HEARING 1. VA'S COMPLIANCE WITH YEAR 2000 REQUIREMENTS

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

JUNE 26, 1997

Printed for the use of the Committee on Veterans' Affairs

Serial No. 105–14

U.S. GOVERNMENT PRINTING OFFICE

44–672 CC WASHINGTON : 1998

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-056138-8

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CONTENTS

HEARING 1. VA'S COMPLIANCE WITH YEAR 2000 REQUIREMENTS

THURSDAY, JUNE 26, 1997

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

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

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

OPENING STATEMENT OF CHAIRMAN EVERETT

Mr. EVERETT. Good morning. We will come to order.

Today's hearing will examine if the VA computer systems will work or fail after 12:00 a.m. on the morning of the year 2000. Many computer systems we use today use a two-digit date to recognize the year. With a two-digit format, computers will fail to operate correctly, because the year 2000 will read 1900.

GA warns that the payments to veterans with service connected disabilities could be severely delayed, because VA's compensation and pension systems either halt or produces checks so erroneous that the system must be shut down, and the checks must be processed manually.

Time is certainly running out. Our computer generated display on your left is a real time countdown which comes from the Internet. It shows how much time is left before January 1, 2000. Our low technology back-up display which we prepared in case the computer system went down shows how many calendar days, 918, are left.

Will VA's computers crash or shut down, malfunction or compute incorrect information? How widespread of a problem will this be? What will be the cost of these errors? Will health care be delivered to our veterans safely and without interruption? Will their paychecks and pension checks get their safely without interruption?

We'll examine VA's efforts since they testified on their modernization efforts almost a year ago. It is interesting that the Veterans Benefits Administration made the year 2000 Y2K problem a priority only last June.

Today we will hear from our colleague, Steve Horn, Chairman of the Government Reform and Oversight Subcommittee on government management information and technology. We will also hear

from the GAO, which has done extensive analysis on the Y2K problem, governmentwide and in the VA.

The VA will explain what they have done to address Y2K. Tom Shope of the Food and Drug Administration will tell us what actions the FDA is taking to address Y2K issues, to ensure the safety and effectiveness of medical devices in the health care industry, including the VA.

I think we have a pretty full plate for discussion today, and I look forward to hearing testimony from all our witnesses. I will now recognize the ranking member, Mr. Clyburn.

Mr. EVERETT. I will now recognize the ranking member, Mr. Clyburn.

OPENING STATEMENT OF HON. JAMES E. CLYBURN

Mr. CLYBURN. Thank you, Mr. Chairman. I am pleased to join with you today in calling for this extremely critical hearing on the VA's efforts to achieve Year 2000 compliance.

The GAO tells us that the VA has a long way to go to solve this problem, but not much time to get there. I am encouraged that this subcommittee has decided to place a watchful eye on the VA's progress in this regard. I am hopeful that, through continued oversight by this subcommittee, we can help to ensure that the VA is able to achieve Year 2000 compliance.

The purpose of this hearing is to hear a status report from the VA on their progress on this critical issue, to underscore our subcommittee's interest and concern, and to make clear this committee's expectation that our deserving veterans will receive uninterrupted benefits and services in the year 2000 and beyond.

I believe it is important to recognize that this is not a problem that is unique to the VA. As a recent cover story in *Newsweek* magazine points out, this is an issue that effects everything from the personal computers many of us have in our homes to private business and industry and to nearly every local, State and Federal government across the globe.

Mr. Chairman, I would ask unanimous consent that the June 2, 1997 *Newsweek* cover story titled "The Day the World Shuts Down" be included in this year's hearing record.

Mr. EVERETT. Without objection.

[The attachment appears on p. 37.]

Mr. CLYBURN. It is also important to recognize that the VA has been working hard over the past several months to get their act together on this issue. I want to commend these recent efforts and want to make it clear that I do not doubt the sincerity of the VA's interest in addressing and ultimately solving this vexing problem.

I must say, however, that the objective views of knowledgeable outsiders strongly suggest that the VA's task is more daunting and difficult than its written testimony to this subcommittee might seem to suggest.

I would also like to note for the record this morning that the Gartner Group, a leading independent industry group, has conducted extensive research into the Year 2000 problem and has monitored the steps private industry and government have taken to address the problem.

Unfortunately, scheduling difficulties prevented the Gartner Group from providing live testimony before our subcommittee today. The Gartner Group has graciously volunteered, however, to provide written responses to any questions any of the members of this subcommittee may have.

Mr. Chairman, I ask unanimous consent that subcommittee members be allowed 5 business days to provide the committee with written questions to the Gartner group and that the responses be included in the formal hearing record.

Mr. EVERETT. Without objection, so ordered.

Mr. CLYBURN. Thank you. Mr. Chairman, as I stated at the outset of my remarks, the GAO tells us the VA has a long way to go to achieve Year 2000 compliance, and the clock tells us they don't have much time to get there.

Through continued close scrutiny and oversight by this subcommittee, I am hopeful that we will remain committed to doing what we can to help ensure the VA makes it to the year 2000.

Thank you, Terry, for your leadership on this issue.

Mr. EVERETT. Thank you, Jim.

[The prepared statement of Congressman Clyburn appears on p. 33.]

Mr. EVERETT. Mr. Mascara, do you have any comment?

OPENING STATEMENT OF HON. FRANK MASCARA

Mr. MASCARA. Yes. Thank you, Mr. Chairman, and thank you for calling this hearing this morning to examine a serious VA computer problems.

Last evening I read over the material provided by the committee, and I must say I am most alarmed that, if this problem is not corrected, and corrected quickly, it could result in late benefit checks and denied benefits to millions of veterans across America, a situation which this subcommittee cannot tolerate.

I understand that, since my colleagues on the House Committee on Government Reform and Oversight gave the VA a D for its efforts to correct this problem and this hearing was scheduled, the VA has begun to move. Those in the know, however, say that the plan being developed by the VA is very general and raises more questions than it answers.

I am hoping that today's testimony will help alleviate the committee's concerns and not give us cause for further heartburn.

The bottom line is that too much is at stake here to even think of the VA not getting the problem corrected. Veterans are relying on us to keep the pressure on the VA, and you can all rest assured we will do exactly that until this problem no longer exists.

Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. EVERETT. Thank you very much.

[The prepared statement of Congressman Mascara appears on p. 45.]

Mr. CLYBURN. Mr. Chairman, before we get started, I think it may be worth noting that this is Mr. Mascara's first day as a member of this subcommittee. I want to welcome him to the subcommittee.

Mr. MASCARA. Thank you, Mr. Clyburn.

Mr. EVERETT. We certainly do. We do welcome you, and we need all the help we can get.

Mr. MASCARA. And I'm delighted to be a part of it.

Mr. EVERETT. I've got great help right here, but I always welcome more.

Now, of course, I'd like to welcome my colleague, Steve Horn, not only a colleague but a classmate. He's Chairman of the Government Reform and Oversight Subcommittee on Government Management, Information and Technology.

Steve, in the beginning I would say that this is an elusive target. I started first having hearings on this as Chairman of the Compensation, Pension, Insurance, and Memorial Affairs Subcommittee 2 years ago. I think perhaps there's been some movement. We, frankly, though, are not near where we need to be, and I'm certainly going to be interested in hearing your testimony this morning, if you will please begin.

STATEMENT OF HON. STEPHEN HORN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. HORN. I thank you very much, Mr. Chairman. I'm delighted you and I have been colleagues, and they picked the right person for the subcommittee chairman, since a publisher who knows what an investigation is is certainly worthwhile presiding over one of these groups.

I'm going to skip-read through some of my testimony. I assume that's put in the record at this point.

Mr. EVERETT. The complete testimony will be entered into the record.

Mr. HORN. Let me just say a few general things, since you're into this subject. The year 2000 problem, when our Subcommittee on Government Management got into it, the Federal Government had hardly paid any attention to it in terms of the Executive branch. A few State governors were working on it, Governor Ridge in Pennsylvania, a former colleague here, Governor Wilson in California, and some others.

They brought in chief technology officers to pull things together. So the States were a little ahead of us, and we thought we would see what's going on in 24 departments and executive agencies, and I believe you have the results before you.

Counsel for this study on my right, Mark Uncipher, has been with this for a year and a half now, and our 16th report of the full committee is about this subject. So I commend it to you and the staff, and our 24 agencies and the grades we gave them are in there.

The Veterans Affairs Agency got a D. There were four basic questions we asked at that time: Has the agency a Year 2000 plan? The answer out of Veterans Affairs was no. Is there a Year 2000 program manager that's been appointed to get some direction and focus in this area? Now Veterans Affairs did say they had that.

Now does the agency have any cost estimates for the Year 2000 solution? No, big blank. Did you answer the rest of the questions we asked, which were about 11 or 12 other questions? They did answer those.

When we went through this, we only had four A's in the whole Executive branch, Agency for International Development, Office of Personnel Management, Small Business, and Social Security.

There were three B's, three C's, 10 D's, four F's. Being a former professor, I grade on the absolute. I do not grade on the curve. So the D's and F's in many universities would have become C's and B-'s, but not here.

Now that shook them up a little. We had two cabinet secretaries that never even heard of the problem. One was the Secretary of Energy, and I figured she wouldn't have heard of the problem since she was traveling so much, and we were doing a separate investigation on that.

The one that surprised me was the Secretary of Transportation at that time, and he's a very able person, and he hadn't heard about, and we didn't know at that time what we know now, that one of his key agencies in the Transportation, the Federal Highway Administration, had been working on this problem since 1989. They were a first, along with Social Security, that's been working on the problem since 1989.

We look to Social Security to be sort of the guards, tackles, everybody else that's running down the field ahead of the other agencies and, hopefully, a model; because, as you and I know, if Social Security can't get this problem solved by January 1, 2000, there will be 435 district offices of members of the House that will have a few hundred thousand people saying where's my check, where's my eligibility. This is a very serious question.

When we started people thought, oh, well, you know, what's this all about, science will solve it. Science hasn't solved it. Now all of this happened, as we know—and I remember using those computers in the university 20-25 years ago. We had very little storage capacity, and somebody had the bright idea, hey, we can save a few things here and there. Instead of having 1966, let's just put in 1966.

So you put in 1966, and you can't get the whole thing in. So when you get to the year 2000, you got two zeroes there, and the computer doesn't know what to do. Sounds crazy, but it's there.

Nobody has solved the problem yet. If there is a simple solution, they will be a billionaire overnight, because as Gartner testified when they appeared before us, a consultant group, fairly widely recognized, it's a $600 billion worldwide problem.

We're half the computers in the world. It's a $300 billion U.S. problem, private, nonprofit, governmental. The Federal Government, they estimated, was a $30 billion problem. My instinct said I don't think it's that much, but it's something serious.

As I ought to say, I'm the least knowledgeable person probably in the Congress on computers. So don't take my instincts as gospel, but the fact is that we asked through the Appropriations Subcommittee for the budget director, in submitting the President's budget for Fiscal Year 1998, to give us an estimate of what they think it is.

Now Mr. Raines has done an excellent job in getting the Executive branch to take this issue seriously. He's the first one that really ran with it, and he also, I think, agrees with what I've been say-

ing. Don't send us a big budget request and waste a year up here going through the process; reprogram money, and get on it now.

He has taken exactly that philosophy, and the people in the Executive branch have received the message, get with it, don't just whine about it. I think that is very important.

Anyhow, he got into it when he was nominated and confirmed for Director of Office of Management and Budget, and he started getting some quarterly reports from them. Then he put up his estimate for the budget for Fiscal Year 1998, and generally it was $2.3 billion. Well, I started laughing at that one. That was just plain too low, and my instincts, I think, are right on that; because I then held a hearing.

Assistant Secretary Paige, General Paige of Defense, said, well, $1 billion of that 2.3 of his is from the Department of Defense, and we haven't even started assessing anything. Now the Department of Defense has some very complex problems. They don't even know the extent of them yet, but they are working on it, and I suspect when this gets all sorted out, it will be somewhere between $10-15 billion problem.

Now there is a timetable that the Director of OMB has set and, as you look at it, you start worrying, because some of it is pushed right up into 1999. Now anyone that's ever dealt with massive computer purchases and implementation—and I have, both as a university president and as an oversight chairman where we've had such wonders to look at as the IRS's $4 billion mess, and when I was on the Aviation Committee chaired by Mr. Oberstar in the 103rd, he took a couple of us out to look at the FAA boondoggle, and you could walk in the room and see that it was a boondoggle, and they were at the $4 billion point, too.

I've asked both those agencies, why can't you learn something at the $4 million, $40 million, $400 million point? Why does it seem to have to go to $4 billion. It's because they have had poor management, and everybody that had a bright idea overnight starts changing the thing, and there was no focus.

You can't be up to the latest point in time. You're always going to be behind in the advance of technology, and they need to realize that.

So what we have been after is working with OMB in a sort of joint questions that go out. They share them with us. We just have the new batch in. We will be grading those and probably releasing it sometime in July. We want to take a very careful look and be very fair about it, because I think a lot of the agencies do now have the message.

I think, when you look at the Veterans one, as I mentioned, they really only had two of four base categories the last go-around, and we would hope by that time that there would be progress; but I also find the comments contained in the GAO testimony that you're going to hear today very troubling.

I don't want to steal the General Accounting Office's thunder, but I'd be concerned that there is not yet a complete inventory of local computer applications, that there's not a better system for prioritizing mission critical applications and that there are not contingency plans for systems failing, and they inevitably will.

I've seen this across America in universities that had millions spent on student registration. The whole system breaks down, and the poor little old ladies that have been running registration for years get called back from retirement to go back and do it the old way where you stand in lines for 3 days.

So we need contingency plans that work, and I think that's about it for the once over lightly, and I commend you for keeping after the agency under your jurisdiction.

[The prepared statement of Congressman Horn appears on p. 52.]

Mr. EVERETT. Thank you very much, Steve.

Before I go into some questions, I'd like to mention we've been joined by the full committee ranking member, Lane Evans, who was also the very able chairman of this committee before it was disbanded a couple of years ago. His knowledge and expertise and the desire he has for our veterans is well known here on the Hill.

Steve, you bring up several interesting points, and one that I discussed a little bit with VA is trying to nail down source code, where it is, who has it, who has the ability to write it. From what I've been able to gather, source codes are changed in a number of different regions and places.

That has led partially to the problem that we have now in trying to, number one, find where the source code is; and, number two, once you get a number of different people changing source code on a program, then you have people working at cross-purposes.

Seems to me, it would be much better off—I don't know if this exists in other agencies or not, but it would be much better off when we approach solving this problem if we centralize where these changes can be made rather than having, as you mentioned a minute ago, anybody that came up with a bright idea made a change.

Would you have any comment on that?

Mr. HORN. Well, not really. I think you need to get in a panel of experts, but I do know this, that when you have millions of lines of code that you've got to work your way through and ask the question, does this agency need this to carry out its operations—and Social Security would be a good group to have in. They've worked with this.

They have millions and millions of lines of code. They estimate at Gartner why they got to $600 billion was that it would be about the cost of a dollar to look at each line, when you take in the wages of the people involved.

In solving this, this is not simply a money problem. This is a human resource problem, because as we get nearer and nearer to 1999, there's going to be a lot of panic set in in the private sector, which we're also trying to alert, and nonprofits, local State governments, so forth, that might have been lagging along.

That means the cost of those experts that know how to bring up the code, deal with it, and adjust it will be going up and up. That's why we might well have a $300 billion national problem here, but if we do this now in an orderly manner, maybe the problem can be solved without the scarcity of resources and talented people not being around to solve it.

Mr. EVERETT. We are also concerned about the problem of embedded chips, particularly those with medical devices that may

malfunction because of the Year 2000 problem. What more should Congress be doing to improve the awareness and response to this problem that, while it may be small, it could be critical?

Mr. HORN. Yes. I think you ought to get in a panel of people from the industry. We worry about the medical device problem and the embedded chip also, and that's where the assessment of these agencies is so very crucial.

If you're dealing with huge hospital systems, as the services have and the VA has, that might compound your problem many times over, and we're just not aware of it.

So all I can commend to you is go out and get some good people that know something about the technology to talk to the experts as they are grappling with these questions. As I say, time is the significant limiting factor here. The clock keeps ticking, whether we're acting or not.

Mr. EVERETT. Mr. Clyburn.

Mr. CLYBURN. Mr. Chairman, I have a question, but I wondered if I ought to yield to the ranking—I do have a question, Mr. Horn. Have you taken a recent look at the VA and seen where they are today as opposed to where they were when they received the D grade?

Mr. HORN. Well, we have not come out with the latest. We did have the chief technology officer, chief information officer for the VA, before us in a panel; but I couldn't give you a grade at this point. We just haven't sat down and looked at the pieces, and I don't like to shoot from the hip.

Mr. CLYBURN. I appreciate that, but I just wondering if you had taken a look at it.

Mr. HORN. No. We are——

Mr. CLYBURN. I think I've made a B or two in my lifetime but, fortunately, I didn't stay down there. I was just wondering whether or not any movement had been made, according to your assessment.

Mr. HORN. Well, I think all agencies are now moving after our little April 1996 hearing and the grading during the summer, but the question is how fast are they moving. We don't really have that information until we go through this latest report, but the key is pinning responsibility, getting organized, and starting to make the basic assessment.

You asked about the embedded chips. That's exactly the problem there. I understand that, really, the percentage of devices in equipment may be only 2 to 5 percent, and they may be affected. They may malfunction. However, in some pieces of equipment such as a medical device, with that being in there that's a catastrophic situation, and you might just not—you might overlook that, if you don't think about it hard.

Mr. CLYBURN. Well, I want to commend you for looking into this matter, and I think that, from what I hear, you and ranking member Maloney have been very diligent, and I commend you for it.

Mr. HORN. We've had 100 percent cooperation from everybody.

Mr. CLYBURN. Thank you. That's all I have, Mr. Chairman.

Mr. EVERETT. Thank you, Jim. I would say for the record that our colleague, Congresswoman Maloney, was scheduled to appear

here and was unable to do so at the last minute, and we will welcome here testimony for the record.

Lane? Oh, I'm sorry. We do come—first come, first served. All right, Lane.

Mr. HORN. I want to say to the gentleman from Pennsylvania, we miss you, Frank. Why did you leave us? We could use you.

Mr. EVERETT. Don't we need him?

Mr. EVANS. Mr. Chairman, I want to thank you and the ranking member for holding this hearing and to thank our colleague from California for joining with us. We hope we'll continue to tag team with you as we progress, hopefully progress, on this issue.

What's our next step? When do the next report cards come out?

Mr. HORN. July. We want a chance to look at the data—the data has just come in—and really go over it thoroughly, perhaps send Mr. Uncipher and some others on the team out to some of the agencies.

Mr. EVANS. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you, Lane.

Steve, we certainly appreciate your enlightening testimony. We also appreciate your dedication to this subject matter. It's not a very romantic thing that gets a lot of attention, but it's a most critical thing that could cause this nation great harm and great, great expense if we don't get the problem solved, and I share your pessimism in the way we're moving right now.

Thank you for coming.

Mr. HORN. Well, if every authorizing committee does what Veterans Affairs is doing, we don't have to worry.

Mr. EVERETT. Thank you very much.

Mr. EVERETT. I'd like to introduce our second panel, Mr. Joel Willemssen, Director, Information Resources Management, Accounting and Information Management Division of the GAO, and ask him to please introduce his panel.

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

Mr. WILLEMSSEN. Thank you, Mr. Chairman, ranking member Clyburn, ranking member Evans, Congressman Mascara. Thank you very much for inviting us here today to testify on VBA's efforts to address the Year 2000 computing issue.

Accompanying me are Helen Lew, Assistant Director, and L.J. Latham, Technical Assistant Director.

As requested, I will briefly summarize our statement.

As with other agencies, VBA could face widespread computer system failures as the Year 2000 nears, due to the use of two digits to represent the year. More than most other agencies, however, VBA's failure would be felt by millions of people if the benefits and services on which they rely were disrupted.

Eligibility for many of these benefits and services is date-dependent, which places their delivery at risk. Especially susceptible to disruption could be compensation and pension systems that relate dates to benefits, such as dates of birth or military service.

VBA recognizes that the Year 2000 computing issue poses a serious challenge to them. Its information resources management plan clearly states that achieving Year 2000 compliance is the agency's number one priority.

VBA has also initiated actions to assess its vulnerability and perform the modifications that must be made to its information systems. However, several substantial risks remain.

In a report issued to you, Mr. Chairman, and being released publicly today, we detail these risks, and I'd like to briefly highlight a few of those.

First, the structure of VBA's Year 2000 program management office needs strengthening, and technical and managerial issues need to be addressed. An agency level program office is needed to coordinate and manage the full range of interdependent information systems activities.

A critical technical deficiency is VBA's lack of an overall systems architecture or blueprint to guide and constrain the development of replacement systems and the evolution of related systems.

Second, much work remains to be done in determining whether VBA's information systems and their components are Year 2000 compliant now. VBA expected to have completed all of its inventories of systems by September 30, 1996. However, by that date inventories had only been completed for software applications at its three systems development centers.

According to VBA, part of the reason for the delay in completing inventories is the agency's loss of well qualified employees to retirement during recent agency buyouts. VBA's inventory also does not include local applications developed by regional offices.

According to VA's own Year 2000 readiness review, without a complete inventory of regional applications, VBA cannot adequately predict or plan for the impact of the Year 2000.

Third, VBA has not developed contingency plans for all of its critical systems. Three of its major business areas currently lack contingency plans to ensure continued operations in the event of Year 2000 failures.

Fourth, VBA does not yet have sufficient information about the costs and risks associated with its Year 2000 activities. As a consequence, it lacks the information necessary to make decisions about prioritizing its information technology projects.

Given the serious risks associated with VBA's Year 2000 activities, our report recommends that the Secretary take ten specific actions to help ensure the agency's success in making its systems Year 2000 compliant.

In commenting on a draft of our report, the Secretary stated that he concurred with all of our recommendations. We also note that VA's and VBA's CIOs took quick action to address areas of concern that we've identified. As we've said in our report, we're very encouraged by these steps.

