HEARING 2 ON YEAR 2000 COMPUTER COMPLIANCE IN THE DEPARTMENT OF VETERANS AFFAIRS

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

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HOUSE OF REPRESENTATIVES

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HEARING 2 ON YEAR 2000 COMPUTER COMPLIANCE IN THE DEPARTMENT OF VETERANS AFFAIRS

THURSDAY, SEPTEMBER 25, 1997

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

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 334, Cannon House Office Building, Hon. Terry Everett (chairman of the subcommittee) presiding.

Present: Representatives Everett, Evans, and Mascara.

Mr. EVERETT (presiding). The hearing will come to order.

Good morning. This morning's hearing is a follow-up to the hearing the Subcommittee on Oversight and Investigations had on June 26, on the VA's efforts to achieve year 2000 computer compliance. Our last hearing emphasized the picture within Veterans Benefits Administration, VBA, and this hearing will emphasize the Veterans Health Administration, VHA, with an overview of the Department-wide activities. As some industry analyst predicted, the more the problem is examined, the bigger it appears to be. Cost estimates are rising remarkably and rapidly.

I stated during the last hearing that time is running out. We again have a real-time computer display, this one new and improved with audio, counting down to the year 2000, which occurs here on the Internet. There are 828 calendar days left, not a lot of time for the amount of work that we have to do.

Today, we will hear from the General Accounting Office which the subcommittee asked to look at—particularly at VHA. Also, of course, we hear again from the VA, and we'll hear again from the Federal Drug Administration on Y2K impacts on health care delivery and patient safety issues related to non-compliance medical devices and equipment.

I look forward to having the hearing. At the outset, let me also thank our full committee ranking member, who will take over the Chair of this hearing. I regret, unfortunately sometimes we serve on more than one committee and I have a bill that I have to introduce in another committee, and our ranking member is not feeling well today and sends his apologies for not being here.

I appreciate the witnesses turning up, and I'll look forward to reviewing your testimony. At this time I would ask Lane Evans—as I said, our ranking full committee chairman, and who is no stranger to this seat also—to take over. His interests and my interests

have parallel on this particular problem for a number of years. So, Lane if you'll take over, I'd appreciate it.

OPENING STATEMENT OF HON. LANE EVANS, RANKING DEMOCRATIC MEMBER, HOUSE COMMITTEE ON VETERANS' AFFAIRS

Mr. EVANS. I am very pleased that Chairman Evans has scheduled this all-important follow-up to this summer's hearing on the VA's efforts to achieve year 2000 compliance. In June, the GAO told us that the VA has a long way to go to solve this problem, but not much time to get there. Time obviously doesn't stand still, at least not in this life, so we've got to do all we can on the committee to ensure that the VA is able to provide high-quality, non-interrupted service to our veterans once the clock turns over to the next millennium.

I am encouraged that the subcommittee continues to carefully monitor the VA's progress on this issue. I am particularly pleased with the steps that the Veterans Benefits Administration has taken to bolster the management of its year 2000 compliance efforts, and I am hopeful that the Veterans Health Administration will make similar progress in the days and weeks to come. Still there is no doubt that the VA has a daunting management task ahead of itself if it is to meet the year 2000 goals.

I believe I also speak for the chairman when I say that this subcommittee stands ready to continue its aggressive oversight on this issue so that the VA will be in the best possible position to ensure that it brings its mission-critical systems into year 2000 compliance.

Again, I want to thank Chairman Everett for his continued leadership, and I look forward to today's testimony.

Mr. EVERETT. At this time I would like to have recognition for panel number one: Joel Willemssen, Director, Information Resources Management, Accounting and Information Management Division of the GAO, and ask him to introduce his colleagues.

STATEMENT OF JOEL C. WILLEMSSEN, DIRECTOR, INFORMATION RESOURCES MANAGEMENT, ACCOUNTING AND INFORMATION DIVISION, GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY HELEN LEW, ASSISTANT DIRECTOR, INFORMATION RESOURCES MANAGEMENT, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE, AND LEONARD J. LATHAM, TECHNICAL ASSISTANT DIRECTOR, OFFICE OF THE CHIEF SCIENTIST, ACCOUNTING AND INFORMATION MANAGEMENT DIVISION, GENERAL ACCOUNTING OFFICE

Mr. WILLEMSSEN. Thank you, Mr. Chairman. Accompanying me today is Helen Lew, Assistant Director, and L.J. Latham, Technical Assistant Director.

Thank you for inviting us here today to testify on the progress being made by the Federal Government, and in particular VA, in addressing the year 2000 computing challenge. As requested, I will briefly summarize my statement.

Regarding the Federal Government's overall efforts to address the year 2000 issue, the progress of many of the major agencies

continues to be too slow. Seventy-five percent of the agencies' total number of 8,500 mission-critical systems still need to be repaired or replaced, and the total cost estimate has now increased to $3.8 billion up about $1 billion from the estimate of 3 months ago.

Reports of several of the agencies are disappointing, and therefore, OMB is now placing more urgency on this issue and beginning to demand evidence of progress.

Turning to the VA, it's critical that the Department's systems be made year 2000 compliant to avoid disruption to benefits and services. Our past and current work at VA indicates that the Department recognizes the urgency of its task, and it has made progress. But much remains to be done if it is to avoid wide-spread computer failures. If left uncorrected, the types of possible problems that could occur include: late or inaccurate benefits' payments, lack of patient scheduling for hospital treatments, and misinterpretation of patient data.

As we testified in June, VBA has responded to the challenge by initiating a number of actions. However, several risks remain. These include: schedules for the renovations of key applications such as compensation and pension being compressed and other renovations schedules being very tight. In addition, although VBA has completed an inventory of its internal and external data-interfaces, it still has not assessed the majority of these for year 2000 compliance. If VBA is to avert serious disruption, it will need to address issues such as these.

The year 2000 challenge for the health side of VA is enormous. VHA is in the initial stages of assessing the compliance of its mission critical systems. It does not plan to complete assessment until January 1998, and renovations until July 1998. To effectively assess and renovate, it is necessary to understand how local facilities are using National applications. If it is true that some local facilities have customized these National applications, it's important that VHA know where these applications have been changed so as to ensure that they also are year 2000 compliant.

Physical facilities are another area of concern. VHA has not yet completed an inventory of facilities' related systems and equipment such as: ventilating systems, security systems, and disaster recovery systems. Such elements are vital to providing health care services.

Biomedical devices could also be affected by the year 2000. The impact could range from incorrect formatting of a print-out to incorrect operation of the device, having a potential to affect patient care or safety. In attempting to precisely determine this impact, VHA has sent letters to manufacturers. Based on the responses received from its first letter, VHA recently sent more detailed letters asking more specific questions. These letters were sent to about 1,600 manufacturers on September 9, with a request for a response by October 3.

FDA, in its role of protecting the public from unsafe or ineffective medical devices, also recently began communicating with manufacturers. FDA sent a letter in early July of this year to about 13,000 such manufacturers reminding them of their responsibility to ensure that their products will not be affected by the century change. According to FDA, one response was received to this letter. An

FDA official explained that it was not the agency's intention to solicit a specific response because FDA expects manufacturers to report any problems through normal reporting channels.

That concludes a summary of my statement, and I'd be pleased to address any questions that you may have Ranking Member Evans or Congressman Mascara. Thank you.

[The prepared statement of Mr. Willemssen appears on p. 32.]

Mr. EVANS (presiding). Thank you very much. We appreciate your testimony. The Office of Management and Budget places the VA in the upper-half of Federal agencies as far as year 2000 compliance efforts are concerned. Would you agree with this assessment?

Mr. WILLEMSSEN. I have a fairly good idea on the progress of the other agencies and I would say, especially in terms of its recognition of the urgency of the issue, its commitment to make it a top priority, and its devotion to put the necessary resources towards it, VA would definitely be in the upper half of the 24 major departments and agencies at this point in time.

Mr. EVANS. How realistic is the VA's $162 million budget estimate for its year 2000 compliance efforts?

Mr. WILLEMSSEN. At this point, it's the best we have. Frankly, I would anticipate that you will see it gradually escalate over the next several months as the assessment of VHA is completed. It may not necessarily escalate, but that would be our best estimate at this point.

Mr. EVANS. As you indicated, we've seen a $1 billion increase in OMB's estimate for Government-wide Year 2000 operations in the last 3 months or so, up to $3.8 billion. Is that something we can expect as well?

Mr. WILLEMSSEN. Yes, sir. Until full assessments are done at all the major agencies you can still expect some gradual increases in all likelihood.

Mr. EVANS. I think almost everyone agrees with the view that the year 2000 compliance problem represents management rather than technical challenges to Federal agencies. Would you agree with such an assessment, and if so, could you specify what additional steps VA must take to adequately address these management issues?

Mr. WILLEMSSEN. We would definitely agree that the challenge is more managerial than technical. Regarding VHA, it's absolutely crucial to complete, from a management perspective, their assessment and renovation activities as soon as possible. As they begin collecting more information on the health side, including biomedical devices, it is especially important that they disseminate that information as widely as possible so that every one knows exactly what they and others are finding in terms of the compliance of their systems and various medical devices. I think there is also an open question for both the VHA and, more importantly FDA, on the extent to which they may decide to independently assess manufacturer claims that various devices are indeed year 2000 compliant.

Mr. EVANS. The VA's testimony in June suggested that this problem was not nearly as severe at the Veterans Health Administration as it is at the Veterans Benefits Administration. Your testi-

mony suggests, however, that enormous challenges remain at VHA. Are you satisfied with the steps the VA has taken to address these problems? And how would you compare VHA's efforts to those of VBA's?

Mr. WILLEMSSEN. I'd say that VHA and VA recognize the enormous challenge they face, but frankly, looking at the statistics, VHA is obviously a little behind its counterpart on the benefits side. And, I think before we can say exactly what the magnitude of the problem is, VHA has to get through the assessment phase as quickly as possible.

One of the concerns that we have, and we mention it in our statement, is the extent to which individual hospitals and other facilities have customized National applications software. To the extent that this has happened to a wide degree, it is going to be incumbent on VA to go out and check each of those facilities to make sure they are year 2000 compliant. But whether that is the case right now or not, I don't think anyone fully knows until that assessment has been completed.

Mr. EVANS. The Veterans Health Administration has sent several letters to manufacturers of medical devices that may not be year 2000 compliant. VHA also intends to rely on the Food and Drug Administration to seek similar feedback from manufacturers in order to better gauge the health and safety risks if certain devices are non-compliant. Is this all the VA can do at this point to address the medical device safety issue? And what would be additional steps you would recommend for the VA and the FDA in this regard?

Mr. WILLEMSSEN. On the medical device area, I would say number one: it is especially critical that whatever activities VHA has engaged in, that they widely disseminate the data that they are collecting to all affected parties so that everyone knows what the manufacturers' claims are. And then secondly, as I mentioned before, I think VHA and FDA have to think about next steps after they've received all the manufacturers' claims about their products; is there going to be some kind of independent assessment of whether those claims are in fact true. As you know, we have just recently begun our assessment at VHA, and that's an issue that we plan to explore further.

Mr. EVANS. At this point I yield to the majority counsel.

Mr. Kingston SMITH. Thank you, Mr. Chairman.

Mr. Willemssen, at this point, what does GAO believe are the top three issues that Veterans Benefits Administration must aggressively address regarding the year 2000 compliance problem?

Mr. WILLEMSSEN. On the benefits side, the top three would probably be: first, regarding the tight and compressed schedules for various key applications, there must be urgent management attention to the progress in actually renovating those applications to make sure that the schedule is met. And to the extent that the schedule starts slipping more, VA management will have to look at other options since we can not have a slip in the schedule.

Secondly, regarding data exchanges and interfaces, we think it is especially critical that they be assessed for compliance as quickly as possible. To VBA's credit, they have identified about 590 interfaces, but now the next important step is to assess whether those

interfaces are compliant; and to the extent that VA can't get the cooperation from other external entities, it needs to raise those issues as quickly as possible.

And third, we would say it's fairly critical that VBA consider updating the risk assessment that it did earlier this year to take into account its revised strategy in its year 2000 program.

Mr. Kingston SMITH. Thank you, Mr. Chairman.

Mr. EVANS. The gentleman from Pennsylvania.

Mr. MASCARA. Thank you very much, Mr. Evans.

I have an opening statement I'd like to include in the record.

Mr. EVANS. Without objection, Frank, it will be entered in the record for this proceeding.

[The prepared statement of Congressman Mascara appears on p. 28.]

Mr. MASCARA. I had an opportunity to read over some of the statements last night; and is the problem with the VA unique some how, or does this transcend the VA across the entire government—the problem of 2000 compliance?

Mr. WILLEMSSEN. The problem transcends the Federal Government.

Mr. MASCARA. Do you think perhaps the President or the administration or the Congress should appoint some kind of czar who would be in charge of a coordinated effort to solve the problem? I mean, as I see, and from what I read, you said that the budget, "The Office of Management and Budget has determined the VA is making much more progress than many other agencies." So each agency is dealing with the 2000 problem?

Mr. WILLEMSSEN. That's correct, Congressman.

Mr. MASCARA. Do you believe that perhaps some concerted effort by the administration or the Congress to appoint some czar to deal with this problem would be to our benefit and maybe we would solve the problem before we get to the year 2000?

