

**THE YEAR 2000 COMPUTER PROBLEM:
WILL THE HEALTH CARE INDUSTRY BE READY?**

HEARING
BEFORE THE
**SPECIAL COMMITTEE ON THE
YEAR 2000 TECHNOLOGY PROBLEM**
UNITED STATES SENATE
ONE HUNDRED FIFTH CONGRESS
SECOND SESSION

ON

WHERE THE HEALTH CARE INDUSTRY STANDS IN RELATION TO MEET-
ING THE YEAR 2000 AWARENESS, ASSESSMENT, VALIDATION, AND
IMPLEMENTATION DEADLINES

JULY 23, 1998

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YEAR 2000 TECHNOLOGY PROBLEM

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THURSDAY, JULY 23, 1998

U.S. SENATE,
SPECIAL COMMITTEE ON THE YEAR 2000
TECHNOLOGY PROBLEM,
Washington, DC.

The committee met, pursuant to notice, at 9:55 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Robert F. Bennett (chairman of the committee), presiding.

Present: Senators Bennett, Smith, and Dodd.

OPENING STATEMENT OF HON. ROBERT F. BENNETT, A U.S. SENATOR FROM UTAH, CHAIRMAN, SPECIAL COMMITTEE ON THE YEAR 2000 TECHNOLOGY PROBLEM

Chairman BENNETT. The committee will come to order. I apologize to the witnesses and other visitors for the delay. Occasionally, the work of the Senate gets in the way of the work of the Senate. I expect we will have other members of the committee here shortly, but in the interest of starting the hearing, we will begin. There is a vote going on on the Senate floor right now, which is why other Senators have not been here, and I want to—well, I will wait until Senator Dodd arrives to express the committee's gratitude to him for his leadership in getting us focused on the health care issues.

We welcome you to the fourth hearing of the Special Committee on the Year 2000 Technology Problem. To date, we have held hearings on the energy utilities and financial services industries, and we plan hearings, as those of you who follow this issue know, on telecommunications, transportation, general government services and general business.

Let me begin today's hearing by saying that health care is America's largest single industry, generating \$1.5 trillion annually, more than one-seventh of our economy. More importantly, the quality of life of virtually every American family is directly impacted if this industry is not ready in time for the next millennium.

Unfortunately, I have troubling news today. Clearly, the health care industry is not ready for the Year 2000. If tonight, when the clock struck midnight, the calendar flipped to December 31, 1999, large portions of the health care system would fail. There are some 6,000 American hospitals, 800,000 doctors and 50,000 nursing homes, as well as hundreds of biomedical equipment manufacturers and suppliers of blood, pharmaceuticals, linens, bandages, et cetera, along with insurance payers and others that are not yet prepared.

Today, we want to present a balanced picture of where the health care industry stands in relation to meeting the Year 2000 awareness, assessment, validation and implementation deadlines. The committee has been unable to find a central repository of this kind of information, so I look forward to the contributions of each of today's witnesses, out of which we hope will come some kind of consensus.

Since World War II, the United States has undergone one cultural change after another but probably none as profound as the one occurring in the health care industry. The very name health care industry is in sharp contrast to the solo-practicing doctors which dominated medicine when my father was a member of the U.S. Senate. So, before we get into discussing the potential effects of Y2K on health care, I think a quick view of the changing times in medicine is in order.

Not too many years ago, when you made an appointment to see your doctor, he would greet you at his office, inquire about your family and ask the purpose of the visit. When you told him, he would probably take your blood pressure, test your lungs and heart with a stethoscope, ask a few more questions, look at your medical record folder and prescribe treatment. There is no Y2K in that picture.

Today, when you enter a doctor's office, outpatient clinic, hospital or HMO, you first encounter medical electronics as you submit your insurance or Medicare card to the admission clerk. The data in your card is entered into a desktop computer that is linked to Medicare or insurance eligibility files, maintained on a mainframe computer in some distant city. The same computer will bill the insurance company and you as a co-payer.

Electronic complexity continues at every step, starting with computerized medical records. Virtually every diagnostic and therapy machine is powered by one or more microprocessors. If a patient requires hospitalization, his physician electronically schedules a time-specific hospital admission date as a preparatory step as well as the medical orders. The hospital computer will generate a letter telling the patient the medically-necessary tests that will be needed, and every test uses one or more date-sensitive microprocessors which automatically feed your biological results into the hospital's computer-based clinical data system.

This same computer schedules the time, surgical suite location and staffing levels for your operation as well as a list of essential medical needs for the surgery. Throughout the operation, the patient will be connected to life-saving machines: monitors, ventilators, anesthesia control and infusion pumps that are all, again, microprocessor operated. High technology follows the patient into the intensive care unit to help ensure full recovery. Finally, the patient is wheeled into a ward and begins receiving food from a computer-generated dietetics menu. The only thing that has not changed since my father's day is the taste of that hospital food. [Laughter.]

In addition, electronic data interchange, EDI, is used for most of the business transactions of the medical institutions. These include patient billing and payment systems which are interconnected, so that a failure at one can reverberate throughout the entire system.

Based on what you will be hearing from various witnesses today, there is trouble in River City and most of the rest of the nation, because the health care industry is lagging behind other industries in making crucial Y2K fixes.

The Gartner Group says that over 90 percent of the individual physician practices are not yet aware of their Y2K problems, and two of our witnesses have equally alarming data that they will share with us. Finally, if the insurance and Medicare eligibility process cannot function, doctors' offices and hospital admission processes would default to paper. That sounds easy, but the daily output is nearly 4 million Medicare claims and approximately 27 million pages of medical records. That is an awful lot of paper. Health care paperwork could back up like traffic on an interstate highway after a bad accident, and this could immediately affect a patient's access to quality health care.

Concurrently, the nation's 1.6 million providers would have monumental cash flow problems without electronic payment from insurers and Medicare, which accounts for nearly 50 percent of health care payments, almost \$1 billion a day. The problem is exacerbated by the lack of a national fix-it program by the health care industry. I try not to be too harsh, but I find it hard to understand why the manufacturers of biomedical devices, represented by the Health Industry Manufacturers Association, have not provided a central clearinghouse for the data that only they possess.

The complexity of biomedical products causes me to take the unusual step of publicly requesting that the health care industry help solve the Y2K problem which they helped create. We will hear from them today.

Again I had hoped that Senator Dodd could be here for his opening statement, but I understand that he is tied up on the floor. The vote is still on. So, we will go to Senator Dodd and other members of the committee as they arrive.

We will begin with Andrew Lowenthal and a staff presentation of the complexities of the health care industry and how they are susceptible to the Year 2000 problem. Mr. Lowenthal is Senator Dodd's assistant and has been directly connected with this right from the beginning. Mr. Dan Nutkis, president of the Odin Group, which is a consulting group to major companies in the medical industry will describe the extensive electronic interrelationships that exist in today's health care environment. Then, Dr. Kenneth Kiser, the Under Secretary for Veterans Affairs, who is responsible for the 170-hospital VA Hospital System and an outstanding emergency room physician in his own right, will demonstrate the impact of Y2K on biomedical devices.

Mr. Lowenthal, thank you for your willingness to be the spokesperson for the staff, and let me thank the entire staff. This has been an extraordinary experience for me, to see how quickly this staff has come together, operating under difficult physical conditions down in the basement of this building, to do an outstanding job pulling all of this information. Mr. Lowenthal is the representative of that extraordinary group.

STATEMENT OF ANDREW LOWENTHAL, STAFF, SPECIAL COMMITTEE ON THE YEAR 2000 TECHNOLOGY PROBLEM, WASHINGTON, DC

Mr. LOWENTHAL. Thank you very much, Chairman Bennett, and as you said, I work on the special committee for Vice-Chairman Dodd, and I am here representing the staff, and I particularly think it is important to note the contributions of Robert Cresanti, John Stephenson, and Frank Reilley in putting this together. I am here on all of their behalfs, but they did outstanding work, and the success of their presentation is really much more theirs than mine.

The staff was asked to put together an overview of the points in the health care delivery system in which there are Year 2000 implications from the point at which a patient presents themselves through diagnosis and treatment. In order to facilitate this and provide the Senators and the committee with the best possible presentation, two representatives were selected: Daniel Nutkis, president of the Odin Group will provide the committee with a broad overview from his vantage point as head of an organization whose members include hospitals, other health care providers, insurance companies, pharmaceutical manufacturers and distributors, and then, Dr. Kiser, who is the Under Secretary for Veterans Health at the Department of Veterans Affairs will present an overview that will focus a little bit more on the particular implications for hospitals and specifically focusing on medical devices and diagnostic equipment.

Thank you very much, Mr. Chairman.

Chairman BENNETT. Mr. Nutkis, we appreciate your being here.

Mr. NUTKIS. Senator Bennett, Senator Dodd.

Chairman BENNETT. Senator Dodd, do you want to make an opening statement before we get into the panel?

Vice Chairman DODD. Yes, if you do not mind, just for a minute or so.

Chairman BENNETT. I said nice things about you before you came.

Vice Chairman DODD. And I was outside the door listening.

Chairman BENNETT. They were all deserved. Senator Dodd is the one who insisted that we focus early and specifically on the health care industry. If it had not been for that insistence, we probably would be getting around to this later than we are in our schedule. I acknowledge that and acknowledge that he was absolutely right in his priorities.

OPENING STATEMENT OF HON. CHRISTOPHER J. DODD, A U.S. SENATOR FROM CONNECTICUT, VICE CHAIRMAN, SPECIAL COMMITTEE ON THE YEAR 2000 TECHNOLOGY PROBLEM

Vice Chairman DODD. Mr. Chairman, I thank you, and I thank you immensely for this early hearing on such an important subject, and there are other subjects that we will no doubt review, but as we have both come to appreciate, the health care industry clearly falls into the category of mission critical, and as we both discovered earlier this week in a visit to a local hospital, in fact my sense of urgency about it was heightened even further by some of the things that we heard at a very fine hospital here in the Greater Washington area.

So, I am deeply appreciative of the effort here this morning. There is no sense, I suppose, in trying to beat around the bush. The question that many Americans are asking today, as they begin to focus on this issue, is are people going to die as a result of the Year 2000 complications in the medical industry. My answer is I do not think so at all. We may have some problems, but I hope that these problems will be of a limited scope. My goal however, is to heighten awareness and increase preparation not to create panic.

But it is entirely possible—it is entirely possible, in my view, that the millennium conversion could put the health care industry in intensive care as a result of this problem. The industry faces significant Year 2000 challenges which could result in significant disruptions across the country. And as I said regarding the utility industry, we are no longer talking about whether there will be any disruptions. We are talking about how severe those disruptions are going to be.

While I am very hesitant to say that these disruptions will be life-threatening, there is a reasonable chance that they will compromise the quality of extended patient care in all parts of the country. My concerns are based upon three factors, very briefly, which I want to touch on here in this opening set of remarks. First, there are serious Year 2000 problems in many medical devices, from diagnostic tools to dialysis machines, and I am deeply disturbed by the fact that instead of taking steps to deal with the problem, the medical device industry as a whole seems to be exacerbating the problem by refusing to provide information to either the Food and Drug Administration, which regulates the device safety, or even to the hospitals and clinics which use their devices every day.

And just as an aside, Mr. Chairman, we went through the FDA reform legislation, and I was very active on that issue in the Labor and Human Resources Committee, and we have significant medical device companies in my State of Connecticut of which we are very, very proud; they have done some very innovative work. But I am deeply concerned about this issue, and for those in the audience who may be listening who are from this industry, this is unacceptable, and any industry that comes looking for protection on liability, in my view, who is lacking in responsiveness as the medical device industry is, at this point—do not look to this Senator for any support. You want support on liability issues; you better get going on this issue of being responsive to these inquiries, and right now.

So, it is very, very serious. We have 500 days left; no time to be fooling around in responding to questionnaires when they come from the FDA and other sources. It is stunningly short-sighted, in my view, and can only cause harm to both the makers and the users of these devices.

A secondary concern is that the Medicare system, which processes nearly a billion claims a year and provides nearly a billion dollars a day will not be ready. If there are any disruptions in the Medicare system, and I should also include state-run Medicaid programs in this area, many health care providers, some of whom depend on Medicare payments for as much as 40 percent of their operating budgets, will not be able to operate.

And last, I am concerned about rural hospitals and municipal hospitals or other institutions that are strapped for resources. As I mentioned, the chairman and I saw a hospital the other day in the area which is a fine, fine institution and really first class and really working very aggressively to deal with their issues. Unfortunately, many hospitals do not have the kind of resources that this facility does, and I am worried about institutions in our rural areas or inner cities and urban areas that do not have the resources that some of the more affluent ones do.

So, again, I think this is a very timely hearing. I am very grateful to the chairman for placing it as high in the agenda as he has, and we are very interested in hearing what our witnesses have to say. We are not going to get all of the answers we want this morning, but I think we are beginning an important discussion of what we can do at a governmental level and how we can encourage and support the private sector in a sense of cooperation on this issue to see to it that we minimize the problems on January 1, 2000, that could occur in the health-related industries.

Thank you, Mr. Chairman.

Chairman BENNETT. Thank you very much.

Mr. Nutkis.

STATEMENT OF DANIEL S. NUTKIS, CHAIRMAN, ODIN GROUP

Mr. NUTKIS. Senator Bennett, Senator Dodd.

Chairman BENNETT. We would ask that you pay attention to the lights. We have got a lot of witnesses, and if you could hold your presentation within the time of the lights, we would appreciate it.

Thank you.

Mr. NUTKIS. Earlier this year, Odin Group started a process of examination of Year 2000 issues in health care, not unlike the process that the Senate committee is going through now. Our members were becoming increasingly concerned about the heavy interdependence of a wide range of trading partners, the fact that small players still represent the bulk of the entities in today's health care system, the resource pressures that affect many of those players, the lack of sophistication regarding Year 2000 and the need to develop comprehensive contingency plans and to ease public concerns.

I am not saying anyone will entirely escape disruptions within their own organizations no matter how well they are prepared, but the more trading partners you have, the greater the likelihood that you will feel the disruptions of other organizations. For these reasons, Odin Group initiated the Vital Signs 2000 project. Its ultimate objectives are to help the industry understand these possible disruptions; to encourage development of contingency plans by individual organizations and the industry at large and to ensure continuity of patient care.

While many other parties and studies are focusing on one segment of the health care industry, Vital Signs 2000 is focused on the bigger picture. Let me show you one of our high-level models that we are using to make the complexity of this industry more understandable and manageable. You can turn to the first chart attached to my testimony, the one describing the interaction matrix.

Down the vertical axis, you will see that the players are categorized into five broad domains: customers, providers, suppliers, payers——

Chairman BENNETT. For the audience, the chart is over here. Do you want to identify which one it is?

Mr. NUTKIS. The chart to the left.

Chairman BENNETT. OK.

Mr. NUTKIS. Down the vertical axis, you will see the players are categorized into five broad domains: customers, providers, suppliers, payers, and regulatory bodies. There is more detail in my written testimony.

Now, let us overlay this list of domains with a variety of processes that require intense interaction to deliver patient services. The matrix shows these processes along the horizontal axis, grouped into four value chains. Care delivery: this includes processes that the patient experiences along the continuum of care; customer management includes all elements of customer service, accounting, managing benefit plans and formularies; supply chain management covers the business processes to receive orders and fulfill orders; and provider management, which includes claims and reimbursement and internal management processes.

The point of this interdependence model is to underscore how complexity drives up risk. Organizations can better handle failures if they are prepared for them, which is why some companies in this industry are spending half a billion dollars on Year 2000 mitigation. But a much greater problem is the failure you have not thought of until the beeper goes off, and that is assuming the beeper does go off.

When an individual organization has a Year 2000 failure for which it is not prepared, it will greatly impact its trading partners. Those partners, unless properly prepared, will not be able to support the next level of trading partners. And on it goes, with each failure piling on top of the last and everything ultimately piling on the patient. Dr. Kiser is addressing medical devices, so let me take a different scenario, the case of a payer organization serving 2,000 group plans and 1 million employees or dependents. When the systems malfunction, plan sponsors start seeing inaccurate bills and premium notices. Payments may be lost or made for services that are not covered in the plan. The provider starts seeing a flurry of eligibility denials, claim denials and payment delays. The doctors may be unable to make specialist referrals.

Meanwhile, failures in the doctor's own offices add to the snarls, as doctors have trouble accessing patient records, submitting claims and scheduling appointments. The actual time the doctor can spend with patients drops from 4 hours a day to 2. Frustrated patients start wondering where else they can go for medical services, but health care is not as portable as it used to be.

Health care organizations deal with failures every day. But what happens when they have to deal with more failures and longer-lasting failures than they ever have known before?

By now, it is getting clear why an interdependent health care system requires an integrated approach to the Year 2000 problem and why our central theme should be triage and contingency planning. We need to answer questions like how critical is each compo-

nent and how well prepared; which failures could cause widespread disruptions; what are the contingency planning scenarios, including their financial, operational and technical implications?

Odin Group has spent months studying the complexities and interrelationships I have just described and the impact on various failures. Now, we are undertaking a survey involving all parts of the health care industry to better understand where failures are likely to occur. Then, we will form working groups to conduct industry-wide contingency planning. Researchers, advisors and industry members will work together to identify, recommend and test industry plans. A final report will be presented to a gathering of CEO's to make sure the top industry leadership fully understands what must be done.

Contingency planning must be part of a comprehensive approach to the Year 2000. The last chart to my testimony depicts what Smith Kline Beecham is doing. It is the chart to the right. In the center circle are the internal systems. Around that is a second ring representing their infrastructure. This includes telecommunications, lab equipment and process control. In the next circle are end user systems, on the desktops of tens of thousands of employees worldwide.

But even if you have got all of that right, you are not going to make it through January 2000 unless you consider external relationships with customers, suppliers and anyone you do business with. In this particular case, the company even considers involvement in industry groups to be part of its Year 2000 effort, and contingency planning is incorporated throughout. This chart could have come from any number of organizations we have studied. If these companies can do it, so can every player in this industry. A comprehensive Year 2000 methodology has to include awareness of the problem, assessment of what is required to fix a specific device or system, prioritization and triage of the most critical issues, remediation, which may include the repairing, replacing or retiring of the system, testing, which should also include critical trading partners and contingency planning.

What can this committee do to help? The health care industry, like most others, is greatly concerned with issues of liability concerning Year 2000 comprehensive efforts. It encompasses antitrust issues but also has to do with whether a company creates new liabilities for itself by sharing information which later proves to be wrong or even damaging. President Clinton's proposal for a Good Samaritan law to cover such situations is right on track. Odin Group members would be pleased to work with their Senators and this committee to make sure the provisions of such a law are appropriate for and helpful to the health care industry.

I would also ask this committee to be watchful for regulatory initiatives that add complexity and drain resources from Year 2000 efforts. Every additional Year 2000 failure has the potential to make the situation exponentially worse, and every major new regulatory requirement adds to the complexity of information systems work being done over the next 17 months. Odin Group's approach is to leverage the strengths of the leaders who are preparing well for the Year 2000 to make sure that everyone in the health care industry prepares as best they can.

Through Vital Signs 2000, we are producing specific recommendations regarding contingency planning, including operational and financial implications, industry-wide preparedness, and testing. The Government cannot do this job for industry but can raise awareness.

Mr. Chairman, I would like to officially invite you and your esteemed colleagues on this committee to attend the Vital Signs 2000 CEO conference to hear the results firsthand. There are no excuses for any player in this industry not having a good plan, and there are no excuses for industry not having a contingency plan that reaches across the entire expanse of health care in America.

I wish to thank you for the opportunity to testify on this matter and hope my testimony contributes in some small way to helping the health care system.

[The prepared statement of Mr. Nutkis can be found in the appendix.]

Chairman BENNETT. Thank you. What is the date of your invitation?

Mr. NUTKIS. October 27.

Vice Chairman DODD. Good timing. [Laughter.]

Chairman BENNETT. The only thing more important than Y2K is the reelection of the vice-chairman and the chairman of this committee. [Laughter.]

We may both be involved on that date.

Vice Chairman DODD. Teleconference us in.

Chairman BENNETT. Yes.

Dr. Kiser.

STATEMENT OF KENNETH W. KIZER, M.D., UNDER SECRETARY OF VETERANS HEALTH, DEPARTMENT OF VETERANS AFFAIRS

Dr. KIZER. Good morning, Mr. Chairman and members of the committee. I appreciate the opportunity to brief you on health care issues posed by the Year 2000 compliance problems. My oral comments will be directed towards biomedical equipment and medical devices based, in part, on the experience of the Veterans health care system to date.

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

Chairman BENNETT. Without objection.

Dr. KIZER. Technology has been responsible for so many of the advances and wonders of modern health care, and so, it is somewhat ironic that this same technology may now present hazards to patient care when the 21st century begins. I know that the committee is familiar with the genesis and the background of the Y2K problem, so I am not going to spend any time going into that. Suffice it to say that the essence of the problem from the biomedical technology point of view is the fact that when the Year 2000 is entered as 00, systems and devices may not recognize this entry as a correct year, and thus, programs may fail. They may not perform as designed. They may reject legitimate entries, or they may yield erroneous results.

There are thousands of medical devices which may be affected by one or more of these problems—what I have collectively called the

millennium bug syndrome or MBS. Any technology-related process that sorts by date or that requires a comparison by dates; any process that calculates age; or any other process that performs some date-related task is subject to the millennium bug syndrome. This includes hospital information management systems, building systems that control heating, ventilation and air conditioning, security, the elevators, billing and accounting, etc.

While many of the problems that have been identified to date are relatively minor and can be fixed, many health care institutions across the country simply are not positioned to accomplish those repairs. More importantly at this time, though, is that too many health care institutions do not yet know whether they have a problem or how big of a problem they have.

There are many aspects to this problem, as Mr. Nutkis and the chairman have noted already, and as other witnesses will discuss this morning that I am not going to talk about.

Let me turn my comments to biomedical equipment and specifically to some of our experience with this at the Department of Veterans Affairs. As you know, the Veterans Health Administration in the Department of Veterans Affairs operates the largest fully-integrated health care system in the United States. We have a wide range of electronic information systems, biomedical equipment, facility management systems and other computer-based system products that are vital to support services at our over 1,100 sites of care. This includes 171 hospitals, which includes the array from very complex tertiary and quaternary care facilities to small, rural hospitals. On average, we estimate that each of these facilities have 7,000 to 8,000 devices per facility. When you add onto that the more than 600 clinics and outpatient sites we have, the 131 nursing homes, and the array of other facilities, I think it begins to paint a picture of how many devices we have and how large this could be for a system of our size. The inventory of devices runs the gamut from very general things like suction machines and blood pressure cuffs to magnetic resonance imaging and computerized tomographic systems.

We have been working on this problem since 1996. A number of aspects of this are detailed in my written testimony. Specifically, with regard to biomedical equipment, beginning early last summer, we identified about 1,600 manufacturers that we had purchased equipment from over the years. I think that we are typical of most hospitals or health care systems in that we have an array of devices and equipment that has been purchased over the last two or three decades, in addition to more recent years. Much of the equipment that has been produced in recent years is not subject to this MB's, but much of the older material is.

Now, of those 1,600 manufacturers, which is out of a universe of about 16,000 manufacturers of medical supplies and devices, we have surveyed them up to four times to get information as to whether their devices are compliant. I can report to you at this time that 694 of those manufacturers have certified to us that their products are Y2K compliant, and therefore, at least, per the manufacturer's report, there should not be any problems with them.

Thirty-four manufacturers that account for a total of 182 models of equipment have reported that their devices are not compliant

and that they are no longer supported by the manufacturer; these models are considered obsolete and will not be fixed, even though many of those things are still commonly used.

Some 102 manufacturers have reported that they produce a total of 673 models that are currently not compliant but that they do intend to repair or otherwise fix the device, although in almost all of these cases, the manufacturer has not stated exactly how the device is not compliant or exactly what will be done to fix it.

Likewise, the manner in which they will be providing the fix ranges across the board as to whether they will charge or not charge for it; whether they will send a technician to the facility; whether you have to send the device back to the facility. These responses are across the board.

Fifty-three manufacturers have reported that they are still doing analyses on their products, and they cannot tell us if their products are compliant. For 201 manufacturers we have gotten return to sender notices, and after four attempts at trying to identify those manufacturers, we are assuming that we probably will not ever get information from them.

Some 96 other manufacturers have either gone out of business or have been acquired and have presented difficulties in tracking them down.

Finally, 233 manufacturers have not responded to us at all, despite our multiple inquiries.

Thus, overall, we know at this time that we have 855 models of devices and equipment that are not Y2K compliant and that about 20 percent of these will not be made compliant by the manufacturer. And after four separate queries, we have not been able to get a response from about 30 percent of manufacturers. I think it is relevant to note that in interpreting these figures, you should keep in mind the size of the customer that VHA is and that there is a business interest on the part of the manufacturers to be responsive to us. Other than that, we have no reason to believe that our experience is not, or will not be, typical of that of other health care providers.

Let me conclude these oral comments by reiterating that the millennium bug syndrome clearly has implications for every industry and many households nationwide. It is particularly critical for health care, since health care today is so dependent on the use of biomedical equipment and devices that rely on embedded, date-dependent information technology. We now know that many medical devices are not compliant, and many of those are not going to be made compliant. We also know that when the clock rolls forward to the 21st century about 526 days from now that about 3.8 million Americans each day will be receiving health care at hospitals or clinics or nursing homes. Many more are being treated at home. Each of these patients will typically have multiple different interactions, sometimes hundreds of interactions, per day with biomedical equipment, devices and information technology systems. When you consider the extraordinary number of interactions that that translates to, I think it becomes clear how large the potential for adverse events is, even if the problem involves only a very small percentage of devices or systems.

The good part of it is that we still have time to ensure that no patient suffers harm as a result of the millennium bug syndrome if concerted and very aggressive action is taken in the months ahead.

I thought it might be useful to the committee to perhaps demonstrate for you or show you some of the different devices and the types of problems they have—i.e., how this Y2K bug might manifest itself in an array of equipment, and let me just, if I can move up here.

Chairman BENNETT. Yes; we have turned off the light for the show and tell.

Dr. KIZER. Show and tell, OK.

What we have done here is try to present a number of different devices to demonstrate the different types of problems.

This one is a defibrillator. It is a relatively simple problem in that the date will not print out. That is not very serious if everyone remembers to write the date on the pages. Conversely, here is another device—this is a monitor that is used in intensive care units to monitor heart rhythms and other aspects of patient care.

The problem here is that the software is designed so that the alarm may not go off when the date doesn't register correctly. The problem, in essence, is that in the typical ICU setting, if someone were to develop ventricular fibrillation or ventricular tachycardia, you may have a matter of only seconds or a couple of minutes to respond to that. If you do not hear the alarm, you may not respond in a timely manner, and therefore, the patient may suffer adverse results as the result of the alarm not going off.

Let me turn now to a couple of pictures. These devices are too large to bring into the hearing room. But the one here, a linear accelerator, which is used in cancer therapy where the dose is absolutely critical if you are going to do proper treatment.

Vice Chairman DODD. Pull that microphone, will you? Because we can hear you, but they cannot hear you.

Chairman BENNETT. We have an overflow room with as many people in it as are here. So, they are getting it electronically; hopefully, there is no Y2K bug between here and there.

Dr. KIZER. Are you sure?

Chairman BENNETT. Yes.

Dr. KIZER. This is considered an obsolete unit, and there is no intent to fix it by the manufacturer. So, here, you get into replacement costs.

Another aspect, this is a picture of a sterilizer. There is nothing as basic to operation of a hospital as sterilization, and this is a time dependent process. This is an example of one where, despite multiple entreaties to find out its compliance status we cannot get a response from the manufacturer as to whether this is going to be compliant or not. It obviously creates some problems.

Here is another one. This is an infusion pump that is used to supply medication to patients. The problem here is simply that you cannot enter a date, and we know that the date is needed, for example, for preventive maintenance, or if there is a problem, from a repair point of view. For example, maintaining the battery is critical. If you are infusing a drug to a patient, you want to make sure that the device continues to operate while you are treating the pa-

tient. So, preventive maintenance is critical. But the date will not allow you to know whether your preventive maintenance is on schedule or not, because you cannot manually enter the date into it, and the software is programmed so that it will not recognize the Year 2000. So, this is a particular problem in that it may work, but as far as maintenance or servicing the machine, we do not know whether it will work from that perspective.

Here is another example. This is an electrocardiographic machine where the problem is that it will not print a date. In interpreting EKG's, it is critical to compare readings from different dates. What happens in this case is every time the machine is turned off, and it is meant to be a portable machine so you can transport it around the hospital to do EKG's. Because every time you turn it on, you have to recalibrate the machine so it will print out the date, it may take 10, 15, 20 minutes extra. The machine works OK, but it is just another example of how Y2K noncompliance may complicate providing care. Obviously, it will not function as it is intended, so, there are replacement costs, or you have to find some other way to use it.

Another example here has to do with CT scanners and SRI scanners. It is interesting that 2 weeks ago, when we held a press conference on this subject with the American Medical Association, the American Hospital Association, the American Nurses Association, and some other entities, we noted that we had not been able to get information from the company. We have in excess of 100 of these CT scanners for about \$1.3 million each. We have 50 or so MRI scanners from this company at about \$1.7 million each. After multiple entreaties, we had not been able to get information from them. After the press conference, we did get a call, and interestingly, last night, we got a call saying that the information has now been put on the Web site. So, it has been perhaps—shedding some light on it may have been helpful in getting some information from that company, which is a very large company, and I would say that some of the other manufacturers from whom we have not gotten information are not necessarily small companies. There have been some very large manufacturers there.

Just a couple of others. There is another defibrillator here.

Vice Chairman DODD. I would like to see that list, and I think we ought to put it in the record.

Dr. KIZER. We can provide this for you.

Vice Chairman DODD. Good.

[The information requested by Senator Dodd can be found in the appendix.]

Dr. KIZER. Here is another defibrillator, and it is much the same problem. This is one in which the clock does not work on it, so you do not, again, have a date printed out on it. This is one which the manufacturer will not replace. And each of these cost about \$10,000, so if one is going to have to replace all of these in a facility, and there may be 10, 20, 30 or 40 or more of these in a facility, there is obviously a significant cost associated with that.

Vice Chairman DODD. Could you give us just a quick assessment of what the costs are of each of these pieces of equipment are that you have in front of you, just rough numbers?

Dr. KIZER. Most of these would be in the several thousand dollar range, but there are also—for example, this pump, at every bed in an intensive care unit, there would be one. A typical large hospital might have 20 or 30 intensive care beds. They have backup units as well. So, while the individual price is significant but not like a million-dollar CT scanner, the numbers add up very quickly, and certainly for very small hospitals, this is very significant.

Just two other things I would mention here. One of them that we have a photo of is the dental x-ray machine. This is, again, a common device. The problem here is that we tried repeatedly to find the manufacturer, and it took some months before we could find out that this company had been acquired and changed ownership. It illustrates the difficulty in tracking down the source of information. Because of the changes, as the chairman noted earlier, the changes going on in health care. There has been a lot of consolidation, and the manufacturer of equipment that you have may not be the one that is taking care of it today.

And finally, the last piece of equipment I would mention is a computerized medical system radiation therapy unit that uses cobalt, but the calculation of the dose is dependent on the software. It is absolutely critical if you are not going to overdose the patient with radiation that date-related calculations are correct. The manufacturer has indicated that these machines should be discarded. Again, this becomes an issue of cost. The current replacement cost would be about \$250,000 per machine. We have three of these in operation today, and there are many others around the country.

Hopefully, this presentation of devices gives you some sample of the types and the nature of the various ways that this millennium bug syndrome may manifest itself in biomedical devices.

Senator SMITH. Doctor, can you tell me how are the manufacturers trying to absolve themselves of litigation or mitigate damages that can flow from the malfunction of these pieces of equipment? Are they writing you letters and saying that they are obsolete, and we have no further obligation; the burden is yours? What is the MO?

Dr. KIZER. I am not sure I can speak from a real informed point of view as far as how one mitigates their liability. I would say that the response of the industry has been across the whole gamut. We have some manufacturers who have been totally responsive; they have been absolutely forthcoming, and have been leading the charge very proactively. Then, we have others, some very large manufacturers, who, despite multiple letters, have either not responded or have given us what we characterize as courtesy responses that contain no information.

Senator SMITH. Do you want to offer an opinion? What ought our response to be on legal liability? Should we do anything trying to absolve them, or should we see this as a vehicle to get them to change and to improve their products, update them? Because, I mean, it seems to me we are talking about life and death kinds of equipment here.

Dr. KIZER. Well, I think as illustrated by this, the potential is of that magnitude. The response I have given in some other settings on this is that this is a completely preventable problem. No one should have to suffer harm as a result of this, and it seems to me

that the best vaccine against liability is to be as forthcoming and to be as proactive as possible in providing information and providing that information to the users, the health care providers, hospitals, physician offices, others. That would be the best way to protect against liability in my opinion.

Senator SMITH. I agree.

[The prepared statement of Dr. Kizer can be found in the appendix.]

Chairman BENNETT. Thank you.

Senator Smith, did you have an opening statement?

Senator SMITH. No.

Chairman BENNETT. OK.

We have put up, Doctor, a list of the kinds of devices after you took us through some sample examples. This is a list of categories of devices, and we are dependent, or thankful is the better word, to the people at INOVA Fairfax Hospital for this. That is the facility that Senator Dodd and I toured earlier this week, and they are very forthcoming on the impact of this on patient care. As we walked through the hospital, they would say this will not be compliant; this will not be compliant; this will. This is where we are.

I was impressed—Senator Dodd, before you got there, I said this is great that you are focusing on patient care and your internal systems, but you know me; I wanted to go horizontally. Have you looked at the impact on people outside your hospital? He said Senator, down to the traffic light controlling people turning into our property from the freeway to make sure that it, too, will be Y2K compliant. This is an example of a group that is doing it right.

Do you want to make any comment about that list? I know we are springing it on you, so, if you say it is too confusing, we will—

Dr. KIZER. I think I could be more helpful if I responded for the record after having a chance to look at the list and perhaps compare it with our results. I might just add a comment that is partially responsive to you and to Senator Smith, that the issue from our perspective really is one of protecting patients. One of the responses we have gotten from industry is that they do not want to provide us with the information until they have provided us with a fix, a technological fix.

And while that may sound OK to some, we do not think it is really adequate. It is nice to have the fix, and we want that, but the real issue is we need to know about the problem, so we can take interventions to protect patients. If we know a device is not going to work, then, we can fashion some sort of way to protect the patients ultimately and work about the technological fix as needed.

Vice Chairman DODD. It goes to the contingency planning issue, which—

Dr. KIZER. Exactly.

Vice Chairman DODD [continuing]. Is absolutely critical. I mean, you mentioned before and the chairman has, and actually, I am very glad to hear you, Mr. Nutkis, talk about the contingency planning. That ought to be moving up on the priority list of actions that institutions, private and public, are taking right now in preparation for the difficulty of compliance as we get further, the clock

moves further along. So, I think that is an all-important consideration.

Dr. KIZER. And let me give you a very specific example of that. One of the devices, the Space Labs monitor that we talked about regarding the alarm, the company has indicated that it will provide a patch, or a fix, but it has to be ordered by December 15, 1998. If it is not ordered by that time, they will not be able to supply it. Therefore, obviously, we are going to have to know about it well before that date, or a facility will have to know about it well before that if they are going to be able to order it in time to get the fix.

Chairman BENNETT. One other question: this is a lot of money. Now, let us talk about the VA, because it is the largest hospital system in the country. Do you have enough money?

Dr. KIZER. That is a loaded question.

Chairman BENNETT. I know; asking any bureaucrat that—

Dr. KIZER. Particularly with Senator Dodd sitting next to you.

Vice Chairman DODD. The answer is no.

Chairman BENNETT. Yes, yes.

Vice Chairman DODD. I must say, I should tell you, and Dr. Kizer very graciously was in Connecticut about a week ago.

Dr. KIZER. A week ago, yes.

Vice Chairman DODD. On a totally separate set of issues dealing with the VA in West Haven and did a very, very fine job meeting with the entire congressional delegation from Connecticut, which is a rarity, to get an entire delegation together on an issue, but the doctor was very forthcoming and went through and explained some of the difficulties, and it is a financial issue we were talking about in terms of the various nets of veterans' hospitals.

But I would be remiss in his presence here if I did not thank him for being in category last week and meeting with us. We were inaugurating a new outpatient facility at the hospital, which the doctor was the keynote speaker at, and we appreciate it very much.

Dr. KIZER. The pleasure was all mine to be there, Senator.

Chairman BENNETT. I am told I have misspoken. Columbia HCA is twice as large as the VA system.

Dr. KIZER. They have more hospitals.

Chairman BENNETT. They have more hospitals. [Laughter.]

But the reason I raise this, as you know, we have a unique situation on this committee in that we have as ex-officio members the chairman and the ranking member of the Senate Appropriations Committee, Senator Stevens and Senator Byrd. I do not want to look back on this problem and say, well, the VA did not get it solved because of a snarl in the appropriations process, and the money needed to make these kinds of replacements was simply not made available by the Congress.

We are going to have enough responsibility for this problem. I do not want to add to that the responsibility of not appropriating what is necessary to get this done. So, I am giving you the kind of dream question that every bureaucrat would love to have from an appropriator, which is tell us how much money you think you are going to need.

Dr. KIZER. We actually are trying to get our hands around this. One of the problems in defining the extent of the replacement costs is when we do not have a response from 30 percent of the manufac-

turers, that leaves a big hole. We know at this point that replacement costs are probably over \$50 million.

Chairman BENNETT. I am surprised it is that low.

Dr. KIZER. Well, we know it is over \$50 million.

Vice Chairman DODD. Better answer.

Chairman BENNETT. Yes. [Laughter.]

All right; thank you both very much.

Vice Chairman DODD. Very, very helpful.

Chairman BENNETT. We appreciate it.

All right; we now welcome the Honorable Kevin L. Thurm, Deputy Secretary of the Department of Health and Human Services; the Honorable Michael A. Friedman, M.D., who is Acting Commissioner of the Food and Drug Administration; and the Honorable Nancy-Ann Min DeParle who is the Administrator of HCFA.

Once again, on behalf of the committee, I welcome you all and thank you for your willingness to testify. Mr. Thurm, we will start with you.

**STATEMENT OF KEVIN L. THURM, DEPUTY SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. THURM. Good morning, Mr. Chairman, Vice-Chairman Dodd, Senator Smith, and thank you for inviting me and my colleagues here today. I would like to submit a written statement for the record and offer a brief oral statement summarizing my testimony.

Chairman BENNETT. Without objection, your written statement will be made part of the record.

Mr. THURM. I am accompanied today by Dr. John Callahan, who is our Assistant Secretary for Management and Budget and our Chief Information Officer at HHS; by Nancy-Ann Min DeParle, the administrator of the Health Care Financing Administration and Dr. Michael Friedman, who is the Acting Commissioner of the Food and Drug Administration.

The American people expect reliable service from their Government and deserve confidence that critical government functions will be performed accurately and in a timely manner in the next millennium. Like other departments and agencies, we are striving to meet the Year 2000 challenge. The Department is making progress in correcting computer code for a wide array of software systems; in modifying the underlying infrastructure on which these systems operate; in working with our partners with which we exchange data and with others reliant on our services and in constructing contingency plans in case our systems or our partners' systems are not ready on January 1, 2000.

The Secretary and I have declared the Year 2000 issue to be our highest information technology priority. We have involved all parts of the Department to ensure that our information systems are able to recognize the Year 2000. No matter what else we do and what other initiatives we undertake, we must ensure that our ability to accomplish the Department's missions is not impaired.

Of all of the Department's programs, the Medicare program, administered by HCFA, proves to be our greatest Year 2000 challenge. Payment of health care claims is accomplished by over 60 external contractors, which operate and maintain a base of software programs that process nearly 1 billion claims each year from over

1 million health care providers. Ms. DeParle will explain these issues in more detail, but let me add that the Department is fully supportive of her and the agency in identifying the necessary human and financial resources and in prioritizing the work of the agency, including delaying implementation of a number of the Balanced Budget Act provisions.

We are also addressing the need to develop public information about the compatibility of systems embedded in biomedical devices. Because it is imperative, as Dr. Kizer has already testified and as Dr. Friedman will testify, that medical equipment continues to function properly in the next century, the Department and, in particular, the Food and Drug Administration, is requesting information about the Year 2000 compliance of medical devices and scientific laboratory equipment manufactured by biomedical equipment manufacturers.

In addition, HHS is working with the Department of Veterans Affairs to better serve our mutual interests in the Year 2000 compliance of biomedical equipment by merging our efforts. We have convened a steering committee and have asked the Department of Defense to participate as well. We will work through the health care outreach sector and the White House Year 2000 Conversion Council to enhance our ability to make this information available to you and the public. Dr. Michael Friedman will address these issues in depth, but again, the Department is fully supportive of the agency's efforts.

In response to the Year 2000 issue, the President's Council on Year 2000 Conversion, led by John Koskinen, has enlisted agencies to increase awareness of the problem and to facilitate Year 2000 compliance of public and private sector organizations. HHS, through our operating divisions, is currently implementing efforts aimed at both the health care and human services communities. Outreach efforts have included speeches, meetings, publications, conferences, developing Web sites and making Year 2000 compliance a term and condition of all future grant awards.

HHS still faces substantial challenges in our Year 2000 efforts. However, let me assure you that on behalf of Secretary Shalala, we will continue to vigorously pursue Year 2000 remediation as our most important information technology initiative. We recognize our obligation to the American people to ensure that HHS' programs function properly now and in the next millennium.

I want to thank the committee for its interest and oversight on this issue. Thank you, Senator Bennett, as well for holding hearings with private sector representatives and encouraging them to work with the Federal Government and for your support on the Senate Treasury-Post Office Appropriations bill, which provides for over \$3 billion for Year 2000 remediation as emergency funds. I would be happy to answer any questions that the committee has.

[The prepared statement of Mr. Thurm can be found in the appendix.]

Chairman BENNETT. Thank you very much.
Dr. Friedman.

STATEMENT OF MICHAEL A. FRIEDMAN, M.D., ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. FRIEDMAN. Thank you, sir.

Mr. Chairman, Mr. Vice-Chairman, Senator Smith, I, too, am pleased to be here today to provide information on the Year 2000 issue as it relates to devices used in the care and treatment of patients. We recognize that Year 2000 problems have the potential to cause disruption in many computer systems and, simply put, the Food and Drug Administration takes this issue very seriously. The agency believes that if solutions being developed and offered by manufacturers are properly implemented, there need be no significant problems to endanger or discomfort patients, and with your permission, I will briefly outline the steps that we have taken and that we are taking and will continue to take to ensure that medical devices are compliant.

The scope of this problem is potentially large, because medical devices include over 100,000 products and more than 1,700 product categories. While many devices rely on computer chips and software to function properly, the Year 2000 bug will not affect the majority of the medical devices that rely on computerized control, because they do not require knowledge of the current date to operate safely and effectively, and you have heard many examples of those: pacemakers, ventilators, and so forth.

That is not to say, however, that problems could not arise when software enhances the operation of a device; for example, so-called non-embedded software, which may not be integrated into the medical device itself, might run on a personal computer or workstation that is connected to the device. If this secondary software relies on two-digit year format to operate properly, it may be vulnerable to the Year 2000 bug. You have heard some examples of that, most significantly with the cobalt radiation therapy machine that Dr. Kizer described.

Now, medical device systems that use a date relying on the two-digit format in their algorithm, in their calculations or record-keeping are at risk, and we estimate that up to 2,700 manufacturers may produce such equipment. Our outreach efforts for these manufacturers began last June of 1997, when our Center for Devices sent a letter to 13,407 medical device manufacturers, both domestic and foreign, addressing this issue. The letter reminded manufacturers that they have the responsibility to investigate and correct any problems with their products.

In January, our Center for Biologics posted specific guidance for the blood industry software, to alert them to this concern. This spring, our device center developed a guidance document describing our expectations of medical device manufacturers concerning the Year 2000 date problem. Very helpfully, a second letter was sent from the Department of Health and Human Services in January 1998 by Deputy Secretary Thurm. Some 16,000 biomedical equipment manufacturers were asked to voluntarily provide information on the compliance status of their products. The response from the manufacturers so far has been fairly low: only about 1,800 of the manufacturers contacted in January have provided the requested information.

To further boost awareness of the need for companies to report, FDA authored an article for the medical device trade press, and we have been actively working with the trade associations. These are potentially important allies in this regard.

Furthermore, a discussion in this June issue of the Journal of the American Medical Association had an article from FDA outlining our concerns in this regard. We have also sent a medical bulletin to approximately 700,000 health care professionals this last summer. Three weeks ago, FDA also sent a followup letter to nearly 3,000 manufacturers, and we are beginning to receive some responses. While the data are incomplete, of the 1,800 who did respond, about 1,650 said that their products either do not use date-related information or are already Year 2000 compliant. Eighty-eight manufacturers reported one or more products with date-related problems, and of this group, 53 have set up Web sites on the Internet that provide corrective information for their customers.

For the remaining companies, though, the data submitted are incomplete or unclear in some manner. The great majority of the problems that we have detected are relatively minor and typically involve an incorrect display or printing of the date. There are only a few reported cases where the devices will not function. These are very important cases, and we take them seriously, but fortunately, they seem to be only a few.

This information that we are garnering is being posted on a product database managed by FDA at the request of the Inter-agency Biomedical Equipment Working Group. All the information being garnered is shared and placed on the World Wide Web, to provide a comprehensive source of information. The Web site can be found on the FDA Center for Devices and Radiological Health home page.

In addition, we are working with several Federal and private organizations, including the Veterans Administration, the Department of Defense, the American Medical Association and Hospital Association and others to try and address this problem more comprehensively.

Let me close by saying that FDA recognizes the import of this issue. It is a special problem; if you will, a sort of electronic fin de siecle. At this time, we believe, however, that vigorously working with partners, both private and public, with other branches of Government, with our sister agencies and operating divisions and with the device industry will ensure the continued safety of medical devices.

I thank you and will be happy to respond to your questions.

[The prepared statement of Dr. Friedman can be found in the appendix.]

Chairman BENNETT. Thank you very much.

Ms. DeParle.

**STATEMENT OF NANCY-ANN MIN DE PARLE, ADMINISTRATOR,
HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT
OF HEALTH AND HUMAN SERVICES**

Ms. DEPARLE. Thank you, Mr. Chairman, for inviting me here today to discuss my highest priority.

We must ensure that the more than 38 million Medicare beneficiaries experience no interruption in services because of the Year 2000 problem. We must also ensure that providers continue to receive prompt payment, and we must work with the States to ensure that their Medicaid systems are prepared.

