devices will need time to plan and budget for corrective action. This means that Year 2000 status information is needed as soon as possible.

This urgency is reflected in FDA's and DHHS's repeated communications with medical device manufacturers.

F. WHAT IS THE DATA TELLING US THUS FAR?

So far, the overall response from manufacturers has been disappointing and incomplete. As indicated above, FDA believes that approximately 2,000 manufacturers may produce equipment that may be impacted by the Year 2000 problem. Approximately 962 or approximately 50 per cent of the 1,935 manufacturers had responded to FDA by September 21, 1998. FDA knows, however, that there are companies still in the process of assessing their devices. FDA had requested that complete information be submitted. While manufacturers may report that specific products have not been assessed, FDA expects that some companies prefer to complete assessment before reporting. FDA hopes that its recent, targeted mailings to the remainder of the 1,935 manufacturers who have not answered will produce additional responses. The letter included a request that companies still assessing products tell FDA when they expect to post information.

As of September 21, 1998, FDA has entered a total of 2,404 responses from the 16,000 manufacturers contacted. The data from all of these manufacturers who have responded have been entered into the database on the FDA web site. These numbers change daily as data are entered, corrected or even removed at the request of manufacturers. Of the 2,404 manufacturers who have responded, 2,104 have reported that their products do not use date-related data or are compliant. One hundred sixty-four manufacturers have reported one or more products with date-related problems. One hundred and twenty-six manufacturers have provided World Wide Web links (URLs) to data provided on their own manufacturer-operated web sites. There are a few submissions in which the data were incomplete or unclear in some manner. FDA is communicating with these manufacturers to obtain clarification before entering the information into the database.

With regard to the data submitted, the great majority of the date-related problems described present minor concerns, typically involving incorrect display or printing of a date. There are, however, a few reported instances where the device will not function or operate at all unless the date problem is corrected. There are also a number of reports which indicate that the device will function correctly, provided the personal computer (PC) with which it is used is compliant. For many of these PCs, the correction required to correct the date is a straightforward operation. In general, manufacturers are indicating that currently or recently produced products will be corrected at no cost. For old and discontinued devices, the response is quite varied, i.e., from free upgrades, upgrades at a cost, or no upgrade or solution being offered, to a declaration of obsolescence of the device.

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. Of course, we can not make assurances about manufacturers who have not reported product status to us. FDA believes that the information received to date confirms our original expectation that the Year 2000 problems with medical devices are not significant or widespread. Although there will be specific problems which need correction, the current assessment is that they are much more likely to disrupt patient care rather than be of direct danger to patients. Nonetheless, this disruption could be serious and the potential for it to happen certainly merits rigorous attention to the problem.

FDA will continue to emphasize to manufacturers the importance of reporting 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.

IV. CONCLUSION

Thank you for the opportunity to update you about the issue of the Year 2000 and medical devices. Let me assure you that DHHS takes this issue very seriously, as we do with all

problems which could affect the public health. We are committed to a scientifically sound regulatory environment which will provide Americans with the best medical care. In the public interest, DHHS'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. DHHS and FDA recognize 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.

The role of DHHS and FDA is to assure that medical devices are safe and effective and manufactured in accordance with their specifications. DHHS, of course, will 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.

TESTIMONY OF

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

BY

ALAN H. MAGAZINE, PRESIDENT

HEARING ON

YEAR 2000 BIOMEDICAL DEVICE ISSUES

AND

THEIR IMPACT ON THE DEPARTMENT OF VETERANS' AFFAIRS

BEFORE

THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HOUSE COMMITTEE ON VETERANS' AFFAIRS

SEPTEMBER 24, 1998

Mr. Chairman, my name is Alan Magazine, and I am president of the Health Industry Manufacturers Association. HIMA is a Washington, DC-based trade association that represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members make nearly 90 percent of the $58 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $137 billion purchased annually around the world. HIMA is the largest medical technology association in the world.

I want to thank you and the Members of the Subcommittee for this opportunity to provide information about the general readiness of our industry to ensure the safe and reliable operation of medical devices in the Year 2000 and beyond. The medical device industry recognizes and shares the concerns of health care providers, patients, and the public regarding the possible effects of the Year 2000 computer date problem. Affected medical device companies are devoting significant resources to bring their devices into Year 2000 compliance. It goes without saying that the health and safety of patients constitute the paramount concerns of our industry. American medical technology has built a reputation for leadership and excellence that is recognized worldwide, and I am confident that our industry will do whatever is necessary to uphold that reputation as well as the safety and welfare of our patients.

In that vein, I want to make three points for the Subcommittee in my appearance here today:

1. The medical device industry is extremely concerned about the potential hazards associated with the Year 2000 problem and has put substantial effort into ensuring that medical devices function properly and safely after the century change.

