

HEARING ON PROSTATE CANCER: THE SILENT KILLER

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BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE
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CONTENTS

	Page
Opening statement of Senator Charles E. Grassley	1
Prepared statement of:	
Senator Mike Enzi	25
Senator Larry E. Craig	26
Senator Harry Reid	27
Senator Richard Shelby	28
Senator Susan Collins	29
Senator John Breaux	29
Senator Ron Wyden	30
Senator Conrad Burns	30
Senator James Jeffords	31

PANEL OF WITNESSES

Hon. Robert Dole, Former U.S. Senator from the State of Kansas	3
Len Dawson, NFL Hall of Fame Quarterback	8
Mr. and Mrs. Bob Watson, General Manager, New York Yankees	11
Hon. Robert Miller, Governor, State of Nevada	15
E. David Crawford, M.D., University of Colorado Health Sciences Center; Denver, CO	31
Prepared statement of Col. David G. McLeod, M.D., Chief, Urology Service, Walter Reed Army Medical Center, Washington, DC	46
Prepared statement of Richard J. Babaian, M.D., The University of Texas	49
Prepared statement of Thomas V. Holohan, M.D., F.A.C.P., Chief Patient Care Services Offices, Veterans Health Administration, Department of Vet- erans Affairs	52
Prepared statement of Harold Sox, M.D., Dartmouth Medical School	56

APPENDIX

Responses from Len Dawson	61
Responses from E. David Crawford, M.D.	61
Responses from David G. McLeod, M.D., J.D., FACS, Walter Reed Army Medical Center	62
Responses from Department of Veterans Affairs	63
Responses from Harold Sox, Dartmouth Medical School	64
Prepared statement submitted by The American Urological Association	65
Prepared statement submitted by Mrs. Dean A. Gallo	66

HEARING ON PROSTATE CANCER: THE SILENT KILLER

TUESDAY, SEPTEMBER 23, 1997

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 10:22 a.m., in room SD-628, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Grassley, Craig, Burns, Shelby, Hagel, Collins, Enzi, Breaux, and Reid.

OPENING STATEMENT OF SENATOR CHARLES GRASSLEY, CHAIRMAN

The CHAIRMAN. I'm going to call this meeting to order now. I apologize for the Senate having two votes. It is beyond our control.

Also I am going to do something I haven't done in this committee before and that is to ask Senator Shelby to preside over the hearing after I make my opening comments. I want to do that because Senator Shelby requested that I hold this hearing. Second, he has had a bout with this type of cancer and he is very much interested in using every forum he can, as the people who are on our first panel are using their positions and their fame, to bring attention to this during this very important Prostate Cancer Awareness Week.

Because of the number of witnesses and the lateness of our getting started, I will not be able to give the usual courtesies that I have given to my colleagues to make opening statements. I would hope that you could make those opening statements after we are done with the first panel because some of them have to leave shortly. I want to make sure, however, that Senator Breaux and Senator Shelby have an opportunity to make their statements.

As I said, I am very pleased to have Senator Shelby ask for this hearing. I am also honored to have my former colleague and Senate majority leader, Bob Dole, here with us today. I appreciate very much his making this appearance, his first in an official capacity on Capitol Hill since he left the U.S. Senate. We are very honored to have him before this committee.

He, likewise, is a prostate cancer survivor and has had enormous impact on encouraging men to seek screening.

I also welcome all of our other witnesses who will be introduced by Senator Shelby. I thank you all for attending, as well.

As many of you know, Prostate Cancer Awareness Week is here. We hope today's hearing is going to contribute to greater public

awareness about the dangers of this disease. Prostate cancer is the most common form of cancer in American men. It is the second leading cause of death from cancer among men. This year alone there will be over 330,000 new cases of prostate cancer diagnosed.

This disease is especially common among African-American males. In fact, African-American males have the highest prostate cancer mortality rate in the world.

Let me say this issue is not just about men. There is something about men, though, being chicken when it comes to going to the doctor, and my wife could probably attest to that. But in the end, she usually wins out and I think we will see from witnesses today that when wives and children are involved in getting men to be concerned about this issue, it can have a very important impact at a very important time in a man's life.

So we want to make sure that the crucial role of spouses encouraging men to be screened, which ultimately saves lives, is given some attention, as well.

Today's hearing will highlight the prevalence of this disease, the treatment and screening options and the public debate surrounding screening and treatment. The recently passed Balanced Budget Act of 1997 includes a new preventive benefit, the annual blood test known as the PSA test for Medicare beneficiaries age 50 and above. This will become available in the year 2000.

While Medicare is going to cover this screening, there is still controversy in the medical community as to the merits of screening, particularly for men over age 70. We hope to gain more insight about this debate from the experts here today.

So I am happy to have Senator Shelby chair this hearing. Would you please proceed with your statement.

[Prepared statement of Senator Grassley follows:]

PREPARED STATEMENT OF SENATOR CHARLES E. GRASSLEY

It is an honor for me today to have the Senate Special Committee on Aging hold this important hearing on prostate cancer. At the request of Senator Shelby, a prostate cancer survivor, I agreed to bring this issue before the committee to raise public awareness about this deadly disease. I am pleased to hold this hearing and to have my colleague, Senator Shelby, chair this special event.

I am also honored to have my former colleague and Senate Majority Leader, Bob Dole, here with us today. Senator Dole is a survivor of prostate cancer and has had an enormous impact on encouraging men to seek screening. I also want to welcome all the other witnesses here today and to thank you for taking time out of your busy schedule to appear before the committee.

As many of you know, this is Prostate Cancer Awareness Week. We hope today's hearing will contribute to greater public awareness about the dangers of this disease. Prostate cancer is the most common form of cancer in American men. It's the second leading cause of cancer death among men. This disease is especially common among African-American males. In fact, African-American men have the highest prostate cancer mortality rate in the world.

This issue is not just about men. It's about families. It's no secret that most men are big chickens when it comes to going to the doctor. In fact, my wife could testify about how stubborn I can be at times. But in the end, she usually gets her way. Some of our witnesses here today can talk about the crucial role their spouses played in making them get screened which ultimately saved their lives.

Today's hearing will highlight the prevalence of this disease, the treatment and screening options, and the public debate surrounding screening and treatment. The recently passed Balanced Budget Act of 1997 includes a new preventative benefit—annual blood tests known as the PSA (prostate-specific antigen) test for Medicare beneficiaries age 50 and above. This will become available in the year 2000. While Medicare is going to cover this screening, there is still controversy in the medical

community as to the merits of screening, particularly for men over the age of 70. We hope to gain more insight about this debate from the experts here today.

Again, I am pleased to be here today. Now, I would like to turn this hearing over to Senator Shelby, who will be chairing the proceedings this morning. Thank you for coming.

Senator SHELBY. Mr. Chairman, thank you for convening this hearing. Right now I am going to yield my time to Senator Burns, who is in dire need of being at another meeting.

Senator BURNS. Mr. Chairman, we were in Montana a couple of weeks ago and we assisted some people in getting some care for some people who had prostate cancer. They gave me this because they have set up an Internet information page and now they have a club to educate people on prostate cancer.

They have set this up and they gave me this and I want to give this to Senator Dole because not only has he been a great champion of awareness of prostate cancer but they say the prostate is about the size of a walnut. Well, they have a thing they call the Seed Club for survivors who received seed implantation treatment. On this is a little bell that reminds us for whom the bell tolls.

So Rick Ward from Anaconda, MT, gave the golden walnut to me and we are going to give it to you for all of your work on this issue.

I want to thank Senator Dole personally for what he has done in this regard. That is from Rick Ward, Anaconda, MT, and thank you for your nice words on my mother.

Senator DOLE. Thank you.

[Applause.]

Senator SHELBY [presiding]. We will go immediately to our panel. First of all, as I have indicated, Senator Bob Dole is with us. The second speaker will be Len Dawson, NFL Hall of Fame, quarterback fame. We have Mr. and Mrs. Bob Watson here, general manager of the New York Yankees. And we have Governor Miller of the State of Nevada.

Would you proceed, Senator Dole?

STATEMENT OF HON. BOB DOLE, FORMER U.S. SENATOR FROM THE STATE OF KANSAS

Senator DOLE. Well first, let me thank you for inviting me to this hearing. I think it's very timely and very important and I know there are many people in the audience who could probably make better presentations than some of us here. I want to assure people that just because your name is Bob doesn't mean that you're more likely to have prostate cancer. [Laughter.]

Bob Watson, Bob Miller, and Bob Dole. I don't know how Len Dawson got in here. In any event, don't change your name. It'll be all right.

Well, I left Congress about 15 months ago and I am not here lobbying. I am not lobbying for anything. I am just here to talk about a personal experience. I wasn't certain I would be here today but when Senator Grassley calls you, you had better show up. He's very persuasive and I am very honored to be here.

I remember visiting Senator Shelby when he was recovering from prostate surgery. In fact, I put on a doctor's uniform, went in to see him and said we were going to keep him in the hospital until he switched parties. [Laughter.]

And it worked.

But in any event I am very honored to be here with Dr. McLeod, who performed my surgery and many others' here, including Senator Shelby.

But I want to speak about the personal experience and how important I believe it is, and certainly Senator Grassley touched on it. It is hard to get men—I don't know what percent of men; there are experts here—to get an annual physical. We have had a prostate screening booth at my State fair for the past 5 or 6 years. We do PSA tests and mammograms. About 3,000 men a year go through this process. I have watched these people go down the midway and it takes about two turns for the wife to get him into the booth there so he can get the PSA test.

So I would say to men that you owe it to your families and to your job and to your community to have a checkup. I don't recommend any kind of treatment. I'm not giving any medical advice. I had the surgery. Others can tell you they have had great success with other forms of treatment.

But as Senator Grassley pointed out earlier, about 300,000 men heard for the first time maybe last year that they had cancer. When somebody told me that in 1991 I was a bit stunned and surprised and didn't know much about it. In fact, I'll confess I have learned more about prostate cancer since my operation than I knew before.

So I thought, first of all, it had to be a mistake because I couldn't have had anything like this. But it was me and I wasn't even certain that I knew—you know, I had heard about prostate cancer but I never really focused on it because I thought it always happened to somebody else.

But it is life-threatening and is a serious operation in this case, something that should be treated. Of course, early detection is everything.

I remember talking to Dr. Krasner, who was the Capitol physician. He didn't find anything serious about my exam but he did give me a blood test called a prostate specific antigen test or PSA, and the first test turned up a level of 4.8 and this I was told was considered to be elevated, but not by much. Usually 0 to 4 is normal so I said well, it would probably be better next time. It was better; it was 6.9 and then to 8. I finally had the biopsy and was told, "You have a problem."

The result was positive. On December 18, 1991, I underwent what they call a radical prostatectomy by Dr. David McLeod who will be here later this morning. He advised me that they had gotten it all and everything was going to be all right and the good news was that I would need no further treatment, other than periodic PSA tests. Almost 6 years later my PSA test remains at 0.

I guess after the operation I was relieved, like anybody would be after any operation, man or woman, regardless of what it may be. I was a member of the Finance Committee and had been chairman of the Finance Committee and we had talked a lot about this and I learned rather quickly that very little money was going into prostate cancer research. And I am not here to suggest that we ought to choose up sides with different cancers. There ought to be more money for cancer, period, and let the experts decide how it should be dispersed.

So I took an interest in it. I had gone public because it seemed to me that it was important for other men to learn about prostate cancer. So that is sort of what I have done since that time. I have probably talked to—Len has talked to more—400 or 500 men by telephone who have written letters, who have heard about my prostate cancer operation. And men as well as women are frightened when they hear the word cancer.

So it seems to me that we discussed with my wife about going public and I think women were very fortunate to have pioneers like Betty Ford, who candidly and courageously discussed her experience with breast cancer and it seemed to me that men had the same obligation, talking about things that happened to men. For a long time they were sort of private and you didn't want to talk about incontinence or impotence. That is something you do not discuss in public but it is a matter of your health and it is a matter, in some cases, of your life. It is a matter of letting your fellow men know, fellow men around the world and around America, that this is something that can be treated.

So the first thing I did was every speech I gave I started, particularly if I could see a few men I thought were over 40 or 50 in the audience, telling them about prostate cancer and about the PSA test, not suggesting any treatment. But I found later that this was paying off and men were telling me later that they had been to the doctor, they had gotten the PSA test. Some had even had the operation.

I also addressed the women in the audience because, as I said earlier and as the chairman said, it is very important because it is important for the wife to know and work with her husband to get him in to see the right doctor and get the right treatment. So if you can get your husband or your father to visit a doctor's office, that is part of the battle.

The media started picking up on these messages and I found myself on "Larry King." I sort of became the prostate pin-up boy in Washington, DC. I was talking about it a lot because I felt it was important. I didn't talk about politics; I talked about prostate, and maybe that is what happened to me in 1996. [Laughter.]

Before long, the letters and phone calls came pouring in and nearly everybody wanted to know everything about prostate cancer and how to treat it, its side effects, as I said, such as incontinence and impotence, and I was very fortunate to have Vicky Hart on my staff, a nurse who I just sort of turned this over to and she became sort of a depository. We have piles of information. We used to send piles of information out to everybody who would call. As I learned more about it we became sort of a dissemination center on prostate cancer.

So it seemed to me that as more and more men have spoken out, obviously more and more men are seeing their doctor. And by August of 1992, about 8 months after my surgery, I sponsored the first Bob Dole Prostate Cancer Screening Booth and in a few days, with the help of volunteers, including a doctor named Mark Austenfeld, who was a volunteer from the University of Kansas—Len probably knows him—we gave about 300 free PSA tests. I think it was at the 1992 Republican Convention. It was about the

most exciting thing that happened, as I remember it, at that convention.

But in any event, a lot of men came in, got their PSA test and their lives are probably saved because of it.

So I would just say, as another man who has had this experience, that it is important that we speak out, that we talk to our friends about it, that where we have opportunities, since there are the witnesses here to speak out in a public way and have it picked up by the media—it is not partisan; there's no politics involved in it. It is about health. It is about early detection. It is about letting your other friends know that they can live a normal life.

So I would just suggest that a lot of people will benefit from this hearing this morning and I commend all of you for participating. I know you are very busy. You are having votes. But this is a very important matter for a lot of people.

I want to conclude just by quoting from a letter hand delivered from a former staff member of mine talking about her father. I will just read a portion of it.

It is from Janet Sena, who happens to be in the audience. Her father has been battling prostate cancer for several years and he just wanted me to know he appreciated efforts to educate others about prostate cancer.

But that is not the point. Her father's cancer was caught in the later stages, so his treatment has been more focussed on slowing down the rate of growth of the cancer. She states they were fortunate that hormone therapy worked for several years but it stopped working last fall. Since then her father has been undergoing chemotherapy and is unsure whether he will pursue radiation, given its unlikely effectiveness.

But throughout this ordeal, the treatment process seems an undefined path that presents choices without clear solutions. Obviously this is very frustrating for someone who has this problem. He has spent his life identifying and solving problems for others. She indicates that his prognosis is not the best, that this process has sort of opened her eyes to the maze of uncertainty that exists in treating prostate cancer and the need to continually push for solutions.

I would just say that I—I ask that my entire statement be made a part of the record.

Senator SHELBY. So ordered.

Senator DOLE. I guarantee that there be enough men or women or daughters or sons watching this hearing through C-SPAN or whatever that it will save a number of lives across America. And for that I thank everyone who is here this morning.

[The prepared statement of Senator Dole follows:]

SENATOR DOLE'S TESTIMONY BEFORE THE SENATE SPECIAL COMMITTEE ON AGING,
SEPTEMBER 23, 1997

Thank you for inviting me this morning. When I left Congress 15 months ago, I vowed that I would not lobby for any "special interests." So, when asked to testify about prostate cancer this morning, I was a little reluctant. But, as you all know, when Senator Grassley wants something, he is very persuasive. So, I am here along with others to simply speak about our personal experiences with prostate cancer.

Almost 6 years ago, I was one of the more than 300,000 men who had to hear perhaps the most dreaded words one can hear from one's doctor, "You have prostate

cancer." It goes without saying that I was stunned. My first reaction was to think it must be a mistake. He must be talking about someone else. But, it was me.

I have to admit, I wasn't even certain I knew what a prostate was—let alone that it might threaten my life. But, I did know that I had been getting up a lot every night. That, alone, was my only symptom. I mentioned it to the Capitol physician, Dr. Krasner, during my annual physical. Dr. Krasner found nothing suspicious during my exam, but he did give me a blood test, called a prostate specific antigen test or PSA test. The first test turned up a level of 4.8. This, I was told, was considered to be elevated, but not by much. Usually to 4 is a normal level. Dr. Krasner rechecked the level in a few months, and subsequent tests saw that PSA level rising to 6.9 and then to 8. A rising level of PSA, I was told, can signify an increase in the volume of a suspected tumor.

A biopsy was done. The result was positive. On December 18, 1991, I underwent a radical prostatectomy by Dr. David McLeod, who will testify later this morning. Dr. McLeod advised me that cancer had been caught early while it was still confined to the prostate gland. The good news was I would need no further treatment other than periodic PSA tests. Almost six years later, my PSA level remains at zero.

After my surgery was complete, I was immensely relieved, but wanted to know more about this disease. If I, the Senate Republican leader, a member of the Finance Committee where health care issues frequently dominate the agenda, and an individual who had a great deal of personal experience with health care, had never really heard of this disease, would not have known to ask for a PSA test or any other test for that matter, and who really had almost no symptoms, how many other men were out there who didn't know to go to their doctor and get checked. I couldn't possibly be the only person to have had prostate cancer. But, why had I never heard of anyone else discussing it?

Elizabeth and I discussed it, and with her encouragement, I decided to go public with my story. Women were very fortunate to have pioneers like Betty Ford, who candidly and courageously discussed her experience with breast cancer. Who knows how many thousands of lives Betty Ford saved with her candor and how many women today remain the beneficiaries of early detection.

For me the question was, where do I begin? What I started to do was begin every speech I gave by encouraging all the men over the age of 40 in the audience to ask their doctor about a prostate check-up, and to ask about the PSA test. I also addressed the women in the audience. Women are so much better about taking care of their health and seeing a doctor regularly. I concluded, maybe the wives or daughters of men would encourage a visit to the physician's office.

Before long, the media started picking up on these messages I was delivering, and I found myself on "The Larry King Show" and the networks—not talking about politics, but instead talking about prostates. I started referring to myself as the "Prostate Pin-Up Boy", and before long, the letters and phone calls came pouring in. Nearly everyone wanted to know everything about prostate cancer and how to treat it—it's side effects, such as incontinence and impotence—I learned much more about prostate cancer in the process.

While my office was quickly becoming, in a sense, a dissemination center on prostate cancer information, it occurred to me that much of this was happening because of the void out there on men's health issues. It became a personal crusade to increase awareness about prostate cancer.

By August of 1992, about 8 months after my surgery, I sponsored the first "Bob Dole Prostate Cancer Screening Booth." In a few days, with the help of volunteers, including Dr. Mark Austenfeld, a young urologist at the University of Kansas, about 300 free PSA tests were done. We received some media attention because this prostate screening booth was near the convention floor at the Republican National Convention in Houston.

Since then, I have sponsored many screening booths at places such as the Kansas State Fair, the trading floor of the Chicago Mercantile, and again at the 1996 Republican Convention. We expanded our services to include free mammograms. Thanks to the Cancer Research Foundation of America, enough money was raised to screen about 20,000 men for prostate cancer and about 5,000 women for breast cancer.

So, I've learned a great deal about prostate cancer since 1991. But I've also learned a lot about all cancers. And, though I'm not a doctor or a scientist—I've been told by the experts that the cure for prostate cancer, or breast cancer, or any other type will come when we focus on the cure for all cancers.

I've said it all along that there is nothing to be gained by pitting one cancer against another. Or for that matter, one disease against another.

Every cancer can probably benefit from more research dollars. And, I hope in the near future, a way will be found to make that happen.

Let me conclude by emphasizing how important early detection is to saving lives. I have to admit, at the beginning talking about prostate cancer and the possible side effects was difficult and at times awkward. But, when you open a letter from a man who writes to thank you for saving his life, there is no such thing as awkwardness. So, on behalf of all the men, and their families, who will benefit from this hearing this morning—and who may even, themselves, become the next beneficiary of early detection, I would like to express my whole-hearted appreciation for this committee, particularly Senators Grassley and Shelby, for bringing together this very impressive group of witnesses.