I am committed to doing everything possible to address this issue, and I am here to report to you today that we are making some substantial progress. As you know, and as we have discussed, the Year 2000 especially affects the Health Care Financing Administration because of our extensive reliance on multiple computer systems. Medicare and Medicaid use more than 183 systems, and 98 of these systems are considered to be mission-critical. Medicare, in fact, is the most automated health care payer in the country. As your opening statement noted, we process nearly a billion claims every year, and fully 98 percent of the claims that we pay on the Part A side or the hospital side of the business are processed electronically, and 85 percent of those on the Part B side of Medicare are processed electronically.

The renovation process is complicated, because each system, as well as interfaces with state Medicaid programs, banking institutions and some 1.6 million providers, must be thoroughly reviewed and renovated by those responsible for each particular system, and there is a chart here to your right that shows the process that must be undergone to just process a Medicare claim and all of the different interfaces that are involved in the different systems, and it has been attached to my testimony.

For Medicare, Mr. Chairman, that means that we have to renovate some 50 million lines of code. If we do not succeed, we are aware that enrollment systems might not function; that beneficiaries could be denied services because providers might not be able to confirm eligibility, and we are concerned that providers would have cash flow problems, as you noted.

We are committed to succeeding, but we are not only working intensively to renovate and test our systems; we are also developing detailed contingency plans for business continuation in all of the different areas where we provide services. After working on our contingency plans, it is clear to me that our best option and our only option is to successfully complete all of our renovations on time.

That is why we are requiring contractors to be in full compliance with all code renovated and fully future date tested by December 31, 1998. One of the first things that I did when I came to the agency last fall was to sit down with GAO to talk to them about this problem. They recommended to me, and we have negotiated with our contractors, a contract amendment that articulates Year 2000 requirements. All of the contractors with whom we have spoken, including the one that you are going to be hearing from today, indicate that they will sign that amendment.

Renovations to mission critical internal systems also have to be completed by December 31, 1998. We expect to complete end-to-end testing of how claims are processed through our entire network in the spring. We will then have the remainder of 1999 to take any additional necessary action. GAO also recommended to us last year that we hire an independent contractor to review and assess our work. We did that. Intermetrics, our independent validation and

verification contractor, is very actively overseeing our work. Because of their effort and our own increased attention, we now have a much more accurate assessment of the problem and what must be done.

This more accurate assessment makes clear that Year 2000 work has to take priority over all other projects. We have to delay any projects which require complex systems changes or which would occur during a critical window between October 1999 and April of 2000. And so, for example, Mr. Chairman, we had to make the difficult decision earlier this year to postpone transitions to uniform systems for Part B and Part A of Medicare. We were trying to get it down to one system for each of those two sides of our business, but we had to postpone that.

The Intermetrics-IV&V contractor also recommended that we stop parallel development, which meant to stop giving contractors additional work to do in addition to renovating the systems. So, we made the difficult decision to delay implementation of some of the Balanced Budget Act provisions, including the prospective payment systems for outpatient hospital care and home health services.

Also, based on that recommendation, we are looking at the need to delay provider payment updates during that critical window of Year 2000 activity. Those updates are not complicated from a systems perspective, but we have been advised strongly that making that kind of a systems change at that point of potential instability not only in our own systems but in the systems of all of the various providers that we deal with would be not a good idea.

We want to work with you, with this committee and with the Congress to ensure that this does not create a hardship for our providers.

We also will have additional budget needs, and I want to thank you for your leadership and this committee for its leadership in this area, and, of course the Secretary recently reallocated \$40 million from other activities in the Department to devote to Year 2000 efforts at HCFA.

We are making solid and, I think, steady progress now in preparing for the Year 2000. We have taken steps, with your assistance, to obtain necessary resources. We are making difficult decisions to delay other priorities, and we are making necessary contingency plans. I appreciate this committee's support and the help that we have gotten from the General Accounting Office, and I am happy to answer any questions that you might have.

[The prepared statement of Ms. DeParle can be found in the appendix.]

Chairman BENNETT. Thank you very much. We appreciate the testimony of all of you.

Administrator DeParle, you made reference to the independent contractor who came in and assisted you. Let me understand something. I have heard this somewhat piecemeal. Let us get it out and give you an opportunity to get it authoritatively dealt with. I understand that prior to the independent contractor, you assumed that you had 20 million lines of code, and the independent contractor discovered that it was, in fact, 50 million. Do I have those numbers correct?

Ms. DEPARLE. Yes, sir, I believe that is right.

Chairman BENNETT. And this, of course, is a very—what is the phrase, revolting development, that your problem is $2\frac{1}{2}$ times bigger than you thought it was, that you discover almost overnight.

Does that not create a much bigger problem than your overall testimony seems to indicate? I am not challenging that you are on top of it. I am not challenging that you are making it a top priority, but it would seem to me terribly discouraging to be moving along and suddenly discover your problem is $2\frac{1}{2}$ times bigger than you thought. To me that would put you, in the overall analysis of where you are, substantially behind where you thought you were when you made that discovery.

Ms. DEPARLE. I believe that is correct, and I think that what you are referring to is a discussion last year with a different committee that the administrator then had, and at that point, the agency had been doing its assessment on its own and had been talking to different contractors around the country and had the assessment that it was around 20 million lines of code that needed to be renovated, and I believe at that very same hearing, Joel Williamson of the General Accounting Office testified that he thought that HCFA needed to get an independent assessment of that.

And late last fall, we did get the Intermetrics firm in to do such an assessment. They have been out to every one of our contractors, along with our chief information officer, who is with me today, and that is how we now have the assessment that the problem is bigger than we thought. So, yes, sir, we do have a big problem, and the good news is that we learned about it this spring instead of later this year.

Chairman BENNETT. I am told by the staff that the 20 million figure was given to this committee at a briefing on the 7th of July of this year; at least somebody who was briefing the committee did not have that information as recently as earlier this month. It was not something that came up in the spring.

Ms. DEPARLE. Well, if that is the case, Mr. Chairman, I apologize to you, but, as I said, the complexity of this problem has certainly grown, and I am very glad that we got an independent assessment of it, and I think that we now know that it is bigger than it was thought to be.

Chairman BENNETT. All right; Dr. Friedman, I find a little bit of a disconnect between your testimony and Dr. Kizer's. The numbers that you are reporting paint a different picture from the one we had from Dr. Kizer's admittedly anecdotal trip through medical devices. If I had the numbers right, you said there were 1,800 responses to your questionnaire.

Dr. FRIEDMAN. That is correct, sir.

Chairman BENNETT. And 88 of those 1,800 said they produced devices that had date-sensitive problems.

Dr. FRIEDMAN. No, sir; and I apologize for the series of numbers. Let me go through it again. I can give you the exact numbers. I think the larger issue is that we recognize that somewhere around 2,700 to 3,000 manufacturers probably are responsible for producing equipment that has microprocessors or chips embedded and that is the most important group of manufacturers to target. But we felt it was very important to cast the net very widely, and

therefore, in our initial mailings sent out to some 16,000 or more, people who may only make tongue depressors——

Chairman BENNETT. Yes.

Dr. FRIEDMAN [continuing]. People who may only make, you know, other things, we sent out this very large mailing to make sure we tried to capture everybody both domestically and foreign. We believe that it is some 2,700 manufacturers. From that subgroup, we have about 500 responses now and are getting more in daily.

Chairman BENNETT. I see; OK, well, on page 10 of your prepared testimony, I picked up this 88 manufacturers. I thought OK, the folks who are really involved in this are not responding, and it is the tongue depressor people who are coming in, and that is skewing the data.

Dr. FRIEDMAN. Well, and we have gotten a large number of responses from those folks saying no, thank you for asking us, but we do not have anything.

I think it is more important to recognize that the kind of data that Dr. Kizer is garnering will be very helpful and complementary to the data we are getting. He is getting information about very specific pieces of equipment. We are getting information from manufacturers about all of the equipment, and I think that when we have the assistance of the manufacturers and those associations that represent them plus the AMA and the AHA, seeing this as a mosaic where we get all of the information and then post that for public consumption, I think that serves the public in the very best way.

Chairman BENNETT. OK; Senator Dodd?

Vice Chairman DODD. Thank you, Mr. Chairman, and I am going to sort of pick up where the chairman was going here. Let me, if I can, the American Medical Association—I am quoting them here and talking about medical devices—says unreliable equipment cannot be used, because virtually any malfunction could have disastrous consequences. Assessing the current level of risk attributable specifically to the Year 2000 problem within the patient care setting remains problematical. We do know, however, that the risk is present and real. End of quote.

The American Hospital Association calling on Congress and the FDA to enact mandatory disclosure requirements on the device manufacturers, clearly because they believe that they are not getting sufficient information to guarantee patient care. I just want to come back to this. I read, Secretary Thurm, your statement and your written testimony. You said that you see no indications that there will be significant problems that will place patients at risk, assuming that the manufacturers are implementing the reported solutions.

And Dr. Friedman, in your testimony, you repeat that statement almost word-for-word. Now, those statements would be reassuring, I think, to the chairman and myself if we were getting something better here. You said 2,700 of these manufacturers actually producing equipment that appears to be sensitive to the Y2K issue. Here, we have 526 days to go between now and January 1, 2000. You have only heard from 500 of these companies out of almost 3,000.

That is not reassuring to me at all. I have got to tell you; I mean, I find that frightening.

And I—it is important here, because you are the ones who are going to be dealing with these people every day. I mean, we have hearings; we have got 20 other things that we are doing in an hour. We have got to have HHS, and we have got to have the FDA being a lot more aggressive about this, in my view. I do not think this is satisfactory. I do not think that 500 responses from 2,700 businesses that produce this equipment that is highly sensitive and necessary, obviously, to patient care is a good response at all.

Dr. FRIEDMAN. And no, sir; I hope I did not convey that we felt it was satisfactory. This is fractional. We do believe that getting all of the information is important. We began——

Vice Chairman DODD. I know that, but your statement that we see no indications that there will be significant problems, I see every indication that there is a significant problem.

Dr. FRIEDMAN. The full sentence is if the manufacturers address it.

Vice Chairman DODD. Well, they are not. And I agree with: if they do, then, fine. I am all with you. But you have only got 500 responses with 500 days to go from almost 3,000 companies. You ought to be banging the table here, in my view, with all due respect.

Mr. THURM. Senator, I think that is right, and I think that the FDA—two pieces. First, the FDA has followed up recently and comprehensively by narrowing the number of companies that it has targeted because we have not gotten responses, and your point and the chairman's point is exactly right.

The second is, in conjunction with the VA, we have the obligation to coordinate our efforts with what Dr. Kizer has done through the VA and through what he announced several weeks ago, the National Patient Safety Partnership, which includes the American Hospital Association and the American Medical Association, so that we can provide to you and to the American public a more comprehensive and authoritative accounting of that.

Vice Chairman DODD. I have got you; I hear you. But look at this: I mean, here is this letter from the Health Industry Manufacturers Association. Let me quote them. You have got the same one.

Chairman BENNETT. I have got the same letter waiting for the next witness. But go ahead.

Vice Chairman DODD. You know, and I am quoting: HIMA's members understand the Department's interest in this issue. Nevertheless, we do not agree that a Federal Government Internet Web site listing Year 2000 compliance status of various products is an appropriate or necessary step.

That is arrogant. I mean, and they go on to say here, HIMA's members note that the Department has no legal authority to require this submission of the Year 2000 information that is the subject of your January 21 letter. In view of this, HIMA believes that the statement in the letter that there will be targeted followup regarding non-respondents is inappropriate.

Well, I do not know—I can get an amendment adopted to almost any bill in Congress that is floating through here. If there is a legal

problem, I promise we will take care of that immediately. That is—you should let us know about that.

Mr. THURM. That is correct.

Vice Chairman DODD. What is the date of that letter? That is April 1, that letter.

Mr. THURM. Well, the point you are making is precisely right. We need to be more aggressive. HIMA has sent a followup letter, and your call today, Senator, and the chairman's call on the private sector, in particular, medical device manufacturers, assists us in getting them to provide—

Vice Chairman DODD. I hear you, and I understand that, but again, you have got these letters. You have got a January letter that went out on January 21 to the device manufacturers flatly stating FDA must aggressively pursue responses from the remaining equipment manufacturers—excuse me, OMB in their report on 5/15. Your letter went out on January 21. OMB, in its report on 5/15, says FDA must aggressively pursue responses from the remaining equipment manufacturers.

Six weeks later, you sent another letter. That is not, in my view, aggressively pursuing responses. Am I wrong? I mean, is this not 6 weeks basically, June 29? That is May 15, and it is the end of June when we send the next letter? You have got to be much more aggressive than that.

Dr. FRIEDMAN. I do understand what you are saying, Senator, and we have sent out multiple letters. We will continue to do so. We are not going to be satisfied until we have a complete data set, and I think you are absolutely right.

Vice Chairman DODD. I do not know; you have got the clock on. Am I over my time?

Chairman BENNETT. Go ahead. I am loving this. Go ahead.

Vice Chairman DODD. Well, I mean, this is the kind of stuff—you guys are on the front line every day. How often do we have hearings? You know, and I mentioned earlier, look, what I would like to suggest, this is Thursday, and I said earlier we ought to publish the lists of people. Why do we not do this? Maybe before we adjourn, which is maybe, I think, next week, let me say from my point, I have not talked to the chairman about this, but I will forego a week before I will go to the floor of the Senate and publish lists of companies that have not complied.

Let us use this as a week of an opportunity to respond to these letters, and by next Thursday, I want the lists of the people who have not responded.

Dr. FRIEDMAN. I cannot tell you how much we appreciate your stimulus of this. If this brings in responses, it will serve everyone very well, and we do appreciate—

Vice Chairman DODD. My goal is not to embarrass anybody.

Dr. FRIEDMAN. Of course not.

Vice Chairman DODD. But it will be.

Dr. FRIEDMAN. The goal is to have good information available for all of the people who need it.

Vice Chairman DODD. Now, let me get to this quick question here on this, because I think the chairman raised a very, very important point, but I think it has to be pursued a bit as well here to HCFA, and let me just run the chronology here on this thing for

you. You know, you said, publicly stating that it is almost 70 percent complete on its renovations, on its assessment of the size of the problem. I appreciate that.

July 7, you submit materials to the special committee that show that 30 million lines of code required renovations. All right; now, this is your chart you sent us here. The President stated that there were 42 million lines of code at HCFA that needed renovation. Today, Mr. Thurm here stated that there were 49 million lines of code, and last week and again today, you stated that there are 50 million lines of code.

Now, you can ask the question yourself. You understand the question I have. How reliable is this 70 percent? Seventy percent of what? I mean, that is in the space of a few days here, we go from 30 million to 50 million, almost double the number.

Ms. DEPARLE. Well, let me be clear about one thing. The Deputy Secretary is right. The number is 49 million, and I was rounding up to say some 50 million to make it easier.

Vice Chairman DODD. All right?

Ms. DEPARLE. But your point and the chairman's point about the changing numbers is certainly fair. I think I can explain it, and let me try to. Our estimate right now is that there are around 20 million lines of code that are internal that have to be changed. Those are systems that we maintain out in Baltimore primarily; for example, the Medicare managed care system.

Vice Chairman DODD. Right.

Ms. DEPARLE. We pay the HMO's ourselves out of Baltimore. So, that is an internal system. So, for those systems, our estimate is around 20 million lines of code. I do not know what the estimate was last May when the total number was 20 million, but I would assume it was much smaller. So, that estimate was wrong.

We brought in the independent verification and validation contractor, who gave us a better view of it. The external lines of code, we estimate to be around 30 million. When we get the estimates from the contractors, some of them count, I am sorry that my chart is probably hard to see, but some of them counted, when they did their initial assessments, the front-end systems, the standard systems and the back end systems, and the standard systems, if they count that as well, that is double-counting, because we were counting those on another list.

Vice Chairman DODD. Yes.

Ms. DEPARLE. So, what we have done now with our IV&V contractor is try to come up with the best list possible, and I believe it to be, at this point, Senator, 49 million, but I understand your point that it has been difficult to get our arms around this, and that leads you to be concerned about it, and, of course, that is why it is my top priority, because it is a major concern.

Vice Chairman DODD. I appreciate it. And listen, it is the tendency of every institution, particularly in public settings, to stand up and put the best face on things. I mean, and that is true of Congress, true of anybody. So, I understand that. What I think is so important here is that there be these—in fact, there is going to be a greater degree of credibility on the candid, hard assessments. You know, arguably, everybody is late on this issue. I mean, we got a committee formed here about a month ago, you know, and we are

not—despite the fact that the chairman tried for months, and we tried. I mean, it is just hard for people to click onto this issue in a way.

So, we are not sitting up here—you know, we should have been at this years ago in Congress talking about it. So, we are not immune from the criticism about this. But I think we serve the public really well when we lay it out coldly and hardly where we are here, and too often, institutions, public and private, come here, and the thrust is we are doing great.

And then, it is these probing kinds of questions; our statements are written in that regard, and we end up creating more problems than ought to be the case. So, I just urge you to insist, when you go back, tell your own people: look, you know, you want the hard, cold information. You know, someone once said that the higher up you are in this process, the harder it is to get at the truth, because people who walk in do not want to tell the boss things they do not want to hear.

And so, you have got to be tough on your people in terms of getting this stuff, because you do not want to have to come to a committee hearing and sit up here and answer the questions that we are going to ask that we are getting asked, OK?

Ms. DEPARLE. If I could, too, Senator, I would like to correct a misunderstanding in the statement you made at the beginning. My understanding at this point is that we are 77 percent of the way through in renovating our internal systems.

Vice Chairman DODD. OK.

Ms. DEPARLE. That is the 25 or so systems that we maintain. On our external systems, which include the common working file and the contractor systems at the 60 different locations around the country, we are only about 40 percent of the way through there. Five of the six systems that need to be renovated have been renovated, but the most important phase is yet to begin, or we are just beginning, which is testing, and we have followed the GAO recommendations. We have a four-level testing system, and that will be very intensive, and that is where the rubber meets the road, as you know.

So, I would not say that we are 70 percent done.

Mr. THURM. And, Senator, if I can add one thing to your point, which is exactly right, it is not just that the three of us do not want to be here answering the questions, but on January 1, 2000, none of us want to have said on December 31, 1999, oh, no, it is OK, and to ask the hard questions, and I think we are trying to do that within the Department and the private sector. We moved money within the Health Care Financing Administration and we have come up and told you that we are going to have to delay implementation of certain Balanced Budget Act provisions. We have said in our 1999 budget we need more money, and we need it early in fiscal year 1999, because late in fiscal year 1999, we have a problem.

But your hearings and your oversight help us further ask the hard questions sooner rather than later and to which, in our Department, and you all are owed the response sooner rather than later, so we can do contingency planning in case either our systems or our partners' systems do not work, so that we can ensure, as the administrator says, not only end-to-end within our systems but

end-to-end within the whole health care system, so that providers in rural areas, if they cannot receive payments because their systems are not renovated, we have thought about that; they have thought about it, and we have figured out ways to address it.

And those are the kinds of things we are trying to focus on, and these hearings are helpful.

Vice Chairman DODD. I have taken too much time, but I still have a couple of questions. I would like for you to respond, by the way, have your legal counsel respond to HIMA's letter to you in April about the legal authority, and I want to know immediately whether or not you agree with this letter that you lack the legal authority, and if you lack the legal authority, I want you to let us know ASAP on this, and we will find some means to give you the legal authority to see to it that you can list on here.

So, I appreciate——

Mr. THURM. We will certainly do that, Senator.

Vice Chairman DODD. OK?

I have some questions, but I have taken too much of your time.

Chairman BENNETT. Thank you.

We will move on to the next panel. Let me make a few concluding observations. I am glad, Administrator DeParle, for your comment about the 70 percent and the 40 percent and to help us understand that, because I just could not understand how you could get a problem that is suddenly twice as big as you thought it was and still stay at 70 percent remediation.

On your chart, the only point I want to make with respect to that chart is that if there is a failure in any one of those components or in any of the connections between components, the failure runs through the whole system. That is the scary thing about the chart. We could have everything working there and, for example, the connection between Social Security and the—what do they call it—the central processing or central——

Ms. DEPARLE. Common working file?

Chairman BENNETT. The common working file. If the common working file cannot access Social Security to check eligibility, the whole thing comes to a grinding halt, and the same illustration could be made in any other connection on that chart, and from a point of view of the effect of that on the whole system, it is really, really scary. In many ways, you have a bigger burden here than any other governmental official.

As I said, we were at the INOVA Fairfax Hospital, and we got all of the other information to us and got tremendously reassured. If I am ill on New Year's Eve, that is the hospital in the area I want to be in. But I asked the question after they went through all of the things that they were doing, I said what would the impact be if HCFA was unable to process claims, and the answer was a single word: huge.

They can do all of the other things they do. If you fail, or if any one of the connections that you have on the chart fails or any one of the components on the chart fails, the impact on the people who are providing the patient care would be huge—not to send you out of here with an enormous load on your shoulders but to remind you of the enormous load that you already have on your shoulder and to thank you for your forthrightness here today.

Ms. DEPARLE. Thank you, Senator.

Vice Chairman DODD. Let me just ask if they could, on three questions, but I will not ask you to respond to them here, but I would like to get some answers to them. One is, and on the individual care providers, Mr. Thurm, if you could, that would be important for us to get that. I realize you have got a complex and huge area. We have talked on the hospitals and a lot of other areas, but the individual care provider, what is going on there is something I would be very interested in hearing from HHS on.

Second, I want to know, if we can, what your contingency plans are. I am not going to go into it today, but I would like to have someone give us a brief on what your contingency planning is. Everyone is saying it now. It is the right thing to say, but the chairman is absolutely correct. This is one where we better get a good assessment of a billion dollars of processing a day to health care providers out here. We need to have a pretty good sense of what it is to make sure that there is not a failure in that system, with 40 percent of those providers relying or I think 40 percent of their resources come from Medicare and so forth. So, you would have a collapse there.

And last, Mr. Thurm, I would like to know about the rural and more urban hospitals and so forth. If the veterans hospital, you know, with all of the power of the VA, cannot get responses from manufacturers, we heard from the Fairfax Hospital how difficult—and I have got some letters here that they shared with us from manufacturers. They are just downright rude in some instances in terms of their inquiries about equipment they have got to use there.

What does the D.C. General, how are they doing? How is a rural hospital doing when they are trying to get information? And I would like to get some sense from them in terms of how responsive they are and also, you know, what sort of costs are they looking at? And to what extent are we making some assessment. Again, coming back to the chairman's question, we have got a very receptive and willing, I think, Congress that wants to help out in this area. The sooner we know, the better, and if rural and inner-city hospitals are facing some real problems here financially, the sooner we know, the better we are going to be able to step up to the plate and provide some help to see to it that they are getting the equipment that they need to serve that population, OK?

Thank you.

Chairman BENNETT. Thank you all very much.

Ms. DEPARLE. Thank you.

Chairman BENNETT. We now go to the health industry panel. These are representatives from hospitals, doctors, biomedical device manufacturers, insurers, and Y2K consultants. They individually and collectively have knowledge about how the health care industry is responding to the medical and financial challenge facing it in the next 17 months. They may be a little nervous, having heard the rhetoric of the first two panels.

All right; introducing all of the members of the panel, and we will hear from you in the order in which you are introduced, Ms. Jennifer Jackson. Ms. Jackson is general counsel and vice president for clinical services of the Connecticut Hospital Association,

representing the American Hospital Association. I wonder why we have someone from Connecticut doing that? No, we are delighted to have you here.

Dr. Palmisano, Donald Palmisano, is a member of the board of trustees of the American Medical Association. Mr. Ramin Mojdeh, Ph.D., he is director of research and development of the Guidant Corp., and he is here representing the Health Industry Manufacturers Association. Mr. Gil Glover—is it Glover or Glover?

Mr. GLOVER. Glover.

Chairman BENNETT. Glover?

Mr. GLOVER. Glover.

Chairman BENNETT. Glover.

Mr. GLOVER. Glover.

Chairman BENNETT. Glover, all right, director of Year 2000 projects and planning for Blue Cross and Blue Shield and Mr. Joel Ackerman, executive director of Prescription 2000 Solutions Institute.

We welcome you all here. As is always, unfortunately, the pattern in the Senate, we have run over more from the Senators than the witnesses, but we make the witnesses pay for it by asking you to please hold your statements within the 5 minutes indicated by the lights.

Ms. Jackson, we will start with you.

STATEMENT OF JENNIFER JACKSON, GENERAL COUNSEL AND VICE PRESIDENT, CLINICAL SERVICES, CONNECTICUT HOSPITAL ASSOCIATION, REPRESENTING THE AMERICAN HOSPITAL ASSOCIATION

Ms. JACKSON. Mr. Chairman, Senator Dodd, I am Jennifer Jackson, general counsel and vice president of clinical services at the Connecticut Hospital Association, and I am very pleased to be here today representing the American Hospital Association, which represents nearly 5,000 hospitals, health systems, networks, and other providers of care.

Hospitals and health systems are taking the Year 2000 issue very seriously. They face the same potential problems as most other institutions. Their business and communications systems, their security systems, elevators and other parts of their physical plant all could be affected by Year 2000 problems. However, hospitals are unique places that face unique problems because of our patients' reliance on sophisticated technology and equipment. In analyzing these problems, our priority is, as always, the safety of our patients.

The AHA believes that there are several key players who can help prevent Year 2000 problems from occurring in health care. They are hospitals and their associations, manufacturers of medical devices and equipment, the Food and Drug Administration, the Health Care Financing Administration and Congress.

AHA and state hospital associations are working together to ensure that our members know the potential dangers of the millennium bug and are taking steps to avoid those problems. We are getting them the latest information on what their colleagues and other organizations are doing. In fact, in recent weeks, we sent every member CEO a briefing book called Y2K, Mission Critical,

that is filled with extensive information from the history of the problem to sample contract compliance language for use with vendors and suppliers.

When it comes to medical devices and equipment, however, our efforts alone are not enough. Information about whether these devices will be affected by the date change must come from the manufacturers of the equipment. We believe that existing regulations allow the FDA to require manufacturers to perform Year 2000 testing and report adverse results. We urge the FDA to exercise this enforcement authority and ask Congress to do everything in its power to help the FDA ensure that Year 2000 information on medical devices gets from the manufacturers to those who need it most, health care providers.

We are relying on the FDA and manufacturers to make this information available. We ask the FDA to continue to share its plans describing how the agency is getting needed information from manufacturers and make sure that those plans are available to health care providers.

We also need the help of the Health Care Financing Administration. America's hospitals and health systems receive, on average, half of their revenues from Government programs like Medicare. It is critical that the flow of those funds not be jeopardized by Year 2000 problems.

Of course, unforeseen problems could occur. Therefore, HCFA should establish a contingency plan. A fail-safe system to provide periodic interim payments based on past payment levels is one way to do this. At the same time, we do not believe that HCFA, as it recently announced, should delay hospitals' fiscal year 2000 payment update and the implementation of outpatient and home health prospective payment systems while it works on its own computers.

Hospitals are already trying to cope with the Balanced Budget Act's dramatic changes, including severe reduction in hospital Medicare payments. A delay in the fiscal year 2000 PPS update adds to this burden and causes unpredictability for them and for their patients.

Congress also has a key role. Your attention to this issue through hearings like this one reflects your understanding of the gravity of the situation, and you can help America's health care system avoid Year 2000 problems. First, Congress should appropriate whatever resources, including additional authority if necessary, the FDA may need to ensure that manufacturers of medical devices investigate, report and correct Year 2000-related problems in their products. We also urge Congress to speak directly to manufacturers on the need and expectations for prompt, sufficient disclosure.

Second, Congress should enact some form of limitation on liability for health care providers that have taken steps to prevent Year 2000 problems from affecting patient care. Hospitals must rely on manufacturers of medical equipment and devices to disclose whether a Year 2000 problem may occur and how to correct the problem. Health care providers should not be liable for damages related to Year 2000 limitation on those products, especially when they have made good faith, reasonable efforts to minimize the risk and obtain information.

One way to approach this liability issue is to broaden the President's recently-announced good samaritan proposal, which would shield from liability businesses that, in good faith, share information on solving the Y2K problem. We suggest also addressing in that legislative vehicle our concerns about liability and protect hospitals and health systems from liability for treating a patient with a medical device that the manufacturer has reported as Y2K compliant.

Congress should also authorize periodic Medicare payments and ensure that HCFA has adequate funding to ensure Y2K compliance. America's hospitals and health systems, their State associations, the AHA and other national organizations are working together to prepare for the Year 2000. We encourage Congress and our Federal agencies to work with us as well so that together, we can ensure a smooth and healthy transition into the new millennium.

Thank you.

[The prepared statement of Ms. Jackson can be found in the appendix.]

Chairman BENNETT. Thank you very much.

Dr. Palmisano.

STATEMENT OF DONALD J. PALMISANO, M.D., MEMBER OF THE BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Dr. PALMISANO. Thank you, Senator Bennett, Senator Dodd and the committee.

My name is Donald Palmisano. I am a member of the Board of Trustees of the American Medical Association, a member of the Board of Directors of the National Patient Safety Foundation, and the chair of the National Patient Safety Foundation's Development Committee. I also practice vascular and general surgery in New Orleans. On behalf of the 300,000 members of the American Medical Association, I want to thank you for inviting us to testify about the Year 2000 problem today.

Senator Bennett, I request that our written comments be entered into the record in view of the time limitations.

The Year 2000 problem will affect virtually all aspects of physicians' practices, most especially patient care. The good news is that if we act in a timely fashion, this problem is solvable. Within a clinical environment, physicians rely heavily on medical devices to gather or monitor information about their patients. Some of these devices take images; others regulate or assist bodily functions; and others simply monitor different aspects of the patient's condition. All of them are important and provide essential functions for the physician and the patient.

Medical equipment has to be completely dependable. Can you imagine for yourself, for a moment, yourself as the patient? How would you feel if a device which was monitoring your heart failed to sound an alarm when your heart slowed to a dangerous rate or if a digital display incorrectly assigned another patient's name and all of their medical data to you? Obviously, these events would alarm you and your physician.

Nevertheless, with the potential for malfunctions due to Year 2000 bug, there are real risks that have to be anticipated and cor-

rected, and the physicians who are responsible for caring for these patients are calling for this problem to be remedied quickly and effectively. Medical device manufacturers need to disclose immediately whether their products will malfunction or not. Only they have that information. End users, the physicians and the patients, do not have the expertise or resources to determine what devices may or may not fail.

We have to rely on the manufacturers, the Congress and the administration to ensure that they promptly disclose this vital information. We understand that the FDA and the Department of Veterans Affairs have been trying to obtain this information. We applaud their efforts to date but believe that more can be done. In addition to causing serious patient safety concerns, the Year 2000 problem may also wreak havoc on the medical community's ability to conduct even the simplest transactions. Many physicians and medical centers rely on information systems and, to some degree, maintain medical records through these electronic methods.

Physicians need to be able to access this information quickly and reliably. Just as important, it must be accurate and secure. The software cannot assign incorrect data to patients.

Another area of physicians' concern that is heavily tech-dependent concerns electronic billing and claims, and you all have just gone through that, and I will skip over some of this, but we are aware of this in part because of an incident that recently occurred in my home State of Louisiana. As you may have heard, when the Medicare claims processor for Louisiana was planning on implementing a new Y2K-compliant computer system for claims processing, it announced that physicians could anticipate a 2-week delay. The actual implementation time was significantly longer. Many physicians had real problems keeping their doors open to treat patients.

Those physicians who were treating a lot of Medicare patients had difficulty purchasing supplies and paying their employees.

Getting back to HCFA, we understand HCFA's concerns and desire to have physicians and other health care professionals Y2K compliant. We have absolutely no problem with that. We believe, though, that HCFA should lead by example and make sure that its systems are in compliance as soon as possible. This would allow physicians and HCFA to parallel test their respective systems well before the Year 2000.

We understand that in an effort to ensure that its own computer systems are Y2K compliant, HCFA is focusing a lot of its resources on this problem. We just heard from Administrator Nancy-Ann Min DeParle that the Y2K bug is HCFA's No. 1 priority. As a result, HCFA has decided that it is not going to implement some changes required by the Balanced Budget Act of 1997. Instead, HCFA is going to postpone physicians' reimbursement updates from January 1, 2000, to about April 1, 2000, if not longer.

We understand HCFA's reasoning for this decision. We just want to highlight our concerns about some of the potential consequences. First, the Y2K problem has been a known problem for a long time. It is a soluble problem if addressed in time. Nevertheless, HCFA is asking others to accept delays in updates because HCFA has failed to correct this problem. HCFA has told us they are not ask-

ing for this delay to save money for the Medicare trust funds. They have also said that they want to make sure providers are fairly reimbursed for the funds they should have received.

Our concerns regarding updates are fourfold. First, we wonder whether HCFA is going to be able to devise a solution that accomplishes all of these goals. Second, we are concerned that a delay may now affect future calculations of expenditures. Third, the Year 2000 is a critical year for implementing BBA-mandated changes in the resource-based relative value scale, which Medicare uses to determine payments. This is known as the RBRVS.

Fourth, as you may know, many private insurers and Medicaid agencies base their fee-for-service reimbursement on the RBRVS. Delaying the Medicare updates would likely have ramifications far beyond what is currently anticipated.

You have also asked us to address the current level of preparedness of the physician community for the Y2K problem. We have run across a very limited number of studies giving that assessment. One already mentioned here today, the Gartner Group, has found what we knew, that physicians and hospitals rely on thousands and thousands of medical devices which, to a limited extent, may not be compliant. We are not sure of what the full extent is, and we need help from the manufacturers.

Medical practices are among the furthest behind in their survey. Now, what can we do about this, specifically the AMA? The AMA is focusing on three areas: education, communication and cooperation. The AMA already has conducted a seminar at our annual meeting last month and will be holding additional seminars in the future. The AMA has also launched a national campaign entitled "Moving Medicine into the New Millennium, Meeting the Year 2000 Challenge," which focuses on communication and education.

As part of the campaign, the AMA will be holding a series of regional seminars to talk about how best to work with vendors and how to obtain necessary information about devices that could affect health care. We will also be distributing a solutions manual to further educate the participants.

To foster greater communication among physicians, we have put together a special section on our award-winning Web site, a Y2k section, and we encourage everyone to visit ama-assn.org to gather information as we put it on that site.

We believe it will serve as an important interactive resource for physicians by providing regularly-updated information about the millennium bug and by assisting physicians in solving their Y2K problems. The AMA is also promoting cooperation through our involvement with the National Patient Safety Foundation. The AMA launched this foundation and works with its partners. It is a separate corporation, and then, that corporation is now working with the National Patient Safety Partnership. It is a public-private venture, and Dr. Kizer, with the Department of Veterans Affairs, is a leader in this. And so, we are working together with all of these groups.

We would suggest that others communicate to their constituencies, as we are trying to do. This would be a cooperative effort.

And the last point, we need to develop a strategy to properly inform patients who are affected by medical devices of Y2K compli-

ance or potential risk. The patient has to be our No. 1 concern in all of our Y2K efforts. The clock is ticking. Time is of the essence.

In conclusion, I wish to thank you very much once again for inviting me, Mr. Chairman and members of the committee, to testify. On behalf of the AMA, allow me to offer our services in working further with Congress to effectively address this problem. I will be happy to answer any questions. Thank you, sir.

[The prepared statement of Dr. Palmisano can be found in the appendix.]

Chairman BENNETT. Thank you.

Dr. Mojdeh.

STATEMENT OF RAMIN MOJDEH, PH.D., DIRECTOR, RESEARCH AND DEVELOPMENT, GUIDANT CORP., REPRESENTING THE HEALTH INDUSTRY MANUFACTURING ASSOCIATION

Mr. MOJDEH. Mr. Chairman, my name is Ramin Mojdeh. I am a director of research and development at Guidant Corp., which designs, manufactures and sells innovative products to improve the quality of care for people with cardiovascular diseases. We thank you, Mr. Chairman and Senator Dodd for your leadership in raising the awareness of this important issue. Thank you also for the opportunity to testify on behalf of the Health Industry Manufacturers Association regarding the readiness of this industry to ensure the safe and reliable operation of medical devices in the Year 2000 and beyond.

HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. Mr. Chairman, I would like to stress three points. First, the device industry is extremely concerned about the potential hazards associated with the Year 2000 problem. Second, our industry has three compelling reasons to address this issue urgently and seriously. These are humanitarian, business and regulatory. Third, we recognize that timely access to relevant information is critical to patient safety, comfort and confidence.

Today, we give you our assurance that our industry will continue to work with other concerned organizations and the FDA to make compliance information relating to devices publicly available.

The medical industry is quite diverse. Over 50 different medical specialties use thousands of product lines and applications throughout the human body. Additionally, the complexity and sensitivity to the Year 2000 date varies dramatically among devices. Some devices vital to keeping patients alive are not date-sensitive. For example, pacemakers do not use a current date in their operation, and it is unlikely that ventilators and many other products will be affected by the date problem.

Other devices may use date information to make calculations or send data directly to other systems. These devices may be sensitive to the Year 2000 problem. For these reasons, the challenge posed by the Year 2000 bug does not, for the medical device industry, represent a single problem yielding to a single solution. Rather, each company faces a unique set of circumstances involving its own technologies.

The FDA has detailed the device industry's regulatory obligations for Year 2000 compliance. As an FDA-regulated industry, our

member companies are profoundly aware of their Year 2000 compliance responsibilities and of the penalties of failing to meet them. HIMA members are taking strong action to ensure Year 2000 compliance. Some companies with diverse product lines have posted pages of detailed charts on their Web sites containing Y2K compliance information. Others have gone beyond the Internet and contacted their customers directly regarding the compliance status of their products.

Many small companies, founded within the last 10 years, understood the Year 2000 problem in advance and have been designing Y2K compliant products from the start. It has been said here today that a central clearinghouse be established to make Year 2000 information publicly available. I want to assure all concerned that we take our responsibility in this area very seriously. Remember that we, the people, in this industry are also our own customers. The lives of many of us, our parents or our children, as patients, depend on our products.

Every day, we come face to face with co-workers who have, for example, a pacemaker or have a family member whose life depends on safe and reliable operation of one of our products. The sense of responsibility and accountability we live with every day is enormous. Our commitment to safety and reliability of our products is renewed in every encounter like this many times a day, every single day.

So, let me assure you that we share and welcome your interest in this area. Mr. Chairman, you have our strong commitment to continue to work with other concerned organizations and the FDA in making Year 2000 compliance information publicly available in an appropriate format.

Thank you.

[The prepared statement of Mr. Mojdeh can be found in the appendix.]

Chairman BENNETT. Thank you.

I am going to have to leave and will turn the gavel over to Senator Dodd, my apologies to the other two witnesses. Let me just ask a quick question. Do I take it, Dr. Mojdeh, that you think the FDA request is not an appropriate format? You have just said you wanted to make this available in an appropriate format. HIMA's activity with respect to the FDA activities in the past would indicate its concern with the format appropriateness. The letter that Senator Dodd quoted from indicates that you do not think that the FDA has the legal authority to require it, and you say that that is not an appropriate or necessary step. Is that correct? You do not think that what the FDA has tried to do is an appropriate format?

Mr. MOJDEH. With your permission, Mr. Chairman, I would like to ask my colleague, Mr. Bernie Lieberman, to respond to that.

Chairman BENNETT. Surely; just identify yourself for the record, and we are happy to have you respond.

Mr. LIEBLER. Certainly; my name is Bernie Liebler. I am director of technology and regulatory affairs at HIMA.

That initial letter was written on advice of our internal legal counsel. It was our legal counsel's opinion. We have since, as Mr. Thurm on the previous panel indicated, had further correspondence with FDA on this matter, and our last letter was sent yesterday,

and it included our offer to work with other people. It also included with it, as an attachment, a paper that we have written on that.

Our concern about format is that we believe that the total diversity of the industry in terms of size, size of company and resources available to them, may make it difficult for some companies to accumulate the information for location in one spot, as some people have requested. We believe that it is best for us to get together, meet with the organizations that are requesting information, find out what they need, offer what we can provide and work out a really optimum format.

Chairman BENNETT. Well, I am sure Senator Dodd will pursue this. Let me just make the comment that we really do not have any time. That is the primary enemy here, and I understand that legal advice says do not do this. I go back to an experience in my own lifetime. I am unburdened with a legal education. [Laughter.]

Sometimes, that is good; sometimes, that is bad. I know that there are times when I have been very, very blessed to have a good lawyer at my side when I have gotten into some difficulty. But there are times when a CEO has to overrule his lawyer. I have been involved in those kinds of situations. I remember a rather terrifying incident; I was a young man in his thirties sitting before the chairman of the board of a Fortune 500 company where I was working and had the chairman of the board say to me are you telling me I must disregard the advice of the general counsel on a legal matter because of your understanding of the political implications of this? I was then working as the Washington representative of that company.

I took a deep breath and said yes, I am telling you to disregard the legal advice of the general counsel of this corporation plus the Wall Street law firms that are advising you, because this is not a truly legal issue; this is a political issue, and that is my area of expertise, and I am telling you you have to go to Washington and testify, even though the lawyer is telling you do not do it.

I am not sure I would have the courage to do that if I were a little bit older. Maybe it was my youth that cost me that foolishness. He looked at me, and he said I am going to have to think about that. I am happy to report that he came to Washington, he testified, he ignored the advice of the lawyer who would have gotten him in all kinds of trouble and gotten his industry in all kinds of trouble, because this was not a legal problem.

And the point I want to make here through you to all of the lawyers out there who are saying do not disclose this information: we are faced with a crisis here. And you have heard the testimony up until now from others. The crisis is not going to go away unless we get information. We, speaking as a society now, not necessarily the Congress, although it is true of the Congress, we are flying blind into this crisis. We do not know how serious it is.

And I get very, very impatient with people who hide behind a legal opinion and say, well, the lawyer says we may have liability at some point down the road, and we want to make sure that liability does not come to pass, and so, we are not going to cooperate until we are absolutely sure that all aspects of liability have been examined by all law firms that we have retained all the way down the line.

We do not have time for that. And so, I am delighted to know that an additional letter has been faxed. I find it interesting that it is on the eve of this hearing, and if I may, Senator Dodd, I think we can take some credit for having stimulated that letter by virtue of the hearing and the fact that you would have a witness here today. But I would take advantage of your being here to send that message not only to your lawyers but to all of the other lawyers in all of the other parts of the Y2K issue who are telling people to not be forthcoming with information.

That is simply not acceptable. We have a crisis. We are flying blind toward it, and the only way we can resolve it is to get the information. And with that, again, my apologies to the other two witnesses that I will have to leave, but you are in good hands with the Senator from Connecticut.

Senator Dodd [presiding]. Mr. Glover

STATEMENT OF GIL R. GLOVER, DIRECTOR OF YEAR 2000 PROJECTS AND PLANNING, BLUECROSS BLUESHIELD ASSOCIATION

Mr. GLOVER. Thank you, Mr. Chairman.

Mr. LIEBLER. Senator, may we make the second letter a part of the record—

Chairman BENNETT. Absolutely.

Mr. LIEBLER [continuing]. Provide it with the paper?

Mr. GLOVER. Thank you, Mr. Chairman, Senator Dodd. I am Gil Glover, director of projects and planning and Medicare operations at Blue Cross and Blue Shield of Texas. Thank you for the opportunity to testify on behalf of the Blue Cross and Blue Shield Association on the progress Medicare contractors are making for becoming Year 2000 compliant.

As a health insurance company, both our Medicare business and our commercial business face the challenge of becoming Year 2000 compliant. Each independent Blue Cross Blue Shield plan is actively working to make sure that its information system and business operation will function properly in the Year 2000 and beyond. In Medicare, let me assure you that Year 2000 compliance is the top priority for Medicare contractors.

Toward this objective, the Blue Cross Blue Shield Association worked with HCFA to develop a formal process to ensure regular communications with HCFA on major Y2K issues. In response to a Blue Cross Blue Shield recommendation, HCFA established a steering committee to clarify Year 2000 compliance standards and monitor contractor progress. As a member of that steering committee, which is composed of contractors and senior HCFA personnel, I can assure you that the Blue Cross Blue Shield plans and commercial Medicare contractors are working collaboratively to assure that claims will be paid accurately and timely in the Year 2000.

Eight work groups have been established out of the steering committee to focus on various Year 2000 activities, including progress measurement, critical path assessment, provider relations, contingency planning and resource allocation. As a member of the contingency planning work group, I can report that the work group has developed a planning protocol, as supported by a comprehensive

planning template applicable to any risk a Medicare contractor might identify in its operations.

Use of this template is being piloted by work group contractor members and is scheduled for release to all contractors in early August. The work groups' combined input into the development of this protocol has produced a tool that can add significant value to this process and can produce uniform planning documentation. Beyond the specific products of these work groups, operation of the steering committee has facilitated very constructive and useful dialog between contractors and top HCFA management about Year 2000 compliance.

We believe that it is possible to complete basic Year 2000 modifications, testing and implementation by the end of 1998. However, it is important that changes to the Medicare program be minimized during the last quarter of 1998 and first months of 1999. If complex programming changes are made and tested simultaneously with Year 2000 programming changes, resource conflicts will arise, and it will be difficult to isolate whether problems are originating with Year 2000 or with other programming changes.

After Year 2000 testing is completed, and any other problems are resolved, any further changes in 1999 will require retesting and should be kept to an absolute minimum. HCFA is seeking legislation that would dramatically restructure the contracting process for Medicare contractors. This legislation could potentially hurt Medicare contractors' Y2K efforts. HCFA currently has the authority to terminate a contractor for non-performance, including non-performance of Year 2000 responsibilities and is exercising extensive oversight of Medicare contractors' Year 2000 compliance efforts through the use of its own review teams and an independent verification and validation contractor.

Most Medicare contractors have already been reviewed for Year 2000 compliance, with at least two comprehensive on-site reviews. Many contractors are around three of these reviews. In addition, both the Office of the Inspector General and the General Accounting Office are conducting Year 2000 reviews at Medicare contractor sites. There is ample opportunity for identifying and correcting any deficiencies or problems in the Medicare contractor community through these review processes. Additional legislation to enforce Year 2000 compliance is unnecessary.

I would also note that adequate funding is very critical to accomplish this monumental task. We strongly support HCFA's efforts to secure additional fiscal year 1999 funding for Year 2000 activities.

In summary, let me again emphasize that Medicare contractors are working diligently to become millennium compliant by December 31, 1998. We advocate a very careful approach to structuring the Medicare program change burden while Year 2000 remediation is in process. Medicare contractors will continue to work closely and effectively with HCFA to resolve issues that arise and to ensure compliance.

Mr. Chairman, thank you for the opportunity to express these views.

[The prepared statement of Mr. Glover can be found in the appendix.]

Vice Chairman DODD. Thank you very much.

Mr. Ackerman, thank you.

**STATEMENT OF JOEL M. ACKERMAN, EXECUTIVE DIRECTOR,
RX 2000 SOLUTIONS INSTITUTE**

Mr. ACKERMAN. Senator Dodd, my name is Joel Ackerman. I am the executive director of the Rx 2000 Solutions Institute. I am a former computer programmer, so I am a—actually, I did double-digit programming many years ago, so I am very intimately familiar with the issues.