Mr. WILLEMSSEN. We are on record in testimony in July stating that we thought OMB's actions to date at that time had been insufficient and that more urgency needed to be placed on this issue than has been. Frankly, though, we're encouraged by the most recent report of OMB that they are taking this issue more seriously; that they are urging more corrective action; and that, in some cases for certain agencies who clearly haven't made as much progress for their information technology acquisitions, OMB will not necessarily fund those acquisitions unless they are for year 2000 activities. So, I think the bar has been raised as we speak today, even compared to a couple of months ago.

Mr. MASCARA. How long have you been trying to solve this problem; or someone recognized we had a problem and thought we should do something about it? What timeframe?

Mr. WILLEMSSEN. The broad recognition of this being a clear Government-wide and National problem; it's probably best to say about Spring 1996 is when it really started to begin to get attention. However, at the same time, I would say that people who program for a living have known that this would eventually hit all along, but when they were programming many of these systems, 15, 20, 25 years ago, they had no idea they would still be around

as we approach the year 2000, and that's what in many cases has occurred.

Mr. MASCARA. The reason I ask that question, I'm curious because I was a county commissioner in Washington County and under our administration we computerized the county and talked about the year 2000. But even before that, as an accountant who computerized his offices back in the late 1960s and 1970s, we knew there was a problem then. And I'm just wondering why 1996, it took somebody——

Mr. WILLEMSSEN. I think that's when it really started to get a lot of attention. Beyond, I'd say even a year ago, the individuals who are not familiar with computer technology thought that this was still some sort of a scam by the information technology community to acquire additional funds. There was a denial phase that many had to go through. I think we're beyond that now.

Mr. MASCARA. How about cost? I read some figures, and I think the last time we had a hearing someone said that it was in excess of $300 billion worldwide in costs to solve this problem. Is there an estimate of what it's going to cost this government to solve the problem?

Mr. WILLEMSSEN. The most recent estimate for the 24 major Federal agencies is $3.8 billion. That estimate does not include the cost of fixing various State systems which also are frequently helped with Federal funds. It does not include, obviously, the costs of many of the private sector firms that are going to have to make these fixes in order to minimize the economic impact to the country.

Mr. MASCARA. It seems to me, this is a National emergency. If we can't generate the checks for the GI bill, or health benefits, or VA pensions, and Social Security checks, and across the board, isn't this some kind of National emergency problem that someone should step forward and say, "Hey, we have a national emergency here. If we don't solve the problem there's going to be chaos?"

Mr. WILLEMSSEN. We have been trying to sound that message. The year 2000 issue is one of GAO's high-risk areas within the Federal Government that we try to focus attention on and sound the alarm on.

Mr. MASCARA. Well then I guess its true that we work best under crisis, so it's not a crisis yet. We'll wait until 1999 and get into November and December and say, "We have a real serious problem," and maybe we'll solve it.

I don't mean to be cynical, Lane, but someone needs to tell me something—I'm not a computer expert, I don't understand it, at best I'd say let's go back to 1900 and say that that means 2000 and just go forward, if it will accept 1900; I'm not sure if that's the case or not. But someone needs to make a concerted effort, and I don't think all these agencies should be out there running around spending money trying to figure out how we're going to solve it. If one person solved it, would it be across the board that all agencies could use that technology to solve the problem?

Mr. WILLEMSSEN. No. The difficulty——

Mr. MASCARA. It is unique in certain circumstances?

Mr. WILLEMSSEN. Yes, the computing environments are so heterogeneous that there is no single solution. You've got to go into

each individual system and you're not dealing just with applications, you're also dealing with operating systems, databases, telecommunications; so it is something you have to go in—and that's why we said earlier, it's not so much a technical challenge, it's a management challenge. It's a lot of tedious work to go in and analyze all that code.

Mr. MASCARA. Are we hiring outside firms to come in and assist the government in solving these problems?

Mr. WILLEMSSEN. Many of our agencies are hiring outside firms to help, and I think VA could also attest to that, that they are trying to get outside help also.

Mr. MASCARA. Thank you.

Mr. EVANS. Thank you; I appreciate your participation in the hearing today.

We want to thank the GAO for their testimony and excellent response to our questions. We may have some follow-up from members that aren't here, and we'll ask that you respond to those in writing and the questions and answers will be made part of the record of this proceeding.

Mr. WILLEMSSEN. Thank you.

Mr. EVANS. Thank you. At this time, we would like to welcome Mr. Mark Catlett, the VA's Acting Assistant Secretary for Management, the Acting Chief Information Officer, and the Acting Chief Finance Officer, and ask him to introduce his staff appearing with him today.

STATEMENT OF D. MARK CATLETT, ACTING ASSISTANT SECRETARY FOR MANAGEMENT, ACTING CHIEF INFORMATION OFFICER, ACTING CHIEF FINANCIAL OFFICER, DEPARTMENT OF VETERAN AFFAIRS; ACCOMPANIED BY DAVID R. ALBINSON, CIO, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERAN AFFAIRS; AND NEWELL E. QUINTON, CIO, VETERANS BENEFITS ADMINISTRATION, DEPARTMENT OF VETERAN AFFAIRS

Mr. CATLETT. Good morning, Mr. Chairman.

Mr. EVANS. Good morning.

Mr. CATLETT. Accompanying me today are Mr. Dave Albinson, the Chief Information Officer for the Veterans Health Administration; and Mr. Newell Quinton, the Chief Information Officer for the Veterans Benefits Administration.

Would you like me to go ahead with my full statement?

Mr. EVANS. Please, if you would at this time.

Mr. CATLETT. Mr. Chairman and members of the subcommittee, it is my pleasure to testify on behalf of the Department of Veteran Affairs on the status of our information systems for the year 2000. I am accompanied today by the gentlemen I just mentioned. We last met with you on June 26, and today we wish to give you an update on our progress. I have submitted my full statement to the subcommittee, which I ask to be made a part of the hearing record.

I would like to take this opportunity to provide the subcommittee with an update on VHA's, VBA's, and the Austin Automation Center's year 2000 accomplishments.

For the Veterans Health Administration: VHA has prepared and widely distributed a detailed compliance plan, organized in accord-

ance with the GAO's draft year 2000 best practices. We provided a copy of that plan to the subcommittee in June. In the plan, key responsibilities and accountability were assigned to the VHA CIO and associate CIOs; the Veterans Integrated Service Network CIOs, the 22 people there at the networks; and VHA health care facility management.

VHA's goal is to complete its assessment, including the nationwide assessment of biomedical equipment at all VA medical centers by January 1998. VHA's plan is to complete any necessary renovation by July of 1998, validation by January of 1999, and implementation by October of 1999.

As of August 31, 1997, 30 percent of VHA's mission-critical applications are compliant. This percentage represents both the VISTA, which used to be DHCP, and the VHA corporate system applications. I would add that the definition of compliance is the fact that includes those applications that are intended to be retired, as defined by OMB.

VHA has assigned priorities to and scheduled the renovation of VHA mission-critical systems. VISTA information system applications have been categorized according to their criticality to VHA's mission. To support the detailed VISTA application assessment process, VHA has acquired and is using an automated tool to support code analysis for both the National software applications and for locally developed software applications. VHA has begun to use this tool on some of its larger, more complex applications; code that will require renovation appears to be limited. As of August 31, 1997, 31 percent of VISTA applications have been assessed and 27 percent of VISTA applications are compliant or will be eliminated by the year 2000.

VHA is currently assessing all of its corporate information systems. System owners have been asked to determine the compliance status of their systems and to establish schedules for completing the process if the systems are non-compliant. To date, 37 percent of the corporate systems have been assessed, 33 percent are either already compliant or, again, will be eliminated by the year 2000.

VHA has completed its inventory of commercial-off-the-shelf products for each hospital and has begun to determine the compliance of these products.

For biomedical equipment, as we testified in June, the potential year 2000 impact on biomedical equipment is a National issue, clearly, affecting both the private sector and Federal health care communities. VA, along with other agencies and the private health care community, is a consumer of biomedical equipment; we do not regulate the industry. Let me bring the subcommittee up to date on the specific actions VA is taking in the area of biomedical equipment.

VHA formed the Medical Devices Integrated Product Team, a multi-disciplinary oversight committee within VHA, to assist with identifying, inventorying, assessing, and evaluating medical devices at risk.

A subcommittee of this team created a database listing manufacturers of medical devices currently in use in VHA. Experts from the team were consulted to ensure that manufacturers in all specialty areas were included. A letter requesting more detailed infor-

mation and plans from biomedical manufacturers was sent on September 10 to all 1,580 manufacturers in the database. Vendors were asked to respond by October 3; thus far, 135 responses have been received. VHA is reviewing these responses and will share the results with the Food and Drug Administration.

For VBA: significant progress on year 2000 efforts has been made in recent months. As of August 31, 1997, 52 percent of VBA's applications have been renovated and made year 2000 compliant. Two payment applications, Chapter 31, the Vocational Rehabilitation Program; and a small one, the Reinstated Program for Survivors are compliant. Our insurance application is on schedule with its renovation and will begin testing in February of 1998.

We testified in June that we awarded a task order for oversight support. The oversight team completed their assessment of VBA's year 2000 effort. Their assessment substantiates the attention VBA has given this issue. VBA's year 2000 effort is on track and its schedules and resources are realistic. The oversight team has made suggestions and recommendations that are being incorporated into VBA's year 2000 project plan.

Overall, education system milestones are on track for completion within the projected timeframes and well before any application fail date. However, the project completion date provided by our contractor shows a slippage for the Chapter 1606 redesign component of the education system. This slippage has not jeopardized our overall completion date for making education systems compliant.

As for loan guaranty applications, task orders have been awarded, and will be awarded, to renovate non-compliant applications ensuring that all loan guaranty applications are compliant by the projected timeframes and before any fail date.

VBA is developing a new application for real-estate property management. That schedule has slipped, but that will not impact the year 2000 schedule because the existing application is already compliant.

Let me address the compensation and pension application and its status. Forty-six percent of compensation and pension modules are year 2000 compliant. However, year 2000 work is competing with legislative program changes for spina bifida and incorporating Minimum Income for Widows, plus preparing for the annual cost of living adjustments. To minimize the risk that the complexities of implementing legislative changes would jeopardize year 2000 efforts, VBA awarded a contract, very recently, for renovation support of our compensation and pension application. This contract provides an automated year 2000 conversion tool for the application and additional contract support.

The oversight team that we've mentioned, that we've formed, both with a contract and some of our folks, has identified C&P as our highest risk in VBA in the year 2000. Managing the contract and developing detailed plans for applications testing to be done by the VBA staff in Hines, IL need to be improved. We agree with the team's assessment and are taking action to meet this need.

VBA has addressed all areas of potential year 2000 problems. They have assessed all of their third party products and have budgeted for their replacements. In addition, VBA is working hard to

resolve interface issues. Forty percent of their interfaces are year 2000 compliant as of today.

At the Austin Automation Center, we provide VA-wide information technology support for all components of the Department. As of August 31, 1997, 79 percent of the applications they support have been renovated and are year 2000 compliant. The AAC, as I call the Austin Automation Center, plan is to have all systems renovated by September of 1998, validated by October of 1998, and fully implemented by September of 1999.

VA, VBA, and VHA representatives are actively involved in several interagency efforts to find common solutions to year 2000 issues and are representing VA's interest in several subgroups of the Federal CIO Council Subcommittee on the year 2000. Included are: the biomedical equipment, telecommunications, and building systems subgroups.

In summary, Mr. Chairman, VA, organizations have prepared detailed systems inventories; and developed testing methodologies, individual project plans, and contingencies. We are monitoring our progress for each application supporting our mission-critical systems. We are also monitoring such key elements as estimated lines-of-code, number of modules, operating systems and COTS packages.

We are committed to ensuring VA's information systems will provide uninterrupted service supporting the full range of veterans benefits delivery and medical care for the year 2000 and beyond. I thank you for this opportunity to present our progress on the year 2000. Mr. Albinson, Mr. Quinton and I would be happy to answer any of your questions. Thank you very much.

[The prepared statement of Mr. Catlett appears on p. 51.]

Mr. EVANS. Thank you, Mr. Catlett. The GAO and your outside oversight team, have strongly indicated that better management is essential to year 2000 compliance. What additional steps will you be taking to solidify year 2000 management efforts?

Mr. CATLETT. Mr. Chairman, I think the steps that we are now taking are sufficient; and I say that in this way: we meet monthly with these two gentlemen and their staffs to review progress, to look at the tracking that's going on.

I'll raise an issue that you mentioned earlier. You noted that we had identified 11 mission-critical systems, and there was a concern—a legitimate concern—raised by you that that may be too few, when there were other departments that listed hundreds. But, within those 11 systems we have over 500 applications. And we have people on my staff and on these two gentlemen's staffs that are looking at those daily to track them. Frankly, we use the 11 systems to make it easier for you and for me to look at and give you a broad overview of what our progress is in terms of dealing with all the complexities and a wide variety of applications that we deal with.

So again, I'd say that, as we have attention brought to us both by GAO and our own contractors that we're hiring to identify problems in the schedules that we have developed, we'll react to those within this framework that we've set up.

One thing I would add, again it's nothing new based on this GAO report—the GAO has been very helpful in the things they have

identified, but as we did last year we will have an independent assessment of our efforts again in the December to March timeframe. Actually, I would like to have it a little sooner, but we're going to wait for the VHA assessment to be completed and then we're going to have an independent contractor come in and look at what we're saying both in those plans and also the work that's been identified as completed, both in VHA and VBA, and at the Austin Automation Center.

