

DEPARTMENT OF VETERANS AFFAIRS YEAR 2000 (Y2K) READINESS

HEARING BEFORE THE SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON VETERANS' AFFAIRS HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTH CONGRESS FIRST SESSION

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DEPARTMENT OF VETERANS AFFAIRS YEAR 2000 (Y2K) READINESS

THURSDAY, APRIL 15, 1999

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

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

Present: Representatives Everett, Brown, and Evans.

OPENING STATEMENT OF CHAIRMAN EVERETT

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

This hearing will examine the preparations of the Department of Veterans Affairs for year 2000 computer compliance. As is now fairly well known, the problem is that many dates in computer systems use only two digits for the year, not four digits. When the year 2000 arrives, those computers that have not been fixed may not be able to properly process time-sensitive data and may become unreliable or unable to operate.

With our society's reliance on computers, the magnitude of the problem is huge and it affects everybody. The subcommittee's particular concern, of course, is veterans. The VA must be able to provide them with benefits and health care on January 1, 2000, and afterwards.

More than 2 years ago, when I was chairman of the Subcommittee on Compensation, Pension, and Insurance, I first raised the Y2K question at a hearing and it has been a top priority for the VA ever since. The General Accounting Office has been reviewing the Y2K efforts of the VA since that time and the GAO will report again today.

The VA's Office of Inspector General has also been doing other Y2K reviews and will testify regarding their findings.

This hearing is being held now because the VA has just passed a critical milestone in Y2K compliance. On March 31, the VA, like other Federal agencies, was supposed to have accomplished compliance. Our questions to the VA, GAO, and IG are simple. Did VA achieve compliance and what remains to be done? The answers may not be so simple.

I also asked the GAO to examine an issue that, in my judgment, has not received significant attention. This will be the GAO's first public testimony on the subject of how Y2K issues affect pharmaceuticals. Our question is, will there be a reliable supply of vital

drugs and medicines for the veterans served by the VA? The VA spends about \$2 billion a year on drugs and medications and pills, millions of prescriptions each year, many of them essential to sustain life.

Y2K issues affect the pharmaceutical industry from start to finish. Some 80 percent of raw materials in America's drugs and medicines are imported. So the questions begin with the reliability of the supply of the raw materials. Production processes are highly automated, so will they be affected by Y2K? And will distribution and inventories be affected? The questions affect not only VA and veterans but all Americans.

Frankly, one of the concerns is that individuals who depend on the vital drugs and medications will try to hoard or stockpile them if they are not confident in the supply. The way to reassure the public is to provide accurate and complete information. At this point, there are only 8½ left. We have asked the Food and Drug Administration and the Pharmaceutical Manufacturers Association to testify today on what is being done about this important issue.

We have a lot to cover, so now I recognize our ranking Democrat, Ms. Brown.

OPENING STATEMENT OF HON. CORRINE BROWN

Ms. BROWN. Good morning. Mr. Chairman, I am pleased to join you in this, the subcommittee's fourth hearing over the last 2 years on VA's readiness for the year 2000. Through your leadership, the VA, sometimes called the sleeping giant of the Federal agencies, seems to have gotten its wake-up call regarding the Y2K risk. To its credit, VA has taken a real leadership role in alerting others, especially those in the health care industry, to those risks and finding national solutions.

I am pleased to note that the chairman, Steve Horn, of the Subcommittee on Government Management, Information, and Technology, Committee on Government Reform, recently recognized the VA's year 2000 progress with an "A", the only "A" he awarded to a cabinet-level department. I want to repeat that. The VA received an "A", the only "A" he awarded to a cabinet-level department.

As we get closer to the finish line on this Y2K race, we must not relax our diligence or let VA rest on its press notices. Fortunately, we can always count on the GAO and IG to bird-dog issues like this for us. This morning, I am looking forward to hearing their suggestions, as well as the observations of the Food and Drug Administration and the drug industry. Thank you.

Mr. EVERETT. Thank you very much.

Our ranking member of the full committee, Lane Evans.

Mr. EVANS. Thank you, Mr. Chairman. I just want to salute you for holding a hearing following through on this issue. We have to continue to ride herd on it. I appreciate you holding this hearing today.

Mr. EVERETT. Thank you.

Any statements that the members have, the full statements will be submitted for the record.

At this time, I would like to recognize Joel Willemsen, Director of Civil Agencies Information Systems, Accounting and Information

Management Division of the GAO and ask him to introduce his panel.

Before you begin, I again want to commend the GAO's important work, and particularly your staff, in documenting issues and educating the Congress and the American people on the importance of being ready for the year 2000. I know a lot of hard work and many hours and weekends were spent by your staff to produce this testimony. GAO is performing a very valuable public service and the nation should be grateful to them.

At this time, if you would introduce the rest of your staff and proceed with your testimony.

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

Mr. WILLEMSEN. Thank you, Mr. Chairman. Accompanying me are Helen Lew, Assistant Director, and Dr. Nabajyoti Barkakati, Technical Assistant Director.

Mr. Chairman, Ranking Member Brown, Ranking Member Evans, I appreciate you inviting us to testify today on VA's Y2K readiness. In addition, we will testify on the readiness actions of VA and FDA in the biomedical and pharmaceutical areas.

Overall, VA continues to make progress on Y2K. For example, VBA completed a draft business continuity and contingency plan in January, as well as a related planning template for its regional offices. VHA has also made progress in issuing its contingency planning guidebook to assist medical facilities in developing their contingency plans. VA also now reports that 100 percent of its mission critical systems have been renovated and implemented.

However, both VBA and VHA have testing remaining for some of their individual systems. Further, end-to-end testing of multiple systems supporting a key business function still must be done. Only after this testing is done can VA give additional assurance that key areas such as benefit payments should work as intended. At the same time, VA needs to be ready with its contingency plans in the event of unanticipated system failures.

VA also has more work to do in assessing and renovating its facilities systems, systems that are essential to the delivery of health care services. Setting deadlines for getting this work done can help VHA focus on these important systems in the limited time remaining.

Turning to the biomedical area, VHA has made progress in obtaining compliance information from manufacturers and in identifying specific equipment in the inventories of its medical facilities. Also, FDA, in conjunction with VHA, has established a biomedical

equipment clearinghouse that provides the public with manufacturers' compliance status information.

Less progress has been made in reviewing biomedical equipment test results. Last year, we recommended that VA and HHS take prudent steps to jointly review manufacturers' compliance test results for critical care and life support biomedical equipment to give added assurance that such equipment was, indeed, compliant. The response to our recommendation has been disappointing. For example, HHS said that submitting compliance certifications was sufficient and that it did not have the resources to undertake such reviews, although we are not aware of HHS ever requesting such Y2K resources.

In contrast to this position, some hospitals in the private sector believe that testing biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. In fact, hospital officials have told us that their testing has identified some noncompliant equipment that manufacturers had certified as compliant. We continue to believe that, at a minimum, independent reviews of compliance test results are necessary for critical care and life support items.

In the pharmaceutical area, VHA operations also face Y2K risks. For example, about half of VHA's prescriptions are filled by seven consolidated mail outpatient pharmacies which VHA has determined are not Y2K compliant. These are not scheduled to become compliant until mid- to late 1999, leaving little time for any unanticipated implementation problems.

To assess whether it will have a sufficient supply of pharmaceutical and medical-surgical products, VA has taken a leadership role in the Federal Government in determining whether manufacturers supplying these products are addressing Y2K. For example, VA has sent surveys to firms and 2 days ago posted the results to date on its publicly available website. On a broader scale, VHA chairs the Pharmaceutical Subcommittee which reports to the President's Council on Y2K.

FDA's actions in the pharmaceutical area have focused primarily on awareness activities and on providing guidance to its inspectors. FDA also told us that it is thinking about surveying organizations on Y2K. Given that it is now April 1999, it is a little late to only be thinking about this. FDA needs to decide now how it is going to proceed with this effort so that the nation knows where we stand on pharmaceutical Y2K readiness.

In conclusion, Mr. Chairman, VA has made progress with its Y2K efforts. However, key actions remain in the areas of testing, facility systems, and pharmacy operations. Action is also needed in the biomedical and pharmaceutical sectors to provide greater assurance to our veterans and to the American public that Y2K disruptions in these areas will be minimized.

That concludes the summary of my statement and I would be pleased to address any questions you might have.

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

Mr. EVERETT. Thank you very much.

GAO's written testimony indicates that Veterans Benefits Administration and Veterans Health Administration have not completed testing of their mission critical systems. When the VA's ap-

lications report 99 percent compliance, what happens if the VA platforms are noncompliant?

Mr. WILLEMSSEN. If the platforms are noncompliant, there remains a risk that we will have Y2K-induced failures in January 2000 and that is why the emphasis now at VA needs to be focused on broader system acceptance testing, testing all of those components within its systems to make sure they are Y2K compliant, and then going even broader than that to an area we call end-to-end testing and making sure that not only VA's systems but the systems of other partners, such as Treasury's Financial Management Service, are also compliant and those systems work together as intended on January 1, 2000.

Until such time as we have assurance that that work is done, there remains a risk of Y2K-induced failures. VA does have plans to do that testing over the next few months, so we are encouraged by that, but they are not quite there yet.

Mr. EVERETT. Would you explain briefly what a platform is?

Mr. WILLEMSSEN. A platform is the kind of computing environment that you would be working on, let us say, from a micro perspective, an operating system like Windows '95 or if you are in a major IBM mainframe environment, using an MVS operating environment. It is not the software application but it is the environment you are in, whether it is a PC environment, mainframe environment, or client server environment.

Mr. EVERETT. Please explain how noncompliant facility systems can disrupt health care delivery.

Mr. WILLEMSSEN. VHA and the health sector generally have special risks within this particular area of facility systems, because, as you might suspect, heating, venting, and air conditioning, along with special air handling systems in hospitals, are fairly critical to patient health, and to the extent that those systems are not compliant and do not work as anticipated in January 2000, there can be patient-related safety and health risks. For example, in specialized rooms within a hospital environment that use specialized air handlers to make sure that the rooms are germ-free, we have to make sure that those systems work as intended.

Mr. EVERETT. How long can VA hospitals operate if they have a local or regional power failure, if they are cut off a grid, for instance?

Mr. WILLEMSSEN. VHA has recently put out its contingency planning guidebook to its medical facilities and the medical facilities are supposed to submit their contingency plans the end of April. I believe, to the best of our knowledge, each of the facilities is somewhat different, but the instructions we have seen is that each of the facilities is supposed to have all their tanks full of fuel, but I believe those tanks may vary in terms of their volume, so I am not sure there is a specific answer. I believe that over the next several weeks, as those medical facilities complete their contingency plans, we will have more definitive answers to that particular question on how long they can go without electric power.

Mr. EVERETT. But it could be as short as 3 days?

Mr. WILLEMSSEN. That is what I have heard, but I do not have firsthand evidence of that. We are waiting to look at those contingency plans, and I think they will vary by facility. I have heard

ranges, again, not firsthand evidence, just I have heard, between three and 30 days, but I do not know for sure and that is something we definitely want to follow up on as they complete their contingency planning efforts.

Mr. EVERETT. Of course, we are mindful of the recent power outages up here and the fact that people were weeks without getting back on a grid.

VA and FDA have chosen to allow manufacturers to get their own compliance test results and not independently verify their results. How has the private sector addressed this issue? What is the GAO's position on this potential patient safety issue?

Mr. WILLEMSSEN. In terms of the private sector, we have contacted a number of hospitals and some hospitals have elected from a due diligence perspective to go and independently test some of these biomedical equipment items to make sure that they are year 2000 compliant. That is not to say that all hospitals have done that. Some have elected not to. It is a point of comparison to the position of FDA and VHA, which is, right now, we are going to rely on the certifications from the vendors and we do not want, per GAO's recommendation, to expend the resources to independently review the vendors' test results.

Mr. EVERETT. One last question. What should the FDA do in the next few weeks to get on top of the Y2K drug supply issue?

Mr. WILLEMSSEN. I think what FDA needs to do is lay out a strategy, a game plan, on exactly what their objectives are, what they are going to try to accomplish, what milestones they are going to set for those tasks, whether that includes surveying organizations or whatever the case may be. The most critical shortcoming in our opinion right now in the pharmaceutical area is the lack of data. We need data to be publicized on exactly where major pharmaceutical organizations stand. Providing and publicizing that data can help and assist in reducing any panic that otherwise may result because of the lack of data and rumors. So we will continue to push that particular message, not only in the pharmaceutical sector but in other related sectors.

Mr. EVERETT. Thank you. Ms. Brown.

Ms. BROWN. Thank you, Mr. Chairman.

I am concerned with the difference of opinion between GAO and the VA and the FDA about users reviewing manufacturers' test results for biomedical equipment. Could not patients be harmed if internal settings are inadvertently changed and not easily reset by a biomedical technician?

Mr. WILLEMSSEN. Yes, there is a risk of that, and that is why we continue to believe for critical care and life support items there needs to be a third party independent review of certifications that have been submitted by vendors.

Ms. BROWN. Do you not think that the self-testing could void the manufacturer's warranty and service agreements?

Mr. WILLEMSSEN. Additional independent testing does run that risk. That is why our recommendation is not to go as far as additional testing. It is to ask vendors to supply their test results on what they have done with the biomedical equipment item so that a third party can look at those test results and come to some con-

clusion about whether the certification statement is, indeed, accurate or not.

Ms. BROWN. What about the costs associated?

Mr. WILLEMSSEN. There could be some significant costs associated with this. We are not aware of any estimates being put together to do that for critical care and life support items. One consistent theme that I will tell you, having testified before a number of committees on Y2K, is to the extent that there are issues associated with the need for resources, committees are asking agencies, please, tell us what you need. We are not guaranteeing you will get it, but if you need something for Y2K, please make it known up front and early so decisions can be made as to whether those resources will be provided.

Ms. BROWN. I think the life-threatening situations would be a top priority.

Mr. WILLEMSSEN. Those are the ones that we wanted to focus on, life support and critical care items, because of the obvious impact that could occur.

Ms. BROWN. GAO has spent a lot of time overseeing VA's Y2K efforts. How would you compare it with other Federal agencies?

Mr. WILLEMSSEN. I would say, in large part due to the VA's early start, and in large part, that was spurred by the oversight efforts of this subcommittee, that has really made a major impact on getting VA ahead of the curve. I think VA is well positioned relative to other Federal agencies, and as I mentioned, in the biomedical and pharmaceutical areas, we view them as a government leader. Again, in part because of the questions and work of this subcommittee in those areas, I think VA has moved out relatively aggressively.

Ms. BROWN. Later this morning, Deputy Secretary Gober will testify that VA benefit payments will be made without interruption and VA health care facilities will be fully operational on January 1, 2000. For many, such assurances are the bottom line. How much confidence should this subcommittee and America's veterans have in Mr. Gober's assertion?

Mr. WILLEMSSEN. Well, a couple of points. One is no absolute guarantee can be given that systems will work as we think they are going to work on January 1, 2000. Secondly, that is why VA needs business continuity and contingency plans. Even with the best of efforts, systems outside of VA's control, such as electric power and telecommunications, could go down. VA needs to be, therefore, positioned with its contingency plans in the event of those things happening so that it can continue to deliver services.

So while I would agree that VA has made excellent efforts and progress with its work to date, there is much work remaining, and again, no absolute guarantees can be given, and that is why we need VA to continue its excellent work in the business continuity and contingency planning area.

Ms. BROWN. I understand as far as the paid benefits are concerned that the veterans will receive their paychecks, I guess, on the 31st so that it would not be a breakdown in the January payment for sure.

Mr. WILLEMSSEN. Let me defer to my Assistant Director on that. Are you aware of that?

Ms. LEW. Yes. It is our understanding that they plan to make the payments in December. I think the 31st or 30th, and this will allow them time, if there are any problems. They have the month of January to correct those problems.

Ms. BROWN. Thank you, Mr. Chairman.

Mr. EVERETT. I want to thank our ranking member for her questions.

One final question. What is the picture of telecommunications and electric power as it might affect VA hospitals?

Mr. WILLEMSSEN. We have recently done some area in the electric power area and the Department of Energy is working with some of the private associations to get on top of that. The latest available information is from November 1998, which indicates that power utilities were reporting on average that they were about 44 percent complete with their remediation and testing for electric power. However, there were many of these utilities that do not plan to be done until the latter part of 1999, which we thought was too late. So we have suggested that the Department of Energy, working with the President's Council, try to move up those schedules.

In addition, we have also suggested, related to a comment I made earlier, that the President's Council work with State regulatory commissions to try to look at more public disclosure on individual utilities and where they stand. Right now, we do not really know on an individual utility-by-utility basis where they are at, and we would like to see that kind of disclosure at least by the summer so that citizens will have a better idea of exactly where their local power utility is on Y2K.

Mr. EVERETT. That was one of the points of my question, is that some of these VA hospitals are served by local utility companies and we have no idea what status they are in.

Mr. WILLEMSSEN. That is correct. That is why we would like to see the public disclosure, again, working with the State regulatory commissions. I mean, some VA hospitals may, in fact, have had lengthy discussions and exchange of information with their local providers so they may feel more at ease or less at ease depending on what the data shows. But this is not uniformly the case. That is why we would like to see more public disclosure on an individual basis of these major power providers.

Mr. EVERETT. Thank you very much, Mr. Williamson. I again would like to point out that I feel like this nation owes you, your staff, and GAO a tremendous debt of gratitude for your work in alerting the country to this problem, because we would have been in one huge mess, frankly, I believe, if you had not done that. Thank you very much.

Mr. WILLEMSSEN. Thank you very much for your comments, Mr. Chairman.

Mr. EVERETT. I would now like to recognize Michael Slachta, the Deputy Assistant Inspector General for the Department of Veterans Affairs, and if you will, Michael, if you would introduce your staff, I would appreciate it.

STATEMENT OF MICHAEL SLACHTA, JR., DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITING, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY STEPHEN GASKELL, DIRECTOR, CENTRAL OFFICE AUDIT OPERATIONS DIVISION, DEPARTMENT OF VETERANS AFFAIRS; AND THOMAS PHELPS, PROJECT MANAGER, CENTRAL OFFICE AUDIT OPERATIONS DIVISION, DEPARTMENT OF VETERANS AFFAIRS

Mr. SLACHTA. Mr. Chairman, Ranking Member Brown, I am pleased to be here today to comment on the Department of Veterans Affairs efforts to address year 2000 issues. Mr. Stephen Gaskell, Director of our Central Office Operating Division, and his Audit Manager, Mr. Thomas Phelps, accompany me.

While VA has reported its completion of renovation and implementation of all mission critical systems, our recent audit identified a number of key actions in other selected areas that could help make the Department's Y2K efforts more successful, reduce operating costs, and ensure continuity of operations. Given the importance of—

Mr. EVERETT. Mr. Slachta?

Mr. SLACHTA. Yes, Mr. Chairman?

Mr. EVERETT. Would you please pull the microphone a little closer to you? Thank you, sir.

Mr. SLACHTA. Given the importance of correcting Y2K problems in VA computer systems and ensuring that veterans receive uninterrupted services, the OIG has been involved with the review and oversight of the Department's Y2K implementation since 1997.

In early 1998, we initiated a national audit of VA's Y2K implementation. In an effort to assure complete coverage of this vital issue while efficiently using scarce audit resources, we coordinated our national audit efforts with those of the General Accounting Office. Before the start of our audit and again during the audit, our staff met with the GAO staff to share information and assure that our efforts and theirs were complimentary.

As a result of our discussions with GAO, our audit focused on identifying areas where VA's Y2K implementation efforts could be strengthened. As part of our initial work, we visited the three primary VA data processing centers. These are the Veterans Benefits Administration's benefit delivery centers in Hines, IL, and Philadelphia, PA, and the Department's main administrative data center, the Austin Automation Center in Austin, TX. While in Austin, we also visited the Finance Service Center to review their Y2K efforts.

As part of our audit test, we sent survey questionnaires to VA's regional offices, medical centers, and selected VA central office activities requesting general information on Y2K implementation and status information in key areas involving personal computers, locally developed applications, commercial off-the-shelf products, local area networks, data exchange and interfaces, facility preparedness, and biomedical devices. We received 209 responses out of 223 activities that were surveyed. Ten VA medical facilities did not respond to our request.

Based on our analysis of the survey responses and discussion with Department officials, we selected 20 VA field facilities for site visits. We visited 15 VA hospitals and 5 regional offices. In select-

ing the medical centers, we included six of the ten centers that did not respond to our survey.

Given the time sensitivity of all Y2K issues, we provided the Department with four interim survey advisory letters during the course of the national audit. These letters provided early notification to the Department of our audit results so that prompt corrective actions could be initiated to address the Y2K-related issues that were identified. Department program officials responded positively to the advisory letters and reported initiation of various corrective actions.

On March 11, we forwarded a draft report of our findings and recommendations to VA's Acting Assistant Secretary for Information and Technology. Comments to the reports are expected by April 22. The draft report recapped our findings that enhancements to VA's Y2K implementation efforts could be achieved at VA's data centers, for selected central office activities, and at selected field facilities in VHA and VBA.