I guarantee this hearing will make a difference for men all across America.

Senator SHELBY. Senator Dole, thank you. I know you are busy and you have to go in a few minutes but we appreciate this, your first real public appearance on Capitol Hill since you left as our leader and we appreciate your leadership, not only in a lot of political areas and economic areas but in this, to help save lives.

Senator REID. Mr. Chairman.

Senator SHELBY. Senator Reid.

Senator REID. I know that Senator Dole is not going to be here for the entire panel. I just want to say briefly that I personally appreciate your being here and say to anyone within the sound of my voice you haven't only been courageous with this because as a personality you are one of the first to come forward and talk about something so private as prostate cancer, but your record speaks for itself going back to the Second World War and your courageous return to health and serving in the Senate as valiantly as you did. So I appreciate personally your being here today.

Senator DOLE. Thank you.

Senator SHELBY. Mr. Len Dawson, we are glad to have you here. You have a great story. Everybody, I think, knows who you are.

STATEMENT OF LEN DAWSON, NFL HALL OF FAME QUARTERBACK

Mr. DAWSON. Well, thank you very much, Senators. I am very happy to be here today on this panel. I am a prostate cancer survivor. Also I am a representative of the American Foundation for Urologic Disease, also known as AFUD. And as a result of my experiences with prostate cancer, I have been a spokesman for the "Team Up Against Prostate Cancer" program sponsored by AFUD. And I am happy to report that these programs have reached millions of men and, I think more importantly, millions of families, as well.

I would like to thank Congress for adding prostate cancer early detection as a Medicare benefit in the recently enacted Budget Act of 1997.

Now, who am I? I am Len Dawson. I am from a family of 11 children, so I am accustomed to crowds like this. There are seven boys and four girls. I happen to be the youngest boy, so I am the seventh son. Also, I am the seventh son of a seventh son. And I was told very early that that is a good sign. That means good luck. Good things will happen to you, and I am here to tell you that that is exactly right because things have been very good to me and I have been very fortunate.

Athletically, in football, I spent 27 years in organized football, 19 years professionally. The ultimate compliment was presented to me in Canton, OH, in 1987 when I was elected to the Pro Football Hall of Fame.

I think one of the reasons that I was elected is because of the number of years that I played professional football. I played professional football for 19 years and I never had what would be called a career-threatening injury. I never had an operation in the 27 years that I played football and I owe that to the fact—maybe it is because I am the seventh son of a seventh son because I will tell you one thing—I got hit a lot. I was just fortunate that I did not get hit the right way.

I can tell you this, that even though I did not have a career-ending injury, I got hit from my head all the way to my toes. So I knew something about being hurt, something about injuries, and I knew that jeez, if my ankle was swollen, I could handle that because I would put ice on it right away and take care of it. If I didn't feel very well, I knew about that.

But I am here to talk about something that is a silent killer and that is cancer, prostate cancer. I thought that I could handle most anything. But I say I am a very fortunate individual. I am fortunate that I am married to a woman who cares about me and cares about my well-being, and this man next to me.

It happened that unfortunately for Senator Dole, that he had prostate cancer and he was operated on. My wife read an article regarding this operation and how he found out that he did have this problem and the PSA test was part of that.

I do not think she would have read the article if it had not been Senator Dole or someone like a Senator Dole. She became very interested in that because the next day in the newspaper there was an article saying, "Free screening for men. If you are 50 years of age or older and if you haven't had this new technique of the blood test, the PSA, you should have it done."

So being the wife that she is, she made an appointment for me. This was in December 1991. I came home. She said, "I want you to read this article because I've made an appointment for you."

So I read the article. I read what the symptoms were and I said, "I have none of these symptoms." And she said, "Well, I've made the appointment for you." I said, "I'm going to tell you something. I had a physical about 8 or 10 months ago. Part of it was the rectal examination for prostate problems and I got a clean bill of health. I don't have any of these things. I'm not going to do it."

She said, "Well, let me tell you something. You're going to have to cancel that appointment because it'll take you 10 minutes; it's 5 minutes away from where we live, on the way to work."

For the sake of arguing I said, "Well, all right." I thought it was just the blood test. So they took the blood and I was there 5 minutes. I was ready to leave and the nurse said, "Well, step into that room right over there. The doctor will be with you in a minute." I said, "For what?" "To finish the examination." I said, "Ah, no," because I had been around football players all my life that have the rectal examinations and I will guarantee you none of them want it done.

So I went through that. The ironic thing is that my PSA was within the normal range but through the rectal examination they discovered I had a problem, or he thought so. Through further examination they found that I did indeed have a malignant tumor on the prostate gland and gave me my options. One of the options was

surgery and they said the chances are if it is contained within the prostate gland, in 95 percent of the cases it will be fine and I would never have a problem again. Well, as an exquarterback, that is a no-brainer, the 95 percenter.

So I opted for that. That was in 1992. As I say, Senator, it was because of you and because my wife read that article that I am smiling today, because it was the best decision that she ever made.

I say I was very lucky as the seventh son of a seventh son but in my family the first son of a seventh son was not as fortunate. Two summers ago my oldest brother Ronald passed away from prostate cancer. He was not as lucky as me. He did not have the same options and it was too late when they detected it. That is why I am testifying, because if I can help somebody else, the way Senator Dole helped me, I will be very happy. Thank you very much.

[The prepared statement of Mr. Dawson follows:]

PROSTATE CANCER, MY STORY

(A PRESENTATION BY LEN DAWSON, TO THE SENATE SPECIAL COMMITTEE ON AGING, SEPTEMBER 23, 1997)

Good morning Senators Grassley and Shelby and members of the Committee. My name is Len Dawson, I am here as a prostate cancer survivor and as a representative of the American Foundation for Urologic Disease, also known as the A.F.U.D.

The A.F.U.D. is a charitable 501(c)3 organization whose mission is the prevention and cure of urologic diseases through the expansion of research, education, and public awareness. In its 10-year history, the foundation has funded over \$18 million in research grants to innovative investigators as they launched their careers in urologic science; it has distributed over 6½ million patient education brochures; and has been in the forefront of the battle to bring increased public awareness to urologic diseases, including prostate cancer.

As a result of my own experiences with prostate cancer, I have been a spokesman for the "Team Up Against Prostate Cancer" programs sponsored by the A.F.U.D. for the past four years. These programs have reached millions of American men and their families.

I would like to thank Congress for adding prostate cancer early detection as a Medicare benefit in the recently enacted Balanced Budget Act of 1997. However, this benefit will not be effective for two years. I hope this Committee could urge Congress to accelerate that implementation date.

It is vital that American men have the benefits of prostate cancer early detection as soon as possible. I could sit here and quote facts and figures, but my own story makes the point.

I point myself a very lucky person . . . I am the 7th son of the 7th son . . . In the Spring of 1991, I had a complete physical, came home and told my wife Linda that I was in top shape. A few months later she asked if I had a prostate examination during that physical, because she had just seen Senator Bob Dole on television talking about the importance of the use of both the PSA blood test and the digital rectal examination or DRE for the detection of prostate cancer. My physical had included a DRE but not the PSA blood test.

The following day Linda read an article regarding free prostate cancer screening to occur later that month. Linda was adamant that I have the test and called and made an appointment for me to have both the DRE and PSA tests.

During my visit on the 19th, my doctor found my PSA to be regular. It was during my DRE exam that he though the found something. Further testing showed that I had early stage prostate cancer. Fortunately, the cancer was caught in its earliest and most treatable stages. My prostate was removed five years ago and I'm doing fine.

It is an honor for me to be here this morning with Senator Dole. I believe that I owe my life to the fact that my wife heard his message and encouraged me to have a prostate examination.

It saddens me to report that my brother Ron died of prostate cancer two years ago. His cancer was diagnosed at a much later and more virulent stage than mine. This fact has made me even more of an advocate for the early detection of prostate cancer.

At this time, the greatest opportunity we have to present the best chance to cure prostate cancer is through early detection. According to the latest statistics published by the American Cancer Society, if prostate cancer is diagnosed and treated in its earliest stages, a man has a 99 percent probability of living another five years. If the cancer is diagnosed at distant sites such as the spine or brain, his probability of living five years is reduced to 30 percent.

It is clear that we can make a difference to men and their families, if only they can get the message. Now that Medicare is going to cover early detection, let's make sure that Medicare beneficiaries are aware that they have this new benefit. This could be in the form of educational materials from Medicare or even simple announcements in with their Medicare Statements or Social Security checks.

For these men diagnosed with prostate cancer, it is critical that they have access to all appropriate cancer therapies. Many cancer treatments bring significant financial hardships to families who rely solely on Medicare benefits. Many of these folks have saved all their lives, and now must pay out of pocket for medically sound treatments that are not reimbursed by Medicare. Medicare should be amended to provide reimbursement for all FDA approved cancer therapies.

Today, Medicare is denying payment for approved therapies for the treatment of advanced stage prostate cancer on the basis of cost alone. If it takes an Act of Congress to ensure that medical providers and insurers, including Medicare, not be allowed to determine cancer treatments by the lowest alternative cost, it should be done! There is much more to determining therapies for cancer than cost . . . People's lives are at stake.

The health care needs of American citizens have changed dramatically since the inception of Medicare over 30 years ago. I urge that adequate provisions be made for the Medicare reimbursement of all approved cancer treatments.

It has been good to see the federal research funding for prostate cancer rising. There is still a long way to go for the disease to receive the research allocations appropriate to the leading cancer diagnosed and the second leading cause of cancer related deaths in American men.

In order to make the most effective use of each research dollar, Congress should direct the National Institutes of Health to develop a comprehensive prostate cancer research plan that encompasses all of its institutes.

Congress should also direct the Centers for Disease Control to establish prostate cancer registries throughout the country to collect information on all diagnosed cases of this disease. This vital information could be widely shared, disseminated and could become the basis for invaluable prostate cancer research data bases.

Let's team up and support these initiatives that rightfully address prostate cancer as a disease that has a profound impact on American families. Only then will we be able to eliminate it as a disease of serious concern. Thank you for this opportunity of speaking to you today.

Senator SHELBY. Thank you.

Our next panelist is Mr. Bob Watson. We all know him as not only a great baseball player but a great human being and currently the general manager of the New York Yankees, accompanied by his wife. Mr. Watson.

STATEMENT OF MR. AND MRS. BOB WATSON, GENERAL MANAGER, NEW YORK YANKEES

Mr. WATSON. Thank you, Senator. Mr. Chairman and other members of the committee, in 1994 I was diagnosed and successfully treated for prostate cancer. Sometimes I think the real reason why I was detected early with prostate cancer was the fact that I was a general manager of a major league baseball club. I think the reason would be that I could stand on a soapbox or lend my voice to help educate not only men but women about this dreaded disease of prostate cancer.

I think the message might be a little bit clearer when the general manager says that prostate cancer is a threat to all men and the best defense is knowledge and with that knowledge comes the opportunity to exercise some informed choices.

In my opinion it is imperative to get the message out that if you are 40 years old or older and you have a family history of prostate cancer, you need to get screened annually with the PSA blood test and rectal-digital exam. My urologist told me that just a digital exam would have missed mine and I would not be here testifying before you today.

I think the real thing that I really want to get out to you, though, is that when I go around speaking, and I do a lot of speaking about prostate cancer, I find there is a lot of fear. The fear is not just of the ravages of the disease but a lot of fear is in the diagnosis of the disease. And we are talking about the rectal-digital exam.

If I could leave one message with everybody here today it is don't let the digital exam keep you from getting screened. The DRE, as we call it, and the PSA blood test can save your life. I am living proof. Thank you.

[The prepared statement of Mr. Watson follows:]

PREPARED STATEMENT OF BOB WATSON, VICE PRESIDENT AND GENERAL MANAGER OF THE NEW YORK YANKEES

In the spring of 1994, after three decades in professional baseball, I was living the life of my dreams. My wife, Carol, and I had recently celebrated our 25th anniversary and as the first minority to be promoted to the position of general manager of a professional baseball team—the Houston Astros, I was at the highest echelon of my profession. The date for my annual team physical fell on Sunday, April 10, which also happened to be my 47th birthday. But instead of going to the doctor, I elected to spend that fine spring day with my wife.

I finally rescheduled the appointment for May, and as part of the exam, I asked the Doctor to give me a PSA—prostate specific antigen—test in addition to the DRE—digital rectal exam. Several scouts I knew had been diagnosed with prostate cancer the year before and they had urged me to ask for the test. The doctor said, “no, no, you're too young to do that. We don't start giving the PSA blood test until you're fifty or so; we'll just do the digital-rectal exam. I insisted. “No,” I said. “Do the PSA.” Well, the results came back at 5.8, which alarmed our team urologist, who ordered more tests and a biopsy. Out of the six core biopsies, one of the biopsies came back positive. It was a particularly aggressive form of cancer. When I heard the diagnosis, a thousand fearful thoughts raced through my mind. I inquired about surgery, and all of the other alternatives appropriate to this situation.

After considering my relatively young age and the fact that the cancer appeared to be confined to the capsule of the prostate gland, my doctor recommended surgery so that the cancer would not spread to the lymph nodes. After discussions with my wife and the owner of the team, I decided to go ahead and get it done. I had surgery on July 6, 1994, and the cancer was indeed confined to the gland; I did not need any additional treatment. My PSA test was 0.02, and today I am cancer free and feeling great.

Because of early detection and the fact that I am a vice president and general manager of a professional baseball team I can stand and deliver my personal testimony about recovery and help to educate others about prostate cancer. Prostate cancer can hit any man from any walk of life.

If you have a family history of prostate trouble or cancer you are at an even greater risk. The facts have also indicated that men of Mediterranean and African-American extraction have a higher incidence of prostate cancer. This is a disease that all men must acknowledge as a threat. The best defense against this dreaded disease is early detection and education. Getting screened with both the PSA blood test and the DRE by age 40 is imperative.

There are at least 78,000,000 baby boomers coming of age and at least 60 percent of this demographic will be affected by some form of cancer. In this year alone 41,000 men will die from prostate cancer. To put this into perspective that is more than a sell out crowd in the famed Fenway Park in Boston, MA.

My urologist told me that with the kind of malignancy that I had, a digital exam alone would have probably missed my cancer. If there is one message that I can leave with you it is this:

Make an informed choice regarding your health, do not let the fear of the digital exam keep you from getting regular check-ups. Use the three-fold approach and allow the use of early detection, education, PSA and DRE exams to save your life.

STATEMENT OF CAROL L. WATSON, SPOUSE OF BOB WATSON

My exposure to the terrifying world of cancer came to me in a very unexpected way. My saga unfolds around my husband accepting a coaching job with the Oakland A's as their major league hitting instructor. We had moved from Atlanta, GA, to an area in Oakland, CA, called Montclair.

I met a lovely brilliant woman named Bev R. who lived across the street from us. We became close caring and sharing friends. During one of our many discussions she had told me the story of her bout with breast cancer and her recovery. Because of her honesty and courage I began to learn about cancer. With a vengeance I read books on cancer from diets to cures, from miracles to death and dying. Until our friendship cancer was only the big "C" word.

During that year I also had made another friend named Mary S. 4 months into the friendship with Mary S. she told me that her younger sister who was in her early 20's had cancer and was preparing to have chemotherapy and hair loss as a result of the treatment. With this in mind I spent a very tender time with her sister teaching her how to tie her head in scarves.

The world of baseball and life were still moving forward. I was pulling into my garage one day and simultaneously a taxi pulled up with Bev R. my neighbor in it. I looked across the street into Bev's face and I could see that she was visibly shaken, pale and weary. I went across the street and told her that I could see that she was stressed and I asked her if she needed me for anything. She hesitated for a moment, finally she said, "You know how my side has been hurting on and off for the last several months?" I said, "Yes". She said, "Well the cancer is back". Within a relatively short amount of time, cancer took its toll and took my friend.

Within 6 months of her death my step father Eddie who was in his 60's contracted lung cancer. Initially we thought it was his childhood diabetes rearing it's head. Very shortly after the discovery of the cancer he passed away. Four months after Eddie's death Bob accepted a job with the Houston Astros as the first minority assistant general manager in baseball.

Bob and I had lived in Houston had been a part of the Astro organization for 15 years when he was a ballplayer. Upon our return to Houston I renewed an old friendship with one of the sages and comediennes in my life named Mary R. Mary R. was in her 60's but before we would have a chance to renew or nurture our relationship she succumbed to her second bout of cancer in 13 years.

After her death another friend Genita P. called me with the news that she had cancer again for the third time. Adding shock to surprise to heart felt sickness was the call I received from one of my dearest high school friends Judy McC. Judy lives in Nashville, TN. The news was breast cancer. She had a lumpectomy and her prognosis was good.

Three months after Judy's telephone call, my friend Paul A. was diagnosed with lung cancer. Paul A. died from lung cancer. One year to the day, Judy McC. called to say that the cancer had returned.

More dismay, shock and surprise came when my father, Emile L. called to say that he had throat cancer. In short order he died from that same throat cancer. My brother Phillip L. died 6 months later.

On October 25, 1993 which was our 25th wedding anniversary my husband was named general manager of the Houston Astros. We sail along for a while and a few other cancer scares from close friends are revealed.

April 1994 locked my sights on to a consumptive and encompassing trail. The trail of cancer had crossed boundaries, cultures, age and time lines. It twisted and wound itself from some distant fog-covered, unnamed mountaintop that fostered an avalanche that led directly into my home and bedroom door.

In spite of all of my reading and experience this onslaught produced a very dangerous poisonous snake that I did not know existed. This was startling to say the least. We asked our team physicians what options and choices did Bob have with the aggressive cancer that he had contracted. We were told that waiting was one option, radiation and related treatments another and last but not least a radical prostatectomy.

After much discussion we chose the physician who invented the PSA—prostate specific antigen—blood test, Dr. William Catalona to perform surgery. Even though he practices medicine at Washington University, in St. Louis, MO, he mailed to us videotapes and pamphlets, as well as calling Bob on the telephone several times.

We were both very well informed about the possibilities of incontinency and impotency and about the time, energy and effort on both of our parts that aftercare would encompass. The truth helped me to adjust my thinking about this emotionally devastating and jolting event that tumbled into our lives from the avalanche. I am and shall be an advocate of early detection, education, research and choices.

Senator SHELBY. Mrs. Watson, do you have any statement? We welcome you to the committee and we appreciate your accompanying your husband.

Mrs. WATSON. Thank you. As the wife and spouse of a cancer survivor I have my own trail of tears and shock and finally, awareness around cancer. Even though I had had knowledge and experience with cancer before, I had roughly a 4-year period of time where a number of people died in my life from various forms of cancer. So, almost every 4 to 6 months I was either treating someone or helping someone to leave this planet from the disease, but that still did not prepare me for prostate cancer. I didn't know anything about it.

So, I started on this trail that was a lot of ignorance and denial. Along that trail was—I guess I could call it a darkness and a poisonous amount of snakes. It was encompassing and it was bleak. Bob and I had been married for 25 years at that point—we have been married 30 years now—and it was horrifying and it was frightening. I had no knowledge of statistics, odds, communities of support, feelings or the process involving diagnosis and recovery. And denial was a part of my initial reaction. I think that is what happens with all things that sound terminal connected with cancer.

However, denial is not a friend to those of us who choose the path of wellness. In this context, denial can be compared to a tissue paper thin undergarment that in fair times or in the summertime of our lives can be attractive and serve a purpose. But denial is problematic when used as outerwear in inclement weather. Denial will leave men and their families naked and in despair without a hope or a prayer.

Of necessity, because of Bob's job, we had to become public and our personal process of recovery had to move beyond the denial. Today we are all aware that there are seasonal changes in the world relative to aging and good health. We all must move beyond denial into an appropriate set of garments—garments of preparation, education, and humility.

This ensemble of this outerwear is strong enough to weather the storms that the processes of living will bring to everyone. Early detection, education, research, and grace are what saved my husband's life and all these things I'm really grateful for.

As a result of the prostate awareness of that I have had, I have had the opportunity, along with Senator Gallo's widow, Marv Levi's wife, of Buffalo Bills, Mason Adams' wife, Margot Adams—we have made a prostate cancer awareness video that hopefully is going to serve as a public service announcement around the country.

I am glad to be here today to be able to speak.

Senator SHELBY. Thank you for your testimony.

Our next panelist is the Honorable Robert Miller, Governor of the State of Nevada. Governor Miller.