That concludes a summary of my statement, Mr. Chairman. I'd be pleased to address any questions that you or the other members may have.

[The prepared statement of Mr. Willemssen appears on p. 55.]

Mr. EVERETT. Well, I thank you. I hope our D doesn't go to an I, incomplete or something.

Is it correct to characterize your overall testimony as saying that there are serious risks of significant Year 2000 failures that might affect our veterans?

Mr. WILLEMSSEN. That's a fair characterization, but if I may add, it's also fair to add that VBA is clearly aware of these risks. They've been very responsive to the issues that we've raised, and taken action very quickly to try to resolve them, but there are remaining risks. So I think that is a fair characterization.

Mr. EVERETT. I will add to that that I've been very pleased with the private meetings that I've had with those who are charged with this responsibility. I'm gravely concerned, though, that we are so far behind that we may not have a lot of catch-up time.

As a matter of fact, given the very tight compliance schedule, how much margin of error do we have?

Mr. WILLEMSSEN. It is very tight. In looking at the schedule, we believe that VBA, like other major agencies, has to set aside calendar year 1999 to perform critical testing activities to make sure that the fixes that they've put in place are actually going to work as needed.

Related to this, we think it's very important that VBA identify priorities in what systems have to be fixed first, what second, and so on, because it may turn out that we run out of time and we can't fix everything, and we don't want to be stuck at that point with the most critical systems being the ones that aren't fixed.

Therefore, we think it's very important that priorities be established.

Mr. EVERETT. The VA Year 2000 strategy depends on limited financial and personnel resources. Would you say that that's a recipe for failure?

Mr. WILLEMSSEN. Well, we've been pleased with VBA's recent change in their strategy. Actually, we think that the recent change is a less risky approach. What they were planning to do originally on many of their major systems was hope for new system developments to come on board and replace the existing systems.

Instead of that approach, they've now changed the strategy—and part of the credit goes to your subcommittee which last year push VBA to develop a contingency plan. The VBA contingency plan was to try to fix ongoing systems. That has now turned out to be their primary strategy, as they realize that we've got to make sure that ongoing systems are going to work for the Year 2000.

Mr. EVERETT. Your report reflects the situation only at VBA.

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

Mr. EVERETT. Would you compare the two or where they are, or do you have any idea where VHA is?

Mr. WILLEMSSEN. Unfortunately, we haven't done any assessments on VHA, and I don't therefore have really much of a basis to comment.

Mr. EVERETT. Mr. Clyburn.

Mr. CLYBURN. Thank you, Mr. Chairman. Mr. Chairman, I do not wish to take my question too far afield from what we're here for, but I—there's something that's puzzling me a little bit, and I want to ask the panel.

If this problem is not unique to VA, and we know it's not, is there any kind of coordination taking place in the entire Federal Government through GAO or somebody to ensure that, as we bring all of government into compliance, that there is some coordination here? Is VA out doing its track and IRS doing its track, and Social Security doing its track, and everybody is doing their own thing. It seems to me that's been the failure of government.

Is there some central place in GAO or somewhere to make sure that this whole thing is being coordinated governmentwide?

Mr. WILLEMSSEN. OMB has set up a separate subcommittee to address the Year 2000 issue. It has representatives from each of the major departments and agencies. I or a representative from GAO also attend those meetings. They are held monthly. The next one is this Friday.

That has proved to be a good forum to share concerns, and deal with strategies to address the problem. So there is definitely sharing of information, sharing of strategies to fix the problem, because there is indeed no one magical solution, as was pointed out earlier.

The difficulty is every agency has a wide range of heterogeneous systems, applications, database management systems, telecommunications, and operating systems. There are all different kinds and types, and they all require different solutions. So it's a big problem that has to be addressed.

From a governmentwide perspective, OMB has had this subcommittee. I might also point out, we have several reviews, either recently completed or ongoing, at agencies where we think the risk to the American public is most severe.

We have ongoing reviews at the Federal Aviation Administration, and Department of Defense. We've just completed this review on VBA. I testified last monthly on Medicare processing and how they were handling the Year 2000 issue. So we're trying to also target what we think are the most significant agencies in terms of the impact on the public.

Mr. EVERETT. Would the gentleman yield?

Mr. CLYBURN. Sure, I'd be glad to yield.

Mr. EVERETT. His question is a very good question. One of the concerns that we have is, in fact, will DOD be able to talk to VA, and you know, there are so many different systems out there. Who is heading up this thing governmentwide?

Mr. WILLEMSSEN. That is a major concern of ours, too. We are pushing VBA to complete as quickly as possible its understanding and inventory of all the interfaces and data exchanges it has with other entities, and also just within the department itself.

This is a major issue. In my opinion, based on what I've seen thus far, this could turn out to be the Achilles heel within the Federal Government—the data exchange issue. To address data from external sources, agencies may have to put in some sort of bridges or filters so that data coming in from other systems that they're not sure is Year 2000 compliant doesn't come in internally to their systems and corrupt the data.

This is a thorny issue, one that has, I would say, in the last couple of months started to attract much more attention, because agencies now are realizing, well, we can fix all of ours, but what about the other guy. They have to be concerned about that.

Mr. EVERETT. I thank the gentleman for yielding.

Mr. CLYBURN. Thank you, Mr. Chairman. Thank you for your answer.

I find it very interesting that you said, well, we've been looking at VBA but I really can't tell you what's happening at VHA; and if you have that problem in that field, what is happening in the broad spectrum of things.

It seems to me in my short experience here that one of our big problems is trying to coordinate the various aspects of government, and this seems to me to be a great time, a tremendous opportunity, to put in place a system that will allow these agencies to talk to each other, at least for 100 years; and if we can get them to talk to each other for 100 years, we might be able to solve the problem ad infinitum.

Thank you so much, Mr. Chairman. I'll yield back my time.

Mr. EVERETT. Thank you, Jim. Mr. Mascara.

Mr. MASCARA. I'd like to continue on with Mr. Clyburn's question about coordination. The 2000 issue is not unique to government. Does the private sector have a place at the table with the government to jointly try to solve this problem?

Mr. WILLEMSSEN. Yes. The private sector, in particular what we've seen in the banking and financial services industries, many of those companies are out addressing this issue. In many respects, the government is going to have to rely on private contractors to come in and do many of the fixes.

There are a wealth of tools now that are coming out from the private sector that can enable and help Federal agencies tackle this problem in a more expeditious manner. So they are there assisting and being able to support the Federal agencies.

Mr. MASCARA. Do we have sufficient resources and funding to deal with this? I heard these large numbers, billions and billions of dollars.

Mr. WILLEMSSEN. One of the items that we feel that VBA has to identify is to clearly lay out all the costs, benefits, and risks of its Year 2000 initiatives in detail, so that it can then, from a priority setting perspective, balance those against some of its other information technology projects which are also funded.

It may turn out that not everything can be funded, and we have to look at priorities and see what we can do in times of limited budget resources.

Mr. MASCARA. In my former life I was an accountant, and we talked about this as we went into the 1990s, about the problem that we would expect in the Year 2000. It's difficult for me to believe that someone hasn't done something sooner to find a solution to the problem and that there seems to be some kind of a national emergency facing us when we hit the year 2000. Mr. Chairman, someone in this Government should call a summit of some sort and get the best minds possible in the world to sit down at the table to attempt to find a solution to the problem.

I just can't believe we're sitting here saying that, as Mr. Clyburn pointed out, that you're doing something, Social Security is doing something, the IRS is doing something. I think it's too massive for any one Agency to do anything. I think everybody needs a place at the table to solve this problem.

Thank you, Mr. Chairman.

Mr. EVERETT. Thank you very much. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman. I also have some of the same feelings that my colleagues have. So let me just follow up on some of their questions.

In the GAO's view, does VA know enough at this point to determine whether it has committed adequate personnel and resources towards fixing this problem? I understand there have been a lot of retirements that you talked about earlier.

Mr. WILLEMSSEN. They are much further along than they were even a few months ago, but they have not fully completed what we would term the assessment phase of their Year 2000 program. They do not know all the applications, especially out in the field.

Related to that, it's not clear at this point whether they have a full handle on all the staff resources, both internal and external, that they may or may not need. That's why we've been pushing them to set priorities as part of that process.

Mr. EVANS. I understand they have some stated timetables of their own at this point. Are those timetables not fully adequate to solve this problem?

Mr. WILLEMSSEN. My overriding concern is that enough time is left within 1999 to engage in various testing activities. It's one thing to go in and make the fixes, but then we've got to go in and see that those fixes are actually going to work, especially when you begin integrating those systems with many other systems, both internal and external.

Until you've tested them in a full operational and integrated environment, you won't know for sure what the results will be.

Mr. EVANS. All right. Thank you. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you very much.

I want to thank the GAO for the work that they've done for the past 2 years on this. I must say, I attribute this remark to no one but the Chair. Unfortunately, I have seen this progress delayed and delayed and delayed by turf battles, by a culture that, frankly, would not reach out, Mr. Mascara, to some of the best minds that we have in this country, an attitude that we can do it ourselves, when every outside expert that has looked at says, no, you cannot do it yourselves.

We started this with the ranking member 2 years ago, and we have had a very difficult time moving forward, and I'll admit, there has been forward movement, and we're very thankful for it.

Again, I thank you for your testimony.

Mr. WILLEMSSEN. Thank you, Mr. Chairman.

Mr. EVERETT. I will now introduce the third panel, Mr. Mark Catlett, the VA's Assistant Secretary for Management and Chief Information Officer and the Chief Financial Officer, and ask him to introduce his staff, please.

STATEMENT OF D. MARK CATLETT, ASSISTANT SECRETARY FOR MANAGEMENT, CHIEF INFORMATION OFFICER, 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. Shall I proceed, Mr. Chairman?

Mr. EVERETT. Mark, if you would introduce your staff.

Mr. CATLETT. Well, it's not my staff, but this is Dave Albinson, the Veterans Health Administration's Chief Information Officer; and on my right, Newell Quinton, the Veterans Benefits Administration's Chief Information Officer.

Mr. EVERETT. Mark, let me say in the beginning, I was very encouraged at the recent meeting that we had with Mr. Gober and the willingness that all of you had to take a very serious and hard look at this problem, realizing the consequences that would develop if we could not solve it. So we look forward to your testimony here today.

Mr. CATLETT. Thank you, Mr. Chairman.

Mr. Chairman, members of the subcommittee, it's my pleasure to testify today on behalf of the Department of Veterans Affairs, concerning our readiness for Year 2000. We are here today to bring the subcommittee up to date on our plans and progress in resolving Year 2000 problems.

I have submitted my full statement to the subcommittee, which I ask to be made part of the hearing record.

Mr. EVERETT. Without objection, so ordered.

Mr. CATLETT. VA's information systems will provide uninterrupted services supporting the full range of veterans' benefits and medical care up to and beyond the year 2000. As VA's Chief Information Officer, I have established close working relationships with VA's administration level CIOs, these two gentlemen accompanying me today, to lead our effort in the coming year 2000 compliance.

We are working vigorously to make sure VA's systems will function correctly. VA's strategic approach is to make our existing mission critical systems compliant in their current environment. We have identified our mission critical systems and assigned levels of priority to the applications supporting those systems.

As VA's CIO, I'm 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, and staff offices are responsible for developing specific plans and managing the projects within their respective jurisdictions.

Both VBA and VHA have established a 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 organizations' Year 2000 effort.

On March 7, 1997, my office established a detailed internal report 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 individual VA application.

In addition to this formal reporting mechanism, the administration level CIOs and their Year 2000 program officials meet with me monthly to provide status reports addressing their successes and progress towards meeting their milestones.

The monthly reports and meetings provide my office early notice, should an organization fall behind schedule. This early notice gives us the ability to work with the organizations on a corrective action to get back on schedule.

In addition to the monthly feedback I receive, my office is conducting periodic independent assessments of VA's progress in preparing for the year 2000. Last year my office conducted a Year 2000 readiness review of the major VA organizations. This subcommittee received a copy of the review in February.

We are planning another similar independent review by a contractor during the first quarter of Fiscal year 1998.

In managing the overall task, we have prioritized our applications using the three-tiered structure. The first tier includes systems that will directly impact the delivery of medical care and benefits to veterans or are central to the department's mission.

The second tier includes internal agency systems used to improve timeliness and efficiency of administrative processes, operations support or producing periodic reports. These are systems whose failures would not be deemed as having a direct adverse effect on veterans.

Finally, the third tier includes systems scheduled for discontinuation prior to the year 2000. It may include systems scheduled for elimination because there is no further legislative requirement or program need to maintain them.

In addition to our internal activities, we are paying close attention to the services and products we obtain from outside sources. VA has been utilizing the interim Federal Acquisition Regulations' Year 2000 compliance language since it was issued in January of 1997.

Prior to that we used the language recommended by the Federal CIO Council Subcommittee on Year 2000. The subcommittee's language was incorporated into the interim FAR.

At this point I would like to update the subcommittee quickly on progress in each of our organizations. The information systems supporting the National Cemetery System are fully year 2000 compliant.

VBA has completed the assessment phase of its systems. VBA's plan is to complete the renovation phase by November of 1998, validation by December of 1998, and implementation by June of 1999. Every application has been addressed, and VBA has a fixed solution and a planned fixed day for all of its applications.

VBA recently awarded four task orders to bring contractor support on board. Three of these task orders are for renovation of applications, and one is for project oversight. They also amended an existing task order to increase the level of Year 2000 support for their project managers.

As of the end of May, 38 percent of VBA's applications are renovated and Year 2000 compliant. Another 5 percent of their applications are in testing.

VHA completed its comprehensive Year 2000 plan on April 30, 1997. VHA's goal is to complete its assessment, including the nationwide assessment of biomedical equipment at VA medical facilities, by January of 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 the end of May, 23 percent of VHA's VISTA, what we formerly called DHCP, their Veterans Health Information System and Technology Applications, are scheduled for discontinuation. In the OMB definition, these are included in the count as complaint. If we are to discontinue them, OMB considers that to be compliant.

VA, along with other agencies, and the private health care community are consumers of biomedical equipment. The potential Year 2000 impact on biomedical equipment is a national issue, as has been noted here already today, affecting both the private sector and Federal health care communities.

VA recommended to OMB in January that an interagency committee chaired by the Department of Health and Human Services be established to deal with this issue. The first meeting of the committee was held in May. The Food and Drug Administration, in their role as regulators of medical devices and biomedical equipment, will ensure that these devices are Year 2000 compliant.

We will coordinate a public awareness campaign with HHS as it particularly affects veterans with medical devices in their bodies or in use in their homes. Additionally, our patients will be advised as to the status of medical center equipment when the work of the HHS-led committee has identified potential problems.

The Austin Automation Center has made excellent progress in preparing for Year 2000 as well. The AAC, as we call it, provides VA-wide information and technology support to all components within the department. As of the end of May, 74 percent of all applications they support have been renovated and are Year 2000 compliant.

The AAC plans is to have all systems renovated by September of 1998, validated by October of 1998, and fully implemented by September of 1999.

Mr. Chairman, the Department of Veterans Affairs is following a solid plan that will allow us to continue serving veterans and their families without interruption into the next millennium.

This concludes my opening statement. Mr. Albinson, Mr. Quinton and I will certainly be happy to answer your questions or those of the members of the committee.

[The prepared statement of Mr. Catlett appears on p. 71.]

Mr. EVERETT. Thank you very much, Mr. Catlett. I appreciate your testimony. All statements, by the way, will be—entire statements, both from members and all our panels, will be entered into the record.

I again repeat that I was very encouraged at our last meeting in my office and the candor—candid conversation that we had, and along those lines, one of the subjects that we approached—in the corporate world, if a major project fails, the managers of that project are generally fired. My question to you then and is now: If a situation of VA Y2K project—if it fails, who loses their jobs?

Mr. CATLETT. Well, Mr. Chairman, the three of us most responsible for it are sitting before you today. I know the Deputy Secretary made that same commitment that he would be personally involved and committed to that success as well.

Mr. EVERETT. His comment was that he would be one of the first—on the train first, and the rest of you would be right behind him.

Mr. CATLETT. I recall something very much like that. Yes, sir.

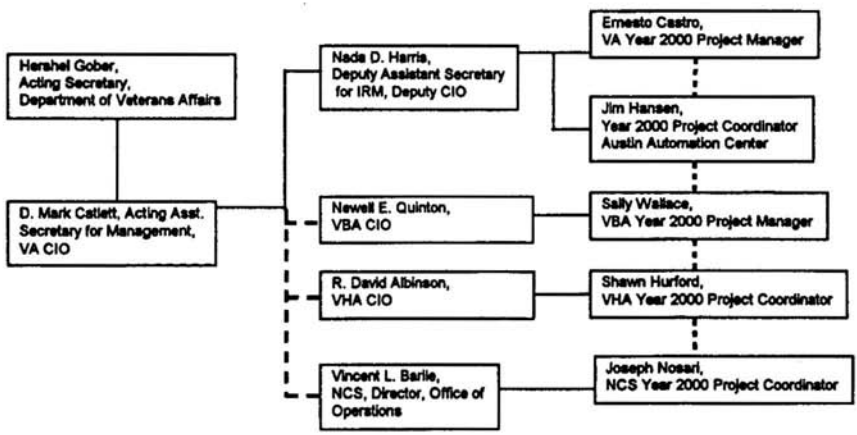
Mr. EVERETT. Well, I want to put that in the record to emphasize how critical this committee views this situation. I come out of the private world where you either produce or you—and if you don't produce, you fail. I, frankly, cannot—I cannot imagine the business world tolerating a situation we're in here today, and I wish for you to provide for me an actual list that I can enter into the record for those who are responsible for this project.

[The information follows:]

Year 2000 Organizational Responsibilities

The Assistant Secretary for Management, VA's Chief Information Officer (CIO) is responsible for overseeing and ensuring the completion of the "Year 2000" project for all VA systems. The Veterans Benefits Administration (VBA) and Veterans Health Administration (VHA) CIOs, and senior information technology managers within the National Cemetery System and staff offices are responsible for managing the project within their respective jurisdictions.

The following is a chart that provides the names of responsible individuals and their relationship within VA.



Mr. CATLETT. I'll be glad to do that, sir. I would note on your comment, this issue does exist for the private sector, and there are a lot of people facing the same pressures and same issues.

Mr. EVERETT. Let me ask you—We also discussed this. Does the VA have adequate resources and personnel to achieve 2000 compliance? Will VA achieve total Year 2000 compliance, with the emphasis there on the word total?

Mr. CATLETT. Sir, as we noted, we have an estimate now of $144 million. We intend to update that estimate. Our next quarterly report due to OMB is in August. The task orders and the oversight activities by contractors that I noted in my statement, particularly in VBA will assist us in updating our cost estimates. We intend to have an assessment from those contractors by August 1. It will be a portion of our updating of that estimate.

VHA will continue with their assessment that they are scheduled to complete in January. I would note that there are several issues here, and it's a question of definitions that has been discussed at the CIO Council and with OMB.

We are replacing systems that we have not identified in that estimate, because we began to replace those systems for reasons other than Year 2000. I think the same will be true in the biomedical area.

There's a replacement schedule for all of our equipment that we use in our hospitals. If we need to accelerate that because of Year 2000 problems, that portion we would identify as a Year 2000 cost.

If it's scheduled to be replaced anyway in 1999, I wouldn't recommend identifying it as a Year 2000 cost, but if it's scheduled to be replaced in 2001 and we have to replace it in 1999, then it would be a Year 2000 cost.

So we will be updating the assessment as we go, and our intention is not to low ball the estimate.

I would add one other thing, going back to VBA. We spoke briefly in your office, as you say, a little more than a month ago, maybe 2 months ago. I'm encouraged. The subcommittee mark in the House appropriations has included an extra $7 million beyond our request in the general operating expenses account.

It's for several issues, including the possibility of our need for more contractor support in our Veterans Benefits Administration applications. Our intention is to complete the re-coding, the renovation, as it's being called, of our existing systems by December of 1998.

We clearly agree with Mr. Willemssen. A year of testing is required. Not that testing won't begin before that, but we want to have re-coding done, essentially completed, so that we can have a full year of testing for all the interfaces.

We've asked, and the committee has responded. We will certainly work with the Senate committee to make sure we have the flexibility, because for systems work, as you note here with your clock 1998 is an important year for us. We can't wait for a 1998 supplemental next summer.

If we find out this August that we need funds, more funds than we've estimated in 1998, we're trying to ensure that it's included in the appropriation completed by the Hill this Summer.

Mr. EVERETT. Finally, to ask you: You mentioned biomedical. We know there are certain safety factors, and we know that we need to assure our veterans who have pacemakers, for instance, what the situation is. My mother-in-law has a pacemaker, and she has

that thing checked by the telephone, and I'm sure some of our veterans are in the same situation.

How does the FY2K situation affect those veterans?

Mr. CATLETT. Could I ask Mr. Albinson to provide that information for you. Thank you.

Mr. ALBINSON. Thank you. Mr. Chairman, the VA currently supports almost 19,000 veterans with implanted pacemakers, and as the single most critical device which also has a date element involved as part of its architecture——

Mr. EVERETT. I understand that affects the telephone situation.

Mr. ALBINSON. Yes, sir. We made a preliminary survey of the vendors who supply these biomedical devices to us, and I'm pleased to relay to you that, having checked 95 percent of those 19,000 devices, that we have found that they are all compliant at this point.

Now we're going to go and continue to check that last 5 percent, but at this point I can tell you that that problem seems well in hand.

Mr. EVERETT. And I'm sure we're getting that word out to our veterans, so that they won't worry about it.

Mr. Clyburn.

Mr. CLYBURN. Thank you, Mr. Chairman. Let me, if I may, get back to your question, Mr. Chairman, how sure we are about compliance?

You mentioned that by August 1997 you were going to make some assessment as to whether or not you need more resources?

Mr. CATLETT. That's this August, in 2 months, in less than 2 months now, 5 weeks.

Mr. CLYBURN. Do you think that in 2 months you will be able to give us a pretty adequate estimation of how much you will need to get this done?