While our review of Y2K implementation activities at the VA's data centers found that Y2K efforts were generally proceeding according to the Department's plans, some Y2K-related issues needed attention. The key issues identified at the data centers included assurance of continued infrastructure support, such as electricity and water; the need to contact VA's trading partners and value-added networks concerning Y2K compliance of electronic data interchange transmission, and receipt of VA procurement transactions; preparation of a zero hour plan covering operational procedures for the night of December 31, 1999, and the succeeding day; approval of pending requests for equipment and software replacements that would reduce operating costs by \$1.5 million and enhance Y2K implementation efforts; authority to pay retention bonuses to staff involved with Y2K implementation efforts; inclusion of all computer applications in the Y2K assessment and renovation process; and reporting of the status of renovation work on mission critical systems.

While our audit found that both central office and field facilities were actively engaged in addressing Y2K implementation requirements, additional efforts were needed to assure that necessary work was successfully completed and the cost of the Department's Y2K-related work was accurately identified and reported.

Key areas that needed to be addressed included completion of medical center risk analysis to address potential infrastructure support failures external to the VA; assuring the Y2K compliance of computers, environmental control systems, and other medical devices provided to veterans for use in their homes; assuring the Y2K compliance of all biomedical devices, including those used in VA's Research and Development Service; completion of Y2K assessment and testing of computers located in facility tenant activities, such as VA's Research and Development Service; assuring adequate procurement lead time for acquisition of replacement biomedical equipment; completion of the memorandums of understanding with data exchange partners to document the Y2K compliance; resolution of infrastructure support issues involving regional offices located in General Services Administration managed buildings; and

finally, tracking the cost of all Department Y2K implementation efforts.

The draft report includes recommendations to assist the Department's Y2K implementation efforts, ensure continuity of operations and delivery of services and benefits to the nation's veterans and their beneficiaries. Based on the audit findings and the continued Y2K risk to the VA, we concluded that Y2K areas should continue to be monitored by the Department as a potential material weakness area.

This concludes my testimony. I would be pleased to answer any questions you may have.

[The prepared statement of Mr. Slachta appears on p. 66.]

Mr. EVERETT. Thank you very much.

You just mentioned biomedical and other devices that are used in home health care for our veterans.

Mr. SLACHTA. Yes, sir.

Mr. EVERETT. Would you elaborate on any Y2K problems that they may have?

Mr. SLACHTA. What we found when we were out at the facilities was that there was biomedical equipment such as, infusion pumps, personal computers, and electric wheelchairs that are worked on the sip-and-puff methods, that were not included in the Y2K assessment and we notified the Department that these should be included. I could not possibly give you the full scope of all of these.

Mr. EVERETT. Would you submit something for the record for us?

Mr. SLACHTA. We will be glad to.

Mr. EVERETT. Thank you. How about noncompliance on biomedical equipment in the research community?

Mr. SLACHTA. Tom, do you want to handle that?

Mr. PHELPS. Our review of the research facilities that we actually visited on the eight sites, in most cases, the equipment itself is data gathering or analysis equipment, but some equipment is actually being used to treat veterans as part of a research protocol. They also had not been included in the analysis, and the plan for implementing changes to biomedical equipment within the facility. Failure of this equipment puts a veteran at risk, life support at risk, perhaps, like any other, and it also may, in fact, negate the results of research that is being conducted, since a failure in one of the systems may mean it fails to process at all or processes incorrectly.

Mr. EVERETT. The Austin Automation Center conducts a couple of million electronic data transfers with over 1,700 trading partners. What is the impact on VA's business continuity if the trading partners are not Y2K compliant?

Mr. SLACHTA. That is a good question. If they are not Y2K compliant, we are not going to be able to make procurements over the system. I mean, that is the bottom line. We know that the technology, the frame relay, is compliant. It is a question of whether or not the trading partners have actually determined the compliance of their own equipment, their own programs and applications.

Mr. EVERETT. So we are dealing with a couple million data transfers—

Mr. SLACHTA. About 1.8 million transactions and about \$3 billion worth of procurements in a year.

Mr. EVERETT. If they are not compliant, it could be serious.

Mr. SLACHTA. Yes, sir.

Mr. EVERETT. Finally, what is the IG's assessment of the GSA's preparations for Y2K as it affects the GSA office space that VA occupies?

Mr. SLACHTA. At the time of our visit at the regional offices and at the data processing centers that were under GSA control, GSA's on-site managers were still waiting direction from their regions.

Mr. EVERETT. Thank you. Ms. Brown.

Ms. BROWN. Thank you. In your testimony, one of the key areas that you indicated the VA should include was computers and medical devices in VA's Research and Development Service. Did you also look into what, if any, impact VA affiliates with medical schools that have data linkage, shared equipment, et cetera, would have on VA's readiness?

Mr. SLACHTA. Tom, do you want to answer that?

Mr. PHELPS. As far as we could, we looked at any connections to activities on campuses. Once it left the campus, it became really a data interchange and we simply asked the question, are you, in fact, sharing data? We pointed out in our draft report that tenant activities, as an example, research, were missing from most of the PC surveys that had been conducted. The same is true with other shared equipment on the campuses. In most cases, data is actually not transferred off the station. It is a sharing of results, but it is not a data interchange in that there is information passing from one system to another without any human intervention.

Ms. BROWN. So what do you think?

Mr. PHELPS. I think that the same—

Ms. BROWN. You are saying it is not human, but it is the computers, the linkage.

Mr. PHELPS. The linkages that exist are computers, that is correct. Our interpretation of a data interchange means information passes from point to point without human intervention, data that is date sensitive. The results of a test that pass from one point to another are only sensitive in the date of the test, in whether or not that shows up appropriately. So we did not look beyond whether or not they were transferring data in that manner.

Ms. BROWN. Okay. As I noted to GAO, later this morning, Deputy Secretary Goyer will testify that VA benefit payments will be made without interruption and VA health care facilities will be fully operational on January 1, 2000. What confidence should the subcommittee and America's veterans have in this assertion that everything is going to be okay?

Mr. SLACHTA. I think GAO's answer is really appropriate. Nobody knows it is going to be 100 percent effective. I think VA is working very hard to make sure that it is ready.

Ms. BROWN. Those are my questions. Thank you.

Mr. EVERETT. Thank you very much, Ms. Brown.

Mr. Slachta, I want to again thank you for the work you and your staff have done. I think what you have all done is sort of filling the gaps to round out for us the complete picture that we need to have, so I thank you very much.

Mr. SLACHTA. Thank you, sir.

Mr. EVERETT. At this time, I would like to recognize the Honorable Hershel Gober, Deputy Secretary of the Department of Veterans Affairs. If you will, Mr. Gober, introduce your staff.

Mr. Gober, I am reminded of our meeting some couple of years ago when we started to work on this and I certainly appreciate the dedication that you have put forward in reaching the position that we have reached. Again, if you will introduce your staff and then we will have your testimony.

STATEMENT OF HERSEL W. GOBER, DEPUTY SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY HAROLD F. GRACEY, JR., ACTING ASSISTANT SECRETARY FOR INFORMATION AND TECHNOLOGY, DEPARTMENT OF VETERANS AFFAIRS; ERNESTO D. CASTRO, VA YEAR 2000 PROGRAM MANAGER, DEPARTMENT OF VETERANS AFFAIRS; SALLY L. WALLACE, VBA YEAR 2000 PROGRAM MANAGER, DEPARTMENT OF VETERANS AFFAIRS; LEONARD R. BOURGET, VHA YEAR 2000 PROGRAM MANAGER, DEPARTMENT OF VETERANS AFFAIRS; AND STEVEN WEXLER, CHIEF, BIOMEDICAL ENGINEERING, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS

Mr. GOBER. Thank you, Mr. Chairman. I have a written statement.

Mr. EVERETT. Your testimony will be entered into the record.

Mr. GOBER. Thank you, sir. I will try to be very brief because I want us to have a very candid discussion and I want to ask our folks to answer all your questions. I want to address any questions that came up from the previous testimony from the two individuals.

I would like to introduce the people I have with me here today. This is my fire team, Harold Gracey, who is our Acting Assistant Secretary for Information and Technology, and this is really his project. He was a great Chief of Staff, as you know, at the Department of Veterans Affairs for several years, has been with the VA for a long time, and he has really dedicated himself to this project.

Ernesto D. Castro, who is our VA Year 2000 Program Manager from the Department of Veterans Affairs; Sally Wallace, who manages Y2K for the Veterans Benefits Administration; Leonard Bourget, who is the VHA Project Manager on the end; and Steve Wexler, who is the Chief of Biomedical Engineering, Veterans Health Administration, who will be pleased to address the question about the biomedical testing.

Mr. Chairman, I am pleased to appear before this committee today. I recognize Ms. Brown. This is a very important issue to us. I want to recognize my associates here, who are the experts in bringing VA's information and technology assistance into compliance for providing service to our veterans and their families in the year 2000.

Mr. Chairman, you were among the first who expressed early on a real concern for potential problems that might develop if the nation's computer systems are not Y2K compliant. When you and I met in July of 1997, just one on one, you expressed your concern about the impact Y2K might have. I promised you then—you asked me very pointedly, you said, "Who is responsible for this?" and I

said, "I am." I promised you that VA would be ready—you know, in the military, we never say ready, we say prepared—and that I would be personally accountable. I reemphasize that again today. I further promised that VA would provide you and this subcommittee regular reports on our progress and I am satisfied that we have done that in an appropriate manner.

My associates across VA have worked very hard to ensure that we will be ready for the year 2000. I have only the highest praise for the diligence and determination they have displayed in moving aggressively to identify any area in which Y2K problems might impede the delivery of services to America's veterans.

I am here to say that I am confident, and I would like to take out the word fully confident, because only a fool would be fully confident of anything, because today in our hospitals, and I want to take out the fully operational, because we are not fully operational in many of our hospitals at this very moment, but I am confident that we will be operational and be able to deliver our benefits.

And on the benefits, yes, we will deliver our checks before December 31, but that is because the holiday falls on a Saturday and we will pay on a Friday. We do this routinely. It is not because we are afraid the system will not work. In fact, our systems are up and running even as we speak right now. We have completed the year 2000 renovation, validation, and implementation of our application, and as we speak, those systems are running. This includes all benefit payments, related applications, and applications supporting health care. The information systems supporting operations of our national cemeteries are also fully 2000 compliant.

Mr. Chairman, with all that said, we will continue to test our information systems and all supportive equipment in our buildings to be sure that we have taken every reasonable action possible to be prepared for the year 2000. Even though I am confident we are going to meet the challenges of Y2K, I will not be overconfident and will stay engaged on this very, very important issue. In addition, we will be working with our partners in government and industry to be sure that they can fully support our services to veterans and their families.

Throughout the Department, we have developed a business continuity and contingency plan for the year 2000. Now each regional office and VA medical center is customizing those plans to meet their individual local needs. These customized plans will be completed by the end of April. The details of all these elements of preparation to make sure that our services to veterans and their families are not interrupted by the Y2K phenomenon are contained in my written testimony.

Mr. Chairman, at the Department of Veterans Affairs, we are committed to ensuring that our information systems will be ready for the coming millennium. I thank you and the members of the subcommittee for your careful oversight of our progress and the support you have given us throughout this process. I also want to thank GAO and our IG for the support that they have given us. I appreciate this opportunity to present our progress in preparing for the year 2000.

Mr. Chairman, this concludes my remarks and I would be happy to answer your questions, and I would ask that, with your permis-

sion, that when a specific question is asked of a technical nature, that one of my colleagues be permitted to answer that question.

Mr. EVERETT. Without objection.

[The prepared statement of Mr. Gober appears on p. 69.]

Mr. EVERETT. First of all, let me say that I am mindful of the work that you and your staff in VA has done, and as our ranking member, Ms. Brown, has pointed out, in some areas, you certainly led all government agencies, and we are appreciative of that.

I would point out that we are now sort of at the place where the rubber meets the road and there will be some issues that we will sort of hone in on and try to make sure that we are all in agreement. Let me start off by picking up on a subject that we have not discussed today and that is, is it correct that none of the VA's seven mail order pharmacies, called CMOPs, are Y2K compliant? Also, do they provide about 50 percent of veterans' prescriptions?

Mr. BOURGET. If I may, Mr. Chairman——

Mr. EVERETT. Certainly.

Mr. BOURGET. That is correct. As of today, none of the seven CMOPs, which do provide 50 percent of the prescriptions in the VA, are compliant. That is a combination of the software which orders the prescriptions, which is the VISTA software, which is now compliant, and then commercial products which govern the distribution mechanism, very highly automated systems for capturing the prescriptions in bottles and packaging them and mailing them out.

Those computer platforms and operating systems, as Mr. Willemssen described earlier, are in the process of being renovated. I received a new schedule last night which says that the first of the seven will be compliant in May and then the remainder will be made compliant in June, July, and August. So the latest date that we have as of today is August of 1999. We are working with the manufacturer to accelerate that date.

Mr. EVERETT. This is a pretty critical issue. Was it just overlooked? Did something fall through the cracks?

Mr. BOURGET. No, sir. It is a combination of the products that are available from the vendors. These are commercial products that we have to buy from the vendors. These are commercial products that we have to buy and the vendor products are now becoming available and will be installed by a third party in our CMOPs. We are also, at the same time, working on contingency planning for the possibility that one may not be up, and what happens is the prescriptions are distributed to the other CMOPs so that there is no interruption of service to veterans.

Mr. EVERETT. And this third party handles the last two that are supposed to be compliant?

Mr. BOURGET. They are installing the new software products in all seven. The first, as I said, is Leavenworth, Kansas, and it will be ready in May, and then the remaining six will be installed over the period of the next 3 months.

Mr. EVERETT. I am pleased to hear that it has been moved to August rather than the December date that we had.

Mr. BOURGET. Yes, sir. That was not an acceptable date to VHA management.

Mr. EVERETT. VA's computer software applications are more than 99 percent compliant, but as we have been talking about this morning, Mr. Gober, what about the platforms that run the applications? It is my understanding that if they are not compliant, then all VBA's mission systems are potentially affected. Would you please sort of give us an update on the situation?

Ms. WALLACE. Yes, Mr. Chairman. I would be glad to. All of our platforms except for one are compliant. Our Honeywell/Bull was made compliant last year, in July, and then we rolled it out to Philadelphia in September of 1998 and we do not have any issues associated with that platform. The Honeywell/Bull is where the benefits delivery is processed. That, and also on the IBM, and the IBM at Hines was made compliant back in November. We did have an issue with a compiler that we resolved in February. All of the runs have been recompiled and those were completed on the fifth of April.

The only outstanding issue in terms of major compliant issues is our NUMA-Q [ph.]. We have a NUMA-Q. It is a super mini-computer we use in Austin. Now, the test platform is compliant, but we have hesitated to install a final piece on the production because we do not want to bring production down until we know it is going to work.

We have some minor third party issues that are outstanding and we are also waiting on one third party product vendor who, it looks like, is going to have a patch or two that are still forthcoming.

Mr. EVERETT. What has been the remediation failure rate in the VA? That is, how many times did the first attempt to become Y2K compliant fail? Do we know?

Ms. WALLACE. We really have not tracked that, but we have been making year 2000 changes since in the late 1970s. We made changes in 1982 and we made changes in the 1990s. We really have not had that many failures and we have not tracked them.

Mr. GRACEY. We did have one, if I could, Mr. Chairman, we did have one major system, which was the BIRLS, Benefits Identification and Records Locator System, where a contractor provided the renovation and then in the testing phase we discovered that everything was not renovated as the contractor had alleged. We brought our government staff to bear on that, moved the contractor off the job, and completed that renovation and implemented the system in October without a hiccup. We have had some other occasions where testing proved valuable and caught some problems, which is what it was designed to do.

Mr. EVERETT. I see the yellow light is on, but finally, I would like to commend the VA for leading the way on building a website database on pharmaceutical Y2K information. How specific would VA like pharmaceutical information to be for its website, and is that data being provided by the manufacturers?

Mr. BOURGET. The information that the VA sought from its manufacturers was as a customer to its suppliers and we asked some very specific information. We then wrote back to those same manufacturers and said, we are going to display this information so that it is available to the public. We believe, as consumers, that is an appropriate level of information, reassurance that the manufacturers are ready, and if they are not, what they are doing about it.

Our response rate to date has been about 55 percent. We are still working with the pharmaceutical and medical device community to increase that response rate.

Mr. EVERETT. Thank you, Ms. Brown.

Ms. BROWN. Thank you, and welcome back, Mr. Gober. My constituents and I are glad to hear that all the VA services will continue without a hitch after January 1. Over the spring recess, I certainly got a lot of questions about what was going to happen with the January VA checks.

I also want to congratulate you and your staff for the "A" for VA's Y2K progress from Chairman Horn. As I noted in my opening remarks, you were the only cabinet-level department to receive an "A".

You are also to be commended for VA's leadership in Y2K readiness, especially in the area of health care. Your web pages are most helpful. The timely information you are providing over the Internet regarding medical device compliance is a valuable public service to America.

Last night, I received a copy of the VA's contingency plan handbook, this book. Mr. Chairman, have you seen this, this handbook?

Mr. EVERETT. Yes, I have.

Ms. BROWN. This detailed, strategic approach to reducing potential Y2K risks to patient safety, of course, helps VA medical facilities and their veteran patients. But I am pleased that this guidebook is being made available to assist community hospitals and other local health care organizations address their contingency planning requirements in case their systems fail on January 1. I really think government needs to do more partnering in this way and I want to commend you on that.

Would you comment on the IG's concern about computers, environmental control systems, and other medical devices that VA has provided to veterans for use in their homes?

Mr. BOURGET. If I may, Congresswoman, that is a concern and we are addressing that in two ways. We are working with the program offices in headquarters, prosthetics and blind rehab, and we are also including home health care as a specific item for VISN (Veterans Integrated Service Network) directors to check with the medical care facility directors.

Further in that guidance document which you just held up, there are specific requirements for the hospitals to check with their patients in home health care. In many instances, we will be recommending that they bring those patients back into the hospital because they will be safer in the VA hospital than they would in their homes because of our emergency electrical capability.

Ms. BROWN. Thank you. What assurances can you provide that computers and biomedical devices being used in VA's Research and Development Service or VA affiliates who are linked to the VA database are Y2K compliant or will not pose direct harm to the patients if they are not in compliance?

Mr. BOURGET. Again, a two-phase approach. We are going with the VISN directors checking specifically on the inclusion of research medical devices and computers when they do Y2K oversight for the medical care facilities, and we are working with the chief research and development officer in headquarters to do a survey

from a program point of view. So we are going to ask the questions both programmatically and operationally to make sure that all of those devices and PCs have been included in the hospital inventory and the hospital Y2K remediation.

Ms. BROWN. My last question, what assurances of Y2K compliance do you have from GSA regarding its infrastructure support of VA regional offices located in buildings it manages?

Ms. WALLACE. Yes, ma'am. We have done a survey of our own, and we completed that back in 1998. We have been in close contact with GSA. We have been attending their meetings. But the regional office directors are well aware that they need to rely on their own resources to get the job done.

Ms. BROWN. Okay.

Mr. EVERETT. Thank you, Ms. Brown.

As Secretary Guber has mentioned, we want to have a very candid conversation here, and I am going to extend it for a second round.

Ms. Wallace, in speaking of the platforms being in compliance, the NUMA-Q and the sequence, which are the backup, are they in compliance?

Ms. WALLACE. Okay. The production NUMA-Q, it is not compliant. It has got one software upgrade that needs to be made. But our test NUMA-Q system has been compliant, so we have been able to test our applications on that platform and we have delayed the upgrade so that we do not interrupt production.

Mr. EVERETT. VA's Austin data center processes veterans' benefit checks on its computers and I understand it has an emergency power system and fuel on hand for 5 days. What happens if Y2K power problems go beyond the 5 days?

Mr. CASTRO. Mr. Chairman, I may be able to answer that. The benefit checks are actually made at Hines Data Processing Center in Chicago, however the Austin Automation center has been working with the local Texas power company and is trying to get their level of priority for power restoration increased. The local Texas power company will take care of hospitals and life-threatening issues first.

The 5 days may be adequate, but we can get additional fuel to run the generators past the 5-day period. They just keep on stock the 5-day supply. But for Hines, I think we have 3 to 5 days at Hines, which is actually where we do the benefits processing.

Mr. EVERETT. Let us assume we have a situation like we did up here in the Northeast not long ago and you had folks off the grid for a couple of weeks. Would it not be logical to assume that everyone would be out there buying the fuel for the generators and there might not be fuel available?

Mr. CASTRO. Well, one thing we are trying to encourage through Mr. Koskinen is that we do not expect that type of failure. We do not want people to hoard gasoline or fuel. We think a 3-day to 5-day period of time is reasonable and prudent.

Beyond that, we do not expect that kind of interruption. We have been working with the power companies, as Joel mentioned earlier, to assess what they have stockpiled and we are finding that in the normal course of business, they keep 3 to 5 months of supplies to keep the power running. For example, here in Washington, DC, at

PEPCO, they are going to be keeping extra electrical capacity available, so if there are issues.

What they are looking at in the power companies are scenarios like you are presenting, where there are ice storms or other problems, and they are going to be looking at that this year and the electrical companies will be contacting their customers to assess if we are going to be on or off so they can balance the load so there are not brownouts or outages.

Mr. EVERETT. In describing the communications between Austin and, did you use the term local power company?

Mr. CASTRO. Yes, for Austin.