STATEMENT OF HON. BOB MILLER, GOVERNOR, STATE OF NEVADA

Governor MILLER. Thank you, Senator, and thank you for calling these hearings and allowing me to appear with these distinguished gentlemen and lady discussing this disease.

About a year about at this time I had assumed the chairmanship of the National Governors Association and felt I was much too busy to take an annual physical exam. But for the persistence of my friend and physician, Dr. Elias Ghanem, I finally gave in and took that exam.

I knew I was in great health. I was only 51. I was playing basketball a couple of times a week and exercising regularly and the exam proved to reach the result that I expected. Everything was fine.

At the end the doctor said to me, "You know, I want you to see a urologist. Your PSA is 4.1. That is about normal but we ought to go see a urologist." And so we did.

The urologist's digital exam and ultrasound exam were both negative but my physician insisted that I have a biopsy in any case. Since all three of us were sure it would be negative, they thought it would be easy for me to just call in in a couple of days and get the results. About 2 days later I was delivering the eulogy for a friend who had died of cancer and as I walked out of the funeral into the car, I called the doctor, the urologist, and he said, "It's positive. Come in in the morning." Fortunately I wasn't driving or I would be here talking about vehicular accidents, as well.

My wife was with me. We went into an office. I had the same feeling I know each of these gentlemen and others have had that when you're told you have cancer, that you have had, Senator, where you think, "Why me? My God, this can't be right;" you think of any possible reason why this is not going to happen to you.

I called a person I knew that had had prostate cancer and asked his advice. He, of course, asked me what my PSA was, which I knew. He then asked me what my Gleason was. Well, I'd been involved with the American Cancer Society for 25 years. There is a building across from the UNLV in memory of my parents, who both died of cancer, and I realized I did not know much about prostate cancer because the only Gleason I could think of was Jackie, and I was relatively certain he was not referring to him. In fact, he was referring to a measurement of the aggressiveness of the form of cancer.

We ended up talking to a number of doctors, my wife and I, and finally decided to pursue medical treatment with Dr. Skip—Stuart Holden of Cedar Sinai, who is the medical director of a private foundation called CaPCURE that Mr. Watson is on the board of.

I decided amongst the various options that I would, in fact, have a radical prostatectomy. In the interim, however, since I was Governor and in a public situation, like all these other gentlemen, I called a press conference to announce that I was one of 318,000 men that had been told that year, last year, that I had prostate cancer. I answered all the questions I could about incontinence and impotence and all the other diagnoses. The only one I saved until after the press conference was one question about would I describe

particularly in detail what a digital-rectal exam was. I decided I would but I would save that until after the press conference.

The option I chose was the radical prostatectomy. I remember after the procedure the doctor came in and he said, "We've done a pathology and it's great news. We can't find the cancer." And he walked out elated. And I started thinking that night, "Maybe that's not good news."

The next day he came back and he said, "We've done a second pathology. Great news. We haven't found the cancer." I said, "Whoa, wait a minute. Maybe the wrong Bob is in this bed"—or Len or whomever. But in any case he said, "No, I'm sure you have it; that's an indication it's very early." And the third day, in fact, they did find it, the earliest detection of his 25-year career. So I was fortunate that the biopsy had hit the right spot and determined that I did, in fact, have cancer.

I have been trying to be as public as I can about it in Nevada and elsewhere because I, too, have had the experience of men who have been diagnosed with it calling me, about 2 or 3 a week, so that I can hopefully give them the information that was provided to me by others who preceded me.

Today my PSA is 0 and I feel otherwise very healthy. I think my prospects, because of this early diagnosis, are very good. But 41,000 men last year lost their lives to prostate cancer and this year it is up to about 334,000 that are anticipated to be diagnosed with prostate cancer.

I think that men, like ourselves and others, need to continue to speak out and your hearing is so important because we are following an example set by the brave women of a decade or so ago who broke the barrier and spoke out about breast cancer, a taboo subject, just like prostate cancer, very personal. It has resulted in more women receiving tests, getting an early diagnosis and having a better survival rate.

Hopefully that is what can be accomplished by today's testimony, that more and more men will obtain the test; there will be more dollars available for research to study the dietary components thereof. I know that Bob knows, as do I, that the CaPCURE has done a lot of studies about diet and particularly the Japanese diet, and so I suspect all of us are taking some form of tofu. I take it every morning. There diet is determined to be some anti-cancer antigens. But there are many other potential anti-cancer antigens and other ways to treat this disease and the side effects, which we are not fully aware of because there aren't sufficient funds to support all of the research.

So it is very important that you have had this hearing today and I appreciate the opportunity to be present and testify.

[The prepared statement of Governor Miller follows:]

PREPARED STATEMENT OF NEVADA GOVERNOR BOB MILLER

Mr. Chairman, Distinguished Members of the Committee: Good Morning.

I am Bob Miller, Governor of the State of Nevada. Thank you for allowing me to speak on one of the most important health issues facing American men.

I come before you as a survivor of prostate cancer. My main mission today is to speak to the importance of early detection of prostate cancer and to urge that additional resources be brought to bear against this often fatal disease.

I am a living example of the benefit of early detection of prostate cancer. Had it not been for early detection, I would probably be walking around today with a malignant time bomb inside of me, ready to spread lethal cells throughout my body.

Instead, due to the diligence and alertness of my personal physician, Dr. Elias Ghanem of Las Vegas, the time bomb was quickly defused. I am free of prostate cancer, and my prognosis is excellent.

It was just about a year ago that I had my annual physical examination by Dr. Ghanem. He told me my PSA level was up a little: 4.1. On his advice I visited a urologist. That examination and the ultrasound proved negative. But Dr. Ghanem, ever diligent, prescribed that a biopsy be performed . . . just to be overly cautious. The results almost certainly be negative, too.

It was early October, 1996. I had just delivered a eulogy for a friend who had died of cancer. I was no stranger to the terrible toll of the disease, having lost both my parents to it years before . . . and having worked actively in support of the American Cancer Society for 25 years. A cancer education center in Las Vegas bears my family name.

On that October afternoon, I placed a call from my car phone to get my biopsy results. The only word that describes my feeling is shock. There was no doubt. I had cancer.

But I also had a better than fighting chance of beating this thing, because of early detection. And that early detection was made possible through a simple, painless blood test called the PSA. This is why the word must go out to all men of middle age or older that they get a PSA test. It can be, as I know so well, a matter of life, rather than death.

I had the tremendous advantage of early detection, but I realized I was totally uninformed about treatment options. A close friend who survived prostate cancer asked me what my Gleason was. The only Gleason I knew was Jackie. Later I would learn that the Gleason results tell you the severity of your case.

With the steadfast help of my wife, Sandy, I embarked on a search for answers that would lead to the best choice of treatment for me.

The search led us to Dr. Stuart Holden of Cedars Sinai Hospital in Los Angeles. Dr. Holden is Medical Director of CapCURE, a foundation dedicated to conquering prostate cancer.

He presented a variety of treatment options, including surgery and also radiation seed implants. He urged me to take some time and weigh my options. My father-in-law, also a prostate cancer survivor, had chosen radiation implants. I chose, however, a radical prostatectomy, even though there is some risk of long-term impotence or incontinence despite recent surgical improvements that spare critical nerves.

One of the cruelties of prostate cancer is that it strikes not only the body, but at our self-esteem and self-image. No one likes to be stigmatized by a disease that brings to mind the change to impotence or incontinence. And, certainly, it's not a discussion you like to have in public.

But as a governor, I had the responsibility to share my diagnosis—and the medical ramifications—as publicly as I could. A few days after learning of diagnosis, I held the longest news conference of my life . . . the reporters were sensitive to the personal nature of my condition and reported it responsibly . . . but the news conference got down to the nitty gritty. Let me say that the questions demanded answers that were, how shall I say? . . . anatomically correct.

But my candor paid off. It attracted a great deal of attention in Nevada to prostate cancer . . . and to the critical importance of early detection. Men by the droves went in for PSA tests. Some of those tests were positive, detecting the disease and giving these men the advantage of time in fighting it. This is why I never turn down an interview on this topic, and why I speak about it whenever I can.

In turn, I have received the support of hundreds of people with whom I have the common bond of experiencing the fear and uncertainty of being diagnosed with prostate cancer. I continue to be deeply moved by the advice and support that comforted me so much.

Today, my PSA is zero and I feel great. The surgery limited my activities for a while, but within a few months I was back to the gym and the basketball court. As I approach the anniversary of my bout with prostate cancer, I have no significant remaining problems. I feel I'm a walking billboard for why men should have the PSA test. At age 52, they say my life expectancy is not changed by the fact I had prostate cancer. Again, early detection and treatment made this possible.

It is my belief that those of us who've had prostate cancer must talk about it and publicize it as much as we can. Even today, men typically do not know enough to protect themselves against it. Overcoming ignorance and misconceptions about prostate cancer is one of the keys to reducing the large number of those who die from it. 41,000 men lost lives last year. 317,000 new cases were diagnosed. Those are

numbers we don't have to put up with. Early detection and treatment can dramatically reduce this tragic toll.

Those of us who've survived prostate cancer can take our lead from survivors of breast cancer. Like prostate cancer, breast cancer was once a topic to be avoided. But the brave, women who have stepped forward to confront the disease publicly and urge support for early detection, treatment, prevention, and research have saved countless lives. While breast cancer remains a formidable enemy, and we need all the resources available to fight it, progress is being made.

Members of the Committee, I urge you to do all you can to advance the cause of beating prostate cancer, through early detection and research. I understand that promising research is under way which deserves more of this nation's support. The grim toll of prostate cancer is not a specter future generations have to face, if public awareness, prevention, and research are supported to the best of our ability.

Again, thank you for this opportunity to appear before you today and share with you my experience.

Senator SHELBY. Thank you.

Senator Grassley, do you have any questions?

The CHAIRMAN. I will ask one question in order to allow my colleagues time to ask questions. I really appreciate everybody being here today. This is a wonderful turn-out of our committee for this very important issue.

I am not going to ask any of you to give medical advice. You have all said that you are not trying to do that. But there is this debate in the medical community about the value of screening and treatment for older men. Some advocate screening regardless of age. Others, however, say that most older men will die of something other than prostate cancer, so it is better for the patient not to have the anxiety of knowing he has cancer, especially when watchful waiting is a method of treatment recommended.

Would you recommend men getting screened regardless of their age and if so, what is your personal view about this issue? Senator Dole or anybody who wants to respond can do so.

Senator DOLE. I know that doctors will be on the panel but most men are going to die with it, not from it. That is what they told me. So I assume there is a cut-off. I have just talked to Bill Rusher. Some of you may know Bill Rusher, who is 80. He is deciding now what to do. I think he is going to have radiation. So there is an example of an 80-year-old and there may be others.

But I would say this. We talk about the older men. I think Dr. McLeod will tell you his youngest patient was a 30-year-old. So age itself is not the only factor. But my view is I was in my sixties so I obviously had it done but I assume there is an age where you probably would not recommend screening. You would just have what they call watchful waiting. That's what I do in my practice.

Governor MILLER. It is my own opinion that every man should seek the diagnosis and be able to make the informed choices. Watchful waiting is a primary option under some health care plans in other countries, in Scandinavia in particular, but I think that that denies people the opportunity to make the choice for themselves. No matter what age you are, there are options, even if it is just dietary changes, some of which have proven to be successful in slowing or reversing the cancer, that you can make.

I know on an airplane I had a gentleman come up to me who was a year younger than myself, telling me he had the same disease. I said, "What was your PSA?" He did not know what a PSA was. I said, "What was your Gleason?" He did not know what a Gleason was, either, and he did not care. He had chosen watchful waiting.

He was just going to wait till his doctor said something to him about "Now's the time."

I think that approach is too dangerous, in my estimation, that every man ought to be able to make an informed decision if they want to have a procedure. I know in my doctor's office I encountered another gentleman from Nevada who was about 80 years of age and he had had a radical prostatectomy just a month before.

Mr. DAWSON. I think the important thing is to communicate and that necessarily the older but anybody 50 years of age or older, just like me because I had no idea about it, what it was—I did not know what a PSA was; I did not know what a prostate gland was.

I have found since there are an awful lot of people like that and what we need to do is to communicate with the people and let them know what is available out there, that the PSA is there, the rectal examination is there. These are indicators that perhaps there is a problem and the important thing is if you get it done and it is detected early enough, like we have, then you can do something about it and correct it.

Hopefully down the road somewhere all of our goal is to find a cure for prostate cancer.

Mr. WATSON. I really would like to say the reason why I even insisted on having the PSA blood test in my physical was because some of my senior scouts, gentlemen who were 70, 75 years old, had told me about the PSA blood test. So I think the age really would bear out that those senior guys helped me out. At the time, I was 47 years old. I have talked to my doctor, Dr. Catalona, who had told me that he has had some patients that have had prostate cancer in their early thirties.

So there is a wide spectrum there and communication, at whatever age, is very important.

Senator SHELBY. Thank you all for coming.

Senator Breaux.

Senator BREAUX. Thank you very much and I thank all the panel members for being with us, our colleagues and friends.

No one enjoys, I would imagine, discussing their personal medical history with the entire world but I think what you have done is very important. Congress can do a lot of wonderful things with the laws we pass but sometimes the most important thing we can do is trying to educate the American public about difficult subjects. And, of course, that is the purpose of the hearing today and all of you have made a major contribution in that regard.

I think that too many people in this country have the mindset that if they do not go to a doctor, they will not get sick. It's much like saying: If I do not take the test, I will not have the problem. Of course, just the opposite is true.

All of you at this table, I think, are men and women of financial means. Fortunately, this is not something that is available just to the wealthy in society or financially well off. This is a relatively inexpensive test. In fact, Congress, in this year's budget, has made the PSA screening part of the Medicare Program, eligible for Medicare beneficiaries. Unfortunately, it does not kick in until the year 2000 and maybe we need to address that, Mr. Chairman, and as a result of these hearings, implement it before the year 2000.

Again, there is controversy about how often we should do screening and who should be subject to screening, and the medical panels will address that issue. I just say thank you for helping to educate the American public about something that is incredibly important.

Senator SHELBY. Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. As I was listening to Mr. Dawson talk about his reluctance to go to the doctor, a reluctance that I believed is shared by many men, I was thinking that here is a gender difference that really benefits women. We are so used to going to the doctor for an annual check-up, to being examined and probed, that it is just a fact of life, an unpleasant fact, perhaps but something we accept.

It seems to me that one of the things we need to do is to get men to start approaching routine health care the way that women do. There is clearly a gender difference in this area and I think Mrs. Watson would agree, as well.

Senator Dole, I was really moved by your testimony today and hearing Mr. Dawson talk about the influence that you had on him. It is clear that you may have saved his life and that you have certainly saved many others.

What a lot of people in this room do not know is how often you have picked up the phone to call the father of a staff person or a constituent or someone you may have heard about but never met to talk to them about your experience and reassure them about their own.

I wonder if you could tell us a little bit more about not just your public attention to this issue but some of the private conversations you have had and what insights you have gathered from those experiences.

Senator DOLE. As I said just briefly, men are just as frightened as women when somebody says cancer. When I was in the hospital the word went out that I had gone public and I had a lot of male, men reassuring me that everything was going to be fine.

So it seemed to me, since somebody had reassured me, that I had the same responsibility. You learn a lot from men. I don't try to give them medical advice. I try to get them to see the physician of their choice and decide on which treatment to have. But I think just calling someone or calling somebody in the family means a great deal to men and I have done a lot of it, continue to do it because I think it is important and I am certain that everybody at this table does a lot of it. Bob Miller said two or three a week and Bob Watson probably, and Len is out there every day.

So I think that is one way, sort of networking, getting the word out one at a time, with 318,000 cases being detected this year. But I think hearings like this are probably more effective.

There are a number of our colleagues who are not here today who have gone through this process. Senator Helms had radiation. Senator Stevens had the operation. I think there are others who I may not be aware of, and all these people are out there talking.

I remember going out to visit General Schwarzkopf when he had the operation and he went public and that made a big impression on a lot of people. So we will continue to make phone calls because we want men to know that this is the beginning, not the end.

Senator COLLINS. I appreciate that.

Mr. Watson, it is my understanding that African-American males are particularly at risk for prostate cancer, that there is a higher incidence of prostate cancer in this group. Do you think there is more that we could do to try to target outreach and education efforts towards African-American males?

Mr. WATSON. Without a doubt. That is one of the reasons why I am here, is to get that message out. We need to educate the African-American community. We just don't know why that is, that we have a higher incidence. When you look at the number of people who are going to pass away, to put that number in perspective, somewhere in the neighborhood of 41,000 men are dying this year and that is more men than will fit into the famed Boston Fenway Park, and that is a lot of people.

We have the opportunity to educate. Education is the best defense. I am here to stand up and say, "Look, don't be afraid to get the exam." And the screening process, that is something that I guess doctors, they have to be educated a little bit more, too, to talk to their patients and get the word out.

Senator COLLINS. Thank you very much, Mr. Chairman. I want to thank all of our witnesses for sharing their experiences with us.

Senator SHELBY. Thank you, Senator Collins.

Senator Reid.

Senator REID. Thank you, Mr. Chairman. I have a little different history than the four men at the witness table. A few weeks ago I went for my annual physical and as Governor Miller, I feel I take pretty good care of myself and was stunned when the Capitol physician told me that he thought I might have a problem with my prostate and that I should go to Walter Reed to be examined by Dr. McLeod.

I went and did that, did the ultrasound and the biopsy and it turned out negative. That is I didn't have cancer. My PSA was low and the biopsy proved to be negative. But I feel just a little bit of what you at the witness table went through because the time that we waited for the test to come back was certainly frightening to me and to my wife.

So I appreciate very much your being here. I have a better understanding of each of what you have gone through today than I would have had a month ago. Each of you are doing what needs to be done, focusing attention. This is an educational program today. Millions of people are watching this program and through the fact that each of you—a Hall of Fame football player, general manager of the New York Yankees, one of the 50 Governors of a State, a man that ran for President of the United States—people are going to be more concerned about this.

So it is admirable that each of you are here. Each of you have many things to do rather than taking your time to be here but there isn't anything more important that you could do.

But having said that, we know that Mr. Watson, you are representing a segment of the American community that has a tremendously more difficult problem. African-American males are 70- to 80-percent more likely to get prostate cancer than Caucasians. We don't know why, but it is a fact. And for the \$100 million we are going to be spending this year at the National Institutes of Health, maybe we can learn more.

We also are talking here with people who are substantial people in the community. You talk about going and having your PSA test done. We have 40 million Americans who have no health insurance. What about them? They can't simply go to their annual physical. They don't have money to do it. I think we owe an obligation to these millions of people, these millions of men who have no health insurance.

As well intentioned as we are here today, it is a problem that we have not, I feel, addressed very well in the Congress. Over 40 million people have no health insurance. And I repeat, it is easy for us to talk about—I went over and had my physical; each of you did. Some people cannot do that because going for this physical is a choice of not making the car payment that month.

So as important as this hearing is, we have to go one step further in Congress and do something about the millions of people who have no health insurance.

I have a number of questions, Mr. Chairman. I would ask to be able to submit them to these witnesses in writing.

Senator SHELBY. Without objection, so ordered.

Senator REID. I ask that if they would respond to them.

Let me just close, as all of the panelists have said here today, I am very grateful that you are here. I only feel a little bit of what you have gone through and the courage each of you has shown by coming here today, using your celebrity status to focus attention on this disease. That is extremely important.

Senator SHELBY. Senator Burns.

Senator BURNS. Thank you very much, Mr. Chairman. To summarize, and I don't have a long statement here; nor do I have a question. I am surprised to see Len Dawson here. I not only remember him from the Chiefs; I remember him when he was at Purdue. That is a sign that I am way over the hill.

We men are such wimps; we are. We are scaredy cats. We jump at our own shadow. And if there is one thing I gave that gold walnut to Senator Dole, that when I sat down with that young man, who was a young man in Montana and who had gone through this treatment and said we just have to get something started, and that is what they did. They have a Golden Seed Club on the Internet. They visit about it. It is growing every day and you cannot imagine the amount of hits, so-called hits, on their web page with regard to the information.

So the influence that you will have here on everybody else and what we can tell America, that information is available everywhere; just do it. Don't read about it; just do it. Thank God that we are all married to spouses who care about us very much and we get forced into doing some things that sometimes we wimps will not face up to. We just won't face up to it.