So, we understand the urgency, we understand it's a lot of work and we're putting forth a good effort and we'll continue that and certainly intensify it as indications come, both from ourselves, from our contractors, and from GAO.

Mr. EVANS. During your testimony in June you downplayed the seriousness of the problem within the Veterans Health Administration. Do you still have that same level of optimism with regard to the year 2000 challenges faced by VHA.

Mr. CATLETT. I'm going to quibble with your words there in terms of "downplaying." We have a schedule. I still define the problem of VHA as one that's broad but not very deep. As we know, the size of that system and the number of applications and the number of specific activities out there are numerous, huge in number. And, we have to look at all of those. VHA is on the schedule that they had projected and we had submitted to you in June; and as I said, I'm sure, that as we have had with VBA to date, we'll find areas where we will have to intensify our effort. I think the resources are there within VHA to do that, both in terms of the personnel that will be needed to do it and the dollars that will be necessary to do that.

The one thing I would add, is that in terms of biomedical equipment, 1999 is the year of concern for me for biomedical. In terms of systems work, that has to be underway now; and particularly through 1998. For biomedical equipment, it's largely going to be funding, if its non-compliant, the replacement of that equipment. We at this point, don't expect that to be a huge number. But we will want to have that information in time to make an adjustment to our 1999 budget request, if necessary, for biomedical equipment.

Mr. EVANS. Because of a pending vote, I'd like to yield to the gentleman from Pennsylvania, in case he might not be able to make it back. If there are any questions?

Mr. MASCARA. My question is, deals with the possibility of not solving the problem entirely, and what could happen then. Do you have a back-up plan? If all else fails, the worst possible scenario not being able to solve the problem entirely by the year 2000?

Mr. CATLETT. Well, Mr. Congressman, as GAO noted, there are a lot of negative consequences for not getting it done. We will—we do have plans, and as GAO says, we need to update our risk assessment, which we agree with and will do. But, I don't believe this is an issue of not getting the checks out. We could be late getting the check out; we may get the wrong amount out; and that's a problem, I'm not minimizing that. But it is not a question of veterans not getting paid. If we have to do it by paper and pencil, we'll do it. But again we don't think that we're in that mode of a crisis.

I agree with some of the things that you had to say in the sense that this is a huge problem. But again, we think we're on top of

it, and fully expect in that there will be problems that come up that we haven't anticipated; but we think we have the resource levels required. Much of the resources we need, we already have. It's not a question of getting contractor help for the first time, as VBA already has. But a lot of the work in VHA that's going to be required, will be done by their own staff. It's a matter of making sure within the staff that deals with information technology systems, that they get a focus. And, Mr. Albinson has it under way. And I'm very confident that we are paying attention to this and tracking this monthly so that when problems do arise, as they will, we will respond quickly. Our cost estimates will probably go up, but we are a very, very tiny part of that billion dollar increase that's been talked about here today; I want that on the record. We've increased our estimate by $18 million on a base of $144 million over this three year period. I expect that they will go again.

And as I said in June, in biomedical equipment, we haven't estimated the impact there. We expect it not to be large; but not to be large is in the sense of a $17 billion a year operation that the health care system is. So we will be seeing our prices go up as we get the information on biomedical that we expect.

So, again, we are tracking the problem, we are watching the problem, and as issues rise that we haven't anticipated, I am confident that we have the resources to address those.

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

Mr. EVANS. Thank you. We're going to go to recess now because of a pending vote which may be followed by another vote, as I understand it. So, we're going to recess and try to get back by about 10:30 or so.

Mr. CATLETT. Sure, Mr. Chairman, we'll be here.

Mr. EVANS. We'll recess at this time.

[Recess.]

Mr. EVANS. The hearing will now resume, and we'll yield to majority counsel.

Mr. Kingston SMITH. Thank you.

Mr. Catlett, the VA has some significant computer interfaces with other agencies and departments of the Federal Government. What are those interfaces, and what is the status of Y2K compliance for those interfaces?

Mr. CATLETT. I'm going to ask Mr. Quinton to give you some information on that, and we'll probably need to provide some specifically for the record, to get more detailed information on it.

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

VBA Year 2000 Project Office

VBA Year 2000 External Interface Approach

A profile of VBA External Interface Partners

Interface Partner	*Hines*	*Austin*	*Philadelphia*	*Total*	*%*
VA Entities	133	195	9	337	52
DOD	40	18	12	70	
Treasury	43	0	4	47	
Dept. of Labor	43	0	0	43	
Internal Revenue	4	22	0	26	
Social Security	10	0	3	13	
Credit/Banks/Ins. Cos	7	28	0	35	
Colleges/Congress/Vets	0	23	0	23	39.5

Mr. CATLETT. But, as you noted or implied, clearly, with the major departments and agencies throughout the government, we have a lot of interfaces as we move payments and move information back and forth. The one I'm most concerned about now is the Department of Treasury. I've had preliminary discussions with the CIO there. We have met. We have a list of the interfaces with Treasury that affects primarily our payments to veterans, which is the first focus that we all have. We'll be meeting with them soon at a staff level, including the Financial Management Service, FMS, as they call it, and their CIO. We will review our roles and responsibilities and reach agreement on the list of interfaces.

And as I said, Mr. Quinton's office has put together a comprehensive list of the interfaces that VBA has with Treasury. We have done some work at our Austin Automation Center for the same thing, and we will be meeting with them in the next several weeks.

Mr. QUINTON. Sir, our inventory of interfaces shows a total of 731, and that includes interfaces to all of our mission-critical systems at our Hines facility, Philadelphia and Austin. Of the 731, 342 involve the Hines Data Processing Center and reflect the interfaces which provide information to or from our payments system. I think it is important to note, when we speak of interfaces, a significant amount of these are for information and are not payment-related.

As we said earlier this morning, 40 percent of those interfaces are compliant; 33 percent are not compliant, and our approach right now is to continue to look at every single interface to make a determination of whether it involves a date field and then to get it resolved. A significant percentage of the 731 interfaces are internal to VA, as opposed to sharing information with other Federal agencies, as Mr. Catlett indicated.

Another effort that we will take with interfaces is to separate those that result in the generation or execution of a payment from those that would involve information for report purposes. This will provide a focus for us to address the payment issues first.

Mr. Kingston SMITH. Thank you. It's our understanding that the VA is planning to take $5 million from VETSNET funding to help fund the increased financial requirements of the year 2000 compliance. Is that correct?

Mr. CATLETT. I'm glad you raised the question. We had a hearing last week on GPRA, and that issue came up as a side item. As we discussed with you, this committee, over this past year, we've made the commitment; the Deputy Secretary and now the Secretary-designate made the commitment that, if we have a funding need for year 2000 purposes, that is more than other sources can produce, we would use our VETSNET money. But that's different than what folks are looking at now in terms of an Appropriations Committee report, a Senate report, that said, shift that $5 million. The $5 million I think you're referring to is in a Senate Appropriations subcommittee report that says, for 1998, to move the VETSNET money. I think they've reached that conclusion, based in part at least on the NAPA report.

We have expressed our opinion that it's important to move forward with VETSNET. We understand the concerns about the timing and the schedule for VETSNET, but, nonetheless, we support

the VETSNET effort, and will continue to move with that. So, as I said, the distinction is we may have to take some money off VETSNET for year 2000. As stated last spring, we're still committed to that. Right now we don't think we'll need to, but, again, it all depends on what happens in the conference the next few days for the 1998 budget. That same commitment stands; if we need it, we will move it. At this point, making an assumption about the amount of money we expect to get for 1998, we don't think that will be necessary.

Mr. Kingston SMITH. Thank you.

Mr. EVANS. Your testimony and the testimony of GAO indicates that the renovation of VBA's compensation and pension application appears to be a major hurdle. Can you describe in detail what the oversight team recommended in this regard and outline what steps you will be taking to address this issue?

Mr. CATLETT. Yes, sir, I'd ask Mr. Quinton to give you those details.

Mr. QUINTON. Yes, sir, Mr. Chairman. We agree that the compensation and pension program is certainly our most critical system, and it is also one that we must pay closest attention to. In essence, the oversight team focused on the issue of increased management of the conversion effort, and that effort is focused on a change in approach with our in-house staff at Hines. Their experience truly is in the development and maintenance of the compensation system, where they have the expertise developed over some 20 to 30 years. We have accelerated our effort to make the systems compliant, and in that process we have added a significant contractor effort.

The concern raised in oversight is whether or not our staff, who over the years have been developing and maintaining that system, had the contract management expertise, and we recognize that that is a shortfall. So we have to provide training and provide onsite support to manage a contract. We do not believe this is insurmountable. In essence, with the contractor actually being onsite, working hand-in-hand with our developers, it becomes more manageable than it would be if the contractor was offsite and we were looking for a deliverable. So the focus truly is one of adding an extra task to our staff at Hines to say; in addition to doing the work that has been done for the last 25 or 30 years, also manage the day-to-day activities of a contractor. It is our intention right now to provide additional management support to the staff, as I said earlier, and to provide immediate training to our project management staff at Hines.

Mr. CATLETT. Mr. Evans, I would add, I think as I noted earlier, this obviously will be an item that we will review in our monthly status reports with Mr. Quinton, and we'll be glad to keep the committee informed of our progress there.

Mr. EVANS. All right. With regard to the medical device issue, are you satisfied with the feedback you've received to date from the manufacturers? Do you believe that the Food and Drug Administration has conducted sufficient outreach to accurately determine the severity of the problem among medical device manufacturers?

Mr. CATLETT. The answer to your first question is yes, and I'm going to ask Dave to speak to the second because I think he's had

more direct communication and involvement than I have with the FDA.

Mr. ALBINSON. Thank you, Mark.

Earlier this month we sent a letter from the VA to the 1,580 manufacturers of medical devices actually in use at our facilities. We have been very encouraged by the response of industry to this letter, and over the past 3 weeks we've already received nearly a 15 percent response rate. Of those who have answered back, 70 percent have indicated that there is no time clock involved in their particular medical device; approximately 15 of the remaining 30 percent, were almost half, have indicated that they do use a clock; it is compliant, and the remaining 15 percent have indicated that they need to check further into the problem.

Working through the numbers, that means that we have somewhere between 200 and 300 manufacturers of biomedical devices which may produce an issue for us. We feel this is a manageable number, and we're addressing it directly, and we've been very encouraged by the cooperation we've received from industry.

Mr. EVANS. Can I get you to submit that data for the record, please?

Mr. ALBINSON. I certainly will.

Mr. EVANS. Thank you.

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

Status of Medical Device Manufacturer Responses to VHA Industry Letter
(as of September 23, 1997)

Total Number of Manufacturers Written to: 1580
Total Number of Responses Received: 213
Percentage of Manufacturers Responding: 13.5%

Date responses received	Manufacturers asserting product(s) have no time clock, and are therefore compliant	Manufacturers asserting product(s) have a time clock, have been checked, and are compliant	Manufacturers asserting that product(s) require further analysis to determine compliance	Total number of responses
19-Sep-1997	76	15	12	103
23-Sep-1997	74	14	22	110
Total	150	29	34	213
% of Total Responses	70%	14%	16%	100%

Mr. EVANS. All right, I yield to majority counsel.

Mr. Kingston SMITH. Thank you.

What action does the VHA plan to take on those manufacturers who have not responded to your September 9, 1997 letter?

Mr. ALBINSON. Well, we're going to give it a little more time. It's been 2 weeks. At some point we will follow up with them directly, and the letter was couched such that it required a response whether or not they thought there was a problem. So we intend to get a response from all 1,580 manufacturers eventually.

Mr. Kingston SMITH. At this point does VHA have any indications of Y2K compliance problems with any of its biomedical equipment?

Mr. ALBINSON. Our current indications are that 15 percent of the respondents have indicated that they need more time in order to get back to us, and we're assuming that there may be problems with those manufacturers. They have been highlighted in our efforts.

Mr. CATLETT. Kingston, I'd add that we would, if we have difficulty with manufacturers corresponding with us, this is an issue that we'll raise back through the CIO council committee on this that I believe FDA has. I know it's an HHS-led effort, and we will make sure that that committee and OMB, if necessary, are involved with that, to bring some leverage to getting that attention on this issue. So it's something that, as Mr. Albinson said, we will follow up ourselves this fall, in the month of October, and if there's continued lack of correspondence, then it's an issue that we'll raise within the administration with the OMB-led effort to make folks aware of that, to try to bring some more leverage on the issue.

As we testified, we're not probably—for many of these companies, we do a lot of business from our view, but from their view we may not be a large customer. So we wanted to bring all the leverage we can with the Federal Government effort, not just our own.

Mr. EVANS. I want to thank the panel for testifying today, and we'll excuse you right now.

Mr. CATLETT. Thanks.

Mr. EVANS. And at this time we'll bring our third panelist forward: Tom Shope, Acting Director of the Division of Electronic and Computer Science, Office of Science and Technology, Center for Devices and Radiological Health, of the Food and Drug Administration.

Doctor, you may proceed when you're ready.

STATEMENT OF THOMAS SHOPE, ACTING DIRECTOR, DIVISION OF ELECTRONIC AND COMPUTER SCIENCE, OFFICE OF SCIENCE AND TECHNOLOGY, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

Mr. SHOPE. Thank you. Good morning, Mr. Chairman and members of the subcommittee. I'm Thomas Shope. I'm the Acting Director, as the chairman said, of the Division of Electronics and Computer Science in the Office of Science and Technology of the Center of Devices and Radiological Health of the Food and Drug Administration.