Mr. CATLETT. Mr. Clyburn, we have an estimate now of what our resources needs are, particularly for our systems work. We do not have that for the biomedical, but for our systems work we have an estimate now.

We intend to utilize the contractors in the Veterans Benefits Administration area for their systems work. We intend to get their estimate as well, with the goal being to update the cost estimate to complete renovation of our current code by December of 1998, giving us the full year to test.

So if our estimate is short, we intend to be aware of that with an August 1 report from our contractors. So we want to know their opinion, in effect, of our estimate. Recognizing that doesn't always fit with the schedule in terms of appropriation action, with the speed at which appropriation action is being completed, we are making known to the Appropriation Subcommittees, both House and Senate, that we'd like to have some flexibility in our 1998 appropriation that affects VBA so that we can provide support for our recording if the estimate is higher than what we've projected at this point.

Mr. CLYBURN. I think you used a figure of $7 million that's been put in, an additional 7 million.

Mr. CATLETT. I just saw this this morning. That's what I understand was the very recent action. I've been on travel a few days, but sometime early this week the House Appropriations Sub-

committee has included an additional $7 million beyond the President's request for the general operating expenses appropriation, which funds VBA.

They are indicating in the report, as I understand—again, that these extra funds are for several purposes: Benefits processing improvement, as well as a need for the Year 2000 contractor support.

Again, if in August we think we need more support than we've now projected for 1998, we're very encouraged that at this point the House subcommittee has reacted, and we clearly intend to address this issue with the Senate subcommittee as well.

For systems work—1998 is the crunch year. Biomedical, as I see it, the crunch year is 1999.

Mr. CLYBURN. Well, I just wanted to be sure I understood this. This is 7 million beyond what you originally thought it would cost.

Mr. CATLETT. No, sir. The committee has added $7 million. We do not yet know if we need another million dollars beyond what we've estimated. We're going to have——

Mr. CLYBURN. You just asked them to add.

Mr. CATLETT. I didn't ask for a specific amount. I just asked for flexibility. They've reached that decision, and they're looking at a lot of things; and as I said, it goes beyond just Year 2000. They're going to note, but I'm very encouraged they're giving us flexibility.

So as I said, we have an estimate of our contractor support to complete renovation by December of 1998. We have contractors in place now that will give us their assessment as well, and we're asking for that by August 1. We'll be glad to—Obviously, we'll share that with you.

So all this is an encouraging factor, is what I'm saying to you. I wouldn't look at any one number right now, other than we do have a positive signal from the appropriations subcommittee that they recognize and agree this is an issue we need to be ready to address quickly.

Mr. CLYBURN. Right, I agree, but I think you'll find that all of the committees and subcommittees up here are real sensitive about this, as you can imagine. I think that our colleague said it very well. We'll have 435 district offices that—that is, provided all of us are around here at that time—that will have real problems with this. So we are sensitive to it.

I just wanted to be sure that the flexibility you're talking about, that—it would seem to me that you would have that flexibility within your request, and if this is 7 million beyond, that sweetens the flexibility quite a bit.

Mr. CATLETT. Yes, sir. We have, as was noted, I think, by Chairman Horn, in general the approach has been that we will have to reprogram or shift our funding, instead of trying to wait for the 1999 budget, particularly in systems work.

The work has to be well underway now and early in 1998 in order for this to be completed.

Mr. CLYBURN. Explain something to me a little bit, if you could. I have in my notes here that $148 million cost estimate over the next 3 years. Explain to me what happens if you need additional money beyond the Year 2000. I mean, how would all this work?

Mr. CATLETT. Well, I'm not exactly sure of your question. We will reprogram if we need additional funds, and we will update that estimate in August for you.

Mr. CLYBURN. And that will include the entire——

Mr. CATLETT. It will be the VA—Yes, sir, over this period. As I noted, the biomedical estimate I don't anticipate being there by then, because the work being done and led by HHS and FDA will not be completed. I don't think we'll have sufficient responses to give you a satisfactory answer on the biomedical equipment estimate that we need by August.

Mr. CLYBURN. Oh, so that's going to be another figure?

Mr. CATLETT. Yes, sir, because I don't think we're going to have that in 5 weeks or 6 weeks.

Mr. CLYBURN. Okay. All right, thank you.

Mr. EVERETT. Thank you, Jim. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman. Mr. Catlett, I forwarded you a series of prehearing questions, and you've raised some additional questions. I do appreciate your responses.

Mr. CATLETT. Thank you.

Mr. EVANS. I'd like to ask you a few of those, if I could. Your written responses indicate that not all of the interfaces for VBA and VHA related programs have been inventoried for Year 2000 compliance. The Department states that 148 out of 429 VBA interface files have been assessed, and that 57 out of 148 are compliant. Eighty-four files are not compliant, and seven files have been retired.

In other words, the VA believes approximately one-third of its inventoried files are compliant. The Department also indicates that the VBA interface management plan is on target for completing its interface inventory by June 30, 1997, just 4 days from now.

Since the rest of the inventory process is near completion, can you give us at least a thumbnail sketch of VBA inventory expectations? Can we expect a similar ratio of compliant versus noncompliant files?

Mr. CATLETT. I would ask Mr. Quinton to provide that information.

Mr. QUINTON. Yes, sir. Mr. Evans, the number indicated there, the 429 interfaces, is our latest estimate of the interfaces. The other number you referred to, 148—we showed that as the number that we had looked at to verify whether or not they were compliant, at this point in our review.

What we're trying to do is continue that process, looking at each interface and determining if there's a date issue with the interface. In some cases there may not be a date issue; in some cases, there may be. We have to look at each and every one of the group of 429 to verify whether we have a date problem or not, and that's being done system by system.

So the total number of interfaces we determined at this point is the 429 interfaces. We will continue to look at each and every one of those by system.

Mr. EVANS. Mr. Catlett, the VA has indicated that VHA is presently creating a profile of interfaces between its systems and other systems throughout the VA, other Federal agencies and other commercial systems. You also indicate that VHA has sent a Year 2000

compliance letter to corporate systems' owners and managers and has asked for detailed information on interfaces.

When did this process of creating an interface profile within the VHA begin? How far along are you in the process, and when will such a profile be completed?

Mr. CATLETT. I'll ask Mr. Albinson to provide that. I'm sorry, could you repeat the last two questions?

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

An initial effort to update VHA's inventory of corporate or national systems/databases began in March 1996. One item of information requested at that time was a listing of data sources that fed each of these systems. As VHA's awareness of the Year 2000 problem increased, we decided to verify the existing information and solicit additional information on out-going interface data. The first VHA Corporate Systems Year 2000 compliance status request letters were sent to System Managers of Record (SMRs) of forty of VHA's Corporate Systems on June 2, 1997. Letters to the System Managers of Record of the remaining 129 VHA Corporate Systems were sent on July 21, 1997. These letters requested detailed information on interfaces between VHA Corporate Systems/databases and other systems, and plans for assuring that the exchange of data is Year 2000 compliant. Initial responses are requested by the end of August, 1997. Any necessary follow-up responses will be received by October 1997. The assessment phase for all Corporate Systems is scheduled to be completed by January, 1998.

We are also investigating the interfaces and dependencies of our VISTA programs with their environment. VHA will be taking steps to ensure they continue to operate correctly by monitoring their integration with other information systems within VA, other Federal agencies and commercial products or equipment. A complete inventory of external interfaces to each of the 141 VISTA applications is being conducted and a final assessment is scheduled to be completed by January 1998.

VHA is writing to vendors of medical devices and asking them to assess their products for Year 2000 compliance. Vendors are being requested to provide a description of all interfaces; the type of data exchanged between these devices and interfaces; and plans for assuring Year 2000 compliance. VHA has mailed letters to 120 vendors of medical devices beginning on June 20, 1997. The first group of those vendors was asked to provide a written plan to VHA by July 18, 1997. While responses to date have been limited, those who have responded indicated that their equipment would either not be affected by the Year 2000, or that compliance efforts are currently underway. VHA expects to continue to send out letters as more vendors are identified.

VHA has established an expert panel, Medical Device Integrated Product Team, to evaluate and validate these vendor responses affecting medical devices and the interfaces connected to these devices. The assessment phase for all Medical Devices is scheduled to be completed by January 1998.

Mr. EVANS. When will the process of creating an interface profile within the VHA begin? How far along are we in the process, and when will such a profile be completed?

Mr. ALBINSON. I can provide the actual dates that the letters went out and the expected responses for the record. I can tell you that it is part of our assessment process which will be completed by the end of this calendar year.

Mr. EVANS. Mr. Chairman, I have a number of other questions, rather technical in nature. I'd like to submit them for the record and ask that the questions and the responses be made part of the record.

(See p. 87.)

Mr. EVERETT. Absolutely. Matter of fact, I might add that I think the second half of my question on if the VA will achieve total Year 2000 compliance—I don't think we got around to that, and I also have some costs, how much money has been spent so far. I'll ask that you submit those for the record also.

Mr. CATLETT. Certainly.
(The information follows:)

AGENCY-WIDE SUMMARY ON OBLIGATIONS FOR INFORMATION TECHNOLOGY FOR YEAR 2000 DEPARTMENT OF VETERANS AFFAIRS

[In millions of dollars]

As of June 30, 1997

		FY 1996	FY 1997	FY 1998	FY 1999
1	Equipment				
	a. Capital purchases	0	15	15	15
	b. Other equipment purchases/leases	0	0	0	0
	Subtotal	0	15	15	15
2	Software				
	a. Capital purchases	0	10	10	10
	b. Other equipment purchases/leases	0	0	0	0
	Subtotal	0	10	10	10
3	Services	0	2	1	1
4	Support services	1	3	3	2
5	Supplies	0	0	0	0
6	Personnel (compensation/benefits)	3	19	20	13
7	Other (DOD only)	0	0	0	0
8	Intra-governmental payments	0	0	0	0
9	Intra-governmental collections	0	0	0	0
10	**Total Obligations**[1]	4	49	49	42
11	Workyears (FTE)	31.7	355.5	355.5	324.5

Note: Pending our completion of Year 2000 compliance assessments of vendor provided commercial-off-the-shelf products, including hardware and software, additional costs may be incurred to upgrade or replace these products in FY 1998 and FY 1999. This will affect the determination of total mainframe costs associated with compliance.

[1] *Numbers may not add due to rounding.*

Mr. EVERETT. Do you have additional questions, Lane?

At this time I'd like to recognize Dr. Snyder, also a very knowledgeable member of our subcommittee, who has joined us, for any questions he may have.

Dr. SNYDER. Thank you, Mr. Chairman. I'm sorry I'm late. One of the advantages of being late is you can ask any off-the-wall question you want, and everybody will say this poor fellow, he just didn't attend the hearing.

Would you help me, please, with this problem, which I know is not just a VA problem. It's a problem throughout the world with computer services. Have you all had any discussions amongst yourself looking back to the folks you contracted with five and ten and 15 and 20 years ago for your data processing, why we were set up for these kinds of problems?

I mean, it seems like the time to have corrected this was at the beginning of computerizing records, not 2 or 3 years before the turn of the century. Has there been any—You know, what's the results

of some of your Monday morning, 20/20 hindsight? Have you been angry with any of your vendors, saying why didn't you all—you set us up for a problem here by not seeing this coming?

Mr. CATLETT. Well, very generally now, I think Chairman Horn spoke earlier about it, that it was a matter of efficiency when these systems were set up to use two digits instead of four. I'm sure there was other streamlining that happened.

It's been noted here that this is now an issue for the next 2 or 3 years; clearly, we have with the interest of the committee and others, intensified our efforts; but this issue has been addressed and identified in the VA for a decade.

VBA began some work and made some changes long ago. Our office automation center did the same as well. So it's been underway for sometime. So again, it's—Like you say, it seems so trivial to many people. Yet it's going to cost a lot of money, and it's a worldwide problem to address.

Dr. SNYDER. I understand that. It just seems like this is a problem that, when we purchase computer services, that we know the VA is an institution that's going to be around in the year 3000, that some of our vendors should have said, you know, what we use at a hardware store which may not be around in 3 or 5 or 10 years may not be acceptable for the Veterans Administration 20 years from now.

Thank you, Mr. Chairman.

Mr. CATLETT. I would make one other point. Despite the fact that we more and more go to the market to buy software, we're not a large enough share of the market to dictate that supplies change that.

Now in order for the software to work, it has to be done; but I don't think we could have 5 years ago, even if we were more prescient than anyone else, to say, hey, you have to do this for us. We're not a big enough portion of the market to demand that type of change, I don't think.

Dr. SNYDER. I apologize for being late. Thank you, Mr. Chairman.

Mr. EVERETT. Thank you, Dr. Snyder.

Mark, we appreciate your appearance here today and that of your panel members. I would reemphasize how this chairman would view the failure to achieve this. It's very critical. I would add to that that it would not only, in my estimation, be the VA's failure and something ought to be done about those who fail, but it would be also this committee's failure, if we don't exercise proper oversight, if you will, to nudge VA where we feel like they ought to be nudged in solving this problem.

I can't emphasize, as I know you realize, how great this problem is to our Nation as well as our VA.

So I thank you for appearing here today, and if you will, tell Hersh I'll look forward to seeing him in another capacity before too long.

Mr. CATLETT. Thank you, Mr. Chairman. Appreciate it.

Mr. EVERETT. Thank you.

Mr. EVERETT. At this time I would recognize our last panel, Dr. Tom Shope. He is the Acting Director of the Division of Electronics and Computer Science, the Office of Science and Technology, Cen-

ter for Devices and Radiological Health of the Food and Drug Administration, and that's a lot of electronics. Doctor, welcome here.

STATEMENT OF THOMAS SHOPE, Ph.D., ACTING DIRECTOR OF THE DIVISION OF ELECTRONICS AND COMPUTER SCIENCE, OFFICE OF SCIENCE AND TECHNOLOGY, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

Mr. SHOPE. Good morning, Mr. Chairman, and members of the subcommittee.

Mr. EVERETT. Doctor, we're going to ask you to adhere to our 5-minute rule. Your complete testimony will be entered into the record.

Mr. SHOPE. Thank you, sir. I believe you have our testimony already. I'll just briefly summarize that.

My name is Thomas Shope. I'm the Acting Director, as you said, of the Division of Electronics and Computer Science, Office of Science and Technology, Center for Devices and Radiological Health in the Food and Drug Administration.

I'm pleased to be here to provide information about the Year 2000 date issue and its impact on medical devices. Let me assure you that the FDA does not currently believe there will be any major impact on medical device safety from the Year 2000 problem.

FDA is responsible for protecting the public health by helping to 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 algorithms or calculations or in record keeping, and if a two-digit year format was used in their design.

Let me explain the types of software that are used in medical devices. First, there is embedded software which is software typically contained in a microelectronic circuit or a micro-chip which controls device operation. Examples of such devices are pacemakers, infusion pumps, ventilators, and many others.

It is very unlikely that these products would be directly impacted by the Year 2000 problem. These devices do not require knowledge of the current date to operate safely and effectively.

For example, pacemakers do not depend on a current date system in order to function properly to support the patient. These use counters or clocks, but not explicit dates. Programmers or external controllers for these devices have the potential to be affected, but the manufacturers with whom we have discussed these issues see no problems which will not be addressed.

Second, there is non-embedded software. Non-embedded software is intended to be operated on a separate computer system, often a personal computer or a workstation. Such software devices may be used to enhance the operation of another device or devices.

These products may also use a two-digit year format. Some examples of non-embedded software devices include radiation treatment planning systems, transmission or storage of medical images,

offline analysis of EKG data—or ECG data, rather, digital analysis and graphical representation of electrocardiograph data, and systems used to adjust the rate response of pacemakers, the programming portion of using a pacemaker.

While there is a chance that the two-digit year format may affect the performance of these software devices, we believe that the Year 2000 risk will be mitigated through aggressively working with the manufacturers, as the Center is presently doing.

The Center is preparing to send a letter to all medical device manufacturers to ensure that manufacturers address the Year 2000 issue and review both the embedded and non-embedded software products.

In addition, we will ask manufacturers to review any computer controlled design, production or quality control processes for their potential impact with regard to the 2-year digit format.

The Center anticipates sending this letter very soon, and we would be glad to provide a copy to the subcommittee for the record.

The letter will remind manufacturers that, pursuant to manufacturing regulations, they must investigate and correct devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations.

For devices that are already on the market, FDA will request that manufactures conduct hazard and safety analyses to determine whether device performance is affected.

We expect manufacturers to identify products which have a date-related problem that could affect safety or effectiveness of a device and to take the necessary action to remedy the problem.

Again, let me stress that we do not anticipate any 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 issue before it arises.

For future medical device pre-market submissions to the agency, FDA will review design processes and features to assure that the products have been designed to perform date recording and computations properly.

Thank you, Mr. Chairman, for the opportunity to tell you about the issue of the Year 2000 and medical devices. Let me assure you that we at FDA take this issue very seriously, as we do all problems that could affect the 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.

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 effort results in the best medical device products.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Shope appears on p. 78.]

Mr. EVERETT. Thank you, Dr. Shope. I appreciate your testimony. As you know, there is a good amount of uncertainty out there right now.

Mr. SHOPE. Yes, sir.

Mr. EVERETT. In your testimony, you state on page 3—are you confident that there is no safety problem? This is something on which you wouldn't want to be wrong.

Mr. SHOPE. No, sir, we would not want to be wrong. I think the—You can't make a blanket statement that there are going to be no problems with computer controlled medical devices, but I think there will be problems of the type that are easily overseen, anticipated, and dealt with by the physicians using the devices.

Probably the most typical kind of problem will be a date/time stamp on a record of some sort that will not be properly implemented, if that's not corrected; but we hope that, by bringing this attention and working with the manufacturers, those kinds of software upgrades can take place before the impact would occur.

Mr. EVERETT. In other words, your testimony is that we know of no devices that would cause any serious problems to the patients at this point?

Mr. SHOPE. I think that's a fairly accurate statement. We do know of certain devices that, if they are not fixed by the year 2000, could present problems, and we know that the manufacturers are working on those.

An example is a radiation treatment planning system that uses a radioactive isotope as the source of the radiation for the treatment. If a computer algorithm used in that kind of a device used a two-digit date, the strength of the radioactive source might be inappropriately entered in the prescription for the radiation.

We know that there are those kinds of problems and that the manufacturers are working on them to fix the problem. That's a software upgrade, and we expect that will occur long before the year 2000 comes around. So that's an example of a non-embedded kind of problem with a—basically, with a computer program that just needs the software to be updated.

Mr. EVERETT. Would you furnish this committee with a list of all devices, biomedical devices and otherwise, that you feel like could present a problem if they are not fixed?

I would further ask you to follow up and, as each of these devices—as you are sure that each of these devices' problems have been solved for these devices, that you would let this committee know.

Mr. SHOPE. Certainly, the FDA would be pleased to work with the committee and provide whatever information we can. I'm not sure that we're going to have a report from every device manufacturer as they correct the problems.

The current regulations and the legislation do not require those kinds of reports to be presented to FDA under our current regulations. We would learn if there was a problem which presents a significant risk to health and safety, and we would be working then with the manufacturer as they correct those; but if a manufacturer has no problem, we won't necessarily know that he has no problem.

Mr. EVERETT. And you've contacted all these manufacturers that you know of?

Mr. SHOPE. Our letter will be going out to all 13,000 medical device manufacturers registered with FDA in the near future, yes.

Mr. EVERETT. In June 1997 my question to you would be why the letters have not gone out earlier?

Mr. SHOPE. We began to look at this problem last year, as I mentioned. We became aware of the need to let the device manufacturers know that they need to look at this.

I think—and the way medical devices are developed and the software that's developed is a very structured engineering process that goes on, which is a hazard analysis to look at all the potential modes of failure and make sure that you've addressed issues to deal with those, and I think, a large majority of devices, that has been the case. The year 2000 date is not going to be a problem.

That doesn't answer the question of why we didn't do it last year. We've been doing, I guess, lots of other things, and this didn't come to the attention of us at an earlier time.

Mr. EVERETT. I would hope it is to your attention now, and I would urge FDA to move on this as quickly as possible, and also to inform this committee when those letters have all gone out.

In addition to that, I would like for you to keep this committee updated on what the responses are and what your evaluation of those responses might be.

At this time, I'd like to turn to my colleague, Dr. Snyder, for any questions he may have.

Dr. SNYDER. Thank you, Mr. Chairman. On page 5 you gave a list of the non-embedded software devices. Could we run through a few of those, and you give me some scenarios of potential problems that—why you put them on your potential list. Give me a specific example of a doctor and a patient and what could be happening in a hospital or clinic, at a VA facility that might cause—or any medical facility that might cause problems.

Mr. SHOPE. The issue of pacemaker telemetry data, for instance—The problem that we could foresee there is likely with a personal computer type control of the evaluation of the data from the pacemaker that's received by telemetry. There it would be a date/time stamp kind of thing, you know. The date at which this is being done could be incorrect if the PC program is not recording dates appropriately.

As you know, many personal computer type programs will have problems with the dates, if you don't take the right adjustment to deal with that.

Dr. SNYDER. Okay. So let's give us an example. So we're getting to—It's New Year's Eve, and I've tied one on, and January 1st 00 comes along, and I go into super-ventricular rhythm or something. So tell me how then that's going to impact—How do you see that would be a problem?

Mr. SHOPE. That's not going to be a problem. The problem would be perhaps 3 weeks later when you come for your routine monitoring with the physician, and he records the data. His computer records might not have the right date associated with it.

Dr. SNYDER. If the computer hadn't been upgraded. So——

Mr. SHOPE. It's not a direct impact on patient care. It's more a record keeping issue.

Dr. SNYDER. So they try to read it, and you're saying that when he pulls off the information, because it's an 00 that it may not pull

off that particular time. It might consider it the year 1900 or something and too old to be pulled up?

Mr. SHOPE. It's not—We don't know the details of how that might work, but my assumption would be perhaps in the record it just records two digits, and you would see that this happened in 00, and you would have to realize that wasn't 1900. We didn't have computerized devices at that time. So it is 2000, but the details of those kinds of interactions——

Dr. SNYDER. But that's not a big problem that you just described there.