Mr. EVERETT. Is that a municipality that sells the power or is that a part of a larger system?

Mr. CASTRO. As I understand it, sir, there are three grids in America. There is an Eastern power grid, a Western power grid, and Texas. So they essentially have their own grid, being the size of the State. The Center has been working with the City of Austin to make sure we are on a priority level for restoration. They are aware of it and we continue to work with them.

Mr. EVERETT. What has the VA health care system done for emergency planning—we talked about some of this—should the VA hospitals be called upon by surrounding communities to provide emergency health care services, say that there are serious power grid problems there again?

Mr. GRACEY. As you know, Mr. Chairman, since you have conducted reviews of what we have done in the past, we are often involved in exactly that situation in communities. As a result of Y2K coming, which is, if the worst were to happen, a disaster for which we know in advance the disaster date and events, we are pulling those plans out, reviewing them facility-by-facility level and examining how we interact with the community, how we would respond, what that would mean, not only to the operation of our own facility but how we would support the surrounding community and interact. That is part of the facility-by-facility contingency planning update that is going on right now.

Mr. EVERETT. You say HHS is coordinating these efforts?

Mr. GRACEY. HHS, when there is a Presidentially-declared disaster, is the commander, if you would, of the Federal health care presence. We, however, are the only substantial provider of Federal health care and so we are usually a resource in the community that plays a major hands-on role in providing staff, equipment, supplies, and facilities.

Mr. EVERETT. And VA is satisfied that these efforts are adequate?

Mr. GRACEY. Again, like lots of the other issues we have talked about, it is a local issue and so it takes very hard work at each site in order to make sure that the plans are well thought through and actually executable. But we are as comfortable as you can be knowing a disaster might be coming.

Mr. EVERETT. Finally, VA did not request any additional funding from Congress for the Y2K compliance, so am I correct in saying that funding has not been an obstacle to compliance, and how much has the VA spent on Y2K compliance?

Mr. GRACEY. We have spent about \$200 million over the last several years. Because we got such an early start, Mr. Chairman, we were able to spread out some of the work that we would have otherwise had to accomplish in a shorter period of time and, therefore, spread it across budget years and do a lot of things as a matter of course, for example replacing equipment, by rearranging schedules and doing one place ahead of another. So you are right. We have not requested any additional resources for Y2K.

Mr. EVERETT. Thank you. Ms. Brown.

Ms. BROWN. Yes. I just want to commend the VA for their leadership in this area, Mr. Chairman. Because of the number of questions that came up during the recess from my constituents at town meetings, I think it would be good if we could just kind of maybe do a joint statement on the progress of this committee, VA, and commend you for your leadership for putting VA ahead of the game. There is a lot of concern in the community concerning Y2K.

Mr. EVERETT. I certainly thank the gentlelady and we would be happy to do that.

Again, Secretary Goyer, let me echo what our ranking member has said. We appreciate the fact that VA is a leader in this. A great deal of that credit goes to you and your staff. I, for one, am very grateful that we were able to have our candid conversation in the very beginning and decide to fix this problem and that we are in the position that we are today. Thank you very much.

Mr. GOBER. Thank you, sir.

Mr. EVERETT. At this time, let me recognize Mr. William Hubbard, Acting Deputy Commissioner for Policy for the Food and Drug Administration. Mr. Hubbard, if you would introduce your panel and then proceed with your statement, and your statement will be entered into the record.

STATEMENT OF WILLIAM K. HUBBARD, ACTING DEPUTY COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY TOM SHOPE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION; AND MARTIN GOLDBERGER, CENTER FOR DRUG EVALUATION RESEARCH, FOOD AND DRUG ADMINISTRATION

Mr. HUBBARD. Yes, Mr. Chairman. Thank you, Mr. Chairman. To my left is Dr. Tom Shope of our Center for Devices and Radiological Health, who has been responsible for our biomedical products. To my right is Dr. Martin Goldberger of our Center for Drug Evaluation Research. He is our resident expert in drug shortages at FDA.

I have a written statement for the record, Mr. Chairman, but I will not read it today. I will not take your time. But I do think that I can say we have taken a number of steps already in this area of pharmaceutical availability, as well as devices. As you know, we have worked a lot on our internal system to make sure they are all compliant.

We have created the biomedical product website that I am sure you are well aware of. We have given the pharmaceutical industry a significant amount of guidance about Y2K and the need to be concerned about it. We have developed an inspectional strategy so

that when our investigators are in firms, they know to ask these sorts of questions. We have developed rapid response contingency plans for problems that may appear with drug firms or device firms as the year 2000 approaches.

We have done quite a bit of liaison with the Congress, of course. There have been a lot of questions and we certainly appreciate your leadership in this.

We have done a significant amount of outreach to the industry to work closely with them by sending them letters particularly asking them to focus on issues like sole-source drugs and these foreign suppliers that you mentioned earlier. We were one of the instigators of a recent conference by the drug industry to increase awareness by individual companies. We are working closely with the VA's pharmaceutical acquisition and distribution group, and, of course, there is this planned White House summit on pharmaceuticals that I am sure you know about that we certainly intend to participate in.

I think the real question is, what more can we do? What is next for FDA? And there, we are examining a number of options, whether to push the industry more and assure that they are being certain that their products are compliant. We also are looking at whether we could utilize the existing industry surveys of their members to determine if that is sufficient information to reassure the public.

And we are also considering doing our own survey with the hope of perhaps getting a greater response rate and a greater ability to assure the public, because in the end, that is the goal, is to assure the public that there will not be a problem, that the drugs will move out of the manufacturing facilities into the pharmacies and the hospitals and the VA facilities and the DoD facilities and wherever they go. So our goal is to work with the VA and other components of the administration so that patients will have access to prescription drugs.

With that brief introduction, Mr. Chairman, I will be glad to take questions.

[The prepared statement of Mr. Hubbard appears on p. 84.]

Mr. EVERETT. Thank you very much.

When will the FDA's list of compliant equipment become user functional by listing specific makes and models of the equipment?

Mr. HUBBARD. I believe you are talking about medical devices. I will ask Dr. Shope to answer that.

Dr. SHOPE. The website operation is functional currently. We sent our letter to the manufacturers requesting information on compliant products. That letter went out dated March 29, and I think to date we have had return information from about 30 manufacturers already. The data is coming in. As the data arrives, it gets put into the database, and so the database is growing daily and the search capability and functionality is there now.

Mr. EVERETT. That letter went out when?

Dr. SHOPE. March 29.

Mr. EVERETT. But we have almost 400 of those manufacturers out there.

Dr. SHOPE. I think maybe I am answering the wrong question here.

Mr. EVERETT. The medical device manufacturers.

Dr. SHOPE. Right. We have just recently requested manufacturers to give us information, a listing of all their compliant products, and I thought that was the question you were posing.

I think you are asking about the situation with manufacturers of medical devices that we asked to report noncompliant products and where we stand with that effort. To date, we have raised our estimate of the number of the manufacturers that we think make vulnerable products, based on the kinds of information we have received over the past year, so we are now looking at about 2,200 manufacturers that make potentially vulnerable products. These are the type of products that could use computers in their design and operation.

We currently have less than 400 of those that we have not heard from, not specifically reporting to us the status of their products. We are continuing to follow up individually with those companies. Our contractor is attempting to make telephone contact with them to determine their situation.

Mr. EVERETT. You know, you only have 260 days left to do this. I do not—well, perhaps I do mean to be critical, but it seems to me that the FDA should have started this process a long, long time ago.

HHS stated that it did not have the resources to undertake an independent review of equipment manufacturers' compliance certification. Has HHS ever asked Congress for the resources, and if not, why not?

Dr. SHOPE. We have not made such a request. I think the question in my mind, and I think at FDA, is the feasibility of that. The situation with medical devices in the U.S., our whole regulatory process, when products come to market initially, they do not get that kind of oversight in detail by FDA. We review the manufacturers' processes for designing and developing products and their production capabilities during our inspectional efforts.

Any remediation that is being done to a product for the specific Y2K problem is being done the same way they fix any other kind of problem and they have procedures in place, their quality systems, to do this. We have our oversight through our factory inspection process.

Mr. EVERETT. Of course, we do not have a Y2K problem to occur every day, either.

Dr. SHOPE. No, sir.

Mr. EVERETT. Let me ask you why, again, has the VA had to take the leadership and not FDA in obtaining and sharing information of Y2K readiness of the pharmaceutical industry?

Mr. HUBBARD. Well, I repeat, Mr. Chairman, we have done a number of things. We believe that our main responsibility is assuring that a manufacturer of a product we regulate can adequately make that product and ship it on to the pipeline. We have much less authority and responsibility and ability to control the pipeline once it gets there.

We certainly are participating and will continue to participate and perhaps participate more in assuring that these manufacturers are Y2K compliant and that they can produce product and move it into the pipeline. Now, there are questions, of course, about wheth-

er there is public anxiety that causes people to get drugs from their pharmacy through a prescription that could cause shortages. That is not really within FDA's traditional role. We certainly want to help in that, but our main interface with pharmaceuticals is with assuring that the manufacture of those pharmaceuticals is safe and effective, and thus far, the industry is assuring us that they are worrying about the problem and making their systems compliant.

I think there is a question about whether the government should independently go back out and affirm that what the industry is saying is accurate, and we are talking to the industry among ourselves about whether that, in fact, would be a necessary thing to do.

Mr. EVERETT. Ms. Brown.

Ms. BROWN. Thank you. What is FDA's policy on who bears the costs of renovating a medical device so that it can be Y2K compliant, the manufacturer or the user?

Dr. SHOPE. The situation with regard to upgrades or remediation of a medical device is primarily a commercial interaction between the purchaser and the seller. FDA does not have a role in that issue except for the situation where there is a problem with a product that presents under the Food, Drug, and Cosmetic Act Section 518 a significant risk to public health, and if that occurs, FDA can exercise its mandatory recall authority to require the manufacturer to take appropriate actions.

Typically, we do not have to do that. Manufacturers usually take the initiative, do a voluntary recall, and take the appropriate action. But FDA does not have authority to direct who pays for what in these situations when it is not a significant risk to health and we are doing a mandatory recall. A mandatory recall requires there actually be a problem. The year 2000 has not occurred yet, so we are not in a position to take those kinds of problems.

Our approach has been to work with the manufacturers to get them to correct these problems beforehand, before they occur, to provide the solutions. The situation with how the solution is paid for is a commercial decision on the part of the manufacturers in trying to meet their customer demands. It is a matter of economics in terms of the number of products that need to be fixed, the cost of that fix, what the future demand for that kind of a product may be. So it is a rather complex issue, but it is a commercial transaction between the purchaser and the seller.

Ms. BROWN. Have we identified those medical devices that could be hazardous to health?

Dr. SHOPE. Well, we have looked at——

Ms. BROWN. You said that we are not in the year 2000, but what we are trying to do is get ready for it.

Dr. SHOPE. We have looked at the types of products that would potentially pose a significant risk to patients. I must say that there is a lot of discussion about medical devices not being compliant. The nature in which those medical devices are not compliant typically is a rather minor type of noncompliance. It either prints or displays a date incorrectly and has no real impact on the actual functionality of the product. It is more a problem with recording what the device did and when it did it.

But we have looked at five or six categories of devices that do pose a risk if, in fact, they had a date problem and that problem was not corrected, and we are working individually to identify those manufacturers to assure that we have their information on our website. We are in the process right now of follow-up telephone calls to those few manufacturers we have not heard from. We have listed in a letter that went to Congressman Waxman and Congressman Turner back in February those categories, the five or six types of devices, such as radiation treatment planning systems, hemodialysis systems, some clinical laboratory systems, obviously blood bank software programs, those kinds of things.

Ms. BROWN. There is a lot of anxiety with the public, and my question is, what kind of public information programs will FDA conduct to head off stockpiling and hoarding of pharmaceuticals that could disrupt the distribution and availability of supplies?

Mr. HUBBARD. That is clearly one of the things that we are thinking about. We certainly want to work with the VA and other components of the administration to get the message out there to consumers that there will not be a problem, they do not need to rush to their physician or rush to their pharmacy and stock up on prescription drugs and, therefore, potentially to deny them to other patients.

The question is, can we do that credibly? Do we have the objective evidence that there is not a problem, that the manufacturers have done their job and that the products will be produced, will be in the pharmacies, will be in the hospitals, will be in the VA facilities, whatever, and that is a very good question and that is clearly one of the things we are focusing on.

Ms. BROWN. Well, it is something that we need to get ahead of, because in listening to you, I feel like I need to make sure I have my supplies of medicine.

Mr. HUBBARD. Well, Ms. Brown, at the moment, as you will hear from PhRMA later, we believe the companies have the incentives to worry about the problem. They have worried about the problem. They are fixing the problem. But I think we need to make virtually 100 percent sure that is the case and, in fact, there is not a problem.

Ms. BROWN. What is your comfort level that the VA patients will not be harmed by the year 2000 problem as it relates to medical devices and pharmaceuticals?

Mr. HUBBARD. I do not think we can tell you today that veterans' facilities are going to have the drugs they need, but I think we need to be able to say that later in the year. While I think there is a certain level of confidence now, as I said earlier, you need to also have objective evidence that that is, in fact, the case. Just saying we think that is okay is not enough, and that is what one of the purposes of all the surveys the industry has been doing and the various thinking that we in the FDA and other parts of the administration are doing.

Ms. BROWN. Well, when do you think you will be able to tell us that?

Mr. HUBBARD. Responses are coming into the surveys that have been done. They seem to be very positive. We certainly want to be able to have the kind of message out there very soon, perhaps by

Memorial Day, that says to the public, well before the end of the year, well before the turn of the century, that these issues have been attended to and the products will be there.

Ms. BROWN. So we are going to have some kind of follow-up on this?

Mr. HUBBARD. And as I said, the White House summit coming up, which will bring together all the different parties in this, will hopefully be able to build that message to assure the public and to assure the committee.

Ms. BROWN. But you know the public really looks to your agency on a broad basis for its medical, pharmaceutical, and drugs and devices.

Mr. HUBBARD. I think that is right, Ms. Brown, and certainly in terms of making sure that safe and effective products are made by these manufacturers, we accept that responsibility and we have some authority to make sure that happens. When drugs leave the plant, however, FDA is less responsible and less able to assure that, for instance, physicians do not over-prescribe, patients do not make demands, pharmacies do not do certain things. We do not regulate those entities, and so it is a big difference. That is why you have got to have a broader coalition of different players, including the hospitals and the various government purchasers of drugs and others that are major players in this.

Mr. EVERETT. I thank the gentelady.

I think you get a feeling that we, frankly, do not find any reassurance in your testimony. For instance, on page 17 of your testimony, you point out that with only 260 days left, that you are now meeting internally to avoid disruptions in the drug supply and how to address foreign bulk product supplies and also the possible—possible—collection of data to assess the year 2000 readiness and contingency plans.

What I am saying to you is we do not see a plan here, or if you have got one, you failed to convey it to us. It seems to me that, in all due respect, the FDA is way behind in this process.

Mr. HUBBARD. Well, I certainly respect your opinion. I think there is validity to your perception. I will make the note that if we had done, for instance, surveys a year ago, they would have probably been of relatively little use because it has only been in the past few months that the industry has really stepped up and done this. So a survey last year would have probably found a very low compliance rate and would, if anything, have potentially caused more of a concern.

So I think that what we were doing last year was trying to make sure that the industry knew that they had a responsibility, knew they had to worry about this and undertake any work, and in many cases, firms were well ahead of us on that and had been working on it for a number of years.

The surveys that are being done now may be more timely because they capture more of the success that has been underway in recent months and perhaps give us a greater snapshot of where things will be later in the year than anything along those lines that would have been done, say, a year ago.

Mr. EVERETT. As our ranking member correctly pointed out, despite the fact that the VA has done an outstanding job in listing

the pharmaceutical companies and that sort of thing, the public does not look to the VA for that reassurance. They look to the FDA.

Mr. HUBBARD. I understand, Mr. Chairman.

Mr. EVERETT. And that is one of the points that we are trying to get across here. We do not see that assurance yet.

Mr. HUBBARD. All right.

Mr. EVERETT. But we do thank you for your testimony today and we will have some more direct questions for the record that we would ask you to respond to. Thank you.

Mr. HUBBARD. Of course, Mr. Chairman. Thank you.

Mr. EVERETT. At this time, I would like to recognize Ms. Judy Bello, Executive Vice President for Policy and Strategic Affairs at the Pharmaceutical Research and Manufacturers of America.

STATEMENT OF JUDITH H. BELLO, EXECUTIVE VICE PRESIDENT FOR POLICY AND STRATEGIC AFFAIRS, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; ACCOMPANIED BY DEL PERSINGER, VICE PRESIDENT, FINANCE AND OPERATIONS, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Ms. BELLO. Thank you, Mr. Chairman.

Mr. EVERETT. Let me say that we appreciate the lateness that we got the invitation to you and your willingness to participate with us here.

Ms. BELLO. We thank you for having us. Mr. Chairman and Ranking Member Brown, I am Judy Bello and here at the table with me is Del Persinger, our Vice President for Finance and Operations. Also with us are our colleagues, Mayra Guarduce of our Federal Affairs Staff, Mark Grayson of our Office of Public Affairs, and our Counsel, Matt Van Hook.

On behalf of the Pharmaceutical Research and Manufacturers of America, PhRMA, we are pleased to report that the research-based pharmaceutical industry will be well prepared to meet the systems-related challenges presented by the year 2000. We represent the country's leading research-based pharmaceutical companies, which are investing this year over \$24 billion in the search for new cures and treatments.

Because we are keenly aware of the critical importance of our products to people's lives and welfare, our industry launched a massive readiness effort more than 3 years ago to ensure that there will be a continuous supply of medicines to patients during the year 2000. Our companies are continuing to perfect their systems to combat any Y2K problems.

A survey of our members released 10 days ago shows two major findings. One, all respondents have a Y2K plan in place and are developing contingency plans to ensure the continuous supply of medicines to patients. Two, our companies expect to spend almost \$2 billion to address Y2K issues. The respondents to this survey represent about 90 percent of the U.S. research-based pharmaceutical industry.

Our industry's ability to cope with Y2K challenges is enhanced because we do not operate on a "just-in-time" manufacturing basis. For this reason, we have learned from discussions with wholesalers

and retailers that the supply chain, on average, contains a 90-day supply of medicines.

Further, a robust rapid response network of manufacturers, wholesalers, and retailers already exists to deal with supply shortages, whether at a particular pharmacy or caused by any emergency or national disaster. We are working to ensure that this rapid response network will be prepared to handle Y2K disruptions.

We are also fully cooperating with Congressional Y2K committees, including certainly this committee with its leadership, the President's Council on the Year 2000, the Food and Drug Administration, and the Departments of Veterans' Affairs and Health and Human Services in preparing for year 2000.

For example, one, on February 22, we cosponsored a Y2K symposium with FDA and the Biotechnology Industry Association.

Two, Health and Human Services issued a press release in which it encouraged others in the health care sector to follow our example with our survey and to share information widely with the public.

Three, the President's Council has sent our survey to other trade associations as a model for what it would like to receive.

We are committed to working with our suppliers and distribution channels around the world, as well as with both Federal and State governments, to continue our efforts to facilitate an uninterrupted supply of medicines throughout the health care chain. We also are committed to reassuring physicians, patients, and consumers, including, of course, the veterans' community, by informing them of what we are doing and what we will continue to do to ensure a continuous supply of medicines.

Ultimately, success in meeting the Y2K challenge depends not only on our industry and other links in the supply chain, but also on doctors, hospitals, insurers, and, of course, patients. Hoarding and stockpiling by patients could create a greater threat to the uninterrupted supply of medicines than any computer glitch.

In closing, Mr. Chairman and ranking member and staff, let me stress that we in the industry recognize we face two Y2K challenges. Our first job is to fix any problem. Our second job is to fully cooperate with this committee, the Congress, the administration, and the many other parties involved in health care to engender fact-based consumer confidence that the problem is, indeed, being fixed.

These two industry jobs are linked. We cannot succeed in avoiding panic-driven hoarding by correcting the problem alone. We must also engender consumer confidence that hoarding is not needed, that you do not need to extend the supply of medicines that you have. On the other hand, we cannot engender the confidence unless we first fix the problem.

Please understand that the same experts within our member companies who are working to correct and, indeed, avoid any problems are the same folks who have the facts that numerous parties are seeking to assess Y2K readiness in health care. To avoid a health care problem, we are committed to succeeding in doing both our jobs.

We thank you for having us and we look forward to answering your questions.

[The prepared statement of Ms. Bello, with attachments, appears on p. 100.]

Mr. EVERETT. Thank you very much for your testimony, Ms. Bello.

What was the state of your preparedness a year ago? You said your industry started 3 years ago working on this.

Ms. BELLO. We started working on it 3 years ago, but it is fair to say that we have intensified our efforts as the year 2000 has grown closer. We obtained the results of our survey how recently, Del?

Mr. PERSINGER. Our survey data is as of the end of 1998, which is the first time that we went out to collect quantifiable information.

Mr. EVERETT. And the end-of-year 1997, your state of preparedness would have been what?

Mr. PERSINGER. That, we cannot tell you. We did not do a survey at that time.

Mr. EVERETT. The reason I am kind of searching around here, we had previous testimony from FDA that it would have been useless to have any of this information a year ago, and we will follow up with a question of FDA to clarify that.