2. HIMA welcomes and strongly endorses the interest on the part of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs and other government agencies in determining the Year 2000 compliance status of medical device manufacturers. We believe federal agencies have a necessary and crucial role in fully informing physicians, patients and health care providers about the safety of medical technologies on which lives and patient health depend. Moreover, the federal government, as a large purchaser of our industry's products, is entitled to answers about the Year 2000 compliance and safety of the biomedical equipment that the government buys. Cooperation with and support for the federal Year 2000 compliance effort as it relates to our industry are HIMA priorities.

3. HIMA members recognize that timely access to Year 2000 compliance information about individual device company's products is an integral part of the solution to the overall Year 2000 problem. Earlier this year, we pledged before Congress to work with the federal government and other concerned organizations to make Year 2000 compliance information about our products publicly available. I am here today to renew that pledge and to report to you on our efforts so far.

An Early Roadblock to Year 2000 Information Dissemination

I also want to take this opportunity to express my frustration and frankly—some embarrassment—at the degree to which liability concerns initially handicapped the response of our industry to this issue. Unfortunately, early on, there was understandable confusion—as well as legal concerns—on the part of industry regarding the Year 2000 problem and public dissemination of compliance information. The prevailing legal wisdom has been that companies should proceed aggressively with their own Year 2000 compliance efforts and address their customers' needs, but refrain from public comment about it. That has been true not only for the medical device industry, but also for other industry sectors, such as telecommunications and transportation, to name two examples. By recently taking up legislation to address Year 2000 liability issues, Congress has signaled its recognition of this potential roadblock to the dissemination of vital Year 2000 compliance data. As you know, last week, the Senate Judiciary Committee passed legislation that would allow companies to issue statements about their Year 2000 readiness with the guarantee that the statements could not be used, except in narrow circumstances, as an admission of liability in court. We support the goal of this legislation, which is to facilitate communication with the government on the Year 2000 problem—not to stop lawsuits based on Year 2000 computer failures.

Nonetheless, we have taken strong steps to address the confusion in our industry and to engage in a process of education. We have moved forward with a comprehensive program to advise HIMA members and nonmember companies regarding their responsibility to provide compliance information to the government. We are working closely with the FDA in disseminating the necessary information, and we want to work with other concerned organizations in this continuing effort. We are as conscious as everyone else that the clock continues to tick toward January 1, 2000, and we will do whatever patient health and safety require.

HIMA's Year 2000 Activities

In our efforts to date, HIMA has strongly encouraged, through a variety of communications, all of our members to:

- Work to ensure their devices are Year 2000 compliant
- Use the FDA World Wide Web site to communicate their Year 2000 compliance status
- Ensure that information about their Year 2000 compliance status is also available to their customers

HIMA has also:

- Communicated these same messages to more than 6,000 non-HIMA-member companies in the industry
- Established a member committee to advise on and oversee the Association's efforts to successfully address Year 2000 issues
- Maintained a constant stream of communications with members on Y2K information dissemination and compliance and will continue to do so
- Created a Year 2000 section on HIMA's Web site to communicate with HIMA's members as well as external audiences on compliance-related issues. It includes information on how to access the FDA Web site and other Year 2000 correspondence from the FDA.

Of the more than 6,500 FDA-registered device companies, the Agency has identified 1,935 whose products are likely to have a date-dependent function. We are encouraged by recent information provided by FDA that 962 device companies have now responded to FDA's request for Year 2000 compliance information— a number which has more than doubled since mid-July.

It should be stated, however, that it is quite complicated to track compliance information in the current 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 slightly more than 800 companies actually consists of 300 companies and parent companies and their more than 500 separate subsidiaries and divisions. It is not hard to see how it may initially be difficult to determine whether a corporate headquarters has responded for all of its divisions or whether each division or subsidiary has provided compliance information for itself.

New HIMA Initiatives

Thus, as a second phase of our Year 2000 campaign, HIMA is publicly committing today to:

- Contact each of HIMA's 300 member parent companies at the senior executive level to encourage and facilitate their corporate and subsidiary compliance efforts
- Work with the FDA and the Veterans Affairs Department to help identify and contact companies that have not responded to their inquiries

- Work with the agencies to ensure that their communications are going to appropriate individuals within companies
- Actively participate in the Health Care Sector of the President's Council on Year 2000 Conversion to help formulate a plan to reach out to the health care community at large on Year 2000 issues
- Organize educational seminars for HIMA members to help provide guidance in assessing and addressing Year 2000 issues.

I'd also like to highlight the fact that many of our companies are taking a leadership role in educating the industry. For example, one HIMA member company will be participating in the RX2000 Solutions Institute conference tomorrow to discuss "best practices" for Year 2000 compliance.