Mr. SHOPE. Yes.

Dr. SNYDER. It would be a big problem if it didn't pick it up, for some reason. Is that—How about offline analysis of EEG data?

Mr. SHOPE. Well, I think offline analysis—It's again the type of—

Dr. SNYDER. Did you mean to say EEG?

Mr. SHOPE. No, that should have been ECG in the testimony. I think I said ECG in my oral remarks. There it would be the issue of a computer algorithm that is used to evaluate—to review the trace and provide some information to the physician.

Very often these algorithms need to know the patient's age to do that. So you might enter the birth date, and the computer would subtract the birth date from today's date and come up with an age in years or days or whatever that's used in the algorithm. So there could be an error in that calculation which would result in perhaps a misinformation to the computer algorithm that is doing the evaluation.

That's overseen by the physician, typically. We don't rely on just these programs. So we think that's not an immediate threat to patient safety. It could lead to confusion in the patient's records. Those things do need to get fixed. It's a small computer programming type correction that will need to be made.

It's not clear, I must say, that any of these auxiliary type programs have the problem. The manufacturer is the one who knows how he designed the algorithm. We at FDA don't have that detailed data. That's why we are saying to the manufacturers, you need to review your products, work with your customers to make any corrections that may be necessary.

Dr. SNYDER. So let me see if I got that example right. So in that situation, we're doing an EKG in February '00, and it's going to be a computer read thing that a lot of, say, rural hospitals would use and will enter in there an age and a birth date.

Now if the program interprets it based on the age, 95 years old or something, we'll be okay or 3 months old, but if it reads it off the date '00 and calculates it incorrectly, then your norms for a pediatric patient aged 6 months is going to be different from an adult patient in some things. That's the kind of thing you're talking about?

Mr. SHOPE. Right, and so the determination that the computer might give in the way of advice about the trace could be in error, because it assumed the wrong age for the patient.

Dr. SNYDER. So as more and more hospitals, I think, are moving—or clinics moving to do some telephone interpretation of things, you're going to have to know what's at the other end to be sure you're getting—or both ends are going to have to know.

Mr. SHOPE. But, ultimately, I think, even if it's a telephone interchange of information, the physician ultimately is going to look at the trace. You don't rely on the computer program solely. You can use that for confirmation, for supporting information, but I see it's not a direct impact unless somehow the doctor is not in the loop at all, and I'm not aware that——

Dr. SNYDER. Well, a lot of us use it like red flags. If you get a red flag back that says, oh, this is an abnormal 6-monther, and it's really because it was interpreted as being a 95-year-old, that's something.

In terms of—You gave the example up above on the radiation. I'm one of those in my naivete that think the real problem begins at the turn of the clock January 1. In some of these kind of things, I could foresee potentially that the problem could actually present itself before we get to the year 2000 if you're looking ahead. Okay?

It's, you know, 1999, February, and we're going to be calculating your dose and over the next year to get the '00, that somehow it could ensnare problems prior to the year 2000. Am I off base on that? As a computer programmer would look ahead over the next, okay, 18 month course of therapy, and then we enter an '00 for treatment number 17——

Mr. SHOPE. Yeah. I'm really not expert in the therapy delivery, but I'm not aware that there are very many regimes that spread it out over that length of time. It's typically a few weeks or a few months.

The issue is going to be——

Dr. SNYDER. I see what you're saying.

Mr. SHOPE. The issue is going to be in any of those situations how the algorithm has done the two-digit date, and if it's simply it works okay with 1999, but doesn't work okay with double zero, that's not going to be a problem until they plan a treatment after the year 2000. It's the planning and not the delivery that's the issue here.

Dr. SNYDER. Mr. Chairman, may I ask one final question?

Mr. EVERETT. Certainly.

Dr. SNYDER. Just a quick question unrelated to your role here, but in terms of the manufacturers and your relationships with them, do we not also have at play in this whether—I'm a family practice doctor—whether we like it or not, the whole medical malpractice, the liability considerations?

I mean, these manufacturers, if you don't do anything, I mean they have a responsibility. If they get no notice from you, I mean, they need to be looking ahead at these kind of problems and have an absolute responsibility to get this clarified and cleaned up, so that family doctors like me can rely on this stuff. Is that a fair statement?

Mr. SHOPE. Yes. I think manufacturers, in order to have satisfied customers who expect the products they've bought to meet the specifications and the function—Nobody that I'm aware of contracted to buy devices that wouldn't work after January 1. So I think there's a very large incentive for manufacturers to satisfy their customers' needs here.

Dr. SNYDER. I mean, hopefully, when you send out your 13,000 letters, you're going to get 13,000 responses that say we've been looking at this for 5 years, and it's all taken care of.

Thank you, Mr. Chairman.

Mr. EVERETT. Thank you. Dr. Shope, I must tell you, I'm extremely disappointed in the FDA, the fact that they have not sent these letters out yet. This chairman had hearings on this almost 2½ years ago, and in my opinion, it was at that time too late to start some of the actions that we need to start such as the biomedical.

Very frankly, I can't imagine that FDA would sit over there that long and still not have had these letters out. As I said, this chairman had hearings in Pensions and Compensation Subcommittee almost 2½ years ago on this problem, and the problem was known prior to that.

I would hope, as I said, that these letters go out immediately. I would also point out that I have had very candid conversations with our friends over at VBA. This is a problem of the most serious nature, not only to the veterans but to the Nation as a whole.

I don't enjoy putting pressure on people, but as I said earlier, I view this as a joint failure, if this is not achieved. Now I do know that the folks over at VBA depend on information coming in from you, and the process of giving that information to them hasn't even started yet, the result of those letters.

So I would again hope that VHA is given the information that they need as quickly as possible. I do thank you for your testimony here. We will have additional questions that we will put to you for the record.

Mr. SHOPE. Yes, sir. I'm sure we would be glad to provide those answers.

Mr. EVERETT. Thank you very much.

In closing, let me say that, based on today's testimony, I must say that I am extremely concerned about the prospect of major Year 2000 computer system failures, but I'm also happy to hear that the Veterans Benefits Administration has heeded the GAO's recommendations and has taken quick action to address the areas that they have identified.

The subcommittee will continue to closely follow VA's efforts to ensure that their computer systems will be able to provide uninterrupted benefits and safe and quality health care to our Nation's veterans.

The subcommittee will hold follow-up hearings to review the VA's progress, as I said. Finally, I expect the VA to immediately inform the subcommittee of any missed milestones in their compliance program.

This hearing is closed. Thank you all for attending.

[Whereupon, at 11:10 a.m., the subcommittee was adjourned.]

APPENDIX

STATEMENT OF HON. JAMES E. CLYBURN
RANKING DEMOCRATIC MEMBER
HOUSE VETERANS AFFAIRS
SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS
HEARING ON VA YEAR 2000 COMPLIANCE
JUNE 26, 1997

I AM PLEASED TO HAVE JOINED WITH CHAIRMAN EVERETT IN CALLING FOR THIS EXTREMELY CRITICAL HEARING ON THE VA'S EFFORTS TO ACHIEVE YEAR 2000 COMPLIANCE.

THE GAO TELLS US THE VA HAS A LONG WAY TO GO TO SOLVE THIS PROBLEM, BUT NOT MUCH TIME TO GET THERE. I AM ENCOURAGED THAT THIS SUBCOMMITTEE HAS DECIDED TO PLACE A WATCHFUL EYE ON THE VA'S PROGRESS IN THIS REGARD. I AM HOPEFUL THAT THROUGH CONTINUED OVERSIGHT BY THIS SUBCOMMITTEE, WE CAN HELP TO ENSURE THAT THE VA IS ABLE TO REACH YEAR 2000 COMPLIANCE.

THE PURPOSE OF THIS HEARING IS TO HEAR A STATUS REPORT FROM THE VA ON THEIR PROGRESS ON THIS CRITICAL ISSUE,TO UNDERSCORE OUR SUBCOMMITTEE'S INTEREST AND CONCERN, AND TO MAKE CLEAR THIS COMMITTEE'S EXPECTATION THAT DESERVING

VETERANS WILL RECEIVE UNINTERRUPTED BENEFITS AND SERVICES IN THE YEAR 2000 AND BEYOND.

I BELIEVE IT IS IMPORTANT TO RECOGNIZE THAT THIS IS NOT A PROBLEM THAT IS UNIQUE TO THE VA. AS THE RECENT COVER STORY IN NEWSWEEK MAGAZINE POINTS OUT, THIS IS AN ISSUE THAT EFFECTS EVERYTHING FROM THE PERSONAL COMPUTERS MANY OF US HAVE IN OUR HOMES, TO PRIVATE BUSINESS AND INDUSTRY AND TO NEARLY EVERY LOCAL, STATE AND FEDERAL GOVERNMENT ACROSS THE GLOBE.

MR. CHAIRMAN, I WOULD ASK UNANIMOUS CONSENT THAT THE JUNE 2, 1997 NEWSWEEK COVER STORY TITLED "THE DAY THE WORLD SHUTS DOWN" BE INCLUDED IN TODAY'S HEARING RECORD.

IT IS ALSO IMPORTANT TO RECOGNIZE THAT THE VA HAS BEEN WORKING HARD OVER THE PAST SEVERAL MONTHS TO GET THEIR ACT TOGETHER ON THIS ISSUE. I WANT TO COMMEND THESE RECENT EFFORTS AND WANT TO MAKE IT CLEAR THAT I DO NOT DOUBT THE SINCERITY OF THE VA'S INTEREST IN ADDRESSING AND ULTIMATELY SOLVING THIS VEXING PROBLEM.

I MUST SAY, HOWEVER, THAT THE OBJECTIVE VIEWS OF KNOWLEDGEABLE OUTSIDERS STRONGLY SUGGEST THAT THE VA'S TASK IS MORE DAUNTING AND DIFFICULT THAN ITS' WRITTEN TESTIMONY TO THIS SUBCOMMITTEE MIGHT SEEM TO SUGGEST.

I WOULD ALSO LIKE TO NOTE FOR THE RECORD THIS MORNING THAT THE GARTNER GROUP, A LEADING INDEPENDENT INDUSTRY GROUP, HAS CONDUCTED EXTENSIVE RESEARCH INTO THE YEAR 2000 PROBLEM, AND HAS MONITORED THE STEPS PRIVATE INDUSTRY AND GOVERNMENT HAVE TAKEN TO ADDRESS THE PROBLEM. UNFORTUNATELY, SCHEDULING DIFFICULTIES PREVENTED THE GARTNER GROUP FROM PROVIDING LIVE TESTIMONY BEFORE OUR SUBCOMMITTEE TODAY. THE GARTNER GROUP HAS GRACIOUSLY VOLUNTEERED, HOWEVER, TO PROVIDE WRITTEN RESPONSES TO ANY QUESTIONS ANY OF THE MEMBERS OF THIS SUBCOMMITTEE MAY HAVE.

MR. CHAIRMAN, I ASK UNANIMOUS CONSENT THAT SUBCOMMITTEE MEMBERS BE ALLOWED FIVE (5) BUSINESS DAYS TO PROVIDE THE

COMMITTEE WITH WRITTEN QUESTIONS TO THE GARTNER GROUP AND THAT THE RESPONSES BE INCLUDED IN THE FORMAL HEARING RECORD.

MR. CHAIRMAN, AS I STATED AT THE OUTSET OF MY REMARKS, THE GAO TELLS US THE VA HAS A LONG WAY TO GO TO ACHIEVE YEAR 2000 COMPLIANCE, AND THE CLOCK TELLS US THEY DON'T HAVE MUCH TIME TO GET THERE. THROUGH CONTINUED CLOSE SCRUTINY AND OVERSIGHT BY THIS SUBCOMMITTEE, I AM HOPEFUL THAT WE WILL REMAIN COMMITTED TO DOING WHAT WE CAN TO HELP ENSURE THE VA MAKES IT.

THANK YOU TERRY FOR YOUR LEADERSHIP ON THIS ISSUE AND I LOOK FORWARD TO THE TESTIMONY.


June 2, 1997
LT. FLINN: SEX, LIES AND THE MILITARY
Newsweek
MAY 27
THE DAY THE WORLD CRASHES
Can We Fix the 2000 Computer Bug Before It's Too Late?
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DO NOT TAKE FROM THIS ROOM
LA FOLLETTE/LM 202

WILL power plants shut down and your phone go out?

WILL your Social Security checks disappear into cyberspace?

WILL your bank account vanish? By Steven Levy and Katie Hafner

THE DAY THE WORLD SHUTS DOWN

DRINK DEEP FROM YOUR CHAMPAGNE GLASSES AS THE BALL DROPS IN TIMES SQUARE to usher in the year 2000. Whether you imbibe or not, the hangover may begin immediately. The power may go out. Or the credit card you pull out to pay for dinner may no longer be valid. If you try an ATM to get cash, that may not work, either. Or the elevator that took you up to the party ballroom may be stuck on the ground floor. Or the parking garage you drove into earlier in the evening may charge you more than your yearly salary. Or your car might not start. Or the traffic lights might be on the blink. Or, when you get home, the phones may not work. The mail may show up, but your magazine subscriptions will have stopped,

PHOTO ILLUSTRATION BY JOHN EDER

HOSPITALS: Everything from neonatal monitors, X-ray machines and CT scanners to patient-record databases, prescription-dispensing equipment and blood-bank dating systems needs to be evaluated. In most cases, hospitals have to rely on manufacturers to do the testing.

your government check may not arrive, your insurance policies may have expired.

Or you may be out of a job. When you show up for work after the holiday, the factory or office building might be locked up, with a handwritten sign taped to the wall: OUT OF BUSINESS DUE TO COMPUTER ERROR.

Could it really happen? Could the most anticipated New Year's Eve party in our lifetimes really usher in a digital nightmare when our wired-up-the-wazoo civilization grinds to a halt? Incredibly, according to computer experts, corporate information officers, congressional leaders and basically anyone who's given the matter a fair hearing, the answer is yes, yes, 2,000 times yes! Yes—unless we successfully complete the most ambitious and costly technology project in history, one where the payoff comes not in amassing riches or extending Web access, but securing raw survival.

What's the problem? It's called, variously, the Year 2000 Problem, Y2K or the Millennium Bug. It represents the ultimate indignity: the world laid low by two lousy digits. The trouble is rooted in a seemingly trivial space-saving programming trick—dropping the first two numbers of the date, abbreviating, say, the year 1951 to "51." This digital relic from the days when every byte of computer storage was precious was supposed to have been long gone by now, but the practice became standard. While any idiot familiar with the situation could figure out that the world's computers were on a collision course with the millennium, no one wanted to be the one to bring it up to management. And, really, which executive would welcome a message from nerddom that a few million bucks would be required to fix some obscure problem that wouldn't show up for several years?

So only now, as the centurial countdown begins, are we learning that the digit-dropping trick has changed from clever to catastrophic. Because virtually all the mainframe computers that keep the world humming are riddled with software that refuses to recognize that when 1999 runs out, the year 2000 follows. When that date arrives, the computers are going to get very confused. (PCs aren't as affected; sidebar.) So that seemingly innocuous trick now affects everything from ATMs to weapons systems. Virtually every government, state and municipality, as well as every large, midsize and small business in the world, is going to have to deal with this—in fact, if they haven't started already it's just about too late. Fixing the problem requires painstaking work. The bill for all this? Gartner Group estimates it could go as high as $600 billion. That amount could easily fund a year's worth of all U.S. educational costs, preschool through grad school. It's Bill Gates times 30!

ELEVATORS: Might shut down, thinking they're overdue for maintenance

That tab doesn't include the litigation that will inevitably follow the system failures. "You can make some very reasonable extrapolations about litigation that take you over $1 trillion, and those are very conservative estimates," says Dean Morehous, a San Francisco lawyer. (Conservative or not, this is more than three times the yearly cost of *all* civil litigation in the United States.)

Come on, you say. Two measly digits? Can't we just unleash some sort of robo-program on all that computer code and clear it up? Well, no. Forget about a silver bullet. It seems that in most mainframe programs, the date appears more often than "M*A*S*H" reruns on television—about once every 50 lines of code. Typically, it's hard to find those particular lines, because the original programs, often written in the ancient COBOL computer language, are quirky and undocumented. After all that analysis, you have to figure out how to rewrite the lines to correctly process the date. Only then comes the most time-consuming step: testing the rewritten program.

It's a torturous process, but an absolutely necessary one. Because if we don't *fwat* the millennium Bug, we'll have troubles everywhere.

Electricity. When the Hawaiian Electric utility in Honolulu ran tests on its system to see if it would be affected by the Y2K Bug, "basically, it just stopped working," says systems analyst Wendell Ito. If the problem had gone unaddressed, not only would some customers have potentially lost power, but others could have got their juice at a higher frequency, in which case, "the clocks would go faster, and some things could blow up," explains Ito. (Hawaiian Electric revamped the software and now claims to be ready for the year 2000.) Another concern i- nuclear power; the Nuclear Regulato Commission says that the Bug might affec

JEFF TYTONIS—GAMMA-LIAISON (TOP); RICK CASTELLUCCIO

The Birth of a Computer Catastrophe

BY LARRY GONICK

If programmers are so smart, how could they do something so stupid? A cartoonist's explanation of history's biggest software boo-boo.

"security control, radiation monitoring ... and accumulated burn-up programs [which involve calculations to estimate the hazard posed by radioactive fuel]."

Communications. "If no one dealt with the year 2000 Bug, the [phone] network would not operate properly," says Eric Sumner Jr., a Lucent chief technology officer. He's not talking about dial tones, but things like billing (watch out for 100-year charges). Certain commercial operations that run phone systems by computer could also go silent if the software isn't fixed.

Medicine. Besides the expected mess in billing systems, insurance claims and patient records, hospitals and doctors have to worry about embedded chips—microprocessors inside all sorts of devices that sometimes have date-sensitive controls. The year 2000 won't make pacemakers stop dead, but it could affect the data readouts it reports to physicians.

Weapons. NEWSWEEK has obtained an internal Pentagon study listing the Y2K impact on weapons and battlefield technologies. In their current state, "a year 2000 problem exists" in several key military technologies and they will require upgrading or adjustments. One intelligence system reverts to the year 1900, another reboots to 1969. The report confidently states that as far as nuclear devices like Trident missiles are concerned, "there are no major obstacles which will prevent them from being totally Year 2000 compliant by Jan. 1999."

Money. Banks and other financial institutions generally will go bonkers if they don't fix the year 2000 problem. The Senate Banking Committee is even worried that vertiginous computers might automatically erase the last 99 years' worth of bank records. Some Y2K consultants are advising consumers to make sure they don't enter the 1999 holiday without obtaining hard-copy evidence of their assets. According to Jack Webb of HONOR Technologies, Inc., ATMs won't work without fixes.

Food. In Britain computers at the Marks & Spencer company have already mistakenly ordered the destruction of tons of corned beef, believing they were more than 100 years old.

Air-Traffic Control. "We're still in the assessment stage, determining how big the problem is," says Dennis DeGaetano of the Federal Aviation Administration. One possible danger is computer lockup: while planes will keep moving at 12:01 a.m. on Jan. 1, 2000, the screens monitoring them, if not upgraded, might lock. Or the computers might know where the planes were, but mix them up with flights recorded at the same time on a previous day. ("You can bet we're going to fix it," says DeGaetano.)

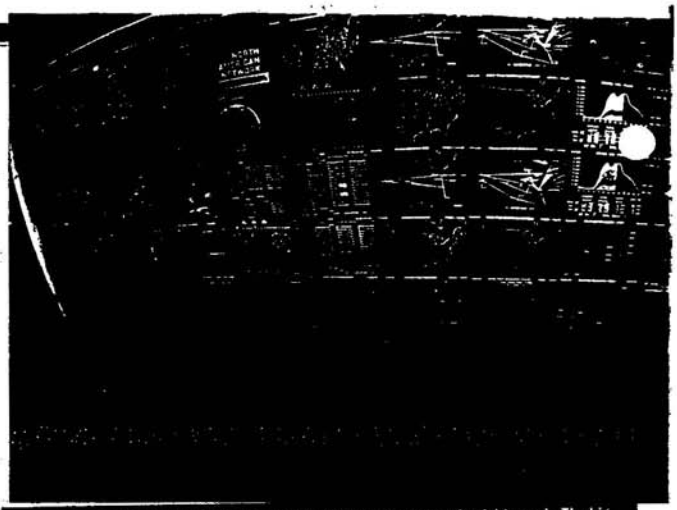
Factories. Ford Motor Co. reports that if the Bug isn't fixed, its buildings could literally shut down—the factories have security systems linked to the year.

"Obviously, if you don't fix it, your busine[ss] will stop in the year 2000," says For[d] David Principato. Even if a manufacturing company aggressively solves its own problem, though, it might be flummoxed by a supplier who delivers widgets in the wrong century.

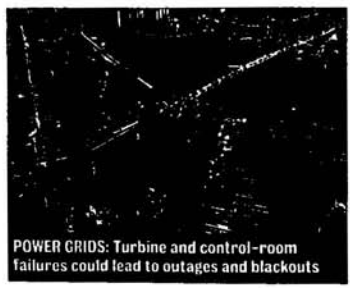
Just About Everything Else. Larry Martin, CEO of Data Dimensions, warns that if not adjusted, "on Jan. 1, 2000, a lot of elevators could be dropping to the bottom of buildings," heading to the basement for inspections they believe are overdue. Similarly, automobiles have as many as 100 chips; if they are calendar-challenged, experts say, forget about driving. Computerized sprinkler systems could initiate icy midwinter drenchings.

Like leaves rustling before a tornado, there have already been harbingers of a bureaucratic meltdown. At a state prison, a computer glitch misread the release date of prisoners and freed them prematurely. In Kansas, a 104-year-old woman was given a notice to enter kindergarten. Visa has had to recall some credit cards with expiration dates three years hence—the machines reading them thought they had expired in the McKinley administration.

The $600 billion question is whether we'll fix the Bug in time. The good news is that the computer industry is finally sponding to the challenge. For mont[h]



TELEPHONE SYSTEMS: Some consultants think the network might crash. The big carriers insist there's no way that will happen, but admit it's possible you'll get a bill that says you made a long-distance call to Grandma that lasted 100 years. People who work in offices might have bigger problems: dead phones.