The companies you represent are mainly the big players in the pharmaceutical industry, but you do not represent the folks who make the generic drugs, is that not correct?

Ms. BELLO. That is correct, Mr. Chairman. Our members represent over 98 percent of the research-based pharmaceutical industry. Research-based products account for about 55 percent of the pharmaceutical sales in the United States. We do not represent and we simply do not have information about Y2K readiness on the part of the generic industry.

Mr. EVERETT. You said 55 percent?

Ms. BELLO. Of sales, yes, sir.

Mr. EVERETT. So that means that perhaps 45 percent, we have no idea about the state of readiness.

Ms. BELLO. We have no idea about it. I am sure that others do, and I would hasten to point out that the generic industry is represented in the President's Council on the Year 2000.

Mr. EVERETT. How specific do you think information to the public needs to be to provide the level of public confidence needed to avoid what you were just speaking about and what my colleague mentioned a little earlier, and that is the stockpiling? What all do we need to do, and specifically, can the Congress be of help in this?

Ms. BELLO. What we are committed to doing and what we are doing today, and it is significant that we have Mr. Grayson of our public affairs staff here, is we are, one, fixing the problem, but two, it is important to share the information that we are doing this with the Congress, the media, the administration, and the public in a meaningful way.

We think, however, that we want to be careful and make sure that the kinds of information that we share with the public are appropriate. The patient community does not know a lot of details about the production process. So, for example, the specific number of days of supply or specific inventory levels is likely to be mislead-

ing information to them. They would be unable to use this information productively to draw meaningful conclusions.

So we are pleased with the kinds of information that we obtained in our survey results and we will cooperate with all interested parties, certainly including the Veterans Administration and this committee, to make sure that this information is made available to patients.

We cannot solve the problem only by fixing the Y2K readiness issues and having our systems ready. If patients do not find our assurances credible, they will stockpile and hoard anyway and that will create a much greater problem potentially than any of the Y2K readiness problems. So fixing the problem is the critical start in this process, but we are committed to going the rest of the way and working with everyone on sharing appropriate kinds of information that will assure patients they do not need to run to their doctor and get a longer supply than they normally do.

Mr. EVERETT. Well, it is of great concern, fixing the problem. For instance, is the 80 percent of the raw materials in pharmaceuticals that are imported, is that included in your definition of fixing the problem, the problems we may have with that?

Ms. BELLO. That is a figure that the Food and Drug Administration supplies. It is an average figure for the pharmaceutical industry as a whole. The generic industry imports more materials than we do, but we do import a significant number of materials. Many of them, I would hasten to point out, are from subsidiary or affiliate companies of our member companies. So often when we are talking about imported materials or imported finished products, that is from a company abroad that is affiliated with one of our member companies.

We are working throughout the supply chain because we cannot provide a solution by ourselves. We need to work with all of our suppliers and everyone else in the distribution chain because the patient only has access to the medicines if we have all fixed our individual problems and then worked cooperatively together to ensure a continuous supply of the medicines the patients need.

Mr. EVERETT. Are you satisfied that that cooperative effort is taking place?

Ms. BELLO. This effort is underway. It is ongoing. It, in fact, of course, is accelerating. We are pleased to work with everyone. We can speak with the most assurance, of course, about our own efforts within our own industry, but in the President's Council on the Year 2000 and many other fora, we see the participation and the commitment of others in the supply and distribution chain, as well, and we all know that we do well when we do good. The good that we do is with the patient community. So we have not been successful unless patients have access to the medicines they need throughout the year 2000.

Mr. EVERETT. Thank you. Ms. Brown.

Ms. BROWN. I really think, Mr. Chairman, you have asked all of my questions. I do not have to ask them over again, but let me just say that public information programs are so extremely important. I am sitting up here knowing that I have to have my medicine. Other people need a level of confidence to know that it is going to be available. If not, we will make sure we stockpile it.

Ms. BELLO. We could not agree with you more, Congresswoman. For example, when there was a story in the newspaper recently about a patient named Lorraine West, she calls herself the patient's advocate, she is from Utah and she has a brain tumor and she became concerned early on about whether or not she was going to have an adequate access to the medicine she needs. We have reached out to her and talked with her and she is satisfied at this time that stockpiling is not necessary.

So we are working closely not only with different parts of the Federal and State governments, but Mr. Grayson and others on his staff every day are working with the media to provide the facts that allow patients to conclude for themselves, based on this information, that they do not need to worry and to stockpile their medicines.

We are also stressing that if people do stockpile medicines, this actually presents a greater risk to the continuous supply of medicines. So we are trying to discourage inappropriate stockpiling and to share information with as many parties as possible.

Ms. BROWN. I think it would be good if you shared that information with the members of the Congress because we have town meetings and hearings. We do not try to sensationalize the information. Sometimes the media may be guilty of that, maybe not. But you indicated that you had a planned program that you had given to the President's committee. Can you share that also with us?

Ms. BELLO. Del, would you like to elaborate on our activities going forward?

Mr. PERSINGER. Certainly. We would be happy to share the information. In fact, we plan to do that. We have been working intensively not only in our own manufacturing industry but with the wholesalers and the retailers, the entire supply chain, in particular to make sure that not only are the systems of these groups ready but that the supply chain works together the way it needs to and the drugs get to the people that need them.

In addition, we are working on our existing emergency response network, which is quite robust and quite sophisticated. It has been used many times in the past, as Ms. Bello said, to respond to emergency situations or natural disasters. It works very well. We are reviewing it. We will be enhancing it, if necessary and where necessary, to make sure that it is ready for Y2K.

This is the message that we will be carrying forward that we hope will be reassuring to you and members of the public. We intend to meet with Mr. Koskinen in the very near future and bring in representatives from the entire supply chain and discuss this in full with him so that he understands and so that he is reassured and can help us in our communication efforts. We would be pleased to have you or your staff attend. We would intend to invite the Senate Special Committee, also FDA, VA, HHS. We would like to get this message out as broadly as we can.

Ms. BELLO. And in doing that, we are working particularly closely with the patient community. Many patients accord great credibility to the facts that are shared with them by national and local patient-level groups. So we are working closely to provide the facts

to the patient organizations which, in turn, share them with the patients who are interested in a particular disease or condition.

Ms. BROWN. Thank you, Mr. Chairman, for your leadership.

Mr. EVERETT. Thank you, and I thank this panel.

I want to again thank all our witnesses for their testimony today. Zero hour for Y2K is only 260 days from now and time is running out. VA has made significant progress in its Y2K preparations, but we do have a few housekeeping things that we need to clean up. GAO and the IG have outlined the specific areas in which VA has work left to do. I know the VA has been working hard, but it is too early to relax. I know I will not rest and I suspect, considering the fact that my cohort has to have medication, that she will not rest, either, until we know everything is worked out at the VA.

It is important that every effort be made to reassure our veterans and the public about the supply of drugs and medication move quickly. FDA and the industry have a lot of work ahead of them to do that and there is not a lot of time.

The subcommittee will have one more hearing in the fall before this session of Congress adjourns. At that time, essentially, everything should have been fixed and all the items that GAO and the IG pointed out should be resolved. Along with this subcommittee, they will continue to monitor the VA's progress. I salute the VA's overall progress and await the final report in the fall.

Much of what we have done over the last 2 years is not glamorous. It is just getting in here every day and doing the work. I want to express my appreciation to Secretary Goyer, to FDA, to your organization and the other organizations, GAO and the IG, that have helped us during these years to do it. Also, I would like to express my appreciation to the members of this committee and both the majority and minority staff for the work that they have done.

I feel we are very close. We have not crossed that finish line yet, but we are certainly very close. I think that the progress that has been made has been significant.

This hearing is adjourned.

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

A P P E N D I X

GAO

United States General Accounting Office

Testimony

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

For Release on Delivery
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**YEAR 2000 COMPUTING
CRISIS**

**Action Needed to Ensure
Continued Delivery of
Veterans Benefits and Health
Care Services**

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



Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to participate in today's hearing on the readiness of the Department of Veterans Affairs (VA) to deliver benefits and health care services through the turn of the century. We will focus on the Year 2000 (Y2K) readiness of automated systems that support such delivery, the compliance status of biomedical equipment used in patient care, and the Y2K readiness of the pharmaceutical and medical-surgical manufacturers upon which VA relies. In discussing biomedical equipment and pharmaceutical products, we will also share with you information on the Food and Drug Administration's (FDA) Y2K efforts.¹

In brief, VA continues to make progress in its Y2K readiness. However, key actions remain to be performed. For example, the Veterans Benefits Administration (VBA) and Veterans Health Administration (VHA) have not yet completed testing of their mission-critical systems to ensure that these systems can reliably accept future dates--such as January 1, 2000. Also, VHA has not completed assessments for its facility systems, which can be essential to ensuring continuing health care. In addition, neither VA nor FDA have implemented our prior recommendation to review the test results for biomedical equipment used in critical care/life support environments. Further, VHA's pharmaceutical operations are at risk because the automated systems supporting its consolidated mail outpatient pharmacies are not Y2K compliant. Lastly, VHA does not know if its medical facilities will have a sufficient supply of pharmaceutical and medical-surgical supplies on hand, because it does not have complete information on the Y2K readiness of these

¹ Biomedical equipment refers to both medical devices regulated by FDA and scientific and research instruments, which are not subject to FDA regulation.

manufacturers. It is critical that these concerns be addressed if VA is to continue reliably delivering benefits and health care.

KEY ACTIONS REMAIN TO ENSURE THAT VA CAN DELIVER BENEFITS AND HEALTH CARE INTO THE NEXT CENTURY

Like many organizations, VA faces the possibility of computer system failures at the turn of the century due to incorrect information processing relating to dates. The reason for this is that in many systems, the year 2000 is indistinguishable from 1900, since the year is represented only by "00." This could make veterans who are eligible for benefits and medical care appear ineligible. If this happens, the issuance of benefits and the provision of medical care that veterans rely on could be delayed or interrupted.

As we reported last August,² VBA had made progress in addressing the recommendations in our May 1997 report³ and making its information systems Y2K compliant. It reported it had renovated 75 percent of its mission-critical applications as of June 1998. At the same time, VHA reported it had assessed all and renovated the vast majority of its mission-critical information systems.

² Year 2000 Computing Crisis: Progress Made in Compliance of VA Systems, But Concerns Remain (GAO/AIMD-98-237, August 21, 1998).

³ Veterans Benefits Computer Systems: Risks of VBA's Year 2000 Efforts (GAO/AIMD-97-79, May 30, 1997).

Despite this progress, VBA was making limited progress in renovating two key mission-critical applications—the compensation and pension online application and the Beneficiary Identification and Record Locator Sub-System. And, except for its Insurance Service, VBA had not developed business continuity and contingency plans for its program services—Compensation and Pension (the largest), Education, Loan Guaranty, and Vocational Rehabilitation and Counseling—to ensure that they would continue to operate if Y2K failures occurred.

VHA's Y2K program likewise had areas of concern. For example, although VHA's medical facilities had hospital contingency plans, as required by the Joint Commission on Accreditation of Healthcare Organizations, they had not yet completed Y2K business continuity and contingency plans. To address these areas and to reduce the likelihood of delayed or interrupted benefits and health care services, we recommended that VA

- reassess its Y2K mission-critical efforts for the compensation and pension online application and the Beneficiary Identification and Record Locator Sub-System, as well as other information technology initiatives, such as special projects, to ensure that the Y2K efforts have adequate resources, including contract support, to achieve compliance in time;
- establish critical deadlines for the preparation of business continuity and contingency plans for each core business process or program service so that mission-critical functions affecting benefits delivery can be carried out even if software applications and commercial-off-the-shelf (COTS) products fail, including a description of resources, staff roles, procedures, and timetables needed for implementation; and

- ensure rapid development of business continuity and contingency plans for each medical facility so that mission-critical functions affecting patient care can be carried out if software applications, COTS products, and/or facility-related systems and equipment do not function properly, including a description of resources, staff roles, procedures, and timetables needed for implementation.⁴

VA Continues to Make Progress

VA has been responsive to our recommendations. For example, VBA reassessed its mission-critical efforts for the compensation and pension online application and the Beneficiary Identification and Record Locator Sub-System, as well as other information technology initiatives. It also reallocated resources to ensure that the Y2K efforts had adequate resources, including contract support, to achieve compliance.

In addition, VBA completed a draft business continuity and contingency plan in January 1999 for its core business processes, as well as a related planning template for its regional offices. The plan provides a high-level overview of the resources, staff roles, procedures, and timetables for its implementation. It addresses risks, including mitigation actions to reduce the impact of Y2K-induced business failures, and analyzes the effect on each business line of a number of potential Y2K disasters—such as loss of electrical power, loss of communications, loss of data processing capabilities, and failure of internal infrastructure. According to VBA, the plan, which it expects

⁴ GAO/AIMD-98-237, August 21, 1998.

to test this August, is an evolving document, to be revised and updated periodically until January 1, 2000.

VBA's plan makes no reference to contingencies for the failure of three of VBA's benefit payment systems—Compensation and Pension, Education, and Vocational Rehabilitation and Counseling. However, it is currently developing a payment contingency plan for these systems and expects this to be completed in May 1999. A VBA official told us that the payment contingency plan should have been referenced in VBA's business continuity and contingency plan, and will be in future versions. The current plan also does not contain the designation of an information technology security coordinator and a physical security coordinator—individuals that VBA acknowledges are essential to the agency's Y2K efforts, with responsibility for ensuring overall security for VBA's network and web site, and backing up data storage before, during, and following January 1, 2000. This type of information will be necessary if security-related failures occur. According to VBA, it expects to designate these individuals by August 1999.

VHA has also made progress in developing business continuity and contingency plans for its medical facilities. Last month VHA issued its Patient-Focused Year 2000 Contingency Planning Guidebook to its medical facilities describing actions they can take to minimize Y2K-related disruptions to patient care. The guidebook discusses how the facilities should develop contingency plans for each major hospital function—such as radiology, pharmacy, and laboratory—as well as each major support function—such as telecommunications, facility systems, medical devices, and automated information systems. The guidebook also contains examples of plans, policies, and solutions for problems that a medical facility may face and

provides Y2K templates describing the areas a facility should address by specific hospital function. VA provided this guidebook to the medical facilities early last month and expects the facilities to use it to prepare their individual business continuity and contingency plans, set to be completed by April 30. The guidebook stresses that these plans should be tested and suggests that the medical facilities begin testing in June.

The guidebook addresses external emergency preparedness as well as internal operations. Specifically, it discusses three functions that medical facilities should perform in order to ensure that potential external hazards are considered and planned for. These are (1) performing an assessment of hazard vulnerabilities—that is, the types and kinds of Y2K problems that are anticipated within the community; (2) conducting an inventory of community resources—people, money, clinical space, supplies, and equipment—available to address these hazards; and (3) closing the gap between vulnerabilities and capabilities by putting into place measures that will mitigate potential disruptions in critical services by developing new working relationships with various government agencies, non-VA health care organizations, and vendors of critical supplies.

In addition to implementing our recommendations, VA continues to make progress renovating, validating, and implementing its systems. On March 31, 1999, VA reported to the Office of Management and Budget (OMB) that the department has renovated and implemented all of the mission-critical applications supporting its 11 systems areas. As shown in table 1, VBA has six of these areas, and VHA has two.

Table 1: Reported Status of VA's Mission-Critical Computer Systems Areas and Their Applications

Component/Office (Number of systems)	Systems Areas	Number of Applications Renovated or Replaced
Veterans Benefits Administration (6)	Compensation and Pension	30
	Education	24
	Insurance	3
	Loan Guaranty	19
	Vocational Rehabilitation	4
	Administrative	27
	Total	107
Veterans Health Administration (2)	Veterans Health Information Systems and Technology Architecture	105
	Veterans Health Administration Corporate Systems	95
	Total	200
National Cemetery System (1)	Burial Operations Support System/Automated Monument Application System	1
	Reengineer	1
	Total	2
Office of Financial Management (2)	Personnel and Accounting Integrated Data	8
	Financial Management System	1
	Total	9
VA Total	11	318*

Source: VA. We have not independently verified this information.

*Of this total, 316 applications were renovated and two were replaced.

Testing of Mission-Critical Systems Not Yet Complete

Complete and thorough Y2K testing is essential to providing reasonable assurance that new or modified systems will process dates correctly and will not jeopardize an organization's ability to perform core business operations.⁵ Because the Y2K problem is so pervasive, potentially affecting an organization's systems software, applications software, databases, hardware, firmware, embedded processors, telecommunications, and interfaces, the requisite testing can be extensive and expensive. Experience is showing that Y2K testing is consuming between 50 and 70 percent of a Y2K project's time and resources.

According to our Y2K guide, to be done effectively, testing should be planned and conducted in a structured and disciplined fashion. Our guide describes a step-by-step framework for managing Y2K testing, which includes the following key processes:

- *Software unit testing* to verify that the smallest defined module of software (individual subprograms or procedures) continues to work as intended.
- *Software integration testing* to verify that units of software, when combined, continue to work together as intended. Typically, integration testing focuses on ensuring that the interfaces work correctly and that the integrated software meets requirements.

⁵ Year 2000 Computing Crisis: A Testing Guide (GAO/AIMD-10.1.21, November 1998).

- *System acceptance testing* to verify that the complete system—that is, the full complement of application software running on the target hardware and systems software infrastructure—satisfies specific requirements and is acceptable to users. This testing can be run separately or in some combination in an operational environment (actual or simulated), and collectively verifies that the entire system performs as expected.

According to VBA and VHA officials, their testing criteria were based on their software development life-cycle guidance documents. They said that upon completion of software unit and integration testing, a system is considered Y2K compliant. They said this type of testing had been completed for all of their mission-critical systems.

As of March 31, 1999, neither VBA nor VHA had completed systems acceptance testing—which requires that each system be tested, including full forward-date testing, on a compliant platform—for all their mission-critical systems. Specifically, according to VBA officials, the agency had completed systems acceptance testing for half of its mission-critical systems—Insurance, Loan Guaranty, and Vocational Rehabilitation and Counseling. According to VBA's March 1999 draft test plan, systems acceptance testing of the Compensation and Pension and most of the Education systems was to start in mid-April 1999. One of the reasons provided to us by a VBA official for the late systems testing was that the IBM platform at its Hines, Illinois, data center was not made Year 2000 compliant until the compiler⁶ was upgraded in February

⁶ A compiler is a computer program that converts human-readable source code into a sequence of machine instructions that the computer can run.

1999. According to VBA, the Compensation and Pension and most of the Education systems will be future-date tested throughout April.

VHA also plans to begin system acceptance testing of its mission-critical systems this month and complete it this June. According to VHA officials, they could not perform this type of testing before March of this year because VHA did not have a separate Y2K-compliant test environment to isolate the testing from the hospital systems in use.

In addition to testing of individual systems, end-to-end testing of multiple systems is also critical. End-to-end testing, as defined in our test guide, verifies that a defined set of interrelated systems, which collectively support an organizational core business area or function, continues to work as intended in an operational environment, either actual or simulated. For example, in order to successfully process a compensation benefit payment to a veteran, VBA's Compensation and Pension System must work correctly with its Beneficiary Identification and Records Locator Sub-System, Treasury's Financial Management System, the Federal Reserve System, and financial institution systems.

VBA and VHA plan to conduct end-to-end testing between now and this July. VBA is defining end-to-end testing as verification that core mission-critical business functions, including benefit payments and vendor and payroll payments, process correctly. The interfaces between VBA's benefits system and Treasury's Financial Management System are to be tested in May. VBA also plans to test transactions that interface with VHA systems, such as information related to veteran eligibility. VHA is defining end-to-end testing as verification that core mission-critical business

functions, including patient-care transactions and vendor and payroll payments, process correctly. Once these tests are completed, VBA and VHA plan to conduct a “business process simulation” during the July 4, 1999, weekend. This simulation of day-to-day work at VA is to include users at the VBA regional offices and VHA test laboratories, who will simulate various transactions and process them through a set of interrelated systems necessary to complete a core business function. VBA expects to pretest the business process simulation during May.

Assessment of VHA's Facility Systems Not Yet Complete

VA's facility systems are essential to the continued delivery of health care services. For example, heating, ventilating, and air conditioning equipment is used by hospitals to ensure that contaminated air is confined to a specified area such as an isolation room or patient ward. If computer systems used to maintain these systems were to fail, any resulting climate fluctuations could affect patient safety.

Despite their importance, VHA has not yet completed its assessment of facility systems. As of February 28, 1999, VHA medical facilities reported that they had assessed 55 percent of their facility systems. According to VHA's Director of Safety and Technical Programs, the remaining 45 percent have not been fully assessed primarily because (1) facility systems tend to be a combination of unique elements that have to be separately assessed for compliance—a time-consuming process, and (2) VHA is still awaiting compliance status information from facility system manufacturers. VHA has not established milestones for completing its assessment and

implementation of compliant facility systems. To help ensure that sufficient time remains to complete these activities, we recommend that VHA consider setting such deadlines.

In the event that facility-related systems and equipment do not function properly due to Y2K problems, VHA medical facilities will need to ensure that they have business continuity and contingency plans addressing how mission-critical functions affecting patient care will be carried out. According to VHA's Director of Safety and Technical Programs, most of its facility systems have some kind of manual override or reset that will allow them to continue functioning after a Y2K problem. He agreed, however, with the importance of developing contingency plans that fully document continued delivery of essential services in the event of a facility system failure. VHA medical facilities expect to have individual business continuity and contingency plans completed by April 30.