Having previously testified before this subcommittee at the June 26th hearing, I'm pleased to be here today to provide further infor-

mation about the year 2000 date issue and its impact on medical devices. Although FDA has not received any significant information since the previous hearings to indicate that there will be any major impact on medical device safety, I am here to assist the committee in its efforts to examine the issue.

FDA is responsible for protecting the public health by helping ensure that medical devices are safe and effective. Any computer software that meets the statutory definition of a medical device is subject to applicable FDA medical device regulations. An issue that has been identified as warranting review is the impact of the year 2000 on some medical device computer systems and software applications. These products could be impacted by the year 2000 date problem only if they use a date in their algorithm or calculation or function or in recordkeeping and if a two-digit year format for the date was used in their design.

At the last hearing, I described some of the technical issues associated with the types of products that we regulate. I'll not go into that in detail today. It is in our written testimony.

In July, the Center sent a letter to all medical device manufacturers, approximately 13,000, both domestic and foreign, to ensure that manufacturers were addressing the year 2000 issue, and we reviewed both embedded and non-embedded software product issues in that letter. In addition, we asked manufacturers to review any computer-controlled design, production, or quality control processes for the possible impact of a two-digit date in any of these computer applications.

This letter reminded manufacturers that, pursuant to manufacturing regulations, they have a legal obligation to investigate and correct devices that fail to operate according to their specifications because of an inaccurate date-recording or calculation operation.

Our letter did not require a response from the manufacturers. We have regulations already in place that require manufacturers to notify us, FDA, of problems with devices that could lead to a significant risk to public health.

For devices that are already on the market, we requested manufacturers to conduct hazards and safety analyses to determine whether device performance is affected. We expect manufacturers who identify products which have a date-related problem that could affect safety or effectiveness of a device to take the necessary action to remedy the problem. It is the obligation of the manufacturers to notify FDA of problems with devices that present a risk of serious injury, and of corrective actions taken to reduce a risk to health. Again, let me stress that we do not anticipate a large number of devices to be impacted or a large number of significant problems which would affect patient safety with individual medical devices. We want to ensure the continued safety and effectiveness of these devices by addressing the issues before they arise.

Currently, and for future medical device pre-market submissions for new products, FDA will review device design and function to assure that the products have been designed to perform date recording and computations properly and safely. We will also be working with manufacturers on any reported problems with the devices that are currently on the market and in monitoring their activities.

Thank you, Mr. Chairman, for the opportunity to tell you about the issue of the year 2000 in medical devices. Let me assure you that we at FDA take this issue very seriously, as we do all problems that could affect public health. We have been evaluating the possible impact on devices since early last year. We are committed to a scientifically-sound regulatory environment that will provide Americans with the best medical care. FDA has looked at this issue and does not see any major problem with medical devices that cannot be addressed satisfactorily. It is the manufacturer's responsibility to meet high standards in the design, manufacture, and evaluation of their products. They are ultimately responsible for these products, but FDA will provide the regulatory framework to ensure that the collaborative efforts of both the FDA and the manufacturers result in the best medical device products.

That's all my oral statement, sir.

[The prepared statement of Mr. Shope appears on p. 58.]

Mr. EVANS. Thank you, Doctor. Your testimony indicates that the FDA has sent a letter to all medical device manufacturers reminding them of their obligation to advise the FDA, should there be any serious safety risk associated with the year 2000 problem. Given the FDA's ultimate responsibility to address the year 2000 problem, what additional steps will you be taking to ensure the safety and effectiveness of such devices?

Mr. SHOPE. There are a number of steps that we are involved in or that we are contemplating taking to further our activities in this area. For one thing, we'll be stressing with our inspectional force that visit the manufacturing plants to raise this issue with the manufacturers during those inspectional visits. We will be carefully monitoring any reports of corrections or recalls that manufacturers are required to give us about products that could present a significant risk when they take an action to either correct a problem or to recall their product, and particularly we'll monitor those for any year 2000-type problems.

We are probably most active with the Chief Information Officers' Subcommittee on the Year 2000 Working Group which is dealing with medical devices and scientific research instruments. These are two types of products for which the Federal Government has a large interest in the year 2000 compliance issue, as purchasers and users of those kinds of products, as well as an interest in making sure that the public users of those kinds of products have information on the possible year 2000 impact.

This group is looking at ways to provide information to the Federal purchasers of these products, as well as to the public, on those products which will have problems due to the year 2000 date problem, and the steps which the manufacturers of those products plan to take to deal with the problem.

Our current approach to this is probably going to be the establishment of a website, hopefully in conjunction with the current GSA year 2000 website, and to provide the opportunity for manufacturers to provide information on that site regarding the year 2000 status of their products. We would expect that this would be a mechanism where by the manufacturer could either provide the information which would be posted there or provide a link to their own web site, where they could provide the detailed information

themselves on the status of their products. This would provide a central facility for anybody who's concerned about their product status to check and verify.

We will continue to look at new products coming to market to make sure they're compliant, and we'll investigate any reports, as we have been doing this summer, about products that may have a problem. We have seen in the public press and in other venues reports of products that have problems. We've actively investigated any of those that have come to our attention. Most of those—in fact, all of them that we have looked into—have turned out to be unfounded reports. It is not the defibrillators that are going to have problems as far as we can determine. Pacemakers are not going to have problems. Our last episode was looking into the infusion pump issue. We contacted all the U.S. manufacturers of infusion pumps, and were not able to determine a date problem associated with the operation of infusion pumps from those contacts.

So we will continue to actively follow up on any reports that we have. We expect that as manufacturers assess their products and determine that there may be a product that contributes a risk, we'll get that information from the manufacturer and we'll monitor their efforts to correct the problem.

Mr. EVANS. Apparently, the FDA regulations require that manufacturers alert the agency if they think a medical devise poses a safety threat, but don't require manufacturers to provide feedback if they do not anticipate a safety. Put in fairly simply terms, how do we know whether the manufacturers are up-to-speed on possible year 2000 issues? How can we be sure that these manufacturers are properly addressing possible year 2000 issues?

Mr. SHOPE. Well, I think we have taken a number of steps to make sure manufacturers are aware of the issue. I think our letter is the first step. We have had conversations with the major associations that represent the medical device manufacturers, the Health Industry Manufacturers Association, National Electrical Manufacturers Association, and the Medical Device Manufacturers Association—to bring it to their attention and to encourage their communication with their membership as to the problem and the need to take actions here, and to discuss with these groups the usefulness and receptivity of the industry to the website idea of a way to centralize and post the information. That's one of the areas where we've taken steps to try to make manufacturers aware of the issue. We'll continue to follow up on any voluntary reports and reports from user facilities that we obtain that would indicate a problem with a device.

I think manufacturers, though, outside our regulatory scheme, have the desire to satisfy their customers and some liability issues that would probably be more influential in their actions, perhaps, than some of the FDA inquiries that we might be making as to the status of things. So I think there are a number of things that push the manufacturers to deal with this problem and to deal with it in an upfront manner.

Mr. EVANS. From a policy perspective, do you believe your agency has the necessary tools to adequately survey and receive useful feedback from manufacturers on the year 2000 compliance issue? And given the unique nature of this issue and the limited amount

of time left to address it, is there anything Congress can do to assist you in getting a better handle on this situation?

Mr. SHOPE. Well, I think we have done the things that the current law and regulations give us in the way of tools to explore these issues. I think if Congress has some other ideas on things that might be done to assist us in gathering information, we'd certainly be glad to discuss those with you and see what could be worked out there.

We are different than, say, the Veterans Health Administration, who can go to a manufacturer and ask questions because of the contractual relationship they have as customers, and prospective customers, to be asking for information on things they may be buying. We, as a regulatory agency, have to make sure we don't impose reporting burdens on manufacturers or the public that aren't appropriately consonant with our OMB reporting requirements, information request requirements. So we work within the existing framework. There might be some things that could be done to that framework that would give us additional flexibility, but I personally think that we have the tools that we need to address this problem. The manufacturers will be responsible, will take the necessary actions.

One of the things about medical technology is it's a very fast-moving kind of technology, so it wouldn't be unusual to find that only very old products are the ones that are affected here, and those are likely to be on a replacement schedule.

Mr. EVANS. Your testimony indicates there are a very limited number of devices that will probably have year 2000 problems. Can you give us a list of devices that might have those kinds of problems that you're aware of at this time, and submit that to us for the record?

Mr. SHOPE. We could attempt to put together such a list, I think. That will be based on our internal expertise of our medical device review staff as to the technologies involved and which ones of those could have a potential problem. Again, without knowledge of the actual algorithms that manufacturers have implemented, it's a little difficult to know exactly which products will or will not have problems.

(See p. 72.)

Mr. EVANS. At this time I recognize majority counsel.

Mr. Kingston SMITH. Dr. Shope, what happens if manufacturers do not live up to their legal obligations and public responsibilities? What harm could come to members of the public and to veterans?

Mr. SHOPE. If there is a product that somehow encounters a year 2000 problem, I think there's a possibility for either failure of diagnosis or failure of treatment, based on that failure.

Mr. Kingston SMITH. Has the FDA done any systematic analysis of the types of risks that might be posed to the public?

Mr. SHOPE. As I say, when we started looking at this problem about a year-and-a-half ago, we had discussions with all the medical device review staff, basically polled and did a consideration of in what kinds of devices could a year 2000-associated problem lead to a significant risk to the patient or to public health, and I have to tell you that, from our internal discussions of our knowledge of the various technologies and the way devices function, it was a

rather short list of those that came up that could be potential problems. We don't know for sure whether there are problems with those products because of not knowing the intimate details of the algorithms that were used, but we do have a list of a few kinds of products for which there is a potential for risk. Followups with some manufacturers of those products, however, have indicated that they are not subject, typically, to date problems because they didn't use a two-digit date format.

Mr. Kingston SMITH. If a manufacturer doesn't live up to its obligations to make information available to the FDA, how will the FDA know there's a problem until after it's occurred?

Mr. SHOPE. I think there will be a lot of commercial pressure to satisfy customers, and so I think manufacturers are unlikely to not live up to their obligations. There are, of course, penalties for failing to notify FDA of problems that come to the attention of the manufacturer. We've put the manufacturers on notice that this is a potential problem with our letter. That means that they're obligated to investigate and to deal with any potential problem. Failure to do that is a violation of the regulations and would subject the manufacturers to sanctions.

Mr. Kingston SMITH. Thank you.

Mr. EVANS. Thank you, Doctor. We appreciate your testimony today.

This concludes our hearing. Without objection, I will include Chairman Everett's closing statement in the record.

[The statement of Chairman Everett follows:]

CLOSING STATEMENT

I appreciate the attendance and testimony of our witnesses this morning.

It does appear that VA, particularly the Benefits Administration, is making progress on Y2K compliance. But, as GAO points out, substantial risks remain for the VA, and that means substantial risks remain for our veterans. So we're not out of the woods yet.

I remain concerned about the biomedical equipment situation. It's a much bigger problem than just the VA. FDA's rather relaxed approach strikes me as inadequate and I do not see the kind of leadership within the administration that is necessary to assure the American public that the biomedical equipment used in this country is going to be safely and effectively operating on January 1, 2000. The basic approach of leaving it up to the equipment manufacturers does not inspire confidence—at least not my confidence. I intend to continue my interest in this subject.

This has been hearing II on these issues. In the next session, or sooner if need be, the subcommittee will have more hearings, and we will maintain our focus until the VA has achieved full Y2K compliance and we can tell our veterans that.

Mr. EVANS. I thank all the witnesses and interested citizens for being here today, and we now conclude the hearing.

[Whereupon, at 11:05 p.m., the subcommittee adjourned subject to the call of the Chair.]

APPENDIX

REMARKS OF THE HONORABLE JAMES E. CLYBURN RANKING DEMOCRATIC MEMBER

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ON YEAR 2000 COMPLIANCE

SEPTEMBER 25, 1997

I WOULD LIKE TO COMMEND CHAIRMAN EVERETT FOR HAVING THE FORESIGHT TO PUT TOGETHER THIS CRITICAL HEARING THIS MORNING.

IF THE VA IS UNABLE TO SUCCESSFULLY MANAGE ITS TIME AND RESOURCES TO DEAL WITH THE IMPENDING YEAR 2000 CRISIS, IT WILL PLACE THE VETERANS IT EXISTS TO SERVE AT GREAT RISK.

I AM PLEASED THAT THE VA HAS BEGUN THE MAJOR SYSTEM-WIDE CHANGES THAT MUST BE DONE IF VA IS ABLE TO BRING ITS MISSION CRITICAL SYSTEMS INTO YEAR 2000 COMPLIANCE.

THE VA, AND PARTICULARLY THE VETERANS BENEFITS ADMINISTRATION, HAS BEEN WORKING HARD OVER THE PAST SEVERAL MONTHS TO ADDRESS THE YEAR 2000 ISSUE, AND I WANT TO COMMEND THEM FOR THEIR EFFORTS.

THE YEAR 2000 PROBLEM IS OF CRITICAL CONCERN TO THIS COMMITTEE AND TO OUR VETERANS. THANKS TO THE LEADERSHIP OF CHAIRMAN EVERETT, THE VA CAN EXPECT CONTINUED OVERSIGHT ON THIS ISSUE

THROUGHOUT THE REMAINDER OF THIS CONGRESS.

THANK YOU AGAIN, MR. CHAIRMAN. I LOOK FORWARD TO THE TESTIMONY THIS MORNING.