Vice Chairman DODD. You could get a very good job today.

Mr. ACKERMAN. There are lots of openings, and I am getting lots of calls.

But 2½ years ago, when we founded Rx 2000, we felt like a voice in the wilderness, and actually, 1½ years half ago, we still felt that way. So, we are glad to see that things are finally changing. Rx 2000 is an independent, nonprofit member supported organization that is open to all organizations in the health care community, and we have no conflicting ties to health care organizations, manufacturers, pharmaceutical companies or consulting groups. Our sole objective is to help ensure the survival of health care organizations into the next millennium and to minimize the impact on patient care. We felt when we founded this organization that health care needed an information clearinghouse, and that is exactly what we set out to do for the Year 2000.

Some of the services we offer include a Web site at rx2000.org, which has gotten a lot of recognition as a leading Internet health care Year 2000 Web site as well as a list server with currently over 1,100 subscribers representing 20 countries in addition to the United States, discussing health care Year 2000 issues.

We are also currently developing a health care Year 2000 database that includes information submitted by organizations primarily focusing on field test information, and one of the things I have heard in the presentations today is a lot of emphasis on information from suppliers. There has not been enough emphasis on actual field testing, because we are finding that information from vendors, while it is very important to try to get that, and it needs to be as accurate as possible, it is very unreliable, and we have field examples to support that.

A couple key points. I will skip a lot of what I had planned on talking about, because it has already been covered today, but there are some key points I want to make. In health care, we do not have a big three or a big six driving the health care industry on Year 2000 issues. Other industries have that. In health care, we have a very diverse, fragmented industry with lack of coordination, lack of cooperation between the payers, providers and other manufacturers and other organizations.

That is a significant issue for us. We do not have the coordination and cooperation that is necessary. There is also a very strong fear of acknowledging and sharing information about Year 2000. I have talked with payers who do not want to talk about the issues with their providers, because they are afraid of incurring additional liability. We have to get around those kinds of problems. Health care organizations, as it has been pointed out a couple of times, are

very late to the Year 2000 table, and that has resulted in a lack of awareness and significant denial on the issues.

And it is important to recognize that most organizations have, at most, one budget cycle left before the Year 2000, and every organization that we have talked to about budgeting, estimating, they have significantly underestimated the cost and effort associated with the Year 2000. That is a key problem.

There is also a lack of consensus in the health care community as to how to deal with these issues. We are talking with hospitals and other organizations that are planning on relying strictly on information from the vendors, the manufacturers. As we have heard, they are having trouble getting that, but also, it has not been pointed out strongly enough that a lot of that is unreliable and cannot be counted on, and therefore, they need to be doing testing in addition to that. I wanted to emphasize that strongly, that relying solely on vendor information is a mistake at this point based upon the field experience.

We recently held a national meeting of a health care Year 2000 special interest group, and we had organizations from all over the country participating, and we did a survey of those organizations at the end of the meeting, and these are the people in the trenches, actually working on the issues, and some of the statistics we got were very interesting. Virtually all of the participants agreed that the Year 2000 issues will have significant impact on payers, providers, health care suppliers, and vendors. Ninety-seven percent of the people responding agreed that health care Year 2000 issues have a significant potential to negatively impact the quality of care. Now, again, these are the people in the trenches.

Ninety-four percent of them agreed that the Year 2000 issues have significant potential to lead to unnecessary deaths in our health care system. Sixty-nine percent agreed that health care lags behind most other industries in dealing with these issues, and 62 percent of these organizations said that they have already experienced Year 2000 failures. So, it is not something that will hit in December or January of 1999 or 2000.

We have heard about many of the areas of Year 2000 risks. There are a couple of key things that I want to point out. There has been emphasis on getting a statement from suppliers. That is good. But you have to be careful about a single point in time assessment. What we are finding is that everybody is learning still. Things are changing. Things we thought were OK 6 months ago, we are finding out that they are not. So, it is important to have ongoing, continuous monitoring.

There is a significant shortage of personnel, including biomedical engineers who can deal with issues. I brought with me today Mr. Dan Forrester of St. Joseph Health System who heads a group of 12 biomedical engineers in their hospitals in Texas and California. They are finding currently a 19 percent failure rate in medical devices, and he would be happy to answer questions if you wish.

I am running short on time, but in my testimony, there are some recommendations in there that we obtained both from Rx 2000 Institute as well as from the participants on our listserver. We asked them what would you like Congress to do about the Year 2000 issues in health care, and there are some very key things there, in-

cluding a couple of things that have not been addressed, such as providing information to the patients, the people that are out there. We are starting to get a lot of questions. Doctors are getting a lot of questions. There is no place for the patients to go at this point for information or for health care professionals. There are no credible, independent and reliable, unbiased sources of information, and we need to establish that somehow.

I will wrap up. I want to thank you for having me here today. I want to also emphasize that we are Y2K virgins. None of us have been through this before. We really do not know what to expect. So, all we can do is continue preparing and acting in good faith and not just solicit information from vendors but also do our testing.

Thank you.

[The prepared statement of Mr. Ackerman can be found in the appendix.]

Vice Chairman DODD. Thank you very much, Mr. Ackerman. That is some very good points you made, I think, and it is a nice ending here in a sense, having had the—and I appreciate your responding to things you have heard. Too often, people come with testimony, and regardless of anything else that has been said, that is what gotten written, and it is a single point in time testimony, instead of responding to observations that have been made.

I should have made note, Ms. Jackson, at the very outset, of how certainly proud I am to have a resident of my State as a witness here representing the Hospital Association and, of course, from the Connecticut Hospital Association, and we thank you very, very much for coming down from Connecticut to be with us, and I thank all of our witnesses here.

And I might want to get to your—that 19 percent number, I may want to come back and have the man you identified share some thoughts on that. I will try to keep this relatively brief, and we will keep the record open. Senator Bennett or other members of the committee may want to address some questions in writing, and I would urge you, if you could, if that is the case, to respond, and I will try and go through, and I may have some additional ones I will ask as well.

And what I would like to do on this, I will ask questions, and we will try to keep this brief, but if someone feels a need to want to respond to a question that I have addressed to someone else, please feel free to do so. I want to get as many cases for—for those of us here, sometimes, the debate and discussion between people who are at that table can be very, very helpful to us, and you may ask questions that we do not think of that are very important and poignant. So, do not hesitate. If you have something to say, indicate it to me.

Let me start with you, if I can, Ms. Jackson, and again, I thank you immensely for being with us here today. It is—obviously, we are getting a great deal of information about the seriousness of this issue; again, the panelists here today have indicated that as well. Limited budgets of hospitals in rural and urban areas, and I have got a series of questions I could ask you about this, but I want to get at that, and I want to know from your assessment, the assessment of the American Hospital Association, there have been some that said that this could be a—particularly in these hospitals, it is

going to make it very difficult for them to adequately staff Year 2000 efforts, make it unlikely that they will have the extra resources necessary to replace equipment and programs where necessary. I am talking about these rural and inner-city hospitals. How accurate are those views?

Ms. JACKSON. Based on the information that we have, not just from our hospitals but, as I believe you know, there is a consortium of state hospital associations in the AHA that is working together on bringing hospitals together throughout the country to work on Year 2000 issues and particularly focus on developing a database on medical equipment and devices, and what we have heard in talking to the hospitals is that they are very frustrated, because it is difficult for them to yet quantify what the costs are.

Their early indications are that this is very expensive. There is a lot of concern that they will need to replace very expensive equipment that they do not yet know about, because we do not have the information, and therefore, they have not been able to budget for it, even as you point out, if their budgets would allow for it.

Vice Chairman DODD. No.

Ms. JACKSON. So, there is a great deal of frustration on that issue, and we do not know the numbers yet.

Vice Chairman DODD. Well, that statement alone would indicate to me that it is pretty serious.

Ms. JACKSON. Yes.

Vice Chairman DODD. Because clearly, there is going to be replacement necessary or renovation.

Ms. JACKSON. We believe that there will be some replacement and a great number of fixes. Even the indication that we are getting from our database is that although there may not be widespread, drastic harm to patients, that that may be very limited, this is a huge problem because of the administrative burden on assessing all of the equipment, the physical plant—

Vice Chairman DODD. Yes.

Ms. JACKSON [continuing]. All of the issues that hospitals have to deal with.

Vice Chairman DODD. I hope—you know, as I see it, then, there may be certain services because of the lack of resources that less affluent hospitals have that they would end up having to either stop or curtailing those services for lack of the equipment: They do not have resources to buy it; late in applying for it; the waiting lists are long.

Take dialysis: A big issue in urban hospitals, inner-city hospitals. We looked at, I told you, equipment that was bought 2 years ago that is state of the art stuff. I am sort of surprised that something 2 years ago was not—the people were not thinking about whether or not they were going to make it 2000-ready. It seems to me we ought to get some assessment as to what State, local, and Federal Governments might do to assist in those rural and urban settings for those hospitals. And I think it would be very helpful to this committee, through the American Hospital Association, to share some ideas with us as to what we might do.

We are 526 days away from a decision of a major urban hospital, making a decision that they discover that a number of pieces of equipment which are critical are not compliant, could cause serious

health risks and therefore are obviously going to shut them down. What do you do with those patients? Where do they go? Are there plans being made to see to it that other hospitals will accommodate those people, particularly in life-threatening situations, where dialysis—a case that comes to mind immediately. I would be very interested in—people now talk about contingency plans. What are you thinking about in this area? And what are the best minds saying, the best advice you are getting as to how these hospitals that fall into that area might be able to respond to that?

Ms. JACKSON. We have been very intensively studying this issue and working with our hospitals, and we would be very pleased to submit additional information.

Vice Chairman DODD. I appreciate it. It would be very, very helpful.

Let me jump to HIMA if I can, and again, we thank you very much for being here today, and you have asked that this July 23 letter—what is today? Ah, timely piece of correspondence. You have asked that this be in the record, and I will put it in the record.

Mr. MOJDEH. Thank you.

Vice Chairman DODD. But let me point out to you here, as I read down this here, in paragraph two, we continue to maintain that the important thing is for the right people to get the right information in time. Fine. We think that each company is the best judge of which method of communication best fits its operations. Third paragraph. In the next few months, I expect the device industry to work with the FDA and other interested groups to define more clearly the needs of all parties regarding Year 2000 compliance information.

Let me just say, and I am speaking for myself, and other members may have a different reaction, but we are getting here not each company deciding what information it may think is important. We have got places like the Food and Drug Administration and HHS that rely on getting that information out. The company is not going to get that information out to everybody and sort out what needs to be done, and in the next few months, you know, this is not a problem that we can sort of delay.

We all know the day we have got to be kind of ready around here, and the notion somehow in the next few months, we can get to this I do not think is a satisfactory response. I will put this letter in the record, and others may find it to be fine, but I do not. I think you have got to be—this is not a company by company decision. This is really not your call in a sense here in my view. It is going to be others'.

Now, I do not know if anyone wants to comment on this. I have quoted the letter. Doctor?

Dr. PALMISANO. Senator Dodd, I have not read the letter, but the view of the American Medical Association, in working through the National Patient Safety Foundation and the National Patient Safety Partnership, is that we need to have a central clearinghouse so we can all go that site and look, because if we wait for the manufacturers to make that decision, as you point out, I will be very anxious for my patients that they have a piece of equipment that—if a piece of equipment is being used on my patients, I do not want to have to rely on someone saying, well, gee, we failed to get the

information; we did not have the proper address or something like that.

Right now, the FDA site is a voluntary reporting the way we understand it as we visit the site. Why could it not be a mandatory reporting to that site, so we could all go there and look at it and start making plans? We believe there should be a central clearinghouse. What we are doing, we are taking questions from physicians and patients and trying to answer those questions and disseminating the information. We think information needs to be spread so everyone is aware of the problem.

But we just do not know what the true significance—I had the occasion to be on a plane recently on an AMA assignment, and the gentleman next to me saw me working on the computer, and we got to talking, and he said he came out of retirement to work on the Y2K problem. And his quote was, his exact quote, “this will be the biggest problem since the great plague.”

Now, he is selling his services, and that may be a self-serving statement, but that causes you to pause a moment and say, well, wait a minute; we better check this out. And we are very much concerned. We do not want monitors. I mean, he makes a statement to us. I do not know if this is correct. I am not an engineer. We are trying to get people to give us that information, that certain defibrillators, because they have the BIOS, it does internal checking, when it checks, when it goes to 2000, it goes to 00, it says this machine is broken. So, that portable defibrillator will not work. I do not know if that is true or not.

Vice Chairman DODD. Well, let me come back, and I said earlier we have heard now from the VA, the American Medical Association, the American Hospital Association—who else have we got; I do not know if you gentlemen feel likewise, but that this company, the user, says the system is just not working. I wonder if we might get some further reassurance of how HIMA is going to respond to this. Actually, in my view, you ought to be taking the lead in providing the clearinghouse. This would be a wonderful role for HIMA to play, in establishing a clearinghouse, so that a lot of these other organizations, including the Federal Government agencies, could be looking to an association as being cooperative, instead of trying to—when you only get 500 responses to 2,000 or 3,000 manufacturers with a letter sent in January, this is August with the clock ticking.

I mean, do you think I am being outrageous when I raise that? I mean, am I acting irresponsibly when I say to you that, you know, 6 months later, after a letter, you are only getting 500 responses out of 3,000?

Mr. MOJDEH. Well, Senator, the bottom line here is the safety and confidence of the patients.

Vice Chairman DODD. Yes.

Mr. MOJDEH. And the medical community that is responsible for their safety.

Vice Chairman DODD. They have to rely on the equipment, though. I mean, doctors do not—I mean, they maybe do not read that machine, what it says when it prints something out, but they are not responsible for how that thing works.

Mr. MOJDEH. And that is why I emphasize confidence, and that confidence is very important. It is an issue that is related to the quality of life for the patients, the knowing of the fact that the devices that they rely on are reliable and safe and also, the health care community to know that their patients are safe, and there are many different ways of communicating that. The clearinghouse is one method, and there may be other methods that would complement the clearinghouse or instead of the clearinghouse.

Ultimately, HIMA is after understanding what is the direct need of the customers and the health care providers and would act to provide that, and again, I assure you that you have our commitment to be working diligently on that issue. And if it turns out in these discussions that the need expressed by the customers is that, then, HIMA would consider that very, very seriously.

Vice Chairman DODD. Well, you have got 233 manufacturers that have not responded to multiple inquiries from the Veterans' hospitals of this country. I mean, you know, I said earlier I will wait a week on this thing, but I am going to get those names of the companies, and I am going to get on the floor of the U.S. Senate. I am going to issue a press release. I am going to do everything I can, if that is what it takes, to get them to even respond to the VA—our veterans? We have got veterans of this country lying in hospitals relying on this equipment, and American companies, I presume, most of them would not respond to the VA? That is outrageous, absolutely outrageous, putting lives at risk potentially.

I mean, anybody, but, you know, I hope you take this very seriously what I am saying here today. You know, we can get to the mandatory stuff. I will bet you if I go over and offer an amendment on the floor of the Senate, we will make it mandatory within an hour. And if you want it to come to that, we can do that, but I hope it does not come to that. I hope you would respond to it.

Mr. MOJDEH. Sir, you are pointing out very well the need for this communication that HIMA is after to understand those needs and try to provide the best vehicle to get those needs met. If it happens to be the clearinghouse or other—

Vice Chairman DODD. You are not responding to a letter. Come on. You know, I cannot answer you right now; I will get back to you next week. How about that?

Mr. MOJDEH. We will be happy to do that.

Vice Chairman DODD. I mean, that is what I am saying, a letter. Just even responding or assessing it: we do not quite know yet; we will be in touch; here is a number where you can call us. This is not brain surgery we are talking about. This is simple communication, and if it is not happening, then, we are going to make it happen.

Ms. JACKSON. Senator Dodd, I will take you up on your offer of commenting on other people's questions. I believe that you have identified a large part of the solution. What we have found in developing our database is that it is our belief that many manufacturers are not responding because they do not yet know what the solutions are. There is a certain amount of concern, perhaps, from those of us who are burdened with a legal education, in responding when the answers are not clear. And your contention—that the Federal Government, the Congress, should create an atmosphere in

which full and timely disclosure is mandatory—is part of the key here.

We understand that for many manufacturers, from what we hear, testing and finding out what the problem is with the devices is very difficult and may not be completed. But this is your point exactly: If the policy of the Federal Government is: “Tell us what you know so far; you will not be penalized for not having the answers,” that is what we think will help move this solution along.

Vice Chairman DODD. I am sure that does, and I appreciate that. Of course, I will point out that an awful lot of them have found it, that they can respond, and it may be that they have identified the problem, but earlier on, I think the point Mr. Ackerman raised earlier about this, I think I wrote in my note here, the single point in time issue, and I respect that. That is probably true. I mean, there are people who are finding out that their equipment that they thought was going to be OK and so forth, making that statement, then, they discover, as more information becomes available; I was told, for instance, on the embedded chip issue that the manufacturers, in many cases, are using embedded chips as like a bin, and they will be sitting there and plugging in the embedded chips, and the embedded chips could come from any number of different manufacturers, and they are not necessarily taking them all from the same source.

So, two pieces of equipment that are sitting next to each other in two emergency rooms or two operating rooms could have very different manufacturers of the embedded chips in the exact same product, exact same—in fact, made on the same day by the same person who put them in and, yet, relied on different manufacturers. That is how serious this is. I realize that may be information that people did not know about until fairly recently. It does not excuse, in my view, the failure to communicate with the Veterans Administration and HHS and other organizations seeking to collect data and information on this. That is irresponsible, in my view.

Mr. ACKERMAN. Senator Dodd, yes, if I may.

Vice Chairman DODD. Yes.

Mr. ACKERMAN. You bring up a very good point. It is important that the vendors not only disclose their test results but also their test processes, so that they can be repeated in the individual institutions, because there are variations. We are finding differences in different serial numbers of the same unit. And so, it is very important that individual organizations do their own testing if they want to be 100 percent sure, which does not minimize the need for disclosure of test results but also the test process information.

Vice Chairman DODD. All right; did you want to comment, Doctor Palmisano, on the rural-urban issue as well as physicians in these areas?

Dr. PALMISANO. We think it is a very important point. You have already emphasized that, and we are going to try to disseminate the information and make sure that every physician working knows about this, so that they can evaluate the needs of their patients, and also, we are working with the National Patient Safety Foundation, National Patient Safety Partnership, and the American Hospital Association recently contacted us to see what we

could do, working together, to make sure that the rural areas also have this information.

So, our goal is to disseminate the information, to cooperate, but we need the information. I mean, I can look at this little thing, and I know it is 2000-compliant, because when I came in here, just for curiosity, I went over to 2001 and everything, and it still works. I know this is OK, because this is not date-stamped, and there is no problem here. But I do not know. I mean, I hear testimony that the defibrillator is going to work, and now, you have raised another issue, which is a very interesting issue, in that the same machine, side-by-side, made on the same day, they grab in a bin, and certain things, the BIOS and so on, some may be, and some may not be. That is another whole dimension.

And we cannot be expected to understand that. So, we need disclosure. We are not looking for blame. The whole attitude of the American Medical Association, through the National Patient Safety Foundation, is to get away from a culture of blame but to have candor, full disclosure. I mean, the liability system, which appears to be worrying everybody, I mean, that is another problem. We have got to address that another day. We know that is a serious problem, and it needs to be fixed. The present liability system does not work.

But what we need to do right now is we have got to look at our patients. We want full disclosure so that we can help our patients.

Vice Chairman DODD. Let me ask Mr. Glover a question that is very important. We have a tendency to talk about equipment and machinery here, and in a sense, people may understand that more. When we get into the Medicare system, you can really glaze over the eyes of even a well-intended listener.

Mr. GLOVER. Right.

Vice Chairman DODD. It is a complicated system and so forth. You point out that there are 4 million Medicare claims made daily. Currently, 98 percent inpatient and 85 percent of the outpatient claims are processed by electronic data interchange, EDI, as it is called. Now, if the Y2K issues are not resolved, what contingency plans does Blue Cross Blue Shield have in place or propose to process the staggering number of claims? What decisions are made? How do you handle it?

Mr. GLOVER. We are still——

Vice Chairman DODD. You mentioned them, but I want to know what they are.

Mr. GLOVER. We are developing those contingency plans now, and I would not say that we have a plan at this point to deal with a serious degradation to paper claims. It is recognized throughout the Medicare community—HCFA—that that would be a serious problem. We think that there is a real payoff to provider education, and at my own company and other Medicare contractors, we are engaging in that kind of education to make sure they understand what the requirements are.

Most, I believe all, Medicare contractors, provide free software for actually generating a claim. We have renovated that and have already distributed that out to those who use it. There is a connection, however, to this whole issue of medical equipment at hospitals and in doctors' offices and so forth. It is a little bit, I guess, off the

subject in a way, but we feel like the problem may not be that the provider, the hospital, the doctor, cannot actually generate the claim format, the record that he needs to, and send it to us electronically——

Vice Chairman DODD. Right.

Mr. GLOVER [continuing]. As much as there is a possibility that systems behind that, their back office systems, their administrative systems, might not support the creation of the claim data. Actually, you know, the information might not be available.

Vice Chairman DODD. Yes.

Mr. GLOVER. And so, that one is a little bit of a concern. It is along the same line, though, as the biomedical type issue. There are a lot of different system vendors, equipment and software vendors who have systems in doctors' offices, clinics, hospitals. So, it is a very broad area.

Vice Chairman DODD. OK; I would be very interested, again. We do not want to add to burdens. We have got enough people. I want you to get on the contingency plan. I am not worried about how well informed we in Congress are about the contingency plan. I am far more interested if you have got one than whether or not I know about it, specifically.

But I would like to just generally have the committee sort of be kept abreast to the extent, you know, what are these contingency plans and how they are going to work, and also, I would like to know how you are going to test, integrated testing, because I think that is going to be—you have got Blue Cross Blue Shield processors, HCFA central working file and disbursement. And that is going to require integrated testing.

Mr. GLOVER. Yes, sir.

Vice Chairman DODD. And I would be curious again. I do not know if you have any specific comment on that this morning, this afternoon. Do you have anything you can share with us, something on that?

Mr. GLOVER. The testing picture, it is complicated.

Vice Chairman DODD. Yes.

Mr. GLOVER. And they are very extensive, but each Medicare contractor has systems that they actually maintain in-house for themselves. They also have—they operate systems that are maintained by other HCFA system maintainer contractors, if you will: the major Part A processing system, the major Part B processing system and the common working file system. So, individual Medicare contractors have to renovate their own in-house code——

Vice Chairman DODD. Right.

Mr. GLOVER [continuing]. Wait for or schedule the introduction of these other renovated software pieces——

Vice Chairman DODD. Right.

Mr. GLOVER [continuing]. Into their environments and do some testing up to certain points before those major pieces come online but are really reliant on that for what is called end-to-end testing, where you would go from the very front end——

Vice Chairman DODD. How soon are you going to be doing that? I mean, I gather that based on people I am talking to that you ought to be testing very quickly on this. Am I right on that?

Mr. GLOVER. Well, we are testing at our location things that we are renovating ourselves.

Vice Chairman DODD. Yes, OK.

Mr. GLOVER. However, the full end-to-end testing of the Part A processing system, the Part B processing system and CWF will occur mostly in the September through December timeframe of this year.

Vice Chairman DODD. Of this year.

Mr. GLOVER. Of this year.

Vice Chairman DODD. Of this year.

Mr. GLOVER. Yes, sir.

Vice Chairman DODD. We have got a vote going on, and I do not want to have you sit around while I go out for a vote and come back. So, let me—who is the gentleman, Mr. Ackerman, you said has been doing some testing on the devices themselves?

Mr. ACKERMAN. Dan Forrester.

Vice Chairman DODD. Dan, why do you not step up here very quickly? That number kind of slipped out of me a little bit, the 19 percent number. Why do you not share that microphone? Tell me what you are finding here very quickly. What is your name, again, for the record?

Mr. FORRESTER. I am Dan Forrester, representing St. Joseph Health System in Orange, CA.

Vice Chairman DODD. OK.

Mr. FORRESTER. We have an enterprise responsible for 16 facilities, and I am in charge of the biomedical equipment discipline of our Year 2000 project. We started testing in early spring. We are physically, hands-on, changing the dates of medical equipment that we can get to on our mission critical, and we have experienced a 19 percent failure rate of mission critical. The failures range from minimal, such as date printout issues like this to total failure, and to reinforce what Mr. Ackerman, my colleague here, had said, we have had letters of compliance from a manufacturer on some significant chemistry analyzers, had the letter in hand, performed the test, and the unit crashed.

Star Wars, and it took about 3½ hours to revive the machine. As we speak today, there is a blood gas analyzer in northern California that has been rebooting for about 3½ months.

Vice Chairman DODD. Been what?

Mr. FORRESTER. Been rebooting.

Vice Chairman DODD. What the hell is that? What the heck is that? [Laughter.]

Mr. FORRESTER. Cannot find its BIOS, reinitializing its configuration. It cannot find its BIOS.

Vice Chairman DODD. Ah.

Mr. Forrester. And that particular manufacturer, quite frankly, has no solution. So, the only letter from a vendor that our system will accept is a letter of noncompliance. All other letters, we put on the record for further litigation purposes, but we are physically testing each piece.

Vice Chairman DODD. That is encouraging.

Nineteen percent; are you surprised by that number?

Mr. FORRESTER. No, sir, because hospitals have not had the luxury of replacing equipment every 2 to 3 years. So, there is lots of old equipment out there.

Vice Chairman DODD. Is my concern about rural, urban, inner-city hospitals versus more ones that have greater resource capacity—

Mr. FORRESTER. That is a genuine concern, Senator.

Vice Chairman DODD. Yes; are you showing much higher rates of failure depending on where equipment is coming from?

Mr. FORRESTER. Yes, sir; typically, the smaller and rural hospitals do not have the luxury of buying new equipment, although just 2 days ago, I tested a product that was 2 months old, and it failed.

Vice Chairman DODD. Well, we may want to get—have you got some—I think you indicated, Mr. Ackerman, that you had a report that Mr. Forrester had done on this. Have you done an interim report on this?

Mr. ACKERMAN. No, I do not have a report. The information that they are gathering, as well as the information other organizations are gathering, the field test data, is being put in our database, and it is being made available to the health care community.

Vice Chairman DODD. OK; that would be very helpful maybe for the staff on the committee, since we are wrapping up. Maybe we ought to sit down before you leave or take off. I would be very interested to have the staff talk to you a bit more and the kinds of questions that we ought to be asking or that HHS and FDA ought to be asking, so that maybe you can help us frame that so we can get more reliable information here.

Mr. ACKERMAN. I think that would be very good, because we see a lot of the wrong questions being asked.

Vice Chairman DODD. I apologize to all of you, because you want to eat and have lunch, I suppose. I am fascinated by what you have to say. You have been tremendously helpful, tremendously helpful. And let me say to HIMA, too, I have worked very closely with HIMA on a lot of issues, and my concern here is I want us to get up and moving on this stuff. I see that clock ticking, and every day we waste and do not get on this thing, it is just—the problem does not get less; it gets worse. So, I hope you will follow up with us on some of these idea and requests.

And with that, on behalf of Senator Bennett, it was very dangerous of him to give me a gavel. I am the only Democrat on Capitol Hill who has been called Mr. Chairman, probably, in the last 6 months, so I appreciate that.

But I should quickly point out this committee has absolutely no legislative authority, so there is no risk whatsoever that I misuse it.

The committee stands adjourned, and thank you all.

[Whereupon, at 12:42 p.m., the committee adjourned.]

APPENDIX

ALPHABETICAL LISTING AND MATERIAL SUBMITTED

PREPARED STATEMENT OF JOEL M. ACKERMAN

INTRODUCTION

Senator Bennett, Senator Dodd and members of the U.S. Senate Special Committee on the Year 2000 Technology Problem, it is my pleasure to be here today to offer this testimony on the Year 2000 technology problem and its implications for the American health care community.

I will begin by briefly telling you about myself and the Rx2000 Solutions Institute. I will follow this with a description of some of the significant patient care and business risks to the U.S. health care community posed by potential Year 2000 failures. I will close with some recommendations for what assistance Congress might offer to help health care institutions prepare for and survive the Year 2000 changeover.

PRESENTER: JOEL M. ACKERMAN, FOUNDER & EXECUTIVE DIRECTOR, RX2000 SOLUTIONS INSTITUTE

I have a confession to make. I am a former computer programmer who used two digits instead of four to denote the year. Granted this was more than twenty years ago, but even then I was aware of the anomaly posed by the year 2000. When I expressed this concern to my supervisor, he laughed and told me not to worry. "There's no way," he said, "that we'll be using these programs twenty years from now."

You can imagine my dismay when I learned less than a year ago, that this government contractor was indeed still using the programs I had worked on which, by the way, were used to control avionics and defense engineering and manufacturing projects.

Over the years my career has take me from programmer to systems executive working for:

- Honeywell, Inc. as a programmer, systems analyst, project manager and management scientist
 - GE Capital, Inc. as an Information Center manager and a manager of systems development
 - EDI Solutions, Inc. (software vendor) as Director of Product Development,
 - and most recently for United HealthCare Corporation as its Vice President for International Information Systems and Director of Advanced Technologies.
- I've chaired several advisory groups including:
- The Workgroup for Electronic Data Interchange created by former Secretary Sullivan of Health and Human Services: Trends & Technologies, Health I.D. Cards and Monitoring
 - The ANSI ASC X12 development of health care eligibility and EDI transactions

Throughout my career I have expressed misgivings about using the two digit year. And while my colleagues have understood my concerns, it has only been within the past 3-4 years that replacing this programming practice with four digit years has been widely accepted as a critical issue for systems development.

RX2000 SOLUTIONS INSTITUTE: HEALTH CARE'S YEAR 2000 INFORMATION CLEARINGHOUSE

Long before most hospital and medical associations and other industry groups, the Rx2000 Solutions Institute was a determined voice in the health care community, raising the alarm about the Year 2000 changeover and the possibilities of significant harm to patient care and institutional survival. Organized in early 1996, the Rx2000

Solutions Institute is an independent, non-profit, member-supported organization with no conflicting ties to health care organizations, manufacturers, pharmaceutical companies or consulting groups. The Institute's sole objective is to help ensure the survival of health care organizations into the next millennium with minimal impact on patient care.

The Rx2000 Solutions Institute's initial funding came from its founders and early users of its services. The Institute has recently become a membership organization. Members and users of Institute services come from large and small health care organizations including:

- Aetna/U.S. Healthcare, Hartford, Connecticut
- Mayo Foundation, Rochester, Minnesota
- Allina Health System, Minneapolis, Minnesota
- Medical College of Georgia, Atlanta, Georgia
- St. Joseph Health Care System, Orange, California
- Phycor, Nashville, Tennessee
- Vanderbilt University, Nashville, Tennessee
- HIP of New York
- Texas Health Resources, Dallas, Texas
- George Washington Medical Center, Washington, DC
- University of Virginia Hospital System, Charlottesville, Virginia
- Bellin Hospitals System, Green Bay, Wisconsin
- Several state hospital associations
- And more upon request.

The Institute provides services in three areas:

- Year 2000 education and awareness,
- Year 2000 information sharing,
- external organizations monitoring and reporting

Rx2000's Web site at <http://www.rx2000.org> as the leading Internet source for health care Year 2000 information.

The Rx2000 List Server & Discussion Forum has more than 1,100 members discussing a broad range of health care Year 2000 issues online. This includes participants from at least twenty other countries.

Rx2000's Year 2000 Solutions Vendor & Matching Service helps health care organizations efficiently locate appropriate sources of tools or assistance.

Rx2000 is developing the definitive International Health care Year 2000 Products Database of manufacturer and user product test results and compliance information for medical devices, software, and other products used in health care.

Other services include a Health care Year 2000 Electronic Newsletter, health care Year 2000 Special Interest Group meetings, a speakers bureau, supplier, provider, and customer reporting/monitoring services.

EXPERIENCES AND OBSERVATIONS ABOUT THE YEAR 2000 CRISIS IN U.S. HEALTH CARE

We are convinced the American health care community is in deeply serious trouble due to anticipated problems of the Year 2000 changeover. Rx2000 believes that patient care and indeed, patient lives are at stake.

Why? The reasons are rooted in the very nature of our health care system.

1. The health care community has a heavy dependence on computing technology including:

- Date sensitive information systems and electronic medical records
- medical devices and other equipment containing date-sensitive embedded chips
- information intensive outsourced services.

2. The industry is almost totally dependent upon the electronic exchange of information with insurers and claims processors, physician practices, laboratories and affiliated institutions.

3. The U.S. health care community is a fragmented, diverse industry with no "Big 3" or "Big 6" to drive activity. There has been little or no coordination of Year 2000 activities and significant duplication of Year 2000 efforts.

4. There has been little or no Year 2000 cooperation between segments of health care including payers, providers and vendors.

5. There is fear of acknowledging Year 2000 issues and offering information or assistance due to concerns over who will ultimately be liable for Year 2000 failures.

6. The U.S. health care community, like many other focused industries, struggles with the concurrent problems of rapid industry change (consolidation, cost containment, etc.) and rapid technology change (medical and information technologies)

7. Even more so than other industries, the health care community is late coming to the Year 2000 table. Because of this there has been a lack of awareness of the

breadth and depth of year 2000 issues coupled with a denial and minimization of problems.

8. Year 2000 problems can come from both internal and external sources and are likely to threaten the whole institution. If they are not fixed, Year 2000 failures could compromise patient care, interrupt core practice continuity and create substantial liability exposure.

9. Small, rural health care providers lack the necessary project management, technical and financial resources for Year 2000 preparation.

10. Organizations have, at most, one budget cycle remaining before January 1, 2000. Every organization we have talked with has, in their initial projections, significantly underestimated the costs and level of effort needed.

11. There is a significant shortage of qualified personnel, particularly biomedical engineers.

12. There continues to be significant denial regarding the severity of the Year 2000 problem. Even at this late date, many health care professionals are hoping for the "silver bullet" or for Bill Gates to "fix" the problem.

13. There is a potentially catastrophic lack of consensus in health care regarding the best and most effective practices for resolving the problems associated with the Year 2000 changeover. Some health care institutions, for example, intend to rely almost entirely on vendor assurances of compliance, even though experience has proven these to be unreliable.

14. There are often dramatic differences among health care institutions regarding testing protocols. Some systems are aggressively testing for operational compliance. Some are performing minimal tests solely for developing a trail of due diligence. Others are simply collecting compliance letters from manufacturers.

But these reasons are almost too generic for our use today. What is more telling is some of the input we've received from participants in Rx2000 Solutions Institute activities. These include the Special Interest Group (SIG) meetings we host around the country.

SURVEY RESULTS FROM THE APRIL RX2000 HEALTH CARE YEAR 2000 USERS GROUP MEETING

Participants representing 55 health care organizations with most actively working in health care Year 2000 issues (i.e., "in the trenches") responded to our survey with the following outcomes.

- Agree that Year 2000 issues will have significant impact on: Payers (100 percent), Hospitals (100 percent), Multi-Specialty Clinics (100 percent), Small Provider Offices (97 percent), Health care Suppliers/Vendors (100 percent)
- 97 percent agree that Year 2000 issues have significant potential to negatively impact the quality of health care
- 94 percent agree that Year 2000 issues have significant potential to create errors that lead to unnecessary deaths in health care
- 69 percent agree that health care lags behind most other industries in addressing Year 2000 issues
- 62 percent have already experienced Year 2000 failures in their organizations

OBSERVATIONS ON THE EVOLUTION OF HEALTH CARE'S YEAR 2000 ACTIVITY SINCE THE CREATION OF THE RX2000 SOLUTIONS INSTITUTE

Two years ago there was:

- Little or no significant activity (except among payers).
- A primary focus on internal information systems.
- A significant lack of awareness of:
 - supply chain issues
 - embedded systems issues

One year ago, we observed:

- Large, leading hospitals and hospital groups were initiating projects.
- A quickly-growing awareness (almost a panic) about medical device and supply chain issues.

As recently as six months ago:

- Approximately 25 percent of hospitals we addressed had even an awareness effort underway.
- There was still no significant activity among small & rural health care providers.

And today:

- There has been a significant increase in awareness of basic Year 2000 issues primarily due, we believe, to media coverage and internal awareness of potential legal exposure.

- Although most health care organizations have at most one budget cycle left before 1/1/2000, almost every organization we've spoken with has significantly underestimated the costs and level of effort needed.

CONFUSION AND MISINFORMATION ARE RIFE WITHIN THE HEALTH CARE COMMUNITY

Following are some of the areas about which participants in our Rx2000 List Serve have had questions or have expressed concern:

- Internal information systems
 - Administrative
 - Clinical
- Embedded systems
 - Medical devices (e.g. 18 percent failure rate observed by a large health care system doing extensive testing)
 - Facilities
 - Business systems
 - Transportation (ambulances, helicopters, etc.)
- Supplier & vendor issues
 - Suppliers of goods
 - Food service, linen service
 - Medical supplies, pharmaceuticals
 - Medical gases, blood banks
 - Services
 - Laboratories
 - Claims clearinghouses, EDI networks
 - Police, fire, 911
 - Utilities
 - Power
 - Water
 - Communications
 - Inadequacy of a "single point in time" supplier/vendor assessment
- Trading partner issues (customers, contracted providers, suppliers, regulatory agencies, etc.)—potential for interruptions in payment and information flows
- Under-addressed risk areas:
 - Personnel
 - Shortages
 - Retention
 - Burnout (noticeable increase!)
 - Who is going to talk to the patients about health care Year 2000 issues?
 - There's a notable and growing concern among patients who are asking hard questions about health care's Year 2000 readiness.
 - Year 2000 concerns may lead to patients avoiding needed care.
 - Home health care issues are a particular issue, especially among the senior and disabled population, and include the potential for medical device failures, interruption in the availability of pharmaceuticals, transportation, communications, etc.

A DISCONNECT EXISTS

It's obvious that there is a significant disconnect between public messages of readiness and the feelings and beliefs of those professionals who are working in the trenches. Following are just a few of the thousands of messages the Institute has received on its Year 2000 List Serve.

Biomedical Devices

A few of us have been deeply "embedded" in testing. I am a Director of Technology Management (Biomedical Engineering) tasked with identifying the risks within our system of ten acute care facilities and numerous clinics and home health entities. My team is, quite frankly, horrified at the risks within the laboratories. A few of the manufacturers have told us to not test their product with a date roll-over, for fear that it will experience catastrophic failure.

You know what? They are right. We have had significant hard crashes with chemistry analyzers, hematology analyzers and urine analyzers, coagulation profilers, and immuno-assay analyzers. A technology cousin most usually found in Respiratory Care Departments, the blood gas analyzer, is also quite risky. And, of course, in terms of risk assessment here in the United States, most of our surgical procedures rely on blood gas analyses once the patient is anesthetized. And the imaging devices that our physicians rely on to see inside the body are not in real good shape either. Many of the imaging manufacturers have outsourced their programming through

the years while they developed the illustrious million-dollar hardware, so remedy is not imminent. So, at last we are able to substantiate those fears that have been identified as hype and chicken-little! My colleagues, I shall not be a frequent web-buddie, simply because time does not permit me to sit in my hotel room and chat. My advice is to get off our laurels, quit inquiring about who is doing what, forget the presentations, quit chasing the soothsayers and prophets of doom, and get to work!

In biomedical equipment we found that we need to test all of them. Manufacturer's model and serial numbers may be alike, but the chips and boards inside test with different responses. Some work and some ail. Also the manufacturers know about this.

Count us in! We have 20,000 devices, some date sensitive, some not. We have just begun to assess Y2K compliance for embedded devices * * * had one device already certified by the vendor as compliant which failed the leap year test!

Budgeting

FYI * * * we just found out that FSB has stated new equipment can be capitalized but consultant fees and upgrades cannot. We did a rough estimate of computers, software and clinical devices to extrapolate the dollar costs. Hardest part was consultant costs. We just guessed on that one.

At "C" we have not prepared a detailed budget for TOTAL cost. Without an inventory and without vendor status I don't think we can. We have prepared a budget for corporate staff, consultant costs, inventory.

The important point here is that you need however much money you need! Do your best to budget based on what you know and the help you can get from people on this listserve. But do not let the budget committee think they have heard from you for the last time. The odds are HUGE that you will have to go back to them and this is a contingency for which they must be prepared. Y2K budgeting does not fit into the annual cycle model. Any attempt to make it do so at this state could be disastrous.

Drug Availability

I've discussed this subject with my pharmacist and the answer is "YES", that the drug supply problems could be a major impact of Y2K. Currently they are dealing with shortages of blood by-products under normal operations. Throw Y2K computer problems into the mix and certain products may nearly "disappear" from the market.

I am a bit confused as to why there would be a shortage. I could see the possibility that the pharmacy may not be able to dispense with the meds due to a Y2K failure on the computer end, but they should have a contingency plan in place, due to the fact that the computer could fail now with a power failure or a system crash.

A response from another listserve participant

The real issue is in moving back up the supply chain. The possibility exists that the manufacturer may not be able to make or ship the product. Then the middle man that distributes the product may not be able to inventory, pick, pack or ship the product. You may not be able to create or send the order to the middle man through EDI or the middle man may not be able to receive and process the transmission. The chain is where the problem may exist and not in the ability of the pharmacy to dispense the product.

RECOMMENDATIONS

We asked members of the Rx2000 listserve to suggest ways the federal government might help the healthcare community prepare for the Year 2000 changeover. The following summarizes the Institute's and its listserve participants' recommendations.

The federal government and health care community should:

1. aggressively maintain this critical sense of urgency. Given the short amount of time available, this urgency coupled with a sense of responsibility toward patients' well being and safety, will help give health care professionals and business managers the will to persevere in the face of negative publicity, aggressive head hunters and a loss of hope as the century change becomes more imminent.
2. accept the fact that we will not be able to eliminate the risk, but we can continue to work to minimize it.
3. aggressively build awareness through existing networks.
4. place more emphasis on medium, small and rural health care providers.

5. be prepared to respond to patient fears, especially as the Year 2000 draws closer. What should patients do, where can they get information? Who will answer their specific concerns?

6. increase national & international health care Year 2000 information sharing.

This means removing the fear of sharing product test information. The Rx2000 Institute has experienced this as a significant problem as it develops its Year 2000 International Health Care Products Database. Several health care organizations, for example, have been hesitant to share their test information. This is due to:

- fear of legal liability and litigation from vendors and others.
- concerns over customer loss of confidence
- fear of interference and oversight from regulatory agencies
- concerns over staff retention

Concerns about information sharing can only result in significant duplication of efforts, increased costs and the potential for failure due to lack of testing time etc.

7. provide assistance in the form of low interest loans or other financial mechanisms to help smaller health care organizations do what needs to be done.

8. support the rapid expansion of comprehensive Year 2000 services provided by private organizations such as the Rx2000 Solutions Institute and government agencies. Services should include:

- education and training
- information sharing
- vendor, customer and provider monitoring and reporting services

9. strongly support continuing efforts by HCFA to assist Medicare and Medicaid intermediaries in their year 2000 compliance efforts. We also encourage HCFA to develop a contingency plan for use with any unforeseen problems.

Additionally, the Rx2000 Solutions Institute strongly urges Congress to authorize a interim payment for the Medicare program which can ensure the uninterrupted delivery of quality health care.

10. very, very carefully consider requests for limitations on Year 2000 liability. Some in the industry have compared limitations to liability or “safe harbor” legislation to a “license to kill”. We believe that any limitation to liability should provide relief only to those organizations which have demonstrated responsible behavior as defined by stringent standards of due diligence. We need to keep serious pressure on all organizations in health care to act responsibly in preparing for the Year 2000.

11. Support the creation of two national hot lines to provide informed, credible and responsible answers to Year 2000 questions and concerns from patients and health care professionals.

CONCLUSION

I want to thank Senator Bennett, Senator Dodd and members of this committee and its staff for inviting me to be here today. We are all Year 2000 virgins. No one has lived through the Year 2000 before and we can only make calculated guesses about the extent and severity of problems related to the millennium change. The Year 2000 is not “somebody else’s responsibility. Working together we can reduce the risks of failure and increase hope for the professionals and patients in global health care community.

The Rx2000 Solutions Institute is and shall remain unalterably committed to serving the health care community “until the dust settles” past January 1, 2000.

We shall bring our database of product test results to broad American & international health care audience.

We shall continue our aggressive monitoring of the Year 2000 readiness of health care suppliers, customers and contracted providers.

We shall continue operating our web site, list server, user group meetings as our contribution towards enhancing information sharing.

Thank you.

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PARTIAL LIST OF ORGANIZATIONS WORKING WITH Rx2000 OR PARTICIPATING IN
Rx2000 HEALTHCARE YEAR 2000 SPECIAL INTEREST GROUP (SIG)

Aetna Year 2000 Projects	Columbia/HCA
Allina Health System	Comdisco Healthcare Group
American Continental Insurance Co.	Crow Consulting Group. Inc.
AnswerThink Group	CSC
Anthem, Inc.	Detroit Medical Center
Aon Risk Services	Fairview Health System
Bellin Hospital	Family Health Systems
BES Medical Claim Service	Fedota, Childers & Rocca, P.C.
Blue Cross & Blue Shield Association	G.J. Sullivan Company
Blue Cross Blue Shield of Illinois	Gardner, Carton & Douglas
Blue Cross Blue Shield of Minnesota	George Washington University Med. Ctr.
Carle Clinic Association	Giga Information Group
CDHS	Gillette Children's Specialty Healthcare
Central Dupage Hospital	Glencoe Area Health Center
Cerner Corporation	Guident-CPI
Clark Information Services	Hancock Rotherth & Bunshoft
Cleveland Clinic Foundation	Harvard Pilgrim Health Care
CNA HealthPro	Healthpartners
CNA Insurance	HealthSystem Minnesota
Columbia Wesley Medical Center	Hexaware Technologies, Inc.

HIP Plans, Inc.	Noridian Mutual Insurance Company
Holy Cross Health System	North Memorial HealthCare
Humana, Inc.	NRC-GIG
IBM Global Services	Oakwood Healthcare System
IKON	OHA: Assoc. for Hospitals & Health
Jacquard Systems Research	System
JCAHO	PhvCor
Kanabec Hospital	Price Waterhouse
KARE Computing	PROMINA Health System
KPMG Peat Marwick	Provena Health
Lake View Memorial Hospital	Regence BCBS of Oregon/Regence HMO
Litton Enterprise Solutions	RHEMA Association, Inc.
Lutheran Health Systems	Rider, Bennett, Egan & Arundel, LLP
MacNeal Hospital	Rockford Health System
Manitoba Health	Rush North Shore Medical Center
Martin, Clearwater & Bell	Rush Presbyterian St. Luke's Med. Ctr.
Mayo Foundation	Rx2000 Solutions Institute
McGladrey & Pullen	SafeNet Consulting
Medical Center at Princeton	Salina Regional Health Center (SRHC)
Memorial Health System	Scott & White Hospital
Mercy Health Services	Sierra Health Services
Mercy Hospital of Pittsburgh	SSM Health Care
Metropolitan Health Plan	St. Joseph Health System
Michael Reese Hospital	St. Jude Medical Center
Miller Christerson McNaboe & Cortner	The Toronto Hospital
Ministry of Health, British Columbia	U.S.NRC
MN Hospital & Healthcare Partnership	University Medical Center Arizona
Modern Healthcare Magazine	University of Virginia Hospital System
Monterey Bay Group	Vanderbilt University Medical Center
Naval Medical Logistics Command	Y2Kplus
NCH Healthcare System	Zelle & Larson

PREPARED STATEMENT OF CHAIRMAN ROBERT F. BENNETT

Good morning, and welcome to the fourth hearing of the Special Committee on the Year 2000 Technology Problem. To date, we have held hearings on the energy utilities and financial services industries. Subsequent hearings will include telecommunications, transportation, general government services, and general business.