On April 14, 1999, VA informed us that its February 28, 1999, report contained an error. The corrected numbers for facility systems at the end of February were 91 percent assessed and 9 percent not assessed.

**BIOMEDICAL EQUIPMENT: ADDITIONAL STATUS INFORMATION AVAILABLE,
BUT TEST RESULTS NOT REVIEWED**

The question of whether medical devices such as magnetic resonance imaging (MRI) systems, x-ray machines, pacemakers, and cardiac monitoring equipment can be counted on to work reliably on and after January 1, 2000, is also critical to VHA. To the extent that biomedical equipment uses embedded computer chips, it is vulnerable to the Y2K problem. Such vulnerability carries

with it possible safety risks. This could range from the more benign—such as incorrect formatting of a printout—to the most serious—such as incorrect operation of equipment with the potential to adversely affect the patient. The degree of risk depends in large part on the role the equipment plays in a patient's care.

Additional Biomedical Equipment Status Information Available

Last September we testified before this Subcommittee that VHA was making progress in assessing its biomedical equipment, but that it did not know the full extent of the Y2K problem with this equipment because it had not received compliance information from 398 manufacturers (26.7 percent).⁷ According to VHA, as of March 16, 1999, the number of nonresponsive manufacturers had been reduced to 126 (8.5 percent).⁸ As shown in table 2, about 19 percent of the manufacturers in VHA's database of suppliers had at least one biomedical equipment item that was either noncompliant or conditionally compliant.

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

⁸ According to VHA, 101 of the 126 letters sent to manufacturers were marked "return to sender."

Table 2: Status of Manufacturer Responses to VHA as of March 16, 1999.

Category	Number of manufacturers	Percentage of manufacturers
Compliant manufacturers ^a	816	55.2
Noncompliant manufacturers ^b	126	8.5
Conditional-compliant manufacturers ^c	156	10.5
Pending manufacturers ^d	29	2.0
Manufacturers merged or bought out	226	15.3
Nonresponsive manufacturers ^e	126	8.5
Total	1,479	100.0

^aFor inclusion in this category, 100 percent of the manufacturer's products had to be considered compliant.

^bFor inclusion in this category, only one of the manufacturer's products had to be considered noncompliant.

^cFor inclusion in this category, the manufacturer had to have no noncompliant equipment, no equipment pending, and at least one conditional-compliant item.

^dFor inclusion in this category, the manufacturer had to have no noncompliant equipment and at least one equipment item pending.

^eFor inclusion in this category, VHA had to have no compliance information from the manufacturer.

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

To identify specific biomedical equipment in the inventories of VHA's medical facilities that still require Y2K compliance status information from manufacturers, VHA's Chief Network Officer sent a letter to the directors of VHA's 22 Veterans Integrated Service Networks (VISNs). This letter requested that they (1) review VHA's list of manufacturers that have yet to respond and compare it with a list of manufacturers from whom their medical facilities still require compliance information, and (2) indicate the equipment item that the facility owns for each manufacturer. According to VHA's Y2K project director, as of mid-March—with 135 of 147 medical reporting sites—47 biomedical equipment items involving 35 manufacturers were

identified as still requiring compliance status information. The project director told us that VHA medical facilities have been instructed to replace or eliminate equipment in their inventories for which they do not know the compliance status by June 30. According to VHA's February 1999 status report on medical devices, medical facilities estimated that the total cost of renovations will be about \$41 million.

We have previously reported that most manufacturers citing noncompliant products listed incorrect display of date and/or time as the Y2K problem.⁹ According to VA, these cases do not present a risk to patient safety because health care providers, such as physicians and nurses, can work around the problem. Of more serious concern are situations in which devices depend on date calculations—the results of which can be incorrect. One manufacturer cited the example of a product used for planning delivery of radiation treatment using a radioactive isotope as the source. An error in calculating the strength of the radiation source on the day of treatment could result in a dose that is too high or too low, which could have an adverse effect on the patient. Other examples of equipment presenting a risk to patient safety identified by manufacturers to FDA include hemodialysis delivery systems; therapeutic apheresis systems;¹⁰ alpha-fetoprotein kits for neural tube defects;¹¹ various types of medical imaging equipment; and systems that store, track, and recall images in chronological order.

⁹ Year 2000 Computing Crisis: Compliance Status of Many Biomedical Equipment Items Still Unknown (GAO/AIMD-98-240, September 18, 1998).

¹⁰ Such equipment allows therapeutic apheresis, which refers to the exchange or purification of blood plasma. Therapeutic apheresis is recognized as a successful treatment for more than 40 autoimmune diseases.

¹¹ Devices that use computer calculations of gestational status to help assess the risk of neural tube defects in the fetuses of pregnant women.

To track the compliance status of its biomedical equipment, VHA uses a monthly status report on medical devices based on information provided by the VISNs. According to the February 1999 report, approximately 426,000 of 531,000 medical devices in VHA medical facilities are compliant. Of the remaining devices, 86,452 were identified as conditional-compliant or were not assessed for Y2K compliance because the manufacturers certified that the equipment contained no software or embedded chips; and 19,073 were reported as being noncompliant. Of the noncompliant devices identified, 15,621 are to be repaired, 1,582 are to be replaced, 757 are to be used as is, 255 are to be retired, and 858 are still awaiting a decision on the remedy. According to VHA's Chief Biomedical Engineer, most of the noncompliant devices identified incorrectly displayed date/time.

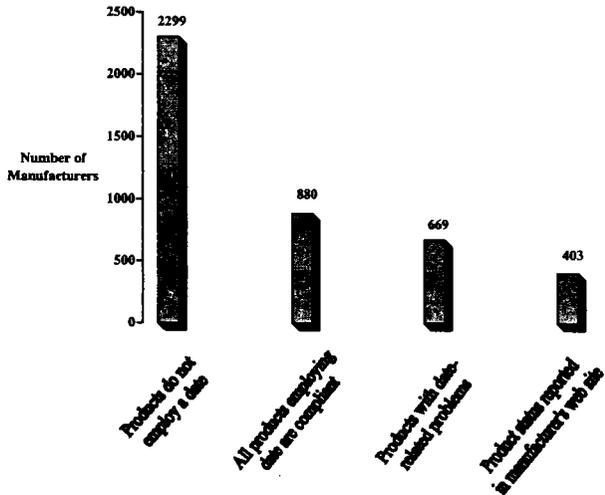
As we reported last September, FDA was also trying to determine the Y2K compliance status of biomedical equipment.¹² Its goal is to provide a comprehensive, centralized source of information on the Y2K compliance status of biomedical equipment used in the United States and make this information publicly available on a web site. At the time, however, FDA had a disappointing response rate from manufacturers to its letter requesting compliance information. And, while FDA made this information available to the public, it was not detailed enough to be useful. Specifically, FDA's list of compliant equipment lacked information on particular make and model.

¹² GAO/AIMD-98-240, September 18, 1998.

To provide more detailed information on the compliance status of biomedical equipment, as well as to integrate more detailed compliance information gathered by VHA, we recommended that VA and the Department of Health and Human Services (HHS) jointly develop a single data clearinghouse that provides such information to all users. We said development of the clearinghouse should involve representatives from the health care industry, such as the Department of Defense and the Health Industry Manufacturers Association. We recommended that the clearinghouse contain such information as (1) the compliance status of all biomedical equipment by make and model, and (2) the identity of manufacturers that are no longer in business. We also recommended that VHA and FDA determine what actions should be taken regarding biomedical equipment manufacturers that have not provided compliance information.

In response to our recommendation, FDA—in conjunction with VHA—has established the Federal Year 2000 Biomedical Equipment Clearinghouse. With the assistance of VHA, the Department of Defense, and the Health Industry Manufacturers Association, FDA has made progress in obtaining compliance-status information from manufacturers. For example, according to FDA, as of April 5, 1999, 4,251 biomedical equipment manufacturers had submitted data to the clearinghouse. As shown in figure 1, about 54 percent of the manufacturers reported having products that do not employ a date, while about 16 percent reported having date-related problems such as incorrect display of date/time. FDA is still awaiting responses from 399 manufacturers.

Figure 1: Biomedical Equipment Compliance-Status Information
 Reported to FDA by Manufacturers as of April 5, 1999.



Note: Total number of manufacturers = 4,251.

Source: Department of Health and Human Services.

FDA has also expanded the information in the clearinghouse. For example, users can now find information on manufacturers that have merged with or have been bought out by other firms.

In collaboration with the National Patient Safety Partnership,¹³ FDA is in the process of obtaining more detailed information from manufacturers on noncompliant products, such as make and model and descriptions of the impact of the Y2K problem on products left uncorrected.

Review of Biomedical Equipment Test Results Lacking

We reported last September that VHA and FDA relied on manufacturers to validate, test, and certify that equipment is Y2K compliant.¹⁴ We also reported that there was no assurance that the manufacturers adequately addressed the Y2K problem for noncompliant equipment, because FDA did not require medical device manufacturers to submit test results to it certifying compliance. Accordingly, we recommended that VA and HHS take prudent steps to jointly review manufacturers' compliance test results for critical care/life support biomedical equipment. We were especially concerned that VA and FDA review test results for equipment previously determined to be noncompliant but now deemed by manufacturers to be compliant, or equipment for which concerns about compliance remain. We also recommended that VA and HHS determine what legislative, regulatory, or other changes were necessary to obtain assurances that

¹³ The National Patient Safety Partnership is a coalition of public and private health care providers, including VA, the American Medical Association, the American Hospital Association, the American Nurses Association, and the Joint Commission on Accreditation of Healthcare Organizations.

¹⁴ GAO/AIMD-98-240, September 18, 1998.

the manufacturers' equipment was compliant, including performing independent verification and validation of the manufacturers' certifications.

At the time, VA stated that it had no legislative or regulatory authority to implement the recommendation to review test results from manufacturers. In its response, HHS stated that it did not concur with our recommendation to review test results supporting medical device equipment manufacturers' certifications that their equipment is compliant. It believed that the submission of appropriate certifications of compliance was sufficient to ensure that the certifying manufacturers are in compliance. HHS also stated that it did not have the resources to undertake such a review, yet we are not aware of HHS' requesting resources from the Congress for this purpose.

More recently, VHA's Chief Biomedical Engineer told us that VHA medical facilities are not requesting test results for critical care/life support biomedical equipment; they also are not currently reviewing the test results available on manufacturers' web sites. He said that VHA's priority is determining the compliance status of its biomedical equipment inventory and replacing noncompliant equipment. The director of FDA's Division of Electronics and Computer Science likewise said FDA sees no need to question manufacturers' certifications.

In contrast to VHA's and FDA's positions, some hospitals in the private sector believe that testing biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. Officials at three hospitals told us that their biomedical engineers established their own test programs for biomedical equipment, and in many cases

contacted the manufacturers for their test protocols. Several of these engineers informed us that their testing identified some noncompliant equipment that the manufacturers had certified as compliant. According to these engineers, to date, the equipment found to be noncompliant all had display problems, and was not critical care/life support equipment. We were told that equipment found to be incorrectly certified as compliant included a cardiac catheterization unit, a pulse oxymeter, medical imaging equipment, and ultrasound equipment.

VHA, FDA, and the Emergency Care Research Institute¹⁵ continue to believe that manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. They further believe that manufacturers are the ones with full access to all design and operating parameters contained in the internal software or embedded chips in the equipment. VHA believes that such testing can potentially cause irreparable damage to expensive health care equipment, causing it to lock up or otherwise cease functioning. Further, a number of manufacturers also have recommended that users not conduct verification and validation testing.

We continue to believe that, rather than relying solely on manufacturers' certifications, organizations such as VHA or FDA can provide users of medical devices with a greater level of confidence that the devices are Y2K compliant through independent reviews of manufacturers' compliance test results. The question of whether to independently verify and validate biomedical equipment that manufacturers have certified as compliant is one that must be addressed jointly by

¹⁵ An international, nonprofit health services research agency. This organization believes that superficial testing of biomedical equipment by users may provide false assurances, as well as create legal liability exposure for health care institutions.

medical facilities' clinical staff, biomedical engineers, and corporate management. The overriding criterion should be ensuring patient health and safety.

VHA PHARMACEUTICAL OPERATIONS ALSO FACE Y2K RISKS

Another critical component to VA's ability to deliver health care at the turn of the century is ensuring that the automated systems supporting VHA's medical facility pharmacies and its consolidated mail outpatient pharmacies (CMOPs) are Y2K compliant. VHA reported that in 1998 it filled about 72 million prescriptions for 3.4 million veterans, at an estimated cost of about \$2 billion. About half of the prescriptions were filled by the over 200 pharmacies located in VA's medical centers, clinics, and nursing homes. These pharmacies rely on the pharmaceutical applications in VISTA for (1) drug distribution and inventory management, (2) dispensing of drugs to inpatients and outpatients, (3) patient medication information, and (4) an electronic connection between the pharmacies and the CMOPs. Y2K failures in these applications could impair the pharmacies' ability to fill prescriptions.

The remaining 50 percent of VHA's prescriptions are filled by 7 CMOPs, geographically located throughout the United States. These facilities are supported by automated systems provided by one of two contractors—SI/Baker, Inc. and Siemens ElectroCom.¹⁶ For example, the CMOP electronically receives a prescription for a veteran through the medical center. The prescription is downloaded to highly automated dispensing equipment to be filled. The filled prescription is then validated by a pharmacist who compares the medication against a computerized image of

¹⁶ These include operating systems, databases, and pharmacy fulfillment application software.

the prescribed medication. Afterward, the prescription is packaged and an automatically-generated mailing label is applied for delivery to the veteran. Lastly, the medical center is electronically notified that the prescription has been filled. Because of the reliance on automation, the CMOPs' ability to fill prescriptions could be delayed or interrupted if a Y2K failure occurred.

VHA has determined that the automated systems supporting its CMOPs are not Y2K compliant. Specifically, neither of the systems provided by their contractors are Y2K compliant. According to the Y2K coordinator for the SI/Baker facilities, failure to make the SI/Baker systems Y2K compliant may delay the filling of outpatient prescriptions. The SI/ Baker systems are used by three of VHA's CMOPs—Hines, IL; Charleston, SC; and Murfreesboro, TN; they handle about 58 percent of all prescriptions filled by CMOPs. In contrast to the SI/Baker systems, according to a contractor hired by the CMOPs that use these systems, failure to make the Siemens ElectroCom systems Y2K compliant may result in delays in processing management reports for prescriptions filled, but not the actual filling of prescriptions.

Although the CMOPs plan to replace their noncompliant systems with compliant ones, these systems are not scheduled to be implemented until mid- to late-1999. As shown in table 3, the earliest estimated completion date for implementing a compliant system is June 30, 1999, while the latest is December 1, 1999. This leaves little time to address any unexpected implementation problems.

Table 3: Schedule of Estimated Implementation Completion Dates and Current Daily Workload by Consolidated Mail Outpatient Pharmacies

Location	Estimated Completion Date	Current Daily Workload (prescriptions filled)
West Los Angeles, California ^a	June 30, 1999	15,000
Bedford, Massachusetts ^a	June 30, 1999	15,000
Dallas, Texas ^a	June 30, 1999	14,000
Leavenworth, Kansas ^a	July 31, 1999	16,000
Charleston, South Carolina ^b	September 1, 1999	23,000
Murfreesboro, Tennessee ^b	September 30, 1999	38,000
Hines, Illinois ^b	December 1, 1999	21,000

^aSiemens ElectroCom automation

^bSI/Baker, Inc. automation

Source: VA.

Given the late schedule for implementing compliant systems, it is crucial that the CMOPs develop business continuity and contingency plans to ensure that veterans will continue to receive their medications if these systems are not implemented in time or fail to operate properly.

As of March 31, VA had not completed a business continuity and contingency plan for the CMOPs. The Y2K coordinator for the Siemens ElectroCom system has been tasked with developing this plan, which is to be completed by the end of this month.

Further, VA did not include the CMOP systems in its quarterly reports of mission-critical systems to OMB. According to VHA's Y2K project director, VHA considered the CMOP systems to be COTS products and, therefore, did not report them as mission-critical systems.

Given the criticality of these systems to VHA's ability to fill prescriptions at the turn of the century, we believe VA should reassess this decision reporting CMOPs as mission-critical to VA

top management and OMB to help ensure that necessary attention is paid to and action is taken on them.

VA Taking Action to Determine Y2K Readiness of Pharmaceutical and Medical-surgical Manufacturers

VA, like other users of pharmaceutical and medical-surgical products, needs to know whether it will have a sufficient supply of these items for its customers. Therefore, it has taken a leadership role in the federal government in determining whether manufacturers supplying these products to VHA are Y2K-ready. This information is essential to VHA's medical facilities and CMOPs because of their "just-in-time"¹⁷ inventory policy. Accordingly, they must know whether their manufacturers' processes, which are highly automated,¹⁸ are at risk, as well as whether the rest of the supply chain will function properly.

To determine the Y2K readiness of their suppliers, VA's National Acquisition Center (NAC)¹⁹ sent a survey on January 8, 1999, to 384 pharmaceutical firms and 459 medical-surgical firms with whom it does business. The survey contained questions on the firms' overall Y2K status and inquired about actions taken to assess, inventory, and plan for any perceived impact that the

¹⁷ This term refers to maintaining a limited inventory on hand.

¹⁸ Many pharmaceutical manufacturers rely on automated systems for production, packaging, and distribution of their products, as well as for ordering of raw materials and supplies.

¹⁹ This organization is responsible for supporting VHA's health care delivery system by providing an acquisition program for items such as medical, dental, and surgical supplies and equipment; pharmaceuticals; and chemicals. The NAC is part of VA's Office of Acquisition and Materiel Management.

century turnover would have on their ability to operate at normal levels. In addition, the firms were requested to provide status information on progress made to become Y2K compliant and a reliable estimated date when compliance will be achieved for business processes such as (1) ordering and receipt of raw materials, (2) mixing and processing product, (3) completing final product processing, (4) packaging and labeling product, and (5) distributing finished product to distributors/wholesalers and end customers.

According to NAC officials, of the 455 firms that responded to the survey as of March 31, 1999, about 55 percent completed all or part of the survey. The remainder provided general information on their Y2K readiness status or literature²⁰ on their efforts. As shown in table 4, more than half of the pharmaceutical firms surveyed responded (52 percent), with just less than one-third (32 percent) of those respondents reporting that they are compliant. Among the pharmaceutical firms that had not responded as of March 31, however, were two of VA's five largest suppliers.²¹ The three large pharmaceutical suppliers that did respond provided general information on their Y2K readiness status, rather than answering the survey, and estimated that they will be compliant by June 30, 1999.

²⁰ This includes annual and quarterly financial reports required by the Securities and Exchange Commission for companies listed on the New York Stock Exchange.

²¹ On April 14, 1999, a NAC official told us that of the two suppliers that had not responded as of March 31, one responded on April 12, and the other responded on April 14.

Table 4: Status of Companies Surveyed by VHA as of March 31, 1999

Responses	Pharmaceutical	Medical-surgical
Y2K compliant	65	166
Will be compliant by 1/1/2000 or earlier ^a	90	70
Provided no compliant date	50	14
Total number of responses	205	250
Non-responses	179	209
Total number of firms surveyed	384	459

^aEstimated compliance status ranged from 3/31/99 through 1/1/2000; about 71 percent of pharmaceutical firms and 80 percent of medical-surgical firms estimated they will be compliant by 7/31/99. One firm responded that it will be compliant by 1/01/2000.

Source: VA. We did not independently verify these data.

Table 4 also shows that 54 percent of the medical-surgical firms surveyed responded, with about two-thirds of them (166) reporting that they are Y2K compliant. All five of VA's largest medical-surgical suppliers have responded. Specifically, two reported being compliant, two reported they would be compliant by June 30, 1999, and the remaining supplier did not report an expected compliance date.

On March 17, 1999, NAC sent a second letter to its pharmaceutical and medical-surgical firms, informing them of VA's plans to make Y2K readiness information previously provided to VA available to the public through a web site (www.va.gov/oa&mm/nac/y2k). VA made the survey results available on its web site on April 13, 1999. The letter also requested that manufacturers that had not previously responded provide information on their readiness. NAC's Executive Director said that he would personally contact any major VA supplier that does not respond. On a broader level, VHA has taken a leadership role in obtaining and sharing information on the

Y2K readiness of the pharmaceutical industry. Specifically, VHA chairs the Year 2000 Pharmaceuticals Acquisitions and Distributions Subcommittee, which reports to the Chair of the President's Council on Year 2000 Conversion. The purpose of this subcommittee is to bring together federal and pharmaceutical representatives to address issues concerning supply and distribution as it relates to the year 2000. The subcommittee consists of FDA, federal health care providers, and industry trade associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA), the National Association of Chain Drug Stores, and the National Wholesale Druggists' Association. Several of these trade associations have surveyed their members on their Y2K readiness and made the results available to the public. However, the information is not manufacturer-specific or as detailed as VHA's survey results.