CONGRESSMAN MASCARA'S STATEMENT

VA HEARING ON YEAR 2000 COMPUTER COMPLIANCE

SEPTEMBER 25, 1997

GOOD MORNING MR. CHAIRMAN. I AM PLEASED TO BE TAKING PART IN THIS IMPORTANT HEARING TO ASSESS WHAT PROGRESS THE VA HAS MADE IN RECENT MONTHS IN FIXING THE YEAR 2000 COMPUTER COMPLIANCE PROBLEM.

I READ OVER THE PREPARED TESTIMONY LAST EVENING AND I AM SOMEWHAT TORN BY WHAT IT INDICATES. WHILE I WAS GLAD TO READ THAT THE OFFICE OF MANAGEMENT AND BUDGET HAS DETERMINED THE VA IS MAKING MUCH MORE PROGRESS THAN MANY OTHER AGENCIES, I REMAIN WORRIED THAT THE PROGRESS IS NOT FAST ENOUGH. IF THE SITUATION DOES NOT DRAMATICALLY IMPROVE, I AM AFRAID VETERANS COULD STILL FIND THEMSELVES FACING DELAYED PAYMENTS AND

COUNTLESS OTHER PROBLEMS ONCE THE CALENDER REACHES JANUARY 1, 2000.

THIS IS UNACCEPTABLE AND I WANT TO GET SOME REASSURANCE TODAY FROM VA OFFICIALS THAT THEY ARE SOMEHOW GOING TO RECTIFY THIS SITUATION, PARTICULARLY AS IT PERTAINS TO COMPUTER PROGRAMS HANDLING VA PENSIONS, HEALTH AND G.I. BENEFITS.

I ALSO MUST SAY THAT I CONTINUE TO BE ASTONISHED THAT THE EXECUTIVE BRANCH DOES NOT YET SEEM TO GRASP THE SERIOUSNESS OF THE PROBLEM IT FACES IN MAKING SURE ALL GOVERNMENT COMPUTERS ARE ABLE TO HANDLE THE TRANSITION TO THE NEXT CENTURY.

I WAS STUNNED TO READ IN THE GAO TESTIMONY THAT 75 PERCENT OF OUR AGENCIES' SO-CALLED "MISSION-CRITICAL SYSTEMS" STILL NEED

45-928 - 98 - 3

TO BE REPAIRED OR REPLACED AND THAT THE TOTAL COST HAS NOW RISEN ANOTHER $1 BILLION TO $3.8 BILLION.

AS I SAID AT THE LAST HEARING, THE PRESIDENT NEEDS TO APPOINT A COMPUTER CZAR TO DEAL WITH THIS PROBLEM AND HE OUGHT TO DO IT NOW.

WHEN I WAS SERVING IN COUNTY GOVERNMENT, MANY YEARS AGO, WE WERE TALKING ABOUT HOW THE COUNTY WAS GOING TO DEAL WITH THIS PROBLEM.

IT IS SIMPLY AMAZING TO ME THAT A LOCAL GOVERNMENT HAD THE FORESIGHT TO RECOGNIZE THAT THE YEAR 2000 PRESENTED A MAJOR COMPUTER PROBLEM AND BEGAN TO WORK TOWARDS A SOLUTION, WHILE THE FEDERAL GOVERNMENT WAS "FIDDLING WHILE ROME WAS BURNING."

AGAIN, WE MUST ALL DO BETTER AND HOPEFULLY THIS HEARING TODAY WILL SPUR FURTHER ACTION.

THANK YOU MR. CHAIRMAN. I YIELD BACK THE BALANCE OF MY TIME.

THE END

United States General Accounting Office

GAO

Testimony

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

For Release on Delivery
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VETERANS AFFAIRS COMPUTER SYSTEMS

Action Underway Yet Much Work Remains To Resolve Year 2000 Crisis

Statement of Joel C. Willemssen
Director, Information Resources Management
Accounting and Information Management Division

GAO/T-AIMD-97-174

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the progress being made by the federal government and, in particular, the Department of Veterans Affairs (VA), in making sure that its automated information systems are ready for the upcoming century change. As you know, we testified before the Subcommittee earlier this summer, at which time our report was released detailing the activities of one VA component[1], the Veterans Benefits Administration (VBA), to make its systems Year 2000 -compliant.[2]

As requested, my testimony today will first summarize federal progress in addressing the Year 2000 problem and will then examine VA and its major components. My statement will discuss action taken by VA as a whole, and steps taken by VBA in response to recommendations contained in our recent report. We have just begun a detailed review of the Veterans Health Administration's (VHA) Year 2000 activities; consequently, my testimony in this area will be limited to results to date.

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[1]Along with VBA, the other two major VA components are the Veterans Health Administration and the National Cemetery System.

[2]Veterans Benefits Computer Systems: Uninterrupted Delivery of Benefits Depends on Timely Correction of Year-2000 Problems (GAO/T-AIMD-97-114, June 26, 1997) and Veterans Benefits Computer Systems: Risks of VBA's Year-2000 Efforts (GAO/AIMD-97-79, May 30, 1997).

FEDERAL AGENCY PROGRESS:
EFFORTS MUST BE EXPEDITED

As we testified in July,[3] time is running out for agencies and the pace needs to be accelerated if widespread systems problems are to be avoided as the Year 2000 approaches. We stressed in our testimony that the Office of Management and Budget (OMB) and key federal agencies need to move with more urgency. Among the other related issues we noted was that increased attention was required on validation and testing of Year 2000 solutions, data interfaces and exchanges, and contingency planning.

OMB's most current Year 2000 progress report on the federal government's efforts, released last week, again demonstrates that although federal agencies are generally making progress toward achieving Year 2000 compliance, the overall pace of that progress is too slow.[4] Based on individual agency reports, 75 percent of the agencies' approximately 8,500 mission-critical systems remain to be repaired or replaced, and the

[3]Year 2000 Computing Crisis: Time Is Running Out for Federal Agencies to Prepare for the New Millennium (GAO/T-AIMD-97-129, July 10, 1997), before the Subcommittee on Government Management, Information and Technology, House Committee on Government Reform and Oversight, and the Subcommittee on Technology, House Committee on Science.

[4]Progress on Year 2000 Conversion, U.S. Office of Management and Budget, August 15, 1997.

total cost estimate has risen to $3.8 billion, up $1 billion from the previous quarterly report.[5]

According to OMB, reports of several of the agencies were disappointing; consequently, it placed agencies in one of three categories, depending upon evidence of progress. In the first category are four agencies that OMB found had "insufficient evidence of progress."[6] For these agencies, OMB established a "rebuttable presumption going into the Fiscal Year 1999 budget formulation process this Fall that we [OMB] will not fund requests for information technology investments unless they are directly related to fixing the year 2000 problem."

OMB's second category contains 12 other agencies for which it cited "evidence of progress but also concerns." These agencies were put on notice that continued funding for information technology investments would be contingent on continued progress.[7] Finally, for the eight remaining agencies that, according to OMB, appear to be making progress--and this includes VA--funding requests will be handled in the usual manner,

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[5]Getting Federal Computers Ready for 2000: Progress Report, U.S. Office of Management and Budget, May 15, 1997.

[6]Agriculture, Education, Transportation, and the Agency for International Development.

[7]These are Commerce, Defense, Energy, Health and Human Services, Interior, Justice, Treasury, Environmental Protection Agency, Federal Emergency Management Agency, National Aeronautics and Space Administration, Office of Personnel Management, and Small Business Administration.

although progress at all agencies will be reevaluated on the basis of their next quarterly reports, due November 15.[8]

We are encouraged by OMB's statements and believe they reflect an increased urgency to address the Year 2000 issue. Further, we note that in its report, OMB states that it plans to address other issues that we raised in our July testimony.[9]

- OMB emphasized that proper validation of changes was critical to success. It stated that it planned to meet with agencies over the coming months to discuss the adequacy of scheduled timetables for completing validation.
- OMB said it would discuss with agencies the preparedness of communications interfaces with systems external to the federal government, including those of state and local governments and the private sector.
- OMB asked agencies for a summary of the contingency plan for any mission-critical system that was reported behind schedule in two consecutive quarterly reports so that it could summarize such plans in future reports to the Congress.

We look forward to implementation of these key activities as we continue monitoring OMB's leadership of the federal government's Year 2000 effort.

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[8]Along with VA, this category encompasses Housing and Urban Development, Labor, State, General Services Administration, National Science Foundation, Nuclear Regulatory Commission, and Social Security Administration.

[9]GAO/T-AIMD-97-129.

VA: THE STAKES ARE HIGH

VA is very vulnerable to the impact of the new millennium because of the large number of veterans and their dependents that it serves; this is why it is so important that VA's systems be made compliant in time to avoid disruption to the benefits and services on which millions of Americans depend. Our past and current work at VA indicates that the Department recognizes the urgency of its task, and it has made progress. But much remains to be done if it is to avoid the widespread computer failures that unmodified systems could bring. If left uncorrected, the types of possible problems that could occur include but are not limited to late or inaccurate benefits payments, lack of patient scheduling for hospital treatments, and misinterpretation of patient data. The number of areas vulnerable to problems is vast.

The Department's June 1997 Year 2000 plan (VA Year 2000 Solutions) outlines VA's strategy, activities, and major milestones. According to this plan and in line with OMB guidance, VA's primary approach is to make its 11 existing mission-critical systems compliant; one, in fact, already is. Table 1 lists these systems, along with the numbers of applications they serve and the responsible VA component or office.

Table 1: VA's Mission-Critical Computer Systems (11) and Their Applications (464)

Component/Office (Number of Systems)	Systems	Number of Applications
Veterans Benefits Administration (6)	▪ Compensation & Pension ▪ Education ▪ Insurance ▪ Loan Guaranty ▪ Vocational Rehabilitation ▪ Administrative	157
Veterans Health Administration (2)	▪ Veterans Health Information Systems and Technology Architecture ▪ Veterans Health Administration Corporate Systems	143 160
National Cemetery System (1)[a]	▪ Burial Operations Support System/Automated Monument Application System--Reengineer	2
Office of Financial Management (2)	▪ Personnel and Accounting Integrated Data ▪ Financial Management System	1 1

[a]The only system that VA considers to be fully Year 2000 compliant.

Source: VA.

Responsible for overseeing the Year 2000 problem at VA is its chief information officer (CIO); he is assisted by the CIOs of both VBA and VHA, by senior information technology managers in the National Cemetery System, and by staff offices at VA headquarters. VA has also designated a Year 2000 project manager, responsible for general oversight and monitoring.

According to VA's August 14, 1997, quarterly report to OMB, the Department has made progress in addressing the Year 2000 problem. As noted in the report, one of its 11 mission-critical systems--the one serving the National Cemetery System--is already fully compliant. Of the ten remaining mission-critical systems and their applications, 85 percent have been assessed and 51 percent have been renovated. In addition, VA has updated its total Year 2000 cost estimate from $144 million (May 1997) to $162 million; VA's stated reason for the increase is the need for upgrades to its commercial off-the-shelf software and hardware, and more contractual support.

Further, VA's current estimate shows that it expects systems assessment to be completed by the end of next January, renovation of systems by November 1998, validation by January 1999, and implementation by October 1999--2 months earlier than VA reported in May.

VBA HAS BEGUN TO IMPLEMENT GAO RECOMMENDATIONS

As we testified before the Subcommittee in June,[10] correcting the Year 2000 problem is critical to VBA's mission of providing benefits and services to veterans and their dependents. VBA has responded to this challenge by initiating a number of actions,

[10]GAO/T-AIMD-97-114, June 26, 1997.

including developing an agencywide plan and a Year 2000 strategy, and creating a program management organization. However, several substantial risks remain. If VBA is to avert serious disruption to its ability to disseminate benefits, it will need to strengthen its management and oversight of Year 2000-related activities.

Our May 30, 1997, report contained ten specific recommendations to the Secretary of Veterans Affairs on actions that VBA needed to take to address the Year 2000 problem.[11] VA concurs with all ten, and is in the process of implementing them. For example, according to VBA:

- To strengthen its Year 2000 program management office, it has assigned oversight and coordination responsibilities for all Year 2000 activities to this office alone.
- It has completed inventories of data interfaces and third-party products (hardware, software, mainframes, minicomputers, operating systems, and utilities). VBA has also determined that most of its third-party products are Year 2000 compliant--98 percent of its personal computers, local area networks, minicomputers, and commercial software; and all of its imaging equipment and associated software.
- It has renovated half of the 157 applications that make up its six mission-critical systems. It plans to renovate the remaining applications by November 1998.

[11]GAO/AIMD-97-79.

While we are encouraged by these positive actions, we understand from discussions with VBA officials that key work schedules have been compressed, creating added pressure. For example, renovation of VBA's largest and most critical applications--those necessary to the functioning of its Compensation and Pension Service--may not be completed by VBA's target date of December 1998. Changes to these applications have had to be delayed in order to effect this year's legislatively mandated changes and cost-of-living increases. Time is similarly short for work on the loan guaranty system, for which all phases[12]--including assessment--remain to be completed. For example, the new claims and verification application is scheduled to start in early fiscal year 1998, but it has a fail date[13] of December 1998. This leaves VBA only slightly over one year to design, develop, test, and implement this application.

A further challenge for VBA is that it has not modified its schedule to take into account recent problems and delays in its attempts to replace an education payment system for selected reservists known as chapter 1606. Such schedules are important to ensuring that all mission-critical applications are fixed; they therefore need to be modified or updated to reflect realistic estimations of the difficulty of the work involved.