Let me begin today's hearing by saying that health care is America's largest industry generating \$1.5 trillion annually, more than one-seventh of our nation's economy. More importantly, the quality of life of virtually every American family is directly impacted if this industry is not ready in time for the next millennium.

Unfortunately, I have troubling news today. Clearly, the health care industry is not yet ready for the Year 2000. If tonight when the clock struck midnight the calendar flipped to December 31, 1999, large portions of the health care system would fail. There are some 6,000 American hospitals, 800,000 doctors, and 50,000 nursing homes, as well as hundreds of biomedical equipment manufacturers and suppliers of blood, pharmaceuticals, linens, bandages, etc., insurance payers, and others that are not yet prepared.

Today, we want to present a balanced picture of where the health care industry stands in relation to meeting the Year 2000 awareness, assessment, validation and implementation deadlines. The Committee has been unable to find a central repository for this kind of information so I look forward to hearing the contributions of each of today's witnesses.

Since World War II, the United States has undergone one cultural change after another, probably none as profound as the one occurring in the health care industry. The very name "health care industry" is in sharp contrast to the solo-practicing doctors which dominated medicine when my father was a member of the Senate. Before we get into discussing the potential effects of Y2K on health care, a quick view of the changing times in medicine.

Not too many years ago when you made an appointment to see your doctor, he would greet you at his office, inquire about your family and ask the purpose of the visit. When you told him, he would probably take your blood pressure, test your lungs and heart with a stethoscope, ask a few more questions, look at your medical record folder, and prescribe treatment. No Y2K problem in that picture.

Today, when you enter a doctor's office, outpatient clinic, hospital or HMO you first encounter medical electronics as you submit your insurance or Medicare card

to the admission clerk. The data in your card is entered into a desktop computer that is linked to Medicare or insurance eligibility files maintained on a mainframe computer in some distant city. This same computer will bill the insurance company and you as a co-payer.

Electronic complexity continues at every step, starting with computerized medical records. Virtually every diagnostic and therapy machine is powered by one or more microprocessors. If a patient requires hospitalization, his physician electronically schedules a time-specific hospital admission date as a preparatory step, as well as medical orders. The hospital computer will generate a letter telling the patient the medically necessary tests that will be needed. Every test uses one or more date sensitive microprocessors, which automatically feed your biological results into the hospital's computer based clinical data system.

This same computer schedules the time, surgical suite location and staffing levels for your operation as well as a list of essential medical needs for the surgery. Throughout the operation the patient will be connected to life saving machines—monitors, ventilators, anesthesia control, and infusion pumps that are microprocessor operated. High technology follows the patient into the Intensive Care Unit to help ensure full recovery. Finally, the patient is wheeled into a ward and begins receiving food from a computer-generated dietetics menu. The only thing that has not changed since my father's day is the taste of that hospital food.

In addition, electronic data interchange (EDI) is used for most of the business transactions of medical institutions. These include; patient billing and payment systems, which are interconnected, so that failure at one can reverberate throughout.

Based on what you will be hearing from various witnesses today, there is trouble in River City and most of the rest of the nation because the health care industry is lagging behind other industries in making critical Y2K fixes. The Gartner group says that over 90 percent of the individual physician practices are not yet aware of their Y2K problems. Two of our witnesses, Mr. Nutkis and Dr. Palmisano, have equally alarming data.

Finally, if the insurance and Medicare eligibility process cannot function, doctor's offices and hospital admission processes would default to paper. Their daily output is nearly 4 million Medicare claims and approximately 27 million pages of medical records. Health care paperwork could backup like traffic on an interstate highway after a bad accident. This could immediately affect a patient's access to quality health care. Concurrently, the nation's 1.6 million providers would have monumental cash flow problems without electronic payment from insurers and Medicare, which accounts for nearly 50 percent of health care payments—almost \$1 billion per day.

The problem is exacerbated by the lack of a national "fix it" program by the health care industry. I find it hard to understand why the manufacturers of biomedical devices, represented by the Health Industry Manufacturers Association, have not provided a central clearinghouse for the data that only they possess. The complexity of biomedical products causes me to take the unusual step of publicly requesting the industry to help solve the Y2K problem which they helped create, and we will hear from them today.

GENERIC LISTING OF POTENTIAL DATE SENSITIVE EQUIPMENT

Aerator, Ethylene Oxide	Blood-Flow Detector, Ultrasonic
Anesthesia Unit	Breath Analyzer, Alcohol
Anesthesia Unit Ventilator	Camera, Gamma
Anesthesia Unit, Monitoring System	Camera, Identification
Angioscope	Camera, Microscope
Apheresis Unit	Camera, Video
Apnea Monitor	Carbon Dioxide Analyzer
Arthroscopic Shaver System	Carbon Dioxide Monitor, Exhaled Gas
Aspirator, Emergency	Cardiac Output Unit, Thermal Dilution
Audiometer	Cardiodynameter
Automatic Implantable Defibrillator	Cataract Extraction Unit,
Function	Phacoemulsification
Battery Conditioner/Charger	Catheter, Cardiac Ablation
Bed, Electric	Centrifuge
Biofeedback System	Chloridometer
Blood Cell Processor	Chromatography Equipment
Blood Gas/pH Analyzer	

Circulatory Assist Unit, Intra-Aortic Balloon	Monitoring System Central Station Recorder
Circulatory Assist Unit, Ventricular	Multiple Medical Gas Monitor, Respired/ Ane
Clinical Chemistry Analyzer	Nephelometer
Coagulation Analyzer	Network Communication Gateway
Compressor, Medical Air	Nurse Call System
Computer	Osmometer
Computer, ECG Interpretation	Oximeter
Computer, Nuclear Medicine	Oximeter, Pulse
Computer, Pulmonary Function	Oxygen Analyzer, Sampling
Continuous Positive Airway Pressure Unit	Oxygen Monitor
Cystic Fibrosis Screening Device	Oxygen Monitor, Transcutaneous
Data Analysis System, Ultrasound, Cardiac	Pacemaker Analyzer
Date-Time Stamp	Pacemaker Programmer
Defibrillator	Pacemaker, Cardiac
Dialysate Delivery System, Single-Patient	Peritoneal Dialysis Unit
Disinfecting Unit, Liquid, Flexible Endoscope	pH Meter
ECG Monitor	Photometer
Electrocardiograph	Physiologic Monitoring System, Neonatal
Electroconvulsive Therapy Unit	Physiologic Monitoring System, Stress Exerci
Electroencephalograph	Physiologic Recording System
Electrolyte Analyzer	Platelet Aggregation Analyzer
Electromyograph	Plethysmograph
Electrosurgical Unit	Polygraph
Emission Control System, Ethylene Oxide	Polysomnography Analyzer, Computerized
Enzyme Immunoassay Analyzer	Positron Emission Tomography (PET) System
Ethylene Oxide Monitor	Pressure Infuser
Evoked Potential Unit	Pressure Monitor, Airway
External Pacemaker Analyzer	Pressure Monitor, Blood, General/ Invasive
Film Digitizer	Printer, Video
Flowmeter, Blood, Ultrasonic	Pulmonary Function Analyzer
Fluorescence Immunoassay Analyzer	Pump, Circulating-Fluid, Localized Heat
Gastrointestinal Motility Analyzer	Pump, Enteral Feeding
Heart Rate Monitor	Pump, Extracorporeal Perfusion
Hematology Analyzer	Radiographic Systems
Hemodialysis Unit	Recorder, Chart
Hemofiltration Unit	Recorder, Long-Term, ECG, Portable
Hemoglobinometer	Recorder, Video Tape
Hyperthermia Unit, Circulating-Air	Regulator, Line-Voltage
Hypo/Hyperthermia Unit	Respiration Monitor
Immunofluorescence Equipment	Scanner, Computed Tomography
Incubator, Laboratory, Thermocycling	Scanner, Long-Term Recording, ECG
Information Storage Unit, Magnetic Disk	Scanner, Ultrasonic
Infusion Controller	Spectrophotometer, UV/Visible
Infusion Pump	Speed Control/Selector, Treadmill
Injector Contrast Media Angiography	Sphygmomanometer, Electronic Automatic
Irradiator, Blood	Stereotactic Radiosurgical System, Linear Acc
Irrigation/Distention System, Arthroscopic	Sterilizing Unit
Laser	Synchronizer, Gamma Camera
Laser Imager	Telemetric Monitoring System
Lensometer	Television Monitor
Light, Examination	Thermometer, Electronic
Line Isolation Monitor	Tissue Embedding Equipment
Linear Accelerator	Tissue Processor
Lithotripter	Trainers, Auditory
Magnetic Resonance Imaging (MRI) Unit	Transmitter/Receiver System, Telephone. EC
Microbiological System	Ultrasonic Cleaning System
Monitor, Fetal	Unit-Dose Dispenser, Tablet, Electronic
Monitor, Physiological	Urinometer
Monitoring System Arrhythmia Computer	

Urodynamic Measurement System	Washer, Flexible Endoscope
Uroflowmeters	Washer/Decontaminator
Ventilation Monitor	Washer/Sterilizing Unit
Ventilator	X-ray Control Panel
Video Image Processor	X-ray Film Processor, Automatic, Sheet-
Visual Function Analyzer	Film
Vital Signs Monitor	X-ray Image Recorders
Warmer, Blood/Solution	Xenon System

PREPARED STATEMENT OF NANCY-ANN MIN DePARLE

Chairman Bennett, Vice Chairman Dodd, distinguished committee members, thank you for inviting me here today to discuss my highest priority. We must assure that the more than 70 million Medicare and Medicaid beneficiaries experience no interruption in services because of the Year 2000 computer problem. We also must assure that the approximately 1.6 million Medicare and Medicaid providers continue to receive prompt and efficient payment for their services.

PROGRESS

I am committed to doing everything possible to address this issue, and we are making substantial progress in addressing the Year 2000 problem. Since I became HCFA Administrator in November we have:

- completed renovation of five of our six standard systems;
- completed renovation of 24 of our 37 most critical internal systems;
- initiated testing of renovated systems;
- conducted at least one site visit to every claims processing contractor, and at least two site visits to every systems maintainer for independent verification and validation;
- provided clear instructions to contractors on everything they must do to be Year 2000 compliant, and made sure they assessed their status based on those instructions;
- negotiated a contract that makes clear the responsibility Medicare claims processing contractors have in ensuring that their systems are Year 2000 compliant;
- developed more realistic cost estimates for Year 2000 work after contractors reassessed their workload based on the instructions we provided;
- conducted outreach to states, providers, and other health care entities; and
- gathered data from states on Medicaid system Year 2000 status.

SCOPE

The Year 2000 especially affects Medicare because of our extensive reliance on multiple computer systems. More than 183 systems are used in administering the Medicare and Medicaid programs, and 98 of these are considered "mission critical" for establishing beneficiary eligibility and making payments to providers, plans, and states. Medicare is the most automated health care payer in the country. We process nearly one billion claims each year, or about 17 million transactions each week. Fully 98 percent of inpatient hospital and other Medicare Part A claims are processed electronically, as are 85 percent of physician and other Medicare Part B claims.

The renovation process is complicated because each system used by Medicare and by its 60-plus claims processing contractors, as well as interfaces with State Medicaid programs, banking institutions and some 1.6 million providers all must be thoroughly reviewed and renovated by those responsible for each particular system. They must be tested, both alone and for the complicated interfaces among them. To fix Medicare systems alone, nearly 50 million lines of internal and external systems code must go through the renovation process. We must renovate all Medicare-specific software, and work with new versions of vendor-supplied software, including operating systems that drive the hardware we use. Some hardware must be upgraded, and our telecommunications equipment and software must be compliant. We must assure that all data exchanges with thousands of partners are compliant. I have attached a chart to my testimony which depicts the systems that must interface to process Medicare claims.

Testing of Year 2000 changes presents a far greater burden than testing of routine system changes because we must test multiple times on a range of different dates. For example, we must test February 29, 2000 and March 1, 2000 because 2000 is a leap year. Normally we would never consider so much change and testing at one time, but we have no choice.

If we do not fix all information systems that might have Year 2000 problems, enrollment systems might not function, beneficiaries could be denied services because providers may not be able to confirm eligibility, and providers could have cash flow problems because of delayed payments.

Processing paper claims by hand is one contingency if we fail. Given the nearly one billion Medicare claims we process each year, it is a possibility that strongly motivates us to succeed. Paying providers prospectively, based on previous payments to them, is another option, which would be a considerable endeavor itself. Clearly our best option is to successfully complete all of our Year 2000 renovations.

That is why we are requiring contractors to be in full compliance with Year 2000 requirements, with all code renovated and fully future date tested, by December 31, 1998. Renovations to mission critical internal systems also must be complete by December 31, 1998. We expect to complete end-to-end testing of how claims are processed through our entire network of renovated systems in the Spring, and then have the rest of 1999 to fix any remaining glitches and take any additional corrective action that might be necessary.

Year 2000 compliance for the Medicare program is considered a mission critical activity and as such, is being closely scrutinized and monitored by many sources, including the Office of Management and Budget, General Accounting Office, Office of the Inspector General and the Department of Health and Human Services Chief Information Officer, the Assistant Secretary of Management and Budget.

COMMITMENT

I have committed significant staff and other resources to this priority. Actions taken include:

- setting up special teams of employees whose sole responsibility is making Year 2000 fixes;
- hiring retired federal programmers to assist with Year 2000 efforts;
- hiring Intermetrics, a special Independent Validation and Verification contractor, to make sure Year 2000 fixes are done right;
- hiring Seta Corp. to independently test systems after we and our contractors conclude renovation and testing to make sure they work properly;
- negotiating contract amendments with the more than 60 Medicare fiscal intermediaries and carriers to ensure that they use information technology that is Year 2000 compliant;
- closely tracking contractor progress to ensure that work is on schedule;
- creating a special contingency planning unit to make sure disruptions do not result from any unexpected problems;
- working with the Congress to redirect \$62 million within the Agency and Department to this effort for fiscal year 1998; and,
- working with Congress to obtain an additional \$62 million for fiscal year 1999.

Intermetrics is now very actively providing comprehensive oversight of contractors, with more site visits for those with high volumes of claims or evidence that they are behind schedule. Intermetrics is monitoring contractors' Year 2000 resources, quality assurance, test plans, use of commercial software, and progress in non-Medicare systems in order to fully assess their Year 2000 status. Because of their efforts and our own increased attention to this problem, we now have a much more accurate assessment of what must be done and how it should be accomplished.

NECESSARY POSTPONEMENTS

This more accurate assessment makes clear that, because of the Year 2000 imperative, related work must take precedence over other projects that require systems changes. Many other private and public organizations, including most major insurance companies, have reached the same conclusion and are halting other projects involving information technology changes to clear the decks for the Year 2000. Intermetrics advises that we must clear the decks of projects that could interfere with Year 2000 work. Intermetrics specifically advised us to "seek necessary relief from Congressional mandates, system transitions and version releases to allow near-term, focused attention to achieving Y2K compliant systems." This includes projects that are complex, or which would occur during a critical window between October 1999 and March 2000. Otherwise, they warned, "many of your most critical system renovations have risk of significant schedule slippage."

Most of the more than 300 provisions affecting HCFA in the Balanced Budget Act of 1997 do not have to be delayed. That is because they are already complete, or can be completed before major systems must be frozen for the critical Year 2000 transition period.

Projects affected by the Year 2000 include both Balanced Budget Act provisions and other Agency priorities. For example, in April, we made the difficult decision to postpone final transitions to uniform systems for Part A and Part B contractors. Over the past two years we have whittled the number of different computer systems used by our contractors down to six from nine. Uniform systems will go a long way in helping us to streamline Agency operations and provide better access to program data. But the delay is essential if our contractors are to renovate and test systems before our December 31, 1998 deadline. Postponing this activity allowed us to redirect both valuable programmer time and \$20 million in fiscal year 1998 appropriated funds to Year 2000 work.

At present, Balanced Budget Act provisions whose implementation we believe must be postponed include:

- prospective payment systems for outpatient hospital care and home health services;
- consolidated billing for physician and other Medicare Part B services in nursing homes; and,
- a new fee schedule for ambulance services.

These activities must be postponed because they involve complex systems changes and interactions with other systems that would interfere with critical Year 2000 work. Our claims processing contractors concur with the decision to postpone these activities; a July 7, 1998 letter expressing their support is attached to my testimony.

We may also need to delay some activities that are not complicated but which involve changes that could create an unstable environment during a critical window of Year 2000 activity, such as provider payment updates. We will work with Congress and providers to evaluate our options and ensure that any necessary delays in provider updates do not create a hardship.

If Year 2000 system renovations are completed ahead of schedule, we will make every effort to put these provisions back on their original schedule. But at this time it appears that postponing some projects is necessary to focus resources and freeze systems so essential Year 2000 work can be done, and thereby avoid complicating factors in the critical months right before and after the new year.

CONTRACTOR AMENDMENT

As mentioned above, we have developed with our claims processing contractors an amendment to their contracts articulating the requirement that they be Year 2000 compliant by December 31, 1998. It includes a clear definition of Year 2000 compliance, a clear statement that contractors will not be held accountable for factors beyond their control, and expressly states that Year 2000 activities are functions under the contract for which the Indemnification and Limitation of Liability provisions will apply. It also acknowledges our responsibility to provide adequate funding. All contractors with whom we have spoken about this indicate that they will sign the amendment.

BUDGET

HCFA began funding millennium efforts to renovate both its internal and external systems in fiscal year 1996. The Agency spent \$7.6 million in fiscal year 1996 and \$14.5 million in fiscal year 1997 on millennium related activities.

The continually evolving definition of what is required to meet millennium requirements has a significant impact on the budget process. This year, we recognized that the fiscal year 1998 funding of \$45 million we had allocated was not enough to support millennium efforts at our claims processing contractors. We reallocated \$62.1 million in additional funds from within the Agency and the Department to fund these essential activities. We have already spent approximately \$53.4 million of the \$107.1 million we have budgeted for millennium activities in fiscal year 1998.

The constantly evolving definition of millennium compliance also impacts our fiscal year 1999 budget estimate. The President's budget requests \$37.5 million to support millennium activities. We are working with Congress to acquire an additional \$61.5 million, which would provide a total of \$99 million to continue millennium code renovation and other millennium related activities. It is also likely that we will need additional funding in fiscal year 1999 and fiscal year 2000 to be prepared for the possibility that not all our remediation efforts will be completely successful. As we continually reassess our millennium compliance funding needs, we will work with Congress to ensure that funding will be available to support this critical project.

CONCLUSION

We are making solid, steady progress in preparing for the Year 2000. We have taken steps to obtain and direct necessary resources. We have made difficult decisions to delay other priorities in order to clear the decks for necessary Year 2000 work. We are closely monitoring our own efforts and those of our contractors to ensure that we are on track. And we are making necessary contingency plans to prepare for any unexpected problems. We appreciate this committee's support, and I am happy to answer any questions you might have.

JULY 7, 1998.

NANCY-ANN MIN DEPARLE, *Administrator,
Health Care Financing Administration, 7500 Security Boulevard Baltimore, MD.*

DEAR MS. DEPARLE: We are writing in our capacities as the contractor members of the Joint HCFA/Contractor Y2K Steering Committee to comment upon the "HCFA Year 2000 Fact Sheet" which describes the priorities HCFA has established to balance the resource requirements demanded by:

- Y2K modifications to the numerous inter related systems;
- Testing the systems against one another to assure Y2K readiness; and
- Managing the numerous program, HIPAA change requirements and initiatives which will be implemented while these Y2K modifications and testing are occurring.

As you know, we have been working with senior HCFA management to help develop the HCFA/Contractor collaboration which will assure that fee for service Medicare claims will be processed timely and accurately on January 1, 2000.

A substantial portion of our advisory work with HCFA has been devoted to examining the critical processes in assuring Y2K readiness. We concluded, and recommended to HCFA, that as many non Y2K system changes as possible should be removed from contractor workloads so that technical resources could be devoted to assuring Y2K readiness. Non Y2K systems development work should be added back only after HCFA is satisfied that the contractors' and HCFA's systems are certified Y2K ready. We also recommended that no material system changes be introduced between October 1, 1999 and February 1, 2000.

The priorities described in the HCFA Year 2000 Fact Sheet are consistent with advice from our technical experts that resources must be focused on the Y2K effort. We believe that prioritization established by HCFA is an aggressive but feasible workload that is consistent with the availability of systems technicians and Medicare "subject matter experts." However, there is little doubt that even these priorities will require HCFA and its Medicare contractors to manage resources to very high levels of productivity. Also, additional funding for contractors will be necessary to assure that sufficient resources can be acquired, and we appreciate the progress HCFA has made in acquiring that funding.

We appreciate the difficult decisions involved in HCFA's prioritization effort and look forward to a collaborative and intensive working relationship to assure that claims are paid accurately and timely in the Year 2000.

Sincerely,

BRUCE A. DAVIDSON,
Blue Cross & Blue Shield of Florida.

BARBARA GAGEL,
Administar Federal, Inc.

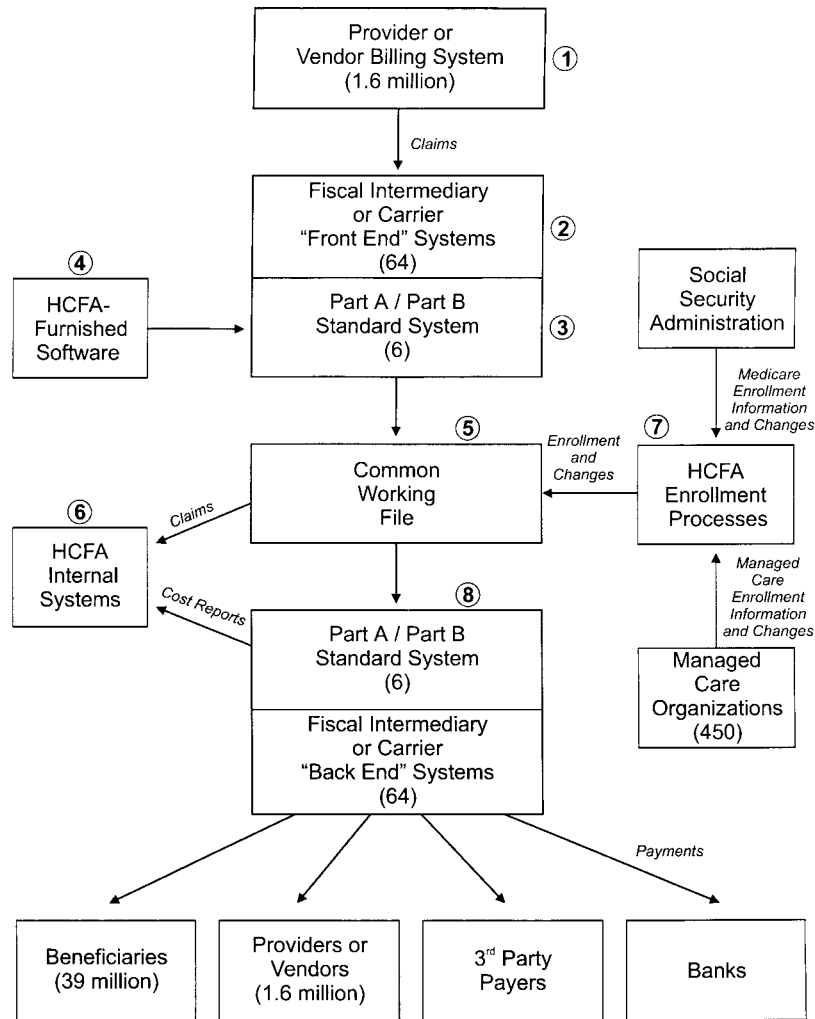
GEORGE GARCIA,
Transamerica Occidental Life Insurance Company.

HARVEY FRIEDMAN,
Blue Cross & Blue Shield Association.

GIL R. GLOVER,
Blue Cross & Blue Shield of Texas.

EDWARD BURRELL,
CIGNA.

Processing a Medicare Claim



PROCESSING A MEDICARE CLAIM

A SYSTEMS PERSPECTIVE

- (1) *Providers* or their billing agents submit claims.
- (2) *"Front End" Systems* at each local contractor collect, format, and edit claims data.
- (3) *Standard Systems*—two for Part A, three for Part B, and one that is a combined Part B/Durable Medical Equipment system—validate claims data, put claims through medical review screens, make sure claims are not duplicates, validate services, check for fraud and abuse, assign payment rates, and compute any patient financial liability.

(4) *HCFA-furnished Software* is integrated into the claims process at each operating site to address provider codes, service groupings, payment rates and fee schedules, and reimbursement statistics.

(5) *The Common Working File (CWF)* maintains information about Medicare beneficiary entitlement, eligibility, deductibles, payment limits for specific services, whether they have other insurance that has to pay before Medicare does, hospice enrollment, end-stage renal disease status, and managed care enrollment status.

(6) *HCFA Internal Systems* collect information from the CWF and the contractors' systems when the processes are completed. (7) *HCFA Enrollment Systems* interface with Social Security for new enrollees, changes in beneficiary data, and billing of beneficiaries and states, and they track managed care enrollments.

(8) *"Back End" Systems* at each local contractor issue payments, explain benefits to beneficiaries, settle provider cost reports, coordinate with other insurers, maintain history files, and perform interim rate reviews and payment adjustments.

RESPONSES OF NANCY-ANN MIN DEPARLE TO QUESTIONS SUBMITTED BY
CHAIRMAN BENNETT

Question. Lines of Code

What do the different numbers on lines of code to be renovated—30 million, 42 million, 50 million—mean? Is the Y2K problem growing 40 percent weekly?

Answer. HCFA has approximately 49 million lines of code that must be reviewed to see if they need renovation. The estimated number has increased as we and our independent verification and validation contractor have conducted more thorough assessments of the situation.

Question. IV&V Reports

Submit for the record reports by our IV&V contractor that display the status of the Y2K Medicare renovation, including the 64 fiscal intermediaries, carriers, and Central Working File?

Answer. A hard copy of the most recent monthly status report is attached.¹ All IV&V reports on fiscal intermediaries, carriers and standard system maintainers are shared with the General Accounting Office (GAO) as they are received. If the committee wishes to have earlier reports, HCFA will be happy to provide them.

Question. Year 2000 Workload Implications

What are the Medicare Y2K remediation and testing workload implications, including meeting deadlines, staffing, and budget?

Answer. Our Year 2000 effort will likely be the single most extensive and expensive information systems effort since the inception of the Medicare program. It has required us to postpone many other information system initiatives because we must keep systems changes to an absolute minimum so Year 2000 work can be done on time. We have taken the unprecedented step of rehiring several federal retirees, without reducing their retirement pay, to ensure that we have sufficient staff to complete Year 2000 work on time. We have transferred funds and staff from the Medicare standard systems transition project in order to add resources to the Year 2000 effort. We reallocated a total of \$62.1 million in additional funds from within the Agency and the Department so we have a total of \$107.1 million to fund these essential activities this fiscal year. The continually evolving definition of what is required to meet millennium requirements has a significant impact on the budget process. The President's fiscal year 1999 budget requests \$37.5 million to support millennium activities. Since the hearing in July, we have estimated an additional \$204.1 million will be needed in fiscal year 1999 to support our Y2K efforts. It is also likely that we will need additional funding in fiscal year 2000 to be prepared for the possibility that not all our remediation efforts will be completely successful. As we continually reassess our millennium compliance funding needs, we will work with Congress to ensure that funding will be available to support this critical project.

Question. Common Working File Software

What are the problems for HCFA to monitor the status of Y2K renovation if there are multiple versions of CWF software throughout the payment system? Does HCFA have any plans to standardize on a single controlled version of CWF prior to the Year 2000 in order to assure reliability of Y2K performance?

Answer. There is only one version of the Common Working File system in use. It does not present any special problem for monitoring renovation. The most recent version, installed in July, has been renovated for Y2K and will be installed in test mode at the four CWF test Host sites for shared systems and contractors to self-

¹ The copy of the status report has been retained in committee files.

certify Y2K compliance. This version includes the most complex of the Balanced Budget Act changes. It will be installed in test mode at our four CWF test sites. All claims processing centers will use it to verify that shared systems and local processing systems are Year 2000 compliant.

Question. IV&V Monitoring

How does the IV&V contractor effectively monitor the status of Y2K renovation at all the disparate sites (CWF, shared systems, 64 contractors) when the Medicare payment systems appear to lack standardization or uniformity?

Answer. Intermetrics performed a Criticality Analysis and Risk Assessment (CARA) of all standard systems maintainers and claims processing contractors. The CARA results were used to determine the level of IV&V attention for each site. Sites with the highest scores require the most or "comprehensive" IV&V attention, sites with scores in the middle range receive "focused" IV&V scrutiny and sites with the lowest scores receive "limited" IV&V scrutiny.

Regardless of the level of IV&V attention, each site is assessed using a standardized site visit protocol and agenda. The agenda is designed to obtain answers to the questions from the Intermetrics risk assessment database. The risk assessment answers from each site visit are reviewed by the same panel of Intermetrics staff in order to obtain risk assessment scores. Risk scores are updated following each site visit.

Question. Credibility of Compliance Reports

On a scale of 1 to 10, rate the level of credibility on reports of Y2K compliance meeting the time deadline?

Answer. Review by our independent validation and verification contractor indicates that the reports of progress in systems renovation are credible. Testing to confirm Year 2000 compliance is just getting under way. Problems in meeting deadlines are possible. However, they would result from the complexity of the problem and would not be a reflection on the credibility of current reporting.

Question. Renovation Completion

By what date does your IV&V contractor estimate that all systems will be renovated?

Answer. The Y2K status reports as of August 25, 1998 show that renovation of all internal mission-critical systems will be completed by September 30, 1998. Renovation is already completed for 20 of these 25 systems. All external mission-critical systems will be renovated by December 31, 1998. Renovation is already completed for 30 of these 78 systems. However, our IV&V contractor cautions that some test plans are incomplete and that other test plans concentrate a great deal of work in a short time frame, thereby increasing the risk that some systems may not be certified by December 31, 1998.

Question. Testing Renovated Systems

How will HCFA test the renovated Medicare payment systems, considering the diversity of 64 sites and 6 shared systems and the CWF?

Answer. We are requiring claims processing contractors, including maintainers of shared systems and the Common Working File, to self-certify each of their systems. They must use a compliance definition and testing guidelines approved by our IV&V contractor. All systems will be subject to repeated testing by both us and our independent testing contractor, the SETA Corporation. We also are establishing an independent telecommunications network that mirrors key components of the normal Medicare network to allow us to test all pieces of our operation in a future date environment.

Question. Integrated Testing with Providers

How will HCFA contractors conduct integrated testing with providers, the 6 shared systems and CWF to ensure that all Y2K changes are correct and that the payment system works?

Answer. From September through December of this year, each contractor will identify applicable test data cases and test those cases to validate that information will flow properly on renovated systems from the providers' initial submission of a claim through their entire payment system.

Question. Contingency Plans

What are your contingency plans for eligibility determination and medical payments in the event that one or more of the 64 contractors cannot function Jan. 1, 2000?

Answer. Eligibility is determined by HCFA and the Social Security Administration and is not dependent upon Medicare contractors. However, possible contingencies for claims processing include making estimated payments based on historical payments to individual providers, or routing claims to another contractor that is able to process payments. On August 13, 1998, HCFA sent a draft program memorandum to all Medicare intermediaries and carriers detailing the require-

ments for contingency planning. This draft was shared with Committee staff. HCFA's Chief Information Officer, Gary Christoph, and other HCFA staff briefed the Committee's staff on contingency planning efforts on August 24, 1998. We will continue to keep the staff apprised of our efforts and have committed to meet with them again in 6 to 8 weeks.

Question. Preventing Fraud and Abuse

Has the HHS Inspector General conducted any analysis on HCFA's ability to prevent flagrant Medicare fraud and abuse during the period of Y2K vulnerability?

Answer. We are not aware of any Y2K Medicare fraud and abuse initiatives planned by the HHS Inspector General. Our greatest vulnerability would occur if we have to issue payments to providers outside of normal payment systems. HCFA's Director of Program Integrity, Penny Thompson, is developing a strategy to address potential vulnerabilities. Contingency plans for issuing provider payments will assure that providers are accurately identified and payment information properly recorded before payments are issued thus minimizing the potential for fraud and abuse.

RESPONSES OF NANCY-ANN MIN DEPARLE TO QUESTIONS SUBMITTED BY
SENATOR COLLINS

Question. Lines of Code

How many lines of code does HCFA have to renovate?

Answer. HCFA has approximately 49 million lines of code that must be reviewed to see if they need renovation. The estimated number has increased as we and our independent verification and validation contractor have conducted more thorough assessments of the situation.

Question. Progress to Date

How far along is your agency in this process?

We have:

- completed renovation of five of our six standard contractor claims processing systems;
- completed renovation of 20 of our 25 most critical internal systems;
- initiated testing of renovated systems;
- conducted at least one site visit to every claims processing contractor, and at least two site visits to every systems maintainer for Independent Verification and Validation (IV&V);
- provided clear instructions to contractors on everything they must do to be Year 2000 compliant, and made sure they assessed their status based on those instructions;
- negotiated a contract that makes clear the responsibility Medicare claims processing contractors have in ensuring that their systems are Year 2000 compliant;
- developed more realistic cost estimates for Year 2000 work after contractors reassessed their workload based on the instructions we provided;
- conducted outreach to States, providers, and other health care entities; and
- gathered data from States on Medicaid system Year 2000 status.

Question. Expected Completion Date

How long do you estimate it will take your agency to complete the Y2K remediation and testing process?

Answer. We are requiring contractors to be in full compliance with Year 2000 requirements, with all code renovated and fully future date tested, by December 31, 1998. Renovations to mission critical internal systems also must be complete by December 31, 1998. We expect to complete end-to-end testing of how claims are processed through our entire network of renovated systems in the Spring, and then have the rest of 1999 to fix any remaining glitches and take any additional corrective action that might be necessary.

Question. Home Health Agencies

In your estimate, what percent of home health agencies will not be able to stay in business if the prospective payment system is not implemented on October 1, 1999?

Answer. We are working with Congress to address concerns raised by providers about the interim payment system and ensure that they can continue providing appropriate care.

Question. Provider Payment

Will HCFA's efforts to solve its Y2K problems jeopardize or delay physician, home health agency, or hospital payments? If so, how will that affect patient care?

Answer. Our Year 2000 renovation, testing and certification process will not affect provider payments. Provider payments would be jeopardized only if we do not suc-

ceed in renovating claims processing systems. However, Year 2000 work is delaying changes in how providers are paid that were enacted in the Balanced Budget Act. These include prospective payment systems for outpatient hospital care and home health services, consolidated billing for physician and other Medicare Part B services in nursing homes, and a new fee schedule for ambulance services. These activities are being postponed because they involve complex systems changes and interactions with other systems at the very time such activity would interfere with critical Year 2000 work. Year 2000 work may also require use to delay updates to provider payments during a critical window of Year 2000 work from October 1999 through April 2000.

Question. Cost Estimate

What is your cost estimate for Y2K? Do you believe the agency has sufficient funding to resolve the problem?

Answer. We spent \$7.6 million in fiscal year 1996 and \$14.5 million in fiscal year 1997 on millennium related activities. The continually evolving definition of what is required to meet millennium requirements has a significant impact on the budget process. This year, we recognized that the fiscal year 1998 funding of \$45 million we had allocated was not enough to support millennium efforts at our claims processing contractors. We reallocated \$62.1 million in additional funds from within the Agency and the Department to fund these essential activities. We have already spent approximately \$53.4 million of the \$107.1 million we have budgeted for millennium activities in fiscal year 1998. The President's fiscal year 1999 budget requests \$37.5 million to support millennium activities. Since the hearing in July, we have estimated an additional \$204.1 million will be needed in fiscal year 1999 to support our Y2K efforts. This increased request results from better information about the size of the Year 2000 task, especially the testing effort, and also because the cost of resources continues to rise. It is also likely that we will need additional funding in fiscal year 2000 to be prepared for the possibility that not all our remediation efforts will be completely successful. As we continually reassess our millennium compliance funding needs, we will work with Congress to ensure that funding will be available to support this critical project.

PREPARED STATEMENT OF VICE CHAIRMAN CHRISTOPHER J. DODD

Thank you Mr. Chairman. I believe that this is a very important hearing and I appreciate that you've scheduled it early in the special committee's oversight of the readiness of the Nation to meet the Year 2000 challenge.

There's no sense in beating around the bush: The question that everyone wants answered is:

"Are people going to die as a result of Year 2000 complications in the medical industry?"

To be honest, I don't think so.

But its entirely possible that millennium conversion could put the health care industry into intensive care.

The health care industry faces significant Year 2000 challenges, which could result in significant disruptions in medical service across the Nation.

As I said at our hearing on the utility industry, we're no longer talking about whether there will be any disruptions, but we are talking about how severe those disruptions will be.

While I am very hesitant to say that these disruptions will be life-threatening, there is a reasonable chance that they will compromise the quality and extent of patient care in all parts the country.

My concerns are based upon three factors that I hope will be addressed in some detail today:

First, there is a serious Year 2000 problem for all sorts of medical devices, from diagnostic tools to dialysis machines.

I am deeply disturbed by the fact that instead of taking steps to deal with this problem, the medical device industry, as a whole, seems to be exacerbating the problem by refusing to provide information either to the FDA, which regulates device safety, or even to the hospitals and clinics which use the devices every day.

This attitude is stunningly short-sighted and can only cause harm to both the makers and users of these devices.

My second area of concern is that the Medicare system—which process nearly a billion claims a year and pays health providers nearly a billion dollars a day—won't be ready.

If there are disruptions in the Medicare system—and I should also include the state-run Medicaid programs in this area—many health care providers, some of

whom depend on Medicare payments for as much as 40 percent of their operating budget, will not be able to operate.

Lastly, I am deeply concerned that rural hospitals, municipal hospitals, or other institutions that are strapped for resources, will not be able to undertake renovations or replacements necessary to fix the year 2000 problem, even if they have the time and funds to make a comprehensive assessment in the first place.

Senator Bennett and I toured a large, well-equipped and well-funded hospital in the DC suburbs on Tuesday morning.

While I was very impressed by the steps the hospital was taking to deal with the Year 2000 problem, like replacing or renovating 35 percent of their medical devices, I couldn't help but wonder how hospitals that are already stretched to the limits are dealing with this problem.

For example, the hospital that we were touring is planning to replace its kidney-dialysis machines, bought just 2 years ago at a cost of \$14,000 per machine, because those machines are not y2k compliant.

But can an inner city hospital afford to do that? Can a hospital serving rural communities in South Dakota afford to do that? Or will those hospitals be forced to stop providing those services dependent on high-technology machines until their budget allows them to purchase compliant equipment?

The possible answers to those questions are chilling.

These are just a few of the critical areas that I expect to begin addressing here today; and while I don't expect comprehensive answers yet, I hope that will get a blueprint of where the committee needs to go from here on this significant issue.

Again, Chairman Bennett, I thank you for devoting the time and resources to bring this hearing about in such an expeditious manner.

PREPARED STATEMENT OF MICHAEL A. FRIEDMAN

INTRODUCTION

Good morning, my name is Michael A. Friedman, M.D., Acting Commissioner, Food and Drug Administration (FDA). I am pleased to be here today to provide information on the Year 2000 date issue as it relates to medical devices. This is an important issue and FDA has taken a number of steps to ensure that medical devices are Year 2000 compliant and I will describe those steps to you today.

WHAT IS A MEDICAL DEVICE?

According to the definition in the Federal Food, Drug, and Cosmetic (FD&C) Act, a "device" is:

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

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

FDA is responsible for promoting and protecting public health by helping to ensure that medical devices are safe and effective. FDA carries out its mission by evaluating new products before they are marketed; assuring quality control in manufacture through inspection and compliance activities; and monitoring adverse events in already marketed products, taking action, when necessary, to prevent injury or death. A device manufacturer must comply with all the requirements of the FD&C Act, including: establishment registration and device listing, premarket review, use of good manufacturing practices (GMPs), reporting adverse events, and others.

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

COMPUTER SOFTWARE

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

Embedded software

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

Non-embedded software

Non-embedded software is intended to be operated on a separate computer, often a personal computer or work station. Such software devices may be used to enhance the operation of another device or devices and, further, may use the two-digit year format. It is possible that non-embedded software devices may rely on the current date for proper operation and might be affected by the Year 2000 date change.

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

Other examples of non-embedded software devices include: conversion of pacemaker telemetry data; conversion, transmission, or storage of medical images; off-line analysis of ECG data; digital analysis and graphical presentation of ECG data; calculation of rate response for a cardiac pacemaker; perfusion calculations for cardiopulmonary bypass; and calculation of bone fracture risk from bone densitometry data. Since there is a chance that the two-digit format may affect the performance of these software devices, we believe that the Year 2000 risk needs to be mitigated through proactively working with manufacturers.

POTENTIAL IMPACT OF THE YEAR 2000

An issue which has been identified as warranting review is the impact of the Year 2000 on some medical device computer systems and software applications. These products could be impacted by the Year 2000 date problem if they use a date in their algorithm or calculations, in record keeping or in the computer's operating system and system clocks; and a two-digit year format was used in their design. Manufacturers of such products are the only reliable source of information as to the details of the methods used in the programming and whether these two conditions are met.

Letter to medical device manufacturers

In light of the review of the impact of the Year 2000 on some medical device computer systems and software applications, FDA sent a letter dated June 25, 1997, to 13,407 medical device manufacturers (8,322 domestic and 5,085 foreign) to ensure that manufacturers address this issue and review both embedded and non-embedded software products. We reminded manufacturers that, in addition to potentially affecting the functioning of some devices, the two-digit year format also could affect computer-controlled design, production, or quality control processes. We requested that the manufacturers review the software used to determine if there is any risk.

FDA recommended specific actions to ensure the continued safety and effectiveness of these devices. For currently manufactured medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the Year 2000 date change. If these analyses show that device safety or effectiveness could be affected, then appropriate steps should be taken to correct current production and to assist customers who have purchased such devices. For computer-controlled design, production, and quality control processes, manufacturers should assure that two-digit date formats or computations do not cause problems beginning January 1, 2000.

In our letter to industry, we reminded manufacturers that under the GMP regulation and the current Quality System Regulation (which incorporates a set of checks

and balances in manufacturers' design processes to assure a safe, effective finished product), they must investigate and correct problems with medical devices. This includes devices which fail to operate according to their specifications because of inaccurate date recording and/or calculations.

We expect manufacturers who identify products which have a date-related problem which can pose a significant risk to the patient to take the necessary action to remedy the problem. This might include notification of device purchasers so that their device can be appropriately modified before the Year 2000.

Manufacturers who discover a significant risk presented by a date problem are required to notify FDA and take appropriate action. Again, we do not anticipate any significant problems with individual medical devices provided appropriate corrections are made, however, we want to ensure the continued safety and effectiveness of these devices.

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

DATA COLLECTION AND ESTABLISHMENT OF THE WORLD WIDE WEB SITE

In a letter dated January 21, 1998, Department of Health and Human Services (DHHS) Deputy Secretary Kevin Thurm, asked approximately 16,000 biomedical equipment manufacturers to voluntarily provide information on the Year 2000 compliance status of their products. Included in the mailing were all registered manufacturers irrespective of the specific kind of device produced, even though only about 2,700 manufacturers are believed to produce computerized products which might be 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 gave instructions on ways to submit the data 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.

The product database was established and is being maintained by FDA on its World Wide Web site at the request of the Interagency Biomedical Equipment Working Group. This Working Group was organized under the Chief Information Officer's Council's Subcommittee on the Year 2000. The web site is intended to give the general public, government agencies, and the healthcare and research communities one comprehensive source of information about this issue. The web site is found at: <http://www.fda.gov/cdrh/yr2000/year2000.html>. Manufacturers also may establish a World Wide Web link to their own web site where the requested information is provided to the public, if they so choose.

So far, the overall response from manufacturers has been incomplete. As indicated above, FDA believe that approximately 2,700 manufacturers may produce equipment that may be impacted by the Year 2000 problem. We believe approximately 500 of that 2,700 have responded. To date, approximately 10 percent of the total 16,000 manufacturers (many of which do not produce medical devices which could be affected by a Year 2000 problem) contacted through the January 21 letter have provided the information requested. We know, however, that there are companies still in the process of assessing their devices, and we requested that complete information be submitted. While manufacturers may report that specific products have not been assessed, we expect that some companies prefer to complete assessment before reporting.

FDA's Center for Devices and Radiological Health's (CDRH) Division of Small Manufacturers Assistance recently provided an article entitled "Biomedical Equipment Manufacturers Urged to Share Year 2000 Information" to 12 Medical Device Trade Press contacts and to 65 United States and 35 foreign medical device trade associations in order to facilitate the dissemination of information to their members regarding the web site database and to encourage the posting of data by manufacturers.

In addition, the web site and database are mentioned in the FDA Column of the June 3, 1998, Journal of the American Medical Association and in an article in FDA's Medical Bulletin that was sent to approximately 700,000 healthcare practitioners this summer.

In addition to the informational efforts, FDA issued a targeted, follow up letter to about 2,732 specific manufacturers of computerized devices urging that they respond to the January 21 request to submit product data. This letter was sent out

on June 29, 1998, and is another request for voluntary submission of data. FDA will continue to work with manufacturers to obtain product data.

WHAT IS THE DATA TELLING US THUS FAR?

As of July 16, FDA has received 1,790 responses from manufacturers. Of these, data from 1,782 manufacturers had been entered into the database served on the FDA web site. These numbers change daily as data is entered, corrected or even removed at the request of manufacturers. Of the manufacturers, 1,649 have reported that their products do not use date-related data or are compliant. Of the 1,649, 392 manufacturers have reported that all of their products are compliant. Eighty-eight manufacturers have reported one or more products with date-related problems. Fifty-three manufacturers have provided World Wide Web links (URLs) to data provided on their own manufacturer-operated Web Sites. There are submissions for which the data submitted were incomplete or unclear in some manner. We are communicating with these manufacturers to obtain clarification before entering the data into the database.