POWER GRIDS: Turbine and control-room failures could lead to outages and blackouts

BENALI GIFFORD—GAMMA LIAISON (TOP); HIROTUKI MATSUMOTO—TONY STONE IMAGES

now, squadrons of digital Jeremiahs have been addressing tech conferences with tales of impending apocalypse. The most sought-after is Peter de Jager, a bearded Canadian who scares the pants off audiences on a near-daily basis. "If we shout from the rooftops, they accuse us of hype," he complains. "But if we whisper in an alley, no one will listen." Last week in Boston de Jager demonstrated the rooftop approach: "If you're not changing code by November of this year," he warned, "you will not get this thing done on time—it's that simple. *We still don't get it.*"

But we're starting to. Most major corporations now have year 2000 task forces, with full-time workers funded by multimillion-dollar budgets, to fix a problem that their bosses finally understand. They're aided by an army of consultants and specialized companies. Some, like Data Dimensions, offer full Y2K service, providing tools, programmers and guidance. Others, like Peritus, sell special software to help find offending code and, sometimes, even convert it. (The final, most arduous stage, testing, still defies automation.) These firms are the new darlings of Wall Street. But buyer beware—consultants are coming out of the woodwork to exploit the desperation of late-coming companies. Someone might promise a phalanx of brilliant programmers to fix the Bug, but "for all you know, it could be 10 people in a garage doing it by hand," says Ted Swoyer, a Peritus exec. Still, the creation of a Y2K-fixing infrastructure is encouraging.

It's not uncommon to find gung-ho efforts like the one at Merrill Lynch: an 80-person Y2K division working in shifts, 24 hours a day, seven days a week. It'll cost the company $200 million, a sum that could hire Michael Eisner and fire Mike Ovitz. "Our return on investment is zero," says senior VP Howard Sorgen. "This will just enable us to stay in business."

So maybe we're not in for a full-scale disaster. Let us assume—*oh God let it be true*—that those in charge of life-sustaining applications and services will keep their promises to fix what needs fixing. The costs and liabilities of not doing so are too huge not to. (On the other hand, when did you last see a huge software project that met its deadline and worked perfectly? Just asking.) Still, there will almost certainly be severe dislocations because of the mind-boggling enormity of the problem.

Even the most diligent companies don't have total confidence they can fix everything. Consider BankBoston, the 15th

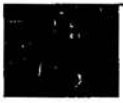
The Sky Is Falling, the Sky Is Falling!

One of the most perplexing aspects of the millennium bug is the fact that no one really knows what will happen. Best guess: no apocalypse, but lots of trouble.

AIRLINES

Worst scenario: At midnight, the nation's air-traffic-control systems go dead. Some planes lose the ability to navigate properly. Chaos in the skies.

Likely to happen: Travelers get very familiar with the airport lounge. Airlines' fleets stay aloft, but delays abound. The bottom line: stay home and watch bowl games.



Worst scenario: Security systems leave workers locked outside the front gate. Assembly lines stop moving. Those 1999 models remain on showroom floors.

MANUFACTURING

Likely to happen: The big companies get their act together, but suppliers have problems that slow shipments; 1999 models stay on showroom floors.

BANKING

Worst scenario: The entire financial infrastructure, including the stock market, goes haywire. Balances, records and transactions are lost.

Likely to happen: Some patrons may be temporarily shut out of their accounts. Electronic wire transfers may be disrupted. It may be best to keep a few dollars under the mattress.

Worst scenario: As the ball drops in Times Square, hospital machinery, like IV units and cardiac monitors, suddenly shuts down. The last thing patients see is Dick Clark.

MEDICAL

Likely to happen: Hospital paperwork, billing and patient records get fouled up. Suppliers lose records; tongue depressors become scarce.

NUCLEAR POWER

Worst scenario: Aooougal Aooougal Control chip opens the wrong release valve. Radiation problems make Three Mile Island look like a picnic.

Likely to happen: Safety systems suffer small problems. Minor malfunctions cause short-term shutdowns. Stock up on candles and flashlight batteries.

MILITARY

Worst scenario: Defense systems weakened by software snafus. Global positioning satellites get lost, leaving the nation vulnerable.

Likely to happen: Some old battlefield equipment is junked rather than fixed. High-tech systems get even more temperamental. Faltering programs order $200 hammers.

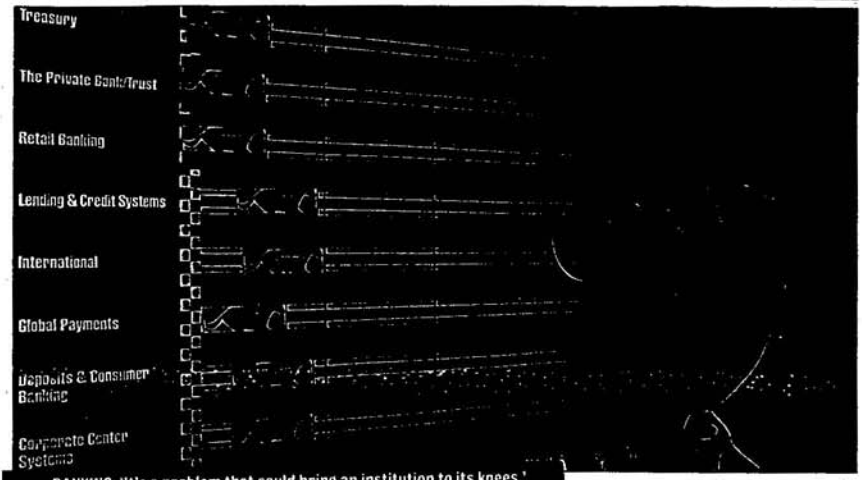
Worst scenario: Feds lose track of government-benefits recipients. The IRS figures your tax bill is equal to the national debt. Deadly viruses kept under computer lock are released.

GOVERNMENT

Likely to happen: Though it got a late start on the bug, most major systems are intact. Some benefits checks are late. Techno-veep Gore takes a hit.

DANTE CHINNI

TOP TO BOTTOM: PETER GRIDLEY—FPG; TRACY BAKER—SIPA; CHUCK SAVAGE—STOCK MARKET; BEN EDWARDS—TONY STONE IMAGES; FPG; NO CREDIT; ROBERT TRIPPETT—SIPA



BANKING: 'It's a problem that could bring an institution to its knees,' says David Iacino, who heads a year 2000 task force at BankBoston. The company has to test and fix 60 million lines of code in 200 applications. 'Every day we see something new that we hadn't thought about.'

largest commercial bank in the United States. Early in 1995, the company realized that "it was a problem that could bring an institution to its knees," says David Iacino, who heads the bank's Team 2000. To stop a meltdown, BankBoston has to probe 60 million lines of code. The harder BankBoston works at solving the problem—it now has 40 people working full time on it—the more complicated it seems. "Every day, when we see something new we haven't thought about, we get additional angst," says Iacino.

Of the 200 BankBoston applications that need revamping, only a handful have been completed so far. BankBoston is now separating the essential work from the noncritical, and if the Bug causes less dire problems, like the heavy vault doors swinging open on New Year's Eve, it'll just cope: "Vaults are physical things," says Iacino. "If push comes to shove, we can put a guard in front."

Now, if BankBoston, which started early and has been driving hard, is already thinking triage, what is going to happen to institutions that are still negotiating in the face of a nonnegotiable deadline? The Gartner Group is estimating that half of all businesses are going to fall short. "There's still a large number of folks out there who haven't started," says Matt Hotle, Gartner's research director.

As businesses finally come to terms with the inevitable, it's going to be panic time. In about a year, expect most of the commercial world to be totally obsessed with the Bug. "Pretty soon we have to just flat stop doing other work," says Leo Verheul of California's Department of Motor Vehicles.

But no amount of money or resources will postpone the year 2000. It will arrive on time, even if all too many computers fail to recognize its presence.

"It's staggering to start doing mind games on what percentage of companies will go out of business," says Gartner's Hotle. "What is the impact to the economy of 1 percent going out of business?" Or maybe more: Y2K expert Capers Jones predicts that more than *5 percent* of all businesses will go bust. This would throw hundreds of thousands of people into the unemployment lines—applying for checks that may or may not come, depending on whether the government has successfully solved *its* Y2K problem.

AUTOMATIC TELLER: Whoops, it thinks it's 1900 and you're broke

What is the U.S. government doing? Not enough. "It's ironic that this administration that prides itself on being so high tech is not really facing up to the potential disaster that is down the road a little bit," says Sen. Fred Thompson. If Y2K indeed becomes a calamity, it may well be the vice president who suffers—imagine Al Gore's spending the entire election campaign explaining why he didn't foresee the crisis. (Gore declined to speak to NEWSWEEK on the Y2K problem.)

Here's the recipe for a federal breakdown: not enough time and not enough money. While the Office of Management and Budget claims the problem can be fixed for $2.3 billion, most experts think it will take $30 billion. Rep. Stephen Horn held hearings last year to see if the federal agencies were taking steps "to prevent a possible computer disaster," and was flabbergasted at the lack of preparedness. His committee assigned each department a letter grade. A few, notably Social Security, were given A's. (The SSA has been working on the problem for eight years and now has it 65 percent licked; at that rate it will almost make the deadline.) Those with no plan in place—NASA, the Veterans Administration—got D's. Special dishonor was given to places

SETH RESNICK (TOP); NINA BERMAN—SIPA

where inaction could be critical, yet complacency still ruled, like the departments of Labor, Energy and Transportation.

State governments are also up against the 2000 wall. California, for instance, finished its inventory last December and found that more than half of its 2,600 computer systems required fixes. Of those, 450 systems are considered "mission critical," says the state's chief information officer John Thomas Flynn. These include computers that control toll bridges, traffic lights, lottery payments, prisoner releases, welfare checks, tax collection and the handling of toxic chemicals.

As bad as it seems in the United States, the rest of the world is lagging far behind in fixing the problem. Britain has recently awakened to the crisis—a survey late last year showed that 90 percent of board directors knew of it—but the head of Britain's Taskforce 2000, Robin Guenier, worries that only a fraction really understand what's required. "I'm not saying we're doomed, but if we are not doing better in six months, I really will be worried," he says. He expects the cost to top $50 billion. On the Continent, things are much worse; most of the information-processing energy is devoted to the Euro-currency, and observers fear that when countries like Germany and France finally tackle 2000, it might be too late.

Russia seems complacent. Recently Mikhail Gorbachev met with Representative Horn in Washington, expressing concern about how far behind Russia is in dealing with the Bug. Gorbachev raised its possible impact on the country's nuclear safeguards.

The list can go on, and on and on. "It's like an iceberg," says Leon Kappelman, an academic and Y2K consultant. "I would certainly be uncomfortable if Wall Street were to close for a few days, but I can live with that. But what if the water system starts sending water out before it's safe? Or a chemical plant goes nuts? Anybody who tells you 'Oh, it's OK' without knowing that it's been tested is in denial."

It's tough out there on the front lines of Y2K. And in less than a thousand days, it might be tough everywhere. "There are two kinds of people," says Nigel Martin-Jones of Data Dimensions. "Those who aren't working on it and aren't worried, and those who are working on it and are terrified."

Tick, tick, tick, tick, tick.

With GREGORY L. VISTICA *and* RICH THOMAS *in Washington,* DEBORAH BRANSCUM *and* BRONWYN FRYER *in California,* JULIE EDELSON HALPERT *in Detroit,* JENNIFER TANAKA *in New York and* WILLIAM UNDERHILL *in London*

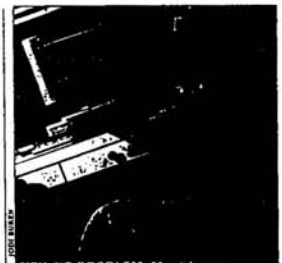
Will My Home PC Die?

Probably not. But taking a few precautions before New Year's Eve 1999 could prevent a lot of headaches.

SO WHAT IF MULTI-billion-dollar multinationals are facing a digital hairball of unprecedented proportions? You want to know what will happen to your PC at home. Chances are, nothing much. The most likely year 2000 hiccup involves a piece of PC arcana called the Basic Input/Output System, or BIOS. The BIOS is simply the software that starts the computer before an operating system, such as Windows 95, kicks in. It's the BIOS that contains a machine's internal clock information.

If your PC is less than 2 years old, it probably contains a newer BIOS that will sail through midnight at century's end without incident. But if you are using an older machine, and Windows 95 or one of its predecessors, you could see a glitch. The first time you turn your computer on in the new year, you're likely to see the clock set to 1980.

Even if your PC's clock enters a time warp, fixing the problem is relatively easy. Just reset the date with normal Windows or DOS commands, and you'll be fine for the next 100 years (with Windows 95, double-click on the date in the lower-right-hand corner of the screen or go to the Control Panel). It's like resetting your household clocks for daylight saving time. Microsoft's current version of Windows NT fixes the BIOS problem automatically. So will the next version of Windows 95, due out next year.



JOSH RIEBEN

HEY, NO PROBLEM: Most home systems will handle the transition

Microsoft advises against performing any tests yourself, such as setting the computer to 11:59 p.m., Dec. 31, 1999, and waiting to see what happens. If your machine contains applications with time limits on them, the software might be fooled into thinking it had expired, or be damaged. If you're unsure whether your BIOS will trip on the date change, your best bet is to contact the computer manufacturer; 386 and 486 machines may possibly need a BIOS upgrade. Apple Computer assures users that all its Macintosh computers recognize dates up to 2040.

As for your applications, when in doubt, call the software company and ask how year 2000 friendly its products are. Microsoft, for one, points out that all of its products store dates in four-digit form. The makers of Intuit's popular personal-finance program, Quicken, say it will not go berserk and automatically pay 100 years' worth of bills for you come 2000. If you're one of the handful of people using 8-year-old DOS versions (3.0 or below), your program won't roll over to the year 2000—but it's time you upgraded anyway. Microsoft says the same for its Quicken-like Money program (both claims were borne out by informal NEWSWEEK tests).

Whether you should unplug your computer in case your electric power goes haywire is less easy to predict. In general, it pays to take a few low-tech precautionary measures against year 2000 snafus. Keep backup records (both on floppies *and* on paper) of bank balances, credit-card statements and utility bills. That's what year 2000 expert Capers Jones is doing. He also plans to enter the next millennium with a full tank of gas in his car (automated gas pumps might spit back his credit card, he worries) and plenty of traveler's checks in his pocket. Just in case.

KATIE HAFNER *with* DEBORAH BRANSCUM

STATEMENT BY CONGRESSMAN FRANK MASCARA

HEARING ON VA 2000 COMPUTER PROBLEM

JUNE 26, 1997

THANK YOU MR. CHAIRMAN. I WANT TO CONGRATULATE YOU FOR CALLING THIS HEARING THIS MORNING TO EXAMINE THIS SERIOUS VA COMPUTER PROBLEM.

LAST EVENING I READ OVER THE MATERIAL PROVIDED BY THE COMMITTEE, AND I MUST SAY I AM MOST ALARMED THAT IF THIS PROBLEM IS NOT CORRECTED, AND CORRECTED QUICKLY, IT COULD RESULT IN LATE BENEFIT CHECKS AND DENIED BENEFITS TO MILLIONS OF VETERANS ACROSS AMERICA, A SITUATION WHICH THIS SUBCOMMITTEE SIMPLY CANNOT TOLERATE!

I UNDERSTAND THAT SINCE MY COLLEAGUES ON THE HOUSE COMMITTEE ON GOVERNMENT REFORM

AND OVERSIGHT GAVE THE VA A "D" FOR ITS EFFORTS TO CORRECT THIS PROBLEM AND THIS HEARING WAS SCHEDULED, THE VA HAS BEGUN TO MOVE.

THOSE IN THE KNOW, HOWEVER, SAY THAT THE PLAN BEING DEVELOPED BY THE VA IS VERY GENERAL AND RAISES MORE QUESTIONS THEN IT ANSWERS.

I AM HOPING THAT TODAY'S TESTIMONY WILL HELP ALLEVIATE THE COMMITTEES CONCERNS AND NOT GIVE US CAUSE FOR FURTHER HEART BURN.

THE BOTTOM LINE IS THAT TOO MUCH IS AT STAKE HERE TO EVEN THINK OF THE VA NOT GETTING THIS PROBLEM CORRECTED. VETERANS ARE RELYING ON US TO KEEP THE PRESSURE ON THE VA AND YOU ALL CAN REST ASSURED WE WILL DO

EXACTLY THAT UNTIL THIS PROBLEM NO LONGER EXISTS.

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

--THE END--

REMARKS OF THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
HOUSE VETERANS AFFAIRS
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS
HEARING ON YEAR 2000 COMPLIANCE
JUNE 26, 1997

I WOULD LIKE TO COMMEND CHAIRMAN EVERETT AND JIM CLYBURN FOR HAVING THE FORESIGHT TO PUT TOGETHER THIS CRITICAL HEARING THIS MORNING. I HAVE TO ADMIT MY EYES SOMETIMES GLAZE OVER WHEN I TRY TO UNDERSTAND ISSUES RELATED TO COMPUTERS BUT I UNDERSTAND ENOUGH TO KNOW THAT COMPUTERS ARE AN ESSENTIAL PART OF BUSINESS AND GOVERNMENT LIFE IN THE 1990S.

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.

AS THE GAO HAS POINTED OUT IN ITS TESTIMONY, UNLESS MAJOR SYSTEM-WIDE CHANGES ARE MADE AT THE VA, VETERANS COULD RECEIVE INACCURATE COMPENSATION AND BENEFIT CHECKS – IF THEY ARE LUCKY ENOUGH TO RECEIVE THEM AT ALL. VETERANS COULD RECEIVE DEBT-COLLECTION LETTERS EVEN WHEN THEY DON'T

OWE THE VA A THING. FORECLOSURE PROCEEDINGS COULD BE INITIATED BECAUSE OF MISTAKEN DATE CALCULATIONS.

IN ADDITION, NOBODY SEEMS TO HAVE ANY IDEA WHAT IMPACT THERE MIGHT BE WITHIN THE VETERANS HEALTH ADMINISTRATION (VHA). WHO KNOWS WHAT COULD HAPPEN IF COMPUTER CHIP-IMBEDDED PACEMAKERS OR HEART DEFIBRILLATORS SPIT OUT INCORRECT DATA OR RESPOND INAPPROPRIATELY? HOW WILL THIS AFFECT FOLLOW-UP TREATMENT BY VA PHYSICIANS?

OBVIOUSLY THE MANY UNANSWERED QUESTIONS RELATED TO THIS YEAR 2000 COMPUTER COMPLIANCE PROBLEM ARE OF CRITICAL CONCERN TO THIS COMMITTEE AND TO OUR VETERANS. THE URGENCY OF THIS HEARING CANNOT BE OVERSTATED, AND THE NEED FOR CONTINUED CONGRESSIONAL OVERSIGHT ON THIS ISSUE CANNOT BE UNDEREMPHASIZED.

AGAIN, I SALUTE TERRY AND JIM FOR CALLING THIS HEARING, AND I LOOK FORWARD TO TODAY'S TESTIMONY. THANK YOU.

Statement by Rep. Luis V. Gutierrez
Subcommittee on Oversight and Investigations
Committee on Veterans Affairs
June 26, 1997

Mr. Chairman, thank you and Ranking Member Clyburn for permitting me to join with your Subcommittee this morning and submit a formal statement.

I wanted to participate in this hearing because the ramifications of the "Year 2000" problem are very serious for veterans throughout America.

In a study conducted about a year ago by Representative Horn's Subcommittee on Government Management, Information and Technology the Department of Veterans Affairs received a **D** for their efforts to resolve the "Year 2000" question.

While I am sure that both the Veterans Benefits Administration (VBA) and the Veterans Health Administration (VHA) have made progress since this time to develop and implement a comprehensive plan to deal with this possible crisis, I remain concerned that the benefits and medical devices that thousands of veterans depend are in jeopardy.

Interruption of the delivery of disability compensation payments to veterans in need or the malfunction of computer-chip driven medical devices that thousands of veterans depend on is an absolutely unacceptable scenario that must be avoided at all costs.

Allow me to emphasize costs.

I strongly believe that all the appropriate resources that are required and available to address this matter must be allocated and employed as soon as possible.

If it is a question of money, than Congress and the VA must do what is right and what is needed and come up with the capital.

In our nation's wars, in Normandy or Khe Sanh, veterans did all they could to defend our national interests.

Now, we are obligated to follow that example and do all we can to defend their interests.

Thank you Mr. Chairman, I look forward to hearing from our distinguished witnesses today.

REPRESENTATIVE STEPHEN HORN (R-CA), Chairman,
Subcommittee on Government Management, Information, and Technology

Testimony before the Veterans Affairs Committee
June 26, 1997

I would like to begin by thanking the Chairman for holding this hearing today. Hearings and other oversight activities are crucial if we are going to keep up the pressure on agencies to fix their Year 2000 problems. December 31, 1999 is a deadline that cannot be extended. If it is not met, the Federal Government will fail to provide important and even essential services to the public. The full ramifications are unknown and threaten to be massive.

As more and more people are learning, most computer systems throughout the world run software that employs two digits to signify the year. "97" means 1997. For this simple reason, these systems are at risk of failing on Saturday, January 1, 2000. The two digits of the year 2000 -- "00" -- will not be interpreted to mean 2000. Most computers will interpret "00" to mean 1900. Some systems may even misunderstand the digits to mean no date at all.

The result of this "Year 2000 Problem" could be, in effect, a global computer virus, with computer systems unable to send or receive accurate information or, in some cases, to even function.

During the last Congress, an investigation of the Subcommittee on Government Management, Information, and Technology first brought to light the near-total lack of preparation by the Federal Government for the Year 2000 problem. Despite recent efforts by Federal departments and agencies, I cannot report that sufficient progress has been made toward preparing the Federal Government before the year 2000.