So I want to just thank you for coming today, taking time out of your schedule because I think it is very, very important and I just thank you, from this old Montana kid. I was raised north of Kansas City. I got out of there.

Senator SHELBY. Senator Enzi.

Senator ENZI. Thank you. Thank you, Mr. Chairman. I, too, appreciate the time and effort that you have gone to to come and re-

late this problem more publicly than we have been doing in the past and realize that that is part of what we have to do.

I am reminded of a Robert Fulghum story. He wrote "All I Really Need to Know I Learned in Kindergarten." He also talked about his college days and some problems that he was having with a place where he was working where they fed him the same food every day and he complained to the man that came on to work after him. But the man that came to work after him had been through Auschwitz and had a little different view of life and raised the issue that in life, some things are an inconvenience and some things are a problem. He concluded by saying that there is a difference between a lump in your oatmeal, a lump in your throat and a lump in your breast, or any other place in your body.

I really appreciate the efforts that you all go to to help bring this issue of cancer to more people's attention. It is one of the solutions.

Of course, in our capacity one of the things that we are trying to do is figure out what the Federal Government's role ought to be in this problem, and it is not just an inconvenience; it is a problem.

So do any of you have any suggestions for ways that we, in our official capacities, can help you in your public capacity to solve this problem?

Mr. DAWSON. That is out of my department; I will tell you that. I just know one thing, that when I found out that I had cancer, you figure, I can handle it, but cancer affects everybody who is concerned about that individual.

Talking about quality of life, I mentioned my brother. I saw the quality of life that he had for the last 5 or 6 months of his life here on Earth and it was not very good; it was terrible.

That is why I say that my role is to try to get people to get out and learn about it, take the test, the PSA and the rectal examination to see if there is a problem. From there it is going to be up to that individual and the doctor but that information is very important. But how you go about doing it, yes, it is a tremendous problem. I don't know the answer.

Governor MILLER. I think, Senator, if you can consider the funding mechanisms and the advanced allocations of the funding that is already in place that is going to be delayed until the year 2000, many of the scientists that I joined at a CaPCURE scientific retreat in Lake Tahoe a few weeks ago were very enthusiastic about the prospects that they have for early detection and some actual cures but they need more money to be able to do their studies.

As we have seen those successes in breast cancer and AIDS awareness and the courageous people who have spoken out there, hopefully in prostate cancer we can devote more of our resources to that, as well, as well as encouraging people to get out and take the test, as all of us have done.

Mr. WATSON. Senator, what I would just like to add from this corner would be the funding to continue to educate, maybe some screenings because, as Senator Reid just mentioned; there are a lot of people who cannot afford to be screened. And in that screening process there is going to be a lot of people that we make a huge difference in their lives.

Senator REID. Thank you and I would yield back the balance of my time.

Senator SHELBY. Senator Hagel.

Senator HAGEL. Mr. Chairman, thank you. I want to say thank you to our witnesses for your inspiration, for your leadership. If Senator Dole was here, Mr. Chairman, I might make note that two of the three doctors that will appear on the next panel, their names are David. I don't know if that means anything but I know Senator Dole is interested in the names.

But thank you all very, very much. We are a grateful Nation for your leadership. Mr. Chairman.

Senator SHELBY. Thank you. I want to thank, on behalf of the committee and on behalf of the Senate, all of you, including Senator Dole, our former colleague, for appearing here today. It is appearances like this and speaking out like you have done here today that will make a difference in a lot of people's lives in America.

As Len Dawson said earlier and others have experienced, if people are not aware of the problems of prostate cancer and how silent it is but how deadly it will become, they will ignore it. Perhaps by holding hearings like this and having a lot of public service announcements and with people like you being involved, we will save a lot of people's lives and that is what this hearing is all about. Thank you.

Senator REID. Mr. Chairman.

Senator SHELBY. Yes, Senator Reid.

Senator REID. I think, before the panel is excused, we have talked a lot about everybody today except you. The reason we are holding this hearing is because of you. You are one of the senior members of this committee. You requested the chairman and the vice chairman to hold this hearing. That is why we are here.

I would say, Mr. Chairman, I know how sick you were and you have done a lot for the cause yourself and I think that should be noted.

Senator SHELBY. Well, thank you, Senator Reid. That will give me an opportunity to say this because I, too, have spoken out. Senator Dole was an example for me. He told me, when he came to see me in the hospital, he said, "You're going to get well. I've got confidence in one of our next panelists, Dr. McLeod," and so forth.

But I can tell you, as I've told a lot of people all over America, including my State of Alabama, when Dr. McLeod told me basically that I had cancer, I was in a state of shock. I couldn't believe it but it was true, and I knew I had to live with it. But he also reassured me that there was good chance, a good chance that the early detection, because of the PSA that I had gone through early, perhaps I would be OK. He could not assure me positively early. Perhaps he's never assured me positively but he's given me a lot of assurance. But that was a good feeling.

But it is a deadly disease and if we can save people's lives as we are doing this—I did request this hearing as a member of the committee. I have been speaking out and I join my colleague and others in trying to get the money to have early screenings for all Americans because we will not only save lives but we will save money on health care costs all over America and we will retain a lot of good years, productive years, of a lot of the males in America. Some of us are living examples. Some of you at the table are today. Perhaps in the past, people didn't have that opportunity.

But I am going to continue to work and Senator Reid and others are to make sure that all Americans have that opportunity, regardless of who they are, where they come from. I think that is important and it is an important message, Senator Reid. Thank you.

Our next panel will be very important to all of us. Dr. David McLeod, chief of urology, Walter Reed Army Medical Center in Washington, DC, my doctor, along with Senators Dole, Stevens, and a number of others here; Dr. David Crawford, University of Colorado Health Science Center, Denver, Colorado and Dr. Richard Babaian, professor of urology, University of Texas, Houston, Texas will comprise our second panel.

This is a distinguished group of urologists that know a lot about prostate cancer and I appreciate all of you coming to the Senate today to give some of your personal views and professional attitudes toward the treatment and containment of prostate cancer.

Senator REID. Mr. Chairman.

Senator SHELBY. Senator Reid.

Senator REID. While they are settling in, I have a Senate Democratic leadership meeting at quarter till and I may not be able to listen to all the testimony. I just wanted to publicly state, as you did, about Dr. McLeod and what a fine person he is, how well he handles his patients and we are very fortunate that he is part of the federal Government. We hear so many negative things about the Government that he is a part of. I appreciate your being here and the good work you have done for me and all my colleagues that you have treated.

Senator SHELBY. I thank you. Dr. McLeod, I want to say again publicly that I more than likely would not be here today if it hadn't been for you and your staff and your skill as a great surgeon and I would publicly acknowledge that. I consider you not only my doctor but a good friend.

You have spent a lot of time. You have brought a lot of leadership to this area of medicine and I know you could have gone many places in America, in the world, but we are glad you chose to stay at Walter Reed and others, I'm sure, that we could say the same thing about.

Your written statement will be made part of the record in its entirety.

Senator REID. Senator Shelby, I don't want to ruin his reputation but you know he is a lawyer, also.

Senator SHELBY. I understand that. I wasn't going to tell that. He did that because he is intellectually curious.

Senator ENZI, do you have any statement here?

Senator ENZI. I do have a statement but I just ask that it be entered into the record.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT BY SENATOR MICHAEL B. ENZI

Thank you, Mr. Chairman. I appreciate your holdings this hearing to raise awareness of the prevalence of prostate cancer and to discuss the issues related to the management of the disease. I particularly commend our first group of panelists for their courage to come forth with their own personal experiences with prostate cancer. Your testimony raises the profile of the disease and encourages other men to seek testing.

It is a bit alarming that a disease that is so widespread has received so little publicity. I am confident that the efforts of our first group of panelists will change that.

I am also confident that the recent increases in research funding will have a significant effect on improving the screening and treatment methods of prostate cancer.

There are three particular issues related to prostate cancer that have attracted my attention. The first is the cost-benefit concern related to the increase in PSA testing. The recent Balanced Budget Act provides for Medicare coverage of the PSA and DRE screening tests beginning in the year 2000. I certainly do not doubt the benefits of this new coverage. I do, however, think that the potential costs of the post-screening treatments, such as surgery or radiation, have to be considered. The number of PSA tests will no doubt increase dramatically around the time that the Baby Boomers begin to retire in 2012. The cost of administering a PSA test is insignificant in terms of Medicare financing. If each questionable result, however, was followed by a biopsy and then surgery or radiation, the costs will skyrocket and contribute to the financial instability of Medicare.

The challenge will be to achieve a consensus within the medical and scientific community on the appropriate diagnostic approach once a PSA test result raises questions. A significant issue facing the prostate cancer research community is the current inability to distinguish between cancerous cells in the prostate that will remain latent and never cause any adverse effects and those cells that will become virulent and threaten an individual's well-being. This often results in unnecessary treatment for prostate cancer, which causes unnecessary discomfort and unnecessary expense for the individual.

My second issues of interest involves the funding for prostate cancer research. I am confident that the recent increases in funding for prostate cancer research will yield valuable new methods of detection and treatment. Prostate cancer is such a painful, debilitating disease that all efforts to effectively cure it, with minimal complications, should be made. Funding for prostate cancer research at the NIH has risen from \$40 million in 1992 to an estimated \$100 million for 1998. The Senate has already gone on record with a commitment to double funding to the NIH over the next five years, and has begun that process by increasing funding 7.5 percent for 1998. I believe that the NIH conducts important, beneficial health research and I will continue to support it throughout my Senate career. In addition to NIH funding, the Department of Defense has also received a total of \$45 million for prostate cancer research in 1998. I trust that such increases in research funding will produce dramatic improvements in both the screening process and in the physician's ability to determine the best method of treatment for each individual patient.

The last point that I would like to bring up involves the disproportionate number of African-Americans who are diagnosed with prostate cancer. The statistics related to the prevalence of prostate cancer in African-Americans are alarming. African-Americans have the highest rate of prostate cancer in the world, twice that of other Americans! In addition, they have a much greater chance of dying from the disease. This is quite an aberration and efforts should be made to find out why this disparity exists and to alert the African-American community about their greater risk so that they can seek the appropriate care.

Once again, I thank the Chairman for holding this hearing. It is important that the issue of prostate cancer be brought fully into the spotlight so that its prevalence and treatment possibilities can be thoroughly highlighted. It is necessary that we all make a strong effort to immediately improve the awareness and knowledge of this disease so that we are better equipped to deal with the dramatic rise in its occurrence as the Baby Boomers begin to retire.

Senator SHELBY. It will be made part of the record. I also have a written statement by Senator Craig, who was with us earlier, and it will be made part of the record in its entirety.

Senator REID. I would like my statement to be made part of the record also, please, Mr. Chairman.

Senator SHELBY. Your written statement will be made part of the record in its entirety. Also I would ask that my written statement be made part of the record in its entirety.

[The prepared statements of Senators Craig, Reid, Shelby, Collins, Breaux, Wyden, Burns, and Jeffords follow:]

PREPARED STATEMENT OF LARRY E. CRAIG, UNITED STATES SENATOR

Mr. Chairman, I would like to thank you for holding this hearing today to address a serious epidemic: prostate cancer. Today, prostate cancer is the most prevalent malignant cancer in American men. It is important that this concern be ad-

dressed, and I believe these hearings today will help us find workable solutions to this problem.

In 1997 an estimated 334,500 new cases of prostate cancer will be diagnosed, accounting for 43 percent of all male cancer. One out of every ten men will develop the disease at some time in his life. There are also 41,000 American men who die each year, needlessly and tragically, of prostate cancer. The most profound risk factor lies in age; 80 percent of all prostate cancer diagnosed occurs in men over the age of 65. Race is also a significant risk factor; African-American men have the highest incidence—70–80 percent greater than caucasians—and mortality rates, while Asian men have the lowest rates.

Faced with these grim statistics, we must support research and early detection for this deadly cancer. We can glean some insight about future problems by looking at present circumstances. That is why we hope to make great strides not only in finding a cure but also in educating the public on early detection methods and available treatments for prostate cancer.

Early detection by screening can detect the cancer before it spreads, offering a chance for a cure. Without screening, most prostate cancer will spread and become incurable before it is found. For these reasons, the American Urological Association and the American Cancer Society both recommend yearly screening for men over the age of 40.

After being diagnosed with prostate cancer, a man must work with his doctor to decide what tests and treatments are available and right for him. We must get information out to the public about prostate cancer. The cancer victim must be aware of the facts and options that are available. For example he should know, there are four basic treatments: Watchful waiting, surgery, radiation therapy, and hormonal therapy. Each treatment offers some benefits for individuals, and for that reason, each must be seriously considered before deciding what path will be taken.

Presently, more than 20 bills have been introduced in this Congress related to prostate cancer. In general, the bills contain provisions which will expand research and education programs. We hope that by making this topic a priority here in the Aging Committee, we will be able to save many lives through open communication, truthfulness, optimism, perspective, and knowledge that is vital.

As the ever increasing number of prostate cancer victims continue, it will be our obligation to supply clear and concise information and support. So again, I am glad to see that the Special Committee on Aging is holding this hearing today to bring attention to this deadly disease.

PREPARED STATEMENT OF SENATOR HARRY REID

Good morning Mr. Chairman, members of the committee, ladies and gentlemen. I would first like to welcome everyone to this morning's hearing on prostate cancer. I was very pleased when I learned that Senator Shelby had taken the lead in arranging a hearing on this topic. It is most appropriate that we hold this hearing during National Prostate Cancer Awareness Week. I am aware that for many, especially men, prostate cancer is not a subject we like to discuss. This is tragic when you consider that every 90 seconds another American is told he has prostate cancer. In 1997, an estimated 334,500 new cases of prostate cancer will be diagnosed. Nearly 42,000 will have their lives claimed by this cancer in 1997. When we know so much, it is unfortunate that we do so little.

I would like to welcome all of today's panelists and thank them for their willingness to come forth and discuss openly what we know about this topic. Specifically, I would like to personally welcome my former colleague Senator Bob Dole and the current Governor of my home state of Nevada, Governor Bob Miller. Governor I thank you for making the trip and am grateful that you accepted the committee's invitation to come forward and share your story.

We know that 1.5 million Americans have been afflicted with prostate cancer in the last decade. One in every eight men is at a lifetime risk for prostate cancer. Prostate cancer accounts for 43 percent of all male cancers and is the second leading cause of cancer death in men. We know that race is a significant risk factor with African-American men having a 70–80 percent greater risk of prostate cancer than white men. We also know that age is a profound risk factor with over 80 percent of all prostate cancers diagnosed in men over the age of 65. It is therefore appropriate that the Senate Special Committee on Aging hold a hearing on this cancer.

While we know so much, we still, I am afraid, are doing far too little. I am pleased that we have included coverage for prostate cancer screening in the recently passed Balanced Budget Act of 1997. Funding for research on prostate cancer has also been increased. In 1992 NIH received \$40.1 million for prostate cancer research. In 1998

it is estimated to be \$100 million. Last year Congress also gave the Department of Defense a total of \$45 million for prostate cancer research. The private sector as well is playing a major role in research. While there is still a great distance to travel, there is heightened awareness mounting in supporting research on prostate cancer. It is my hope that our hearing will only add in that effort. In my view what is still critically needed is at the individual level, where all men will ensure, at the appropriate time, appropriate interval, and in consultation with their physicians, that they are screened for this cancer. There is so much that can be done if detected in the early stages. Although prostate cancer is a "man's disease," it effects the lives of countless women as it strikes their husbands, fathers, brothers or even sons. Women can play a pivotal role in providing support and encouragement to their loved ones by talking openly about this cancer and the critical need to be screened.

In my home State of Nevada, it is estimated that in 1997 there will be 1,800 new cases of prostate cancer diagnosed. This same estimate holds that 220 will die from this cancer during the same period. This is no small number and to the many victims and families who will suffer with them, our hearing could not come any sooner.

I thank all the witnesses for coming forward today and again want to extend a special welcome to Governor Bob Miller who has done so much for raising awareness about this cancer both in Nevada and on the national level. Mr. Chairman, I commend you for your leadership in seeing to it that we discuss this topic, no matter how uncomfortable we may be in the process. By talking about it we make it acceptable for men across America to be screened and if necessary get the treatment they need.

PREPARED STATEMENT OF SENATOR RICHARD C. SHELBY

Thank you and good morning.

"You have cancer." Those were the words I heard in March of 1994. Dr. David McLeod, who is with us today, delivered the news to me. It was a day I will never forget. I went to see Dr. McLeod, for a routine physical examination. He performed the customary battery of tests and sent me on my way. I had no idea that there was anything wrong with me, much less that I might have cancer.

When Dr. McLeod phoned me to deliver the news, I was in shock. Thankfully, because the cancer was detected early, I am here to tell others about my experience. It is my hope that by telling my story and by requesting this hearing from Chairman Grassley, we can foster more open dialog about this disease. Very simply, we need to begin to increase awareness about the deadliness of prostate cancer so more men seek early detection.

The routine PSA test that was administered to me was key to detecting my cancer at an early stage. Without it, it is likely that the cancer would have continued to grow undetected, thus decreasing not only my chances of full recovery, but my chances of survival as well. Because I believe in the importance of early detection, I was very pleased to see that the Balanced Budget Act of 1997 contained a provision that will allow for Medicare coverage of PSA exams. The rationale for covering PSA's is that by focusing on early detection and preventive measures, we will not only save lives, but we can actually help reduce long-term health care costs as well.

We have made a great deal of progress in our battle against prostate cancer, but we still have a long way to go. Prostate cancer is the second leading cause of cancer death among American men. It affects 1 out of every 11 men and has a 25 percent mortality rate. It is nearly as prevalent—and as deadly—for men, as breast cancer is for women, yet research for prostate cancer is only about one-fourth of that of breast cancer. I want to be clear that I am not questioning the level of research spending for breast cancer.

However, I do believe that research spending on prostate cancer is insufficient in light of the prevalence and deadliness of the disease. Now that we have made progress in the area of screening, we must now put prostate cancer research at the top of our list of priorities. Like periodic screening, a strong commitment to prostate cancer research will not only save lives, but will actually lower health care costs over the long haul.

I want to thank the witnesses for taking time out of their busy schedules to be here today. I look forward to hearing their comments.

PREPARED STATEMENT OF SENATOR SUSAN M. COLLINS

Senator Shelby, as this is Prostate Cancer Awareness Week, it is particularly appropriate the you have called this morning's hearing to explore the issues surrounding prostate cancer, which is the most common form of cancer in American men.

As many as one in ten American men will develop prostate cancer in his lifetime. The American Cancer Society estimates that this year, 334,500 new cases will be diagnosed, and 41,800 lives will be claimed by this increasingly common and potentially deadly disease.

In many ways we are victims of our own success. The life-span of Americans is increasing, and because this disease most often strikes men who are in their sixties and seventies, more and more men are now afflicted. These numbers can only expect to increase as the baby boom generation ages.

The single largest factor in the sharp increase in prostate cancer diagnoses is the increasingly widespread use of the prostate-specific antigen, or PSA, test, which in many cases can detect the disease far earlier than other screening methods. The good news is, that by making early detection and treatment possible, this test could eventually reduce the number of prostate cancer deaths. The bad news is that increased use of the PSA test for routine screening could lead to an increase in premature or even unnecessary treatment. And, for many men, the fear of the available treatments for prostate cancer, and the impact that those treatments could have on their quality of life, exceeds their fear of the disease itself.

At this morning's hearing we will hear from a number of witnesses—among them former Senate Majority Leader and Presidential candidate Senator Robert Dole, who have fought and won the battle with prostate cancer.

Others have not been so fortunate. In recent years, prostate cancer has claimed the lives of thousands of American men. Some, like media mogul Steve Ross, actors Telly Savalas and Don Ameche, and rocker Frank Zappa were rich and famous, demonstrating that wealth and fame provide no protection.

The thousands of other men confronted with prostate cancer are not so famous, but they are our fathers, grandfathers, husbands and brothers, proving that none of our families is immune to this disease which is second only to lung cancer as the largest single killer of American men.

Mr. Chairman, I am particularly looking forward to the testimony of our first panel this morning and to hearing the straight facts about prostate cancer and its treatment from those who have personally fought the battle against this deadly disease and won. I am also looking forward to hearing about new advances in treatment and research and to discussing the public policy implications surrounding coverage for prostate cancer detection and treatment.