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

In reviewing the data received from the manufacturers so far, we see no indications that there will be significant problems which will place patients at risk, assuming the solutions being developed and offered by manufacturers are implemented. Of course, we can not make assurances about manufacturers who have not reported product status to us. We believe that the data received to date confirm our original expectations that the Year 2000 problems with medical devices are not significant or widespread problems, although there will be specific problems which need correction. With only a 10 percent response rate, however, it is not possible to draw definitive conclusions at this point. We will continue to emphasize to manufacturers the importance of reporting and have taken 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.

OTHER INITIATIVES

In January 1998, FDA's Center for Biologics Evaluation and Research (CBER) posted a guidance for industry entitled "Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products" on the FDA web site. The guidance provided specific recommendations to assist industry in its evaluation of computer and software systems used in the manufacture of blood products and to assist in evaluating the impact of potential Year 2000 problems. In the Spring of 1998, CDRH developed a Guidance Document on the Agency's expectations of medical device manufacturers, concerning the Year 2000 date problem. The guidance already has been made public and is available on the FDA web site. The guidance also was published in the Federal Register on June 24, for greater dissemination. The guidance re-emphasizes the requirements in existing regulations that require manufacturers to address any date problems which may present a significant risk to public health.

FDA staff organized, with the staff of the Emergency Care Research Institute, a half-day session on the Year 2000 date problem at the June 2, 1998 annual meeting of the Association for the Advancement of Medical Instrumentation. This meeting was attended by hospital clinical engineers, representing the device purchasers and users, medical device researchers and developers, and device manufacturers. The session permitted an exchange of information on all aspects of the Year 2000 problem as it relates to medical devices and the actions healthcare facilities should be taking to address this issue.

A video teleconference on the Year 2000 issue for device manufacturers is planned for September 1998.

CONCLUSION

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

FDA's role is to assure that medical devices are safe and effective and manufactured in accordance with their specifications. The Agency, of course, will provide any assistance it can to address any specific problem any other agency, such as the Department of Veterans Affairs, identifies. FDA also is working with other agencies, patient groups, medical associations and industry to optimize data collection and information sharing. FDA also 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION,
Rockville MD.

Hon. CHRISTOPHER DODD,
Vice Chairman, Special Committee on the Year 2000 Technology Problem,
U.S. Senate,
Washington, DC.

DEAR VICE CHAIRMAN DODD: Thank you for the opportunity to testify before your Committee at the July 23 hearing on the impact of Year 2000 computer problems on health care issues. You asked important questions concerning the preparedness of the health care system, particularly with respect to the need for information from medical device manufacturers on Year 2000 compliance. This letter responds to the particular question you posed concerning the extent of the legal authority the Food and Drug Administration (FDA or Agency) has to require responses from medical device manufacturers on Year 2000 compliance of medical devices. You referenced the enclosed April 1, 1998, letter from the Health Industry Manufacturers Association asserting that FDA had no legal authority to require such submissions (Tab A).

Enclosed is a list of manufacturers who have not responded to FDA as of July 20, 1998, with information on Year 2000 compliance (Tab B(1)).¹ A cover sheet also is provided with Tab B which explains the data presently available on the FDA Year 2000 web site. The list of non-responders is compiled from those manufacturers which were sent FDA's letter mailed on June 29, 1998, a follow-up to the January 21, 1998, letter from the Department of Health and Human Services requesting information on Year 2000 compliance status of medical devices. At Tab B(2)¹ is the list of manufacturers to whom the FDA follow-up letter was mailed. Also attached at Tab B(3)¹ is a listing of all the manufacturers who have responded to FDA and are listed on the FDA Year 2000 web site.

Please be assured that FDA is working with the Department of Veterans Affairs and others to compare and coordinate information received from all sources so that the web site can include all know information on the compliance status of medical devices. We are also working with other executive branch agencies, manufacturers, trade associations and others to obtain information from more companies and on more medical devices. Your hearing helped publicize the lack of response from the industry and we believe it will encourage additional cooperation from the manufacturers who have the information on the Year 2000 status of their medical devices.

FDA LEGAL AUTHORITY

Under its current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant.

¹ Retained in committee files.

FDA's Quality System Regulation (QSR) does impose a continuing requirement on manufacturers to identify, investigate, and correct problems or potential problems with devices covered by the regulation. 21 CFR Part 820. Devices automated with computer software are subject to all requirements of 21 CFR Part 820 unless expressly exempted by regulation. Under the QSR, manufacturers must document and correct problems with covered devices, including problems arising from the use of two digits to represent the year. 21 CFR §820.100. Manufacturers must make records of such corrective actions available to FDA during facility inspections. Manufacturers are required to report recalls and corrective actions they have undertaken to reduce a risk to health or prevent a violation of the Act that may present a risk to health. Manufacturers that have corrected a Year 2000 problem with their device that, if not corrected, could present a risk to health must report the correction to FDA. When we receive such information, we will include it on our web site.

FDA does not have explicit statutory authority to order all device manufacturers to submit information immediately on Year 2000 compliance status for all medical devices. The Agency does have general statutory authority to require reporting and recordkeeping for medical devices under section 519(a) of the Food, Drug, and Cosmetic Act (FD&C Act). The Agency may implement this statutory authority, however, only by regulation. Appropriate implementing regulations setting forth a Year 2000 reporting requirement have not been promulgated. The Agency has promulgated regulations using the reporting authority under section 519(a) in only limited circumstances in which adverse events have already occurred. To have any regulation in effect concerning the submission of information on Year 2000 compliance status in time for the reports to be of value to the Agency and the public, FDA would need to establish that complying with the Administrative procedure Act's requirements for prior notice and comment would be impractical, unnecessary, or contrary to the public interest.

Moreover, even if the threshold for waiving prior notice and comment could be met, section 519(a)(4) requires that any regulation promulgated under it may not impose unduly burdensome requirements on the regulated industry, taking into account the cost of complying, the need for protection of the public health, and the implementation of the FD&C Act. The legislative history of section 519(a) expresses a particular concern that regulatory agencies not impose industry wide requirements for reporting when the requirement pertains to only a segment of the industry. Hence, FDA would either need to demonstrate that the public health risk of Year 2000 compliance justified a reporting requirement on the entire industry, or the Agency would need to develop reliable criteria for narrowing the population of manufacturers and devices to those likely to be affected by the Year 2000 issue. Identifying only the affected segment of industry has been difficult since device information already provided to FDA under the medical device review process does not always contain specific data which would allow identification of all devices that might be impacted by the Year 2000 date change.

FDA believes section 519(a) provides statutory authority to require (through implementing regulations) device reports in the absence of adverse events. The device industry, however, might challenge in court FDA's promulgation of regulations under this authority to require reports of Year 2000 compliance for all medical devices because of the strong concern on the part of some in the industry about the burdensome nature of such reporting requirements. Such a challenge could delay significantly, and thereby reduce the effectiveness of, the subject reporting requirement.

Finally, even if FDA were able to develop a regulation that could meet the standards of section 519(a), FDA would still have the burden to demonstrate that the regulation met other statutory requirements, such as the Paperwork Reduction Act and Regulatory Flexibility Act requirements.

RESOURCES

Finally, requesting, receiving, analyzing and posting information on Year 2000 compliance on a significant number of devices and manufacturers is resource intensive. We are working with the Department of Health and Human Services and the Administration to identify those resources necessary to ensure the completeness of the Year 2000 effort.

We hope this information is helpful. We will be glad to work with you in addressing this issue. A similar letter has been sent to Senator Robert F. Bennett.

Sincerely,

MICHAEL A. FRIEDMAN, M.D.,
Acting Commissioner of Food and Drugs.

Enclosures.

JAMES S. BENSON,
EXECUTIVE VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS, HIMA,
April 1, 1998.

Mr. KEVIN THURM,
*Deputy Secretary, Health and Human Services,
Hubert H. Humphrey Building,
200 Independence Avenue, S.W. Room 606G,
Washington, DC.*

DEAR MR. THURM: On behalf of the members of the Health Industry Manufacturers Association, I am writing in response to the January 21, 1998 "Dear Biomedical Equipment Manufacturer" letter that you sent regarding Year 2000 computer issues. As you know, HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems.

HIMA's members share the Department's goal of providing quality health care services without significant interruption caused by Year 2000 computer limitations. To that end, manufacturers are diligently working to ensure that medical device products will operate safely and effectively in the Year 2000 (and beyond). Due to the diversity of the medical device manufacturing industry, one approach will not fit all products. Each manufacturer will need to develop its own plan to evaluate the systems in current use and determine the actions to be taken to negotiate Year 2000 requirements.

HIMA's members understand the Department's interest in this issue. Nevertheless, we do not agree that a federal government Internet web site listing Year 2000 compliance status of various products is an appropriate or necessary step. Instead, manufacturers should be encouraged to address Year 2000 issues with customers (including the federal government) directly, in one-on-one interactions discussing particular products. This type of interaction is the hallmark of quality business practices that are a traditional part of our free enterprise economic system in the United States. Such direct interactions ensure that customers receive adequate and complete information, and have an opportunity actively to ask questions and receive responses. Indeed, many medical device manufacturers have Internet web sites of their own that are a source of Year 2000 information and encourage direct interaction with customers.

HIMA's members note that the Department has no legal authority to require the submission of the Year 2000 information that is the subject of your January 21, 1998 letter. This is also obvious from the fact that the Department's letter is "requesting" this information. In view of this, HIMA believes that the statement in the letter that "there will be targeted follow-up regarding non-respondents" is inappropriate.

Even if "requesting" this information for listing on an Internet web site to be operated by the federal government were a good idea, the sixty-day time limit given in the letter is not nearly sufficient and does not further a sense of goodwill and cooperative interaction between industry and government. As stated above, manufacturers are currently engaged in determining whether their products will face Year 2000 computer issues and developing appropriate solutions. Therefore, much of the information requested by the January 21, 1998 letter will not be available in a sixty-day time frame, or even in the near future.

As you may know, the Internet web site maintained by the FDA's Center for Devices and Radiological Health (CDRH) also contains some information and requests on Year 2000 issues. These do not seem to be coordinated with the items specified in the Department's January 21, 1998 letter. Accordingly, manufacturers are confused by the inconsistency and the Department should work with CDRH to resolve these differences.

In conclusion, HIMA's members view the Year 2000 issues as vitally important to pursue in order to continue to provide safe and effective products to promote the public health. While we agree with the concern that the Department expresses to ensure that appropriate activities are undertaken to develop "Year 2000 compliant" products, we do not agree with the method described in the January 21, 1998 letter. Instead, HIMA's members will continue to develop, on a company-by-company basis, appropriate implementation plans to address the Year 2000 issues. In addition, companies will continue to provide customers directly with information on their products, including the Year 2000 issues, through traditional business interactions on a company-by-company basis.

HIMA would be willing to meet with the Department and CDRH to discuss Year 2000 issues. Please feel free to contact me if you would like to arrange such a meeting.

Sincerely,

JAMES S. BENSON.

EXPLANATION OF FOOD AND DRUG ADMINISTRATION DATA

The testimony provided by the Food and Drug Administration contained approximate figures concerning the number of manufacturers who had received a mailing from FDA on June 29, 1998 and the number of response received. In reviewing the data, accurate numbers were determined and are provided in this explanation.

MANUFACTURERS DETERMINED BY FDA TO BE MOST LIKELY TO HAVE MEDICAL DEVICES THAT COULD BE AFFECTED BY THE YEAR 2000 DATE CHANGE

2,232	Addressees of June 29, 1998 FDA letter requesting Year 2000 compliance information. ¹
297	Duplicate addressees.
1,935	Distinct addresses used for the June 29, 1998 letter.

¹It should be noted that FDA has received approximately 50 returned, non-deliverable letters from the June 29, 1998 mailing. These returns are reflected in the "no responses" list.

As of July 20, the total data in the FDA Year 2000 database reflects the following information:

93	Total number reporting Year 2000 date related problems.
(58)	(Addressees of June 29, 1998 mailing.)
423	Total reporting products are compliant.
(150)	(Addresses of June 29, 1998 mailing.)
63	Total providing Web Links. ¹
(48)	(Addressees of June 29, 1998 mailing.)
1,287	Total indicating no date or computer used in product.
176	(Addresses of June 29, 1998 mailing.)

¹The 63 manufacturers providing WEB links may also be included in the other database categories, as some have provided both product data and a WEB link.

RESPONSES OF MICHAEL A. FRIEDMAN TO QUESTIONS SUBMITTED BY CHAIRMAN BENNETT

Question. Mr. Commissioner, FDA waited until January 1998 to ask the industry for non mandatory Y2K compliance data for biomedical devices.

—FDA is usually very assertive in following up on patient safety and regulatory programs. Why has FDA been so passive in its follow-up on the biomedical Y2K issue?

Answer. In order to ensure Year 2000 (Y2K) compliance of medical devices that use computer software, FDA sent a letter dated June 25, 1997, to 13,407 medical device manufacturers to ensure that manufacturers reviewed this issue and reviewed both embedded and non-embedded software products. FDA recommended specific actions to ensure the continued safety and effectiveness of these devices and to remind manufacturers of their responsibility to ensure that their products will not be affected by the century change.

Because we must assist medical providers and physicians avoid injuries from medical devices with embedded microchips which may not function at the turn of the century, the Department of Health and Human Services (HHS) also has been involved in the effort to ensure the compliance of biomedical equipment (includes medical devices regulated by FDA and other medical equipment not regulated by FDA). On January 21, 1998, Deputy Secretary Kevin Thurm issued a letter to 13,000 manufacturers of medical devices and, working through professional associations, approximately 3,000 manufacturers of scientific laboratory equipment. This letter asked the manufacturers to provide information concerning the compliance status of their products.

In addition, on June 29, 1998, Dr. D. Bruce Burlington, Director of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH)

issued a follow-up letter to approximately 1,935 manufacturers. This letter was targeted to manufacturers of computerized devices urging again that they respond to the January 21 request to submit product data. The Agency will continue to periodically remind manufacturers of this program.

Finally, on September 2 Dr. Michael Friedman sent a letter to the Health Industry Manufacturers Association (HIMA) to get their input on how to eliminate the disincentives so that manufacturers will be more forthcoming with product status information and urges HIMA to develop a plan of specific actions to increase progress by industry.

FDA's Center for Devices and Radiological Health's (CDRH) Division of Small Manufacturer's Assistance recently provided an article entitled "Biomedical Equipment Manufacturers Urged to Share Year 2000 Information" to 12 Medical Device Trade press contacts and to 65 U.S. and 35 foreign medical device trade associations in order to facilitate the dissemination of information to their members regarding the web site database to encourage the posting of data by manufacturers. In addition, the web site and database are mentioned in the FDA Column of the June 3, 1998, *Journal of the American Medical Association* and in an article in FDA's Medical Bulletin that was sent to approximately 700,000 health care practitioners this summer.

FDA's objective remains the provision of a comprehensive, centralized national source of information on the Y2K compliance status of medical devices used in the United States and to make this information publicly available through its web site. Our joint efforts with the VHA and OASD/HA are designed to better leverage our collective information and influence. We are already working together to enhance the existing web site to be the national biomedical equipment clearinghouse by adding equipment inventories from other organizations and by conducting additional follow-up activities. These activities include checking whether a medical device manufacturer has met a planned date for availability of a compliant product version, and inspecting records relating to the Y2K compliance of computerized medical devices during FDA medical device facility inspections.

We believe that this series of actions demonstrates FDA's commitment to ensuring that adequate public information becomes available to the public on a timely basis.

Question. Mr. Commissioner, the Committee is concerned with the safety of patients dependent on Y2K compliant medical devices. We know there are millions of these devices in current use. We are concerned that the FDA biomedical device web site for the Center for (Medical) Devices and Radiological Health (CDRH) is incomplete (only 1,000 companies) and has inadequate data to assist potential users.

—Do you have any plans to establish a complete database for all biomedical devices with product descriptions, ID numbers, and software versions?

Answer. Many different types of products are regulated as medical devices. Medical devices include over 100,000 products in more than 1,700 categories. Most of these have no microprocessors, software, or computer linkage. We do not believe that listing all compliant products is either necessary or cost-effective. We do not believe anyone could reasonably want information on Y2K compliance on such products as: crutches, hip implants, sutures, or a dip stick test for pregnancy. In addition, even for potentially Y2K vulnerable products, the FDA web site already includes a certification statement assuring total compliance from those manufacturers who report all of their products are compliant. FDA believes information at the individual model level is needed for non-compliant products only. If a manufacturer's entire product line is compliant, users of the clearinghouse would receive no additional benefit from the model-level information, which would be quite expensive to obtain and enter into the database. Furthermore, manufacturers also may establish a World Wide Web link to their own web site where the requested information is provided to the public, if they so choose.

HHS and the Veterans Administration already are working as a Federal partnership to develop a single data clearinghouse. Our private sector associates, mostly professional associations such as the American Medical Association, the American Hospital Association, and the Joint Commission on Health Care Accreditation, will provide advice and assistance as requested. It would be useful to provide an indication of whether a particular manufacturer has or has not provided information on Y2K compliance for manufacturers of electronic products that are susceptible to Y2K concerns. To that end, FDA will post on the web site the identity of manufacturers who have not provided compliance certification.

—Do you require legislative assistance to acquire the data from manufacturers or budget help to promptly establish and maintain the biomedical database until after Y2K?

Answer. Under its current regulations, FDA does not have the authority to require all device manufacturers to submit reports on whether their devices are Year 2000 compliant. FDA's Quality System Regulation (QSR) does impose a continuing requirement on manufacturers to identify, investigate, and correct problems or potential problems with devices covered by the regulation (21 CFR Part 820). Devices automated with computer software are subject to all requirements of 21 CFR Part 820 unless expressly exempted by regulation. Under the QSR, manufacturers must document and correct problems with covered devices, including problems arising from the use of two digits to represent the year. Manufacturers must make records of such corrective actions available to FDA during facility inspections. Manufacturers are required to report recalls and corrective actions they have undertaken to reduce risk to health or prevent a violation of the Act that may present a risk to health. Manufacturers that have corrected a Year 2000 problem with their device that, if not corrected, could present a risk to health must report the correction to FDA. When FDA receives such information, FDA will include it on the web site. FDA sent a letter to the Committee on July 31, 1998, and provided a more detailed response regarding the full extent of the legal authority FDA has to require responses from medical device manufacturers on Y2K compliance of medical devices. FDA has been providing technical assistance to the Committee regarding possible legislation, and will gladly continue to provide assistance if the Committee determines that legislative assistance is necessary.

Requesting, receiving, analyzing and posting information on Y2K compliance on a significant number of devices and manufacturers is resource intensive. We are working with the Department of Health and Human Services and the Administration to identify those resources necessary to ensure the completeness of the Y2K effort.

Let me assure you, we at FDA take this issue very seriously as we do all problems which could affect the public health. We are committed to continue working with the Committee to urge manufacturers to ensure the continued safety of their medical devices by ensuring that their devices can perform date recording and computations that will be unaffected by the Y2K date change.

PREPARED STATEMENT OF GIL R. GLOVER

Mr. Chairman and members of the committee, I am Gil Glover, Director for Projects and Planning in Medicare Operations for Blue Cross and Blue Shield (BCBS) of Texas. I am testifying on behalf of the Blue Cross and Blue Shield Association, the organization representing 54 independent Blue Cross and Blue Shield Plans throughout the nation.

Each independent Blue Cross and Blue Shield Plan is actively working to ensure that its information system and business operation will function properly in the Year 2000 and beyond. One of the strengths of the Blue Cross and Blue Shield system is the ability of these independent Plans to inter-operate in support of local, national and international customers. Therefore, the Year 2000 readiness of the information systems that support inter-Plan transactions is a top priority for the Blue Cross and Blue Shield system.

The Blue Cross and Blue Shield system is a major presence in the Medicare program. Blue Cross and Blue Shield Plans process 85 percent of Medicare Part A claims and about two-thirds of all Part B claims. Blue Cross and Blue Shield Plans also provide Medicare HMO coverage to more than three-quarters of a million Medicare beneficiaries, which makes the Blue Cross and Blue Shield system the second largest Medicare HMO provider in the country. At BCBS of Texas, we process about 7.7 million Part A claims and 47.6 million Part B claims a year.

Like any other health insurance company, our Medicare business and our commercial business face the challenge of becoming Year 2000 compliant. I appreciate the opportunity to testify before the committee today on the progress Medicare contractors have made toward becoming Year 2000 compliant.

MEDICARE CONTRACTORS' COMMITMENT TO BECOMING MILLENNIUM COMPLIANT

Since its inception, the traditional Medicare fee-for-service program has been administered through a successful partnership between private industry and the Health Care Financing Administration (HCFA). Blue Cross and Blue Shield Plans and commercial insurers contract with HCFA to handle much of the day-to-day work of paying Medicare claims accurately and in a timely manner.

Medicare contractors have successfully met many significant challenges over this thirty-three year partnership with HCFA. These include:

- Handling a dramatic increase in workload that has grown from 61 million claims in 1970 to 889 million in 1998.
- Quickly implementing major programmatic changes under extremely tight time frames, such as the institution and refinement of the Medicare prospective payment system for hospitals and the physician resource-based relative value payment system.

We are very proud of our role as Medicare administrators and our record of efficiency and cost effectiveness.

One of our next major challenges is to assure that Year 2000 computer adjustments are made accurately and in accordance with the timetable set out by HCFA. There are three specific points I would like to make today:

1. Year 2000 compliance is a top priority for Medicare contractors.
2. New contracting legislation is unnecessary, and actions arising out of such changes could actually make Year 2000 compliance more difficult.
3. Stable and adequate funding for Medicare contractors is critical to administering the traditional Medicare program efficiently and effectively through the Year 2000 readiness phase and beyond.

Year 2000 compliance is a top priority

Year 2000 compliance is a top priority for Medicare contractors. Despite the significant challenges, let me assure you that Medicare contractors are working toward becoming compliant on a timetable that will meet HCFA's deadline of December 31, 1998, which is two months earlier than the government-wide target date set by the Office of Management and Budget (OMB).

Medicare contractors will make every effort to meet this challenge just as they have successfully met other challenges in the past. It is in everyone's interest—Blue Cross and Blue Shield Plans, the government, providers and beneficiaries—for contractors to become millenium compliant on time. For Blue Cross and Blue Shield Plans, both their Medicare and private business depend on meeting this challenge.

I want to state clearly that Medicare contractors are committed to Year 2000 compliance. In recent congressional hearings and press reports, it has been suggested that contractors are not being diligent in their efforts to meet this requirement and that HCFA needs additional authority to assure compliance. Nothing could be further from the truth.

The Blue Cross and Blue Shield Association and Medicare contractors have been working closely with HCFA on compliance issues. As part of this process, BCBSA has been working with HCFA to find an agreeable contract amendment related to Year 2000 compliance. Last fall, HCFA sent all Medicare contractors a contract amendment intended to assure Year 2000 compliance. BCBSA had several concerns with the amendment, including concerns that it would have required contractors to assume liability for compliance of all vendors (e.g., financial institutions, facilities managers who control elevator programming, etc.) or face civil monetary penalties. HCFA acknowledged that it had drafted the amendment too broadly and agreed to work with contractors to rewrite the amendment. I am happy to report that three weeks ago, HCFA and BCBSA developed a contract amendment agreeable to both parties.

In addition to the work on the contract amendment, BCBSA has worked with HCFA on developing a regular, formal process to assure regular communication with HCFA. In response to a BCBSA recommendation, HCFA established a steering committee chaired by HCFA's chief operating officer and vice-chaired by BCBSA. The role of the steering committee is to:

- Clarify Year 2000 compliance standards, time lines, and reporting requirements;
- Monitor progress; and
- Facilitate coordination, cooperation, and communication among HCFA and its contractors.

I serve as the technical project management advisor to the steering committee. Let me briefly describe the accomplishments of the committee. The committee established eight working groups that are meeting to address the following areas:

1. Progress Measurement—Monitors the progress of individual contractors and contractors as a whole.
2. Critical Path—Identifies necessary activities, risk points, and key assumptions for Year 2000 compliance.
3. Priorities—Evaluates competing program priorities, including standard system transitions, Balanced Budget Act (BBA) implementation, and Health Insurance Portability and Accountability Act (HIPAA) administrative simplification.

4. Provider Relations—Informs providers about Year 2000 issues and provides training.
5. Common Testing Protocols—Develops testing procedures.
6. Common Efforts—Identifies areas of common interest and concern to contractors and looks for efficiencies.
7. Contingency Planning—Determines processes and time frames for paying providers if systems are not Year 2000 compliant.
8. Resource Allocation—Defines standard definitions for Year 2000 activities and estimate costs.

Very good progress is being made in these workgroups. As an example, the Contingency Planning group has developed a protocol that is supported by a comprehensive planning template applicable to any risk a Medicare contractor might identify in its operations. Use of the template is being piloted by work group contractor members, and is scheduled for release to all contractors in early August. While contractors are already performing contingency planning exercises, the work group's combined input into development of this protocol has produced a tool that can add significant value to this process and produce uniform planning documentation.

Beyond the specific products of these work groups, operation of the steering committee has facilitated very constructive and useful dialogue between contractors and HCFA about Year 2000 compliance. The committee has met with the HCFA administrator, and meets regularly with many of the agency's key directors and other top management staff. We look forward to continuing these cooperative efforts with HCFA.

In reviewing the issues related to Year 2000 compliance, the committee should be aware of four additional issues that have made Year 2000 compliance activities even more challenging:

- Significant Change in Direction.*—Originally, many of the system changes that were necessary for compliance would have been accomplished by the conversion of all Medicare contractors to the Medicare Transaction System (MTS). As you know, the MTS initiative was dropped last year. As a result, contractors have been required to make significant changes that, in the absence of the MTS initiative, they would have been working on for a long time.
- Transition to New Standard Systems.*—Instead of converting to the MTS system, HCFA has directed contractors to transition to a new single Part A and a new single Part B system. In some cases, this conversion to different systems has complicated efforts to focus on millenium compliance activities. As a result, several contractors requested HCFA to delay transition requirements so they could focus on Year 2000 issues. We are very pleased that HCFA recently agreed to delay transitions for some Medicare contractors.
- Adequate Funding is Absolutely Critical.*—We anticipate Year 2000 compliance to be very costly. We were very pleased that Congress reprogrammed \$20 million in the fiscal year 1998 supplemental appropriations bill to cover contractor millenium costs. We also understand that HHS has taken administrative actions to allocate another \$41 million to cover Year 2000 costs. However, to date, contractors have received less than the total amount allocated. We look forward to receiving full funding.
- Numerous and Broad Programmatic Demands.*—Numerous initiatives (e.g., HIPAA requirements and BBA) will be implemented while Year 2000 modifications and testing are occurring. HCFA has already said that it will not be able to implement all of the BBA requirements because of the need to concentrate on Year 2000 efforts. We recommended to HCFA that as many non-Year 2000 system changes as possible should be removed from contractor workloads so that technical resources could be devoted to assuring Year 2000 readiness.

Contractor reform is not necessary and would jeopardize year 2000 efforts and BBA implementation

HCFA is seeking legislation that would dramatically restructure the contracting process for Medicare intermediaries and carriers. It has been argued that contractor reform is necessary to assure Year 2000 compliance. BCBSA believes that, in fact, contractor reform would not improve the Year 2000 problem, and could make it more difficult.

Contractor transitions are significant technical projects in their own right, and add risk to Medicare processing stability even without Year 2000 factors. New contractors would have to learn Medicare's extremely complex and intricate rules and regulations while simultaneously working to achieve millenium compliance.

HCFA is exercising extensive oversight of Medicare contractors' Year 2000 compliance efforts through the use of its own review teams and an independent verification and validation contractor. Most Medicare contractors have already been re-

viewed for Year 2000 compliance progress with at least two comprehensive on-site reviews—many contractors are at round three of these reviews. In addition, both the Office of the Inspector General (OIG) and the General Accounting Office (GAO) are conducting Year 2000 reviews at Medicare contractor sites. There is ample opportunity for identifying and correcting any deficiencies or problems in the Medicare contractor community through these processes.

Moreover, contractor reform is not necessary to replace contractors that are not millenium compliant. HCFA currently has broad authority to sanction, replace, or terminate contractors that are not in compliance.

Success in Medicare claims administration requires that HCFA and the contractors work together toward their mutual goal of accurate and timely claims payment. BCBSA does not believe these legislative changes are necessary to assure efficiency and high performance levels.

Stable and adequate funding is critical

We strongly support HCFA's efforts to secure additional funding for Year 2000 activities in fiscal year 1999. While Medicare contractors must be Year 2000 compliant by the end of this calendar year, contingency planning and risk mitigation actions must continue throughout 1999 to ensure rapid, effective response to any problems actually encountered in calendar year 2000. Contingency plans that can not be deployed in 1999 may have little value if they must be started from scratch in 2000. Additionally, there is significant on-going system testing that must occur throughout 1999 even after Year 2000 compliant systems have been implemented. This "regression testing" is essential to ensure that essential changes implemented in 1999 do not adversely effect Year 2000 readiness.

Medicare contractors also need stable and adequate funding to fulfill the critical role as the program's first line of defense against fraud and abuse. We urge the committee to support the Medicare contractor funding level proposed in the fiscal year 1999 President's budget and approved by the House Appropriations Committee. The Committee recommended appropriating \$1.27 billion, without the user fees proposed in the President's budget. We fully support this funding level without the user fees.

CONCLUSION

The Year 2000 compliance issue poses monumental challenges. Blue Cross and Blue Shield Plans and commercial contractors are committed to meeting these challenges just as they have done in the past.

Let me reiterate that Medicare contractors are working diligently to become millenium compliant by December 31, 1998. We will continue to work with HCFA to resolve issues that arise and to ensure compliance. A cooperative approach between contractors and HCFA will achieve the best results. BCBSA feels that proposed contractor reform legislation raises fundamental issues and implications for the Medicare program that work against the cooperative effort needed at this critical time when experience and focus are so essential. The keys to Year 2000 compliance in the Medicare contractor community are stable, adequate funding for the required resources and consistent prioritization of Year 2000 activities over any other potential changes in the Medicare program.

Thank you for the opportunity to speak with you on these important issues.

RESPONSES OF GIL R. GLOVER TO QUESTIONS SUBMITTED BY CHAIRMAN BENNETT

Question 1. What is the status of Y2K discovery and renovation action?

Answer. Year 2000 readiness status is gathered from contractors regularly by HCFA. In addition to their own analysis and feedback actions with contractors, HCFA regularly reports Y2K status to OMB, GAO and Congress. The Blue Cross and Blue Shield Association (BCBSA) does not independently collect readiness status from the Medicare contractors.

Question 2. What is the BCBSA's plans for integrated testing?

Answer. Integrated testing with providers is part of each contractor's Y2K Readiness Project Plan. All such project plans have been filed with HCFA and are a part of the formal Medicare Agreement between HCFA and its contractors. Integrated testing protocols will vary depending on the provider's choice of electronic media, the standard claims processing system in use for Medicare and the corporate front-end hardware/software configuration used for electronic data interchange.

Question 3. What is the contingency plan if the providers can't do EDI?

Answer. Contingency planning is being considered nationally by HCFA to insure that standardized responses and actions will be in place for all contractors in the event that some providers are not able to achieve Y2K readiness timely. It should

be emphasized, however, that achieving Y2K readiness for billing Medicare claims is a provider responsibility.

Question 4. What is the status of the BCBSA Y2K?

Answer. The BCBSA is an association of 54 independent licensees. BCBSA itself is not an insurance company, and therefore does not process health claims. The Association is working to ensure that its inter-Plan programs, e.g., FEP, BlueCard, will function properly with respect to dates beyond December 31, 1999. Individual Plan management and boards of directors are responsible for ensuring Y2K readiness of their respective local Plan operations.

PREPARED STATEMENT OF JENNIFER JACKSON

Mr. Chairman, I am Jennifer Jackson, General Counsel and Vice President, Clinical Services, at the Connecticut Hospital Association. I am here on behalf of the American Hospital Association (AHA), which represents 5,000 hospitals, health systems, networks, and other providers of care.

We appreciate this opportunity to present our views on an issue that is of critical importance to our members and the patients they care for: the potential for the "millennium bug"—the inability of computer chips to recognize the Year 2000—to interrupt the smooth delivery of high-quality health care. The AHA and its members are committed to taking whatever steps may be necessary to prevent potential Year 2000 problems from affecting patient care.

Hospitals and health systems operate 7 days a week, 24 hours a day. Their doors are always open because the people they serve trust that they will be there whenever the need arises. Our number one concern is the health and safety of our patients, and that is why I am here.

Hospitals and health systems face the same potential problems as most other institutions. Cellular phones, pagers, security systems, elevators—all could be affected by Year 2000 problems. However, hospitals are special places that also rely daily upon unique medical devices and equipment. We are concerned about the potential impact of Year 2000 computer problems on patient safety—and hospitals, health care providers and their associations cannot reduce, let alone eliminate, that risk by themselves. We need your help and cooperation, and that of the federal agencies that regulate the health care field: namely, the Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA).

In particular, we need the federal government to exercise its authority in this area—now. We need the federal government to create an atmosphere in which everyone involved in the health care field will view the full and timely disclosure of Year 2000 computer problems not only as diligent and prudent behavior—the right thing to do—but also as mandatory conduct.

In fact, our belief that medical device manufacturers, health care providers, consumers and the government must work together to solve this problem is one reason why we have joined the National Patient Safety Partnership, a voluntary public-private partnership of national health care organizations. The partnership, in a press conference just last week, called for a national clearinghouse for information about the Year 2000 compliance status of medical devices. The organizations also called for:

- Medical device manufacturers to identify and provide Year 2000 compliance information about their devices to their health care provider customers and the public;
- Health care practitioners to become familiar with Year 2000 issues and take steps to mitigate risks and inform the people they serve; and
- Health care consumers to become familiar with Year 2000 issues and seek advice about equipment in personal and home use.

One of the AHA's primary concerns has to do with potentially non-compliant medical devices and equipment. Microchips (or microprocessors) that use date-sensitive logic are embedded in many medical devices, and we need to find out whether those devices will be affected by the date change to the Year 2000, and, if so, how we can fix them to avoid an interruption or other malfunction. The manufacturers of these devices are the best and, in some cases, the only source of this information. Assuming that prudent medical device and equipment manufacturers are engaging in Year 2000 testing, we need to know what they are discovering, especially if they are uncovering problems. Here lies the heart of our concern.

While we as health care providers can ask manufacturers to disclose Year 2000 information to us, we cannot force them to do so. We do not have the legislative or regulatory authority to compel disclosure. We believe that is a job for Congress and the FDA.

THE ROLE OF AHA AND STATE HOSPITAL ASSOCIATIONS

Hospitals and health systems are doing their part. Across the nation, hospitals are preparing for the date change, and making a commitment to take appropriate steps to avoid any disruption in patient care. Continuing a tradition of partnership in addressing issues that affect our mutual members, the AHA and the nation's state hospital associations are working together to inform and educate hospitals and health systems about the Year 2000 issue.

We are committed to informing our members of the dangers of the millennium bug. We are making sure they have the latest information on what their colleagues and other organizations are doing to address the problem. And we are helping them learn about potential solutions.

Our State Issues Forum, which tracks state-level legislative and advocacy activities, is hosting biweekly conference calls dedicated entirely to the Year 2000 issue. On these calls, state and AHA staff share information. A special AHA task force on the Year 2000 problem has been drawing up time lines for action to make sure our members get the latest information and know where to turn for help.

Articles are appearing regularly in AHA News, our national newspaper, in Hospitals and Health Networks, our national magazine for hospital CEO's, in Trustee, our national magazine for volunteer hospital leadership, and in several other national publications that are published by various AHA membership societies. Several of these societies, such as the American Society for Healthcare Engineering and the American Society for Healthcare Risk Management, are deeply involved in helping their members attack the millennium bug in their hospitals.

In addition, the AHA Web site has become an important clearinghouse of information on the Year 2000 issue, including links to other sites with information that can help our members.

THE ROLE OF THE FOOD AND DRUG ADMINISTRATION

When it comes to medical devices, however, our efforts are not going to be sufficient to solve the problem, unless the manufacturers cooperate fully and quickly. While we anticipate that the number of devices that are affected may be limited, it is critical that accurate and thorough information be available from manufacturers. While health care providers can inventory their thousands of devices and pieces of equipment, the information about whether these devices are Year 2000-compliant—that is, whether or not they will be affected by the date change—must come from the manufacturers. Several organizations, both public and private, have undertaken concerted efforts to collect this information. Key among them are the Veterans Administration, the FDA, and a consortium of state hospital associations and the AHA, through the Security Third Millennium product.

The FDA has an especially key role to play in this area. The Center for Devices and Radiological Health (CDRH), the arm of FDA responsible for regulating the safety and effectiveness of medical devices, has taken a number of steps to ensure that manufacturers of medical devices address potential Year 2000 problems. We commend the center for its actions. Dr. Thomas Shope, who is heading FDA's efforts, has been very receptive to our concerns. We urge the FDA to work with other public and private parties in maintaining a national clearinghouse. Congress should provide the FDA with adequate resources to sustain and maintain this important effort.

We believe that current regulations allow the FDA to require manufacturers of medical devices to perform Year 2000 testing and report adverse results. We urge Congress to speak directly to manufacturers on the need and expectation for prompt, sufficient disclosure. Congress also should provide FDA with the resources necessary to ensure timely reporting of Y2K compliance—including additional authority, if needed.

THE ROLE OF THE HEALTH CARE FINANCING ADMINISTRATION

On average, America's hospitals and health systems receive roughly half of their revenues from government programs like Medicare and Medicaid. If that much revenue were to be suddenly cut off, hospitals could not survive, and patient care could be jeopardized. Hospitals would not be able to pay vendors. They would not be able to purchase food, supplies, laundry services, maintain medical equipment—in short, they would not be able to do the job their communities expect of them. All this would occur even as hospitals and health systems faced the substantial costs of addressing their own Year 2000 system needs—costs that are not recognized in the calculation of current Medicare payment updates.

We applaud HCFA's recognition that the Y2K issue must be dealt with. We urge the agency to take the steps necessary to also ensure that state Medicaid programs are Y2K compliant.

With regard to Medicare, we are concerned about the agency's decision to delay the routine Year 2000 Medicare payment update while it works on its computers and those of its contractors. In addition, the agency has not yet committed to any provision to pay interest for that period. Hospitals are already trying to cope with the BBA's dramatic changes, including significant spending reductions. A delay in the Year 2000 update adds to their burden and causes unpredictability for them and their patients.

HCFA's actions could affect hospitals' ability to provide the highest-quality care possible not just to Medicare beneficiaries, but to our other patients as well. Hospitals still must pay the bills associated with providing that care, and those bills will keep coming throughout HCFA's effort to update its computers. Routine updates in current PPS payments are not complex. However, if they cannot be provided as scheduled, then HCFA must quickly create an alternate payment method that ensures the smooth flow of funds even as it updates its computer systems, including paying hospitals prospectively.

HCFA also must make sure its contractors—including Medicare + Choice plans—take steps to ensure that their performance will not be interrupted by Year 2000 problems caused by the millennium bug. HCFA should make readily available its work plan, and progress reports, for bringing the contractors and Medicare + Choice plans into compliance and monitor their efforts. Letting providers know what changes may be required of them is also important. This would allow providers, contractors and plans to prepare simultaneously and ensure that their systems are compatible.

Even if HCFA and its contractors express confidence that their payment mechanisms will not be affected by the millennium bug, unforeseen problems could crop up. Therefore, it is imperative that HCFA establish a fail-safe contingency plan in case HCFA or its contractors' payment mechanisms somehow fail at the turn of the century. We would like to work with HCFA to ensure that these short-and long-term concerns about the Year 2000 are adequately addressed.

Medicare beneficiaries' health care needs will remain constant, regardless of how well we are prepared for Year 2000 problems. If carrier and fiscal intermediary payment systems are clogged up by the millennium bug, hospitals' ability to continue providing high-quality health care could be severely affected. A system to provide periodic payments, based on past payment levels, is one way that this could be done. It would ensure that hospitals have the resources necessary to care for Medicare patients. We urge Congress to enact legislation to authorize such a system, and require that HCFA subject such contingency plans to public comment.

THE ROLE OF CONGRESS

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

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

- Congress should speak directly to manufacturers on the need and expectation for prompt, sufficient disclosure of their medical devices' Y2K compliance, and provide FDA with any additional authority and support needed for the public/private Y2K assessment effort to be a success.
- Congress should enact some form of limitation on liability for health care providers that have taken steps to prevent Year 2000 problems from affecting patient care. To a great extent, hospitals must rely on manufacturers of medical equipment and devices—and on vendors providing other systems and products—to disclose whether a Year 2000 problem may arise, and how to correct the problem. In addition, some products and systems may have been purchased by hospitals years ago, before the Year 2000 date change became a consideration. Providers should not be liable for damages for the Year 2000 limitations of those products and systems, especially when they have taken good faith, reasonable steps to minimize the risk.
- One way to approach this liability issue is to broaden the president's recently announced "Good Samaritan" proposal. The aim of the proposal is to shield from liability businesses that, in good faith, share information on solving the Y2K

problem. First, we suggest also addressing in that legislative vehicle our concerns about liability mentioned above. In addition, protecting hospitals and health systems from liability for treating a patient with a medical device that the manufacturer has assured us is Y2K compliant, but turns out to have caused harm because it is not compliant, is also necessary.

—Congress should authorize periodic payments under Medicare. These payments, based on past payment levels, should be implemented to ensure adequate cash flow for providers in case carrier and fiscal intermediary payment systems fail due to the date change. Congress also should ensure that HCFA has adequate funding to ensure Y2K compliance, including the testing needed to demonstrate that the claims processing and payment systems work for the government, providers, contractors, and beneficiaries alike.

Mr. Chairman, the Year 2000 issue will affect every aspect of American life, but few, if any, are as important as health care. America's hospitals and health systems, their state associations, and the AHA are partners in the effort to prepare for the Year 2000. We encourage Congress and our federal agencies to work with us as well. Together, we can ensure a smooth—and healthy—transition into the new millennium.

RESPONSES OF JENNIFER JACKSON TO QUESTIONS SUBMITTED BY CHAIRMAN BENNETT

Question 1. [Status of biomedical device discovery, remediation, and testing in hospitals]

Ms. Jackson, your testimony points out the potential patient safety problems with noncompliant Y2K biomedical devices, and you call for a national clearinghouse for information about compliant Year 2000 biomedical products. As you stated, only the manufacturers of the devices have this Y2K data.

—How do you recommend establishing and operating this clearinghouse?

—What specific recommendations can you make to hospitals which may be behind in their Y2K efforts or struggling to understand the scope of biomedical devices?

Answer. The emphasis should be on a public-private partnership. There are currently a number of data bases, including the FDA's, the Veteran Administration's, and the one developed by a consortium of state hospital associations and the AHA, the Security Third Millennium product, that can serve as a base for this effort. AHA plans to follow-up with the FDA and others to explore the potential for sharing information and any legal or other impediments. Any clearinghouse effort, however, will be dependent on getting the needed information from the manufacturers. If the FDA believes it does not have the authority to mandate disclosure, we urge Congress to enact self-implementing legislation that would mandate disclosure by the manufacturers.

AHA offers a range of services through which members can access relevant literature, vendors and products, and be connected with their peers to exchange information about their experiences in addressing Y2K issues. A briefing book developed for members, Y2K: Mission Critical, provides a framework for approaching the full range of Y2K issues, starting with an inventory and assessment of what potentially may be affected. (A copy of this book has been shared with staff of the Special Committee and an additional copy will also be forwarded with this letter.) A hospital can either assign someone the responsibility to develop a plan based on the many resources available, or subscribe to a service that will bring together the specific information an individual hospital needs, like Security Third Millennium.

Question 2. [Rural hospitals]

Ms. Jackson, the Committee keeps hearing about potentially serious Y2K problems with hospitals serving rural populations. Reports to our staff indicate that the limited budgets of small hospitals make it difficult for them to adequately staff Y2K efforts. In addition, the fact that there may not be an alternative health care facility for many miles makes their situation even more dire.

—Are these reports accurate? If so, what suggestions would you have for small hospitals?

—Do you see a role for the federal, state, or local government?

Answer. Preliminary information from a survey conducted by AHA that accompanied the Y2K: Mission Critical briefing book, suggests that rural hospitals are not significantly different from others with respect to the issues they have been examining and the steps they are taking to become Y2K compliant. While rural hospitals do not have the staff and other resources available to larger hospitals, they also do not have the same scale of operation, nor the same high-tech equipment demands

as larger hospitals. However, it is still too early to know what the ultimate cost or resource requirements will be. Small and rural hospitals that are part of larger systems will have the benefit of the system's expertise and resources. Coalitions of smaller entities are also being formed to share information.

Small and rural hospitals are particularly concerned about the Y2K readiness of others upon whom they must depend and over whom they have no control. The uninterrupted flow of payments from Medicare, Medicaid and other payers is a top priority. All levels of government have a role to play in making sure that government programs pay on time, and have adequate contingency plans to ensure that this happens. In addition, the government can ensure that the basic services that help support the operation of hospitals is not interrupted (e.g. water, power, communications).

Question 3. [Contingency Plans for Y2K hospital operations and Medicare payments]

Ms. Jackson, your testimony raises the issues of Y2K contingency planning. Could you please share your thoughts on two specific "What if something goes wrong?" scenarios.

- If Y2K disruptions prevent hospitals from being able to medically function, what kind of contingency planning does AHA recommend? For example, how would a hospital evacuate patients and where would they take them?
- What if HCFA cannot promptly pay Medicare health claims? What is the recommendation of AHA on how the government should pay Medicare health claims while protecting the fund against fraud and abuse?

Answer. Hospitals are routinely required to have disaster and contingency plans. The Joint Commission on Accreditation of Health Care Organizations also addresses the need for contingency plans. Y2K contingency planning would supplement what already exists. The specifics of a Y2K plan will vary depending on the Y2K compliance of the hospital and the readiness of its community. Hospitals need to be actively engaged with their public safety and public health partners. It is likely that hospital contingency plans will evolve as more and better information becomes known about the extent to which their own operation is Y2K compliant, as well as that of others within their community.

HCFA should establish a fail-safe contingency plan to address potential non-compliance at all stages in the claims payment process. Advance periodic payments, based on past payment levels, is an important component of a contingency plan. AHA recognizes that the use of past payment levels could result in underpayments based on actual services delivered, as well as overpayments. Records would have to be maintained and a reconciliation would ultimately occur, based on the same standards as would otherwise apply. At the same time, many hospitals and health care organizations have established formal compliance programs designed to achieve the best possible compliance with the complex billing requirements and regulations of the Medicare program.

Question 4. [Medicare Payments]

Ms. Jackson, you stated that the Health Care Financing Administration will not meet some of the Balanced Budget Act of 1997 changes in Medicare formulas and rates due to Y2K renovation and testing activities. Has AHA estimated how much the BBA delays will affect the hospital industry, and what do you propose as a solution?