FDA's Y2K Efforts for Pharmaceutical and Biological Products Industries Were Initially Focused on Awareness

FDA's oversight and regulatory responsibility for pharmaceutical and biological products²² is to ensure that they are safe and effective for public use. Because of its concern about the Y2K impact on manufacturers of these products, FDA has taken several actions to raise the Y2K awareness of the pharmaceutical and biological products industries. In addition, it is thinking about conducting a survey to determine the industry's Y2K readiness.

One of FDA's actions to raise industry awareness was the January 1998 issuance of industry guidance by the Center for Biologics Evaluation and Research (CBER) on the Y2K impact of

²² Biological products include vaccines, blood, and blood products.

computer systems and software applications used in the manufacture of blood products. In addition, as shown in table 5, FDA has issued several letters to pharmaceutical and biological trade associations and sole-source drug manufacturers.

Table 5: FDA Letters to Manufacturers Regarding Y2K

Date	FDA Source	Recipient	Purpose
October 1998	Center for Drug Evaluation and Research	Pharmaceutical manufacturer trade associations	To relay to members FDA's expectation that the pharmaceutical industry would (1) make resolution of Y2K a high priority, (2) ensure that production systems were fixed and tested prior to January 1, 2000, and (3) urge manufacturers to develop Y2K contingency plans.
October 1998	Center for Biologics Evaluation and Research	Biologics manufacturer trade associations	Same as above.
January 1999	Center for Drug Evaluation and Research	Sole-source drug manufacturers	Same as above. Also (1) noted that the impact of Y2K on pharmaceutical safety, efficacy, and availability merits special attention for firms who are the sole manufacturers of drug components, bulk ingredients, and finished products; and (2) stated that pharmaceutical industry suppliers must have Y2K-compliant systems to protect against disruption in the flow of product components, packaging materials, and equipment to pharmaceutical manufacturers.

Source: FDA.

Further, on February 11, 1999, FDA's director of emergency and investigation operations sent a memorandum on FDA's interim inspection policy for the Y2K problem to the directors of FDA's

investigations branch. The policy emphasizes FDA's Y2K awareness efforts for manufacturers. It states that FDA inspectors are to (1) inform the firm of FDA's Y2K web page (URL <http://www.fda.gov/cdrh/yr2000/year2000.html>); (2) provide the firm with copies of the appropriate FDA Y2K awareness letter; (3) explain that Y2K problems could potentially affect aspects of the firm's operations, including some areas not regulated by FDA, and that FDA anticipates that firms will take prudent steps to ensure that they are not adversely affected by Y2K; and (4) provide firms with a copy of FDA's compliance policy guide "Year 2000 (Y2K) Computer Problems."

In addition, FDA and PhRMA jointly held a government/industry forum on the Y2K preparedness of the pharmaceutical and biotech industries on February 22, 1999. The objectives of this forum were to (1) share information on Y2K programs conducted by health care providers, pharmaceutical companies, FDA, and other federal agencies; (2) provide a vehicle for networking; and (3) raise awareness.

On March 29, 1999, FDA revised its February 11, 1999, interim inspection policy. The revision states that field inspectors are now to inquire about manufacturers' efforts to ensure that their computer-controlled or date-sensitive manufacturing processes and distribution systems are Y2K compliant. Inspectors are to include this information in their reports, along with a determination of activities that firms have completed or started to ensure that they will be Y2K compliant.

Further, FDA inspectors may review documentation in cases in which firms have made changes to their computerized production or manufacturing control systems to address Y2K problems.

The purpose of this review is to ensure that the changes were made in accordance with the firms' procedures and applicable regulations. If inspectors determine that a firm has not taken steps to ensure Y2K compliance, they are to notify their district managers, and the responsible FDA center.

FDA's interim policy describes steps inspectors are to take in reviewing manufacturers' Y2K compliance. However, FDA stated that the primary focus of its inspections for the remainder of 1999 will be to ensure that products sold in the United States are safe and effective for public use and comply with federal statutes and regulations, including "good manufacturing practice" (GMP).²³ FDA officials explained that the agency does not have sufficient resources to perform both regulatory oversight of the manufacturers and in-depth evaluations of firms' Y2K compliance activities.

Nevertheless, according to the March 29, 1999, memorandum, field inspectors are to note any concerns they may have with a firm's Y2K readiness in the administrative remarks section of their inspection reports. These reports are to be reviewed by FDA district managers. If the Y2K concern appears to present a serious problem to a firm's ability to produce safe, effective medication, the district manager can discuss this issue with FDA's Office of Regulatory Affairs and determine a course of action. However, FDA officials have stressed that the agency cannot take any regulatory action toward the firm until a Y2K-related problem affects a pharmaceutical or biological product.

²³ GMP requirements include federal standards for ensuring that products are high in quality and produced under sanitary conditions (21 CFR parts 210, 211).

Like VHA, FDA is interested in the impact of Y2K readiness of pharmaceutical and biological products on the availability of products for health care facilities and individual patients. FDA's Acting Deputy Commissioner for Policy informed us on March 24, 1999, that the agency is thinking about surveying pharmaceutical and biological products manufacturers, distributors, product repackagers, and others in the drug dispensing chain, on their Y2K readiness and contingency planning. In anticipation of a possible survey, the agency has published a notice in the March 22, 1999, Federal Register, regarding this matter. The Acting Deputy Commissioner said that potential survey questions on contingency planning would include steps the manufacturers are taking to ensure an adequate supply of bulk manufacturing materials from overseas suppliers. This is a key issue because, as we reported in March 1998,²⁴ according to FDA, as much as 80 percent of the bulk pharmaceutical chemicals used by U.S. manufacturers to produce prescription drugs is imported.

In summary, VBA and VHA continue to make progress in preparing their mission-critical systems for the year 2000. However, key actions remain to be taken in the areas of mission-critical systems testing, VHA facility systems compliance, and CMOP systems compliance. We also reiterate the need for VHA and FDA to take prudent steps to ensure that the test results of critical care/life support biomedical equipment are obtained and reviewed. Lastly, VHA needs

²⁴Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program (GAO/HEHS-98-21, March 17, 1998).

information on the Y2K readiness of specific pharmaceutical and medical-surgical manufacturers. Until this information is obtained and publicized, VHA medical facilities and veterans will remain in doubt as to whether an adequate supply of pharmaceutical and biological products will be available. FDA and the pharmaceutical and biological trade associations can play key roles in helping VHA obtain this information and publicize the results in a single data clearinghouse.

In carrying out this assignment, we reviewed and analyzed VA's Y2K documents and plans, comparing them against our guidance on Y2K activities. We also reviewed and analyzed FDA documentation relating to its Y2K efforts on biomedical devices and pharmaceutical manufacturers. In addition, we visited selected VHA medical centers, VA data centers, and VHA consolidated mail order pharmacies to discuss their Y2K activities, and interviewed VA and FDA officials on those activities. We also interviewed officials of the Emergency Care Research Institute regarding their statements on biomedical equipment testing. Finally, we interviewed selected private hospital officials about their Y2K actions and pharmaceutical trade associations on their Y2K readiness surveys of pharmaceutical manufacturers.

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.

(511266)

VA'S READINESS FOR YEAR 2000**TESTIMONY OF
MICHAEL SLACHTA, JR
DEPUTY ASSISTANT INSPECTOR GENERAL FOR AUDITING
DEPARTMENT OF VETERANS AFFAIRS****HOUSE COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**

April 15, 1999

Mr. Chairman and Members of the Subcommittee, I am pleased to be here today to comment on the Department of Veterans Affairs (VA) efforts to address Year 2000 (Y2K) issues and become Y2K compliant. While VA has reported its completion of renovation and implementation of all mission critical systems, our recent audit identified a number of key actions in other selected areas that could help make the Department's Y2K efforts more successful, reduce operating costs, and ensure continuity of operations beyond the millennium.

The Department's Y2K efforts have been substantial and A management reports show that it completed implementation of all mission critical systems by the March 31, 1999 milestone date established for all Federal agencies. VA has 11 mission critical systems that involve 319 applications and 17 million lines-of-code. VA has reported that it has completed renovation of all of these applications. The estimated cost of VA's Y2K implementation effort is about \$202 million.

Given the importance of correcting Y2K problems in VA computer systems and ensuring that veterans receive uninterrupted services, the OIG has been involved with review and oversight of the Department's Y2K implementation efforts since 1997.

In an effort to assure complete coverage of this vital issue while efficiently using scarce audit resources, we coordinated our efforts with those of the General Accounting Office (GAO). Before the start of our audit and again during the audit, our staff met with the GAO staff to share information and assure that our efforts and theirs were complimentary.

1997 Management Advisory Letter

In 1997, the OIG advised the Department on key Y2K issues that needed to be considered in its Y2K compliance efforts. At that time, we found that not all VA facilities had completed their assessment of locally developed computer applications. As a result, we advised the Department that:

- Facilities should complete required inventories and analyses as soon as possible.
- Status reports should be required to enhance oversight of the efforts to help ensure that adequate progress was made and resources were available to make all the necessary systems compliant.
- Actual costs and staff hours required to make the systems compliant should be tracked for all facilities and compared to the previous estimates.

At that time our discussions with Department officials indicated that they would consider our input on these issues as they proceeded with their Y2K implementation efforts.

1998-1999 OIG Y2K Audit

In 1998, the OIG initiated a national audit of VA's Y2K implementation efforts. The objective of the audit was to assess VA's efforts to address Y2K issues and become Y2K compliant. The audit focused on identifying areas where VA's Y2K implementation efforts could be strengthened.

As part of our initial survey work, we visited the primary Veterans Benefits Administration (VBA) Benefits Delivery Centers in Hines, Illinois and Philadelphia, Pennsylvania; the Austin Automation Center (AAC), and the Austin Finance Service Center (AFSC), Texas; to review VA's Y2K efforts. We also sent surveys to VBA Regional Offices (RO), Veterans Health Administration (VHA) medical centers, and selected VA Central Office (VACO) activities requesting general information on Y2K implementation and status information in key areas involving: (1) personal computers (PC), (2) locally developed applications, (3) commercial-off-the-shelf products (COTS), (4) local area networks (LAN), (5) data exchange/interfaces, (6) preparedness, and (7) biomedical devices. We received 209 responses out of 223 activities that were surveyed. We received responses from 23 VACO activities, 58 ROs, and 128 of 142 VHA facilities surveyed. Some VHA responses contained information on more than one facility.

Based on our analysis of the survey responses and discussions with Department officials, we selected 20 VA field facilities for site visits. We visited 15 VHA facilities and 5 ROs.

Given the time sensitivity of all Y2K issues, we provided the Department with four Interim Survey Advisory Letters (July, August, September, and December 1998) during the course of the national audit. These letters provided early notification to the Department of our audit results so that prompt corrective actions could be initiated to address the Y2K related issues that were identified. Department program officials responded positively to the Advisory Letters and initiated various corrective actions. On March 11, 1999 we forwarded a draft report of our findings and recommendations to VA's Acting Assistant Secretary for Information and Technology. Comments to the report are expected by April 22.

The audit found that enhancements to VA's Y2K implementation efforts could be achieved at its data centers, for selected VACO activities, and at selected field facilities in VHA and VBA. Our review of Y2K implementation activities at the Philadelphia and Hines Benefits Delivery Centers and the Austin Automation Center found that Y2K efforts at these Centers were generally proceeding according to Department plans. However, some Y2K related issues needed attention to assure the effectiveness of VA's Y2K implementation efforts. Key issues identified at the centers that needed attention included:

- Assurance of continued infrastructure (e.g. electricity, gas, and water) support requirements.
- Need to contact trading partners and value added networks concerning Y2K compliance of electronic data interchange transmission and receipt of VA procurement transactions.
- Preparation of a 'zero hour plan' covering operational procedures for the night of December 31, 1999 and the succeeding day.
- Approval of pending requests for equipment and software replacements that would reduce operating costs by \$1.5 million and enhances Y2K implementation efforts.
- Authority to pay retention bonuses to staff involved with Y2K implementation efforts.
- Inclusion of all computer applications in the Y2K assessment and renovation process.
- Reporting of the status of renovation work on mission critical systems.

While our audit found that both VACO and field facilities were actively engaged in addressing Y2K implementation requirements, additional efforts were needed to assure

that necessary work was successfully completed and the cost of the Department's Y2K related work was accurately identified and reported. Key areas that needed to be addressed included:

- Completion of medical center risk analysis to address potential infrastructure support failures external to VA facilities.
- Assuring the Y2K compliance of computers, environmental control systems, and other medical devices provided to veterans for use in their homes.
- Assuring the Y2K compliance of all biomedical devices including those used in VA's R&D Service.
- Completion of Y2K assessment and testing of computers located in facility tenant activities such as VA's Research and Development (R&D) Service.
- Assuring adequate procurement lead time for acquisition of replacement biomedical equipment.
- Completion of Memorandums of Understanding with data exchange partners to document their Y2K compliance.
- Resolution of infrastructure support issues involving ROs located in General Services Administration managed buildings.
- Tracking the cost of all Department Y2K implementation efforts.

The report includes recommendations to assist the Department's Y2K implementation efforts, ensure continuity of operations, and delivery of services and benefits to the nation's veterans and their beneficiaries beyond the millennium. Based on the audit findings and the continued Y2K risk to VA, we concluded that the Y2K area should continue to be monitored by the Department as a potential material weakness area.

In addition to our current audit effort, we also plan to complete follow-up work on VA's Y2K implementation effort later this year. This audit effort is expected to focus on key facility level implementation of contingency plans and determine the status of facility assessment efforts involving biomedical devices, especially equipment issued to veterans for use in their homes.

This concludes my testimony. I would be pleased to answer any questions you may have.

**STATEMENT BY
THE HONORABLE HERSEL W. GOBER
DEPUTY SECRETARY
DEPARTMENT OF VETERANS AFFAIRS**

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

APRIL 15, 1999

* * * * *

Introduction

It is my pleasure to testify on behalf of the Department of Veterans Affairs (VA) on the status of our readiness for the Year 2000. I am accompanied today by Harold Gracey, VA's Acting Chief Information Officer (CIO) and some other key staff from Information and Technology, VBA, and VHA who have been involved in Y2K full-time for the last several years.

The essence of the Year 2000 problem is that when the year changes from 1999 to 2000 or is entered as "00," systems and devices may not recognize this date as the intended or correct year.

Mr. Chairman, when I met with you in July 1997, you expressed your concern about the potential impact of this issue on us and the delivery of benefits and health care to veterans. I promised you then that we would be ready and I would be personally accountable.

We have worked very hard across VA to ensure we will be ready for the Year 2000. We have program delivery people and information technology people working hand-in-hand within and across Veterans Benefits Administration (VBA); Veterans Health Administration (VHA), National Cemetery Administration (NCA) and other VA organizational elements to ensure that we provide uninterrupted support of benefits delivery and healthcare services.

I appear before you today to say benefit payments will be made without interruption, and our healthcare facilities will be fully operational on January 1, 2000. Veterans will continue to receive their benefits on time, as well as the highest quality of health care in the Year 2000 and beyond. Because December 31 is a holiday and January 1 is a Saturday, VA's regular recurring benefit payments, including compensation and pension, most education programs, vocational rehabilitation, Restored Entitlement

Program for Survivors, and those for Vietnam veterans' children with Spina Bifida, will be posted to beneficiaries' accounts and be available on the morning of December 30, 1999. This will mitigate any unexpected Year 2000 interruptions of benefit payments arising from sources outside our control.

VA has demonstrated that we can successfully process multiple century dates. Since most of VBA benefits use forward projections, changes were made as early as 1982 to accommodate Year 2000 requirements. For example, in 1989 we corrected the 10-year delimiting date for education benefits in our systems. Another example is future award changes based on a child reaching age 18 after 1999 that are being successfully processed today. Further, our beneficiaries often maintain a relationship with VA lasting several decades. For example, we still cover insurance policy holders born in the 19th century.

VA Status

I am pleased to report that we have completed the Year 2000 renovation, validation, and implementation of our applications including all benefit payment-related applications and applications supporting health care. We have repaired and implemented applications supporting compensation and pension, health care, insurance, vocational rehabilitation, education, loan guaranty, financial management, payroll, and national cemeteries.

VA has also completed business continuity and contingency plans for benefits delivery and health care to reduce risks due to other potential Year 2000 interruptions such as loss of power supplies, water and telecommunications. I'd be happy to submit these for the record if you like.

VA is also playing an active role as a member of the President's Year 2000 Conversion Council chaired by John Koskinen. VA has representatives on the healthcare, education, financial and benefit payment sector work groups of the Year 2000 Conversion Council. VHA is also leading a subgroup of the healthcare sector dealing with issues regarding pharmaceuticals.

How VA Categorized Mission Critical Systems

Let me take a few moments to address how we classified our systems at VA. When VA began the Year 2000 tracking and reporting process in March 1997, we categorized all of our applications into 11 mission-critical system areas reflecting our business functions. Those systems are compensation and pension, education, loan guaranty, insurance, vocational rehabilitation, administrative, VISTA, VHA corporate systems, national cemeteries, financial services and payroll. These 11 mission-critical systems represent

over 300 applications and 17 million lines-of-code. In addition, each of the applications supporting our 11 mission-critical systems areas runs independently of all others. For example, there is no single loan guaranty system. Instead, we have 18 independent applications supporting the loan guaranty business function.

We also prioritized all applications supporting these mission-critical areas into a three-tiered structure, providing a common VA-wide priority ranking for VA's applications inventories supporting these VA mission critical system areas: Level I - business priority applications directly impacting the delivery of medical care and benefits to veterans; Level II - internal support systems that improve timeliness and efficiency of administrative processes and operations support; and, Level III - discontinued (retired) systems. VA considers both Level I and Level II as mission critical, and we have completed the renovation and implementation for both Level I and Level II applications.

Year 2000 Update

I would like to take this opportunity to specifically bring you up-to-date on NCA, VHA and VBA status, accomplishments and VA business continuity and contingency planning efforts.

National Cemetery Administration (NCA)

The information systems supporting NCA are fully Year 2000 compliant. Non-compliant NCA systems were replaced in December 1996. NCA has also completed business continuity and contingency plans for NCA operations in January 1999.

Veterans Health Administration

VHA has two mission-critical systems, *VISTA* and VHA Corporate systems consisting of 200 applications. VHA has completed the renovation, validation and implementation of both *VISTA* and VHA Corporate Systems.

VISTA is the name given to the standardized set of national software applications that form the automated systems environment supporting integrated healthcare delivery at local VA healthcare facilities. The *VISTA* inventory consists of 105 applications and all of the applications have been renovated, validated and implemented.

VHA Corporate Systems perform a variety of corporate-level functions within VHA. These systems range from management decision support tools to

patient information systems to systems for tracking construction project progress. The VHA inventory of 95 corporate systems has been renovated, validated and implemented.

Medical Devices

The potential Year 2000 impact on medical devices is a national issue, affecting both private sector and Federal healthcare communities. VA, like any other healthcare provider, buys these devices from industry. The Food and Drug Administration (FDA) regulates these products.

VHA has worked very hard for the past two years to develop a comprehensive approach and Year 2000 strategy for managing medical devices. This approach was developed with input from VHA Headquarters specialists and VHA field biomedical engineers in order to take advantage of their collective knowledge and to tailor a process for the actual users of medical devices.

VHA established the Medical Devices Integrated Product Team, a collaboration of engineers, clinicians and technologists, which reviewed the manufacturers' assertions of Year 2000 status of their devices. The members of this group are the leading Year 2000 experts on the potential problems with medical devices within VHA.

Beginning in September 1997, VHA sent letters to biomedical equipment manufacturers whose products are used within VHA. To date, we have achieved a 99% response rate. We have sent follow-up letters, made phone calls and have met with those companies that have not responded. The information we have gathered has been published on our internal network for the use of all VA medical facilities, and we have shared our database with FDA, the Department of Defense (DoD) and the Department of Health and Human Services (HHS).

Based on preliminary findings and comments from field facilities, our estimates are as follows: 82% of the vulnerable devices we use are compliant, 16% are conditionally compliant (meaning a fix or upgrade will be provided by the manufacturer) and 2% are non-compliant.

It important to note that through our exhaustive efforts we have found only one non-compliant medical device that could potentially pose direct harm to a patient. This device is a radiation dosage therapy system owned by three VA healthcare facilities. Two of these systems have already been replaced and the remaining healthcare facility is awaiting delivery of its replacement. In many cases, noncompliance is date-stamp related (for example, printing "00" on a report) and is not life-threatening. Almost all non-compliant devices are still clinically functional.

In addition, both VHA and DoD have worked together with large manufacturers of medical devices to increase the timeliness of Year 2000 fixes, negotiate charges for solutions, and organize their web pages to make them more user-friendly. These efforts not only help other Federal users of medical devices, but also further assist smaller providers and rural healthcare organizations in managing such a complex task.

The VHA Medical Devices team has aggressively pursued manufacturers of medical equipment who are trying to charge VA for Year 2000 fixes. VHA's posture has been that medical device malfunctions are a design issue or a latent defect and that the manufacturer should fix any device under 10 years of age at no charge. Over the past year, the VHA Medical Devices team invited several of the large manufacturers to VHA to discuss charges and solutions. To date, through this series of meetings with manufacturers, VHA has successfully negotiated a cost avoidance of \$2 million dollars.