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[12]The Year 2000 program phases are *awareness, assessment, renovation, validation,* and *implementation.*

[13]The date on which this application will experience the effects of dates on calculations.

In addition, although VBA has completed an inventory of 590 internal and external interfaces, as of July 31, 1997, only 26 percent of the interfaces had been assessed for compliance. VBA's Year 2000 project manager indicated that VBA is encountering problems determining whether its external interfaces[14] are Year 2000 compliant because external sources have not provided the necessary information.

VBA also has not updated its January 1997 risk assessment to reflect the recent change in its Year 2000 strategy. Specifically, in response to concerns raised regarding its initial approach, VBA redirected its Year 2000 strategy by focusing on converting its existing benefits payment systems rather than replacing the noncompliant systems. Since risk assessment is an important prerequisite for effectively prioritizing projects and mitigating potential problems, updating the previous risk assessment to take this change into account is essential.

An internal VA oversight committee, established to monitor and evaluate the progress of VBA's Year 2000 activities, identified concerns similar to ours. Specifically, according to a member of this committee, little time remains for VBA to make the necessary modifications to its compensation and pension and loan guaranty systems, and much work remains in assessing the external interfaces for compliance.

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[14]An example of an external interface is the exchange of disability compensation information between the Department of Defense and VBA. Defense currently provides VBA with electronic information on the amount of disability benefits paid to a veteran by Defense for offset against the amount paid by VBA to this same veteran. This offset is necessary because, by law, the veteran cannot be paid twice for the same disability.

VHA HAS BEGUN TO ASSESS ITS SYSTEMS AND RELATED PRODUCTS FOR COMPLIANCE

The Year 2000 challenge for VHA is enormous. As the largest centrally directed civilian health care system in the United States, VHA manages health care delivery to veterans within 22 regional areas geographically dispersed throughout the country; these areas are known as Veterans Integrated Service Networks (VISNs), and they encompass 173 VA medical centers, 376 outpatient clinics, 133 nursing homes, and 39 domiciliaries--a total of 721 facilities. These sites utilize a wide range of electronic information systems, biomedical equipment, facilities systems, and other computer-based system products. Accordingly, it is essential that each of these 22 regional health care networks thoroughly assesses and plans for ensuring Year 2000 compliance so that service delivery is not interrupted.

Within VHA, the CIO has overall responsibility for planning and managing Year 2000 compliance. The CIO created a VHA Year 2000 project office, empowered to develop compliance guidance. In April 1997 this office developed a VHA plan for addressing the year 2000; the plan was approved by VA's Under Secretary for Health on May 14 of this year. The CIOs of each of the 22 regional networks, medical facility directors, and managers have ultimate responsibility for preparing and executing their individual Year 2000 plans, including all required assessment, renovation, validation/testing, and implementation activities.

According to VA's August 14, 1997, quarterly report to OMB, VHA is in the initial stages of assessing the compliance of its two mission-critical systems--the Veterans Health Information Systems and Technology Architecture (VISTA)[15]--formerly known as the Decentralized Hospital Computer Program (DHCP)--and the VHA corporate systems. VA also reported that of the two systems' applications, 17 percent have been assessed and 16 percent renovated. VHA plans to complete this assessment and renovation by the end of January 1998 and July 1998, respectively.

According to VA's Year 2000 readiness review, VHA's strategy for the national VISTA applications is to assess all 143 applications and recode as necessary. According to VHA, 34 of its 143 applications[16] have been assessed; 33 of these 34 were eliminated as a result of the assessment.

In order to effectively assess and renovate, it is necessary to understand how local facilities are using the national VISTA applications. One potential risk is that some local facilities have customized national applications, according to VA's Year 2000 readiness

[15]VISTA represents the national health care information applications along with related commercial products, personal computers/workstations, and other items used in VHA health care facilities.

[16]Examples of applications include dietetics, pharmacy/inpatient, health summary, prosthetics, and laboratory.

review.[17] If this is true, it is important that VHA know where applications have been changed--even in small ways--so as to ensure that they are Year 2000 compliant. Beyond customization, local facilities may purchase software add-ons to work with the national applications; here, too, these must be inventoried and Year 2000 compliance assessed.

An inventory of internal and external VISTA interfaces has not yet been completed; systems developers plan to identify such interfaces when they assess each application. Should internal information be corrupted by exposure to uncorrected external interfaces through network exchanges, system crashes and/or loss of data could result. VA's Year 2000 project manager has expressed concern that this information may not be obtainable from external sources, who have yet to inform VHA whether their interfaces are Year 2000 compliant.

As with interfaces, VHA must be assured that the commercial software products it uses are Year 2000 compliant. It has completed an inventory of its commercial products, such as personal computer operating systems, office automation software, and medical applications; according to the project manager, over 3,000 software products and 1,000 software vendors have been identified. VHA plans to rely on the General Services Administration to provide it with a general list of commercial products that are Year

[17]Such customization includes special-purpose programs written by local information resources management staff or other system users on-site or imported from other VA medical centers. They generally meet a specific local need or extend the functionality of nationally released software.

2000 compliant. For specialized products unique to the health care industry, VHA plans to contact manufacturers for compliance information.

Physical facilities are another area of concern. According to VHA's Year 2000 program manager, VHA has not completed an inventory of facilities-related systems and equipment such as elevators; heating, ventilating, and air conditioning equipment; lighting systems; security systems; and disaster recovery systems. Such elements are vitally important to VHA's ability to provide high-quality health care services. VHA is working with the General Services Administration and manufacturers on this issue. Since it is often critical that medical services not be interrupted, VHA is required to have contingency plans in place in case hospital systems fail. These plans are reviewed and assessed regularly by the Joint Commission on Accreditation of Healthcare Organizations. However, such contingency plans are meant to ensure continued operation in the event of disaster; such approval does not necessarily ensure that all backup systems are Year 2000 compliant.

VHA IS ASSESSING YEAR 2000 IMPACT ON MEDICAL DEVICES

Health care facilities depend on the reliable operation of a variety of biomedical devices--equipment that can record, process, analyze, display, or transmit medical data. Examples include computerized nuclear magnetic resonance imaging (MRI) systems,

cardiac monitoring systems, cardiac defibrillators, and various tools for laboratory analysis. Such devices may depend on a computer for calibration or day-to-day operation. This computer could be either a personal computer that connects to the device from a distance, or a microprocessor chip embedded within the device. In either case, the software that controls the operation of the computer may be susceptible to the Year 2000 problem. The impact could range from incorrect formatting of a printout to incorrect operation of the device, having the potential to affect patient care or safety.

The risks for a specific medical device depend on the role of the device in the patient's care and the design of the device. Although medical treatment facilities have the expertise to understand how medical devices are used, they rely on device manufacturers to analyze designs and disclose Year 2000 compliance status.

As a health care provider and user of medical devices, VHA is a key stakeholder in determining compliance of such tools. Another key player is the Food and Drug Administration (FDA), in its role of protecting the public from unsafe and/or ineffective medical devices.

In attempting to ascertain the potential impact of the century change on its biomedical devices, VHA on two separate occasions sent letters to manufacturers. Its first letter was sent over a period of a few days beginning June 23 of this year to equipment manufacturers identified by selected experts within VHA. In the letter, VHA inquired as

to steps the manufacturer planned to take to resolve the Year 2000 issue. Out of 118 letters, VHA received 32 responses. These responses were reviewed by VHA's medical device integrated product team, comprising internal experts from a variety of fields.

On the basis of the team's analysis, VHA sent more detailed letters asking specific questions, including whether the manufacturer provided any devices to VA that incorporate a real-time clock; if such devices were provided, whether they are Year 2000 compliant; and for those that are not compliant, asking for model numbers, device names, and the specific impact the century change would likely have on the device. These letters were sent to about 1,600 manufacturers on September 9, 1997, with a request for responses by October 3. According to VHA, 50 responses had been received as of September 15.

Product team members plan to review responses to ensure that they are categorized correctly as compliant, noncompliant, or pending; VHA will maintain a database of the manufacturers and their responses. This database will be made available to VA medical centers through the VHA intranet, although key personnel such as biomedical engineers may not have easy access to the intranet at some medical centers. The information will also be communicated to VA medical centers through monthly conference calls among engineers and communications with medical center directors. We feel that it is imperative that such results be widely disseminated; if the VHA intranet is insufficient for this task, other means should be found.

FDA also recently began communicating with manufacturers. According to officials, FDA sent a letter in early July of this year to about 13,000 such manufacturers, reminding them of their responsibility to ensure that their products will not be affected by the century change. In the letter FDA reminded manufacturers that, according to section 518 of the Federal Food, Drug, and Cosmetic Act, they are required to notify users or purchasers when FDA determines a device presents an unreasonable risk of substantial harm to public health. Although one response was received, the acting director of FDA's Division of Electronics and Computer Science explained that it was not the agency's intention to solicit a specific response because FDA expects manufacturers to report any problems found through normal reporting channels. FDA plans to disseminate information on any Year 2000 problems reported by manufacturers to the public through its reporting systems, such as the Medical Products Reporting Program ("MedWatch").

According to the director of FDA's Cardiovascular Division, the agency's strategy for helping to determine whether medical devices are Year 2000 compliant is to rely on the knowledge and experience of its resident experts. These experts, with backgrounds in electrical engineering, software engineering, and/or biomedical engineering, have reviewed the design of selected medical devices to determine whether the devices would be affected by the century change. In the case of pacemakers, for example, FDA experts have concluded that no adverse effect will result. This conclusion was based on the fact that the internal operations of pacemakers do not involve dates. The experts further said

that although pacemaker settings are often changed with the assistance of a computer, which often uses dates and may be noncompliant, a trained physician is always involved in controlling the settings.

A federal entity--the Year 2000 Subgroup on Biomedical Equipment--is working to coordinate the effort to obtain Year 2000 compliance status information from medical device manufacturers. This group plans to follow up on nonrespondents to questionnaires sent out by VHA, FDA, and other federal health care providers to manufacturers requesting this information.

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In closing, Mr. Chairman, I want to stress that while our detailed review of the VHA area is just now underway, it is clear that for VA as a whole to have all of its mission-critical systems compliant by January 1, 2000 will entail a huge, well-coordinated effort.

This concludes my statement. I would be happy to respond to any questions that you or other Members of the Subcommittee may have at this time.

(511236)

STATEMENT BY
THE HONORABLE D. MARK CATLETT
ACTING ASSISTANT SECRETARY FOR MANAGEMENT AND
ACTING CHIEF INFORMATION OFFICER
DEPARTMENT OF VETERANS AFFAIRS

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

September 25, 1997

Introduction

Mr. Chairman and Members of the Subcommittee, it is my pleasure to testify on behalf of the Department of Veterans Affairs (VA) on the status of our information systems for the Year 2000. I am accompanied today by the Veterans Health Administration (VHA) Chief Information Officer, Mr. R. David Albinson, and the Veterans Benefits Administration (VBA) Chief Information Officer, Mr. Newell E. Quinton.

We are committed to ensuring VA's information systems will provide uninterrupted service supporting the full range of veterans benefits delivery and medical care for the Year 2000 and beyond.

I would like to bring the Subcommittee up-to-date on steps we are taking and our progress in resolving Year 2000 problems. As I have previously testified, we are following the standardized, governmentwide Year 2000 best practices phases (assessment, renovation, validation and implementation) established by the Office of Management and Budget (OMB) in conjunction with the Federal CIO Council Subcommittee on Year 2000.

Year 2000 Accountability and Monthly Reporting Requirements

As VA's CIO, I am responsible for overseeing and ensuring the completion of the Year 2000 project for all VA systems. The VBA CIO, VHA CIO, and senior information technology managers in the National Cemetery System (NCS) are responsible for developing specific plans and managing the projects within their respective jurisdictions.

I have established detailed monthly internal reporting requirements to track our progress in addressing Year 2000 problems. This monthly report, modeled after OMB's governmentwide Year 2000 quarterly report, measures the progress of each VA administration for each of the established phases.

In addition to this formal reporting mechanism, the Administration-level CIO's and their Year 2000 program officials meet with me monthly to provide status reports addressing their successes and progress toward meeting the milestones presented in their plans. Monitoring monthly progress reports from each organization provides my office with early notice should an organization fall behind schedule. This early notice gives me the ability to recommend to VA's Chief Operating Officer, the Deputy Secretary, the necessary redirection and refocusing of appropriate resources to bring an organization back on schedule.

Year 2000 Project Offices

Both VBA and VHA have Year 2000 Project Offices that report directly to their organization's CIO. These Project Offices provide for the planning, guidance, oversight and technical support for their organization's Year 2000 efforts.

I would like to take this opportunity to provide the Subcommittee an update on VHA's and VBA's Year 2000 accomplishments.

Veterans Health Administration

VHA Plan

VHA has prepared and widely distributed a detailed compliance plan, organized in accordance with the General Accounting Office (GAO) draft Year 2000 best practices. We provided a copy of the plan to the subcommittee in June. In the plan, key responsibilities and accountability were assigned to the VHA CIO and Associate CIOs, the Veterans Integrated Service Network (VISN) CIOs, and VHA healthcare facility management. Each of the 22 VISN CIOs has the responsibility to develop and execute Year 2000 compliance plans within their respective network. Many of the VISN CIOs have garnered management support, created Year 2000 workgroups, and identified key Year 2000 coordinators within their VISNs. The VISN CIOs have been provided guidance and reporting formats to generate consistent monthly statistics on both compliance status and Year 2000 costs.