Again, thank you, Mr. Chairman, for scheduling this important hearing, and I look forward to the upcoming testimony.

STATEMENT OF SENATOR JOHN BREAUX

Thank you, Mr. Chairman, for calling this hearing and thanks to you, Sen. Shelby, for your leadership on this very important public health issue. I am particularly pleased to join Sen. Grassley in welcoming back one of the true giants of the Senate, former majority leader Bob Dole.

Undoubtedly, one of the worst pieces of news men can hear is that they have prostate cancer. Unfortunately, it is news that is all-too-common, with as many as 20 percent of all men likely to face the disease.

In the past, men have generally been reluctant to have prostate cancer screenings. Sens. Dole and Shelby and our other leading witnesses today have done a great public service for us and our families by highlighting the importance of early diagnosis and treatment. They have turned their own personal battles with prostate cancer into positive educational efforts aimed at raising awareness. But more important, they serve as inspirational role models for others.

With passage of this year's balanced budget agreement, Medicare will begin covering yearly screenings for beneficiaries. The benefits of screening for prostate cancer are clear: lives are saved through early detection.

While there is some disagreement in the medical community as to how routine screenings should be, one point on which we can all agree is that more research is needed in order to find the best ways to treat prostate cancer. There are currently several studies underway that hopefully will help us minimize and eventually eliminate the harmful effects of prostate cancer.

It is especially important to direct outreach and educational efforts to members of the African-American community. Black men are at 70-80 percent greater risk than whites to develop prostate cancer.

I look forward to hearing from our excellent witnesses and learning more about the screening and detection of prostate cancer and how we can raise awareness about this serious disease and the treatment options available.

PREPARED STATEMENT OF SENATOR RON WYDEN

Mr. Chairman, I'd like to thank you and our Ranking Minority Member, Mr. Breaux, for holding this hearing on a very important issue.

Prostate cancer is the most common malignant cancer among men in America and account for 43 percent of all male cancers. The American Cancer Society estimates that in 1997—209,000 new cases of prostate cancer will be diagnosed and 41,800 will result in death.

African-American men are disproportionately affected and have the highest prostate cancer mortality rate in the world. At 44 deaths per 100,000 people, prostate cancer mortality for African-Americans is the highest reported globally and is twice that of White Americans.

The alarming number of men suffering or dying from prostate cancer clearly illustrates our need to increase efforts to promote the importance of early screening.

In recent years there has been an enormous push to encourage women to receive mammogram screening. We need to be equally aggressive in raising awareness about prostate cancer, disseminating information, encouraging men to receive screening tests, and funding clinical research.

I understand that determining who, when, how and whether to screen for and treat prostate cancer are controversial issues but early detection increases the odds of an individual having a favorable outcome. Furthermore, researchers and clinicians agree that screening, early detection, and treatment are the central tenets of cancer control.

Congress has demonstrated their bipartisan support by passing the Balanced Budget Act of 1997 that included a provision to add prostate screening as a Medicare benefit for men over age 50. This benefit will become available in January of 2000. In 2003 any new technology the Secretary finds appropriate for the purpose of early detection will also be available.

We have some women with us today who were instrumental in saving their husband's lives by encouraging them to get screened prostate cancer. . . . I want to applaud their efforts. I also want to encourage other spouses, family members, and friends to take an active role in ensuring that their loved ones receive appropriate screening.

I would like to end by urging men, age 40 and over, to make early detection a priority. Go to your doctor for regular complete physical exams, even if you're feeling well. Often times the symptoms associated with prostate cancer do not appear until the late stages of the disease. So don't wait until you experience problems . . . get screened early so that if cancer is present it can be caught in its earliest and most treatable stage.

PREPARED STATEMENT OF SENATOR CONRAD BURNS

Thank you, Chairman Grassley. I'm pleased that we're providing a forum today to discuss the important issue of prostate cancer prevention.

I want to welcome back to the Senate the former Republican leader, and I welcome Gov. Miller and all of our distinguished guests.

I think the biggest task before us is to follow in the steps of Senator Dole, Governor Miller, and Bob Watson and push for education about prostate cancer. Unlike many forms of cancer, prostate cancer can be detected early using a PSA test and can then be effectively treated in many cases. Unfortunately, most men do not know about this form of cancer and do not get tested for it.

I'd like to recount the story of a Montanan, a veteran who was diagnosed with prostate cancer. He was eligible for health benefits through the VA, but instead of choosing surgery, he felt the best treatment would be radiation seed implants, or brachytherapy. Well, he had a hard time convincing the VA to treat him with seed implants since this treatment was not widely available at VA facilities. After my office intervened on his behalf, the VA did treat him, and it was successful. But it concerns me that veterans may not have the range of treatments that are otherwise available, and I hope the VA will keep working to correct this.

Thank you.

PREPARED STATEMENT BY SENATOR JAMES M. JEFFORDS

Mr. Chairman, I believe that one of the more important—if less often discussed—functions of Senate hearings is to provide consumer information on subjects of importance to the public. With this in mind, I am pleased we have this opportunity to provide our citizens with information on medical research about prostate cancer.

This is a particularly appropriate time to hold a hearing as it is Prostate Cancer Awareness Week. While engaging in this public information function, we must be vigilant to ensure that people are able to access and use that information in a manner that will help them or their loved ones in a meaningful way.

The primary thrust of our health education effort today will be to emphasize the importance of getting screened using the PSA test. This simple, non-invasive test is the first line of defense against development of prostate cancer. Now that we have made reimbursement for the test available to Medicare recipients, I hope that it will become as routine as mammograms are for screening for breast cancer. The second line of defense is the physical exam. With regard to that, I cannot improve on George Forman's exhortation: "Don't die of fright." The other important subject we will address today is balancing the utility of surgery and other therapies in the treatment of prostate cancer. Since this is such a slow-moving cancer, we must look at the debate about "dying of prostate cancer" versus "dying with prostate cancer." To assist consumers in making difficult decisions about the relative merits of different treatments in their own individual case, we must provide them with the latest and best research for discussions with their physician. For post-surgery patients, this includes using the latest biotechnology techniques to examine messenger RNA for PSA and find out if there is any secondary metastasis.

Important Prostate Cancer research continues at the Veterans' Affairs Medical Center in White River junction, Vermont. The researchers are examining the link between the presence of iron in the blood and an increased rate of growth of Prostate Cancer. As the Chairman of the Senate Labor and Human Resources Committee, I know firsthand the importance of not only educating the public about the dangers of prostate cancer, but also of the need to continue important research at the federal level.

I will soon introduce legislation that will focus on health care quality and consumer protection. My bill is premised on the notion empowering the individual's decision-making through good information. I firmly believe that people have a right to know at the time they choose a health care plan exactly what will be covered under the plan. They also have the right to use that information to demand that continuous quality improvement take place. My bill will empower people to expect their health plan to provide the benefits they need. My bill will also help us to understand and promote quality in health care.

Mr. Chairman, thank you again for holding this important hearing.

Senator SHELBY. Dr. Crawford.

STATEMENT OF E. DAVID CRAWFORD, M.D., UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER, DENVER, CO

Dr. CRAWFORD. Thank you, Senator Shelby. It is indeed a pleasure to be here. I am chairman of the National Prostate Cancer Education Council and also represent the American Foundation for Urological Diseases.

Prostate cancer, as we heard, is a male epidemic. In the past 10 years there has been a 500-percent increase in the number of new cases of prostate cancer.

Faced with these grim statistics I think there are a number of strategies that we can look at. One is that we can bury our heads in the sand and say prostate cancer is a cancer of old men and you have to die of something, that there are a lot more pressing health care issues.

I think a second strategy is to try to prevent prostate cancer. We know that there is a low incidence of prostate cancer in Japan and China; yet when men move to the United States from those countries their incidence rises. It is the American diet that plays a role in this.

Also recently there has been a lot of information about ways to prevent prostate cancer—increased taking in of soy products, Vitamin E, selenium, many other things. I think there is a lot of promise in trying to prevent prostate cancer.

I think another strategy, the third strategy is to try to cure advanced prostate cancer. We have made progress. We have drugs; for instance, a drug called Eulexin increases survival rate. The FDA just approved a drug called Mitozantrone to help out with prostate cancer pain. But we do not have a cure. We cannot cure advanced prostate cancer.

The last strategy and the one that I think is the most rewarding at this time is to try to find the disease early, treat it and cure it.

If we look back at what has happened, in 1988 there wasn't a lot of talk about prostate cancer. Men didn't talk about it. It was an ignored male disease. In 1989 we formed the Prostate Cancer Education Council and began Prostate Cancer Awareness Week, which, Senator Shelby, you mentioned is this week. This has turned into an important national event. We have been able to direct a lot of attention to prostate cancer. We heard from Senator Dole, who has helped us out, Norman Schwarzkopf.

One of the distressing things is that African-Americans do not come in for screening. We have Harry Belafonte to help us this year but we still have a paucity of African-Americans who participate in early detection.

A number of important groups have been involved—the American Foundation for Urological Diseases, the American Cancer Society and others. We have accumulated a lot of vital information about prostate cancer and this PSA test, for example. If a man has an abnormal rectal exam and a PSA test that is abnormal, he has a 50-percent chance of having prostate cancer. This compares very favorably to an abnormal mammogram in a woman, where there is only a 20-percent chance of having cancer when you have that.

I think the most important thing, one of the most important things to come out of this early detection effort is that we have eliminated advanced prostate cancer in men who undergo annual screening. We can tell them that they have a very low risk, and I think that is important in altering these grim statistics about prostate cancer.

In spite of all this good news, there is controversy. I don't think the controversy is about the early detection. The tests that we have, PSA and rectal exam, are capable of finding prostate cancer early, as many of the panel members before me have already attested to.

The controversy is in the area of treatment: is it really effective in all the different treatments? Unlike breast cancer where, in the 1960's, money was available to fund studies to determine the value of early detection of breast cancer, we didn't have that for prostate cancer and it is only now going on. But I think there is a lot of evidence that finding the cancer early offers a chance of cure.

Our motto, from the Prostate Cancer Education Council, is that men should choose to know, to know to choose among the various treatment options. And there are a lot of different treatment options available.

PSA testing has been important, as we have already heard, and it is important that it is going to be available, but if it were available January 1 of this year, another 12,000 men could be saved. I think that is important.

So, in summary, there is a lot of good news and bad news about prostate cancer. The good news is we have attracted a lot of national media attention to prostate cancer. There are researchers who are working on the disease. I really feel that a cure is in the future.

The bad news is this: that men have not declared war on prostate cancer. They need to do that. They need to recognize the importance of it. We need to get African-Americans in for screening. They have the highest mortality in the world for prostate cancer.

We know that men die 7 years younger than women. They make one-fourth as many visits to a physician. We need increased research moneys to develop a rapid cure from this disease. In 1989, when we began this Prostate Cancer Awareness Week, \$10 million was allocated to prostate cancer research. From 1990 to 1997, \$376 million has been allocated for prostate research, compared to \$1.8 billion for breast cancer research. I think every \$1 that goes to breast cancer research is indicated, and AIDS and others, but we need to do something relative to prostate cancer.

We know that the expenditures on prostate cancer total about \$4.5 billion a year in treatment of prostate cancer. If you look where that money goes, a lot of it goes to treat advanced prostate cancer in its terminal phases. So a little bit of investment up front in earlier detection and understanding some of the better ways to treat prostate cancer is important.

We need to continue this Prostate Cancer Awareness Week. It needs to be continued indefinitely, I think, to continue to find information and disseminate information about prostate cancer. A number of people here have had their prostate cancer discovered because of the initiation of that.

Also researchers need to have the funding to find these cures for prostate cancer, to better understand ways to diagnose it and treat it. It becomes frustrating when, in fact, you spend a lot of time writing research grants, studying it, and you have a less than 20 percent chance of having it funded.

So I think a great deal of what occurs in this disease over the next decade is dependent upon research dollars available for education, detection, prevention, and treatment and I sincerely request your assistance on behalf of the American male. Thank you.

[The prepared statement of Dr. Crawford follows:]

Senate Subcommittee on Aging
September 23, 1997

E. David Crawford, M.D.
Chairman, National Prostate Cancer Education Council
Associate Director, University of Colorado Cancer Center

Prostate cancer represents a male epidemic. During 1997, it is projected that over 200,000 men will be diagnosed with prostate cancer --- and 41,000 will die as a direct result of the disease. In the past 15 years, the number of new cases of prostate cancer diagnosed has increased by three-fold. Less than seven years ago, greater than 80% of the cases of prostate cancer diagnosed were advanced, and therefore incurable. During this presentation, I will explain why testing for prostate cancer is important as well as discuss the urgent need for research support.

Faced with these previously mentioned grim statistics regarding the rising incidence and mortality from prostate cancer, there are a number of possible strategies to pursue. One can bury his head in the sand and ignore the problem, citing the fact that prostate cancer is usually a disease of older men, and you "have to die of something". Others might rationalize that our healthcare system cannot afford to deal with this disease because there are so many other pressing issues such as AIDS, childhood immunizations, smoking cessation, etc. In fact, during a trip to Europe just two weeks ago, I found that many countries subscribe to the latter way of thinking.

A *second strategy* is to try to prevent the disease. Ideally, this would be the optimal solution. In the past decade, we have learned a lot about what causes prostate cancer. This knowledge leads to strategies to alter its initiation. If we

examine the worldwide incidence of the disease, we see that it is extremely low in Japan, China, and other Oriental cultures. Yet when you examine the US incidence, it is dramatically increased -- especially in African-American males -- why?

A Western diet which is high in fat plays a major role in the development of prostate cancer, since when men from countries with a low incidence move to the United States and partake of our diet, their incidence of prostate cancer dramatically increases.

Table 1

**Worldwide Age-Adjusted
Prostate Cancer Death Rates
per 100,000 Population**

Sweden	21.1
Demark	19.5
United States	17.5
United Kingdom	17.1
Spain	13.2
Singapore	4.4
Japan	4.0

Recently, there have been reports of a reduced incidence of prostate cancer in men consuming tomato products, soy, vitamin E, selenium, and other items in our food chain. These findings offer exciting leads to see if adding one or more of these substances to our natural diet will decrease the risk of prostate cancer. I believe there exists a lot of exciting potential in preventing prostate cancer -- but unfortunately, even if we knew how to prevent prostate

cancer today, it would be many years before a positive impact would occur on either the incidence or mortality rates. And why do African-Americans have such an alarmingly high rate of prostate cancer and increased mortality? In some cases it is due to the lack of access to healthcare, but many other factors are emerging through research in the area. It is critical that we understand these factors if we are to change the high incidence and death rate from prostate cancer experienced by African -Americans.

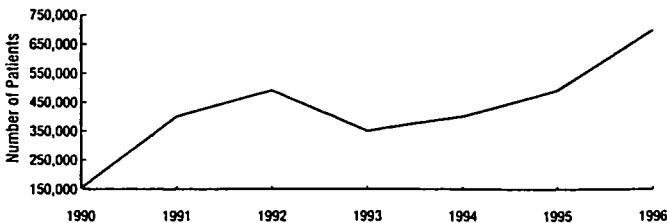
A *third strategy* would be to develop some a cure for advanced prostate cancer. Progress has been made in this area during the last decade, but the "magic bullet" has yet to be discovered. Doctor David McLeod from Walter Reed Army Medical Center will talk about a large, randomized clinical trial that we performed in advanced prostate cancer, where the simple addition of a well-tolerated oral antiandrogen (Eulexin) improved survival in this fatal disease by 26%. Recently it has also been reported that a well-tolerated chemotherapy drug called Mitozantrone can improve the quality of life in men dying of dying of prostate cancer. Neither one of these treatments represents a cure; however, as I travel around the world to visit research centers, it is apparent that significant potential exists. I have become very optimistic that progress is being made which will either cure many patients with advanced prostate cancer, or at least slow its growth.

The *fourth strategy*, and one with the most immediate benefit, is to find it early, treat it, and to cure it. In 1988, we did a survey of several hundred men over the age of 40 -- asking questions about whether or not they had a regular physical exam, and what they talked about with their physician. Surprisingly, less than 50% of men had a physical exam within the last two years, and -- of greater concern -- of those who did, less than half of their physicians had performed a rectal exam to attempt to detect prostate cancer.

In 1989, prostate cancer became the most common cancer diagnosed in American males, surpassing lung cancer in incidence. That same year, we formed the Prostate Cancer Education Council to try to inform men about how common prostate cancer was and to try to encourage early diagnosis. One of the first challenges was to try to find a national spokesperson. We couldn't find a prominent male with prostate cancer who was willing to help us. However, former Pittsburgh Steeler running back, Rocky Bleyer, agreed to help that year -- primarily because his grandfather had prostate cancer. We utilized Mr. Bleyer to generate national media coverage and launch Prostate Cancer Awareness Week the last week of September, 1989. During that Prostate Cancer Awareness Week, nearly 10,000 men visited sites around the country to find out about prostate cancer, as well as to undergo early detection with a rectal examination. We did attract a lot of media attention, and it appeared that men were starving for information about prostate cancer.

The growth of Prostate Cancer Awareness Week has been phenomenal. We have been able to secure the help of a number of prominent spokespersons, including Norman Schwarzkopf and (for this year) Harry Belafonte. In the past seven years, over three million men have been screened during Prostate Cancer Awareness Week. Millions of others have requested examination because of the publicity generated. The American Urological Association, the American Foundation for Urological Diseases, and the American Cancer Society have all contributed to prostate cancer awareness.

Table 2
Prostate Cancer Awareness Week



Vital information has been accumulated since our initial Awareness Week in 1989. We found that a simple blood test known as PSA (prostate specific antigen) was capable of detecting cancers and at an early curable stage. We discovered that the combination of an abnormal PSA blood test and abnormal rectal exam (DRE) had a 50% predictive value for the presence of prostate cancer.

See Table 3

This compares very favorably to an accepted screening modality, mammography for breast cancer detection. The predictive value for mammography is only 20%. Through careful analysis of our data, as well as that of others, we have improved the sensitivity of testing to detect the disease while reducing false negative results. Recently, different forms of the PSA blood test have been discovered which has further refined our diagnostic accuracy. We've learned to screen for prostate cancer beginning at age 40 in higher-risk groups such as African-Americans and those individuals with a family history of the disease. Finally, we have the virtually eliminated advanced incurable prostate cancer in men who participate in annual screening. Screening for prostate cancer has been shown to be cost-effective compared to the financial outlays to detect breast and a number of other cancers.

See Table 4

In spite of all this good news, there is controversy about the value of screening. A number of prestigious organizations do not endorse screening, yet they do not deny that it might be beneficial.