Answer. Because of its Y2K preparations, HCFA has proposed delaying both routine FY 2000 inpatient hospital Prospective Payment System (PPS) updates as well as implementation of PPS for outpatient hospital and home health payments. Each of these presents specific difficulties for hospitals.

By our estimates, the proposed six-month delay in routine updates to Medicare hospital payments would total approximately \$300 million, with an additional \$40-\$50 million accruing in interest owed to hospitals over this period. HCFA's Y2K efforts should be substantially complete by October 1, 1999. Moreover, AHA believes that HCFA should have no difficulty making these routine adjustments to a 15-year-old system of hospital payment. If in fact, they cannot, in the interim the current (FY99) standardized amount should be increased by the FY2000 updates. Other required adjustments could be made retrospectively. This will help avoid causing cash flow problems in hospitals across the country.

Home health presents a different set of problems. With PPS scheduled to take effect in FY2000, home health providers are being paid under an interim system that has produced very serious unintended consequences for efficient providers. Congress is currently struggling to refine this interim system during this legislative year, a task made much harder if that fix must cover a 3 or 4 year time frame, instead

of 2 years. AHA supports the solution embodied in H.R. 4252, introduced by Reps. English (R-PA) and Neal (D-MA).

Hospitals supported the creation of PPS for outpatient payment in hopes of bringing predictability and simplicity to a very fragmented and confusing payment system. Until PPS is finally implemented, we would ask HCFA not to worsen our situation by requiring us to make further changes—such as implementing the new Ambulatory Surgery Center methodology—without the promised simplification. In addition, contrary to what Congress intended, hospital outpatient payments will be negatively affected by revisions to the physician payment. The best interim solution for outpatient payment is to freeze the system until PPS can be adopted.

Question 5. [Strategic Risk Management]

At what point should hospitals begin to determine whether or not they should refrain from scheduling routine procedures and elective surgeries during the first week of January 2000?

Answer. Contingency planning will be an on-going process. Hospitals will want to minimize the demands on their systems while they begin actual operations in 2000. Their decisions about when to begin business as usual will depend on their own preparations, as well as the readiness of those on whom they must depend. It is certainly the goal of our members that they will not need to make scheduling changes for routine procedures and elective surgery.

Question 6. [Information sharing]

Are you aware of any large health organizations which are working to mitigate Y2K problems in concert with others in the private sector? If so do you know of any plans to share this information with smaller hospitals which may be struggling to afford Y2K programs?

Answer. AHA and its state hospital and health care associations are working to assure that members have access to the information needed to meet the Y2K challenge. This ranges from culling relevant literature and sponsoring educational programs, to connecting hospitals with their peers to exchange expertise and information. Hospitals are getting together to seek information from vendors, as well those who would be interested in volunteering some of their staff to smaller organizations if their liability issues are addressed. The Y2K: Mission Critical book also provides samples of the variety of tools organizations are using to address Y2K issues.

RESPONSES OF JENNIFER JACKSON TO QUESTIONS SUBMITTED BY SENATOR COLLINS

Question. In your estimate, how much will it cost rural hospitals to become Y2K compliant?

Answer. It is still too early to know what will be the ultimate cost for Y2K compliance. Anecdotal information indicates that however reasonable preliminary estimates may be, the actual amount will exceed those estimates. Rural hospitals will be in a better position to make informed estimates as information becomes available from the manufacturers and vendors about the Y2K status of their products and services, and the options for bringing those that are noncompliant into compliance.

Question. What is your primary concern for rural hospitals?

Answer. The primary Y2K concern related to rural hospitals is that they receive information from their vendors and others on which they depend for basic infrastructure support, early enough to permit them to obtain any needed financial resources to carry out their Y2K compliance plans. For the rural hospitals, assuring that there is no interruption in payments for health care services from the government or private payers is also of critical importance.

PREPARED STATEMENT OF KENNETH W. KIZER

INTRODUCTION

Good morning Mr. Chairman and members of the Committee. I appreciate the opportunity to testify before you on the healthcare issues and on the potential risks to patient safety that are posed by Year 2000 (Y2K) technology compliance problems. My comments are especially directed toward biomedical equipment and medical devices, and are based on the experience of the veterans healthcare system in defining the extent of the Y2K problem for hospitals and healthcare systems.

BACKGROUND

Technology has been responsible for many of the advances of modern healthcare, so it is ironic that this same technology now may present hazards to patient care when the 21st century begins.

Most medical devices, like other information technologies, were designed when there was little concern about how year references were reflected in hardware or software. Historically, most dates programmed in computers and medical devices have been based on a two-digit year—i.e., “97” rather than “1997.” This was done in the early days of computing because of the high cost of data storage, and the practice was continued until relatively recently.

The essence of the current Y2K problem stems from the fact that when the year “2000” is entered as “00,” systems and devices may not recognize this entry as a correct year, and thus, programs may fail, they may not perform as designed, they may reject legitimate entries or they may yield erroneous results. Thousands of medical devices may be affected by one or more of these problems that constitute what I have called the “Millennium Bug Syndrome” or “MBS”.

The MBS may occur with technology-related processes that sort by date or that require a comparison by dates, processes that calculate age or processes that perform other date-related tasks. For example, an incorrect date or time sequence in the output of a blood gas analyzer could cause confusion when interpreting the sequential results, causing errors in diagnosis and treatment. Likewise, an incorrect age calculation which is stamped on an automated chest X-ray could prompt unnecessary further testing or even cause a misdiagnosis.

Hospital information management systems; building systems controlling heating, ventilation and air conditioning, security, and elevators; and billing and accounting systems also are all subject to the MBS. All such systems and devices must be thoroughly checked, and repaired or replaced, as required, before January 1, 2000.

While most of the problems identified to date are relatively minor and can be repaired, many healthcare institutions across the country are not positioned to accomplish these needed repairs. More importantly, though, is that at this time too many healthcare institutions do not yet know whether they have a problem, or how big of a problem they have.

GENERAL HEALTHCARE Y2K ISSUES

For the healthcare industry, the inability of many computers to process date information later than December 31, 1999, is more than just a computer or information management problem. For hospitals and healthcare systems, Year 2000 problems originating from both internal and external sources may, if left unattended, threaten the whole institution, not just those departments that are concerned directly with information technology. Uncorrected Year 2000 problems could compromise patient care, disrupt core business functions and create substantial liability exposure.

I believe the healthcare industry is at greater risk than many of the other industries that are also grappling with the Y2K problem because there are so many information systems in hospitals—from admissions to discharges, transfers, medical records, inventory control, clinical informatics and billing—which may be affected by Y2K problems and which may have both direct and indirect effects. For example, delays in payments from third-party payers could be crippling if cash-flow problems result in staffing shortages. Similarly, if a Year 2000-induced error causes a piece of laboratory equipment to skip a function, or perform a function twice, a patient could get the lab results of the patient who preceded or succeeded him or her, with potentially adverse consequences. Likewise, without proper dating systems, inventory reorder dates will be impacted with the consequent risk of running out of needed supplies. This could be particularly problematic for hospitals, since they typically maintain a minimal depth of inventory for perishable items such as sutures and blood products.

Further, modern healthcare depends on many external information technology systems, so simply fixing a hospital's in-house systems and biomedical equipment will not necessarily guarantee a smooth transition into the new millennium. For example, every healthcare system depends upon suppliers for goods and services. What if the linen service, food suppliers, ambulance services, power management systems, oxygen suppliers and reference labs, to name some, have problems in their systems that make it difficult or impossible to take orders, to manage inventory and to deliver what a hospital and its ancillary systems need? Failure or malfunction of any of these systems could potentially disrupt patient care.

VHA'S APPROACH TO THE Y2K PROBLEM

VHA size and scope

Within U.S. Department of Veterans Affairs (VA), the Veterans Health Administration (VHA) operates the largest fully integrated healthcare system in the United States. A wide range of electronic information systems, biomedical equipment, facility management systems and other computer-based system products provide vital support to the delivery of healthcare and other services to veterans at over 1,100 sites of care delivery. (VA medical care assets include 171 hospitals, over 600 ambulatory and community-based clinics, 133 nursing homes, 40 domiciliaries, 206 counseling centers and 73 home health programs, as well as various contract treatment programs.)

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

VHA's diverse systems and equipment inventory includes hospital information systems and applications, corporate information systems and databases, commercial off-the-shelf (COTS) hardware and software, communications systems and networks, biomedical equipment, laboratory and research systems and other computer-controlled facility equipment. There are many data interfaces among the systems and thousands of types of equipment and devices in this extensive inventory. At the core of VHA's systems environment is the Veterans Health Information Systems and Technology Architecture (VISTA). VISTA is a critical element of the total systems environment that provides information management support to VHA healthcare facilities. It is continually being developed and enhanced.

VHA approach

To address potential Y2K problems, VHA established a Year 2000 Project Office in 1996. The Project Office prepared The VHA Year 2000 Compliance Plan in April 1997, which included a structured compliance plan for all categories of VHA's systems and equipment inventory, assigned responsibilities for all actions and provided performance tracking and reporting requirements.

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

VISTA software applications.—The Veterans Health Information Systems and Technology Architecture (VISTA) is the heart of VA medical facilities information resource management activities. VHA's VISTA application development requirements in effect since 1984 dictate a standard method of storing and deriving date information through the use of a pre-existing database management system known as VA File Manager.

VA File Manager uses a seven digit date field that has three digits for the year (rather than the common two-digit year field in most legacy systems) and two digits each for the month and day (date format is YYYYMMDD). The year is specified according to the number of years from the year 1700.

Because of the decision to use the VA File Manager date standard, the core VHA application systems were expected to be able to support date information through the year 2699. This expectation was confirmed in our assessment phase. Our programming approach eliminated most of the two versus four digit year issues for the majority of software applications at VHA medical facilities. The databases used by and linked to these applications, interfaces between these applications and other systems and equipment, and other system products that do not use the VA File Manager date format, have been carefully assessed for Year 2000 compliance. VISTA is a vital part of the total computer systems environment that provides information resources and support at VHA healthcare facilities.

VHA in-house staff assessed, repaired, tested and are now installing needed repairs at our hospitals. Assessment, repair and testing were done centrally, while implementation is being done locally.

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

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

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

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

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

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

Facilities-related systems and equipment.—Facilities-related equipment systems are vitally important to VHA in providing quality healthcare service. These include those systems that control elevators; heating, ventilating, and air conditioning equipment; lighting; security; and disaster recovery. Staff from engineering, information resources, facilities management, acquisition and administration are being involved to ensure that facility-related equipment will be Year 2000 compliant.

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

The Safe Medical Devices Act of 1990 requires manufacturers of medical devices to track and resolve problems with medical equipment that may threaten a patient's well being. As a result, most recently manufactured medical devices should be unaffected by the Year 2000 problem. However, most hospitals and healthcare systems utilize a wide range of devices that have been manufactured over the past two or three decades. In an effort to define the extent of VHA's potential problem with biomedical equipment, early last summer, we identified over 1,600 manufacturers from whom we had purchased equipment or devices over the years; this is out of a universe of over 16,000 medical supply and device manufacturers. Over the past 10 months, we have solicited data from these manufacturers as many as four times (depending on the manufacturer's response). The dialogue continues with manufacturers whom we have not heard from or who have advised us that their product is non-compliant.

VHA has established multi-disciplinary oversight teams to investigate medical devices for compliance at each VA medical center. These Medical Devices Integrated Product Teams include a radiologist, a pathologist, a cardiologist, a surgeon, a nuclear medicine physician, engineers, acquisition specialists and administrative personnel.

VHA has developed a process for identifying, inventorying, assessing, and evaluating VHA medical devices at risk for the millenium change. We have also developed a Year 2000 patch for the VISTA software module used in inventory and our preventive maintenance programs. The software patch for Y2K compliance provides additional fields needed to conduct assessment, track the status and complete necessary compliance reports for Y2K activities

VHA results

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

The results of VHA's assessment revealed that approximately 8 percent of the total VISTA code required renovation to achieve compliance. Renovation was contained in 66 applications, with none of the renovation work being categorized as more than minor repair; renovation is now 100 percent complete. Hospitals are currently averaging 72 percent implementation of the 61 enhancement or modification patches released to bring VISTA applications into compliance.

In the biomedical equipment and medical device area we can now report that:

- 694 manufacturers have certified to us that their products are Y2K compliant, meaning that there should be no problems because the device does not rely on date coding or they have already addressed the issue. (Many of these devices are items manufactured in recent years.)
- 34 manufacturers have reported that a total of 182 models of equipment or devices are not Y2K compliant and are no longer supported by the manufacturer. These models are considered obsolete and will not be fixed by the manufacturer, even though in many cases the device is still functional and commonly used.
- 102 manufacturers have reported that they produce a total of 673 models that currently are not Y2K compliant, but that they intend to repair or otherwise fix the device. In most cases, though, the manufacturer has not stated how the Y2K noncompliance will affect the function of the device or exactly what will be done to fix it. The manner in which the manufacturers will be providing the fix—e.g., whether they will charge for it, send a repair technician to the facility or require the product be sent back, etc.—varies widely among the manufacturers.
- 53 manufacturers reported they are still doing analyses of their products and, thus, we don't know what to expect from them.
- Inquiries to 201 manufacturers were returned to VHA marked "Return to Sender." After four tries over a 10-month period, we are assuming, at this point, that we will never know about the devices produced by these manufacturers.
- We have also identified 96 manufacturers who we believe have gone out of business or have been acquired by another entity since we initially acquired their products.
- The remaining 233 manufacturers have not responded to us despite our multiple inquiries.

Thus, overall, we know at this time that we have 855 models of devices and equipment that are not compliant, and about 20 percent of these will not be made compliant by the manufacturer. And even after four separate queries, we have not been able to get a response from about 30 percent of manufacturers. In interpreting these figures, please keep in mind the size of customer that VHA is and, thus, the business interest of the manufacturers to be responsive to us. Other than that, we have no reason to believe that our experience is not, or will not be, typical of other healthcare providers.

OTHER EFFORTS

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

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

More recently, VHA has been working with other members of the National Patient Safety Partnership (NPSP) to increase awareness of the Millenium Bug Syn-

drome within the healthcare industry. For example, two weeks ago, we joined with the American Hospital Association, the American Medical Association, the American Nurses Association and JCAHO in calling on the nation's medical equipment manufacturers, medical equipment sales and retail industry, retail pharmacies and other organizations that place medical devices in use to join in the effort to identify and address potential patient safety problems resulting from Y2K problems.

At the press conference 2 weeks ago the NPSP called for four things.

First, the Partnership called on all healthcare practitioners and medical treatment facilities to survey their equipment and seek information from their relevant medical equipment, devices or systems manufacturers about their products' Y2K compatibility.

Second, the Partnership called on all healthcare consumers who use medical devices at home to check with the healthcare provider about the product's Y2K compatibility. As you know, a very large amount of healthcare is now provided at home.

Third, the Partnership called upon the nation's medical equipment manufacturers to take immediate action—if they have not done so already—to identify their devices' compliance. We urge in the strongest possible terms that equipment and device manufacturers provide this information no later than January 31, 1999, so that there will be ample time to address identified problems.

And fourth, the Partnership calls for the establishment of a single, national clearinghouse from which this information can be readily accessed by anyone.

CONCLUSION

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

We also know that when the clock rolls forward to the 21st century, 526 days from today, about 3.8 million Americans each day will receive healthcare at hospitals, clinics and nursing homes, with many more being treated at home; each of these patients will typically have multiple different interactions—sometimes hundreds—with equipment, devices and/or information technology systems. When you consider the extraordinary number of such interactions with technology, then it begins to become clear how large is the potential for adverse events to occur, even if the problem involves only a small percentage of devices or systems. Fortunately, we still have time to ensure that no patient suffers harm as a result of the Millenium Bug Syndrome if concerted and aggressive action is taken in the months ahead.

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

YEAR 2000 AND MEDICAL DEVICES: DEMONSTRATION ITEMS

1. ZOLL DEFIBRILLATOR (MODEL PD 1200)

- Preliminary results indicate that functionality of the defibrillator will not be affected
- Date stamp 00, thus requiring manual dating and the attendant increased opportunities for errors
- Manufacturer has responded with a courtesy reply that they will get back to VA, and so we characterize the compliance status of this device as "unknown"

2. SPACELABS PATIENT MONITOR (MODEL PC EXPRESS 90308)

- Cardiac monitor used in critical settings such as ICUs; 50,000 monitors of some type is probably a conservative estimate
- Alarm will not sound unless a software problem is addressed
- As part of a patient monitoring system connected via a local area network, clinicians will not be able to correctly determine when a patient alarm situation has occurred, dramatically affecting care when a response measured in minutes is necessary
- Company reports to VA that a patch will be available in January 1999, hence we characterize the device as "conditional compliant"
- Company current states that the patch (free) *must be ordered by December 15, 1998*; manufacturer's current policy as stated to VA is requests after 12/15/98

will not be filled. Thus, institutions need to be aware of the problem, survey their equipment, and contact the manufacturer by the deadline

3. VARIAN LINEAR ACCELERATOR (MODEL CLINAC 18, SOFTWARE VERSION 5.2)

- Used in cancer therapy; designed to destroy tissue, so precision is critical and under dosage or over dosage is not acceptable
- Although Varian considers this an older, obsolete unit, the manufacturer reports it will supply a patch at no charge—i.e., the status currently is conditional compliant pending receipt of patch and manufacturer's assurance that it addresses the problem

4. VERNITRON STEAM STERILIZER (MODEL R1626RPYI)

- Sterilizers affect the whole operation of a facility, but VA currently has no information as to the Y2K compliance status of this equipment
- Sterilizers were not part of the initial national oversight survey, but have been added
- VA (local facility) has made several attempts at contact the company with no response to date

5. ALARIS INFUSION PUMP (MODEL GEMINI PC4)

- Subtle, but significant Y2K problem. Proper service diagnostics can't be performed on this pump. Since a valid date cannot be entered following service activity or battery replacement, proper and complete routine or emergency maintenance on the device is not possible. This could then lead the device to malfunction and result in patients getting improper doses of medications and/or fluids. In other words, when someone "fixes" or checks the device for routine "maintenance", there will be uncertainty as to whether it has been "fixed" or "maintained" correctly.
- VA currently characterizes the document as conditional compliant

6. MARQUETTE MEDICAL SYSTEM ELECTROCARDIOGRAPH (MODEL MAC 12)

- An error code is printed on the statement instead of a date. Illustrates the problem of the lack of date stamp contributing to a time-consuming, "hassle factor" for healthcare personnel
- When the operator turns the machine off at the end of the day or after use on a patient, the next time the equipment is turned on the entire machine must be recalibrated before using the device because the machine "thinks" it is new and resets its internal clock to 1980
- Recalibration (10–15 minutes) wastes valuable time, and the date still won't print even after recalibration
- Additionally, some devices in this model line are Y2K compliant and will work without the upgrade—compliance depends on when the device came off the assembly line. However, since some models won't work without the upgrade, all machines will need to be checked
- Conditional compliant; company says patch will be available

7. PICKER INTERNATIONAL, INC. CT SCANNER (MODEL PQ2000) PICKER INTERNATIONAL, INC. MRI SYSTEM (MODEL EDGE 1.5T)

- Compliance had been unknown for these devices and models, although Picker had been contacted by VA several times and even though VA is a significant customer. VA has >100 Picker CT scanners (~\$1.3 million per scanner) and dozens of MRIs at approximately \$1.7 million per unit.
- The day after VA highlighted Picker's non-responsiveness at a press conference, the manufacturer contacted us that it would soon be providing VA with information about the Y2K compliance status of these items. Then, the evening before the Senate hearing, Picker informed VA it had a Web site and that its devices would be compliant.

8. PHYSIO-CONTROL DEFIBRILLATOR (MODEL LIFE PAK 7)

- Unlike the Zoll defibrillator, VA has identified this product as non-compliant based on information provided by the manufacturer. The model is more than 9 years old and no longer produced, though still in use
- The defibrillator is equipped with a real-time clock feature that does not support the change to the Year 2000 and no modifications are planned

- Depending on the device, it either won't print a date or will print an *erroneous* date, which could lead to subsequent treatment or interpretation errors
- Replacement cost is ~\$10,000 per unit, and a typical VA facility might have 10–30+

9. DENSPLY/GENDEX DENTAL X-RAY (MODELS 770 AND 900)

- Illustrates the difficulties in tracking down company information due to the rapid changes in the industry—i.e., mergers, acquisitions and bankruptcies
- Original letter was sent to Gendex, but returned as unknown addressee. Only after 10 months of repeated follow-up and investigations was it learned that Gendex had merged with Densply, which VA is now in the process of contacting for Y2K compliance and assistance. Such follow-up would be difficult for most small systems or individual providers
- Compliance of this particular device is currently unknown
- There will be, without doubt, devices for which compliance will remain unknown on December 31, 1999, necessitating contingency planning for those items

10. COMPUTERIZED MEDICAL SYSTEM RADIATION THERAPY TREATMENT PLANNING DEVICE (MODEL CMS MODULEX RTP SYSTEM)

- Used in radiation therapy (Cobalt 50), but manufacturer considers this particular model obsolete and does not intend to provide a patch; device is non-compliant
- Manufacturer has been open and forthcoming, stating that VA should “turn this device off” and not use it. After December 31, 1999, the device poses a harm to a patient because too much, or too little, radiation could be delivered. Specifically: (i) an incorrect date stamp indicating when the patient received radiation therapy could affect the treatment plan for the individual; and/or (ii) these units involve the use of a “live” radioactive source to treat the patient. Such sources lose their strength, i.e., decay, over time. Since information affecting the strength of the source is entered into the system and tracked by *date*, the calculation for a particular dosage for an individual patient would be affected and an incorrect dosage delivered
- VA has 3 of these units, which originally cost ~\$150,000; replacement cost \$200,000 to \$250,000

VHA Y2K PROJECT OFFICE LIST OF MEDICAL DEVICE MANUFACTURERS WITH NO RESPONSE TO ALL 4 LETTERS

Name of manufacturer	Street address	Received response	City	State	ZIP
ABTOX INC.	104 Terrace Drive	Mundelein	IL	60060
ACCUTOME	490 Lancaster Avenue	Frazer	PA	19355
AEQUITRON MEDICAL	14800 28th Avenue North	Minneapolis	MN	55447
ALLERGAN INC.	92525 Dupont Drive, P.O. Box 19534	Irvine	CA	92713
ALTEC	1515 S. Manchester Ave.	Anaheim	CA	92803
AMEDCO HEALTH CARE DIV. HEALTHCARE PRODUCTS INC.	739 Goddard Ave.	Chesterfield	MO	63005
AMERICAN ELECTROMEDICS	13 Columbia Dr. Suite 18	Amherst	NH	03031
ANGUS ELECTRONICS CO.	P.O. Box 24000	Indianapolis	IN	46224
APEC	83 Pine Street	Peabody	MA	01960
API-LIRCO	118 Starlite Street	South San Francisco	CA	94080
ARNDORFER INC.	5656 Grove Terrace	Greendale	WI	53129
ASPECT MEDICAL SYSTEMS	2 Vision Drive	Natick	MA	01760
AUTOMATED PRESCRIPTION	4333 Shreveport Highway	Pineville	LA	71360
BALDOR ELECTRIC	P.O. Box 2400	Fort Smith	AR	72901
BALLARD MEDICAL PRODUCTS	12050 Lone Peak Parkway	Draper	UT	84020
BARRAMUNDI CORP.	P.O. Drawer 4259	Homosassa Spring	FL	34447
BAXA CORPORATION	13760 East Arapahoe Road	Englewood	CO	80112
BAYLOR BIOMEDICAL SERVICES	2625 Elm St. Suite 102	Dallas	TX	75226
BETA TECHNOLOGY INC.	151 Harvey West Blvd.	Santa Cruz	CA	95060
BIOMARINE INCORPORATED	131 Wallace Avenue, Suite 3	Downingtown	PA	19335
BURKE INC/BED DIV.	1800 Marriam Lane	Mission	KS	66106
CARDIOVISTA SYSTEMS INC.	2691 Picker Ave., Suite 115	Irvine	CA	92714
CASCADE X-RAY SPECIALTIES	P.O. Box 1605	Yakima	WA	98907
CEMAX-ICON INC.	47281 Mission Falls Ct.	Fremont	CA	94539
CHIRON DIAGNOSTICS CORPORATION/CRITICAL CARE DIV.	115 Norwood Park South	Medfield	MA	02052
CLINICAL DYNAMICS CORP.	12 Beaumont Road	Wallingford	CT	06492
CODONICS INC.	17991 Englewood Drive	Middleburg Heights	OH	44130
CORDIS CORP A JOHNSON & JOHNSON CO.	P.O. Box 025700	Miami	FL	33102
CORPAK	100 Chaddick Drive	Wheeling	IL	60090
CWE	25 St. Paul Road	Ardmore	PA	19003
DEBUSK TECHNOLOGY CORPORATION	300 DeBusk Lane	Powell	TN	37849
DIAGNOSTIC SONAR INC.	P.O. Box 456	Cambridge	OH	43725
DIGIVISION INC.	5626 Oberlin Drive	San Diego	CA	92121
DYNAMIC ENGINEERING CORP.	2575 West Beltline Highway	Middleton	WI	53562
ECONOMICS LAB/ECON SYS.	3508 Tchulahoma Road	Memphis	TN	38118
ELCONAP	413 Market Street	Newark	NJ	07105

ERIS MEDICAL TECHNOLOGY	10 Summit Avenue	Berkeley Heights	NJ	07922
FAIRBANKS SCALE	1616 Toal Street	Charlotte	NC	28206
FISONS INSTRUMENTS INC.	55 Cherry Hill Dr.	Beverly	MA	01951
FITNESS EQUIPMENT CORPORATION	P.O. Box 167	Clanton	AL	35045
FORDOM ELECTRIC	Route 6 Stony Hill	Bethel	CT	06801
FRANTZ IMAGING INC. (FRANTZ MEDICAL)	595 Madison Avenue	New York	NY	10022
GRASEBY MEDICAL INC.	3796 N. Dunlap Avenue	Arden Hills	MN	55112
HARVARD BIOSCIENCE	22 Pleasant Street	South Mattick	MA	01760
HEALTHWATCH INC. CAMBRIDGE MEDICAL DIV.	2445 Cades Way	Visia	CA	92083
HOME DIAGNOSTICS INC.	2300 NW 55 Ct.	Ft. Lauderdale	FL	33309
HOSPEX FIBER OPTICS	P.O. Box 353	Chestnut Hill	MA	02167
ISELL DIVERSATRONICS	2430 Boulevard of the Generals	Norristown	PA	19403
JFM ENGINEERING	7880 N.W. 56 St.	Miami	FL	33166
KASON INDUSTRIES	57 Amlajack Blvd.	Shenandoah	GA	30265
KOWA OPTIMED	20001 S. Vermont Avenue	Torrance	CA	90502
LIFELINE INSTS INC.	3830F Charter Park Dr.	San Jose	CA	95136
LIONHART TECHNOLOGIES	P.O. Box 1925	Carson City	NV	89701
LUMEX INC.	81 Spence Street	Bay Shore	NY	11706
MAC BETH DIV. INSTRUMENTS	405 Little Britain Rd.	New Windsor	NY	12553
MANGUM SICKLES IND.	1200 North Sickles Drive	Tempe	AZ	85281
MC KESSON AUTOMATED HEALTHCARE	261 Kappa Drive	Pittsburgh	PA	15238
MEDICAL GRAPHICS	350 Oak Grove Parkway	St. Paul	MN	55127
MEDIMEX	P.O. Box 14	West Hempstead	NY	11552
MEDSCO COMFORT POUCH	185 N Park Blvd., Suite 262	Lake Orion	MI	48362
MESA INDUSTRIES	143 South Jackson Street	Elkhorn	WI	53121
METERTECH INC.	63-2 Cheng Kong Rd. Sec. 1	Nan kang	Taipei, MO	63178
MODERN ENGINEERING	3500 Bernard Street	St. Louis	MO	19355
MODULAR INSTRUMENTS INC.	81 Great Valley Pkwy.	Malvern	PA	92690
NICHOLS INSTITUTE DIAGNOSTICS	33608 Ortega Highway	San Juan Capistran	CA	10604
NORLAND MEDICAL SYS. INC.	106 Corporate Park Dr. Suite 106	White Plains	NY	08012
NOVA HEALTH SYSTEMS INC.	1001 Lower Landing Road, Suite 103	Blackwood	NJ	55107
NOVA MEDICAL INC.	150 Eaton Street	St. Paul	MN	06907
OMEGA ENGINEERING INC.	P.O. Box 4047	Stamford	CT	60061
OMRON HEALTHCARE/BUFFALO MEDICAL	300 Lakeview Parkway	Vernon Hills	IL	20877
ONCOR INC.	209 Perry Parkway	Gaithersburg	MD	53187
ORTHO-KINETICS INC.	P.O. Box 1647	Waukesha	WI	34620
OXFORD MEDICAL	11526 53rd Street North	Clearwater	FL	07013
PHYSITEMP INSTRUMENTS INC.	154 Huron Avenue	Clifton	NJ	02176
PIONEER MEDICAL SYS. INC.	37 Washington Street	Melrose	MA	01803
RADIONICS INC.	22 Terry Avenue	Burlington	MA	

VHA Y2K PROJECT OFFICE LIST OF MEDICAL DEVICE MANUFACTURERS WITH NO RESPONSE TO ALL 4 LETTERS—Continued

Name of manufacturer	Street address	Received response	City	State	ZIP
ROECO MANUFACTURING SERVICE	P.O. Box 357	Monterey Park	CA	91754
ROGERS MACHINERY COMPANY	P.O. Box 23279	Portland	OR	97223
SS WHITE BURS INC.	1145 Towbin	Lakewood	NJ	08701
SENTEC	1218 Combermer	Troy	MI	48083
SIMS FORT MEYERS (INTERTECH)	5100 Tice Street	Fort Meyers	FL	33905
SOLOMAT A NEOTRONIC CO.	The Waterside Bldg, 26 Pearl Street	Norwalk	CT	06850
SONY ELECTRONICS INC. MEDICAL SYS. INC.	3 Paragon Dr. Mail Drop S200	Montvale	NJ	07645
STER-O-LIZER MANUFACTURING	P.O. Box 27488	Salt Lake City	UT	84127
STROM CORP.	P.O. Box 109	Seroggins	TX	75480
SUN MICRO SYSTEMS	2550 Garcia Avenue	Mountain View	CA	94043
SWAN TECHNOLOGIES	3075 Research Drive	State College	PA	16801
SYNNEX INFORMATION TECHNOLOGIES	3797 Spinnaker Court	Fremont	CA	94538
TEK MARKETING	98 Railroad Drive	Warminster	PA	18974
TEKNIKA ELECTRONIC	333 Route 46 Gothic Plaza	Fairfield	NJ	07006
THOMSON CONSUMER ELECTRONICS	600 N. Sherman Drive	Indianapolis	IN	46201
TOMTEC IMAGING SYSTEMS INC.	4775 Walnut Street, Suite C	Boulder	CO	80301
TRIONIX RESREACH LABORATORY INC.	8037 Bavaria Rd.	Twinsburg	OH	44087
TUNTURI INC.	P.O. Box 97047	Redmond	WA	98073
UNITED ELECTRONICS & CONTROL	1177 McCarter Highway	Newark	NJ	07104
UROHEALTH SYSTEMS INC.	5 Civic Plaza, Suite 100	Newport Beach	CA	92660
VOTRAX	1394 Rankin	Troy	MI	48083
WALLACH SURGICAL DEVICES	291 Pepe's Farm Road	Milford	CT	06460
WESTERN ELECTRIC	Guilford Center P.O. Box 20046	Greensboro	NC	27420
TOTAL = 99					

PREPARED STATEMENT OF SENATOR JON KYL

I would like to thank the Chairman and the Vice Chairman for their continued leadership on the Year 2000 Technology problem (Y2K). I would also like to thank our distinguished panel for attending and sharing their insight into the critical healthcare infrastructure.

Arizona's healthcare and research facilities are among the best in the nation and include specialties in cancer research, cardiovascular treatment, respiratory treatment and geriatric care. Arizona maintains a world class healthcare system excelling in both care and accessibility. Arizona's large and small facilities maintain a standard of excellence and sophistication that is the envy of healthcare facilities across the U.S. Overall, our healthcare facilities comprise a mix of outstanding privately owned facilities and those serving our nation's veterans.

But all of this may be put in jeopardy, if the vital information systems, supporting this excellent medical care infrastructure, are disrupted through Y2K failures. Arizona's healthcare system like many other states is a labyrinth of interdependent information systems. Having worked with some of the largest health organizations Arizona, I know first hand the complex process of ensuring patient safety, confidentiality, payment and quality assurance. As we focus on the condition of the healthcare industry today, we will try to develop an understanding of the scope and severity with which Y2K could impact healthcare operations. I would like to stress that the very possibility of a Y2K problem causing serious disruptions in hospitals and medical systems, should capture the full and immediate attention of the entire healthcare industry.

We must also make every effort to ensure that fears of litigation do not impede the exchange of Y2K information needed to fix critical systems and develop contingency plans.

I think it is important to remember that the Y2K problem is not a "bug", like a 24 hour flu which arrives unexpectedly and departs quickly. Y2K is a serious affliction which has the potential to reek long term consequences on the healthcare industry. The only defense against Y2K is a strong preventive maintenance plan. Preventing Y2K-related problems is a lot like preventing heart disease; it requires an informed and disciplined regimen to succeed.

At this point, the readiness of the healthcare industry is largely unknown. Y2K disruptions could easily damage the complex medical payment process or even cause medical equipment to unexpectedly fail. The complexity of the Y2K problem exponentially increases with the number of interfaces and electronic data exchanges. Even if a hospital succeeds in solving its internal Y2K problems, it could still suffer unexpected Y2K problems from an unprepared source such as medicaid, equipment suppliers or a public utility. We must ensure that those who are in need of care such as the elderly, sick children and those in need of emergency services are not forced to deal with the consequences of a congenital but, very treatable computer problem.

I am continuing to examine the liability issues which impede the exchange of technical information between medical equipment manufacturers and the end users, such as hospitals and private physicians. Hospitals are struggling to identify and replace equipment which may not function because of the inability to process certain dates. On the other hand, manufacturers are reluctant to share information on products until they are certain of a Y2K solution.

I look forward to today's testimony for there are far too many unanswered questions about the healthcare industry and the impact of Y2K.

PREPARED STATEMENT OF RAMIN MOJDEH

Mr. Chairman, my name is Ramin Mojdeh. I am director of research & development for the cardiac rhythm management group of Guidant Corporation. Headquartered in Indianapolis, Indiana, Guidant Corporation designs, manufactures and sells innovative products and technologies that improve the quality of care for persons with cardiovascular diseases. Guidant's lifesaving and life enhancing devices are manufactured in Minnesota, California and Puerto Rico and used by persons around the world.

I want to thank you and the members of the committee for the opportunity to speak today on behalf of the Health Industry Manufacturers Association. HIMA is a Washington, DC-based trade association that represents Guidant and more than 800 other manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members make nearly 90 percent of the \$58 billion of health care technology products purchased annually in the United States, and more

than 50 percent of the \$137 billion purchased annually around the world. HIMA is the largest medical technology association in the world.

We welcome this opportunity to provide information regarding both the impact of the Year 2000 computer problem on the medical device industry and the general readiness of this industry to ensure the safe and reliable operation of medical devices in the Year 2000 and beyond. The medical device industry recognizes and shares the concerns of health care providers, patients, and the public regarding the possible effects of the Year 2000 computer date problem. Affected medical device companies are devoting significant resources to bring their devices into Year 2000 compliance. The health and safety of patients constitute the paramount concerns of our industry. That is what we are about in both the business and the humanitarian senses.

In my appearance here today, I want to make three points for the committee:

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

2. HIMA believes that the industry as a whole is taking the necessary steps to address the Year 2000 issues related to our products.

3. HIMA members recognize that timely access to Year 2000 compliance information about individual companies' products is an integral part of the solution to the overall Year 2000 problem. Today, we give you our assurance that the industry will continue to work with other concerned organizations and the FDA to make Year 2000 compliance information relating to medical devices publicly available in an appropriate format.

I also want to take this opportunity to applaud the interest of the Congress and the Administration in proposing legislation in this area. The President's recent proposal, which would allow for sharing of information, may benefit a broad section of the economy in confronting challenges posed by the Year 2000 bug. Unfortunately, it would appear to be of less help to the medical device industry because of this industry's wide spectrum of technologies, products, and company resources. In our diverse industry, it's doubtful that what works for one medical device company can be shared and adopted by others as the President's proposal envisions even if the companies make devices with similar functions.

THE DIVERSITY OF THE INDUSTRY

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

More than 50 scientific and engineering disciplines including such diverse fields as solid state physics and holography are involved in the development of our products. Hundreds of different basic materials are utilized, singly and together, in our manufacturing. Over 50 different medical specialties, such as orthopedic surgery, cardiology, and ophthalmology, utilize the industry's products in applications throughout the human body. There are more than 3,000 distinct, major product lines, and approximately 84,000 individual products. Most are sold in small, niche medical markets.

The universe of FDA-registered medical device companies is more than 18,000, and about 7,700 of these manufacture products in the United States. However, nearly 80 percent are relatively small companies with fewer than 50 workers and annual revenues of less than \$20 million. Only about 150 companies, or divisions of major companies, have worldwide sales greater than \$100 million.

THE COMPLEXITY OF THE PROBLEM

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

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

The number of electrical medical devices containing software to control some or all of their operation has been rising as the cost of microprocessors has been falling. Consequently, almost all electrical devices now contain software. However, the complexity and sensitivity to the Year 2000 date change vary dramatically among devices. Many of the highest risk devices that are vital to keeping patients alive and that utilize embedded software are not date sensitive. For example, pacemakers do not use a current date in their operation, and it is unlikely that ventilators, infusion pumps and many other products will be affected by the date problem.

Other devices perform less life-critical functions, yet they may perform calculations or send data directly to another device that performs calculations requiring accurate date information. Clearly, these devices may be quite sensitive to the Year 2000 problem.

THE ROLE OF THE FDA

The FDA has defined in great detail its expectations for the medical device industry in several documents regarding regulatory obligations for Year 2000 compliance. These documents describe how the agency interprets its regulations regarding manufacturers' responsibilities to determine the effect of the Year 2000 date problem on their devices and to correct any safety-related problems that are revealed. Operating within an FDA-regulated industry, our member companies are profoundly aware of their Year 2000 compliance responsibilities under the law and of the penalties for failing to meet them.

Ultimately, manufacturers must examine all their software-driven processes, products to determine whether they are date dependent, and if they are, they must determine whether the date dependency is sensitive to the century change.

INDUSTRY'S RESPONSE

HIMA members are taking strong action to ensure their Year 2000 compliance. The association specifically advises members to:

- Comply with FDA expectations for identifying and resolving any Year 2000 date-related problems with their devices
- Provide information about the status of their Year 2000 compliance to their customers and others who need it in the most appropriate manner and in a reasonable time frame; and
- Work individually with customers who have specially manufactured devices or who require unique, compliance fixes.

Guidant Corporation's actions

My own company has committed to a strategy that will ensure the Year 2000 date change and leap year do not adversely impact our products, services or business operations. Guidant has had an active effort underway since the first half of 1997. This project has a full time Project Coordinator assigned and multiple support teams organized within each business unit and significant geographic location. Executive management within Guidant is sponsoring this Project and a cross-functional steering committee including systems, legal, auditing and regulatory compliance has been charged with its oversight.

As of today, Guidant has completed a thorough review of the product offerings from all of our divisions, including Cardiac Rhythm Management (CRM), Vascular Intervention (VI) and Cardiac & Vascular Surgery (CVS), with respect to the Year 2000 issue.

We are very confident that Year 2000 will create no adverse effects for our products. Guidant will fully warrant that the products it sells will be free of defects attributable to the Year 2000 date change.

Guidant is taking all reasonable steps necessary to confirm that its business systems, software, and equipment that consider and process date-related information will continue to function properly after December 31, 1999. In doing so, Guidant is paying particular attention to ensuring compliance with all regulatory guidelines regarding Year 2000 issues. Our commitment is to provide our customers with uninterrupted service and continued quality.

We began the inventory/assessment of equipment and software in 1997, and we are currently working on the limited number of corrections that have been identified as necessary. Guidant, as a corporation formed in late 1994, is fortunate to rely upon many relatively new systems, including our enterprise-wide operational support system (the widely used SAP), which has already been certified Year 2000 compliant. As such, the 1998 focus is on assessing manufacturing equipment, facilities infrastructures, and business partners. Based upon this assessment, Guidant will take the necessary actions to correct identified problems. Guidant has a goal of completing all assessment and remediation in the equipment and infrastructure area by mid year 1999. This will allow for internal auditing and testing, as well as any fine-tuning, of these systems to take place in the latter half of 1999. Our efforts in confirming the readiness of our various business partners, while ongoing, will continue up to, and through, January 1, 2000.

Other HIMA members' actions

In providing compliance information to their customers and the public, member companies have found the Internet to be an excellent medium. Many members have posted compliance information on their own Web sites and the FDA's Web site. Examples of HIMA member company actions in this area include, but are not limited to, the following.

- At least one company with a diverse range of products has posted pages of detailed charts on its Web site containing compliance information about each of its devices.
- Another company has posted a short list of only those devices it manufactures that still do not conform to Year 2000 compliance standards.
- A third company has posted compliance information about its products on its Web site and is soliciting e-mail inquiries from its customers.
- Other members have gone beyond the Internet and contacted their customers directly regarding the compliance status of their products. In addition, some have established toll-free telephone numbers for their customers inquiries regarding Year 2000 issues.
- A number of small companies, founded within the last ten years, say that they anticipated the Year 2000 problem and have been compliant from their first day of operation. Similarly, many larger, established companies have designed recent products to be Year 2000 compliant.
- Many companies have developed internal, cross-functional teams or program offices to address Year 2000 product compatibility issues.

As you can see, there is no one way that is the right way for medical device companies to get the information out.

A number of groups, including the National Patient Safety Partnership and its members, including the Department of Veterans Affairs, the American Medical Association and the American Hospital Association, have suggested that a central clearinghouse be established to make Year 2000 information publicly available. I would like to emphasize that making timely compliance information available to the people who need it is also our industry's goal, and we share the concerns of these organizations. HIMA believes that access to such information through appropriate mechanisms is an integral part of the solution to the overall Year 2000 problem.

Mr. Chairman, you have our strong commitment here today to continue to work with other concerned organizations and the FDA in making Year 2000-compliance information publicly available in appropriate formats. I want to assure the concerned groups and individuals that have spoken out on Year 2000 safety issues that we understand and welcome your keen interest in this area, and we share your sense of urgency. Simply put, we must work together.

CONCLUSION

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

We are confident that by working together, we can achieve an appropriate and mutually satisfactory format or formats for information dissemination. And we will continue our intensive efforts to ensure that on January 1 in the Year 2000, the medical technologies on which millions of patients depend continue to function safe-

ly and effectively. We want the patients that we serve as an industry to have that confidence in us. And we will do whatever we must to deserve their trust.

Thank you.

RESPONSES OF MR. MOJDEH TO QUESTIONS SUBMITTED BY CHAIRMAN BENNETT

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Question 1. [Dearth of information on Y2K compliance data for biomedical devices]

Mr. Mojdeh, the Committee has explored many publicly posted data 2YK compliance for biomedical devices, and with a few exceptions, finds it seriously wanting. You indicate in your testimony that the Health Industry Manufacturers Association wants to seek a solution to the Y2K problems and assist all parties that use biomedical devices. The American Hospital Association and the Veterans Administration have demonstrated a willingness today to work with national Y2K clearing house on biomedical devices.

—Will HIMA take the lead in promptly establishing and operating such a national clearinghouse for the health care industry?

Answer. HIMA will take the lead in meeting with concerned parties, including, but not limited to, the National Patient Safety Partnership (NPSP), National Electrical Manufacturers Association, (NEMA) and the Food and Drug Administration (FDA) to develop cooperatively the most efficient mechanism for making Y2K compliance information available publicly. The NPSP includes, among others, the Department of Veterans Affairs (DVA), American Nurses Association (ANA), American Medical Association (AMA), Association of American Medical Colleges (AAMC), and the Joint Commission on the Accreditation of Hospital Organizations (JCAHO). Furthermore, the Association believes that Y2K compliance is of the highest priority and has sent the enclosed memo to all of our members and to approximately 6,000 non-members strongly encouraging them to provide information on the Y2K status of their products via the FDA Website and other means. (Attachment A)

Question 2a. [Patient protection versus corporate protection]

Mr. Mojdeh, President Clinton proposed, and this Committee supports safe harbor legislation on limiting corporate liability in sharing Y2K data. However, in your testimony you say such legislation would not be useful to HIMA.

—Why does HIMA take the position that the sharing of Y2K data between companies is not useful in solving the problem when every health care industry user tells the Committee it is critical?

Answer. The medical device industry is unusually diverse. Medical devices using software range from electronic thermometers that calculate internal body temperature based on infrared radiation to MRIs and CT scanners. Because of this diversity of products and the large number of medical device companies (several thousand), the software used in many, if not most, devices is unique to the device. This uniqueness raises two separate issues:

—Y2K solutions effective for one manufacturer may simply not be useful to another manufacturer. Although their devices may appear similar, and even belonging to the same generic family (i.e., be described with the same general name), the software driving the devices may not use the same algorithms or structure. Because of these differing functional modes, it would be difficult to determine which manufacturer's information would be valuable to which other manufacturer. When one considers that each manufacturer is generally the leading expert on the software in its own devices, the best investment for each manufacturer will be to work directly on solving its own software problems.

—As described in the previous paragraph, much software is unique to the device in which it is used; therefore, much of it is regarded as proprietary commercial information that is a "trade secret." To share software-specific Y2K "solutions" could well require manufacturers also to share some of this proprietary information. Because this is a highly competitive industry, we foresee the sharing of any proprietary information as problematic.

Question 2b. Is HIMA satisfied with the 10 percent response to the FDA call for biomedical manufacturers to disclose Y2K problems and solutions? If not what has HIMA done about getting the response rate up to 90 percent to 100 percent on devices where failure can have serious consequences?

Answer. As we noted in our answer to Question 1, we have communicated not only with our members, but we have gone beyond our membership to communicate our strong recommendation that medical device companies, including those compa-

nies whose products are not affected by Y2K, share information via the FDA Website.

Question 3. [Y2K Contingency Plans for HIMA to produce and publish]

Mr. Mojdeh, your association represents manufacturers that produce millions of biomedical devices annually. What kind of contingency plans do HIMA member companies have to provide emergency assistance to user organizations when Y2K problems occur on January 1, 2000?

Answer. HIMA agrees that contingency planning for companies to provide assistance to customers in the event that problems arise is an important concept for manufacturers to consider in their Y2K planning. HIMA will communicate this message to its members.