VHA Year 2000 Milestones and Status

VHA's goal is to complete its assessment, including the nationwide assessment of biomedical equipment at VA medical facilities, by January 1998. VHA's plan is to complete any necessary renovation by July 1998, validation by January 1999 and implementation by October 1999. As of August 31, 1997, 30 percent of VHA's mission-critical applications are

compliant. This percentage represents both the *VISTA* and VHA corporate system applications.

VHA has assigned priorities to and scheduled the renovation of VHA mission-critical systems. *VISTA* information system applications have been categorized according to their criticality to VHA's mission. To support the detailed *VISTA* application assessment process, VHA has acquired and is using an automated tool to support code analysis for both the national software applications and for locally developed software applications. VHA has begun to use this tool on some of its larger, more complex applications; code that will require renovation appears to be limited. As of August 31, 1997, 31 percent of *VISTA* applications have be assessed and 27 percent of *VISTA* applications are compliant or will be eliminated by the Year 2000.

VHA is currently assessing all of its corporate information systems. System "owners" have been asked to determine the compliance status of their systems, and to establish schedules for completing the process if the systems are non-compliant. To date, 37 percent of the corporate systems have been assessed and 33 percent are either already compliant or will be eliminated by the Year 2000.

VHA has completed its inventory of commercial-off-the-shelf (COTS) products for each hospital and has begun to determine the compliance of these products. My office, in conjunction with VHA and VBA, will share information on COTS provider status with all VA offices and use the federal CIO Council Subcommittee on Year 2000 Web page being established and maintained by the General Services Administration (GSA) on COTS products.

Biomedical Equipment

As I testified in June, the potential Year 2000 impact on biomedical equipment is a national issue, affecting both the private sector and federal health care communities. VA, along with other agencies and the private health care community, is a consumer of biomedical equipment; we do not regulate the industry. Let me bring the Subcommittee up-to-date on the specific actions VA is taking in the area of biomedical equipment.

VHA formed the Medical Devices Integrated Product Team (MDIPT), a multi-disciplinary oversight committee, to assist with identifying, inventorying, assessing and evaluating medical devices at risk. The MDIPT membership includes the following:

Deputy Director of Nuclear Medicine at Ann Arbor, MI,
Biomedical Engineer from VAMC Milwaukee, WI,
Chief, Laboratory and Pathology Medicine at the Dallas VAMC,
Cardiologist from the St. Louis VAMC,
Director, Biomedical Engineering in HQ, and
Chief of Surgery Service at the Salem VAMC.

The team met in August to review and refine VHA's Year 2000 medical device plan. As a result, initial steps were validated and expanded; the model for assessing risk and for establishing priorities was validated and a comprehensive plan was produced.

A subcommittee of the team created a database listing manufacturers of medical devices currently in use in the VHA. Experts from the team were consulted to ensure that manufacturers in all specialty areas were included.

Members of the MDIPT rewrote the initial compliance status request letters using "lessons learned" from responses to the letters sent out in June 1997. A revised letter requesting more detailed information and plans from biomedical manufacturers was sent on September 10, 1997 to all 1,580 manufacturers in the database. Vendors were asked to respond by October 3, 1997; thus far, 135 responses have been received. VHA is reviewing those responses and will share the results with the Food and Drug Administration.

Veterans Benefits Administration

VBA has made significant progress on its Year 2000 efforts in recent months. As of August 31, 1997, 52 percent of VBA's applications have been renovated and made Year 2000 compliant. Two payment applications, Chapter 31 (Vocational Rehabilitation), and the Reinstatement Program for Survivors (REPS) are compliant. Our Insurance application is on schedule with its renovation and will begin testing in February 1998.

Overall Education system milestones are on track for completion within their projected timeframes and well before any application fail date. However, the projected completion date provided by our contractor shows a slippage for the Chapter 1606 redesign component of the Education system. This slippage has not jeopardized our overall completion date for making the Education system compliant. As for Loan Guaranty applications, task orders have been awarded or will be awarded to renovate noncompliant applications, insuring that all Loan Guaranty applications are compliant by their projected timeframes and before any fail date. VBA is developing a new application for real estate property management. The schedule has slipped but will not impact the Year 2000 schedule because the existing application is compliant.

Let me address the Compensation and Pension application and its status. Forty-six percent of the Compensation and Pension modules are Year 2000 compliant. However, Year 2000 work is competing with legislative program changes for Spina Bifida and incorporating Minimum Income for Widows, plus preparing for the annual cost of living adjustments. To minimize the risk that the complexities of implementing legislative changes would jeopardize Year 2000 efforts, VBA awarded a contract for renovation support of our Compensation and Pension application. This contract provides an automated Year 2000 conversion tool for the application and additional contractor support.

We testified in June that we awarded a task order for Oversight support. The Oversight Team completed their assessment of VBA's Year 2000 effort. Their assessment substantiated what we knew all along: That VBA's Year 2000 effort is on track and that schedules and resources are realistic. The Oversight team has made suggestions and recommendations that are being incorporated into VBA's Year 2000 Project plan.

VBA has recently increased the amount of contractor support for their project managers, and will award task orders to support their software quality and testing efforts, as well as some loan guaranty renovations within the next few months. VBA's Oversight team will continue efforts to identify risk areas for VBA, including facility, telephone and non-information technology areas that could impact the delivery of benefits to our veterans.

VBA has addressed all areas of potential Year 2000 problems. They have assessed all of their third party products and have budgeted for their replacements. They have acquired a compliant Honeywell 9000 platform for Year 2000 testing. As you know the Honeywell supports our Compensation, Pension, Education, and Vocational Rehabilitation applications. New, compliant IBM hardware and software is also being installed. In addition, VBA is working hard to resolve interface issues. Forty percent of their interfaces are Year 2000 compliant.

VA's Austin Automation Center (AAC)

The AAC provides VA-wide information technology support to all components within the Department. As of August 31, 1997, 79 percent of the applications they support have been renovated and are Year 2000 compliant. The AAC plan is to have all systems renovated by September 1998, validated by October 1998, and fully implemented by September 1999.

VA working with Year 2000 Interagency efforts

VA, VBA and VHA representatives are actively involved in several interagency efforts to find common solutions to Year 2000 issues and are representing VA's interest in several subgroups of the Federal CIO Council Subcommittee on Year 2000. Included are:

- The biomedical equipment subgroup. This subgroup is chaired by the Department of Health and Human Services (HHS) and includes representatives from FDA, Nuclear Regulatory Commission, National Institutes of Health, DoD and each of the uniformed services.

- The telecommunications subgroup chaired by GSA to address issues in voice and data communications systems.

- The subgroup on building systems chaired by GSA to address issues related to the operation of buildings and facilities.

- The Year 2000 best practices subgroup chaired by the Social Security Administration to share approaches to resolving Year 2000 problems.

- The state and local subgroup dealing with state and Federal Year 2000 issues.

In addition, VHA staff meets monthly with staff from the Office of the Assistant Secretary of Defense for Health Affairs to pursue the identification of Year 2000 issues and solutions common to both organizations.

Summary

VA organizations have prepared detailed systems inventories, and developed testing methodologies, individual project plans and contingencies. We are monitoring our progress for each application supporting our mission-critical systems. We are also monitoring such key elements as estimated lines-of-code, number of modules, operating systems and COTS packages.

We will continue to work with the Federal CIO Council Subcommittee on the Year 2000 and continue sharing information among Federal agencies. We will continue to work with the HHS-chaired biomedical committee to resolve potential issues with biomedical equipment.

We are committed to ensuring that VA information systems will be ready for the coming millennium. VA information systems will continue to provide uninterrupted support to our programs and ensure that we deliver the highest quality benefits and medical care to our Nation's veterans and their families. I thank you for this opportunity to present our progress in preparing for the Year 2000. Mr. Albinson, Mr. Quinton and I would be happy to answer any questions you might have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

THOMAS SHOPE, Ph.D.

ACTING DIRECTOR, DIVISION OF ELECTRONICS AND COMPUTER SCIENCE,

OFFICE OF SCIENCE AND TECHNOLOGY

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 1997

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Mr. Chairman and Members of the Subcommittee. My name is Dr. Thomas Shope. I am the Acting Director, Division of Electronics and Computer Science, Office of Science and Technology, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). Having previously testified before this Subcommittee at the June 26, 1997, hearing, I am pleased to be here today to provide information on the "Year 2000" date issue as it relates to medical devices. Although FDA has not received any information since the previous hearing to indicate that there will be significant problems with medical devices, I am here to assist the Subcommittee in its efforts to examine the issue.

WHAT IS A MEDICAL DEVICE?

According to the definition in the Federal Food, Drug, and Cosmetic Act (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 achievemsnt 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. These 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, fetal stents, and kidney dialysis machines.

FDA is responsible for 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 enforcement activities; and monitoring adverse events in already marketed products, taking action, when necessary, to prevent injury or death. A device manufacturer must comply with all the reguirements of the FD&C Act, including: establishment registration and device listing, premarket review, use of good manufacturing practices (GMPs), reporting adverse events, and others.

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.

Any computer software which meets the legal definition of a medical device is subject to applicable FDA medical device regulations. Medical devices which use computers or software can take several forms including: embedded microchips which are part of, 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.

An issue which has been identified as warranting review is the impact of the "Year 2000" on some medical device computer systems and software applications. These products could be impacted by

the "Year 2000" date problem only if they use a date in their algorithm or calculations, or in record keeping; and a two-digit year format was used in their design. Manufacturers of such products are the only reliable source of information as to the details of the methods used in the programming and whether these two conditions are met. While we are in the process of reviewing this issue, we do not currently believe that there will be any major impact on medical device safety.

Embedded 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 devices are: pacemakers, infusion pumps, ventilators, and many others. It is unlikely that most of these products would be impacted by the "Year 2000" problem. Almost none of these devices require knowledge of the current date to operate safely and effectively. For example, pacemakers do not use the current date in their operation.

Non-embedded 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, further, may use the two-digit year format. Such products 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 used to calculate 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; digital analysis and graphical presentation 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. While there is a chance that the two-digit format may affect the performance of these software devices, we believe that the "Year 2000" risk will be mitigated through proactively working with manufacturers.

Letter to Medical Device Manufacturers

In light of our review of the impact of the "Year 2000" on some medical device computer systems and software applications, CDRH sent a letter in July to 13,407 medical device manufacturers, 8322 domestic manufacturers and 5,085 foreign manufacturers, to ensure that manufacturers address this issue and review both embedded and non-embedded software products. We 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. We requested that the manufacturers review the software used to determine if there is any risk.

CDRH recommended specific actions to ensure the continued safety and effectiveness of these devices. For currently 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 beginning January 1, 2000.

In our letter to industry, we reminded manufacturers that under the GMP regulation and the current Quality System Regulation (which became effective June 1 and incorporates a set of checks and balances in manufacturers' design processes to assure 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.

As a result of our letter, we expect manufacturers who identify products which have a date-related problem which can pose a significant risk to the patient to take the necessary action to remedy the problem. This might include notification of device purchasers so that their device can be appropriately modified before the "Year 2000." Manufacturers who discover a significant risk presented by a date problem are required to notify CDRH and take appropriate action. Again, we do not anticipate any significant problems with individual medical devices, however, we want to ensure the continued safety and effectiveness of these devices.

For future medical device premarket submissions, manufacturers of devices whose safe operation could be affected by the "Year 2000" date change will be required to demonstrate that the products can perform date recording and computations properly, i.e., "Year 2000" compliant.

CONCLUSION

Thank you, Mr. Chairman, for the opportunity to tell you about the issue of "Year 2000" and medical devices. Let me assure you we at FDA take this issue very seriously as we do 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, FDA's commitment to industry must be coupled with a reciprocal commitment: that medical device firms will meet high standards in the design, manufacture, and evaluation of their products. We recognize that this can only be attained through a collaborative effort -- between FDA 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.

POST-HEARING QUESTIONS
CONCERNING THE SEPTEMBER 25, 1997
HEARING ON YEAR 2000 COMPUTER COMPLIANCE
IN THE DEPARTMENT OF VETERANS AFFAIRS

FOR D. MARK CATLETT
ACTING ASSISTANT SECRETARY FOR MANAGEMENT
DEPARTMENT OF VETERANS AFFAIRS

FROM THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Question 1: The oversight team that VA contracted with in June to assess the progress of its year 2000 efforts concluded that "several areas of risk requiring management attention were noted." Can you identify for the Subcommittee the specific risk areas in order of their importance? Can you also detail the steps you will be taking to address these potential trouble spots?

Answer: The SRA International (SRA) assessment concluded that significant progress has been made in the Veterans Benefits Administration (VBA) efforts to make its applications compliant. SRA did identify several areas of risks requiring VBA management attention.

SRA identified the renovation of the Compensation and Pension (C&P) application as a risk because VBA recently awarded a contract for support of Year 2000 renovations. SRA found that the systems development staff at the Hines Benefits Delivery Center, which is responsible for the C&P system, has limited contract management experience and lacked detailed project plans. VBA has since provided contract management training to key personnel and a detailed plan is under development by Hines staff and will be completed in early November.

SRA also identified the two contracts for renovating two applications for administrative functions as risks because, they too, had recently been awarded by VBA's systems development staff in Austin, Texas. VBA management in Austin has contracting management experience, however, the key issues will be the actual vendor plans and performance. Both vendors are being closely monitored by the Austin staff to ensure they are performing as expected.