The Subcommittee on Government Management held an initial hearing on April 16, 1996 to discover what Federal agencies were doing to prevent a possible computer disaster. Alarmed by what the Subcommittee learned at that hearing, I joined my Ranking Member Carolyn Maloney in sending a joint congressional oversight letter on behalf of the Subcommittee. The overall response the Subcommittee received was discouraging. Only nine of the twenty-four agencies responded that they had a plan for addressing the problem. The Subcommittee released its conclusions on agency preparedness in the form of grades. Four agencies were given As, four agencies were given Fs. I regret to report that the Department of Veterans Affairs received a D.

In September 1996 the Committee on Government Reform and Oversight issued a committee report, "Year 2000 Computer Software Conversion: Summary of Oversight Findings and Recommendation." The report expressed concern that many Federal Government departments and agencies were not moving with necessary dispatch to address the year 2000 computer problem.

On January 14, 1997 the Subcommittee sent to each of the statutory department and agency chief information officers a letter requesting updated information on the status of year 2000 activities. Since then we have held two hearings on the issue and plan a third for the second week in July.

Most Americans take computers for granted and find it very hard to believe that this is a serious problem. Yet computers and the mechanisms they control have become an integral part of everyday life -- from the communications we use, to the checks we receive, to our medical care, and even the elevators we ride. This has serious implications for millions of Americans who depend on government computers for health care veterans benefits, unemployment checks, weather forecasts, airline schedules, and financial transactions as simple as cashing a check or as complex as managing a trillion-dollar currency exchange. The possibility for nationwide disruption is almost endless -- and without careful planning and deliberate action, it will be endless.

There is no easy solution to this problem, no silver bullet. Programmers will need to review, line by line, the computer software code in use to determine if date computations are afflicted with the Year 2000 problem. As a technical matter, fixing the software is not very difficult. The heart of the challenge rests in organizing such a sizeable undertaking, and then in the testing and verification of the changes to make sure they have been completed correctly. Yet, the certainty of this deadline, just over two years away, requires immediate and directed action without further delay.

What is most troublesome to me and other members of the Subcommittee on Government Management, Information, and Technology has been the terrible track record the Federal Government has with many of its information technology acquisitions. New Federal Government computer systems frequently take longer to install, cost more, and deliver less than was planned for at the outset.

Based on existing plans submitted to the Subcommittee on Government Management, 12 out of the 14 departments do not anticipate completing their Year 2000

work until the final three months of 1999. Should the Federal Government encounter even a fraction of the delay or difficulties that most acquisition projects have encountered. the Year 2000 computer problem could have calamitous consequences.

There is another troubling aspect to this problem, that of embedded chips. Witnesses have testified before our subcommittee that some devices containing embedded microchips may not be designed to recognize the new century. Critical systems that depend on automated devices include security systems for badge readers, surveillance and home security systems, parking lot gates, and vaults. Other products that rely on embedded computer microchips include telephone systems, video recorders, bar code readers, automatic teller machines, medical devices, factory machinery, civilian and military avionics, process control and monitoring equipment, sprinkler systems, and air-conditioning systems.

Automated devices such as these malfunction when they encounter situations their software is not designed to recognize. Sometimes the malfunction means failing to perform properly. Sometimes it means shutting down altogether. Many products contain multiple embedded systems made by multiple manufacturers. Testing these products for year 2000 compliance is difficult and can be expensive.

Clearly this presents consumers -- individual, commercial, and governmental -- with considerable inconvenience. Where there is failure, the economic and legal consequences could be substantial. We are concerned that technological failure may also present health and safety problems.

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
Expected at
9:30 a.m.
Thursday,
June 26, 1997

VETERANS BENEFITS COMPUTER SYSTEMS

Uninterrupted Delivery of Benefits Depends on Timely Correction of Year-2000 Problems

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

GAO/T-AIMD-97-114

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss actions being taken by the Department of Veterans Affairs' (VA) Veterans Benefits Administration (VBA) to address the computing challenges faced by virtually all major organizations--public and private--with the upcoming change of century. Correct and on-time delivery of benefits and services to some 10 million American veterans and their dependents will hinge on how quickly and how well the agency can meet these demands.

Because readiness for the year 2000 is a critical issue throughout the government, we have recently added the year-2000 problem to our list of federal program areas at high risk of vulnerability.[1] As with all other federal agencies, VBA could face widespread computer systems failures as the year 2000 nears due to the potential for incorrect information processing. This could occur because many existing computer systems have a 2-digit date field, such that the year 2000 would be represented by "00." However, "00" could also be read as 1900. Age and other calculations would be thrown off, creating havoc as systems attempted to verify eligibility for various VBA programs. Because eligibility for many of VBA's benefits and services is date-dependent, services could be seriously disrupted to millions of people.

VBA is aware of these risks, and knows it has work to do. In a report issued to you, Mr. Chairman, and being released publicly today, we detail our findings on VBA's

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[1]High-Risk Series: Information Management and Technology (GAO/HR-97-9, February 1997).

readiness for the change of century.[2] VBA has initiated action to assess its vulnerability and perform the modifications that must be made to its information systems, but severa 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. Unless the systems that run VBA's programs are modified correctly and with adequate time for thorough testing, they will not be prepared to function adequately after December 31, 1999. The Department of Veterans Affairs concurred with all ten of our recommendations. If properly carried out, they will help ensure VBA's success in making its systems year-2000 compliant.

MAKING SYSTEMS READY FOR THE YEAR 2000-- A DEADLINE VBA CANNOT AFFORD TO MISS

There is no question, Mr. Chairman, that VBA *must* make its key information systems year-2000 compliant. Unless these systems changes are made, veterans could receive inaccurate and/or delayed compensation and pension benefits, receive debt-collection letters when they do not actually owe money, cease to receive vocational rehabilitation services, receive inaccurate insurance benefits, or have foreclosure proceedings initiated unnecessarily due to erroneous date calculations. The financial stress that could accrue to million of Americans from incorrect calculations must be avoided.

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[2]Veterans Benefits Computer Systems: Risks of VBA's Year-2000 Efforts (GAO/AIMD-97-79, May 30, 1997).

At VBA, compensation and pension systems that relate dates to benefits--such as dates of birth or military service--could be especially vulnerable to disruption. To illustrate the potentially chaotic result of a system unable to tell 2000 from 1900, a veteran born in 1925 and therefore turning 75 in 2000 could--if the computer system read "00" as 1900--be seen as *negative* 25 years old--not even born yet. The veteran would likely then be judged ineligible for benefits he had already been receiving. While such scenarios would ultimately be resolved, the ensuing delays could be a hardship for many.

Ensuring that information systems are made year-2000 compliant is an enormous, difficult, and time-consuming challenge. Perhaps ironically, however, it is more managerial than technical. Scheduling and monitoring are especially important because systems must continue to work while being changed; the needs of those being served by these applications are not put on hold while the agency prepares for the next century. Consequently, as with all agencies, VBA's success or failure will reflect the quality of executive leadership and program management that is brought to bear on this task. It will be imperative for top agency management--including the agency head and the chief information officer, or CIO--to not only be fully aware of the importance of this undertaking, but to communicate this awareness and urgency to all agency personnel in such a way that everyone understands why year-2000 compliance is so important. The outcome of this challenge will also be determined by the extent to which the agency has institutionalized key systems-development and program-management practices.

STRUCTURED APPROACH, RIGOROUS PROGRAM MANAGEMENT REQUIRED

Addressing the year-2000 problem is not merely a matter of altering every computer system and application. Management decisions relating to impact, prioritization, and resources, among others, must first be made: *Which systems are most important? Can they be converted or must they be replaced? Can corrections to any be delayed? Can any systems be eliminated because they overlap with others or no longer serve any useful purpose? Have sufficient analyses been conducted to answer these questions? Do we have adequate financial and personnel resources? Must our internal capabilities be upgraded?*

GAO has developed a guide[3] that constitutes a framework that agencies can use to assess their readiness to achieve year-2000 compliance. It provides information on the scope of the challenge and offers a structured approach for reviewing the adequacy of agency planning and management of its year-2000 program. An exposure draft of the guide was released in February; it incorporates guidance and practices identified by leading information technology organizations. We have made copies available to VA and to VBA.

The guide describes in detail the five phases involved in this challenge. Since we see each as critical to a successful year-2000 program, I would like to take a few minutes to briefly discuss them.

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[3]Year 2000 Computing Crisis: An Assessment Guide [exposure draft] (GAO/AIMD-10.1.14, February 1997).

AWARENESS. While this may seem obvious or unnecessary, we have found that neither is true. Agency personnel must get the word--from the top--as to what this project is all about, and why it matters. Also in this stage, the agency team that will attack the problem is identified, and begins examining potential impacts and developing a strategy.

ASSESSMENT. When everything is a priority, nothing is a priority. The emphasis in this phase is on setting realistic priorities--those based on assessments of the potential risk of systems' *not* being year-2000 compliant, and the likely impact. Systems that are mission-critical--which therefore *must* be converted or replaced--need to be distinguished from important ones that *should* be changed and marginal ones that *could* be changed now or deferred. Such priority-setting is absolutely essential, and should be undertaken from a business standpoint: systems that are integral to the agency's main function and on which its customers depend should receive the highest priority. Testing strategies must also be devised, and contingency plans developed.

RENOVATION. This phase deals with actual changes--converting, replacing, or eliminating selected systems and applications. In doing this it is important to consider the complex interdependencies among systems, and ensure that changes are consistent agencywide and that information about all changes is widely disseminated to users.

VALIDATION. Here, agencies test, verify, and validate all converted or replaced systems and applications, ensuring that they perform as expected. It is likewise important that

testing procedures themselves be tested, so that agencies can be sure that their results can be trusted. This critical phase can extend over a full year and may take up to half an agency's funds budgeted for the entire year-2000 program. It is, however, necessary--and worth the cost. Unless changed systems reliably work as needed, the rest of the expenditure is wasted.

IMPLEMENTATION. Deploying and implementing compliant systems and components requires extensive integration and acceptance testing. And since not all agency systems will be converted or replaced simultaneously, it may be wise to operate in a parallel-processing environment for a period of time, running old and new systems side-by-side. Such redundancy can act as a fail-safe mechanism until it is clear that all changed systems are operating correctly.

VBA TODAY: ENCOURAGING ACTIONS INITIATED, BUT SIGNIFICANT RISKS REMAIN

VBA clearly recognizes that the upcoming change of century poses serious challenges, and began analyzing the problem in 1991. Its information resources management support plan, issued this past January, states unambiguously that achieving year-2000 compliance is the agency's number one priority. The agency has developed a year-2000 charter, which defines a project-management organization and designates a project

manager, along with coordinators at each of VBA's three systems-development centers: Hines, Illinois; Austin, Texas; and Philadelphia.

Initially, the primary focus of VBA's strategy was to attain compliance by replacing noncompliant systems with new ones. Its goal was to have all systems and applications compliant by November 30, 1998, thus allowing over a year for testing and monitoring. VBA also developed a contingency plan, for its compensation and pension and educational assistance payment systems, to ensure continued operation into the next century should replacement systems not be implemented in time. On the basis of concerns we raised regarding VBA's year-2000 strategy, the agency recently revised it to focus on making changes to its existing noncompliant systems rather than replacing them. Many of these efforts, however, remain unfinished. Some important obstacles to success remain, Mr. Chairman, in the areas of program management, assessment, contingency planning, and the handling of noncompliant systems.

First, the structure of VBA's year-2000 program management office needs strengthening, and technical and managerial issues must be addressed. An agency-level program office must coordinate and manage the full range of interdependent information systems activities involved in the year-2000 effort. Yet, according to VBA's year-2000 project manager, her management functions were limited to conversion projects for the compensation and pension and educational assistance payment systems, and replacement projects for educational assistance payment systems. The functions of

VBA's year-2000 project manager also do not include oversight of locally developed applications used by the 58 regional offices.

In commenting on a draft of our report, the Secretary of Veterans Affairs concurred with our recommendation that VBA strengthen its year-2000 program management office. He has stated that VBA's year-2000 project manager has been relieved of other duties to devote full attention to year-2000 activities. VA also has established an oversight committee to monitor and evaluate the progress of VBA's year-2000 effort.

A critical technical deficiency is VBA's lack of an overall, integrated systems architecture, or blueprint, to guide and constrain the development of replacement systems and the evolution of related information systems. The Clinger-Cohen Act of 1996 requires, among other provisions, that department-level chief information officers develop, maintain, and facilitate integrated systems architectures. Without such a tool, successful systems integration through common standards is placed at added risk.

Specifically, VBA has not yet developed, or has not documented, a comprehensive analysis of the flow of information among the various systems; further, it has not yet adequately (1) defined the interfaces among systems that must share data in order to facilitate delivery of benefits, (2) defined a security architecture because sufficient analysis to allow this has not been performed, or (3) analyzed characteristics or developed standards for measuring performance. Also, it is permitting changes to the

database and data elements themselves without insisting on the appropriate quality-assurance steps.

The Secretary concurred with our recommendation that VBA develop a complete, integrated systems architecture for its new systems development activities. He further stated that VBA is documenting its systems architecture, information architecture, and data architecture. Also, VBA is still developing security services common to all applications and performance characteristics and standards.

A second obstacle to VBA's success in being ready for the year 2000 concerns the fact that much work remains in determining whether its information systems and their components are compliant now. VBA has yet to fully assess the severity of its year-2000 problem. And while inventories of regional applications and internal/external interfaces have been started, they are not yet complete.

According to VBA's December 1996 year-2000 plan, it expected to have completed all inventories by September 30, 1996. By that date, however, inventories had been completed only for software applications at its three systems-development centers. According to VBA's January 28, 1997, year-2000 risk assessment, part of the reason for the delay is the agency's loss of some well-qualified employees to retirement during recent agency buyouts. Regardless of the reason, however, VBA's challenge is more difficult because it has less time and fewer experienced personnel.

VBA's February 17, 1997, inventory shows 153 applications, consisting of over 8,400 modules and over 9 million lines of computer software code. VBA determined that 111 of the 153 applications--almost three quarters--were noncompliant. Decisions relating to about a third of these noncompliant applications had not been made as of that date.

Further, this inventory does not include local applications developed by regional offices. While VBA's CIO has requested that regional offices develop such inventories, he further stated that no regional applications need be included in the inventory of software applications because no locally-developed applications were mission-critical. Yet according to VA's year-2000 readiness review, without a complete inventory of regionally-developed applications, VBA cannot adequately predict or plan for the impact of the change of century.

The Secretary concurred with our recommendation that VBA perform an assessment of how its major business areas would be affected if the year-2000 problem were not corrected in time to help prioritize the agency's year-2000 activities. He stated that such an overall assessment has been completed, and that VBA concluded that all major business areas would be severely affected. The Secretary did not consider it beneficial to spend time developing a detailed analysis when the general business impact is already known. We believe, however, that even when general impact is known, a detailed assessment provides management with valuable information on which to prioritize

activities, as well as a means of obtaining and publicizing management commitment and support for necessary initiatives.

Regarding VBA's inventory of interfaces, the Secretary stated that VBA expects to have this inventory completed by June 30. He stated that the assessment of interfaces is more complicated because VBA, like other government agencies, is dependent upon receiving information from other agencies. In addition, the newly-established oversight committee plans to assess whether VBA's program management office needs to oversee the year-2000 work in the regional offices and include regional applications in its inventory.

A third obstacle is that VBA has not developed contingency plans for all of its critical systems. Three of its major business areas--loan guaranty, vocational rehabilitation and counseling, and insurance--lack contingency plans to ensure continuity of operations. We recently learned that such plans are in development for the loan-guaranty system. VBA managers realize that they may have to return to manual processing if critical systems in these major business areas are not made year-2000 compliant in time.

In his comments on a draft of our report, the Secretary also concurred with our recommendation that VBA develop a year-2000 contingency plan for all critical information systems. He stated that VBA is addressing the development of contingency plans with each program manager.

Fourth, VBA does not yet have sufficient information about the costs and risks associated with its year-2000 activities. As a consequence, it has no basis on which to make decisions about prioritizing its information technology projects to make the best use of its two vital resources: people and money. Its year-2000 strategy calls for converting most existing systems while simultaneously continuing to replace its existing benefits payment systems. Yet both actions depend upon limited financial and personnel resources; it may not be able to complete either in time.

Reliable assessments of costs and risks are important prerequisites for effective prioritization of information technology projects. VA's readiness assessment estimated VBA's year-2000 costs at about $20 million for fiscal years 1996 through 1999. This, however, only included conversion projects, such as those to upgrade the mainframes and operating systems at the Hines and Philadelphia data centers. It did not include costs to replace VBA's aging systems with new, compliant payment systems.

The Secretary concurred with our recommendation that VBA assess the costs, benefits, and risks of competing information technology projects and prioritize them to make effective use of limited people and financial resources. He indicated, however, that this assessment has been completed. But in light of VBA's recent decision to make year-2000 changes to its existing systems its top priority, rather than relying on replacement systems, we believe that VBA *must* reevaluate its cost/benefit and risk assessments under this new strategy. The results of this evaluation are especially important, since in

focusing on conversion of noncompliant benefits payment systems, VBA has decided to exclude only replacement of these specific systems from its overall year-2000 strategy, rather than discontinue the overall replacement strategy altogether. As a result, VBA's new year-2000 strategy and replacement project effort continue to be dependent upon limited personnel and financial resources.

STRONG PROGRAM OVERSIGHT ESSENTIAL; INVENTORIES AND ASSESSMENTS MUST BE COMPLETED QUICKLY, ALONG WITH CONVERSIONS AND CONTINGENCY PLANS

Mr. Chairman, we all agree that VBA must do whatever it takes to be year-2000 compliant. This will not be easy. Until an inventory and assessment of its information systems and their components is completed, it will not be able to make informed choices about the best use of limited personnel and financial resources. Once this has been accomplished, it may be necessary to reallocate resources toward completing the conversion projects and developing contingency plans for all critical noncompliant systems. A stronger program management office structure and improved technical and managerial capabilities will be essential ingredients in helping to make this happen.

Given the serious risks associated with VBA's year-2000 activities, our report recommends that the Secretary of Veterans Affairs direct and ensure that VBA's acting undersecretary for benefits, in conjunction with VBA's CIO, take ten specific actions to

help ensure the agency's success in making its systems year-2000 compliant before the change of century. I have already discussed some of these recommendations in my testimony today. In summary, these actions involve strengthening program management and oversight; developing an integrated systems architecture; assessing the vulnerability of VBA's major business areas to failing to achieve systems compliance in time; completing inventories, analyses, and assessments; developing a schedule for systems conversion/replacement; and developing critical contingency plans.

We discussed our findings with both VA's and VBA's CIOs at the conclusion of our review. Not only did they agree with all of our recommendations, but in addition took quick action to address areas of concern that we identified. We were told that VBA is redirecting its year-2000 strategy to focus on the conversion of existing benefits payment systems. Further, VA has established an oversight committee comprising a VBA executive, a senior manager from VA's Office of Information Resources Management, and an independent contractor, to evaluate VBA's progress in year-2000 readiness. The contractor is to report this August, and is to include an action plan detailing what will be required for VBA to complete software recoding in December 1998. As we said in our report, we are encouraged by these specific steps and we commend the agency both for its receptivity and speed of response. We will continue to work with VBA in evaluating its plans and strategies for accomplishing its goals.

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

(511218)

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

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

JUNE 26, 1997

Introduction

Mr. Chairman and Members of the Subcommittee, it is my pleasure to testify on behalf of the Department of Veterans Affairs (VA) concerning the readiness 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.

As VA's Chief Information Officer (CIO), I have established close working relationships with VA's Administration-level CIOs to lead our efforts in becoming Year 2000 compliant—ensuring our information systems function correctly when using dates beyond 1999. We are working vigorously to make sure VA's information systems will provide uninterrupted service supporting the full range of veterans benefits delivery and medical care.

I appreciate the opportunity to appear before you today to bring the Subcommittee up-to-date on steps we are taking and our progress in resolving Year 2000 problems. In pursuit of our solution, we are following the standardized, governmentwide Year 2000 best practices phases established by the Office of Management and Budget (OMB) in conjunction with the Federal CIO Council Subcommittee on Year 2000. Let me provide a brief definition of each phase:

Assessment - Refers to determining the scope of the problem by creating an inventory of applications and deciding which ones to change, replace or eliminate.

Renovation - Concerns the modification, replacement or elimination of an application to make it Year 2000 compliant. Year 2000 compliant means the referenced application can process dates beyond 1999.

Validation - Refers to the validation of new or changed code for date handling and functionality. Completion of this phase means that unit testing and management approval have all been completed, validating the Year 2000 changes.

Implementation - Completion of full system testing and the placement into use of the revised systems. Applications and systems can process dates beyond 1999 properly and are in production use.

VA's strategic approach is to make our existing mission-critical systems compliant in their current environment. We have identified our mission-critical systems, prepared detailed plans and inventories of our mission critical systems, and assigned levels of priority to the applications supporting these mission-critical systems.

Accountability and Monthly Year 2000 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) and staff offices are responsible for developing specific plans and managing the projects within their respective jurisdictions.

Monthly Report

On March 7, 1997, my office established a detailed internal report 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. The report includes quantitative measures that are based on the percentage completed for each OMB phase. We are measuring the progress of each individual application against the four 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, necessary redirection and refocusing of appropriate resources to bring an organization back on schedule. We are committed to ensuring that veterans receive uninterrupted services up to and beyond January 1, 2000.

Prioritization of Applications

We have prioritized our applications to ensure Year 2000 impacts will not adversely affect the delivery of benefits or medical care to our veteran population. We have established a three-tiered structure, providing a common VA-wide priority ranking for VA's applications inventories.

Level I - Business Priority Systems: These are systems that will directly impact the delivery of medical care and benefits to veterans or are essential to the Department's mission.

Level II - Internal Support Systems: These include internal agency systems used to improve timeliness and efficiency of administrative processes; operations support; or producing periodic reports. These are systems whose failures would not be deemed as having a direct, adverse effect on veterans.

Level III - Discontinued Systems: These are systems scheduled for discontinuation, prior to the year 2000. They may include systems scheduled for elimination because there is no further legislative requirement or program need to maintain them.