Question 4a. [HIMA Letter Discouraging Cooperation with FDA]

Mr. Mojdeh, HIMA in an April 1, 1998 letter to Kevin Thurm, Deputy Secretary of HHS, seemed to be discouraging its members from cooperating with FDA's efforts to build a database of Year 2000 information on big-medical equipment.

—Why did HIMA take this position?

Answer. The April letter was specifically directed to HHS. HIMA was concerned that the wording of the January 23, 1998 letter from HHS to medical device manufacturers contained an implied threat of regulatory action against companies who did not respond to the request for information for the FDA Website. In retrospect, it is probably the case that the language in both letters was unfortunate and that it produced more misunderstanding than cooperation. We have subsequently communicated our willingness to work with FDA and our members to make more Y2K information available on the FDA Website. This communication is attachment B.

HIMA encourages its members to communicate to users and the interested public information regarding the Y2K status of their products, even those products that are not subject to the problem. We also believe that the FDA Website may prove to be the most effective central communications vehicle for this purpose.

Question 4b. Doesn't HIMA believe that it would be more efficient and time saving to share Y2K data on medical devices rather than have each customer request the same information in writing over and over again?

Answer 4. We support the Committee's interest in efficiency. We believe that the most efficient approach is for the interested parties, particularly the NPSP, HIMA, and FDA to meet and develop an appropriate information set that will address their concerns adequately. These data can then be transferred through a variety of means, including the FDA Website.

PRIORITY MEMORANDUM

To: HIMA members.
 From: Alan H. Magazine.
 Date: *August 3, 1998.*
 Subject: The Year 2000 Computer Problem

Congress has delivered a message to our industry that we have heard loud and clear. At a hearing July 23, Senators Robert Bennett (R-UT) and Christopher Dodd (D-CT) spoke out strongly regarding their concern that our industry should be doing more to address patient safety issues arising from the year 2000 computer problem. Senator Bennett, who is chairman of the Senate special committee with jurisdiction on this issue, charged that medical device companies are refusing to acknowledge computer problems associated with the century change because of their product liability concerns.

Senator Dodd was equally direct. "I am deeply disturbed by the fact that instead of taking steps to deal with this problem, the medical device industry, as a whole, seems to be exacerbating the problem by refusing to provide information, either to the FDA, which regulates device safety, or to the hospitals and clinics, which use the devices every day," he said. During the hearing, Senator Dodd indicated his intent to go to the Senate floor to publicize the names of companies that failed to respond to efforts by the FDA and the Department of Veterans Affairs to collect information on their year 2000 compliance status. Of special concern to the senators was the industry's poor response to recent surveys by the FDA and the Department of Veterans Affairs.

In a subsequent July 29 meeting requested by Senators Bennett and Dodd, Senator Dodd indicated that he has received a list from FDA and the VA of companies that have failed to reply to their inquiries. In response to a HIMA action agenda (see page two of this memo) he indicated that he would delay introduction of legislation requiring disclosure by device companies. He also said he would delay the pub-

lic announcement of the names of companies that have failed to reply to the FDA and the VA. However, he refused to commit to how long such a delay would last.

THE CHALLENGE TO INDUSTRY

These are respected lawmakers who have shown their friendship to our industry on several occasions. Their concern is real, and it represents an immediate challenge and an urgent call to action for our industry.

As the year 2000 approaches, we are seeing increased attention by health care organizations, medical professionals, patients, and members of Congress to the possibility that medical devices that are critical to the health and lives of countless patients might malfunction because of flawed computer programming. For example, at a recent press conference, the National Patient Safety Partnership (NPSP), a coalition that includes, among others, the American Medical Association, the American Hospital Association, and the Veterans Affairs Department, called for creation of a national clearinghouse for medical device compliance information.

In response to this increased scrutiny of our industry, our answer must be two-fold:

INDUSTRY'S RESPONSE

First, we must make certain that medical devices are year 2000 compliant. We must ensure that on January 1 in the year 2000, the medical technologies on which millions of patients depend continue to function safely and effectively. We want the patients that we serve as an industry to have confidence in us, and we must do whatever is necessary to preserve their trust.

Second, we must make every effort to ensure that information about the year 2000 compliance status of medical devices is available to the health care providers who use our products. Our industry has a fundamental responsibility to provide information about the safety of medical technology that people rely upon. It is natural that patients and medical professionals have questions about the year 2000 status of essential medical technology, and we must do our best to provide answers in a forthright and timely manner.

HIMA'S YEAR 2000 PROGRAM

HIMA is acting immediately to:

- Organize a working group that will advise on and oversee the Association's efforts to successfully address year 2000 issues.
- Initiate a meeting with representatives of the National Safety Prevention Coalition, its constituent groups (including the American Medical Association, American Hospital Association, and the U.S. Department of Veterans Affairs), and the FDA to discuss a mutually satisfactory and appropriate mechanism for dissemination of company compliance information.
- Work closely with lawmakers on Capitol Hill to apprise them of our industry's progress.

FDA'S ROLE

The FDA has defined in great detail its year 2000 compliance expectations for the industry in several documents. The FDA expects manufacturers to examine all their software-driven processes and products to determine whether they are date dependent, and if they are, they must determine whether the date dependency is sensitive to the century change. The relevant FDA documents include:

- A letter to manufacturers, dated June 25, 1997, posted on the FDA's Web site at www.fda.gov/cdrh/yr2000.html.
- Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem*, posted on the FDA's Web site at www.fda.gov/cdrh/yr2000/y2kguide.html.
- Information Paper on FDA Activities Related to the Year 2000 Date Problem and Medical Devices*, posted at www.fda.gov/cdrh/yr2000/ipyr2000.html.

In hearings before Congress, and in its communications with industry, the FDA has invited the industry to cooperatively address the challenges of year 2000 compliance and information dissemination. Many member companies are implementing programs to ensure that they are year 2000 compliant. Many have dedicated sections of their company Web sites to the disclosure of compliance information about their products, while others have been contacting their customers directly about their year 2000 status. For those devices that aren't affected by year 2000 problems but whose users might have concerns, it is important that manufacturers reassure

them of the continued performance and safety of their devices. In addition to these efforts, HIMA members are strongly encouraged to consider the benefits of utilizing the FDA World Wide Web site for dissemination of compliance information about their products.

As you may recall, the Department of Health and Human Services sent a letter to device manufacturers on January 21, 1998, requesting information about products affected by the year 2000 date problem. A second, follow-up letter was mailed by CDRH in June. These letters outlined an opportunity for manufacturers to identify specific products that will be affected and to share this information with interested parties through the FDA's World Wide Web site. Instructions about how to use the FDA Web site to disseminate your company's year 2000 compliance status can be found at www.fda.gov/cdrh/yr2000/year2000.html. Company information that is placed on the FDA Web site will assist health care facilities and medical professionals in identifying affected products and in planning and taking remedial actions. Companies may submit information that none of their products are affected or information describing all affected products. Alternatively, a company may also submit a Web address for the compliance information that it maintains on its own Web site. The information may be submitted electronically or in writing.

Please do not hesitate to contact me with any questions or concerns you may have regarding year 2000 compliance. Members also can contact Bernie Liebler at HIMA for additional information at (202) 434-7230 or blieber@himanet.com.

We will continue to apprise you of developments as they occur.

JULY 23, 1998.

Mr. KEVIN THURM,
Deputy Secretary, Health and Human Services,
Hubert H. Humphrey Building,
200 Independence Avenue, SW Room 606G,
Washington, DC.

DEAR MR. THURM: I am writing in response to your reply to my April letter. I appreciate your efforts to clarify the Department's intent vis-a-vis its request for industry input to the FDA Year 2000 Website. I believe that since I wrote that first letter there has been much movement to align the industry and the agency more closely on this issue.

Many HIMA companies are now using the World Wide Web to provide information to their customers and as an interactive medium for providing such information. For example, many company Websites contain a great deal of detailed information regarding the Year 2000 Compliance status of that company's products. Furthermore, a number of HIMA member companies have provided information for the FDA Year 2000 Website. Some have done both. However, for some other companies, direct correspondence with their customers may be the most efficient and cost-effective means of dealing with the issue. We continue to maintain that the important thing is for the right people to get the right information on time. We think that each company is the best judge of which method of communication best fits its operations.

HIMA believes that maintaining the safe functioning of medical devices through and beyond January 1, 2000 is extremely important. HIMA members are also committed to providing timely information to their customers and device users regarding that functionality. These ideas are described well in the attachments to this letter: *HIMA Testimony before the Senate Special Committee on the Year 2000* and a HIMA paper entitled, *Medical Devices and the Year 2000*.

In the next few months, I expect the device industry to work with FDA and other interested groups to define more clearly the needs of all parties regarding Year 2000 Compliance information. If we work together, I anticipate that the appropriate information will reach those who need it when they need it.

If you would like any further information, please contact either me or Bernie Liebler, who is handling this issue. You can reach Mr. Liebler at 202-434-7230 or blieber@himanet.com.

Sincerely,

JAMES S. BENSON.

PREPARED STATEMENT OF DANIEL S. NUTKIS

INTRODUCTION

Mr. Chairman, my name is Daniel Nutkis. I am president and director of research for Odin Group, a research and advisory service dedicated to information technology issues in the health care industry. Our members include distinguished organizations across all segments of the industry, including health care providers, payors, pharmaceutical manufacturers and distributors. This unique make-up allows Odin to act as an industry collaborative, sponsored and driven by our members to tackle the most critical information technology issues facing today's leading health care organizations.

Earlier this year, because of concerns raised by members, Odin Group started a process of examination not unlike the process this Senate committee is going through now. Our members were becoming increasingly concerned about:

- the heavy interdependence of a wide range of partners;
- the fact that, consolidations notwithstanding, small players still represent the bulk of the entities in today's health care industry;
- the resource pressures that affect many of those players today, along with the overall lack of sophistication with regard to Year 2000 issues;
- and the need to develop comprehensive contingency plans and to ease public concerns over the level of preparedness.

I'm not saying that anyone will entirely escape disruptions within their own organizations, no matter how well prepared they are. But the more trading partners you have, the greater the likelihood that you will also feel the disruptions of other organizations. For these reasons, Odin Group initiated the VitalSigns 2000 project. Its ultimate objectives are to help the industry understand these possible disruptions; to encourage development of contingency plans by individual organizations and the industry at large; and to ensure the continuity of patient care.

HOW COMPLEXITY INCREASES RISK OF FAILURE

While many other parties and studies are focusing on one segment of the health care industry, VitalSigns 2000 is focused on the bigger picture. Let me show you one of the models that we are using to make the complexity of this industry more understandable and more manageable.

The first chart appended to my testimony is an interaction matrix. Down the vertical axis of the matrix, you will see that the players are categorized into five broad domains.

- First, *customers*.—This means patients, of course, but customers can also be plan sponsors who buy health care services for their employees or members.
- Providers*.—including doctors, clinics, institutions providing acute or ambulatory care, laboratories, testing services, blood banks and pharmacies.
- Suppliers*.—pharmaceutical and life sciences companies, medical device manufacturers, upstream partners who supply the suppliers, and downstream partners who distribute medicine and equipment to the point of care.
- Payors*.—including insurance companies and managed care organizations.
- And *regulatory bodies*, state and federal.

Now, let's overlay this list of domains with a variety of processes that require intense interaction to deliver patient services. The matrix shows these processes along the horizontal axis, grouped into four "value chains."

- Care delivery* encompasses processes that the patient experiences along the care continuum, as well as the management of clinical trial data and adverse event reporting.
- Customer management* includes all elements of customer service and accounting, managing benefit plans and formularies, sales and marketing.
- Supply chain management* covers the business processes to receive orders, fulfill orders, administer payment and manage the next level of suppliers.
- Provider management* includes claims and reimbursement, and internal management processes.

SOME LIKELY FAILURES, AND PATIENT IMPACT

The point of this interdependence model is to underscore how complexity drives up risk. Organizations can better handle failures if they have prepared for them—which is why some companies in this industry are spending half a billion dollars to get ready for Year 2000. But a much greater problem is the failure you haven't thought about until your beeper goes off—and that's assuming that the beeper does go off!

When an individual organization has Year 2000 failures for which it hasn't prepared, it will negatively impact its trading partners. Those partners will then be less able to support the next level of trading partners. And on it goes, with each failure piling on top of the last, and everything ultimately piling onto the patient.

Let's take one example from one value chain—the case of a payor organization serving 2,000 group plans, each of which has an average of 500 employees or dependents. That's one million covered lives, and at least one billion dollars worth of health care services. When the system malfunctions, plan sponsors start seeing inaccurate bills and premium notices. Payments may be lost, or made for services that are not covered in the plan. The provider starts seeing a flurry of eligibility denials, claim denials, and payment delays. Doctors are even unable to make specialist referrals.

Meanwhile, failures in their own offices add to the snarls, as doctors have trouble accessing patient records and scheduling appointments. The actual time the doctor can spend with patients drops from five hours a day to perhaps two. Frustrated patients start wondering where else they can go for medical services, but health care isn't as portable as it used to be. Even if patients go to the emergency room, how are they going to verify eligibility for Medicare or any other benefits program if the payor's systems aren't working?

Health care systems deal with failures every day. But what happens when they have to deal with more failures in one day than they have ever known before?

TRIAGE AND CONTINGENCY PLANNING

By now, it is getting clear:

- why an interdependent health care system requires an integrated approach to the Year 2000 problem;
- why the central themes of the VitalSigns 2000 initiative are “triage” and “contingency planning.”

The health care industry's insurance policy against Year 2000 collapse must start with a proper assessment of which components represent the greatest risk to the system overall. How critical is each component, and how well prepared? Which failures could cause widespread damage to the overall health care system? What are the financial and operational issues, as well as the technological ones, of each contingency planning scenario?

Odin Group has spent months understanding the complexities and interrelationships I have just described, and the impact of various failures and scenarios on individual organizations and the industry as a whole. We have developed models like the one I showed you a moment ago. Now, we are seeking to develop more information through a survey involving all parts of the health care industry.

After Odin researchers have digested this information, we will convene working groups to conduct industry-wide contingency planning. Together we will answer the toughest “what if” and “what then” questions. Researchers, advisors and industry members will work together to identify, recommend and test industry plans.

Finally, in October, we will convene a gathering of CEO's to make sure that the top leadership of the industry fully shares an understanding of what must be done to protect health care in America.

Contingency planning must be part of a comprehensive approach to Year 2000. Let me show you a graphic that depicts the methodology used by SmithKline Beecham. In the center circle are the internal systems. Around that is a second ring representing the infrastructure—site facilities, telecommunications, lab equipment and manufacturing process control. In the next circle are end-user systems, on the desks of tens of thousands of employees. But even if you've got all that right, you're not going to make it through January 2000 unless you consider external relationships with customers, suppliers, and anyone you do business with. In this particular case, the company even considers its involvement in industry groups to be part of the Year 2000 effort.

This methodology could come from any number of major providers, payors, pharmaceutical manufacturers or distributors—Aetna, UPMC Health System in Pittsburgh, Eli Lilly and Company, or Columbia/HCA Healthcare Corporation. My point is simple. If these companies can do it, so can every player in this industry. Comprehensive Year 2000 methodology has to include:

- Awareness of the problem.
- Assessment of what's required to fix a specific system or device.
- Prioritization and triage of the most critical issues.
- Remediation—implementing fixes recommended by the vendor, reprogramming, or replacing the system.
- Testing with suppliers, payors, providers and regulators.

—And contingency planning.

CALL TO ACTION

What can this committee do to help?

The health care industry, like most others, is greatly concerned with issues of liability concerning Year 2000 cooperative efforts. It encompasses antitrust concerns, to be sure, as to whether certain information can be legally shared. But it also has to do with whether a company creates new liabilities for itself by sharing information which later proves to be wrong or even damaging.

President Clinton's proposal for a "good Samaritan" law to cover such situations is on the right track. Odin Group members would be pleased to work with their Senators and this committee to make sure the provisions of such a law are appropriate for and helpful to the health care industry. Clearly, it is time for all companies to participate in sharing and joint planning in every way, putting all possible resources against this problem.

I would also ask this committee to be watchful of regulatory initiatives that add complexity and drain resources from Year 2000 efforts. This is not just another case of industry complaining. The facts are that, in an industry as complex as this, every additional Year 2000 failure has the potential to make the situation exponentially worse. And every major new regulatory requirement adds to the complexity of the information systems work being done over the next 18 months. This Committee, the US Congress, and for that matter, the entire government cannot do this job for industry. But you can raise awareness. Mr. Chairman, I would like to officially invite you and your esteemed colleagues on this committee to attend the VitalSigns 2000 CEO conference in October.

Odin Group's approach is to leverage the strengths of the leaders who are preparing well for the Year 2000, and to try to make sure that everyone in the health care industry has prepared as best they can. Through VitalSigns 2000, we will produce specific recommendations—regarding contingency planning, operational and financial issues, industry-wide preparedness and testing, stockpiling key materials and devices, and regulatory support.

There are no excuses for any player in this industry not having a good plan. And there are no excuses for the industry not having a contingency plan that reaches across the entire expanse of health care in America.

VitalSigns® 2000 Interaction Matrix

The shaded cells identify the places where processes of one health care trading partner directly impact the processes of other trading partners, and represent interdependencies for which year 2000 problems may be critical.

Value Chain Component:	Customer Management						Supply Chain Management						Care Delivery						Provider Mgmt.	
Process	Sales & Marketing	Benefit Plans/Formulary	Group Administration	Membership Support	Cust. Svc./Account Mgmt.	Regulatory Reporting	Order Initiation	Order Fulfillment	Production Management	Payment Administration	Supplier Management	Care Management	Care Delivery	Clinical Resource Mgmt.	Clinical Trial Management	Clinical Info. Mgmt. & Reporting	Event Reporting/Recall	Provider Management	Claims & Reimbursement	
Trading Partner																				
Providers																				
Acute Care Institutions	●				●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Ambulatory Care Providers	●				●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Physicians/Clinics/PPM's	●				●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Ancillary Providers					●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Integrated Delivery Systems	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Payors																				
Indemnity Insurers	●	●	●	●	●	●				●		●	●	●	●	●		●	●	
Managed Care Insurers	●	●	●	●	●	●				●		●	●	●	●	●		●	●	
Government Payors		●		●	●	●				●		●	●	●	●	●		●	●	
Suppliers																				
Life Science & Pharmas	●	●		●	●	●	●	●	●	●	●	●			●	●	●		●	
CROs					●	●	●	●	●	●	●			●	●	●	●		●	
Information Exchange Cos.	●			●	●	●		●	●	●	●	●			●	●	●		●	
Other Suppliers & Mfg.	●				●	●	●	●	●	●	●				●	●	●			
Wholesalers/Distributors	●			●	●	●	●	●	●	●	●				●	●	●			
Customers																				
Employers	●																		●	
Members	●																		●	
Non-Member Customers	●																		●	
Regulatory Bodies																				
HCFA		●		●	●	●					●								●	
FDA	●				●	●	●	●	●	●	●		●		●	●	●		●	
State Agencies		●		●	●	●	●	●	●	●	●		●							

MODEL OVERVIEW—KEY PROCESSES

Care Delivery

Care Management

- Health status assessment
- Population segmentation
- Disease management
- Wellness & prevention program development
- Member/patient care planning
- Demand management

Care Delivery

- Enterprise-wide scheduling
- Diagnostics
- Treatments, therapies and interventions
- Charting/documentation

—Order management

Clinical Resource Management

- Precertification
- Preauthorization
- Utilization tracking

Clinical Information Mgmt. & Reporting

- Clinical information capture
- Clinical information presentation
- Clinical results/outcomes analysis
- Outcomes reporting

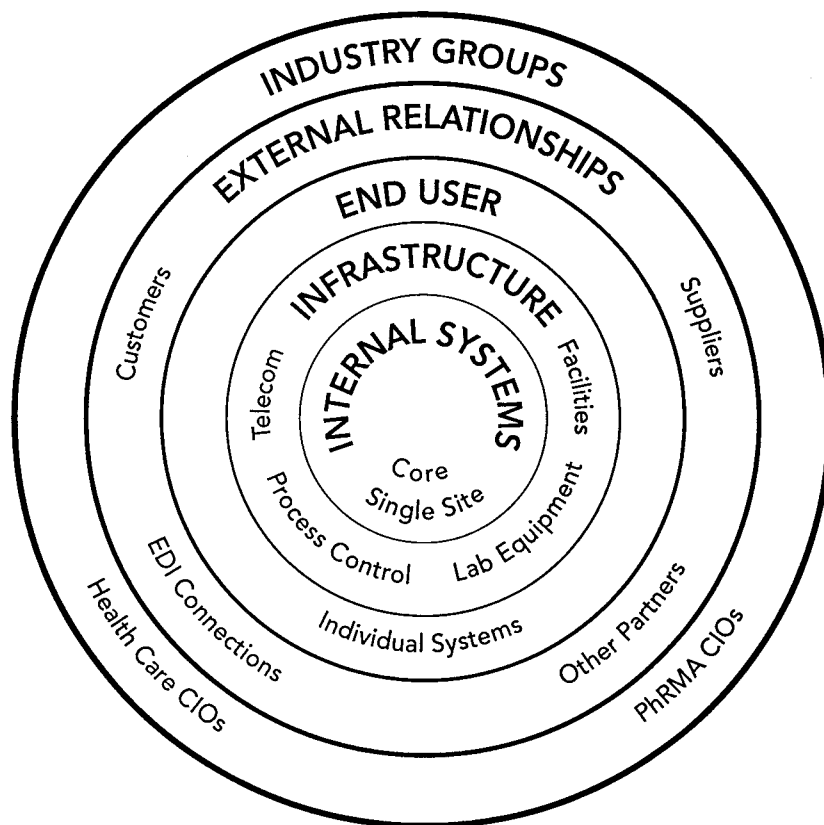
Clinical Trial Management

- Clinical information capture (case report forms)
- Clinical data scrubbing
- CANDA compilation

- Statistical analysis
- Event Reporting/Recalls
 - Adverse reaction/event monitoring (Phase 4)
 - Analysis of events and adverse reactions
 - FDA reporting
 - Lot control and recall of product
- Supply Chain Management**
 - Order Initiation
 - Order submission
 - Order verification
 - Order tracking
 - Order pricing
 - Order Fulfillment
 - Forecasting
 - Order processing
 - Special packaging
 - Distribution and logistics
 - Production Management
 - MRP/inventory management
 - Production
 - Process control
 - Laboratory information management
 - Quality assurance
 - Payment Administration
 - Billing/AR/AP
 - Payment receipt and posting
 - Collections
 - Cash management
 - Chargebacks and rebates
 - Contractual allowances
 - General pricing and discounts
 - Supplier Management
 - Supplier evaluation
 - Supplier certification
 - Contracting
- Provider/Network Management**
 - Provider Management
 - Creation and maintenance of provider files
 - Provider credentialing
 - Provider profiling
 - Network development and management
 - Provider contracting
 - Creation and maintenance of risk pools
 - Provider and network management reporting
 - Claims and Reimbursement
 - Claims entry
 - Claims interface support
- Claims adjudication
- Benefits coordination
- Claims auditing
- Printing and mailing of EOB's
- Management reporting
- Chargeback reconciliation
- Rebate validation
- Customer Management**
 - Sales and Marketing
 - Health plan sales
 - Market research
 - Advertising
 - Product development
 - Broker support
 - Contracting
 - Actuarial/underwriting/pricing
 - Benefit Plans/Formulary
 - Establishment of benefits
 - Plan maintenance
 - Formulary management
 - Group Administration
 - Establishment of group contracts
 - Provision modification
 - Demographic information maintenance
 - Direct pay contract support
 - Administration of flexible benefit plans
 - Broker commission management
 - Premium billing
 - Third-party payments
 - Membership Support
 - Member enrollment and file maintenance
 - Eligibility tracking
 - Processing of terminations and conversions
 - Membership communications
 - ID card generation and mailing
 - Health status assessment data maintenance
 - Member data analysis and reporting
 - Plan participation
 - Customer Service/Account Management
 - Customer inquiry, analysis, and reports
 - Customer correspondence
 - On-line customer assistance
 - Customer satisfaction surveys
 - Regulatory Reporting
 - Regulatory and legal affairs
 - Compliance reporting

Comprehensive Year 2000 Methodology

Internal/External



Milestones tracked by Target T

PREPARED STATEMENT OF DONALD J. PALMISANO

RE: IMPACT OF THE YEAR 2000 PROBLEM ON PHYSICIAN PRACTICES

Mr. Chairman and members of the Committee, my name is Donald J. Palmisano, MD, JD. I am a member of the Board of Trustees of the American Medical Association (AMA), a Board of Directors member of the National Patient Safety Foundation (NPSF) and the Chair of the Development Committee for the same foundation. I also practice vascular and general surgery in New Orleans, Louisiana. On behalf of the three hundred thousand physician and medical student members of the AMA, I appreciate the chance to comment on the issue of the year 2000 problem and its anticipated effect on physicians.

INTRODUCTION

As all of us know, the year 2000 problem exists because a vast number of computer systems and software were created to read only the last two digits of the

“year” field of date data, while the first two digits were implied to be “19.” When data requires the entry of a date in or after the year 2000, these systems and software will be incapable of processing the data properly.

Currently, virtually all industries are in some manner dependent on information technology, and the medical industry is no exception. As technology advances and its contributions mount, that dependency and our consequent vulnerability become more and more evident. The year 2000 problem is revealing to us that vulnerability.

By the nature of its work, the medical industry relies tremendously on technology—on computer systems, both hardware and software, as well as medical devices that have embedded microchips. Virtually every aspect of the medical profession depends in some way on these systems—for treating patients, handling administrative office functions, and conducting transactions. For some industries, software glitches or even system failures, can, at best, cause inconvenience, and at worst, can cripple the business. In medicine, those same software or systems malfunctions can, much more seriously, cause patient injuries and deaths.

POTENTIAL IMPACT ON THE HEALTH CARE SECTOR

The medical profession and the health care industry, in general, rely on information technology for a broad spectrum of services and products, from electronic data interchange for patient records, medical research, and billing, to medical devices in the surgical theater. Clinical operations, patient care, business operations, communications, and even building maintenance are all affected by this technology.

PATIENT CARE

Providing medical care frequently requires the ability to access, monitor, and interpret information. Some applications include imaging, laboratory, pharmacy, and respiratory devices, cardiology measurement and support devices, telemetry and endoscopy equipment and IV pumps, operating room equipment, and emergency room devices. Nearly every piece of medical monitoring and regulating equipment relies in some way on information technology. Physicians and other health care providers must be able to rely implicitly on the medical equipment they use. Unreliable equipment cannot be used, because virtually any malfunction could have disastrous consequences.

Assessing the current level of risk attributable specifically to the year 2000 problem within the patient care setting remains problematic. We do know, however, that the risk is present and it is real. Consider for a minute what would occur if a monitor failed to sound an alarm when a patient's heart stopped beating. Or if a respirator delivered “unscheduled breaths” to a respirator-dependent patient. Or even if a digital display were to attribute the name of one patient to medical data from another patient. Are these scenarios hypothetical, based on conjecture? No. Software problems have caused each one of these medical devices to malfunction with potentially fatal consequences.¹ The potential danger is present.

The risk is also real. Since 1986, the FDA has received 450 reports identifying software defects—not related to the year 2000—in medical devices. Consider one instance—when software error caused a radiation machine to deliver excessive doses to six cancer patients; for three of them the software error was fatal.² We can anticipate that, left unresolved, medical device software malfunctions due to the millennium bug would be prevalent and could be serious.

Medical device manufacturers must immediately disclose to the public whether their products are Y2K compliant. Physicians and other health care providers do not have the expertise or resources to determine reliably whether the medical equipment they possess will function properly in the year 2000. Only the manufacturers have the necessary in-depth knowledge of the devices they have sold.

Nevertheless, medical device manufacturers have not always been willing to assist end-users in determining whether their products are year 2000 compliant. Earlier this year, FDA spokesperson Sharon Snider said that the agency has only received Y2K compliance information from about 11 percent of the 16,000 medical devices manufacturers worldwide. Even when vendors do respond, their responses have frequently not been helpful. The Department of Veterans Affairs recently reported that of more than 1,600 medical device manufacturers it has contacted in the past year, 233 manufacturers did not even reply and another 187 vendors said they were not responsible for alterations because they had merged, were purchased by another company, or were no longer in business. One hundred two companies reported a

¹ Anthes, Gary H., “Killer Apps: People are Being Killed and Injured by Software and Embedded Systems,” *Computerworld*, July 7, 1997.

² *Id.*

total of 673 models that are not compliant but should be repaired or updated this year.³ As an aside, we applaud the federal government's initiative in seeking to obtain Y2K information from manufacturers.

ADMINISTRATIVE

Many physicians and medical centers are also increasingly relying on information systems for conducting medical transactions, such as communicating referrals and electronically transmitting prescriptions, as well as maintaining medical records. Many physician and medical center networks have even begun creating large clinical data repositories and master person indices to maintain, consolidate and manipulate clinical information, to increase efficiency and ultimately to improve patient care. If these information systems malfunction, critical data may be lost, or worse—unintentionally and incorrectly modified. Even an inability to access critical data when needed can seriously jeopardize patient safety.

Other administrative aspects of the Y2K problem involve Medicare coding and billing transactions. HCFA had issued instructions through its contractors to physicians and other health care professionals that until just last week would have required that electronic and paper claims must meet Y2K compliance criteria by October 1, 1998. We were particularly pleased that HCFA last week announced that it would provide all health care providers an additional three months (until January 1, 1999) to alter their claims processing data formats to accommodate the necessary eight digit birth date. Additional time will apparently be granted physicians by HCFA for reasonable good faith exceptions. Well in advance of the year 2000, both physicians and HCFA will need to make sure that their respective data processing systems are functioning properly to assure the orderly and timely processing of Medicare claims data.

Medicare administrative issues are of critical importance to patients, physicians, and other health care professionals. In one scenario that took place in my home state of Louisiana, Arkansas Blue Cross & Blue Shield, the Medicare claims processor for Louisiana, implemented a new computer system—intended to be Y2K compliant—to handle physicians' Medicare claims. Although physicians were warned in advance that the implementation might result in payment delays of a couple of weeks, implementation problems resulted in significantly longer delays. For many physicians, this became a real crisis. Physicians who were treating significant numbers of Medicare patients immediately felt significant financial pressure and had to scramble to cover payroll and purchase necessary supplies.⁴

We support and are encouraging physicians to address the myriad challenges the Y2K dilemma poses for their patients and their practices, which include claims submission requirements. We also believe that HCFA should lead by example and have its systems in compliance as quickly as possible to allow for adequate parallel testing with physician claims submission software and other health care professionals well in advance of the year 2000. Such testing would allow for further systems refinements, if necessary.

REIMBURSEMENT AND IMPLEMENTATION OF BBA

To shore up its operations, HCFA has stated that it will concentrate on fixing its internal computers and systems. As a result, it has decided not to implement some changes required under the Balanced Budget Act (BBA) of 1997 and it plans to postpone physicians' payment updates from January 1, 2000, to about April 1, 2000.

In the AMA's view, the Y2K problem is and has been an identifiable and solvable problem. Society has known for many years that the date problem was coming and that individuals and institutions needed to take remedial steps to address the problem. There is no justification for creating a situation where physicians, hospitals and other providers now are being asked to pay for government's mistakes by accepting a delay in their year 2000 payment updates.

HCFA has indicated to the AMA that the delay in making the payment updates is not being done to save money for the Medicare Trust Funds. In addition, the agency has said that the eventual payment updates will be done in such a way as to fairly reimburse physicians for the payment update they should have received. In other words, the updates will be adjusted so that total expenditures in the year 2000 on physician services are no different than if the updates had occurred on January 1.

³Morrissey, John, and Weissenstein, Eric, "What's Bugging Providers," *Modern Healthcare*, July 13, 1998, p. 14.

⁴"Year 2000 Bug Bites Doctors; Glitch Stymies Payments for Medicare Work," *The Times-Picayune*, June 6, 1998, page C1.

We are pleased that HCFA has indicated a willingness to work with us on this issue. But we have grave concerns about the agency's ability to devise a solution that is equitable and acceptable to all physicians.

Determining physician updates each year is complicated by the fact that physicians, unlike any other providers, are subject to an annual expenditure target or sustainable growth rate (SGR). Under the SGR, updates in future years are influenced by whether actual spending on physician services comes in over or under the target. Delaying the physician updates thus will influence physicians' ability to live within the targets and could affect future updates. If updates are postponed, HCFA therefore must consider the impact on the SGR to ensure that delays do not result in unintended penalties in years after 2000.

Also, as it turns out, the year 2000 is a critical year for physicians because several important BBA changes are supposed to be made in the resource-based relative value scale (RBRVS) that Medicare uses to determine physician payments. This relative value scale is comprised of three components: work, practice expense, and malpractice expense. Two of the three—practice expense and malpractice—are due to undergo Congressionally-mandated modifications in the year 2000.

In general, the practice expense changes will benefit primary care physicians at the expense of surgeons and other procedurally-oriented specialties. Malpractice changes, to some modest degree, would offset the practice expense redistributions. To now delay one or both of these changes will have different consequences for different medical specialties and could put HCFA at the eye of a storm that might have been avoided with proper preparation.

To make matters worse, we are also concerned that delays in Medicare's reimbursement updates could have consequences far beyond the Medicare program. Many private insurers and state Medicaid agencies base their fee-for-service payment systems on Medicare's RBRVS. Delays in reimbursement updates caused by HCFA may very well lead other non-Federal payers to follow Medicare's lead, resulting in a much broader than expected impact on physicians.

CURRENT LEVEL OF PREPAREDNESS

Assessing the status of the year 2000 problem is difficult not only because the inventory of the information systems and equipment that will be affected is far from complete, but also because the consequences of noncompliance for each system remain unclear. Nevertheless, if the studies are correct, malfunctions in noncompliant systems will occur and equipment failures can surely be anticipated. The analyses and surveys that have been conducted present a rather bleak picture for the health care industry in general, and physicians' practices in particular.

The GartnerGroup, for instance, based on its surveys and studies has concluded that the year 2000 problem's "effect on health care will be particularly traumatic * * * [l]ives and health will be at increased risk. Medical devices may cease to function."⁵ In its report, it noted that most hospitals have a few thousand medical devices with microcontroller chips, and larger hospital networks and integrated delivery systems have tens of thousands of devices. Based on early testing, the GartnerGroup found that although only 0.5–2.5 percent of medical devices have a year 2000 problem, approximately 5 percent of health care organizations will not locate all the noncompliant devices in time.⁶ It also found that most of these organizations do not have the resources or the expertise to test these devices properly and will have to rely on the device manufacturers for assistance.⁷

As a general assessment, the GartnerGroup concluded that based on a survey of 15,000 companies in 87 countries, the health care industry remains far behind other industries in its exposure to the year 2000 problem.⁸ Within the health care industry, the subgroups which are the furthest behind and therefore at the highest risk are "medical practices" and "in-home service providers."⁹ The GartnerGroup extrapolated that the costs associated with addressing the year 2000 problem for each practice group will be range up to \$1.5 million per group.¹⁰

⁵ GartnerGroup, Kenneth A. Kleinberg, "Healthcare Worldwide Year 2000 Status," July 1998 Conference Presentation, p. 2 (hereinafter, GartnerGroup).

⁶ Id. at p. 8.

⁷ Id.

⁸ Id. at p. 10.

⁹ Id. at p. 13.

¹⁰ Id.

REMEDIATION EFFORTS—AMA'S EFFORTS

We believe that through a concerted and united effort, the Y2K problem can still be effectively addressed within the medical community before time runs out. For its part, the AMA has already begun devoting considerable resources to assist physicians and other health care providers in learning about and correcting the problem. The AMA has developed a national campaign entitled "Moving Medicine Into the New Millennium: Meeting the Year 2000 Challenge," which incorporates a variety of educational seminars, promotional information, and ongoing communication activities designed to help physicians understand and address the numerous complex issues related to the Y2K problem.

One of the many seminar series the AMA will be sponsoring is the "Advanced Rapid Response Seminars" series. We will hold these seminars in various regions of the country and provide specific, case-study information along with practical recommendations for the participants. The seminars will also provide tips and recommendations on dealing with vendors and will assist participants in identifying important information they need to obtain from these vendors, as well as various methods for obtaining this information. We are also preparing a "Solutions Manual," which will be distributed to the participants of these sessions.

In addition, the AMA is opening a Web Site to provide the physician community additional assistance to better address the Y2K problem. The site will serve as a central communications clearinghouse, providing up-to-date information about the millennium bug, as well as a special interactive section that permits physicians to post questions and about recommended solutions for their specific Y2K problems.

On a related note, the AMA in early 1996 began forming the National Patient Safety Foundation or "NPSF." Our goal was to build a proactive initiative to prevent avoidable injuries to patient in the health care system. In developing the NPSF, the AMA realized that physicians, acting alone, cannot always assure complete patient safety. In fact, the entire community of providers is accountable to our patients, and we all have a responsibility to work together to fashion a systems approach to identifying and managing risk. It was this realization that prompted the AMA to launch the NPSF as a separate organization, which in turn partnered with other health care organizations, health care leaders, research experts and consumer groups from throughout the health care sector.

One of these partnerships is the National Patient Safety Partnership (NPSP), which is a voluntary public-private partnership dedicated to reducing preventable adverse medical events and convened by the Department of Veterans Affairs. Other NPSP members include the American Hospital Association, the Joint Commission on Accreditation of Healthcare Organizations, the American Nurses Association, the Association of American Medical Colleges, the Institute for Healthcare Improvement, and the National Patient Safety Foundation at the AMA. The NPSP has made a concerted effort to increase awareness of the year 2000 hazards that patients relying on certain medical devices could face at the turn of the century.

OTHERS' REMEDIATION EFFORTS

As an initial step, we recommend that the Congress work closely with the AMA and other health care leaders to develop a uniform definition of "compliant" with regard to medical equipment. There needs to be clear and specific requirements that must be met before vendors are allowed to use the word "compliant" in association with their products. Because there is no current standard definition, it may mean different things to different vendors, leaving physicians with confusing, incorrect, or no data at all.

Physicians should be able to spend their time caring for patients and not be required to spend their time trying to determine the year 2000 status of the numerous medical equipment vendors with whom they work.

We further suggest that both the public and private sectors encourage and facilitate health care practitioners in becoming more familiar with year 2000 issues and taking action to mitigate their risks. Greater efforts must be made in educating health care consumers about the issues concerning the year 2000, and how they can develop Y2K remediation plans, properly test their systems and devices, and accurately assess their exposure. We recognize and applaud the efforts of this Committee, the Congress, and the Administration in all of your efforts to draw attention to the Y2K problem and the medical community's concerns.

We also recommend that communities and institutions learn from other communities and institutions that have successfully and at least partially solved the problem. Federal, state and local agencies as well as accrediting bodies that routinely address public health issues and disaster preparedness are likely leaders in this area. At the physician level, this means that public health physicians, including

those in the military, organized medical staff, and medical directors, will need to be actively involved for a number of reasons. State medical societies can help take a leadership role in coordinating such assessments.

We must also stress that medical device and software manufacturers need to publicly disclose year 2000 compliance information regarding products that are currently in use. Any delay in communicating this information may further jeopardize practitioners' efforts at ensuring compliance. A strategy needs to be developed to effectively motivate all manufacturers to promptly provide compliance status reports. Additionally, all compliance information should be accurate, complete, sufficiently detailed and readily understandable to physicians. We suggest that the Congress and the federal government enlist the active participation of the FDA or other government agencies in mandating appropriate reporting procedures for vendors. We strongly praise the FDA for maintaining a Y2K web site on medical devices, which has already helped physicians to make initial assessments about their own equipment.

Although the AMA strongly believes that information must be freely shared between manufacturers and consumers, we strongly caution against providing liability caps to manufacturers in exchange for the Y2K information they may provide, for several reasons. First, as we have stated, generally vendors alone have the information about whether their products were manufactured to comply with year 2000 data. These manufacturers should disclose that information to their consumers without receiving an undue benefit from a liability cap. Second, manufacturers are not the only entities involved in providing medical device services, nor are they alone at risk if an untoward event occurs. When a product goes through the stream of commerce, several other parties may incur some responsibility for the proper functioning of that product, from equipment retailers to equipment maintenance companies. Each of these parties, including the end-user—the physician—will likely retain significant liability exposure if the device malfunctions because of a Y2K error. However, none of these parties will typically have had sufficient knowledge about the product to have prevented the Y2K error, except the device manufacturer. To limit the manufacturer's liability exposure under these circumstances flies in the face of sound public policy.

We also have to build redundancies into the remediation efforts as part of the risk management process. Much attention has been focused on the vulnerability of medical devices to the Y2K bug, but the problem does not end there. Patient injuries can be caused as well by a hospital elevator that stops functioning properly. Or the failure of a heating/ventilation/air conditioning system. Or a power outage. The full panoply of systems that may break down as our perception of the scope of risk expands may not be as easily delineated as the potential problems with medical devices. Building in back-up systems as a failsafe for these unknown or more diffuse risks is, therefore, absolutely crucial.

As a final point, we need to determine a strategy to notify patients in a responsible and professional way. If it is determined that certain medical devices may have a problem about which patients need to be notified, this needs to be anticipated and planned. Conversely, to the extent we can reassure patients that devices are compliant, this should be done. Registries for implantable devices or diagnosis-or procedure-coding databases may exist, for example, which could help identify patients who have received certain kinds of technologies that need to be upgraded and/or replaced or that are compliant. This information should be utilized as much as possible to help physicians identify patients and communicate with them.

CONCLUSION

We appreciate the Committee's interest in addressing the problems posed by the year 2000, and particularly, those problems that relate to physicians. Because of the broad scope of the millenium problem and physicians' reliance on information technology, we realize that the medical community has significant exposure. The Y2K problem will affect patient care, practice administration, and Medicare/Medicaid reimbursement. The AMA, along with the Congress and other organizations, seeks to better educate the health care community about Y2K issues, and assist health care practitioners in remedying, or at least reducing the impact of, the problem. The public and private sectors must cooperate in these endeavors, while encouraging the dissemination of compliance information.

PREPARED STATEMENT OF KEVIN L. THURM

Good morning. I am Kevin Thurm, Deputy Secretary of the Department of Health and Human Services. I am accompanied by Dr. John Callahan, the HHS Assistant

Secretary for Management and Budget and our Chief Information Officer (CIO); Nancy-Ann Min DeParle, the Administrator of the Health Care Financing Administration; and Dr. Michael Friedman, the Acting Commissioner of the Food and Drug Administration. I am pleased to appear before this Special Committee to provide you with a report on the accomplishments and the challenges faced by the health care industry in preparing for Year 2000.

The Secretary and I have declared the Year 2000 date issue to be our highest information technology priority. We have taken and will continue to take actions to ensure that HHS information systems are Year 2000 compliant.

We have involved all parts of our organization, including staff with expertise in information systems, budget, human resources, and acquisition management in our work to ensure that HHS information systems are able to recognize the Year 2000. No matter what else we do and what other initiatives we undertake, we must ensure that our ability to accomplish the Department's mission is not impaired.

We must continue to exchange data with partners and accomplish the Department's mission in the next century. HHS is also working to inform the health care and human service communities about the Year 2000 issue, and to encourage awareness and facilitate Year 2000 compliance of their equipment and facilities.

The Secretary has established December 31, 1998, as our internal deadline for Year 2000 compliance of mission critical systems. This was done in order to provide a full year of operations in which to detect and remedy any adverse interactions among our systems and those of our many service partners, including other Federal agencies, States and local governments, tribes, and contractors. HHS mission critical systems pay Medicare benefits, provide billions of dollars in grant payments, collect and analyze epidemiologic, clinical trial, and other public health data, and track patient care and records data.

HHS'S YEAR 2000 EFFORT

To meet our Year 2000 responsibilities, we have taken a series of strong administrative actions. We have encouraged aggressive reallocation of funds, where necessary, to meet Year 2000 deadlines; we have established direct reporting lines between staff working on year 2000 activities and the Operating Division (OPDIV) Chief Information Officers. Each OPDIV CIO is responsible for regular reporting on Year 2000 efforts directly to the OPDIV head and the Department's Chief Information Officer until Year 2000 date compliance is achieved.

HHS has also taken action to retain, attract, and re-employ qualified information technology professionals, using both employment and contracting authorities. On March 31, HHS received Department-wide personnel authorities from the Office of Personnel Management (OPM) to waive the pay and retirement reduction for re-employed military and civilian retirees who return to work on Y2K remediation. To date, Health Care Financing Administration has used the waiver authority to reemploy 11 annuitants.

HHS agencies collect a tremendous amount of information that requires data exchange. The Department has inventoried our data exchanges and contacted our service partners to emphasize the importance of assuring Year 2000 compliance. HHS is working with the National Association of State Information Resource Executives (NASIRE) and others to assure a coordinated response. On April 22, HHS provided a listing of State interfaces to NASIRE for its review of completeness and accuracy, and we will update this listing monthly until all of our State interfaces are compliant. Later this month, HHS will update the listing on the GSA web-site for NASIRE review. In addition to data exchanges with States, HHS systems also exchange data with other federal agencies, local governments, Medicare contractors and fiscal intermediaries, private insurance companies, universities, banks, and drug manufacturers.

In addition, HHS is requiring all of its operating divisions to conduct thorough testing and independent verification and validation of its renovated systems. We also know there is a possibility that, try as we might, some systems may not be fully compliant in time. All of our Operating Divisions have submitted initial business continuity and contingency plans to the Department. These plans will be finalized and tested, as appropriate, to provide us with the operational policies needed to permit business continuity in the event of system failure.

ENSURING MEDICARE COMPLIANCE

Of all the HHS programs, the Medicare program, administered by the Health Care Financing Administration (HCFA), is our greatest Year 2000 challenge. Payment of health care claims is accomplished by over 60 external contractors which

operate and maintain a base of software programs that process nearly one billion claims each year from over one million health care providers.

All of the external Medicare contractors have completed assessments of their systems. However, two critical steps are needed to ensure contractor compliance: (1) additional resources may need to be dedicated to Year 2000 remediation, and (2) HCFA must delay implementation of a small number of new initiatives to enable Year 2000 remediation efforts be completed on time.

Additional Resources: In May 1998, President Clinton signed a 1998 supplemental appropriations bill redirecting \$20 million of HCFA contractor funds to HCFA's Year 2000 efforts. In addition, HHS in May 1998 shifted discretionary funds to make an additional \$62.1 million available for HCFA's Year 2000 efforts in FY1998. Further, HCFA is working with Congress to provide an additional \$61.5 million above the \$37.5 million requested in the Budget, for a total of \$99 million for FY1999. Finally, it is likely that HCFA will require additional Year 2000 funding for FY2000.

Delaying Implementation of New Projects: To achieve Year 2000 compliance, HCFA estimates that 49 million lines of contractor code will need to be renovated. Assuring services to beneficiaries in the Year 2000 is HCFA's number one priority. Therefore, HCFA instructed Medicare contractors in June 1998 to suspend further work on converting their systems to the HCFA-selected standard claims systems. HCFA will also have to delay implementation of a small number of provisions of the Balanced Budget Act of 1997.