Question 2: Your testimony and the testimony of GAO indicates that the renovation of the VBA's Compensation and Pension application appears to be a major hurdle. Can you describe in detail what the oversight team recommended in this regard, and outline what steps you will be taking in the near term to address this critical problem?

Answer: SRA recommended that the systems development staff at Hines obtain necessary contract management training and develop detailed project plans. The renovation of the C&P application by the Hines staff represents a high risk because the known legislative and maintenance changes to the system diverted resources from Year 2000 work.

VBA has taken several steps to mitigate this risk. VBA has awarded a contract to support Year 2000 renovation of the system. In addition, VBA has provided contract management training and a detailed plan is under development by Hines staff to help ensure timely completion of the Year 2000 renovation. Pending any major changes to the Hines workload, we are confident this strategy will keep us on schedule.

VBA has made significant progress renovating the C&P system in recent months and its Year 2000 efforts is on schedule. As of September 30, 1997, 52% of the C&P application program modules are compliant.

Question 3: It is our understanding that even those applications within the Veterans Benefits Administration (VBA) that have been completely renovated are not necessarily operational, and therefore not year 2000 compliant. Is this understanding correct, and if so, what percentage of the renovated systems within VBA are fully operational at this point?

Applications that are renovated are Year 2000 compliant and operational. These applications are properly processing dates for the Year 2000 and beyond.

Answer: VBA is not counting any application as completing the implementation phase, as defined by the Office of Management and Budget (OMB), until it is actually running on hardware using a compliant operating system. For example, in the case of the Vocational Rehabilitation application, it has been renovated, validated and is in production. However, the fully compliant operating system for the mainframe Honeywell system hardware will not be available for production until early in the second quarter of 1998. Presently, we report to OMB that six percent of VBA's applications have completed the implementation phase and are running using Year 2000 compliant operating systems. The percentage complete for the implementation phase will grow substantially when the remaining compliant operating systems are installed.

Question 4: The oversight team indicated that the VA has yet to put together detailed compliance plans for its Compensation and Pension system. Why are no such plans in place, and when will such a plan be put in place?

Answer: Plans have always been in place for the compliance of the compensation and pension system. However, the oversight team pointed out that the existing plans did not have the specificity necessary for an effort of this magnitude. Action is being taken to revisit these plans and mesh them with the vendor's plan for renovation. VBA expects those plans to be completed by early November.

Question 5: The oversight team has pointed out complex management problems within the loan guaranty program that have raised concern within the agency. Can you briefly explain this problem and explain the VA's plans to address it?

Answer: The oversight contractor pointed out that Loan Guaranty applications are run on several hardware platforms making management of these systems slightly more complex. Multi-platform applications are not unusual today and VBA has an excellent management team with plans in place to manage the renovation of noncompliant Loan Guaranty applications.

As we testified in September, task orders have been awarded to renovate noncompliant Loan Guaranty applications, insuring that all Loan Guaranty applications are compliant by their projected timeframes and before any fail date. We also noted that VBA's schedule for a new application for real estate property management had slipped but would not impact the Year 2000 schedule because the existing application is compliant.

GAO

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

Accounting and Information
Management Division

B-278519

November 7, 1997

The Honorable Lane Evans
Ranking Minority Member
Committee on Veterans' Affairs
House of Representatives

Subject: Veterans Health Administration Facility Systems: Some Progress Made In Ensuring Year 2000 Compliance, but Challenges Remain

Dear Mr. Evans:

This letter responds to your October 10, 1997, letter, which asked a question arising from our September 25, 1997, testimony on Year 2000 initiatives at the Department of Veterans Affairs (VA).[1] Your question and our response follow.

Your testimony indicates that the Veterans Health Administration (VHA) has failed to complete an inventory of the elevator, heating, air conditioning, lighting systems, and disaster recovery systems at its hospitals. How critical a problem is this, and is there still time to address this problem within the VHA?

Ensuring Year 2000 compliance for facility-related systems, such as those systems controlling elevator, heating, air conditioning, ventilation, and lighting as well as the disaster recovery or backup systems for these products, is a critical problem for both public and private organizations. Many facilities built or renovated within the last 20 years contain embedded computer systems that control, monitor, or assist in operations. Many of these systems could malfunction due to vulnerability to the Year 2000 problem. For example, on January 1, 2000:

- Elevators could automatically park themselves on the first floors, open their doors, and shut down.
- Heating and air conditioning units could stop functioning properly.
- Card-entry security systems could cease to operate.
- Automatic lighting devices could fail to reactivate.

Addressing the facility-related systems problem is especially critical for VHA, because it oversees 173 medical centers, 376 outpatient clinics, 133 nursing homes, and 39 domiciliaries–a total of 721 facilities. VHA recognizes the criticality of ensuring Year 2000 compliance for such systems; its Year 2000 plan states that "facility-related system products are vitally important to VHA in providing quality health-care service."

VHA has made some progress. Its Year 2000 project office has begun to develop a centralized inventory for the facility-related systems at its health-care facilities. It established a project team, consisting of 20 technical experts in various facilities systems, to pull together a list of facility-related systems manufacturers to be used by VHA as the starting point for this inventory. The team has drafted and plans to

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

send letters to these manufacturers asking if their products are Year 2000 compliant and what their plans are for achieving compliance for noncompliant systems or products. Also, VHA's medical centers are currently developing an inventory and assessing their facility systems for Year 2000 compliance. Finally, VHA is also working with the CIO Council's newly-formed Year 2000 Building Systems Subgroup on facility-related systems issues.

VHA, however, faces some major challenges.

- VHA has a very short time frame to address the Year 2000 computing problem; there are only 26 months remaining until January 1, 2000. According to VHA's Year 2000 project manager, VHA may not complete its assessments of facility-related systems by January 31, 1998.

- The project manager indicated that manufacturers may not promptly respond to VHA. He further indicated that these manufacturers may not know if their products are Year 2000 compliant because some of the components that make up the product may have been built by others. As a result, manufacturers will have to contact the responsible suppliers to determine whether the components are Year 2000 compliant.

- According to its Year 2000 project manager, VHA is largely dependent upon the manufacturers to determine whether a Year 2000 problem exists and how any Year 2000 problems will be corrected. Once manufacturer responses are received and verified, VHA must provide them to its Veterans Information Service Networks (VISN) and medical centers so that they can complete and implement their plans for Year 2000 compliance.

- Finally, VHA must implement manufacturers' recommendations for achieving Year 2000 compliance of facility systems and validate that all facility-related systems are Year 2000 compliant. Also, in coordination with disaster recovery plans already in effect at its medical centers, VHA must develop contingency plans specifically designed for Year 2000 failures and errors.

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We discussed a draft of this report with VHA officials, and their comments have been incorporated where appropriate. VHA's Year 2000 project manager said that the report accurately reflected VHA's current situation for facility-related systems.

In answering this question, we reviewed and analyzed agency documents referring to Year 2000 projects–such as VHA's Year 2000 Plan and VHA's VISN Year 2000 Plans–and interviewed key VHA Year 2000 officials. We conducted our work from October 20 through November 5, 1997, in accordance with generally accepted government auditing standards.

We are sending copies of this report to the Chairman of the House Committee on Veterans' Affairs, other interested committees, and the Acting Secretary of Veterans Affairs. Copies will also be made available to other parties upon request. If you have any questions concerning this report, please contact me at (202) 512-6253 or Helen Lew, Assistant Director, at (202) 512-9356. You may also e-mail us at *willemssenj.aimd@gao.gov* or *lewh.aimd@gao.gov*.

Sincerely yours,

Joel C. Willemssen
Director, Information Resources Management
(511238)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 30 1997

The Honorable Lane Evans
Ranking Minority Member
Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515-6335

Dear Mr. Evans:

This is in response to your letters of September 19, October 10 and October 27, 1997 regarding follow-up information to the June 26 and September 25, 1997 Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, Hearings on Year 2000 (Y2K) Issues and Their Impact on the Department of Veterans' Affairs. This letter is responsive to the three letters referenced above as the issues in your letters are interrelated.

IDENTIFICATION AND CORRECTION OF Y2K PROBLEMS

Let us begin by assuring you that the Food and Drug Administration (FDA or the Agency), and particularly the Center for Devices and Radiological Health, takes the issue of possible Y2K problems in medical devices very seriously, and we are committed to addressing effectively this matter. We already have addressed this issue with medical device manufacturers, as outlined in our testimony, and we will be taking additional steps, as set forth in more detail below, to assure the continued safety and effectiveness of medical devices.

Premarket review authority is the principal preventive mechanism FDA uses to keep medical devices that are unsafe or ineffective off the market. Unless explicitly exempted by the Agency, since 1976 every medical device must be tha subject of a cleared premarket notification submission or an approved premarket approval application. As we have testified previously before the Subcommittee, for new medical devices, FDA now is reviewing submissions to ensure that the products can perform date recording and computations that will be unaffected by the Y2K date change.

In terms of products already on the market, FDA assures the safety and effectiveness of medical devices marketed and used in the United States primarily through inspections of medical device manufacturing facilities and through monitoring and seeking correction of identified problems which have occurred

with already marketed products. FDA inspects medical device firms to determine compliance with the Federal Food, Drug, and Cosmetic (FDC) Act and FDA regulations, including the Quality System Regulation (previously the Good Manufacturing Practice (GMP) Regulation) (21 CFR 820). Under the Quality System Regulation (21 CFR 820.100(a)(1)), medical device manufacturers must ensure and document that their medical devices perform according to specifications and otherwise comply with GMPs.

FDA believes its authority under the Quality System Regulation to require GMP compliance is our clearest avenue to ensure that medical device software and integrated components are Y2K compliant. This entails directing firms to check and verify whether their products present any potential Y2K problems and to bring potential problems that have been identified to the attention of responsible parties at manufacturing establishments. We would, if necessary, take regulatory action against firms that fail to comply with the Quality System Regulation or other requirements.

We have alerted the medical device industry with the July 1997 letter of their obligation to identify and correct any problems with their products. Moreover, in an effort to clarify this authority, the Agency plans to follow-up the letter with a Federal Register Notice that clearly directs manufacturers to fulfill their obligations under 21 CFR 820.100(a)(1) and that reiterates that it is the manufacturer's existing legal responsibility to identify, to investigate and, when necessary, to correct the cause of product problems, including those related to Y2K issues. The Agency will suggest in this Notice a target schedule to complete this review.

Section 519(f) of the FDC Act, which was added by the Safe Medical Device Act of 1990, requires manufacturers to report certain corrections and removals of medical devices undertaken by manufacturers. Accordingly, when manufacturers conduct their Y2K checks under the GMP Regulation, if problems are found and corrections made "to reduce a risk to health posed by the device, or to remedy a violation of this Act caused by the device which may present a risk to health," these corrections would be reportable to FDA under Section 519(f)of the FDC Act. This is a new provision whose regulations will become effective upon completion of the administrative review procedures under the Paperwork Reduction Act of 1995. The Federal Register Notice will underscore that any such potential Y2K problems must be identified, corrected and reported to the Agency.

LIST OF MEDICAL DEVICES

Based on its scientific assessment of the Y2K issue, FDA believes that there are very few medical devices dependent on calculations which use date information for proper functioning. There are some generic types of devices which may raise Y2K compliance issues, but FDA does not have a list of medical devices which have been determined to be Y2K compliant or non-compliant by industry sources.

The only medical device currently known to FDA to have a Y2K problem which could impact patient safety is one vendor's radiation treatment planning system. That vendor currently is developing a solution for the problem which will be made available to purchasers.

In your letter you state that, "one of the most serious challenges to be addressed involves the Y2K compliance of machinery, such as medical devices, which uses embedded chips." Our engineering analysis indicates that to create a problem the embedded chip also must incorporate the use of a date, and that date must have been represented using a two digit format for the year. It is important to note that this qualification greatly reduces the universe of affected products. There are few medical devices in which the use of a date is critical for the device function.

A system which determines a patient's age for use in an algorithm from information entered detailing the patient's birthday and the current date may have Y2K compliance issues. There are several categories of this type of device, such as electrocardiogram interpretation programs or devices which provide diagnostic information based on various parameters, including the age of the patient, which are provided as input to the device. Other systems with a potential for date-related problems are auxiliary or accessory equipment used with pacemakers to display or adjust device function, but for which the critical functioning of the device (the pacing function) is not date-dependent, and central nursing stations recording data from multiple patients or computer-run systems tracking certain items in an operating room. At this time, FDA has no information which documents non-compliance or problems with any of these types of devices.

CONSULTATION WITH THE VETERANS' HEALTH ADMINISTRATION

Should the Veterans' Health Administration (VHA) request specific consultation or assistance from FDA, we will provide whatever assistance that can be made available. VHA and FDA, along with representatives of other Federal agencies,

participate on the Chief Information Officers Council Subcommittee on the Year 2000 working group on medical devices and scientific equipment. This working group meets regularly to address issues such as you have raised in your letters.

One action under consideration is the creation of an Internet website early in 1998 for disseminating Y2K information on medical devices provided voluntarily or through required reports by manufacturers. The website could be designed to provide public access to the Y2K compliance status of medical devices and scientific equipment voluntarily provided by manufacturers. This information would be available to the Department of Veterans' Affairs, as well as to other Federal and public health care facilities.

We will continue to work with the public, industry, and other interested public health agencies to ensure that any potential Y2K problems affecting medical devices are identified and corrected. We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: The Honorable Bob Stump
Chairman, Committee on Veterans' Affairs

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