VHA Year 2000 Biomedical Equipment Guidebook

VHA has worked closely with its biomedical engineers and technical experts to develop a guidebook that assists healthcare facilities as well as community organizers in managing the complex Year 2000 problem. The goal of the guidebook is to encourage healthcare organizations to conduct a thorough review of their biomedical equipment and to share findings within and across organizations. The strategic approach detailed in the guidebook will assist community hospitals, outpatient clinics, healthcare facilities, physicians' offices, tribal governments and other healthcare organizations through assessment and compliance conversion of their devices, equipment, and systems.

There have been many requests for this guidebook from the public. VHA has supplied the College of American Pathology & Information Services Committee, the Washington State Biomedical Association, the Colorado Rural Development Council, and many manufacturers of medical devices with copies of the guidebook. VHA has distributed over 1600 copies of this guidebook to small and rural hospitals as part of its commitment to assure that no patient is harmed as result of the change to the Year 2000 as well as the commitment for outreach to the President's Year 2000 Conversion Council.

Medical Device Clearing House

Since September 1998, under an interagency agreement, VA and HHS jointly post data to the Federal Year 2000 Biomedical Clearinghouse as an on-line database operated and maintained by the Food and Drug Administration (FDA). This web page disseminates timely information about the potential impact of the Year 2000 date change on specific biomedical equipment to healthcare providers and their patients.

VA Policy Regarding Non-responsive Manufacturers

This month, VHA's Chief Network Officer will be contacting specific VA healthcare facilities that have medical devices for which a) there is no compliance information available and b) the manufacturer has not responded to repeated inquiries. Currently there are 8 medical devices with no compliance information available from non-responsive manufacturers; none of the 8 fall into the category of critical care/life support.

For these 8 devices, VHA is recommending that healthcare facilities develop additional contingency plans including availability of back-up devices in case of unanticipated failure upon the transition to January 1, 2000.

VHA biomedical experts along with clinicians, medical records experts and General Counsel representatives met in February 1999 to discuss the results obtained from manufacturers of medical devices and to determine how stated Year 2000 non-compliance will affect clinical treatment and medical records.

As a result of this meeting, VHA has developed a policy to establish a facility review process including patient safety impact assessment, documentation, and facility management approval for continued use of medical devices for which no compliance information is available or which are identified as non-compliant from Year 2000 assessment activities.

Industry (ECRI), Other Hospital Systems, FDA's and VA Position on Additional Testing of Medical Devices

VHA's approach has not gone unnoticed. Professional working relationships have been established among VHA, Department of Defense (DoD), Food & Drug Administration (FDA), American Hospital Association (AHA), Emergency Care Research Institute (ECRI), and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). These large organizations and owners of medical devices have worked together to validate and reinforce the Year 2000 process for medical devices.

The National Patient Safety Partnership, initiated by VHA in 1997, has used its combined resources to raise public awareness about Year 2000

medical device vulnerabilities, to encourage action by manufacturers, healthcare organizations and consumers and to conduct outreach with particular emphasis on small and rural organizations. The Partnership includes the American Medical Association, the American Nurses Association, AHA, JCAHO and eight other national organizations. VHA will continue to work with the Partnership to provide overall leadership for a national Year 2000 effort.

The medical device industry is highly regulated and is acutely aware of its exposure to legal liability. When potential hazards with the use of medical devices are uncovered, there is a "community standard" or industry response to addressing and correcting the potential hazard. End users and manufacturers alike understand that it is in everyone's best interests to immediately contact the medical device manufacturer to investigate the potential hazard and develop the repair.

VHA views the Year 2000 problem as one large potential hazard and will follow what has proven to be a successful approach for the past several decades. We expect medical equipment manufacturers who have responded promptly and appropriately to identify hazards in the past to continue that course of action regarding Year 2000 problems.

VHA's position is that all medical devices must be tested to determine Year 2000 compliance. However, the primary source to determine the Year 2000 status is the medical device manufacturer. No other source, or combination of sources, can provide device-specific information while simultaneously ensuring proper and thorough testing. This position is consistent with other healthcare entities, including the Emergency Care Research Institute (ECRI) - an international nonprofit health services research agency and a Collaborating Center of the World Health Organization. ECRI is widely recognized as the world's leading independent organization committed to improving the safety, efficacy, and cost-effectiveness of healthcare technology. ECRI represents over 20,000 organization and individuals.

Other healthcare organizations that support this view include Columbia/HCA, Daughters of Charity National Health System, Mediq/PRN Life Support Services, Clinical Technology Services/Premier, Inc. and COHR, Inc. It is important to note that there is no general standard or industry-prescribed approach to end-user testing of medical devices for Year 2000 compliance.

VHA Pharmacy and Medical Supplies Activities

VHA is leading the Year 2000 Pharmaceuticals Acquisitions and Distributions Committee, under the direction of John Koskinen, Chair of the President's Council on Year 2000 Conversion. The Committee has a two-fold mission: 1) to determine the overall status of the pharmaceutical industry's Year 2000 compliance efforts concerning supply and distribution and 2) to homogenize efforts among the Federal government and industry.

The committee includes pharmaceutical industry trade association representatives throughout the supply chain, government agencies such as the FDA, DoD, and the Health Care Financing Administration (HCFA), and consumer advocacy organizations. The key issues the group is addressing are potential disruptions in the pharmaceutical supply chain, information disclosure, legal liability, anti-trust concerns, international issues (i.e. customs, business process, transportation), stockpiling/hoarding and public education.

VA's National Acquisition Center (NAC) collected Year 2000 compliance information from the medical device manufacturers that supply VA facilities with their biomedical devices and equipment. Currently, the NAC is pursuing manufacturers of pharmaceuticals and medical and surgical supplies to survey their Year 2000 compliance status. Surveys were sent to 843 medical and surgical suppliers as well as pharmaceutical manufacturers with whom VA does business. Results of the NAC survey will be available via its Internet site this month.

Industry Roundtable

Mr. Koskinen has asked VHA to help plan an Industry Roundtable on pharmaceutical issues in May. At the roundtable, senior pharmaceutical industry representatives and government representatives will be asked to develop a strategy to address some of the industry's most pressing concerns relating to the Year 2000. The goal of the roundtable is to inform the public on the pharmaceutical industry's Year 2000 compliance status.

Veterans Benefits Administration

VBA has renovated and completed implementation of its applications that support their six mission-critical systems, which include Compensation and Pension, Education, Loan Guaranty, Insurance, Vocational Rehabilitation, and VBA Administrative business lines. VBA's applications are very date sensitive, and today VBA is successfully processing dates for years 2000 and beyond.

VBA is conducting post-implementation testing and will soon begin end-to-end testing with some of its biggest trading partners, including the

Department of the Treasury. VBA has also developed business continuity and contingency plans for benefits delivery, regional office operations and benefit payments.

Compensation and Pension

Let me specifically address the compensation and pension software application. VBA awarded a contract for renovation support of our compensation and pension software application in October 1997. This contract provided an automated Year 2000 conversion tool for the application and additional contractor support for VBA's Year 2000 efforts. All of the code was renovated in October 1998, and the last pieces of the application were implemented in February 1999. The contractor used an automated tool to renovate the programming code and to review the programming code VBA had already made compliant.

Even though we have already conducted an independent verification and validation (IV&V) process for compensation and pension, we are going to undertake an additional IV&V effort by sampling some of the compensation and pension code. If this sample indicates a need for additional IV&V, we will expand the scope of this effort, and if required, we will run the compensation and pension code through another software tool to perform an automated IV&V. In addition to the IV&V I have just discussed, we continue to conduct post-implementation testing on compensation and pension application. These tests will actually test the compensation and pension production code in a Year 2000 simulated environment.

In June, we discussed with your staff a problem we had with the renovation of our Beneficiary Identification Records Locator System (BIRLS) application. BIRLS is our master record locator used for generating a benefit award. Although the contractor we engaged to undertake this job did not deliver, our government staff was able to complete the renovation of this critical application quickly, and it was installed into production in October 1998. We have not experienced any problems with BIRLS since.

VBA's mainframe computers and Information Technology Infrastructure

The VBA infrastructure is ready for the Year 2000. Our Honeywell 9000 platform upgrades were completed in September 1998, and our IBM platform upgrades were completed in February 1999. VBA continues to conduct tests on these platforms to insure they will not experience any problems due to third-party product issues. Last month, we completed the installation of our server and software upgrades to the 58 Regional Offices. We still have three or four commercial off-the-shelf products that still must be upgraded, but these are products used in isolated instances and not across-the-board.

Business Continuity and Contingency Planning

VA is not alone in being susceptible to potential disruptions in operations due to Year 2000 date-related system failures. Vulnerabilities to the Year 2000 problem permeate government agencies and business institutions, creating a situation where large-scale interruptions in essential community services, such as electricity and water, could occur. The Year 2000 problem is unique in that traditional contingency plans and back-up systems may be affected by the same problem(s). Therefore, the Year 2000 problem required a review of our current contingency plans to safeguard continuity of operations.

In December 1998, I sent a memorandum to the Under Secretaries for Health, Benefits and Memorial Affairs emphasizing my expectation that contingency plans be in place to ensure continuity of VA's business operations for our core business functions: benefits delivery and medical care.

VA has developed business continuity and contingency plans (BCCPs) to minimize Year 2000 impacts on our core business functions. BCCP plans for VBA benefits business lines and payments were completed in January. Patient-focused BCCP planning guidelines were completed in early March. Regional offices and healthcare facilities have been provided these plans and templates so that they can customize their individual plans according to their local needs. These customized extensions of the BCCPs will be completed this month.

Healthcare Business Continuity and Contingency Plans

In the case of our healthcare facilities, emergency preparedness plans are required by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and are in place at each facility. These plans help ensure the operation of healthcare delivery systems, including biomedical equipment, patient scheduling, and facility operations such as heating, ventilation and air conditioning. Although contingency plans are in place at each facility, VHA recognized the need for specific Year 2000 BCCPs in order to prevent any disruption to patient care.

A detailed patient-focused BCCP guidebook to assist each VA healthcare facility prepare for continuity of operations before, during and after the changing of the century was completed in March. A VHA expert team, and consultants who have extensive experience in healthcare contingency planning and Year 2000 readiness, developed the guidebook. The guidebook meets JCAHO and GAO requirements, so that following the procedures will not only produce a compliant contingency plan, it will greatly aid in documenting due diligence and reduce each healthcare facility's patient risk

by minimizing the probability of adverse Year 2000 events. The guidebook provides a basic template for Year 2000 contingency planning for all VA healthcare facilities or healthcare systems.

There are four key elements to the VHA Patient-Focused Year 2000 Contingency Plan:

- Leverage existing contingency or disaster recovery plans to the extent possible. It is not necessary to completely rewrite existing plans to address potential Year 2000 failures.
- Build a layered defense by developing plans to protect both mission-critical systems and mission-critical functions.
- Use a common framework for all Year 2000 contingencies that incorporates four separate process components: Planning, Preparation, Execution and Recovery.
- Regularly test, validate and review contingency plans. Assumptions for mission critical scenarios may change and contingency plans must be revisited regularly to reflect changes.

Training for Year 2000

An important aspect of patient-focused BCCP is staff training and assuring adequate resources to replace electronically controlled processes with manual processes of patient care, if necessary. Clinical processes for which VHA is assuring competence include, but are not limited to:

- Manual Cardio-Pulmonary Resuscitation (CPR)
- Manual Suctioning
- Manual Ventilation
- Manual Vital Signs Readings

VISN-Wide/Health Care Facility Drills

Each healthcare facility will complete at least one Year 2000 Contingency Drill as one of the recommended internal or external disaster drills or will participate in a VISN-wide drill. These drills will include: 1) management participation, 2) stressing the system, 3) formal critique, and 4) update of contingency plans based on the critique.

VHA is recommending that VISNs conduct multi-facility Year 2000 Contingency Drills. These drills will incorporate specific mission-critical systems that are at Year 2000 risk for failure. Evacuation of patients between sites can be specifically tested as a tabletop exercise.

Emergency Power Disruption Drills

In addition, each facility will perform an emergency power drill to prepare for various power disruption scenarios. Each facility, under controlled conditions, to prevent any patient harm, will run their emergency generator system for at least eight hours disconnected from the local electrical power supply. This will ensure that healthcare facilities can operate under emergency power, if necessary.

Benefits Delivery Business Continuity and Contingency Planning

In August 1998, VBA established a work group comprised of representatives from each business and service line. This group identified mission critical operations and assessed the potential impact of failures on VBA services. VBA defined failure scenarios and performed risk and impact analyses on each business process. VBA completed Year 2000 BCCP plans for VBA's six business lines supporting benefits delivery in January. VBA is responsible for meeting the needs of its veteran client base through its Compensation and Pension, Loan Guaranty, Insurance, Education, and Vocational Rehabilitation and Counseling Services business lines. VBA's BCCP consists of three elements: 1) business lines functions, 2) regional office operations, and 3) benefit payments contingencies.

VBA's BCCP includes plans for functions conducted at the VA Central Office as well as at VBA's field and regional office facilities. VBA identified the minimum acceptable levels of outputs and services for each of VBA's six mission critical, core business functions. In addition, the BCCP identifies Year 2000 risk scenarios, risk mitigation strategies and contingency "triggers." The Insurance Service developed the first VBA continuity of business operations plan in April 1998.

The objective of the BCCP is to minimize the impact on organizational business functions caused by problems relating to Year 2000 date manipulation. The intent will be, in the event of a Year 2000 disaster, to restore a previously defined, minimal level of critical functions as soon as possible and, if necessary, to implement an alternate strategy to meet the Department's mission. VBA's BCCP will be continually updated as information concerning Year 2000 readiness of such services as water and electricity become available as we approach the actual Year 2000 rollover.

Regional Office Operations

In addition to completing BCCP plans for benefits delivery, VBA has taken the additional step and completed a Year 2000 BCCP template for local regional office operations and personnel to mitigate potential Year 2000 risks and to establish the capability of maintaining minimal levels of operations. This template draws upon the BCCP for VBA's six business lines. The regional office BCCP has been disseminated to the regional offices so that they can customize local BCCP's to the unique needs of the regional office. VBA is currently documenting event specific contingency plans and implementation modes, defining triggers for activating each contingency plan, and establishing business resumption teams. These customized local regional office plans using the template will be completed this month.

VBA's BCCP is aimed at ensuring that its employees are able to carry out the assigned missions of each business line in spite of any evolving Year 2000 problem. The BCCP focuses on maintaining a minimal acceptable level of productivity regardless of the Year 2000 induced problem. The complete document is a collection of well-defined and executable contingency plans for each business line, as well as plans for the supporting services. It details the alternative approaches to performing the required mission of each business line and the strategies necessary for recovering from all Year 2000 induced problems as quickly and as efficiently as possible.

Testing VBA's Business Continuity and Contingency Plans

Finally, VBA will validate the BCCP through testing. Testing is paramount to ensure the plans will work if called upon. VBA is developing test plans and RO staff will obtain training in how to plan and conduct exercises at the Year 2000 Conference planned for July. Tabletop exercises will be conducted, evaluated and documented during August. Additional tabletop exercises will be performed in the November-December period.

In anticipation of concern among our beneficiaries as we enter December, and the possible increase in inquiries, VBA is notifying all of their Central Office and RO personnel of the need to maintain adequate staffing during the months of December and January. Leave usage will be minimized during these months to insure that personnel are available to respond to inquiries and activate contingencies, if they are needed.

Department of Treasury and Payment Contingencies

I would like to spend a few moments to discuss the Department of Treasury and veteran payments. As you may know, VA does not pay veterans directly. We transmit payment information to the Department of the Treasury's

Financial Management Service (FMS) which, in turn, disburses payments to veterans. Payments are made electronically or via a paper check.

We have worked closely with FMS during the course of this project. We have verified that the payment data we currently send to Treasury is compliant and is being processed without error. FMS has also reported that all veterans' benefit payments are now being successfully made through Year 2000 compliant systems. Based on the fact that both VA and FMS are already Year 2000 ready, I am confident that all benefit payments will be made without interruption in the Year 2000 and beyond. To further ensure compliance, VA and FMS have scheduled post-implementation testing to begin in May.

In addition, we have several contingencies in place with Treasury in the unlikely event of a problem. In fact, an entire subset of our contingency plan deals with Treasury issues to ensure that beneficiaries will receive their benefit payments on time and correctly when the new century begins. These plans include a worst case scenario in which the private banking electronic systems fail or have problems. If this occurs, Treasury can revert to the use of paper checks to deliver veterans payments after recertification of those payments by VA. In addition, if the VA systems cannot process in January 2000, we will provide a contingency payment file for Treasury's use so that they can generate veterans' payments. We feel these are unlikely events, but we are ready with contingencies in case they are needed.

Data exchange interfaces

VA has completed its inventory of external data exchange interfaces with other Federal agencies and the private sector. As of January, 99% of VA's interfaces are Year 2000 compliant. However, VA must rely on the trading partner's schedule. We are actively working to resolve any interface issues. VA is closely monitoring progress.

VA has identified three state interfaces that provide mailing addresses of veterans residing in those individual states on a quarterly basis. These interfaces are Year 2000 compliant. With the exception of these three interfaces, VA has no direct state or local government interfaces. This lack of direct interfaces mitigates Year 2000 problems with state and local governments. However, VA does provide information to other Federal agencies which, in turn, may interface with state and local governments.
VA working with Year 2000 interagency efforts

VA, VBA and VHA representatives are actively involved in several interagency efforts to find common solutions to Year 2000 issues. We are actively representing VA's interests in several sector groups created by the

Year 2000 Conversion Council as well as subgroups of the Federal CIO Council Committee on Year 2000. Included are:

- The health-care, education, financial and benefit payment sector work groups of the Year 2000 Conversion Council.
- VHA has the lead on the Year 2000 Pharmaceuticals Acquisitions and Distributions Committee.
- The telecommunications subgroup chaired by GSA to address issues in voice and data communications systems.
- The subgroup on building systems chaired by GSA to address issues related to the operation of buildings and facilities.

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

Summary

We will continue to work with the Federal CIO Council Committee on the Year 2000 and the Year 2000 Conversion Council to continue sharing information among Federal agencies.

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

Statement of William K. Hubbard, Acting Deputy Commissioner for
Policy, Food and Drug Administration, Department of Health and Human
Services

INTRODUCTION

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

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

WHAT IS A MEDICAL DEVICE?

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

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related

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

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

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

A. Embedded Computer Software

Computer software frequently is embedded as a "component" of devices, i.e., software contained on a microchip to control

device operation. Examples of such common, important devices are pacemakers, infusion pumps and ventilators. The majority of these products will not be affected by the Year 2000 problem since almost none of them require knowledge of the current date to operate safely and effectively. For example, pacemakers do not use the current date in their operation.

B. Non-embedded Computer Software

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

An example of non-embedded software is a computer program used to plan radiation therapy treatments delivered using radioactive isotopes as the radiation source (teletherapy or brachytherapy). These treatments possibly could be affected if the computer program that calculates the radiation dose parameters uses only a two-digit year representation. The calculation of the length of time since the source was last calibrated could be in error and thus lead to an incorrect treatment prescription.

Other examples of uses of non-embedded software devices include: conversion of pacemaker telemetry data; conversion, transmission, or storage of medical images; automated analysis and interpretation of ECG data; programming or control of rate response for a cardiac pacemaker; perfusion calculations for cardiopulmonary bypass; and calculation of bone fracture risk

from bone densitometry data. Since there is a chance that the two-digit format may affect the performance of these software devices, FDA believes that the Year 2000 risk requires that healthcare facilities take steps to identify and mitigate such problems through proactively working with manufacturers.

FDA EFFORTS TO ADDRESS YEAR 2000 ISSUE

Year 2000 Database

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

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

choose, where the requested information is provided to the public.

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

RECENT LETTERS TO MANUFACTURERS

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

Biomedical equipment users have expressed the need for specific information on all Year 2000 vulnerable products that are compliant and have urged the establishment of a single, comprehensive source for this information. On March 29, 1999, FDA issued a letter requesting that medical device manufacturers submit a complete list of individual product models that are Year 2000 compliant to the FDA-operated Federal Year 2000 Biomedical Equipment Clearinghouse. Many biomedical equipment users have told FDA that a single statement that all of a manufacturer's products are Year 2000 compliant does not

meet their need to have affirmatively identified specific compliant equipment. Once information on compliant products is received from medical device manufacturers it will be made available, with improved search tools, as part of the Biomedical Equipment Clearinghouse.

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

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

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

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

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

PREVIOUS LETTERS TO MANUFACTURERS

A. June 25, 1997 Notification to Manufacturers

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

control processes. FDA requested that manufacturers review the software used in medical devices to determine if there is any risk.

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

B. January 21, 1998 Request for Information

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

C. Targeted Follow-up with Manufacturers of Computerized Devices

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

Then on September 2, 1998, FDA issued a follow-up to the June 29, 1998 letter, directed to the manufacturers of potentially computerized devices who had not responded to the previous requests to specific manufacturers for information on the Year 2000 status of their devices. In the letter, FDA requested that the manufacturers respond to FDA within two weeks with the Year 2000 compliance status of their devices, or at least indicate that a complete response was being developed.

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

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

manufacturers to obtain this data and report to Congress on the status of these Year 2000 requests.