VA Management Actions to Assure Year 2000 Compliance

VA has been utilizing the interim Federal Acquisition Regulations (FAR) Year 2000 compliance language since it was issued in January 1997. Prior to that, we used the language recommended by the Federal CIO Council Subcommittee on Year 2000. For example, VA's Procurement of Computer Hardware and Software (PCHS) contract, our major information technology equipment and software contract, contains the language recommended by the Federal CIO Council Subcommittee on Year 2000. The language developed by the Subcommittee on Year 2000 was incorporated into the interim FAR.

In October 1996, VBA and the Austin Automation Center began sending letters to commercial-off-the-shelf (COTS) providers concerning individual products' Year 2000 compliance. Vendors are being requested to certify that their products are compliant. Since these COTS products are also in use within VHA, the information is being shared with VHA. VHA has conducted an initial survey of COTS products at VHA facilities. VA will also utilize and share information with the governmentwide COTS compliance web page under development by the CIO Council Subcommittee on Year 2000.

VA Year 2000 Readiness Review

In addition to the monthly reports, my office has plans to conduct independent Departmental reviews similar to our Year 2000 Readiness Review last year of the major VA organizations. A copy of the Year 2000 Readiness Review was provided to the Subcommittee in February 1997. We are planning a follow-up independent review during the first quarter of fiscal year 1998. During the first review, over 80 information systems professionals and managers were interviewed in Washington, DC, and various field locations, including the Austin Automation Center (AAC), Benefits Delivery Centers, and medical centers. We independently assessed our readiness, plans, testing methodologies, contingencies, inventories, and cost estimates.

Year 2000 Project Offices

Both VBA and VHA have established 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.

VA's Status in Preparing Our Systems for the Year 2000

I would like to take this opportunity to update the committee on our organizational progress.

National Cemetery System

The information systems supporting NCS are fully Year 2000 compliant. Non-compliant NCS systems were replaced in December 1996.

Veterans Benefits Administration

VBA has redirected its efforts and made Year 2000 its number one organization priority. VBA has completed the assessment phase of its systems. VBA's plan is to complete the renovation phase by November 1998, validation by December 1998 and implementation by June 1999.

VBA has recently awarded four task orders to bring contractor support on board. Three of these task orders are for renovation of applications and one is for project oversight. We have also amended an existing task order to increase the level of Year 2000 support to our project managers. These efforts have been part of our planning for several months.

The Compensation and Pension application will use contractors for renovation. In this application, making legislative program changes and preparing for the annual cost of living adjustments requires much time and effort. With the contractors focusing on the year 2000 renovation, our staff can proceed with the complexities of implementing legislative changes without interruption.

We have also taken the contractual actions necessary to acquire a compliant Honeywell 9000 platform for Year 2000 testing. As you know, the Honeywell supports our Compensation, Pension, Education and Vocational Rehabilitation applications.

As of May 31, 1997, 38 percent of VBA's applications have been renovated and made Year 2000 compliant. Another 5 percent of their applications are in testing. Therefore, over the next few months, the percentage of compliant applications will continue to rise. Every application has been addressed and VBA has a fix solution and a planned fix date for all of its applications.

Veterans Health Administration (VHA)

VHA completed the development of its comprehensive Year 2000 plan on April 30, 1997.

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 May 31, 1997, 23 percent of VHA's Veterans Health Information Systems and Technology Architecture (VISTA) applications are compliant. This percentage represents VISTA applications scheduled for discontinuation.

VHA Year 2000 Plan

VHA's Year 2000 plan addresses areas beyond information systems, such as biomedical equipment currently in use at VA's medical facilities. The plan provides details on the role of VHA's Year 2000 Project Office in supporting and assisting VHA's 22 Veterans Integrated Services Network (VISN) offices in their efforts to achieve compliance throughout the medical facilities in their networks.

Biomedical Equipment

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, are consumers of biomedical equipment; we do not regulate the industry.

VA recommended to OMB in January that an interagency committee, chaired by the Department of Health and Human Services (HHS), be established to deal with this issue. The first meeting of the committee was held on May 9, 1997, at which a general course of action was developed. The Food and Drug, Administration (FDA) in their role as regulators of medical devices and biomedical equipment, such as pacemakers and defibrillators, will ensure that these devices are Year 2000 compliant.

We will coordinate a public awareness campaign with HHS as it particularly affects veterans with medical devices in their bodies or in use in their homes. Additionally, our patients will be advised as to the status of medical center equipment when the work of the HHS committee has identified potential problems.

VA's Austin Automation Center (AAC)

We are especially proud of the progress we have made at the AAC considering the size and complexity of its computer systems. The AAC provides VA-wide information technology support to all components within the Department. As of May 31, 1997, 74 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.

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 commercial-off-the-shelf (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's chaired biomedical committee to resolve potential issues with biomedical equipment.

We are confident that VA will be ready for the coming millennium. VA fully intends that its information systems will continue to provide uninterrupted support to our programs and ensure that we provide the highest quality benefits delivery 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

JUNE 26, 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). I am pleased to be here to provide information about the "Year 2000" date issue as it relates to medical devices.

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 achievement of its primary intended purposes.

As this definition suggests, many different types of products are properly regulated as medical devices. Medical devices include over 100,000 products in more than 1,700 categories. 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 requirements 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 that 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 that 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; or 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 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 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 EEG data; digital analysis and graphical presentation of EEG 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 is preparing to send a letter to all medical device manufacturers to ensure that manufacturers address this issue and review both

embedded and non-embedded software products. We will remind 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 will request that the manufacturers review the software used to determine if there is any risk.

CDRH will recommend 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 will remind 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 that present a significant risk to public health. This includes devices that 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 <u>future</u> 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 that could affect the public health. We are committed to a scientifically sound regulatory environment that 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.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

CONGRESSMAN EVANS TO DEPARTMENT OF VETERANS AFFAIRS

POST-HEARING QUESTIONS
CONCERNING THE JUNE 26, 1997
HOUSE VETERANS' AFFAIRS COMMITTEE/
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
HEARING ON VA'S COMPLIANCE WITH
YEAR 2000 REQUIREMENTS

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

1. The General Accounting Office has indicated that the testing phase of achieving Year 2000 compliance is perhaps the most critical stage of the process. According to GAO, this phase "can extend over a full year, and may take up to half an agency's funds budgeted for the entire Year 2000 program." Mr. Catlett, how much time will VA devote to this "testing" phase, and what proportion of the VA's budgeted Year 2000 funds will be set aside to complete this phase?

VA has estimated that the validation and implementation (testing) phases will require approximately 40 percent to 60 percent of the Year 2000 total lifecycle time, effort and resources. VA's Year 2000 testing schedules will assure that every renovated application is adequately validated and tested prior to implementation.

FTE resources and test schedules for each individual mission critical application have been estimated. VA performs testing incrementally as soon as each application is renovated. We have already begun the validation and implementation of renovated applications. VA's schedule is to complete the renovation phase by November 1998, validation phase by January 1999, and implementation by October 1999 for mission critical applications. VA utilizes its existing quality assurance and testing process teams in conducting actual testing activities so separate funds are not set aside.

2. GAO's testimony indicates that the Veterans Benefits Administration (VBA) Year 2000 program management office "needs strengthening, and that technical and managerial issues must be addressed." Please identify the VBA program officer responsible for coordinating and managing the VBA's compliance efforts, and explain in detail the steps VA has taken to address the GAO's concerns in this area.

Mr. Newell Quinton, the Veterans Benefits Administration (VBA) Chief Information Officer (CIO) has overall responsibility for ensuring Year 2000 compliance. Ms. Sally Wallace is the VBA Year 2000 Project Manager. To alleviate GAO concerns, the Year 2000 Project Manager has been relieved of non-Year 2000 duties, and the Year 2000 Project Office has been elevated and reports directly to VBA's CIO. Monthly briefings are provided to the VA CIO and VBA Under Secretary on VBA's Year 2000 progress. Quarterly briefings are provided to the Deputy Secretary on VBA's progress.

VBA has contracted with KPMG Peat Marwick to assist with Year 2000 project management support. In the last several months, VBA has instituted reporting procedures to insure that the VBA Year 2000 Project Office receives current status and tracking reports. In addition, VA established a committee to oversee the VBA's Year 2000 project. This committee is composed of representatives from the Office of Management and VBA, and is supported by a contractor, SRA International. Currently, the oversight team is conducting an assessment of the status of the VBA Year 2000 project to date.

3. GAO's testimony indicates that VBA has yet to develop and/or document overall, integrated analysis of the flow of information among the various computer systems within VBA that will insure that data can be shared among systems and that veterans will be able to receive benefits in a timely fashion in the year 2000 and beyond. Please explain in detail how the Department will address these serious concerns? When will VA complete its plans in this regard?

VBA has been working the Year 2000 problem since the early 1990's. In July 1996, the first version of VBA's Year 2000 plan was published. We have detailed milestones and a fix for every application. As of June 30, 1997, 41% of our applications are compliant. To insure compatibility and interoperability among our various systems, all information technology components are being assessed for compliance, including all hardware, software and third party products. Data interfaces and exchanges are also being analyzed and are being worked to insure that data can be shared among systems. VBA's interface inventory was completed in June 1997. We take the Year 2000 problem very seriously. There is no doubt that veterans will be able to receive benefits in a timely fashion in the Year 2000 and beyond.

4. In reviewing the GAO's testimony I am troubled to read that the "VBA has yet to fully assess the severity of its year-2000 problem," and that "while inventories of regional applications and interfaces have been started, they are not yet complete." Mr. Catlett, the VA promised that it would complete such an assessment of all inventories by September of last year, but the GAO indicates that such an assessment has yet to be completed. Why hasn't the VA completed this very basic assessment, and when will such an assessment be complete?

VBA completed its inventory and assessment of its mission critical systems, including those that reside in Regional Offices in July 1996. VBA's interface inventory was completed in June 1997. It is true that VBA has not yet completed the assessment of small, non-mission critical applications at Regional Offices. Non-mission critical items are being worked as time permits. The VA Regional Offices are responsible for their own locally developed non-mission critical applications. VBA's CIO provided guidance to regional offices in September 1996 concerning their Year 2000 responsibilities. VBA's Year 2000 Project Office, working with VBA's Area Offices, has the responsibility in overseeing VA Regional Offices Year 2000 efforts on locally developed non-mission critical applications.

VHA has a comprehensive plan to complete inventories and assessments of all system products by January 1998. A copy of this plan was provided to the Committee on June 20, 1997.

There was no September 1996 milestone to complete Regional Office application and interface inventories. VA's overall milestone for completing the assessment phase is January 1998. The milestones for VA's Year 2000 efforts are contained in VA's Year 2000 quarterly report to OMB and Year 2000 Solutions document. Copies of this report and document were provided to the Committee.

5. Mr. Catlett, given that the VA has been unable to meet its own inventory deadlines for the VBA and the VHA, how can the VA adequately predict or plan for the potential Year 2000 impact on veterans?

VA has not missed its inventory and assessment deadlines. VBA's mission-critical systems have been inventoried and assessed, including mission-critical systems

residing in Regional Offices. VBA has just completed its interface inventory. All inventories are continually maintained and updated.

VHA has a comprehensive plan to complete inventories and assessments of all system products by January 1998. VHA has inventoried its mission critical systems and will refine its Year 2000 plans and analyses as the assessment phase progresses. The impact of Year 2000 issues on the delivery of health care to veterans will be completely analyzed once these assessments are done, and VHA will finish renovation activities well in advance of any projected fail dates for its systems or equipment.

To support its critical mission to provide quality health care to our nation's veterans, VHA has implemented a diverse array of information systems and computer-controlled equipment throughout its national system of health care networks. The VHA Year 2000 Compliance Plan indicates January 1998 as the completion date for assessing its total systems and equipment inventory and for developing the approach to achieve Year 2000 compliance. VHA has completed an inventory of mission critical central systems (**VISTA** and Corporate Systems) and has made substantial progress in inventorying other system product categories while conducting an analysis of individual applications, systems, and equipment that may be at risk. System product categories include: the **VISTA** national application suite, locally developed software applications, VHA corporate systems, databases and data archives, commercial-off-the-shelf (COTS) software, computer and communications hardware, biomedical equipment, and facility-related systems and equipment. To date, the following progress has been achieved:

1. The **VISTA** applications inventory has been completed. Year 2000 assessment of **VISTA** applications is ongoing and will be completed by January 1998.

2. Health care facilities are compiling individual inventories of locally developed software applications. Guidance and tools will be provided to local facilities for assessing software applications in October 1997.

3. The VHA Corporate Systems inventory was completed in 1996 and is being assessed for Year 2000 compliance. Individual systems managers/owners are vested with the responsibility to assess and report on compliance status to VHA's Year 2000 Project Office.

4. The COTS software inventory has been completed. Based on the data received from the 22 VISNs and their health care facilities, VHA is contacting COTS software vendors/manufacturers to determine compliance status and vendor plans.

5. The COTS computer hardware inventory has been completed. VHA is making considerable progress in inventorying and analyzing Year 2000 compliance issues for its telecommunications systems inventory.

6. A Biomedical Equipment plan within VHA's year 2000 Compliance Plan for Year 2000 compliance has been developed. To date, more than 120 major biomedical equipment manufacturers have been contacted.

7. An inventory is being developed for achieving compliance in the area of facilities-related systems and equipment. VHA is participating in various subgroups within the Federal CIO Council Subcommittee on Year 2000 dealing with facilities, telecommunications and biomedical equipment. This will enable VHA to collaborate, share information, and benefit from the interagency Year 2000 work being coordinated by the General Services Administration, the Department of Health and Human Services and other Federal agencies.

8. The inventory of Medical Research databases and archives is being conducted at each research facility. A thorough inventory will be completed by September 1997.

6. What are VA's contingency plans to ensure continuity of operations for its loan guaranty program? Is there a detailed, written plan in place for this program'?

Risk Management and abatement is a key component of VBA's Year 2000 strategy. VBA has a well-thought-out plan for achieving Year 2000 compliance. VBA is being proactive in risk management to ensure VBA's plan executes correctly. The VBA Project Office is on top of all of VBA's risks and potential risks, plus having an oversight team allows another set of "eyes and ears" to do likewise. VA will not have a situation where veterans will not get paid. Veterans will not lose their homes, or not get their checks, due to failure of VBA systems to pay. VBA's Contingency Plan for the loan guaranty program consists of redundant development efforts to insure an operating payment application in the event that a redesign does not make its planned implementation date. The contingency plan for Loan Guaranty is in writing.

7. What are VA's contingency plans to ensure continuity of operations for its vocational rehabilitation programs? Are there detailed, written plans in place for these programs?

The Vocational Rehabilitation system was made Year 2000 compliant in late July 1997. Therefore, a contingency for Vocational Rehabilitation is not needed.

8. What are VA's contingency plans to ensure continuity of operations for its insurance system? Is there a detailed, written plan for this system?

Risk management is the key to ensuring continuity of operations for Insurance. There is no detailed, written contingency plan for Insurance. To mitigate this risk, VA points to the fact 85 percent of the Insurance application modules have been made compliant, and the project is on schedule for completing renovation in February 1998. This allows ample time for testing prior to implementation before its December 1998 fail date.

9. Mr. Catlett, you have indicated that the VA intends to primarily rely on its in-house personnel to achieve Year 2000 compliance, and that roughly 10 percent of the monies directed toward this effort will be set aside to pay private contractor and consultants. Yet VA has blamed VBA inventorying delays, for example, on the loss of well-qualified employees to recent agency buyouts. Given this employment climate, and given that the time is constantly ticking on this issue, should the VA be relying so heavily on its own employees to get the job done?

As mentioned in questions 4 and 5, VBA has met its inventory and assessment deadlines. With regard to the VBA employment climate, if buy-outs are offered, personnel working key projects, such as Year 2000, will be excluded, if the site manager concurs. VBA feels it is optimizing the talents of its employees, who have a vast amount of experience with VBA's legacy applications, by using them on VBA's Year 2000 project. VBA has a healthy mix of contractor support and government personnel working on this project. As of June 30, 1997, 41 percent of VBA's applications were compliant. VBA has reached the 41 percent by the efforts of our talented government staff, and the prudent use of contractor resources.

VHA's plan has invested the 22 VISNs with the responsibility of assuring compliance within each VISN. This is the most effective approach for both

business and management reasons. It makes managing such a large task more practical, with direct management responsibility locally situated. Each VISN office controls the business and financial planning and execution for its medical facilities. These managers will be making the repair, replace or upgrade decisions, and funding them.

IRM staff at the medical facilities, which install and support VHA's nationally released applications, have a strong working relationship with the VHA programmers. VHA has maintained a strong system configuration management program over the years, which will facilitate implementing Year 2000 compliance. VHA may contract out some code renovation work; this contracting effort will be closely integrated into the existing VHA configuration management program.

The VHA Year 2000 Project Office has contractor support on board, to provide additional management support and technical expertise. If needed, the VISN offices may also decide to enlist additional contractor support to acquire additional technical, analytical or project management expertise.

10. The VA has estimated that it will cost $140 million over the next three years to achieve Year 2000 compliance at the VA, and that an unknown additional amount will be needed to deal with the as-yet-to-be-assessed problem with biomedical devices. VA has also indicated that there will be no need for additional monies after FY 2000 because, in theory at least, its job will be done. How realistic are these estimates, and what will the VA do if it later decides that these estimates were wrong?

VA's estimates are realistic and will be updated as needed. VA's estimates reflect redirected funds and not "additional monies." As VA noted in our response to your prehearing questions, VA may incur additional costs to upgrade or replace COTS products in FY 1998 and FY 1999 as COTS providers notify Federal agencies of Year 2000 compliance of individual products. Funds will be redirected as necessary to ensure VA's information systems will provide uninterrupted support of benefits delivery and medical care.

In the case of biomedical equipment, the original equipment manufacturer is the only party with all the information necessary to 1) determine whether or not there is a compliance issue and 2) recommend a course of action for non-compliant devices. VHA will determine the exact amount of money needed to correct any potential problems with medical devices when information from vendors is received. FDA is also taking the lead in dealing with medical device manufacturers. VHA is contacting vendors about the compliance status of their equipment and their remediation plans.

Preliminary expert opinion indicates that only a small number of medical devices have Year 2000 problems. As soon as the number of products with Year 2000 problems and corresponding solutions are identified, VHA will provide an updated Year 2000 cost estimate. Preliminary discussion indicates that equipment affected by the Year 2000 is considered to have a design flaw and the manufacturers are responsible to make the necessary updates rather than government agencies incurring these cost.

11. Mr. Catlett, you indicated to Committee staff last week that VHA intended to have completed a survey of medical device manufacturers doing business with the VA during the first half of 1997, but that the survey responses proved inadequate and another questionnaire was expected to be sent out last Friday. Can you explain what happened with the initial survey, what steps you have taken to correct whatever problems arose, and when you expect to receive the responses and complete a thorough analyses of those responses?

VHA originally intended to use a centralized database of medical devices at the Austin Automation Center. After further investigation, VHA found that this database did not contain all required data for Year 2000 compliance purposes. It is this database, and not a survey, that was referred to.

VHA has explored alternative methods to assess medical devices. VHA has identified vendors of medical devices and began mailing letters to vendors on June 20, 1997. Vendors are expected to assess the effects of Year 2000 on their medical devices and provide a written plan to VHA by August 18, 1997. While responses to date have been limited, those who have responded indicated that there would be no Year 2000 effect on the equipment, or that conversion work is in progress. VHA has made follow-up calls to those vendors who have not yet responded.

VHA has formed a Medical Device Integrated Product Team to assure Year 2000 compliance. This team includes biomedical engineers and experts from a variety of the medical specialties. This team will meet in August 1997 to validate VHA's biomedical approach and review the vendor responses.

12. The VA has told us it is presently identifying and evaluating for Year 2000 issues in biomedical systems. In addition to the survey of manufacturers, please explain how VA is going about such an evaluation.

To assist with identifying, inventorying, assessing, and evaluating these medical devices at risk with the millennium change, VHA has established a multi-disciplinary oversight team to ensure that medical devices are compliant. The Medical Devices Integrated Product Team includes experts from the following fields: Radiology, Nuclear Medicine, Pathology & Laboratory, Medicine, Cardiology, Surgery, Biomedical Engineering, Acquisition & Materiel Management, Medical Research, Prosthetics, and VHA's Year 2000 Project Office.

Specific activities of the team include: validating risk categories for medical devices and systems; setting priorities for assessing, renovating, testing and implementing; establishing schedules and timelines; reviewing vendor responses; and recommending actions to the VHA Year 2000 Project Office, VISN CIOs, and VA medical centers.

13. During a pre-hearing briefing for Committee staff, VHA CIO David Albinson and his staff appeared to downplay the importance of the medical device issue, and stated that there are only "four or five" medical devices that would be impacted by the Year 2000 problem. What is the basis for this belief, and can you identify which four or five devices would be impacted by the Year 2000 problem?

VHA's belief is that there are only four critical medical device categories that the Year 2000 problem would impact is based on information it received from officials at FDA. At the April 1997 federal CIO Council meeting, the department of Health and Human Services (HHS) volunteered to lead a subgroup of Federal Subcommittee on the Year 2000 to deal specifically with biomedical devices and other embedded technology. Gail Finch from HHS' Office of Information Resources Management chaired the first meeting on May 9, 1997, which included representatives from VA, OMB, National Institute on Health, FDA, DOD/Health Affairs, Navy, Army and the Nuclear Regulatory Agency.

Dr. Tom Shope, Deputy Director of the Division of Electronics and Computer Science at FDA, presented a description of the responsibilities under the Safe Medical Devices Act of both the FDA and equipment manufacturers. He indicated that there were seven to ten thousand manufacturers of approximately 80,000

devices regulated by FDA, although not all of those are computer controlled. In October 1996, FDA issued a Federal Register notice regarding quality systems that takes effect in July 1997 which enables FDA to regulate the manufacturing process as well as the product.

Dr. Shope asserted that FDA's preliminary examination of devices identified four possible categories of devices that might be affected by the millennium change. Those medical device categories are:

--Radiation therapy treatment planning systems for Cobalt units
--EKG Automated Interpretation Programs
--Pacemaker Automated programming systems and
--External Defibrillators.