Table 3

Positive Biopsy Detection, by Year

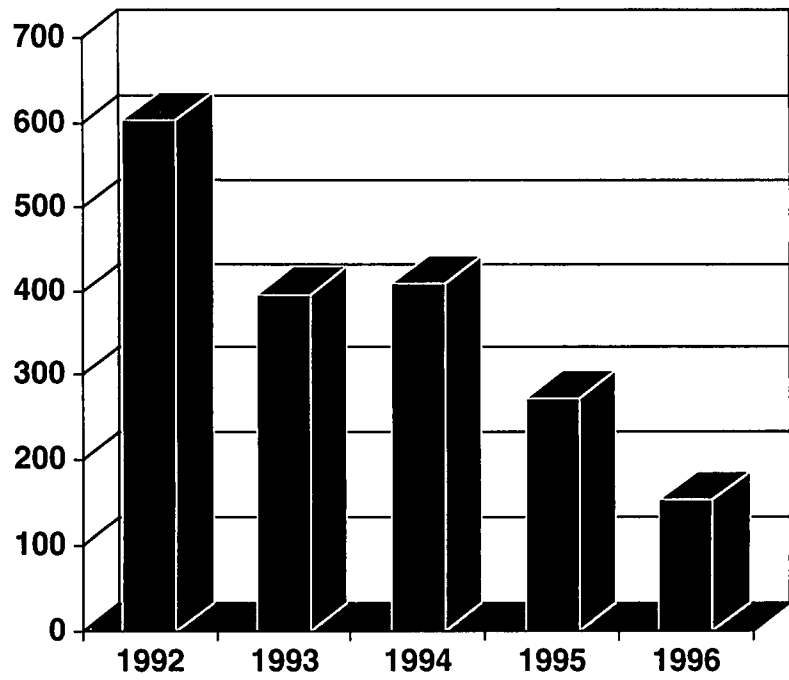
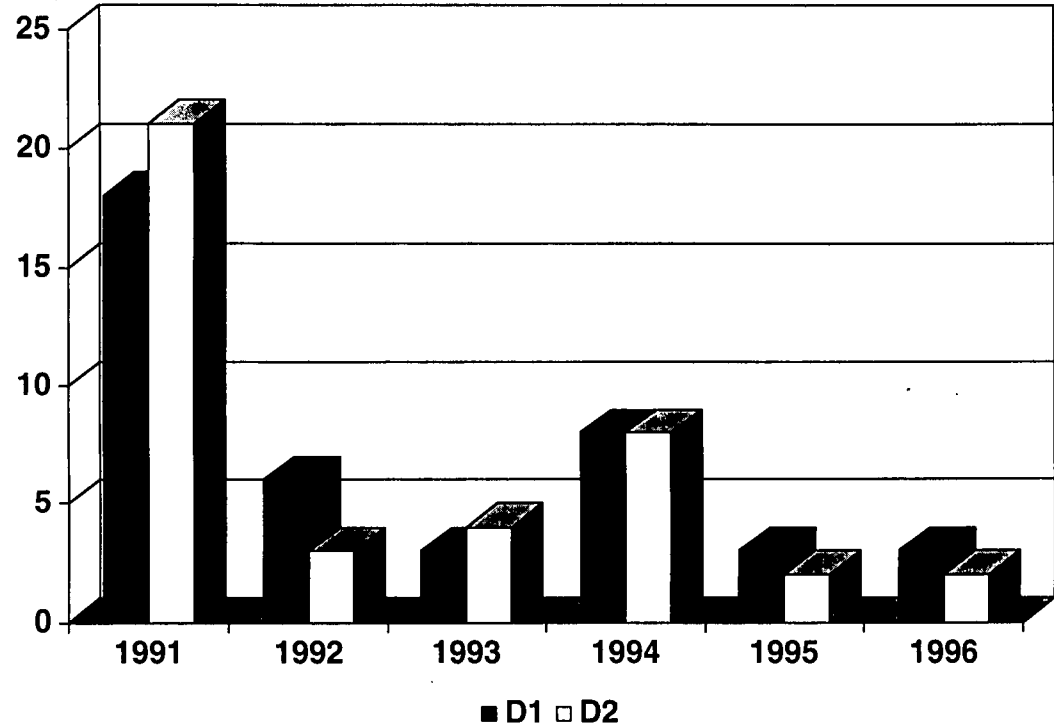


Table 4

Stage of Cancer, by Year with Serial Screenings



I believe that in order to comprehend their position, it is necessary to separate the components of concern. No one can deny that early detection detects early and potentially curable cases of prostate cancer. Early detection is associated with some financial implications, but it is not prohibitive, and falls within cost parameters to detect other cancers, including breast cancer. Through early detection we have reduced or eliminated the presence of advanced, incurable prostate cancer.

The real area of controversy is in the value and side effects of treatment. I believe that if you find and treat an early prostate cancer in a man with a ten-year life expectancy, you can extend his life. Unfortunately, we do not have a randomized clinical trial which proves my conviction. Unlike breast cancer, where research support existed in the early 1960s for studies which ultimately showed a survival benefit, we don't have these in prostate cancer. At the University of Colorado, we are participating in a large and important National Institutes of Health-sponsored trial called the PLCO (prostate, lung, colorectal, ovarian) Cancer Screening Trial. The purpose of this study is to establish the value of early detection. It will be many years (perhaps 10-15) before we know the results of this pivotal study. Because we do not know the value of early detection on ultimate mortality, we have established a motto for Prostate Cancer Awareness Week which states that "men should be able to *choose to know* in order to *know to choose* their treatment". Once they have the reassurance of knowing whether or not they have prostate cancer, they can make an informed decision. If a diagnosis of prostate cancer is made, options from simple watchful waiting to surgery or radiation can be considered. It is discouraging to see many men who are refused the opportunity to have a PSA test and rectal exam. In order to deal with this challenge, three and a half years ago, legislation was enacted in the state of Colorado which mandates the PSA test be covered by health insurance carriers. We need this coverage on a nationwide basis, and

your efforts to provide this coverage through Medicare is important.

We need significant research support to evaluate and improve our results, as well as the side effects from treatment.

In summary, there is a good and bad news about prostate cancer. The good news is that there has been an intense public focus concerning the disease. At least for those men who undergo early detection, we have drastically changed the grim statistics regarding their chance of developing an incurable cancer. Because prostate cancer is so common, more researchers are interested in finding a cure, prolonging survival, and eliminating the pain and suffering that accompanies the disease.

The bad news is that men are still reluctant **to declare war on prostate cancer**. We haven't been able to get significant numbers of African-Americans to participate in early detection when compared to Caucasians. Men still die seven years earlier than women, and make one-quarter as many doctor visits. We don't have enough research dollars to effectively combat this disease. Increased research moneys will result in a rapid development of a cure. These moneys are necessary in the arena of prevention, early detection, cure of advanced disease. In 1989, when we first began to talk about this lack of research support, less than \$10 million were allocated for prostate cancer research. During 1990 to 1997, \$376 million have been directed toward prostate cancer research -- and over \$1.8 billion for breast cancer.

See Tables 5 and 6

I believe that every dollar (and even more!) allocated for breast cancer research is deserved -- but I also believe that what is currently happening relative to prostate cancer research borders on insult to American males, especially

Table 5

National Cancer Institute, 1990-1997.

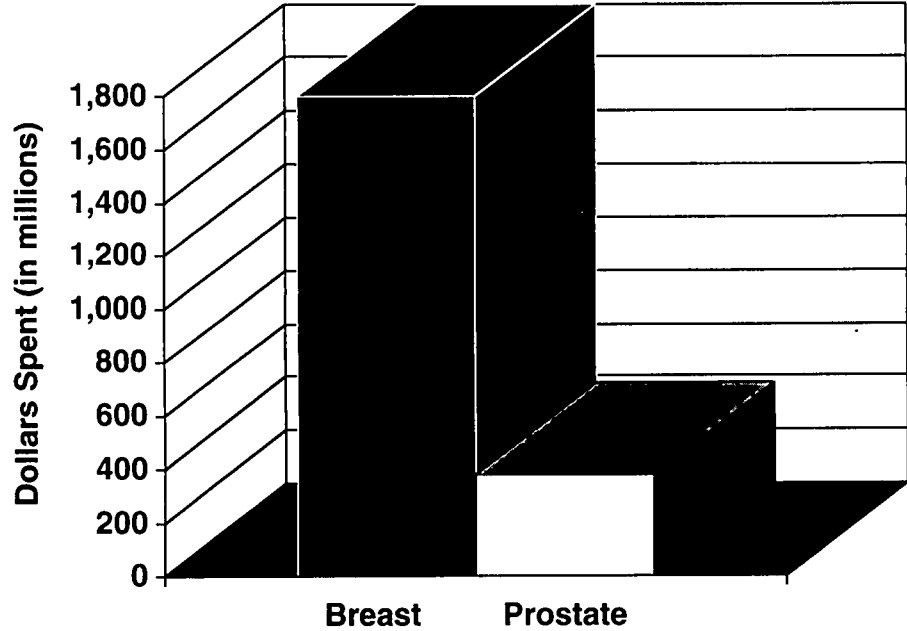
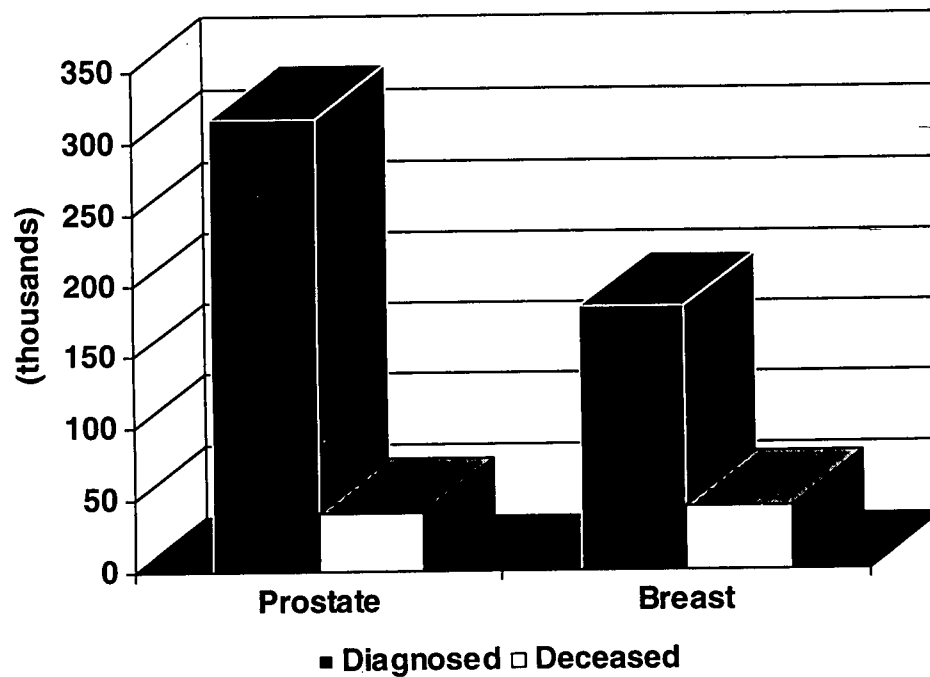


Table 6

American Cancer Society, 1996



those of African-American descent. We need support for programs like Prostate Cancer Awareness Week. It currently costs less than \$200,000 a year to support the awareness week, which is minuscule when one examines its overall impact. We need at least \$500,000 per year to continue this Prostate Cancer Awareness Week under the auspices of the Prostate Cancer Education Council. These moneys will permit us to expand successful promotional efforts, and to analyze and add to our tremendous database.

Researchers become frustrated when great ideas in science exist, when months are spent writing grant applications, and then learn there is less than a 20% chance of any funding. A great deal of what occurs with this disease in the next decade is dependent on the research dollars that are available for education, detection, and treatment. I sincerely request your assistance on behalf of the American male.

Thank you.

Senator SHELBY. Dr. McLeod and Dr. Babaian, we are going to have a problem in just a minute or so in the Senate. There is a Senate rule that you have to have permission to meet. We are trying to get permission for all the committees. Someone is objecting to the committees meeting. We have to go by the rules of the Senate. I am going to have to adjourn this hearing. I hate to do this. I have no choice but your full statements will be made part of the record. Perhaps at another time we can get you before the committee.

[The prepared statements of Drs. McLeod and Babaian follow:]

PREPARED STATEMENT OF COL. DAVID G. MCLEOD, M.D., CHIEF, UROLOGY SERVICE,
WALTER REED ARMY MEDICAL CENTER, WASHINGTON, DC

My name is Colonel David G. McLeod, M.D. I am Chief of Urology at Walter Reed Army Medical Center and Director of the Center for Prostate Disease at the Uniformed Service University of the Health Sciences. The opinions and assertions contained herein are my private views and are not to be construed as reflecting the views of the U.S. Army or the Department of Defense.

The Center for Prostate Disease Research—CPDR—was established in 1991 to manage cooperative research efforts of the Tri-Service Medical Centers. The CPDR is currently funded through the U.S. Army Medical Research and Materiel Command and the Henry M. Jackson Foundation for the Advancement of Military Medicine. Over the years, Congress has provided a total of \$23 million for CPDR activities. The Center is currently involved in a variety of activities including the implementation of a multi-center data base to analyze treatment outcomes on prostate cancer patients, the establishment of a clinical research center, and establishment of collaborative epidemiological and basic research on prostate cancer. The Center is rapidly becoming a vital resource for the improved understanding of prostate disease.

I am pleased to appear before the Committee here today to discuss the treatment of prostate cancer and the role that innovations in treatment are playing in improving patient outcomes.

As Doctor Crawford mentioned in his testimony—prostate cancer is very common among older men. One-in-five men will develop prostate cancer in their lifetime. Most prostate cancer patients will be over 65 when they are diagnosed and will survive 10 or more years with the disease. However, a significant percentage will be diagnosed when they are still relatively young. For most prostate cancer patients, their survival will depend on whether they get early detection or treatment. Many patients will be diagnosed late or have a rapidly-progressing form of the disease.

The good news about prostate cancer is that when detected early in a low stage and grade, it can be effectively “cured” in 80 to 90 percent of patients through surgery or radiation. This is a remarkable result when you think of how rare it is with cancer that we are able to talk about “cures”.

There is even more good news, with the advent of the PSA test, a larger proportion of patients is coming to us at earlier stages of the illness. This detection has helped us provide earlier treatment with a greater rate of success. This year, the Congress extended Medicare coverage to early detection of prostate cancer, effective in the year 2000. You and your colleagues are to be commended on this significant step, because it will make prostate cancer tests completely available to that large portion of men with the disease who are of Medicare age. I only wish that we could advance the date when Medicare will begin paying for these tests.

There is a portion of patients whose treatment will be effective in eliminating the prostate cancer; however, they will have side effects from treatment that may affect their quality of life—mostly urinary incontinence or impotence. For these reasons, not all patients diagnosed with prostate cancer will choose definitive treatment. For older patients, with less than 10 years of life expectancy or those with serious health problems, it may be more appropriate to monitor the progress of the disease and withhold surgery or radiation if the disease does not appear to progress rapidly. It is particularly important that patients be given information about their treatment options and participate actively in the decision making.

While there are complications for some patients, treatment outcomes for prostate cancer are improving dramatically. The advances we are making in forms of treatment are improving the effectiveness of treatment while reducing complications for patients. Earlier detection of these diseases and better outcomes from early treat-

ment are lessening many of the concerns that were raised in the past about prostate cancer detection and treatment.

I would like to start my discussion of treatment advances by describing how we stage and grade prostate cancer and how this information is used to guide the choice of treatment. Doctor Crawford talked about detection—using the PSA blood test and the digital rectal exam—DRE—. A positive result from the PSA blood test and/or DRE is generally followed by a biopsy where we take samples of tissue from the prostate for the pathologist to examine. There are two important questions we need answered in this process:

Stage—Is the cancer still confined to the prostate gland or has it extended beyond the gland and into adjoining tissue, pelvic lymph nodes, or bone?

Grade—Is the form of the cancer cell—the degree of cell differentiation—one that would suggest very rapid progression or one that will progress slowly?

Well-differentiated cancers which are still confined to the prostate gland have the greatest chance of successful treatment. A recent study published in the *Journal of the American Medical Association*, for example, showed that 75 to 97 percent of the patients with organ confined, well differentiated cancer were still alive 10 years after radical prostatectomy.¹ Cancers that have spread beyond the prostate are much less likely to be eradicated. Cancer that has metastasized to the bone will nearly always be fatal.

Once we know the stage and grade of the cancer, as much as can be determined from our clinical evaluation, we discuss treatment options with the patient and his family. There are four basic treatment choices; surgery, radiation, "watchful waiting," and hormonal therapy.

Surgery—surgical removal of the entire prostate gland—radical/total prostatectomy—is a treatment that is appropriate if the cancer is still clinically confined to the prostate. Survival is quite good, and only a minority of men have complications.

Radiation—an alternative to surgery, that may also be effective with some cancers that have spread beyond the prostate gland to surrounding tissue. Outcomes and complications are generally similar to those for surgery.

Watchful waiting—a form of treatment in which the physician actively monitors the disease—through regular patient visits and testing. With this approach, surgery or radiation will be withheld unless the disease begins to progress.

Hormonal therapy—blocks male hormones that "feed the cancer" thus slowing the growth of the cancer. This optimal treatment for the advanced prostate cancer involves combination hormonal therapy—including oral anti-androgens—to completely block production of male hormones. Treatment of advanced prostate disease cannot cure the cancer, but it has been shown to extend life expectancy and improve quality of life for men with late stage cancer. One study I was involved with showed that the addition of oral and anti-androgens in combination with an injectable hormonal compound—an LHRH agonist—to block production of testosterone from the testicles improved survival of patients with advanced prostate cancer by 26 percent. Other studies have shown mixed results in the use of anti-androgens in combination with orchiectomy and surgical castration.

In a perfect world, we would limit surgery to cases in which we were sure cancer was entirely confined to the prostate. Unfortunately, we cannot always be sure of the stage prior to surgery. Occasionally we discovered cancer in surrounding tissue or pelvic lymph nodes when we examine the prostate and nodes after surgery. Significant improvements in diagnosis and staging prior to surgery are helping to reduce the number of prostate cancers that are found to extend outside the prostate. For example, laproscopic surgery can now be used in selected patients to remove the pelvic lymph nodes prior to prostatectomy or radiation to determine whether they contain cancer cells. Surgery can be avoided in patients with evidence of cancer in the lymph nodes.

In recent years, we have made a number of significant strides in treating prostate cancer. I would like to briefly describe these for you and then discuss their importance in improving the chances that treatment will be effective in curing the cancer with minimal side effects.

"Nerve-sparing" prostatectomy—a surgical technique that was pioneered several years ago by Dr. Patrick Walsh at Johns Hopkins to reduce the chances of impotence or incontinence in patients having surgery. In the past, surgeons generally cut through the nerve bundles around the prostate gland to remove the gland. In the nerve-sparing approach, the surgeon attempts to keep the nerves intact that are critical to potency. Studies of this technique have indicated that it reduces impo-

¹Krongrad A, Lai H, Lai S, "Survival after radical prostatectomy," *Journal of the American Medical Association*, 1997; 278; 44-46.

tence and incontinence rates among men having surgery. Unfortunately, there are still relatively few surgeons with extensive training in this technique.

Cryosurgery—an old technique that has recently become popular again, involving the freezing of the prostate gland to kill cancer cells. Since a fellow panelist is discussing cryosurgery, I will not elaborate on it here.

External Beam Radiotherapy—Better methods are being developed to localize the prostate for radiation treatment—conformal radiotherapy. Also, techniques utilizing different types of radiation energy are being investigated—neutron and proton therapy.

Brachytherapy—a form of radiation therapy where radioactive seeds are implanted in the prostate gland to kill cancer cells. Patients have the seeds implanted during one sitting, rather than coming in repeatedly for external beam radiation. The latest technique in brachytherapy is one whereby seeds are placed in the prostate with ultrasound guidance.

Neoadjuvant hormonal therapy—Recently, the FDA has approved the use of combination hormonal therapy with radiation in the treatment of early stage cancer. The hormonal therapy slows the growth of the cancer and shrinks the prostate to enable more effective therapy by radiation. Studies are on-going using neoadjuvant therapy prior to radical prostatectomy.

Chemotherapy—Chemotherapeutic agents have usually been used with patients who have metastatic prostate disease and are no longer responding to hormonal therapy. Recently a chemotherapy drug was approved by the FDA for use in managing pain and reducing PSA levels for patients with advanced prostate disease.

Immunotherapy and Gene Therapy—There is a potential for the use of immunotherapy and gene therapy in preventing prostate cancer. Additional research money is needed to realize this potential.

These treatment advances are encouraging, and offer great hope that we can be quite successful in curing prostate cancer for many patients at some point in the not too distant future. Unfortunately, there are a number of government imposed barriers that may stand in our way. Let me discuss a few of these barriers that I am concerned about.

Delayed Medicare coverage of early detection with the PSA test—Unfortunately, when the Congress extended coverage to the PSA test earlier this year, they stopped short of putting it into effect immediately along with the other preventive benefits. The 3-year wait before the new coverage goes into effect seem unnecessary. A patient who appears at the doctor's office after they have begun to experience pain or difficulty in urination may have prostate cancer that is too advanced for a cure. Early detection has been very helpful in getting patients in early enough to treat them effectively. I would think Medicare costs would be lower if these patients were detected early and treated early than if they were to progress to advanced cancer and have significant, and expensive, complications associated with end-stage disease. I propose that Congress consider accelerating the timetable to put this benefit into effect in 1998.

Inadequate Medicare coverage of treatment—Medicare does not cover some forms of prostate cancer treatment. Of particular concern is the failure of Medicare to cover oral anti-androgens that are now showing promise in neo-adjuvant therapy with radiation and possible with surgery. Back in 1993, when the Congress enacted coverage for oral cancer drugs, it neglected to cover oral anti-androgens. This omission is because the definition was limited to drugs that substituted for injectable drugs, and it did not include drugs—like oral anti-androgens—that supplement injectable drugs. As a result, there is a considerable bias in Medicare payment in favor of less-effective forms of treatment. I believe that Medicare should not be in the business of picking some forms of treatment over others. Instead, I feel it should cover all approved and effective treatments for prostate cancer and let the medical community decide what is appropriate care for particular patients.