ADDITIONAL OUTREACH AND GUIDANCE

In addition to the website and the letters, CDRH has been conducting extensive outreach to the device industry and to other consumers on this issue. CDRH's Division of Small Manufacturers Assistance provided an article entitled "Biomedical Equipment Manufacturers Urged to Share Year 2000 Information" to 12 medical device trade press contacts and to 65 U.S. and 35 foreign medical device trade associations in order to facilitate the dissemination of information to their members regarding the website database and to encourage the posting of data by manufacturers. The website and database were mentioned in the FDA Column of the June 3, 1998, *Journal of the American Medical Association* and in an article in FDA's Medical Bulletin that was sent to approximately 700,000 healthcare practitioners this past summer.

In the Spring of 1998, CDRH developed a Guidance Document on FDA's expectations of medical device manufacturers concerning the Year 2000 date problem. The guidance is available on the FDA website. The guidance was published in the Federal Register on June 24 for greater dissemination. The guidance re-emphasizes the provisions in existing regulations that require manufacturers to address any date problems which may present a significant risk to public health.

FDA also developed an article addressed to the users of radiation treatment planning systems regarding the need to assess these systems. The article was published in the newsletters of relevant professional associations. Staff of

CDRH have participated in numerous conferences and video teleconferences devoted to the Year 2000 problem in healthcare in order to communicate with healthcare facilities regarding the Biomedical Equipment Clearinghouse and the need to address the Year 2000 issue with devices.

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

PHARMACEUTICAL INDUSTRY

In order to raise the awareness of the pharmaceutical industry to the Year 2000 issue, Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, sent a letter dated October 14, 1998, to trade organizations requesting assistance in relaying FDA's expectations regarding the Year 2000 problem as it affects the pharmaceutical industry. FDA believes that the potential impact of the Year 2000 on pharmaceutical safety, efficacy, and availability merits special attention. The Year 2000 issue can cause a variety of problems in how dates are expressed or computed that could adversely affect automated drug process controls. Of special concern are manufacturing processes, which if disrupted by Year 2000 issues could result in shortages of needed pharmaceuticals.

On February 22, 1999, FDA participated in "Y2K Preparedness - Pharmaceuticals and Biotech - A Joint Government/Industry Forum." The objective of this meeting was to raise awareness and help further preparedness for successfully managing Year 2000 related issues. The pharmaceutical industry is expected to address the problem as a high priority, to thoroughly assess and test their computer systems and develop appropriate contingency plans. FDA also has been meeting with trade organizations and associations to further communicate the Agency's expectations regarding the industry's Year 2000 efforts.

In addition, the Agency also has been meeting internally to discuss additional potential initiatives to assess the industry's Year 2000 compliance status to avoid disruptions in the drug supply. These internal discussions have focused on how to address the compliance of manufacturers of single-source and foreign bulk product suppliers, and also possible collection of data to assess Year 2000 readiness and contingency plans. Also discussed have been communication initiatives to inform the public, healthcare providers, associations, etc., that there will be a safe and adequate supply of drugs as we enter the year 2000.

Once our internal deliberations are concluded, we will be happy to provide the Committee with specific details.

WHAT IS THE DATA TELLING US THUS FAR?

As indicated above, FDA believes that approximately 2,000 manufacturers may produce equipment that may be affected by the Year 2000 problem. As of March 30, 1999, FDA has entered a

total of 4,305 responses from the 16,000 manufacturers originally contacted. The data from all of these manufacturers who have responded have been entered into the database on the FDA website. These numbers change daily as data are entered, corrected or even removed at the request of manufacturers. Of the 4,305 manufacturers who have responded, 3,153 have reported that their products do not use date-related data or are compliant. Six hundred seventy-three manufacturers have reported one or more products with date-related problems. Four hundred manufacturers have provided World Wide Web links (URLs) to data provided on their own manufacturer-operated websites. There are a few submissions in which the data were incomplete or unclear in some manner. FDA is communicating with these manufacturers to obtain clarification before entering the information into the database. FDA will continue to post additional responses as they are received.

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

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

Legal Authority

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

The Removals and Corrections Regulation (21 CFR 806) requires manufacturers to submit reports to FDA. In order to be reportable, a Year 2000 problem must pose a "risk to health" as defined in section 806.2(j). Many of the problems reported in the Biomedical Equipment database or on manufacturers' Year 2000 Web pages concern date recording or display problems that are readily apparent to the user and are unlikely to pose a risk to health. In the Year 2000 context, a decision to

correct a problem may occur long before the correction itself is actually announced to customers. Once the decision for action is made, however, and if the action is to correct a risk to health, then the firm has 10 working days to notify the Agency through a report of correction or removal. A firm that previously notified FDA about a removal or correction through a Medical Device Report (under 21 CFR 803) does not have to submit an additional report under 21 CFR 806.

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

CONCLUSION

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

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

Thank you for the opportunity to testify.

Statement



JUDITH H. BELLO,
EXECUTIVE VICE PRESIDENT FOR POLICY AND STRATEGIC AFFAIRS,
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

U.S. HOUSE OF REPRESENTATIVES

April 15, 1999

Mr. Chairman and Members of the Subcommittee:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to report that the research-based pharmaceutical industry will be well-prepared to meet the systems-related challenges presented by the Year 2000 (Y2K). PhRMA represents the country's leading research-based pharmaceutical companies, which are investing more than \$24 billion annually in the search for new cures and treatments. Our members discover and develop the innovative prescription medicines that play such an important role in keeping all Americans, including our nation's veterans, healthy and productive.

Because we are keenly aware of the critical importance of our products to people's lives and welfare, our industry launched a massive readiness effort more than three years ago to ensure that there will be a continuous supply of medicines to patients during the Year 2000. Our companies are continuing to perfect their systems to combat any Y2K problems.

A survey of our members – released 10 days ago – showed that:

- All respondents have a Y2K plan in place and are developing contingency plans to ensure the continuous supply of medicines to patients.
- Our companies expect to spend \$1.75 billion to address Y2K issues.

The respondents represent about 90 percent of the U.S. research-based pharmaceutical industry.

Pharmaceutical Research and Manufacturers of America

1100 Fifteenth Street, N.W. Washington, D.C. 20005 (202) 835-3400

Our industry's ability to cope with Y2K challenges is enhanced because we do not operate on a "just-in-time" manufacturing basis. For this reason, we have learned from discussions with wholesalers and retailers that the supply chain on average contains a 90-day supply of medicines.

Further, a robust rapid-response network of manufacturers, wholesalers, and retailers already exists to deal with supply shortages, whether at a particular pharmacy or caused by any emergency or natural disaster. We are working to ensure that this rapid-response network will be prepared to handle Y2K disruptions.

We are also fully cooperating with Congressional Y2K Committees, the President's Council on Year 2000, the Food and Drug Administration, and the Departments of Veterans Affairs and Health and Human Services in preparing for the Year 2000. For example:

- **On February 22, we co-sponsored a Y2K symposium with FDA and the Biotechnology Industry Organization (BIO).**
- **HHS issued a press release in which it encouraged others in the health-care sector to follow our example with our survey and "share...information widely with the public."**
- **The President's Council has sent our survey to other trade associations as a model for what it would like to receive.**

Our industry is committed to working with our suppliers and distribution channels around the world – as well as with the federal and state governments – to continue our efforts to facilitate an uninterrupted supply of medicines throughout the healthcare chain. We also are committed to reassuring physicians, patients, and consumers by informing them of what we are doing and will continue to do to ensure a continuous supply of medicines.

Ultimately, success in meeting the Y2K challenge depends not only on our industry and the other links in the supply chain, but also on doctors, hospitals, insurers, and – not least – patients themselves. Hoarding and stockpiling by patients could create a greater threat to the uninterrupted supply of medicines than any computer glitch.

In closing, Mr. Chairman and Members, let me stress that we in industry face two Y2K challenges. Our first job is to fix any problem. Our second job is to fully cooperate with Congress, the Administration, and the

myriad other parties involved in health care to engender fact-based consumer confidence that the problem is, indeed, being fixed, in order to avoid the far greater, more certain problem that hoarding would create.

These two industry jobs are linked. We cannot avoid panic-driven hoarding by correcting the Y2K problem alone; we must also engender consumer confidence that hoarding is not needed and, in fact, would be counterproductive. On the other hand, we cannot engender such confidence without first fixing the problem.

Please understand that the same experts within our member companies who are working to correct and avoid any problem are the same experts who have the facts that numerous parties are seeking to assess Y2K readiness in health care. While we are pleased to cooperate with everyone, these experts must be able to fix the problem – which only they can do – so that the public can be assured that the medicine supply will be uninterrupted and hoarding will be unnecessary. To avoid a health-care problem, we must succeed in both jobs, and we are committed to doing so.

The complete results of our survey, a press release about the survey, and a statement by Kevin L. Thurm, Deputy Secretary of Health and Human Services and Chair, Health and Human Services Sector of the President's Council on Year 2000, are attached to my statement. The survey results also are available on our website.

I appreciate the opportunity to testify before the Subcommittee on the vital Y2K issue, and will be pleased to respond to questions.

APPENDIX

PhRMA is aware of House Rule XI, clause 2(g)(4) requiring additional information from nongovernmental witnesses. Federal contract and grant disclosure information is provided on the attached form for fiscal year 1999. PhRMA has not been awarded other government contracts or grants in the two previous fiscal years.

The testimony presented today is on behalf of the association, not any individual member company or group of member companies. PhRMA makes no representation with regard to any federal grants or contracts, if any, received by any PhRMA member company.

**DISCLOSURE FORM FOR WITNESSES
CONCERNING FEDERAL CONTRACT AND GRANT INFORMATION**

INSTRUCTION TO WITNESSES: Rule 11, clause 2(g)(4), of the Rules of the U.S. House of Representatives for the 106th Congress requires nongovernmental witnesses appearing before House committees to submit in their written statements a curriculum vitae and a disclosure of the amount and source of any federal contracts or grants (including subcontracts and subgrants) received during the current and two previous fiscal years either by the witness or by an entity represented by the witness. This form is intended to assist witnesses appearing before the House Armed Services Committee in complying with the House rule.

Witness name: Judy Bello

Capacity in which appearing: (check one)

Individual

Representative

If appearing in a representative capacity, name of the company, association or other entity being represented: Pharmaceutical Research and Manufacturers of America

FISCAL YEAR 1999

federal grant(s) / contracts	federal agency	dollar value	subject(s) of contract or grant
GU 9723171	U.S. Trade & Development Agency	\$81,510.	pharmaceutical orientation visit for Central European officials

News Release



FOR IMMEDIATE RELEASE
April 5, 1999

Contact: Mark Grayson
(202) 835-3465

DRUG INDUSTRY READY FOR NEW MILLENNIUM, SAYS PhRMA

Washington, D.C. - Thanks to a massive readiness effort begun more than three years ago, the pharmaceutical industry is well-prepared to meet the challenges of the Year 2000 (Y2K), the Pharmaceutical Research and Manufacturers of America (PhRMA) announced today in releasing the results of a survey of member companies.

The survey showed that:

- 100 percent of the companies responding—including nearly all of the top 20 research-based pharmaceutical firms—have a Y2K plan in place and are developing contingency plans to ensure the continuous supply of medicines to patients.
- 100 percent of the companies have completed an inventory of their equipment containing embedded chips and are taking corrective action where needed.
- Companies expect to spend \$1.75 billion to address Y2K issues.

"We anticipate no interruption in the supply of medicines due to Y2K problems at our member companies," said PhRMA President Alan F. Holmer. "Ultimately, success in meeting the Y2K challenge depends not only on our industry but on other links in the supply chain and on doctors, hospitals, insurers and – not least of all – patients themselves. Hoarding and stockpiling by patients could create a greater threat to the supply of medicines than any computer glitch."

The pharmaceutical industry is continuing to test its systems to ensure that they will be Y2K compliant. The industry is committed to continue working with our suppliers and distribution channels as well as the federal government, seeking to ensure an uninterrupted supply of medicine across the healthcare chain.

Holmer noted that the pharmaceutical industry has extensive experience in getting medicines to where they are needed in time of crisis, such as sites of hurricanes, fires, other natural disasters and military conflicts.

The Pharmaceutical Research and manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing \$24 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Contact: HHS Press Office
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STATEMENT BY KEVIN L. THURM
Deputy Secretary of Health and Human Services
Chair, Health and Human Services Sector, President's Council on Year 2000

"I am pleased that the Pharmaceutical Research and Manufacturers of America (PhRMA) is sharing its Year 2000 report today on the progress of the research based pharmaceutical industry. I encourage others in the health care sector not only to monitor their Y2K status, but also to share that information widely with the public.

"Pharmaceutical supplies are just one of many interlocking parts of our nation's health care system. Representatives from across the system need to work together to ensure that the whole and all its parts will be prepared to operate smoothly as our data systems transition to the new millenium.

"As part of the President's Council on Year 2000 Conversion, the Department of Health and Human Services is helping the many sectors of the health care industry to work together and to be prepared for the Y2K challenge. While each sector must be responsible for its own preparations, we can make the greatest progress by working together, sharing our knowledge, and keeping the public informed of our progress."

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THE PHARMACEUTICAL INDUSTRY YEAR 2000 AND THE AVAILABILITY OF MEDICINES

Industry Readiness

The pharmaceutical industry understands the importance of our products to people's lives. When patients have extraordinary needs, we have always responded. Year 2000 readiness is a top priority for this industry. It recognized the Y2K challenge early and launched a massive readiness effort more than three years ago. This work continues today. As a result, the pharmaceutical industry does not anticipate interruption in the supply of medicines because of Y2K issues at our member companies.

At the same time, we are only one part of the supply chain. Ultimately, success in meeting the Y2K challenge will mean that patients continue to get the medicines they need. That success depends on our industry, on the rest of the supply chain, on providers, on payers and also on patients themselves. Abnormal purchasing by patients – such as extraordinary advance purchase and hoarding of pharmaceuticals – could create a more significant risk to overall supply continuity of critical medicines than Y2K systems-related issues.

Regarding product availability, it is reassuring that the pharmaceutical industry does not operate primarily on a “just-in-time” basis for the manufacture of its products. Many products depend on various bulk materials for their production, which are in various stages of production in an on-going process. Significant stocks of finished products exist at manufacturing locations and at other points in the supply chain.

Our industry is committed to continue working with our suppliers and distribution channels around the world – as well as with the federal and state governments – to develop contingency and rapid response plans to facilitate an uninterrupted supply of medicine across the health care chain. Also, we are committed to communicating information to patients and consumers – so that they know what we are able and ready to do.

The pharmaceutical industry has extensive experience in getting medicines to where they are needed in times of crisis. For more than a century, we have taken very seriously our responsibility to be fully prepared for situations that potentially affect the availability of prescription medicines. The companies have long had contingency plans to cope with supply of products following hurricanes, fires and other disasters.

In short, the pharmaceutical industry expects to be ready for Y2K and is working with others in the supply chain to help maintain the uninterrupted flow of medicines.

PhRMA Y2K Survey Results

In February 1999, 25 PhRMA member companies were surveyed regarding their Y2K preparations and readiness. The 24 companies that responded include nearly all of the country's top 20 research-based pharmaceutical companies and comprise more than 90 percent of the industry capacity represented by PhRMA, which represents more than 95% of the research-based pharmaceutical industry in the U.S. While progress continues in 1999, key survey results as of year-end 1998 include the following:

- 100% of the companies have a Y2K plan in place.
- Nearly 67% of all software application renovation, replacement or upgrades are complete, with some companies reporting 100% completion of work.
- 100% of the companies have completed an inventory of their research and development and manufacturing operations equipment containing embedded chips and found 85% of these devices to be Y2K compliant. Of devices needing corrective action, approximately half need only simple steps, and half require more significant measures – including replacement and upgrade, which will be completed by year-end.
- 85% of the key business partners of PhRMA companies have already been contacted regarding their Y2K-readiness.
- 100% of the companies are developing contingency plans, and 78% of those plans are expected to be ready by June 30, 1999.
- Some companies expressed concern with preparations being made in countries outside the United States – particularly in Asia and Japan – due to lack of awareness, infrastructure failures such as telecommunications and power, lack of technical skills and the resources to fix problems. These companies are developing contingency plans to help ensure supply continuity.
- PhRMA companies are expected to spend \$1.75 billion to address Y2K issues.

There is a clear indication from the survey that Y2K preparations are well underway in pharmaceutical companies and that most repair work is expected to be completed in early to mid-1999. Companies will spend the rest of the year continuing to check and re-check internal systems and work with external business partners to further minimize the risk of a significant Y2K systems-related failure.

Survey Results in Detail

Participants in the survey included:

- Allergan, Inc.
- American Home Products Corporation
- Amgen, Inc.
- Biogen, Inc.
- Boehringer Ingelheim Corporation
- Bristol-Myers Squibb Company
- Eli Lilly and Company
- Genentech, Inc.
- Genzyme Corporation
- Glaxo Wellcome Inc.
- Hoffman-La Roche Inc.
- Johnson & Johnson
- * Knoll Pharmaceutical Company
- * Merck & Company, Inc.
- * Novartis Pharmaceuticals Corporation
- * Pfizer Inc.
- * Pharmacia & Upjohn, Inc.
- * Purdue Frederick Company
- * Sanofi Pharmaceuticals, Inc.
- * Schering-Plough Corp.
- * SmithKline Beecham, p.l.c.
- * Solvay Pharmaceuticals, Inc.
- * Warner-Lambert Company
- * Zeneca Pharmaceuticals

The information provided below is intended to give pharmaceutical industry averages as of year-end 1998. Actual results vary from company to company.

Question #1: How is your organization's Y2K work organized?

- a) Does the organization have a plan for addressing the Y2K problem? Does it include milestones? Is it approved by the organization's chief executive? Is there a defined Y2K organizational structure?
 - 100% of the companies have a Y2K plan
 - 96% of the companies have defined milestones in their plan
 - 92% of the plans have been approved by senior executives
 - 88% of the companies have a defined Y2K organization structure
- b) How much do you expect to spend on fixing the Y2K problem?
 - Collectively, the companies expect to spend \$1.75 billion on Y2K activities. While the average expenditure per company is estimated at \$92 million, the larger companies will spend significantly more.
- c) How much have you spent to date?
 - Collectively, the companies have spent an estimated \$575.5 million on Y2K activities. While the average expenditure per company to date is estimated at \$36 million, the larger companies have spent significantly more.

Question #2: What percentage of the work of repairing or replacing mission critical systems has been completed for each phase listed below? Identify the planned completion dates for each phase.

- 95% of assessments are complete
- 65% of renovations are complete
- 53% of testing work is complete
- 50% of all applications being repaired have been fixed and returned to production

Many of the larger pharmaceutical companies have already completed their application renovations, and most will complete no later than mid-1999.

Question #3: Are plans for internal and external contingencies in progress? Completed? Target completion dates?

- 100% have contingency planning in progress
- While no companies have reported completed plans
 - 13% expect to complete plans by 1Q99
 - Another 65% expect to complete plans by 2Q99
 - Another 22% expect to complete plans by 3Q99

Question #4: If you operate internationally, are you encountering any special problems due to Y2K?

- a) Which regions and issues are of most concern?
- 55% are concerned with Y2K issues in Japan and Asia
 - 36% are concerned with Y2K issues in Western Europe
 - 27% are concerned with Y2K issues in Eastern Europe
 - 27% are concerned with Y2K issues in South America
 - 18% are concerned with Y2K issues in the Far East

Issues of greatest concern:

- General lack of Y2K issue awareness
- Telecommunications, utilities and other infrastructure
- Lack of technical skill and resources to fix problems

- b) Are you considering suspending activities in any countries?
- No companies are considering suspending business activities in other countries due to Y2K.

Question #5: Are new systems implementation projects part of your Y2K strategy, and if so, what is the planned completion of these projects?

- 96% of the companies are implementing new systems as part of their Y2K readiness efforts, and 10% of the companies have already completed these installations. Others plan to complete by:
 - 20% expect completion in 1Q99
 - 35% expect completion in 2Q99
 - 30% expect completion in 3Q99
 - 5% expect completion in 4Q99

Question #6: Do you plan to contact your key business partners (*suppliers, vendors and customers*) to assess their Y2K readiness, and if so, what percentage of those partners you plan to contact have been contacted?

- 100% plan to contact their business partners to assess readiness
- 85% of the partners that are planned to be contacted have already been contacted to assess readiness
- 83% of the companies will have contingency plans in place for high risk business partners by 3Q99

Question #7: Have you initiated or do you plan to initiate an independent review of your Y2K program?

- 96% of the companies plan to conduct an independent review

Question #8: Respond to the following questions regarding your systems with embedded chips.

- a) Have you completed an inventory?
 - 100% of the companies have completed an inventory of lab, building and process automation equipment
- b) Is your assessment complete?
 - 67% of the companies have completed an assessment of lab, building and process automation equipment
- c) What percentage of devices require corrective action?

- Generally, 15% of a company's devices require Y2K fixes – the other 85% are either already compliant or determined to be not critical to be compliant.
- d) When will all critical systems/devices with embedded chips be fixed?
- 70% will have critical devices fixed by 3Q99
 - 100% will have critical devices fixed by 4Q99

Question #9: Will you be prepared to support the new 4010 ANSI EDI standard and/or other EDI formats?

- 88% of the companies will adopt the new 4010 ANSI EDI standard
- 80% of the companies will be able to support other EDI formats

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