Implementing these new initiatives would delay the Year 2000 renovation process, jeopardizing the Medicare program's ability to ensure that its systems are Year 2000 compliant. If not fixed, enrollment systems might not function, beneficiaries could be denied services because providers may not be able to confirm eligibility, and providers could have cash flow problems because of delayed payments. Because of this imperative, Year 2000 activities must take precedence over other projects that require changes to computer and information systems.

Initiatives being delayed include: implementing a new payment system for Medicare home health agencies, institutional outpatient Prospective Payment System (PPS), and a consolidated billing system that would require nursing homes to bill Medicare directly for all Part B services. In addition, HCFA has been advised by its independent verification and validation contractor, as well as by the Medicare contractors, to delay the provider updates scheduled for October 1, 1999 and January 1, 2000. We will work with Congress and providers to evaluate our options and ensure that necessary delays in provider updates do not create a hardship.

HCFA has been proactive in addressing Year 2000 compliance with its contractors and works closely and well with the contractors through a joint steering committee. The agency established a December 31, 1998 deadline for contractor certification of compliance in order to ensure there is a full year to accomplish end-to-end testing and any final corrections. HCFA is also amending its formal agreements with the contractors to make clear that contractors are responsible for ensuring that their Medicare systems are Year 2000 compliant. All contractors with whom we have spoken have committed to signing the amendment, and at least one amendment has already been signed.

Finally, as you are aware, HHS has sent proposals for Medicare contracting reform to Congress that would have allowed the Secretary of Health and Human Services more authority in dealing with Medicare's Year 2000 compliance efforts. There are a number of provisions in the existing Medicare law that hinder HCFA's ability to manage the Medicare program, including requiring Year 2000 compliance. The Administration's contracting reform proposal would give the Secretary greater flexibility in contracting for claims processing and payment functions and put HCFA on the same footing as other federal agencies. Under this authority, the Secretary could award contracts to a larger pool of qualified contractors. We believe this change would promote competition and potentially allow the Medicare program to obtain better value for its dollar. It would allow us to enhance relationships with our existing partners and give us an opportunity to build new relationships. The new authority would also be helpful in allowing the Secretary to implement contingency plans that permit business continuity in the event of system failure. In addition to having the full support of the Secretary, this proposal has received the endorsement of John Koskinen, Special Assistant to the President for Year 2000, in testimony before the Senate Governmental Affairs Committee. Medicare contracting reform has been, and continues to be, a Department and Administration priority.

OUTREACH ACTIVITIES

In response to the Year 2000 problem, the President established on February 4, 1998 the President's Council on Year 2000 Conversion. To deal with the issue of out-

reach, the Council has enlisted agencies to increase awareness of the problem and to offer support to public and private sector organizations—both domestically and internationally—within their policy areas. Industry trade organizations, which have unique capabilities for communicating with their members about the Year 2000 problem, individuals companies, and State and local governments, are working closely with these agencies.

HHS is currently implementing a public outreach effort aimed at the health care and human services communities.

HHS's outreach to the private sector encourages awareness and facilitates Year 2000 compliance to prevent disruptions to health care and human service providers and those served by those providers. The program also includes, to a lesser degree, an initiative to make health care providers aware of their responsibility to assure that their own information systems are millennium compliant.

Our goal is to make sure that public and private health care insurers, health plans, providers and third party payers have systems that are Year 2000 compliant to avoid cash flow problems and possible disruption of health care services to millions of U.S. citizens. Health care providers generally have patient record and accounting systems that document the care provided to a patient and then bill the patient or his insurer or third party payer for the care provided.

HHS has worked with most of the major insurers, managed care plans and public medical assistance programs in the U.S. to make them aware of the Year 2000 problem and encourage the appropriate remedial action. HHS has a working relationship with most of the major health care provider associations and with most of the health care providers in the U.S. through the Medicare program. It is taking advantage of these direct and indirect relationships to make health care providers aware of the millennium problem and encourage the appropriate corrective action. HHS and its constituent agencies have made millennium awareness a key component of opportunities to address physicians, hospitals, managed care plans, Medicaid State agencies, and other Medicare provider groups. Numerous speeches and presentations by senior departmental and agency officials have contained a millennium message.

The Health Care Financing Administration has employed a variety of strategies to reach organizations and individuals involved in health care activities. HCFA has developed a comprehensive Year 2000 outreach program with three main areas of concern. First, third party payers must be able to assure health care providers that they have taken the necessary steps to receive bills and issue payments. Second, health care providers must take the steps necessary to make sure that their patient record and accounting systems will be able to send bills and receive payments. Finally, health care providers must take the steps necessary to make sure that their biomedical equipment is Year 2000 compliant.

To accomplish its outreach goals, HCFA has:

- engaged the corporate leaders of over 60 major insurers in Year 2000 millennium awareness and renovation activities;
- promoted Year 2000 awareness to over 400 managed care plans;
- offered technical assistance to each State medical assistance program administrator;
- established a provider outreach and education subcommittee; and
- conducted a Year 2000 briefing in Washington, D.C. for representatives of more than 50 national health care provider associations and payer associations.

HCFA is also publishing a Year 2000 awareness article in each of its Medicare carrier and fiscal intermediary provider bulletins this summer. These articles are expected to reach hundreds of thousands of large and small provider offices.

Other HHS operating divisions have also been proactive in issuing guidance, publishing articles in various medical and healthcare bulletins and magazines, and sending letters to state, local, and other public health and health care organizations. This month, the Indian Health Service (IHS) will be sending an awareness package to all tribal governments, tribally operated programs, urban Indian programs, and other Indian organizations. This package will include key references related to the Y2K issue in Indian health programs (the IHS Year 2000 Plan, an awareness presentation for local use, administrative and technical resources available for them from the IHS) to enhance awareness and assist them in their Y2K activities.

The Centers for Disease Control and Prevention (CDC) works closely with public health partners in State and local governments as well as health care practitioners to improve public health through prevention of disease, disabilities, and injuries. In November 1997, CDC distributed a letter to over 300 State, local, and other public health and health care organization recipients informing them about the Year 2000 and proposing a set of public health data standards including one that requires all dates to be Year 2000 compliant. In addition, CDC is currently collaborating with HCFA to ensure effective communications with all clinical laboratories regulated

under the Clinical Laboratory Improvement Act (CLIA) and to ensure that the clinical laboratory community is informed of this issue.

In July 1997, the National Institutes of Health (NIH) established the Y2K Medical and Laboratory Equipment Work Group to advise it on biomedical equipment assessment and to take any remediation action necessary. In the spring of 1998, NIH initiated a study of Y2K impact on all medical equipment owned by the NIH Clinical Center. A notice was published in the NIH Guide for Grants and Contracts, to remind recipients of NIH grants and cooperative agreements that they must anticipate and mitigate any potential problem that might be caused by the Year 2000. This Y2K information is available on a continuous basis via a public NIH web site. The NIH data center had an exhibit at the Information Processing Interagency Conference to advertise Y2K inventory analysis, code conversion, and validation testing services. Finally, NIH has made inquiries to vendors concerning Y2K compliance of Commercial Off-The-Shelf (COTS) software, hardware and biomedical equipment and software. That information is currently disseminated via a clearinghouse on the web.

The Administration for Children and Families (ACF) outreach is a two part effort. One part is directed at State grantees which are responsible for administering ACF's major programs, such as Child Support Enforcement and Temporary Assistance for Needy Families. Another part is directed at sub-State, non-profit service providers and Indian Tribe grantees served by ACF in program areas such as Head Start and Community Services.

Among the key activities involved in outreach to human service providers are the following: identifying key audience members and appropriate points of contact, such as associations and publications; distributing information to those audiences, for example by using attendance at major meetings to raise awareness of the problem; developing and including Y2K awareness language in grant awards; developing Internet Y2K information web-sites; and exploring other opportunities for effective outreach.

The Health Resources and Services Administration (HRSA) is targeting their outreach awareness campaigns at universities and colleges, health care facilities, and local government audiences. In the HRSA Grants Preview, Summer 1998 issue, HRSA has included a section dealing with the Year 2000 policies and provided a list of Year 2000 resources. HRSA has alerted potential grantees/applicants on the Year 2000 issue and asked potential grantees and applicants to address their organizations efforts to become Year 2000 compliant as part of their business or operational plan. The Summer 1998 issue of the HRSA Preview has already been distributed to 14,000 grantees, associations and partners of HRSA. In addition, it is on the Internet in both English and Spanish for grantees and users to see. The Internet address is <http://www.hrsa.dhhs.gov/grants.htm>. The HRSA Preview will also be distributed at the National Association of Local Boards of Health (July 29–August 1, 1998), the Joint Annual meeting of the Association of County and City Health Officials (September 23–26, 1998) and the American Public Health Association Annual Meeting/Convention (November 15–19, 1998).

The Administration on Aging's (AoA) outreach plan involves raising awareness at all meetings, monitoring visits, and presentations made by the Assistant Secretary for Aging, Regional Administrators, and other senior management. The AoA Update, a monthly newsletter reaching over 2000 members of the aging network, will have an article in every issue beginning in August highlighting important Y2K messages. All grant award packages beginning in August will have a Y2K message from the Assistant Secretary for Aging.

Finally, the Substance Abuse and Mental Health Services Administration (SAMHSA) plans to raise awareness of the Year 2000 problem with the various organizations which deal with substance abuse and mental health services. A letter was sent in May 1998 to all State and territorial mental health and substance abuse directors alerting them to the seriousness of the problem and requesting that they review their systems for Year 2000 conformance. Year 2000 requirements have been included in all grant award notices beginning in fiscal year 1998 and in all Request-for-Contracts since late 1996. SAMHSA management staff have been including the Year 2000 issue in all speaking opportunities, and Year 2000 information is being included on the SAMHSA WEB site.

On a regular basis agency representatives will be meeting with me to ensure continued success in our outreach efforts.

BIOMEDICAL EQUIPMENT

We are also addressing the need to develop public information about the compatibility of systems embedded in biomedical devices. Because it is imperative that

medical equipment continues to function properly in the next century, the Department is requesting information about the Year 2000 compliance of medical devices and scientific laboratory equipment manufactured by biomedical equipment manufacturers.

HHS is working with the VA to better serve our mutual interests in Year 2000 compliance of biomedical equipment by merging our efforts on biomedical equipment. We have convened a steering committee to develop a charter and action milestones, and have asked the Department of Defense to participate as well. We will also work through the Health Care Outreach Sector Committee and the White House Year 2000 Conversion Council to enhance our ability to make more information available to the public.

Medical devices and scientific laboratory equipment may experience problems beginning January 1, 2000 if the computer systems, software applications, or embedded chips used in these devices and equipment contain two-digit fields for year representation. Agencies, such as the Department of Defense, Department of Veterans Affairs, and Department of Agriculture as well as HHS, are concerned that the existence of the Year 2000 date problem in biomedical equipment could pose potentially serious health and safety consequences.

On January 21, 1998, I signed a letter sent to over 16,000 biomedical equipment manufacturers, strongly urging them to identify noncompliant products and the actions they are taking to ensure compliance. The manufacturers are responding to this survey developed by the Department and the Food and Drug Administration (FDA). The Food and Drug Administration now operates and maintains an Internet web site listing all biomedical equipment information received from manufacturers relating to Year 2000 compliance. The site address is: <http://www.fda.gov/cdrh/yr2000/year2000.html>. In addition, the FDA moderated a session at the annual meeting of the Association for the Advancement of Medical Instrumentation and issued to industry, "Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem."

The response from manufacturers has been disappointing. To date, approximately 10 percent of the 16,000 manufacturers have provided information. FDA issued a more targeted, follow-up letter on June 29, 1998, to about 2,700 manufacturers of computerized devices urging them to submit product data. Dr. Friedman will provide you with the specific results from the manufacturers' responses, but we see no indications that there will be significant problems that will place patients at risk, assuming that the manufacturers are implementing the reported solutions.

The Food and Drug Administration has held both Executive level and technical meetings with the Veteran's Health Administration (VHA) to assure a unified approach to the Y2K compliance of biomedical equipment. A Steering Committee has been formed, which will define HHS and DVA roles, responsibilities and schedules, determine the scope and content of the data to be collected from the manufacturers, reconcile redundant and conflicting data, merge data collected by VHA and FDA from the same manufacturer into a common format, and disseminate the data to interested parties via a single biomedical equipment website to be housed at FDA.

ADDITIONAL OUTREACH ACTIVITIES

HHS will undertake additional outreach activities to inform the health care and human services community about the Year 2000 issue. These efforts are part of the government-wide outreach efforts developed and managed by the White House Year 2000 Conversion Council. The President's Council on Year 2000 Conversion created over 30 industry sector outreach groups. The purpose of these groups is to inform all the constituents of a given sector about what the federal government is doing to achieve Year 2000 in a timely way and to work with these constituencies, as appropriate, to increase their awareness and their own readiness. HHS chairs two groups—the Health Care Sector Outreach Committee and the Human Services Sector Outreach Committee. In addition, HHS is a member of other outreach committees, such as Benefit Payments, Education, Emergency Management, Employment-related Protection, Food Supply, and Science and Technology. We are also encouraging all our operating divisions with an Internet presence to establish a Year 2000 web site.

CONCLUSION

HHS still faces substantial challenges in its Year 2000 efforts. However, let me assure you, on behalf of Secretary Shalala, that we will continue to vigorously pursue Year 2000 remediation as our most important information technology initiative.

We recognize our obligation to the American people to assure that HHS's programs function properly now and in the next millennium.

I thank the Committee for its interest and oversight on this issue, and would be happy to answer any questions you may have.

RESPONSES OF KEVIN L. THURM TO QUESTIONS SUBMITTED BY CHAIRMAN BENNETT

Question. [State Health and Child Support Systems]

Mr. Secretary your department has been delegated Y2K responsibility to deal with Health and Welfare computer systems in the area of Federal-State Y2K compliance. Please give the Committee an overall status of the following programs. In addition we would like a State by State appraisal for the record.

- Medicaid: both the payment systems and the Medicaid Management System
- Child Support Enforcement: both payment systems and child support enforcement

Answer.

General

The Department of Health and Human Services (DHHS):

- provides funds and technical assistance for "State" systems developed and implemented to support State administration of Federal programs, such as the Medicaid and Child Support Enforcement (CSE); and
- assesses the degree to which State systems projects are successfully implemented and meet program requirements.

In support of States' efforts to address the Y2K problem in their systems, DHHS is exercising these same roles (funding, technical assistance, project assessment, and monitoring). This is explained below in some detail. DHHS is not directly involved in the on-site, day-to-day development and operation of State systems, nor is DHHS directly involved with the day-to-day activities of States Y2K remediation efforts.

MEDICAID: BOTH THE PAYMENT SYSTEMS AND THE MEDICAID MANAGEMENT SYSTEM

General

- HCFA is concerned with monitoring 3 systems:
 - MMIS (Medicaid Management Information Systems)
 - Managed Care which assures the delivery of care and the payment for care
 - IES (Integrated Eligibility Systems)
- Focus is on program eligibility, delivery of services to beneficiaries and payment to providers
- Definition of Certification and Compliance: Medicaid systems must be operational with no disruption of the delivery of service to eligible Medicaid beneficiaries or to the providers of care
- Three areas of complexity in monitoring the Medicaid Y2K status:
 - IES's interface with the MMIS and Managed Care may or may not be a component of the MMIS
 - Two or more State agencies administer these systems in support of their programs: Medicaid/Public Assistance/Child Support/Child Welfare
 - Defining the scope of outreach in terms of interfaces to the IES is problematic.

Outreach activities to date

HCFA has issued Medicaid Correspondence to State Medicaid Agencies:

- HCFA's Center for Medicaid and State Operations (CMSO) issued a State Medicaid Directors Letter on July 17, 1998 which outlined HCFA's millennium compliance strategy as it relates to State Medicaid Management Information Systems (MMIS).
 - Requires States to certify that their MMIS is Y2K compliant by 3/99
 - Requires States to document their contingency plans
 - Strongly urges that States contract for IV&V services (75 percent FFP for MMIS, 50 percent FFP for IES)
- CMSO issued a State Medicaid Directors Letter on August 17, 1998
 - Informs States of institutional, professional, and coordination of benefits (COB) claims processing instructions that have been issued to Medicare Fiscal Intermediaries (FIs) and Carriers
 - Although these new file format instructions apply to Medicare contractors, due to the fact that many providers serve both Medicare, as well as, Medicaid populations, this may impact State Medicaid claims processing. Therefore, this letter strongly encourages States to communicate with their

providers and other respective trading partners to facilitate these data exchange issues

—A National Medicaid Management Information Systems (MINIS) was held from August 10–14, 1998 in Orlando, Florida. The attendees included State Medicaid staff, vendors, and HCFA central and regional office staff. Monday, August 10th a Y2K working session composed of HCFA regional and central office staff was held. In addition, Wednesday, August 12th of the conference was dedicated to Y2K. Among the topics discussed include: HCFA's overall Y2K strategy, HCFA's Medicaid Y2K Strategy, and contingency planning. Part of the day will also be spent in "break-out sessions" with the States. This will help HCFA obtain feedback from States in terms of their status, as well as, what additional activities HCFA can take part in to further assist States in their Y2K projects.

—HCFA has placed Medicaid-specific Y2K Information on the INTERNET, at the following URL:

—[http://www.hcfa.gov/y2k/Future Outreach Activities Regarding Reporting:](http://www.hcfa.gov/y2k/Future%20Outreach%20Activities%20Regarding%20Reporting)

CMSO initiatives in process

—Documents being prepared by CMSO:

- certification criteria for States to self-certify
- on-site review tools for RO visits, and
- contingency planning check list

—A Medicaid-specific IV&V contractor statement of work (SOW) has been written and is being process. The SOW includes the following activities:

—HCFA's Regional Offices will work with an outside contractor to assess the status of State Y2K efforts. Of primary concern are those systems that are used by States to provide payments to Medicaid providers, both fee-for-service and managed care, as well as those that collect patient-related data including that used to verify the status of patient eligibility for the program.

—Based on State self-reported information regarding their assessment of where they are relative to achieving full Y2K compliance, the contractor will assist HCFA in ranking State systems into high, medium and low risk categories, thereby providing a State by State evaluation. The technical support contractor would conduct on-site visits to those States which appear to be of medium and high risk in terms of their Y2K compliancy status.

—The contractor will provide training to regional office to assist in conducting on-site visits of those States who are ranked to be low risk. The regional office staff may also participate in on-site visits of those States in the other risk categories. As a result of the site visits, the technical support contractor shall advise HCFA of the reasonableness of the work effort as reported by the State Medicaid Agencies. As part of the visits, the contractor will review such materials as the States' test plans and contingency plans and shall assist HCFA in assessing the adequacy and appropriateness of such documents.

—The results of the on-site visits, in conjunction with the survey data of the MMIS Y2K status, will be used by the contractor to develop monthly reports summarizing MMIS Y2K status and further refining the ranking of States by risk categories as needed. The contractor will also assist HCFA in developing the criteria that a State MMIS must meet to certify that it is millennium compliant.

—The contractor will collect information on the Y2K status of States' integrated eligibility systems (IES) through a variety of means including telephone surveys. The contractor would be responsible for the analysis of such data and for writing a summary report based upon the results of the survey. Such surveys, and corresponding reports, would be conducted on a regular basis.

—In addition to monitoring and evaluating the States' Y2K readiness, HCFA will work with the contractor to provide a variety of technical assistance vehicles.

—A series of Medicaid Y2K white papers will be developed to serve as guidance to State Medicaid Agencies and the Regional Office Y2K Coordinators (i.e., a Medicaid Y2K compliance definition, a Y2K certification document to serve as guidance to the contractor and RO personnel when conducting on-site visits, and "best practices" and "lessons learned").

—Two national Y2K Conferences, and two Y2K conferences in each region, for Medicaid State Agencies will be conducted to provide Y2K guidance through workshops and presentations.

Joint activities (USDA [FS], HHS [ACF, HCFA])

Two coordinated Action Transmittals (AT) issued by Administration for Children and Families, HCFA and Food and Nutrition Service and signed by all parties were released to State Medicaid and Public Assistance Agencies in July 1998. These ATs are described as follows:

Transmittal No. AT-98-004

Subject: Federal/State Information Technology Policy-Expedited Advance Planning Document Procedures for Year 2000 Compliance Activities

This AT extends the expiration date for the expedited advance planning document (APD) approval procedures through July 1, 2000 to regular match State data processing acquisitions and systems development projected initiated in support of Year 2000 compliance in the State.

Transmittal No. AT-98-006

Subject: State Public Assistance Systems and Year 2000 (Y2K)—Information Sharing

This AT:

- Provides general information pertinent to dealing with the Y2K problem—Federal Y2K contacts
- Seeks to identify State public assistance agency contacts responsible for the Y2K problem in the agency by program area. This information is due to ACE by August 6, 1998
- Informs States that HCFA will conduct a survey in which ACE may participate that will provide information specific to the Medicaid program
- Strongly recommends that State public assistance agencies include IV&V services in their Y2K testing plans
- Will develop a State Y2K project manager contact list to be used to contact each State, by phone, to determine whether their integrated eligibility systems are Y2K compliant. These are the systems that interface with MMIS.

Supplemental information to assist DHHS activities

GAO's 30 page survey titled, *Survey of States' Welfare Automated Systems Year 2000 Compliance (Job 511246)* and the coordinated Action Transmittal mentioned above, requests that States provide Y2K contact personnel by July 6 and August 7, 1998 respectively. This information will be used by DHHS agencies to assess the status of State Y2K activities. In addition, the HCFA/CMSO's Data and Systems Groups' Division of State Systems will use this information to contact State public assistance agencies and State health departments to determine time frames for completion of State Y2K activities regarding integrated eligibility systems. Other public assistance programs that interface with the State's integrated eligibility systems impact the Medicaid Management Information Systems and have been included in the survey. The GAO schedule presented in the Year 2000 Computing Crisis: An Assessment Guide, will be used to compare State time frames against their Y2K activities in the survey being developed.

CHILD SUPPORT ENFORCEMENT: BOTH THE PAYMENT SYSTEMS AND CHILD SUPPORT ENFORCEMENT SYSTEM

Most statewide automated Child Support Enforcement (CSE) systems were developed and implemented in the last 5 years and appear to be Calendar Year 2000 compliant. This is principally because of the Family Support Act of 1988 requirement that established a deadline for developing a single statewide system for child support of October 1, 1997. Despite this, States are for the most part taking the additional precaution of conducting Year 2000 assessments of their entire child support automated systems, including critical interfaces with other systems. ACE is working closely with the States to provide assistance in these efforts. Federal reimbursement under the CSE program for Y2K activities in support of a statewide child support system is eligible for a 66 percent match rate.

The areas of possible impact for Child Support automated systems are as follows:

- Some of the oldest CSE statewide automated CSE systems were developed in the early 1980's and may not be Y2K compliant.
- The State CSE system's dependence on interfaces makes them potentially vulnerable to Y2K even if the Child Support system is Year 2000 compliant. A typical State CSE system has interfaces with State agencies related to TANF, child welfare, and Medicaid, as well as State Employment Security Agencies, DMV, State taxes, Vital Records, and other public and private automated systems, such as consumer reporting, financial institutions, to locate, enforce, and process child support payments. The State Child Support programs are concerned

about whether these other State agencies will have Y2K problems that will affect the transmission of information.

- The high priority being given to may be is impacting some State agency efforts to make enhancements to their CSE systems to meet statutory deadlines. Some States have been advised by their State data centers that Y2K is a priority, and that no mainframe change orders will be accepted until Y2K issues are addressed. This makes it difficult for those States to meet the statutory deadlines in PRWORA.

The General Accounting Office is in the midst of a substantive survey of all State and territories to determine the status of State's plans related to calendar year 2000 for human service programs. About one-third of the questionnaires have been received so far and the GAO is following up with the remaining States to obtain their survey results.

In the interim, in order to determine the status of Child Support Enforcement systems, OCSE intends to do the following:

- OCSE issued revised regulations regarding State Child Support Enforcement systems on August 21st. Among other provisions, these regulations provide that when OCSE determines that a State's child support enforcement systems efforts are at risk due to any one or more of a variety of factors, including Y2K problems, OCSE will take corrective action. This will include requiring the State to obtain independent validation and verification (IV&V) services.
- The regulation also finalizes reinstatement of the Paperwork Reduction Act clearance for OCSE's Advance Planning Document process. Once the regulation is issued, OCSE will request that each State submit a Y2K addendum to its Advance Planning Document Update (APDU) for the State CSE system. OCSE will ask each State to describe the Y2K compliance status and the status of remedial action for State child support enforcement systems, State payment systems, and the most important interfaces between the State child support system and other State systems, such as DMV, vital records, etc.

After the material is received and analyzed, ACF/OCSE will require any State that it deems at high risk of failure due to insufficient attention to Year 2000 issues to obtain an Independent Validation and Verification Contractor to assist the State in addressing this issue.

Question. [Health and Welfare Eligibility]

Mr. Secretary, your department, and the departments of Agriculture (food stamps), Treasury (IRS family income data), Veterans Affairs (veterans benefit data) and the Social Security Administration (data for disability retirement and supplemental security income) collectively share data to determine eligibility for welfare and Medicaid assistance.

- What is the status of the joint agency Y2K effort to determine eligibility? How do you plan to test the system for Y2K readiness?

- Please explain the types of contingency plans you are developing to ensure eligibility determination after the year 2000? Please explain.

Answer. The question refers to the Income Eligibility Verification System (IEVS) requirement under section 1137 of the Social Security Act. This requirement includes a number of mandatory separate and distinct information exchanges between States and various Federal agencies. These exchanges are intended to verify reported client circumstances, primarily including earned and unearned income, in order to avoid program eligibility and payment errors. IEVS is not a "system" in which these agencies "collectively share data," but is rather a series of separate and individual processes.

No single Federal agency is responsible for coordinating the several information exchanges that comprise the IEVS requirements. Each of these exchanges takes place under the terms of a separately negotiated agreement between each State and each Federal agency. To the extent that these requirements involve the exchange of information between a Federal agency and States, they are covered under the individual Y2K corrective action plans of these Federal agencies. The Department of Health and Human Services (DHHS) is not responsible for any of the IEVS mandated information exchanges with States, nor is DHHS a party to any of the individual exchange agreements.

No DHHS systems are used to determine eligibility for the welfare programs. With the implementation of the Temporary Assistance for Needy Families (TANF) block grant program, title IV-A of the Social Security Act prohibits the Secretary of Health and Human Services from prescribing rules or imposing any requirement on States unless specifically permitted by the statute. However, the individual Federal agencies involved will be working with States to ensure that their Y2K contingency plans address the issue of mandatory IEVS interfaces.

Question. [Funding for Y2K Repairs]

Mr. Secretary, HHS like other agencies has had to make tradeoffs in other programs and information technology initiatives to pay for Year 2000 repairs. While the focus of this hearing is on HHS' outreach efforts to the private sector and not HHS' internal systems, I would still like to know if you have all the resources you need to remediate your systems?

Answer. If HHS does not receive sufficient Y2K funding early in fiscal year 1999, it will be unable to finance all of its costs for remediation efforts, outreach, and contingency planning. All of these activities are essential for ensuring that the Department can accomplish its mission without disruption due to the millennium date change. HHS has already dedicated additional resources to Year 2000 remediation. In May 1998, President Clinton signed a 1998 supplemental appropriations bill re-directing \$20 million of HCFA's contractor funds to HCFA's Year 2000 efforts. In addition, HHS shifted discretionary funds in May 1998 to make a total of \$62.1 million in additional funds available for HCFA's Year 2000 efforts in fiscal year 1998. HHS still has additional funding needs in fiscal year 1999 and fiscal year 2000. These cost estimates and chart have been updated again as requested by the Office of Management and Budget's call for Comprehensive Plans and Associated Funding Requirements for Achieving Year 2000 Computer Compliance, as can be seen in the attached exhibit.

DEPARTMENT OF HEALTH AND HUMAN SERVICES: Y2K TOTAL COST ESTIMATES—FISCAL YEAR
1996 TO FISCAL YEAR 2000
[Dollars in millions]

	Fiscal years—			President's budget fiscal year 1999	Supple- mental estimate fiscal year 1999	Total fiscal year 1999	Budget request fiscal year 2000	Total
	1996	1997	1998					
ACF Total		\$0.500	\$3.960	\$1.500	\$4.725	\$6.225	\$0.500	\$11.185
AHCPR Total			0.040		0.420	0.420		0.460
AOA Total					0.600	0.600		0.600
CDC Total		3.000	9.400	1.900	4.299	6.199	1.610	20.209
FDA Total	\$0.200	2.000	7.250	2.215	11.113	13.328	2.000	24.778
HCFA—Internal	0.800	7.000	19.000	15.000	13.000	28.000	27.000	81.800
HCFA—External	6.800	7.500	26.000	22.500	191.100	213.600	208.500	462.400
HCFA—Supplemental			62.100					62.100
HCFA—Total ¹	7.600	14.500	107.100	37.500	204.100	241.600	235.500	606.300
HCFA—Contingency							311.200	311.200
HRSA Total		1.200	1.400		10.000	10.000	1.400	14.000
IHS Total		2.500	2.500	2.300	23.400	25.700	1.000	31.700
NIH Total	0.040	9.200	11.200	5.993	4.832	10.825	3.328	34.593
OIG Total					5.350	5.350	5.200	10.550
OS Total			0.500		2.300	2.719		3.219
PSC Total		0.200	2.300	1.000	7.333	8.333	0.881	11.714
SAMHSA Total	0.095	0.020			0.100	0.100		0.215
HHS Total ¹	7.935	33.120	145.650	52.408	278.572	331.399	562.619	1,080.723

¹ HCFA presented two estimates based upon "most likely" and "pessimistic" scenarios. "Most likely" estimates are in this table. The "pessimistic" alternative estimates are \$299.7M for fiscal year 1999; \$328.1M for fiscal year 2000; and \$536.7M for contingency.

Question. What are the Department's contingency plans, specifically what are the contingency plans for FDA and HCFA?

Answer.

—HHS required all of its operating divisions to develop business continuity and contingency plans that will permit HHS to conduct essential business in the event of computer system problems arising from Year 2000. The GAO draft guide, "Year 2000 Computing Crisis: Business Continuity and Contingency Planning," was used as a foundation. Plans will identify the operating divisions' core business processes, the minimum acceptable level of service, triggers that would cause the contingency plan to be invoked, and the business resumption team, their roles, and responsibilities.

—On June 15 HHS received the business continuity and contingency plans from the operating divisions. These plans constitute an important start, but they were generally not sufficiently complete and detailed. In some cases, the plans did not appear to be feasible or testable. HHS requested all operating divisions to improve their plans.

—In addition, HHS has formed three cross operating division workgroups to develop generic contingency plans for (1) payments of grants and benefits, (2) clinical care and health data, and (3) facilities management areas. Since many of the operating divisions have similar processes, these groups will ensure that all HHS plans in these three areas will have coordinated strategies.

HCFA

HCFA is establishing a high-level enterprise-wide business continuity and contingency plan modeled from the GAO draft guide, "Year 2000 Computing Crisis: Business Continuity and Contingency Planning," and the Social Security Administration's plan. The number, diversity, decentralization, and lack of standardization among HCFA, intermediary, carrier, State, and other contractor systems presents especially unique problems and risks, and requires considerable planning and evaluation before HCFA can develop adequate contingency plans.

As guidance to system and business process owners, a model format for contingency plan development and tracking has been developed. It incorporates a template for standard risks, as well as guidelines for a business process-based risk analysis. It will also include management, environmental, and other risks, as well as the identification of system-specific risks. Versions of this template have been developed for both internal and external systems, and will be shared with key grant, contract, and other business partners.

In view of substantial resource contention, we have developed triage procedures that will waive contingency plan development for systems that are low risk or low impact, and that are not essential to support of a critical business process.

HCFA's number one concern is that beneficiaries continue to have access to needed care. The continuity of payments to providers is fundamental to ensuring that access.

Our focus is on continuity of *key business functions*, not specific systems. Consequently, we are not limiting ourselves to specific mission-critical systems, but instead looking at all core business processes essential to sustain a basic level of service to our beneficiaries.

The HCFA core business processes that are the focus of our contingency plan are:

- Provision of Medicare services and the payment for those services
- Interactions with state Medicaid agencies
- Interactions with states on children's health insurance programs
- Program integrity
- Quality of care
- Research

The specifics of this plan will address:

- Payment Processes
- Eligibility Issues
- Program Integrity
- Litigation
- Managed Care
- Security and Privacy
- Telecommunication Services
- Quality of Care

Some plans already in place

Some contingency plans are already in place; for example, our critical accounting functions will be protected by "bridges" that will assure that we will be able to continue transactions with our external partners even if they are not fully ready.

Specific examples

Intermediaries or carriers may be able to back up some processes—such as enrolling providers—with manual methods, especially those that are not time sensitive.

Every intermediary and carrier will be prepared to operate on a temporary basis, assuring continuity of local eligibility verifications and payments in the event of local unavailability of the Common Working File.

HCFA has also already taken some management actions to focus resources on its Y2K activities.

- HCFA removed several internal systems from their normal environment and assigned those systems to programming "tiger" teams, whose job is to perform Y2k renovations and nothing else until the job is done.
- Second, HCFA is moving aggressively to take advantage of new authority from the Office of Personnel Management to re-employ retired federal programmers to help with Year 2000 activities. To date, HCFA has used the authority to re-employ eleven annuitants.

—And, HCFA is continuing to develop other contingency strategies for use in the event that even the “tiger” team’s efforts fail. For example, HCFA is capable of continuing to make payments to managed care organizations even if its current processes that support such functions totally fail. Similar contingencies will be developed for all HCFA critical processes. Likewise, HCFA is beginning to develop contingencies for its external systems along with trigger points to tell us when to activate a contingency plan.

HCFA requires all owners of critical business processes, including external system maintainers, contractor data centers, and Medicare intermediaries and carriers to develop contingency plans, and has established working groups to develop Agency-level business continuity plans for the most critical business processes. Their IV&V contractor, Intermetrics, is reviewing all of HCFA’s contingency plans as a component of its system reviews. Intermetrics will also review Medicare contractors’ corporate contingency plans to assess whether they are adequately conceived, developed, and supported.

FDA

Background

FDA has developed a strategic business contingency plan, based on GAO’s guidance document, that outlines the process which component organizations are to use in dealing with the impact of the Y2K date change on their core business processes. The plan requires each component organization to perform a business impact analysis by September 15, 1998. Following this, they must develop detailed business continuity plans by December 15, 1998. These plans will address how the processes will continue unabated into the year 2000, regardless of whether the impact is from the failure of a mission critical system or from another area of IT. In addition, the plans will take into consideration external dependencies and their impact. FDA has also completed contingency plans for each of its mission critical systems.

Approach

FDA’s basic contingency for ensuring business continuity in the face of Year 2000 system failure is to revert to manual processes if systems are unusable. To prepare for executing this strategy, the Centers/Offices need to perform the following:

1. *Conduct a business impact analysis.*—This analysis will be performed on each major business process, and will examine the risks of business process failure due to Y2K impact on the Center/Office’s ability to perform its critical work. As part of this business impact analysis, Centers/Offices will define the minimum acceptable level of outputs and services for each critical process.

2. *Build business continuity contingency plans.*—Based on the results of the business impact analysis, Centers/Offices must define specific plans for FDA staff to follow in the event of system failure. In developing these business continuity and contingency plans, managers will consider different alternatives, and document the best contingency plans in terms of cost and benefits.

3. *Test the contingency plans.*—After business continuity and contingency plans have been developed, they must be assessed to determine how realistic they are. This testing allows the Center/Office managers to see how quickly the plan can be implemented and how effective it is at carrying out the Agency’s critical business. Depending on the type of test selected, it may also provide information affecting the cost estimates.

Below are the key program areas and their associated processes for which FDA will develop business continuity plans.

Program area	Business processes
Foods	Conduct product review and approval on products within the food supply. Conduct post-market surveillance and adverse event reporting in accordance with the foods program. Develop Methods and Good Manufacturing Practices in accordance with the foods program. Conduct scientific research in support of the foods program.
Human Drugs	Conduct product review and approval on human drug products. Conduct post-market surveillance and adverse event reporting in accordance with the human drug program. Develop Methods and Good Manufacturing Practices in accordance with the human drugs program. Conduct core scientific research associated with human drugs.

Program area	Business processes
Biologics	Conduct product review and approval on biologic products. Conduct post-market surveillance and adverse event reporting in accordance with the biologics program. Develop Methods and Good Manufacturing Practices in accordance with the biologics program. Conduct core scientific research associated with biologics.
Medical Devices and Radiological Health.	Conduct product review and approval on medical devices and radiological health products. Conduct post-market surveillance and adverse event reporting in accordance with the medical devices and radiological health program. Develop Methods and Good Manufacturing Practices in accordance with the medical devices and radiological health program. Conduct core scientific research associated with medical devices and radiological health program.
Animal Drugs and Feeds	Conduct product review and approval on animal drugs and feeds. Conduct post-market surveillance and adverse event reporting in accordance with the animal drugs and feeds program. Develop Methods and Good Manufacturing Practices in accordance with the animal drugs and feeds program. Conduct core scientific research associated with animal drugs and feeds program.
National Center for Toxicological Research (NCTR).	Conduct risk assessment. Conduct scientific research. Develop methods in accordance with FDA's regulatory mission.
Office for Regulatory Affairs	Educate the public on food and drug issues consistent with FDA's consumer protection mission. Perform compliance monitoring and auditing. Initiate legal action when needed.
Key Support Processes	Oversees Agency-wide budget formulation and execution, accounting, payment processing, financial reporting, foreign and domestic travel, employee relocation, payroll liaison and financial systems. Provide a standard system for the administrative processes that are common across the Agency. Manage the physical security of all FDA facilities. Develop and maintain an overall information system architecture, including telecommunications support.

Schedule

The table below shows the key milestones involved in the contingency planning, as well as the group responsible.

Milestone	Component responsible	Target date
Develop draft strategic business continuity and contingency plan	OCIO	15 June 1998 (Done).
Develop system-level contingency plans for mission critical systems	Center IRM staff	15 June 1998 (Done).
Receive comments back from Centers/offices on draft strategic business continuity and contingency plan.	Agency-wide	15 July 1998.
Conduct business impact analysis on critical business processes	Program staff	15 September 1998.
Develop business process continuity contingency plans for critical business processes.	Program staff	15 December 1998
Complete compliance validation of mission critical systems	IV&V Contractor	31 December 1998
Complete testing of business process contingency plans	Program staff	15 March 1999

Question. What are you doing to help providers meet the Year 2000 requirements?
Answer.

- We have a comprehensive outreach program to help providers understand what they must do about the Year 2000.
- This summer we are publishing Year 2000 awareness articles discussing the need to ensure that patient records and accounting systems, as well as their biomedical equipment are Year 2000 compliant. These will be included in all Medicare contractor bulletins that go out to thousands of providers of fires, large and small.
- We are conducting a series of provider outreach meetings. In July of this year, we held a briefing for representatives of more than 50 national health care provider associations and payer associations to discuss the status of Y2K, our expectations of them, electronic data interchange, biomedical equipment and a

general overview of Y2K and the health care community. A second meeting is scheduled for mid-August, and is expected to focus on the electronic data interchange (EDI) community. We also expect to hold additional outreach meetings in the future to increase Y2K awareness in the provider community.

- We presented our Y2K efforts and expectations for managed care plans and insurers during HCFA Medicare Plus Choice conferences. The conferences were held July 13–14 and August 3–4 in Baltimore, MD, July 21–22 in Chicago, IL, and July 28–29 in Los Angeles, CA which brought together approximately 1,600 persons. We announced during these sessions that requirements for certification and contingency planning are currently being developed and should be released to the managed care community in September, 1998.

We are also committed to providing technical assistance to state medical assistance program administrators, and have provided several written communications to them relating to Y2K compliance. Our latest letter strongly encouraged states to communicate with their providers and other trading partners to facilitate resolution of Y2K readiness of data exchanges.

- We have also scheduled a Y2K working session at the National Medicaid Management Information Systems conference which will be held in mid-August. This session will provide an opportunity for HCFA to discuss its Medicaid Y2K strategy and contingency planning and to obtain feedback from the Y2K states on their individual state operations. HCFA is also exploring using one or more to look at the independent validation and verification (I&IV) contractors Medicaid States' Y2K efforts. This is to give us some assurance that the systems used to provide payments to Medicaid providers, both fee-for-service and managed care, as well as those that collect patient-related data are Y2K compliant.
- Lastly, HCFA has established a Y2K provider relations/Outreach Group. This group is comprised of HCF, Medicare Contractors and State Agency Personnel, whom is charged with developing a strategy for spreading awareness among Medicare, Medicaid and Managed Care Providers of the Y2K problem, providing them with information which can be used to assist them in checking for Y2K compliancy and producing materials which can be used by HCFA employees, Medicare Contractors, State Agencies, Provider Organizations and other partners who can use the information for these purposes.
- The workgroup has surveyed the Medicare contractors and obtained examples of outreach materials they are using. Example of the material collected thus far include a provider checklist to assess Y2K compliance, Y2K articles in bulletins/newsletters, and the establishment of voicemail and E-mail boxes for Y2K questions, the development of millennium logos, Y2K seminars, and a mechanism for testing electronic claims.
- We will continue to closely monitor our own efforts and those of our contractors to ensure that we are on track with becoming Y2K compliant.

Question. In HHS outreach efforts, what has HHS done to take into account the difficulties and concerns that rural hospitals may have because they do have the staff or money to become Y2K compliant?

Answer. HCFA, through the efforts of its fiscal intermediaries, is reaching out to all rural hospitals. The outreach efforts include educational mailings, training seminars, vendor exhibits, along with personalized customer service activities. Examples of these customer service activities are provider Y2K hotlines and provider Y2K web sites.

In addition, a Y2K briefing was conducted on July 16 for national professional and provider organizations. A special meeting is being conducted on August 20 for the benefit of organizations using electronic data interchange for Medicare billings. Other information sharing sessions on such topics as bill payment, biomedical equipment, and telecommunications are planned over the next several months as part of a continuous outreach program for provider organizations.

HCFA will continue to alert and assist all providers, including rural hospitals, on the urgency of Y2K remediation. Over the next several months, HCFA will be developing outreach materials and disseminating them to providers. However, HCFA does not have the authority or resources to fund code renovation and testing at rural hospitals. Rural hospitals currently receive a number of grants to assist in administration. These grant monies can, and should be, utilized to help achieve Y2K compliance.

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

STATEMENT OF THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION

Medical Device Manufacturers Association (MDMA) appreciates this opportunity to comment on the potential impact of the "year 2000 problem" on healthcare for the record of the Senate Special Committee on the Year 2000 Technology Problem. MDMA is a national trade association based in Washington, D.C., representing nearly 130 independent manufacturers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products to the marketplace.

MDMA also appreciates this opportunity to tell you how MDMA and its members are responding to public concerns about this issue. First, however, we want to assure this committee and the public that the hundreds of thousands of people employed by the medical device industry are committed to public health and patient safety. Manufacturers of medical devices that rely on date-sensitive computer hardware and software are well aware of the significance of the potential problem created by two-digit date formats and are working to identify and develop solutions for the "year 2000 problem." The industry intends to solve this dilemma and to prevent even one patient from being endangered by a device that malfunctions or is rendered inoperable by the "millennium bug."

MDMA believes, however, that many concerned organizations have overstated the risk to health and medical device safety posed by the "year 2000 problem." Computer technology is not a component of most medical devices, and the vast majority of medical equipment that does rely upon computer hardware and software is not date-sensitive. In fact, the Food and Drug Administration (FDA), which regulates the medical device industry, testified before Congress last year that the agency does not believe this issue will have "any major impact on medical device safety":

Computer software frequently is embedded as a "component" of devices, i.e., software contained on a microchip to control device operation. Examples of such devices are: pacemakers, infusion pumps, ventilators, and many others. It is unlikely that most of these products would be impacted by the "Year 2000" problem. Almost none of these devices require knowledge of the current date to operate safely and effectively. For example, pacemakers do not use the current date in their operation.¹

Manufacturers are responding to this issue with all deliberate speed because the industry shares a commitment to patient safety with our nation's health professionals and hospital administrators. In addition, FDA regulations require our products to be "year 2000 compliant." Finally, the unwritten laws of business require manufacturers to address any "year 2000 problems" if they hope to maintain customer confidence in their companies and products.

Nevertheless, the industry needs to do more to demonstrate that there is no "year 2000 crisis" for medical devices and to reinforce our commitment to patient safety. Patients and healthcare providers are asking for information about the "year 2000 compliance" of medical products and about manufacturers' plans for addressing any potential problems with date-sensitive devices. Fortunately, an excellent national clearinghouse for information on the "year 2000 compliance" of medical devices already exists: the FDA's Year 2000 World Wide Web site [www.fda.gov/cdrh/yr2000].

The FDA established its Year 2000 Web site earlier this year as a comprehensive database for information on the status or impact on product performance of the "year 2000 problem" for medical devices and scientific laboratory equipment. The

¹ Testimony of Thomas Shope, Ph.D., acting director, Division of Electronics and Computer Sciences, Office of Science and Technology, Center for Devices and Radiological Health, Food and Drug Administration, before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, U.S. House of Representatives, June 26, 1997.

FDA is collecting this information on behalf of federal agencies that purchase and use medical products and need to plan remedial actions in case any such products are affected by date-processing or date-storing problems. This database could serve as the coordinated national clearinghouse sought by concerned health professionals and healthcare institutions

To demonstrate the responsiveness of the medical device industry on issues of patient safety, MDMA has begun an initiative to collect information from its members on the "year 2000 compliance" of their products. Today, MDMA is sending a memorandum that asks our member manufacturers to fill out and return a questionnaire and any necessary supplementary information on "year 2000 compliance" to MDMA as soon as possible but no later than October 6, 1998. MDMA will transmit all completed questionnaires to the FDA as we receive them.

With our members' cooperation, MDMA hopes to complete this initiative by October 7, the day that Congress is scheduled to adjourn for the year. Since this committee and many other members of Congress have expressed interest and concern in this issue, MDMA wants to assure our legislators before they return home for the November elections that the medical device industry is responding to their concerns.

MDMA believes this coordinated response to the FDA's request for information will demonstrate the responsiveness of MDMA and its members on issues of patient safety and, more importantly, will reassure the public that there is no major "year 2000 crisis" in medical devices. Many manufacturers have already posted information about their products' compliance status on the FDA's Web site, and MDMA encourages the media and the groups that represent patients, health professionals, hospitals, and health plans to publicize the existence of this site to their constituents and affiliates. We also encourage these organizations to report responsibility on the true extent of the "year 2000 problem" and medical device safety. Incomplete or misleading pronouncements on this issue will only serve to frighten unnecessarily patients who rely on the life-enhancing and life-saving technologies developed by the medical device industry.