Underfunding for prostate cancer research—In fiscal year 1997, Congress appropriated \$45 million for prostate cancer research through the Department of Defense. Unfortunately, the appropriation for fiscal year 1998 is still uncertain at this time. When signs are pointing to the chance for significant breakthroughs in prostate cancer detection and treatment, we should not be starving the research community dedicated to this problem. We have made great progress, but we need to make much more progress to begin to control this cancer that ravages so many older men.

I commend the Chairman and Senator Shelby, and appreciate the interest other members of the Committee have shown in having this hearing today. I will be pleased to support any activities this Committee can undertake to help us solve the remaining problems in tackling prostate cancer. Thank you.

PREPARED STATEMENT OF RICHARD J. BABAIAN, M.D., THE UNIVERSITY OF TEXAS
M.D. ANDERSON CANCER CENTER

THE POTENTIAL ROLE OF CRYOSURGERY AS A TREATMENT ALTERNATIVE FOR PROSTATE
CANCER

Historical Perspective

Cryosurgery, or freezing of the prostate, was first reported by Soanes and Gonder in 1964. Thereafter, several other investigators in the 1970s employed this technique to treat prostate cancer. In this era, cryoablation of the prostate was achieved by circulating liquid nitrogen through probes that were designed for placement intraurethrally or transperineally. Although the extent of tumor destruction was most impressive, the delivery system was cumbersome and did not allow the operator to control precisely the extent of the freezing process, frequently resulting in extensive damage to the surrounding tissues. This, therefore, resulted in severe complications such as urethrocutaneous and urethrorectal fistulas, as well as prolonged intraurethral tissue sloughing with urinary obstruction. Despite its promise as a method of destroying prostate tissue, the early technique of cryoablation was abandoned because of its associated morbidity. The mechanism by which cryosurgery produces tissue destruction is intracellular dehydration, toxic electrolyte concentration, crystallization with secondary membrane rupture, denaturation of proteins, thermal shock and vascular stases.

Modern Era of Cryosurgery

In 1992, there was a reemergence of interest in the application of cryoablation of the prostate because of a series of technical advances which modernized the procedures for cryoablation. In the late 1980s, transrectal ultrasonography of the prostate became wide-spread with urologists becoming adept at prostate imaging and ultrasound-guided biopsies of this organ. As a consequence of the ultrasound technology, the procedure for cryoablation could be performed with real-time visualization of the prostate and surrounding structures. The resolution of this technology allowed safe and accurate placement of cryoprobes directly into the prostate. In the early 1990s, Onik and Associates demonstrated that the extent of freezing and consequently tissue destruction could be monitored and precisely controlled employing transrectal ultrasound. This was possible because of the ice ball phenomenon which resulted in a striking acoustic image. Therefore, as a direct consequence of modern ultrasound technology, cryoablation could be performed with less risk of the severe complications which led to its abandonment in the 1960s and 1970s. In addition to the technological improvements in ultrasound, advances have also occurred in percutaneous instrumentation (needles, guide wires, dilators, and sheaths) resulting in marked improvement of transperineal insertion of the temperature probes into the prostate. As previously mentioned, the initial cryosurgery units were cumbersome and have been replaced by more innovative systems which can circulate liquid nitrogen or argon in up to eight slender probes at individually controlled rates. Temperature monitoring has also been recently introduced to facilitate the monitoring of the freezing process.

A Summary of Recent Clinical Experience with Cryoablation of the Prostate

Our experience at the University of Texas M.D. Anderson Cancer Center with patients undergoing salvage cryotherapy of the prostate was recently published in the March, 1997 issue of *The Journal of Urology*. Short-term PSA follow-up in our patient population revealed that 31 percent of patients have a persistently undetectable PSA. Patients who had a local recurrence following radiation therapy and who were treated with a double freeze-thaw cycle of cryoablation had a 93 percent negative biopsy rate six months following cryoablation. This was significantly better than the negative biopsy rate of 71 percent in those men who were treated with only a single freeze-thaw cycle of cryoablation. In the 150 patients we reported, there were no operative deaths and no bleeding that required transfusion. There was a 1 percent incidence of fistula formation in this pre-treated group of men with a 3 percent incidence of osteitis pubis, a 1 percent incidence of prostatic abscess formation, and a 17 percent rate of urinary obstruction requiring transurethral prostaticectomy. The major complications of salvage cryotherapy reported by patients who responded to a questionnaire were urinary incontinence occurring in 73 percent, impotency in 72 percent, obstructive symptoms in 67 percent, and severe perineal pain in 8 percent.

In a smaller group of men treated at The University of California in San Diego following relapse after radiation therapy, 86 percent of the men were found to have negative biopsies 3 and 6 months following cryoablation. A serum PSA of less than 0.5 ng/ml was reported in 40 percent of these men. The three-month positive

biopsy rate in men undergoing cryoablation for radiation therapy failure reported by Onik, Miller, and Cohen from Allegheny General Hospital was 27.3 percent.

Primary Therapy of Localized Prostate Cancer Using Cryoablation

A preliminary study reported by Shinohara and Associates from the University of California at San Francisco reveals an undetectable PSA at 6-months in 48 percent of patients and a 70 percent negative post-cryotherapy biopsy rate. Excluding impotence, they reported an overall complication rate of 51 percent. The two most common symptoms were urinary obstruction requiring transurethral resection in 23 percent and penile numbness in 10 percent. It is important to note that the incidence of incontinence in this group of men treated with primary cryotherapy was only 4 percent. A report from The University of California at San Diego with short-term follow-up for patients with localized cancer of the prostate who have received cryoablation reveals that approximately 40 percent of patients have PSAs less than 0.5 ng/ml which is exceedingly low and that the negative biopsy rate in patients undergoing cryoablation as their primary form of treatment was 86 percent. In a report on primary cryotherapy for men with localized prostate cancer using adjuvant hormonal therapy and temperature monitoring, Lee and Associates from Crittenton Hospital report a positive biopsy rate of 3.3 percent one-year following cryotherapy. They also report that one-half of the patients with negative biopsies had an undetectable PSA. Approximately 80 percent of all patients with negative biopsies had a PSA less than or equal to 0.5 ng/ml. The complication rates reported at one year in their 347 patients included an operative mortality rate of 0 percent, a 0.33 percent urethral-rectal fistula rate, an incontinence rate of 0.33 percent, with a 3.2-percent incidence of outlet obstruction. In an unpublished update of their results the distribution of failures by pre-operative PSA levels reveals that 8 percent of men with a PSA of less than 4 have failed. The failure rates in men with a pre-treatment PSA between 4.1 and 10 and greater than 10 were 11 percent and 23 percent respectively. In an unpublished report presented at the Endourology World Congress in September 1997, Oriheula and Associates from The University of Texas Medical Branch at Galveston reported a comparison of the results in 167 consecutive patients with localized prostate cancer who were treated between July, 1992 and April, 1996 by cryosurgery, radical prostatectomy, and radiation therapy.

This preliminary data at 24 months of follow-up shows that the disease-free survival measured by PSA was comparable for radical prostatectomy and cryosurgery (78 percent versus 74 percent, respectively) and was superior to the group receiving radiation therapy (51 percent). These investigators reported that significant complications were more frequently seen in men undergoing radical prostatectomy.

Conclusion

I believe that there is indisputable evidence that freezing destroys cancer cells. The modern techniques of percutaneous instrumentation and ultrasound have been readily adapted for use in cryosurgery of the prostate. There is considerable potential that the use of temperature monitoring which has only recently become available will enhance the treatment outcomes in patients who elect to undergo cryosurgery. While the complication rate for cryosurgery following radiation therapy is formidable, it appears to be considerably lower when used as the primary treatment modality. While the preliminary results with primary cryotherapy are encouraging, clinical trials and long-term follow-up are required before the exact role of this treatment modality for localized prostate cancer can be determined.

Senator Reid, I know you hate that, too, but we have no choice.

Senator REID. Could I ask one question?

Senator SHELBY. Yes, you go ahead.

Senator REID. All the new cases we have found, do you think a lot of that is because of the screening, that most of the cancer was there anyway?

Dr. CRAWFORD. That is true. Because of early detection, we have found more prostate cancers. But the interesting thing that has happened this year is they originally projected 343,000 new cases of prostate cancer; it has actually gone down. It is about 215,000 to 220,000.

So we have eliminated the prevalence of the disease by the screening over the first couple of years. Now what we are finding

is the annual incidence, and we think that is important. Also for first time the mortality rate is going down.

Senator REID. Would the two of you agree to that?

Dr. MCLEOD. Yes, sir. That is exactly what we are doing with this.

Senator SHELBY. Dr. Babaian. I will ask all of you this. If the average American lives to be 80 years of age, and we are living older and Senator Reid and I hope to make that some day, what are their chances of having prostate cancer?

Dr. BABAIAN. Well, the chance of having prostate cancer in men over the age of 60—

Senator SHELBY. Let's say 80.

Dr. BABAIAN. Well, if you get to 80, the chance of having prostate cancer approaches about 70 percent and that increases—

Senator SHELBY. Every year?

Dr. BABAIAN. Yes, sir. This disease is directly related to aging.

Senator SHELBY. Dr. McLeod.

Dr. MCLEOD. That is correct. The older we get now the more apt we are to get it at that age. But obviously if you get prostate cancer at age 90, in general, one can live with the disease.

Senator SHELBY. How important is diet? I know there are a lot of studies there. Doctor.

Dr. BABAIAN. I don't think we have the answer yet. I think diet is beginning to become a very, very important factor in the development of prostate cancer. There is obviously a need, as Dr. Crawford mentioned, for a tremendous amount of research and funding for that research, particularly regarding diet.

Senator SHELBY. Dr. McLeod.

Dr. MCLEOD. That is exactly correct. We are what we eat, I think someone said.

Senator SHELBY. Dr. Crawford.

Dr. CRAWFORD. I agree that diet plays a role.

Senator SHELBY. And genetics also plays a role of some kind, does it not?

Dr. BABAIAN. Yes, sir.

Dr. MCLEOD. Yes, sir.

Dr. CRAWFORD. If a man has a family history, multiple family members with prostate cancer, he has almost a 50 percent risk of having the disease.

Dr. BABAIAN. As the number of family members of that particular gentleman increased, his relative risk also increases.

Senator SHELBY. In the last 10 years—well, I will use the yardstick of 10 years before I am called by the floor in a second—is that when the PSA goes back to? How old is the PSA test, Dr. McLeod?

Dr. MCLEOD. We started about 1990 with it. There was some in 1989 but about 1990, 1991 is when it really took off.

Senator REID. Who developed that?

Dr. MCLEOD. It was developed actually up at Roswell Park with a team of scientists, a Dr. Murphy and Dr. Chu developed this.

Dr. BABAIAN. It was developed in 1979. It took us urologists quite a long time to figure out how important that discovery was.

That is correct, a 10-year hiatus.

Senator SHELBY. What is your greatest hope as physicians that are specialists in the field of treatment of prostate cancer, what is your greatest hope as far as a scientific breakthrough?

Dr. BABAIA. I guess the greatest hope that I have is that we could prevent this disease from occurring so men don't need to be treated.

Dr. MCLEOD. And for those who do get the disease, to be able to successfully treat them.

Senator SHELBY. Dr. Crawford?

Dr. CRAWFORD. We know prostate cancer is very common; it is slow-growing. Maybe all the time we don't have to cure it but if we can slow it down so that men will die of something else before they die of prostate cancer, particularly older men.

I am very encouraged with the fact that through screening we have virtually eliminated advanced prostate cancer, which usually was the way it presented in 1989—incurable prostate cancer.

Senator SHELBY. But we have made progress in the last 10 years, have we not?

Dr. BABAIA. We certainly have. And because of the difference in the biology of this tumor, it is very important to explore different avenues of treatment. There is not one treatment that treats all the patients with this disease.

Senator SHELBY. Everybody's different, I suppose, different profiles.

Dr. BABAIA. Yes, sir.

Dr. MCLEOD. It is very rare for someone at Walter Reed now to walk in with metastatic disease, although it does happen.

Senator SHELBY. Gentlemen, I am under constraints from the floor up here. I want to personally apologize to the third panel. Your written statements will be made part of the record in their entirety because you had a lot to say, too, and I think a lot to say to the American people, but we have to go by the rules.

[The prepared statements of Drs. Holohan and Sox follow:]

PREPARED STATEMENT OF THOMAS V. HOLOHAN, M.D., F.A.C.P., CHIEF PATIENT CARE SERVICES OFFICER, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairman and Committee Members: I am pleased to have the opportunity to discuss the Department of Veterans Affairs' (VA) Prostate Cancer Detection and Treatment Programs. Cancer is second only to cardiovascular disease as a cause of mortality and morbidity in veterans. Because of this significant health challenge to veteran patients, a number of formal programs as well as specific designations of facilities based upon the available expertise in treating cancer have been established. Throughout VA, 103 facility-based cancer programs treat an estimated 50,000 new cases each year. Of those, approximately 9,000 are patients with newly-diagnosed prostate cancer. The total number of all cases of prostate cancer under care by VA is approximately 70,000; about 6,000 are treated on an inpatient basis each year. More than 60 VA facility-based cancer programs are approved by the American College of Surgeons (ACoS) Commission on Cancer. VA's Under Secretary for Health, Dr. Kenneth W. Kizer, has communicated his expectation of a significant increase in the number of sites achieving that recognition.

In 1992, VA headquarters prepared a set of standards for oncology programs that were based upon the ACoS requirements and were subsequently published in VA's policy manual. It is worthwhile to provide some details regarding this process, since promulgation of standards, such as those of the ACoS, is critical to provision of the highest quality of medical care. The goals of establishing those criteria for VA facilities were: To provide state-of-the-art multidisciplinary and humane care; to improve patient access to comprehensive care; to ensure coordination of approaches to cancer

care among the numerous specialists; and to develop cost-effective outpatient programs, including access to lodging facilities where appropriate.

Three levels of cancer care were established. Each medical center is classified as providing primary, secondary, or comprehensive cancer care. It is our intent that each of VA's 22 Veterans Integrated Service Networks (VISN) will have at least one Comprehensive Cancer Center (CCC) which is either certified by the College of Surgeons or possesses conditional approval. Currently, 40 facilities are designated as Comprehensive Cancer Centers.

Briefly defined, a primary care center has diagnostic capabilities focused on screening and prevention programs and has a referral relationship with a Comprehensive Cancer Center.

A secondary level program treats over 100 new cancer cases annually and has the capability to provide some chemotherapy and cancer surgery. Prevention and screening programs are available, as are routine radiology, nuclear medicine, and pathology diagnostic services. Radiation oncology services must be available either in the facility itself or by contract or sharing agreements with an adjacent entity.

A Comprehensive Cancer Center treats over 300 new cancer cases annually. In addition, three additional broad groups of requirements are met.

First, the center meets specified staffing requirements, personnel possess expertise in cancer management, and the center provides a wide range of services to assure the provision of state-of-the-art care. This encompasses diagnostic services including a complete clinical laboratory with cytology, immunopathology and blood bank capabilities, with access to other more specialized testing capabilities. Diagnostic services include invasive and noninvasive radiology, including computerized tomography, magnetic resonance imaging services, and nuclear medicine capabilities; single photon emission computed tomography (SPECT) is recommended.

Second, these centers must provide a complete range of therapeutic services including: Surgical oncology and surgical subspecialties (e.g., thoracic, head and neck surgery, urologic surgery etc.); medical oncology with chemotherapy, including demonstrated familiarity and experience with investigational protocols, and a full complement of internal medicine specialties and services (e.g., pulmonary medicine, cardiology, dialysis, etc.); radiation therapy services including electron beam and interstitial therapy; a nutritional support team; a number of specific residency training programs; a complete pharmacy service that specializes in the preparation of chemotherapeutic agents (using laminar flow hood equipment).

Each CCC program is encouraged, but not required, to have an inpatient oncology unit or its equivalent.

Finally, Comprehensive Cancer Centers are also expected to provide: Social work services; counseling; pain management; nutritional education and support; in- and outpatient rehabilitation; formal interaction with available hospice services; special lodging arrangements for ambulatory patients receiving extended treatment.

Leadership is provided by a multidisciplinary committee which includes representatives from medical and radiation oncology, diagnostic radiology, surgery, and pathology. The committee's responsibility is to monitor quality management and provide for improved care, and to supervise the cancer registry. Interdisciplinary cancer conferences, wherein specific patient case management issues are discussed, are required at regular intervals; these must comprise a minimum of 10 percent of all cases seen at the Center. We have previously provided the Committee a portion of the annual cancer report from the VA Medical Center Long Beach, California, which illustrates the clinical and research activities underway at such centers.

Formal cancer registries are considered critical elements in a cancer program. They provide important epidemiologic information, data on staging, patient demographic, survival statistics, and other clinical outcome data. Currently, there are more than 85 VA healthcare facilities with formal cancer registries, and more than 55 certified tumor registrars. Establishment of a central tumor registry is underway and will enable compilation of accurate incidence statistics, planning for resource allocation, comparison of incidence and outcomes with national standards, analyses of specific management and outcomes, assistance in reporting to the VA Secretary and Under Secretary for Health, and Congress, and contributions to the National Cancer Data Base.

DIAGNOSTIC AND TREATMENT OPTIONS FOR PROSTATE CANCER

Despite the high prevalence of prostate cancer, there are significant gaps in the evidence base regarding screening, diagnosis and treatment. While the number of diagnosed cases of prostate cancer has increased, there has not been a concomitant increase in mortality rates; therefore, some investigators have concluded that data include a disproportionate number of diagnoses of "non-lethal" cancers. Autopsy

studies have demonstrated that a large fraction of elderly men die with, but not from, prostate cancer, and a number of population-based studies have indicated that more cases of prostate cancer that seem to have little likelihood of reducing survival are being detected in screening studies. The essence of the problem is that many early non-aggressive cancers that have limited potential to affect survival are detected (and likely treated); moreover, the early detection of aggressive cancers and those that have already spread and are poorly responsive to current treatment is unlikely to improve outcomes. Indeed, it is still uncertain whether radical prostatectomy or radiation therapy for many early stage prostate cancers will result in survival superior to that provided by careful observation without immediate treatment. Earlier detection of malignancy that is unresponsive to any treatment will result in an apparent increase in survival time (so-called lead-time bias) which is totally unrelated to any intervention(s). Notwithstanding, providing no active treatment to all early stage disease may obviate potentially curative treatment for some cases destined to otherwise progress.

There are a number of appropriate treatment options for each stage of prostate cancer. Selection of specific therapy is therefore dependent upon patient-specific clinical factors, the patient's personal preferences, the clinician's experience and best judgment, and the available technology.

For Stages I and II prostate cancer, it remains uncertain as to whether prostatectomy (with or without lymph node dissection), external beam radiotherapy, brachytherapy, or careful observation will provide the longest survival. Under various circumstances, all approaches could be supportable based upon current evidence. Stage III disease has spread beyond the gland, and the results of prostatectomy are much poorer than in Stage I and II. Nonetheless, for selected patients surgery may be appropriate. Radiation therapy is the most common treatment for this stage, and offers the possibility of cure. Acceptable options also include, for carefully selected cases, observation with treatment provided only for symptoms.

Advanced prostate cancer presents significant therapeutic difficulties. Surgery is not indicated save for local symptomatic problems such as pain or urinary obstruction. Radiation may prove beneficial for the same purposes. Hormonal therapy will provide palliation, and possibly extend survival, but is not curative; and chemotherapy remains primarily investigational at this time. For asymptomatic patients, careful observation may be appropriate.

Therefore, it is not possible to construct definitive statements selecting any specific treatment plan for any stage of prostate cancer. Indeed, if clinicians always selected the most appropriate treatment for each individual patient, it would be apparent that for any patient classification scheme—by disease stage, by age, et cetera—a wide variety of therapeutic strategies would be employed in each category.

The major difficulty in formulating rational treatment plans is the nearly total absence of randomized, controlled trials of various therapies. Almost all the data exist in the form of case series, usually with inadequate description of patient selection criteria and absent direct comparisons of alternative treatments. Patient selection factors often have influenced the choice of treatment and thus make comparisons of therapeutic strategies problematic; for example, it appears that Stage I and II patients treated with radiation therapy have had worse prognostic factors than those provided surgery. Unfortunately, such data constitute the foundation upon which some clinicians have formed their opinions regarding clinical management. Patients, too, form their own convictions based upon incomplete information, which may often derive from sources of questionable reliability and accuracy.