Efforts with the National Patient Safety Partnership

Earlier this year, the National Patient Safety Partnership—a coalition comprised of 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 and safety—suggested that a central clearinghouse be established to make Year 2000 information publicly available. I'm pleased to say that we have been working diligently in cooperation with the FDA to make this happen, utilizing the FDA's World Wide Web site as a central collection point for compliance information. A goal of HIMA's program is to increase the use of the FDA site for company Year 2000 information. We also understand that the Veterans' Affairs Department and the Health and Human Services Department will soon enter into a collaborative agreement to establish a central Year 2000 Biomedical Equipment Clearinghouse. We applaud this effort.

We remain enthusiastic about the opportunity to work with the National Patient Safety Partnership. We look forward to working with them closely to explore areas of mutual concern and cooperation. Our shared objective is the dissemination of compliance information from all companies that the FDA has identified as possibly being susceptible to the Year 2000 computer problem.

The Complexity of the Problem

The Year 2000 problem for our industry is not a simple one in the sense that it is not the same problem or set of problems for each company. For the majority of cases, solutions developed by one firm likely will not be applicable to, or feasible for, others. Our industry's products range from tongue depressors and hypodermic syringes, to sophisticated analytical instruments used in medical laboratories, to medical imaging equipment. The industry encompasses a full spectrum of companies from large, international corporations with multiple product lines to small, entrepreneurial businesses manufacturing one or two products.

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. Hundreds of different basic materials are utilized, singly and together, in our manufacturing. 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. Most are sold in small, niche medical markets.

No Single Solution for a Diverse Industry

HIMA has found that the challenge posed by the Year 2000 bug does not represent a single problem that will yield to a single solution. Rather, each company faces a unique set of circumstances involving its own technologies for the functioning and manufacture of its products. Moreover, these technologies have evolved quickly, because of rapid advances in many scientific fields. Solutions that a company can adopt for a device it manufactures today may be entirely inappropriate for an earlier model of the device that it made only 18 months ago.

Another complicating factor is the degree to which the Year 2000 bug will affect individual companies. Some, but not all, medical device computer systems and software applications will be affected. HIMA members manufacture electrical medical devices that perform functions ranging from measuring physiological parameters and pumping liquids to duplicating or simulating physiological functions to performing chemical analyses. Many of these devices are either life supporting or life sustaining. In addition to differing in function, these devices also differ significantly in size and complexity.

The number of electrical medical devices containing software to control some or all of their operation has been rising as the cost of microprocessors has been falling. Consequently, almost all electrical devices now contain software. However, the complexity and sensitivity to the Year 2000 date change vary dramatically among devices. Many of the highest risk devices that are vital to keeping patients alive and that utilize embedded software are not date sensitive. Other devices perform less life-critical functions, yet they may perform calculations or send data directly to another device that performs calculations requiring accurate date information. Clearly, these devices may be quite sensitive to the Year 2000 problem.

We do agree, however, with the FDA assessment that most medical devices will not prove to be date dependent.

Motivating Factors for Compliance

The FDA has defined in great detail its expectations for the industry in several documents regarding regulatory obligations for Year 2000 compliance. These documents describe how the agency interprets its regulations regarding manufacturers' responsibilities to determine the effect of the Year 2000 date problem on their devices and to correct any safety-related problems that are revealed. As you may know, medical devices are highly regulated by FDA. Their market introduction, including appropriate labeling, is under FDA oversight. Medical devices must also comply with FDA's quality system regulation. Year 2000 compliance failure could subject a manufacturer to penalties for product adulteration and misbranding. Thus, our member companies are profoundly aware of their Year 2000 compliance responsibilities under the law and of the penalties – both criminal and civil -- for failing to meet them.

In addition to the threat of these FDA sanctions, medical device companies are feeling pressure from customers who are concerned about the Year 2000 compliance status of the products they buy. As one of our industry's largest customers, the federal government's influence in this area is also significant. As an industry, we are intensely aware of the recent report by the federal Office of Management and Budget that discussed the possibility of barring the federal purchase of biomedical equipment from manufacturers that withhold Year 2000 compliance information about their products. I don't think there is any doubt that the industry has sufficient inducements to act and to act expeditiously with regard to Year 2000 compliance and information dissemination.

Conclusion

In closing, I would like to say again that the Year 2000 problem for our diverse industry cannot be resolved with an easy, one-size-fits-all solution. Each company faces its own unique technical challenge in this area, and while solutions for each company may differ, we believe that timely access to information about compliance of medical devices is important to health care organizations and practitioners. We have re-committed ourselves here today to working to achieve this goal with all other concerned parties and to provide the information publicly in a reasonable time frame.

We are confident that by working together, we can achieve what we all want, which is that on January 1 in the Year 2000, medical technologies on which millions of patients depend continue to function safely and effectively. We want the patients that we serve as an industry to have that confidence in us. And we will do whatever we must to deserve their trust. We are open to suggestions and look forward to working with the Members of this Subcommittee to achieve our shared goal.

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