Mr. Catlett, I forwarded to you a series of pre-hearing questions on the issue of Year 2000 compliance, and I appreciate the Department responding, to those questions. I am including a copy in the final hearing record. In follow-up to your responses, please answer the following questions:

1. The VA's written responses indicate that not all interfaces for VBA and VHA related programs have been inventoried and assessed for Year 2000 compliance. The Department states that 148 out of 429 VBA interface files have been assessed, and that 57 out of 148 are Year 2000 compliant, 84 files are not compliant, and 7 files have been retired. In other words, the VA believes approximately 1/3 of its inventoried files are Year 2000 compliant. The Department also indicates that the VBA Interface Management Plan "is on target for completing the interface inventory by June 30, 1997," or four days from now. Since the rest of the inventory process is so near completion, can you give us at least a broad thumbnail sketch of your VBA inventory expectations. Can we expect a similar ratio of compliant versus non-compliant files?

VBA completed its interface inventory on-time. It is true that approximately 38 percent of the VBA interfaces assessed thus far are already compliant (they contain no dates or the data structures are compliant). VBA projects that once the assessment of the entire interface inventory has been completed, the ratio of compliant vs. non-compliant interface file structures will have dropped to between 25 and 30 percent.

2. When did you send the Year 2000 compliance letter to corporate managers and owners seeking detailed information on interfaces? When do you expect to receive responses, and when will you complete an analysis of such information?

An initial effort to update VHA's inventory of corporate or national systems/databases began in March 1996. One item of information requested at that time was a listing of data sources that feed each of these systems. VHA decided to verify the existing information and solicit additional information on out-going interface data. The first VHA Corporate Systems Year 2000 compliance status request letters were sent to System Managers of Record (SMRs) of forty of VHA's Corporate Systems on June 2, 1997. Letters to the System Managers of Record of the remaining 129 VHA Corporate Systems were sent on July 21, 1997. These letters requested detailed information on interfaces between VHA Corporate Systems/databases and other systems, and plans for assuring that the exchange of data is Year 2000 compliant. Initial responses are requested by the end of August 1997. Any necessary follow-up responses will be received by October 1997. The assessment phase for all Corporate Systems is scheduled to be completed by January 1998.

3. When asked to outline the contingency plans that are in place should certain systems be non-compliant by the year 2000, the VA told me its primary strategy was to make mission critical systems compliant before the projected system fail dates. VA indicates that individual CIO's are presently developing specific plans. When will such contingency plans be in place, and isn't it getting a little late in the game to be just developing such plans?

VBA's initial strategy to meet the Year 2000 issue was to replatform its applications. In essence, each major system would have been redesigned to operate in the new VBA environment. VBA has changed its primary means of resolving the Year 2000 dates to code conversion on its legacy systems, e.g., the compensation and pension system is being made compliant in its current environment with upgrades to Honeywell equipment. This will also apply to the Vocational Rehabilitation System and Education Systems. In some instances, like the Chapter 1606 Education Payment System, sufficient progress has been made with the VBA redesign effort that it proved to be the best option to pursue.

Each effort is guided by a conversion plan with detailed tasks and milestones. The key component to successful completion is risk management, which is occurring within each project as it moves from milestone to milestone. The following chart shows the conversion efforts by system as well as the development efforts and contingency plan for each application.

Major Systems	Primary Strategy	Contingency
Education Ch. 1606	Redesign	N/A - Scheduled Completion Date - November 1997
Education Ch. 30	Code Conversion	Redesign Following Chapter 1606 Redesign
C&P	Code Conversion	VETSNET C&P
VR&C	Code Conversion	N/A - System Completed as of July 1997
LGY	Replatform and Code Conversion	Development of Four Replacement Systems
INS	Code Conversion	N/A - Scheduled Completion February 1998

Each VHA health care facility has a contingency plan for maintaining health care operations. These contingency plans would be operative in the event of a Year 2000 failure. Additional contingency planning will be developed for all systems based on projected Year 2000 failures.

Each VHA VISN CIO has the responsibility for ensuring that their systems are Year 2000 compliant, and that fall-back plans exist if systems fail. Risk management and contingency planning are continuous processes. The Year 2000 is one aspect of many kinds of possible failures. The management of risk is conducted on a continuous basis, and contingency plans change based on the events that occur. Contingency plans will continue to be updated through the Year 2000.

4. Mr. Catlett, the VHA has indicated to me that lines-of-code are not a useful measure to determine projected costs for achieving Year 2000 compliance, because VHA's medical care operations are written in what is known as "MUMPS" programming language. Industry experts have advised my staff however, that no specific tools presently exist to convert the "MUMPS" programming language to a Year 2000 compliant format. If

this is true, and, if there are no such conversion tools available, how will the VA be able to convert this language, and how will the VA be able to estimate how much it will cost?

VHA has acquired a commercial tool to assist in the identification of date related fields in its MUMPS applications. Using the tool, all 141 applications within the ***VISTA*** system will be assessed by January 1998 for Year 2000 date compliance issues. Once the assessment is complete, VHA will be able to refine its estimate of programming resources required to renovate any applications and achieve Year 2000 compliance for the ***VISTA*** applications. In-house programming resources and contract programmers will be used for analysis and renovation.

As VA noted in our previous response to your prehearing questions, ANSI (American National Standards Institute) MUMPS or M language standards are Year 2000 compliant. There is no need to "convert" the MUMPS language. VHA's standardized usage of a three digit year format provides assurance that VHA's applications that are detected as noncompliant can be quickly renovated and implemented without adverse impact on our veteran population. VHA is investigating interfaces and dependencies VHA applications have on their environment and will be taking steps to ensure they continue to operate correctly by monitoring their integration with VHA's information systems.

5. The VA has indicated that it does not believe cost-per-line-of-code is the most effective method of determining the expected cost of Year 2000 compliance, and that the best way to assess the cost is to inventory and assess individual applications. What is the status of your cost assessment efforts, what is the basis for your view that your method is the best method to access the costs, and has there been any independent verification that your cost assessment methods are preferred?

Our cost estimates represent both actual expenditures and future estimates. Our cost estimates rely on several factors to determine the complexity and cost for conversion for each non-compliant application. These factors include: number of modules, platform, languages, databases, and online versus batch applications.

Line-of-code estimates provided a very basic thumbnail estimate for potential Year 2000 cost during the initial awareness phase for Year 2000. If you used the common industry figure of $1.50 for each line-of-code, VA's cost would be misrepresented as being $26 million dollars. Lines-of-code estimates do not provide an accurate measure as to the complexity or amount of actual code conversion that is needed. There are additional Year 2000 costs that would not be captured by relying solely on lines-of-code costs. Additional costs could include costs to upgrade hardware components (mainframes) and operating systems and costs for procuring Year 2000 compliant COTS products. Our $144 million dollar Year 2000 estimates includes these types of costs.

Although lines-of-code is a useful measure in specific situations such as when a specific application has been contracted out for code conversion, VA's Year 2000 cost estimates are more accurate than solely relying on lines-of-code for cost estimations.

Our methodology is supported by the "best practices" from the CIO Council Subcommittee on Year 2000 and the experiences shared by other agencies, including the Social Security Administration. In addition, VA's method for developing cost estimates has been verified by VA's actual Year 2000 work performed by the Austin Automation Center (AAC) and VBA's Year 2000 efforts as well as actual Year 2000 work on VA's financial and personnel systems. The validity of this methodology has been verified by the completion of the actual

renovation of applications. As of June 30, 1997, the AAC has renovated 74 percent of its applications and VBA has renovated 41 percent.

Our cost estimates are reevaluated on a monthly basis and were independently verified during VA's Year 2000 Readiness Review. A copy of this review was previously provided to the Committee. VA will continue to refine our cost estimates and report any changes in our quarterly reports to OMB.

6. Is it fair to state that at this point, VA is only able to provide us with a broad estimate of the expected cost of achieving Year 2000 compliance? What is the status of your efforts to determine the complexity and cost of conversion?

Our cost estimates are based on specific categories of Year 2000 cost described in our response to Question 5. These estimates represent actual expenditures and projected future costs based on VA's Year 2000 schedule as noted in our response to Question 5. These estimates represent the Year 2000 costs for VBA, VHA, AAC and our financial and personnel systems. VHA 2000 cost estimates will be refined as the assessment phase progresses. VA noted in our previous response to your prehearing questions that cost may increase as we are notified by industry of the Year 2000 compliance of COTS products and biomedical equipment.

VHA has a comprehensive plan to complete inventories and assessments of all system products by January 1998 and perform the required Year 2000 impact analyses. VHA will refine its Year 2000 plans and analyses as the assessment phase progresses. The potential impact of Year 2000 issues on veterans from the perspective of health care delivery will be more clearly understood once these assessments are completed. VHA will complete renovation activities in advance of any projected fail dates for its systems or equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 14 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 July 10, 1997 letter regarding follow-up questions to the June 26, 1997 Subcommittee on Oversight and Investigations Hearing on "Year 2000 Issues and Their Impact on the Department of Veterans' Affairs." The following are responses to your questions.

1. **Dr. Shope, the FDA has been tagged as the lead federal agency responsible for ensuring that there is not a severe problem with non-Year 2000 compliant medical devices. Can you outline to the Subcommittee the steps your agency has taken to meet its responsibilities in this area?**

The Food and Drug Administration (FDA or the Agency) is responsible for protecting public health by helping to ensure that medical devices are safe and effective for their intended uses. The primary responsibility for the regulation of medical devices is vested in FDA's Center for Devices and Radiological Health (CDRH). Medical devices that have the potential for Year 2000 (Y2K) problems fall within the scope of this regulatory authority. Any computer software that meets the statutory definition of a medical device is subject to applicable FDA medical device regulations. Beginning January 1, 2000, computer systems and software applications used currently in medical devices may experience problems if they use two-digit fields for date representation.

In early 1996, staff in CDRH began discussions within the Center to assess the type of computerized medical devices which could have functional problems related to the Y2K problem, or "Y2K non-compliance," that could affect device safety or effectiveness and impact patient safety. This assessment, which encompassed all types of medical devices, included participation of technical staff from each of the divisions within the Office of Device Evaluation under CDRH. The discussions were preceded by presentations on the nature of the Y2K problem. These discussions, which continued into late 1996, revealed only a few types of devices for which significant impact on patient safety due to Y2K non-compliance might be expected.

In early July 1997, FDA sent a letter to device manufacturers to remind them of the Y2K issue and to advise them of actions that should be taken with regard to assessing any potential risks which could result from Y2K non-compliance. This letter was mailed to over 13,000 medical device manufacturers and others. In this letter, FDA reminded medical device manufacturers of their responsibilities to assure that products function as intended in accordance with their specifications. Failure to do so on the part of the manufacturer could result in a determination that products are misbranded or adulterated, with resulting consequences for the manufacturer.

FDA is participating, along with representatives of other Federal agencies, including the Veterans Administration (VA), in the Chief Information Officer (CIO) Council Subcommittee on the Year 2000. This Subcommittee is exploring ways to

facilitate information transfer from manufacturers to purchasers and users regarding the Y2K status of specific devices and scientific equipment.

2. **What role will the FDA play to ensure that the Veterans Health Administration (VHA) is able to properly address the potential Year 2000 problems with regard to medical devices? How much interaction does the FDA expect to have directly with the VA?**

FDA's role is to assure that medical devices, including those used by VHA, are safe and effective and manufactured in accordance with their specifications. FDA, in its July letter, reminded manufacturers that to ensure the continued safety and effectiveness of these devices, manufacturers should ensure that their medical devices can perform date recording and computations that will be unaffected by the Y2K date change. Should the VHA request specific consultation or assistance, FDA will provide whatever assistance can be made available. VHA and FDA both participate on the CIO Council Subcommittee on the Year 2000 which provides a forum for interaction between VHA and FDA staffs.

3. **What information and input have you received to date from private industry and medical device manufacturers concerning the degree to which their devices are Year 2000 compliant? What enforcement authority do you have to ensure that these manufacturers eventually come into compliance?**

CDRH staff have made inquiries of industry regarding the possible Y2K impact on a number of devices with possible patient risk implications. To date, CDRH has learned of no significant problems anticipated by industry which cannot be addressed before the year 2000. While there have been some devices identified as having a potential to be affected by the Y2K problem, these are relatively few in number. The industry contacts, with whom this issue has been discussed informally, have not expressed concern that industry will be unable to address any date-related problems with these products before the problem could interfere with the device's functioning.

All manufacturers of medical devices under the current Quality System Regulation (effective June 1, 1997) and its predecessor, the Good Manufacturing Practices regulations, must investigate and correct problems with medical devices. These problems include devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. These regulations, which apply to all medical devices not expressly exempted, would apply to devices with the potential to be affected by the Y2K problem.

A device with a Y2K problem could be considered to be adulterated or misbranded under several provisions of the Federal Food, Drug, and Cosmetic (FDC) Act (e.g., Section 501(h), if not designed and manufactured in accordance with the Quality System Regulation (GMP); Section 502(f)(1), unless its labeling bears adequate directions for use; or Section 502(j), if it presents a danger to health). Adulterated or misbranded devices are subject to seizure, and responsible parties are subject to injunction, civil penalties, or criminal prosecution, if they fail to bring their devices and operations into compliance with the FDC Act.

The July FDA letter puts all device manufacturers on notice that they should assess the Y2K status of their devices. If the manufacturer confirms a Y2K problem, the Quality System Regulation requires the manufacturer to determine what action

is needed to correct the problem and to prevent its recurrence. The manufacturer should take voluntary action to notify users and correct the problem through a safety alert or recall. The recently issued Reports of Corrections and Removals regulation (21 CFR 806), which becomes effective on November 17, 1997, requires manufacturers to notify FDA of such voluntary action. If the health risk associated with the Y2K problem is serious enough or sufficiently likely to occur, FDA may take action under Section 518 of the FDC Act to require notification of appropriate persons, including device users, to require recall of the device, or to take other remedial action.

4. Can you explain in lay terms the potential implications should medical devices be non-Year 2000 compliant? What risks are associated with non-Year 2000 compliant medical devices? To what extent could data collected through the use of these devices be corrupted or rendered useless because of non-Year 2000 compliant medical devices? Could this affect the treatment prescribed by VA doctors?

The impact of a medical device being Y2K non-compliant means that the device software will not properly process information related to dates. This could impact either recording and recordkeeping functions or calculations and data manipulations involving date information.

As very few devices are dependent on calculations using date information for proper functioning, the impact for those devices that are non-compliant will be in date recording or recordkeeping functions. There might be products, due to their designs, which simply will not function due to problems related to the incorrect date, thus denying the health care facility their use until they are reset or reprogrammed. No specific examples of this type of problem are known currently to FDA. If the Y2K non-compliance is associated only with date recording or recordkeeping, one of two effects may be anticipated. Either the date will be recorded incorrectly, most likely as "00" for the year, or the device will not function due to error detected by the software. In this type of device, the problem very likely can be remedied easily by a software upgrade, a frequent occurrence for computer-controlled products. If the year of the current date is recorded as "00" and the device functions, there is not likely to be confusion due to such "recordkeeping" as there were no computer-generated records in 1900 with which there might be confusion. A date with the year recorded as "00" could interfere with data manipulation processes or perhaps storage of patient birth dates. It is the responsibility of manufacturers to upgrade such software.

For products which use the date in a calculation or other algorithm, and for which the date information must be correct for correct function, there is a possibility that Y2K non-compliance could result in a risk of inappropriate diagnosis or treatment. A radiation treatment planning system is often given as an example of this type of product. Incorrect date information could lead to an incorrect treatment plan and, if not detected, could lead to incorrect radiation treatment with consequent risk to the patient. Again, manufacturers have a responsibility to investigate and correct such problems.

5. Dr. Shope, your testimony indicates that you have only just begun to survey manufacturers of medical devices for Year 2000 compliance, and that the only reliable source of information on the potential impact of non-compliant devices is the manufacturing industry. At the same time, however, you state that you do not believe there will be any major impact on medical device safety. Why has the FDA just begun its review process, and what is the basis for your seemingly premature conclusion that you do not see any major impact on safety?

FDA believes that there will not be a major impact on a large number of devices. Discussions with manufacturers have reinforced our assessment that this will not be a significant problem for medical devices and device users. FDA does not have plans to survey manufacturers formally. This is not to say that there will not be some devices which may be affected. We think that corrections for such devices are not difficult to implement and that there is adequate time for manufacturers to implement any solutions required.

The July FDA letter reminds manufacturers that some computer systems and software applications used currently in medical devices may experience problems beginning January 1, 2000, due to their two-digit fields for date representation. The letter also reminds manufacturers that, pursuant to manufacturing regulations, they must investigate and correct devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations.

FDA regulations require that manufacturers notify FDA if they learn that their devices have caused or contributed to a death or serious injury. For currently manufactured medical devices, FDA recommended, in the July letter, that manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the Y2K date change. For future medical device premarket submissions, for devices whose safe operation could be affected by the Y2K date change, FDA will review the submissions to ensure the manufacturer has demonstrated that the products can perform date recording and computations properly (i.e., Y2K compliant).

6. Your testimony states that "almost none of these medical devices require knowledge of the current date to operate safely and effectively," and that pacemakers present no threat because they "do not use the current date in their operation." Is that the end of the inquiry concerning the possible threats presented by non-Year 2000 compliant pacemakers, or does your Agency intend to give that question a closer look?

We do not expect that there will be Y2K non-compliant pacemakers, although there may be auxiliary or accessory equipment used with pacemakers which could be impacted by the Y2K problem. We expect that, as a result of our letter to manufacturers, FDA's inspectional program, and device regulations, FDA will learn of any problems which may exist and which could present a risk to patients, as well as the steps which the manufacturer will take to correct such a problem.

Manufacturers have been requested by FDA to conduct hazard and safety analyses to determine whether device performance is affected. Manufacturers, pursuant to manufacturing regulations, must investigate and correct devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Section 518 of the FDC Act requires notification of users or purchasers, as well as other

actions, when a device presents an unreasonable risk of substantial harm to public health.

7. Can you specifically identify which medical devices you presently believe require knowledge of the current date to operate safely and effectively?

FDA currently does not have a list of all of the devices which may require knowledge of the current date to function as designed. The data FDA has reviewed to date in clearing devices for market would not necessarily reveal whether the device was Y2K compliant. For new devices, as stated above, FDA will review submissions to ensure the submitter has demonstrated that the products can perform date recording and computations that will be unaffected by the Y2K date change. Manufacturers have this information, and this is the reason why the July FDA letter was sent to manufacturers to remind them of their responsibility under the regulations to assess the impact of the date change on the operation of their devices.

There is a difference in functioning as designed and functioning safely and effectively. Some problems which may develop due to the Y2K non-compliance of a device will not affect safety or effectiveness directly but possibly will have an impact on recordkeeping or date recording functions which, if not corrected, could lead to inconvenience, but not risk, to patients.

The types of devices which require knowledge of the current date are any device which employs an algorithm which does a calculation involving a comparison of the current date with some other date-related data. Specific examples are radiation treatment planning systems for radiation treatments that use a radioactive isotope as the source of the radiation; or systems which determine a patient's age, for use in an algorithm requiring information on the patient's age, from input information on the patient's birthday and the current date. There are several categories of this type of device, such as electrocardiogram (ECG) 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. FDA does not anticipate that there are very many of these types of devices which will be Y2K non-compliant as a result of the use of two-digit representation of the year in dates. Those that do exist are not expected to present significant difficulties to correction by their manufacturers.

8. Your testimony indicates that you believe the Year 2000 risk will be mitigated through proactively working with manufacturers. Can you explain to the Subcommittee what exactly you mean by this? Have you put together a detailed plan to work with manufacturers to address this problem?

By proactively working with the manufacturers, we mean that FDA, through discussions and the July letter, has reminded manufacturers of their responsibility to address this issue and of their regulatory responsibility to investigate and correct problems with medical devices which present a significant risk to public health. The July FDA letter was mailed to 13,407 medical device manufacturers, 8,322 domestic manufacturers, and 5,085 foreign manufacturers. The letter reminded manufacturers of their responsibility under current device regulations and made recommendations concerning future medical device pre-market submissions, currently manufactured medical devices and computer-controlled design, production, and quality control processes used by device manufacturers.

FDA will respond as needed to any issues or questions presented to us by industry or the device user community. In addition, in the July letter, FDA reminded medical device manufacturers that CDRH's Division of Small Manufacturers Assistance is available to provide guidance regarding specific questions about Y2K compliance. FDA will continue to monitor this issue and will work with the Subcommittee to assure that medical device performance will not be affected by the Y2K date change.

9. In your estimation, how long would it take for a manufacturer to adapt its product so that it is Year 2000 compliant? Is there time enough to correct these problems prior to the year 2000?

The length of time which will be required to adapt or modify a software-controlled device to be Y2K compliant will be highly variable and dependent on the type of device and its design characteristics. The pace of technological innovation in medical devices is so rapid, and software-controlled devices are so amenable to revision in many cases, that we expect that there will be more than adequate time for manufacturers to develop, implement, verify, and distribute any necessary corrections.

10. Do you believe the VA is on track to achieve compliance among its medical device manufacturers? What is the basis for your assessment?

FDA is unable to answer this question in any detail as we do not have knowledge of specific activities which the VA is undertaking. FDA is responsible for protecting public health by ensuring that medical devices are safe and effective for their intended uses. FDA has reminded manufacturers that its device regulations could require that manufacturers of devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations take certain actions.

The VA is no different than the rest of the health care community in that it uses the same suppliers of medical devices as the rest of the community. To the extent that industry is not expected to have significant problems, the VA similarly should not need to take specific actions with regard to assuring that their suppliers of devices develop solutions to any Y2K-related date problems. The VA will have to learn from its suppliers which devices will be affected and how the manufacturers intend to address corrections. The activities of the working group under the CIO Council, Subcommittee on the Year 2000, of which FDA is a member, should assist in providing the VA with this information.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

ISBN 0-16-056138-8