Screening for prostate cancer is a topic of great contemporary interest. The value of early detection and treatment of prostate cancer remains unclear, and the issue is controversial. Routine screening is not recommended by the U.S. Preventive Services Task Force, the Canadian Task Force on the Periodic Health Examination, or the American College of Physicians. Also, the American Cancer Society does not promote mass screening. Screening is, however, recommended by the American Urological Association, and the American College of Radiology. Prior to its demise, the U.S. Congress' Office of Technology Assessment concluded that the choice to accept or forego screening should depend on an individual patient's values. Current VA policy regarding prostate cancer screening for veterans is contained in an Information Letter issued by the Under Secretary for Health of January 8, 1997. That document states that the decision to screen, using modalities such as digital rectal examination, prostate-specific antigen (PSA), and transrectal ultrasound imaging with or without ultrasound-directed biopsies, should be made by the patient subsequent to an explanation by the physician of the controversy regarding the value of such testing and the potential benefits and risks for screening.

CLINICAL GUIDELINES

It is our intent that physicians routinely provide the best available care to every one of the 9,000 new prostate cancer patients seen in VA healthcare facilities every year. VA is cognizant of the utility of guidelines for the purpose of providing best practices to our patients. The development of useful clinical practice guidelines is a complex and difficult procedure. Recommended best practices can only be as valid and reliable as the evidence upon which they are based. Moreover, guidelines require frequent review and revision as new information becomes available, and thus obsolescence is a constant problem. In addition, the guidelines must be promulgated and disseminated widely and in a timely fashion, be easily accessible, and "user-friendly" to busy clinicians. For all of these reasons, as part of a newly developed VA National Cancer Strategy requested by VA Under Secretary for Health, Dr. Kenneth W. Kizer, we have selected the Physicians Data Query system (or PDQ), provided by the National Cancer Institute through the National Library of Medicine as representing the standard of care to be provided by VA. In essence, PDQ is our national cancer care guideline. PDQ recommended diagnostic and therapeutic interventions are the result of a comprehensive review process by an editorial board of cancer experts and are based on published studies which are carefully evaluated according to the strength of their evidence (see enclosed PDQ statement). PDQ statements and their supporting evidence are re-assessed by the editorial boards at two-to-four-month intervals, thus assuring contemporaneous information. This database is stored by the National Library of Medicine in electronic format and is available virtually instantaneously, 24 hours a day, at every VA medical facility. The information can be reviewed on a personal computer, or hard copies can be printed for future reference. This database provides an up-to-date summary of the best practices in oncology.

PROSTATE DISEASE RESEARCH IN VA

Recognizing the importance of prostate disease to the veteran population and the large number of unresolved questions from basic biology to its optimal treatment, VA has committed substantial resources to research on prostate disease. Prostate disease research expenditures have grown from \$3 million in FY 1995 to over \$9 million in FY 1996, an estimated \$12.8 million in FY 1997, and a projected \$15.1 million in FY 1998. An additional \$7.3 million was obtained by VA investigators from non-VA sources in FY 1996 to support prostate cancer research projects, further leveraging the VA's direct investment in this field.

Selected examples of VA research include:

Clinical Trials—An ongoing project, The Prostate Cancer Intervention Versus Observation Trial (PIVOT), is a collaboration between VA's Cooperative Study Program, the National Cancer Institute, and the Agency for Health Care Policy and Research. Men 75 years of age or younger who have clinically localized prostate cancer are eligible for the study. Participants are randomly assigned to receive radical prostatectomy with additional treatment for residential or recurrent disease or expectant management with treatment of symptomatic progression or metastatic disease. The goal is to determine which treatment approach is better for patients.

Risk, Screening, and Treatment Preferences—A research investigator in Houston is studying relatives of men with prostate cancer to determine the familial risk of prostate cancer. Investigators in West Haven are evaluating the effectiveness of screening for prostate specific antigen (PSA) for identifying patients with early prostate cancer. They hope to determine whether screening can improve survival rates. A Gainesville investigator is using endorectal magnetic resonance imaging of the prostate as a new way to screen for prostate cancer and to monitor response of the prostate to cancer therapy. Research investigators in Milwaukee are analyzing patient preferences for treatment of localized prostate cancer. They found that the most important factors in making a treatment decision were the doctor's recommendation, life expectancy, and experience of friends or family. Another Houston project is assessing patient preferences associated with treatment of advanced prostate cancer. Since no available treatment can cure these patients, analysis of quality of life among the patients choosing particular treatment might help future patients to make treatment choices.

Basic Medical Research—Research investigators are identifying markers for differential diagnosis and aggressiveness of prostate tumor cells (Washington) while others are developing a panel of biomarkers that will detect individuals at high risk for development of prostate cancer (Oklahoma City). Stimulation and inhibition of growth of prostate cells is influenced by hormones and by various growth factors and their receptors. Studies focusing on specific growth factors include fibroblast growth factor (New York), insulin-like growth factor (Seattle), epithelial growth fac-

tor receptor (Birmingham), and transforming growth factor and parathyroid hormone (Loma Linda). Other projects (Minneapolis, Chicago) are focused on enzymes that may increase the ability of prostate tumor cells to grow in new sites in the patient (metastasis). A Madison group is studying the role different cells have in initiating prostate tumor cell growth. The investigators believe that naturally-occurring enzymes may allow the cells to grow in different parts of the body. These studies may provide new targets for better anticancer treatments.

Other research investigators are concentrating on hormones and their receptors on prostate (Washington) to understand the mechanisms underlying the transition of prostate cell growth from androgen-dependent (treatable) to androgen-independent (fatal).

Some projects concentrate on animal models such as the rat (Atlanta) or mouse (Iowa City) for prostate cancer. Other studies are looking at the role of the immune system and its interaction with prostate cells. Projects include the development of active immunization against prostate cancer cells (Baltimore) and the use of immune cells to destroy prostate cancer cells (Iowa City).

In addition to the ongoing projects described above, a joint VA/DoD planning committee has been formed to set priorities for prostate disease research, issue invitations for investigators to submit proposals, and conduct scientific reviews of proposals prepared by VA and DoD investigators. This committee has drafted a Request for Proposals for a VA/DoD Collaborative Research Program on prostate diseases including cancer that is now undergoing concurrence by both agencies. Scientific review committees are also being assembled to conduct the review of proposals anticipated in response to this RFP. Separately, the VA Cooperative Studies Program is preparing an Announcement soliciting proposals for new treatment trials of prostate cancer that will be released by the second quarter of FY 1998. VA has recently established three Epidemiological Research Information Centers (ERIC's) through its Health Services Research and Development program. Within the ERICs, one study on "Risk of Mortality in Prostate Cancer" has already been funded (West Haven), a "Prospective Cohort Study of Early Stage Prostate Cancer" is projected to be funded in FY 1998 (Boston/Brockton), and a proposal for a "Case Control Study of Prostate Cancer in Black and White U.S. Veterans" is now pending review for scientific merit (Durham).

These new initiatives will continue the strong trend of increasing VA funding of prostate cancer research into FY 1998.

INTERAGENCY AGREEMENT WITH THE NATIONAL CANCER INSTITUTE (NCI)

We believe veteran patients should be provided with the most recent state-of-the-art care and should have the option of participating in promising, novel treatment plans which may become the standard of care for the future. To that end, VA and NCI have signed an Interagency Agreement. The purposes of this agreement are to provide veteran patients with access to the full range of new approaches to prevention, diagnosis and treatment, while increasing VA clinical research and accrual of patients into NCI-sponsored national clinical trials. This agreement will build upon already existing cooperation between VA and NCI. There are currently 22 VA hospital affiliations with NCI-designated cancer centers and 90 formal associations between VA medical centers and various NCI Cooperative Study Groups.

That concludes my statement, Mr. Chairman. Dr. Feussner and I will be pleased to answer any questions you or Members of the Committee may have.

PREPARED STATEMENT OF HAROLD SOX, M.D., DARTMOUTH MEDICAL SCHOOL

My name is Harold Sox. I am a specialist in internal medicine and chair of the department of medicine at Dartmouth Medical School. I am President-elect of the American College of Physicians, which issued guidelines on prostate cancer screening in 1997. I chaired the United States Preventive Services Task Force from 1990 to 1996. The Task Force issued its prostate cancer screening guidelines in 1995. The Task Force is a federally sponsored panel now administered by the Agency for Health Care Policy and Research. Most people consider the Task Force to be the definitive resource for evidence-based prevention guidelines, owing to its rigorous methods for evaluating the evidence and its reputation for impartiality. The Task Force's recommendations strongly influence coverage decisions in the private sector as well as the patient care quality standards of organizations, such as the National Council for Quality Assurance.

Mr. Chairman, this hearing and related efforts have a critical message to impart: that screening and other preventive services can be life-enhancing and, indeed, life-saving. Congress recognized the value of preventive care when it significantly ex-

panded Medicare coverage in the Balanced Budget Act. With this legislation, Congress has made it possible for many people to receive important services. It is now up to the medical profession to decide the often very complex issues of whom to screen and how often, so that the American people receive good value for the support they provide to preventive services under Medicare.

The issue of whom to screen and how often is nowhere more complex than with prostate cancer, the subject of today's hearing. I wish that I had an easy answer for the committee. I wish that physicians knew enough about prostate cancer and its treatment to provide uniform advice to patients, as we do regarding breast cancer screening for some women. There is very high quality evidence that breast cancer screening reduces the death rate from breast cancer in women aged 50-69 years. There is broad agreement that this evidence is compelling and that physicians should encourage women in this age group to undergo mammography.

In comparison, the evidence for prostate cancer screening, like many other areas of medicine, is very weak, and there is no broad professional consensus that prostate cancer screening is effective. Absent firm scientific grounding, it is not possible or desirable, in my opinion, to promote a uniform policy on screening. As I will discuss, our uncertainty about the value of prostate cancer screening means that physicians make screening decisions on an individual basis. The best policy is shared, informed decision making, in which a physician treats each patient as an individual, teaching him about prostate cancer and helping him to decide. Prostate cancer screening is not for everyone.

Prostate cancer is, in many respects, a more complicated disease than breast cancer or colon cancer, for which we have generally agreed-upon screening policies. Prostate cancers vary in their rate of growth; half of prostate cancer patients have very slow growing tumors. Prostate cancer is largely a disease of older men, many of whom have other serious diseases. Therefore, most men with prostate cancer die of something else. The side effects of prostate cancer treatment are more frequent, more long-lasting, and more serious than the treatment of cancer of the breast or colon.

The components of screening are the screening test, a test to verify the diagnosis when the screening test is abnormal, and treatments for proven prostate cancer. The two screening tests are digital rectal examination (DRE) and prostate specific antigen (PSA). Positive results are confirmed by a biopsy of the prostate. Patient with a positive biopsy may undergo staging tests, such as MRI and bone scan, to determine the extent of tumor spread. If these tests are negative, the cancer is "clinically localized," and the patient must decide whether to undergo potentially curative treatments, such as radical prostatectomy or radiation therapy, or to choose no treatment.

Why might some patients with prostate cancer decide against potentially curative treatment? Presumably, they feel that the harms of treatment outweigh the benefits in their case. I believe that everyone would agree that the balance between the harms and benefits of screening should determine a patient's decision. We know some of the harms, but crucial information about benefits is missing.

HARMS

1. Treatment: In the U.S., we introduce new health care technology first and evaluate it only after it has become common practice. As a result, we know a great deal about the harms of radical prostatectomy but next to nothing about its benefits. The principal harms are urinary incontinence and sexual dysfunction. Urinary incontinence was a major problem in a study of Medicare patients who underwent prostate cancer surgery: 32 percent use pads or a penile clamp, 2 percent use an indwelling urinary catheter, and 6 percent require a surgical procedure for incontinence. Sexual dysfunction is widespread also: In the same study of Medicare Patients, 91 percent had erections before surgery, but 61 percent had had no erection since surgery, and only 11 percent had erections firm enough for intercourse in the month preceding the interview. Finally, radical surgery for prostate cancer is the cause of death in 1 percent of patients.

2. The screening tests: Both PSA and digital rectal examination are inaccurate tests that frequently give misleading information. PSA, for example, detects only one-half of patients with clinically localized prostate cancer, so that a normal PSA can give false reassurance that cancer is not present. Because a PSA is abnormal in 10 percent of people who don't have prostate cancer, only one-third of men with an abnormal PSA have prostate cancer.

BENEFITS

Cure of prostate cancer: Screening will have benefits only if it reduces the death rate from prostate cancer by identifying men who can benefit from an effective treatment. But we do not know the effectiveness of treating clinically localized prostate cancer in reducing the mortality rate from prostate cancer. The ideal way to find out is to randomly allocate selected prostate cancer patients to treatment or watchful waiting and measure the death rate from prostate cancer. Randomized clinical trials of screening have been completed for breast cancer, colon cancer, and lung cancer but not for prostate cancer treatment. Several studies are now underway in this country and in Europe. Recently, the American Urological Association Prostate Cancer Clinical Guidelines Panel (December 1995) reviewed all of the evidence and stated their findings as follows: "The panel found the outcomes data inadequate for valid comparisons of treatments." In other words, specialists in prostate cancer treatment agree that there is no proof that radical prostatectomy prolongs life from what it would be with no treatment.

We know that radical prostatectomy is not a perfect treatment because 28 percent of Medicare patients had undergone treatments for metastatic prostate cancer within 4 years of a radical prostatectomy, presumably because their cancers had recurred. Although many men are cured of a prostate cancer that would have caused them suffering and death, other men suffer the side effects of surgery for a slow-growing cancer that would not have caused either suffering or death. We don't know the balance between benefit and harm in prostate cancer surgery. We would have to tell a patient considering screening "if you have prostate cancer, I won't be able to tell you whether treatment is better than watchful waiting."

The role of patient counseling: The ethical principle of informed consent requires that patients with clinically localized prostate cancer learn about these known harms and potential benefits. Many believe that the same principle applies to the decision to undergo screening. The recently released guidelines of the American College of Physicians stated, "Rather than screening all men for prostate cancer as a matter of routine, physicians should describe the potential benefits and known harms of screening, diagnosis, and treatment, listen to the patient's concerns, and then individualize the decision to screen." The underlying assumption is that the potential harms and benefits will differ from patient to patient, and therefore the balance of harms and benefits will also differ. Furthermore, patients are like to differ in how they value a benefit or harm and how they take account of the uncertainty about the benefits of radical treatment of prostate cancer.

Patients can understand complex information that may affect their health and use it to make decisions. In work done at Dartmouth, men at a veterans hospital were randomly assigned to learn about the benefits and harms of prostate cancer screening by watching a videotaped description or to a control group. Eighty percent of the patients who saw the videotape said that they would prefer no treatment if they had clinically localized prostate cancer. Only 40 percent of those who did not see the videotape said that they would prefer no treatment. This result shows that many patients have considerable ambivalence about prostate cancer treatment. Furthermore, learning more about the known harms and unknown benefits of treatment reduced the number who wanted treatment. This research argues strongly against a uniform policy of screening and strongly for informed, individualized decision making prior to screening.

What harm will a screening test do? Why not screen and then deal with the decision to accept treatment when the patient is fully informed about his own status?" In reply to these questions, I hold to the principle that one should not do something to a patient if it could not alter subsequent steps in evaluating him. Many fully informed patients will say, as many of my patients have, "I would not place myself at that much risk of incontinence or impotence unless I was more confident that I could benefit from surgery. There's no point in doing the PSA." The average man on the street believes that a PSA test is as innocuous as any other blood test. In fact, screening places the patient on a slippery slope, in which test results tend to propel the process of evaluation and treatment as physician and patient become caught up in the need to know. The patient should know about the nature of that slippery slope before venturing out on it.

A number of expert panels have considered the question of prostate cancer screening. The US Preventive Services Task Force, the American College of Physicians, and the Canadian Task Force on the Periodic Health Examination have exhaustively reviewed the evidence and made recommendations. The US and Canadian Task Forces recommended against routine screening. The governments of England, Sweden, Australia, and the Netherlands have reached the same conclusion. As noted earlier, the American College of Physicians also recommended against routine

screening but stated that patients need full information in order to make an individualized choice that takes into account their risks and preferences. The American Cancer Society recently changed its recommendation for routine annual screening starting at age 50 years. The current statement says that "screening should be offered starting at age 50" and that patient should be fully informed before deciding. The American Urological Association recommends routine screening starting at age 50 years.

This Congress has enacted legislation authorizing the Medicare program to cover prostate cancer screening. It is now up to the medical profession to use this enhanced coverage wisely, so that it benefits our patients. We will need all the help that we can get. The Health Care Financing Administration can help by framing their regulations for prostate cancer screening so that they acknowledge the uncertain balance of harms and benefits and strongly caution physicians to avoid routine screening. The Congress can help in several ways. Physicians enjoy talking with patients about difficult decisions, but the current health care environment does not reward the time required for counseling. We need to rethink the evaluation and management codes so that they encourage counseling about screening. We need support for research on what constitutes effective counseling and how it affects patients' decisions about prostate cancer screening. Finally, we should evaluate health care organizations on their success in informing patients about screening procedures, such as prostate cancer, in which the balance of harms and benefits is uncertain and may vary from patient to patient.

Senator SHELBY. This committee will have to be adjourned under Senate rules.

[Whereupon, at 11:37 a.m., the committee was adjourned.]

APPENDIX

QUESTIONS AND ANSWERS FROM MEMBERS

QUESTIONS FOR LEN DAWSON

Question. Had you ever considered having a PSA test on your own, without the encouragement of your wife?

Answer. No. At the time Linda made the appointment for me, I had never heard of a PSA test.

Question. It is my understanding that your brother Ron died in 1995 of prostate cancer. Please accept my condolences. How old was your brother at the time of his death and are you aware if he had ever been screened for prostate cancer, and if so by what means? Do you feel that if he had been screened for prostate cancer earlier that it might have saved his life?

Answer. Ron was 76 years old when he passed away. He had been diagnosed with prostate cancer about fifteen (15) years earlier via his annual check-up. At that time PSA tests either were not around or we simply didn't know about them. Well, after a couple of years of some type of treatment (we're not sure what) he was told that the prostate cancer was in remission. He remained cancer free for the next fourteen (14) years and again was diagnosed during his annual physical. While I'm not sure that a screening would have saved him, simply because he was so far along when it was discovered, I have no doubt that his chances for successful treatment would have increased if he had been diagnosed earlier. As our family members understand it, both of Ron's diagnoses were made by a digital rectal exam.

UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER,
DIVISION OF UROLOGY,
Denver, CO, October 27, 1997.

Senator CHARLES A. GRASSLEY,
*Chairman, U.S. Senate Special Committee on Aging,
Hart Building, Washington, DC.*

DEAR SENATOR GRASSLEY: In response to the Committee's questions for me, the following is provided:

1. Why are detection statistics so low for physicians performing the digital rectal exam in screening for prostate cancer?

Most patients with prostate cancer will eventually have an abnormal digital rectal examination. The challenge of relying on digital rectal examination alone is that in many cases when the exam is abnormal, the prostate cancer has already locally advanced or spread. PSA has offered the opportunity to detect cancers before they are palpable by the rectal exam. However, approximately 20 percent of cancers do not produce enough PSA to escalate the level to abnormal. Therefore, digital rectal exam is still an integral part of early detection efforts.

2. In your testimony, you state that "the combination of an abnormal PSA blood test and abnormal digital rectal exam had a 50 percent predictive value for the presence of prostate cancer." If we know so much, why are the numbers so minimal?

In actuality, a 50 percent positive predictive value is very good for screening tests. An abnormal mammogram, which we accept as a good way to detect breast cancer, has only a 20 percent positive predictive value. Nevertheless, we are striving to improve the accuracy of our testing. The recent discovery of the various forms of PSA have further improved the accuracy of the tests.

3. I am fascinated by the research that suggests a relationship between diet and prostate cancer. Could you talk about this in a bit more detail?

There appears to be a relationship between diet and prostate cancer. Men living in Far Eastern countries such as Japan and China have a low incidence of prostate

cancer—yet when they move to the United States, their incidence of prostate cancer rapidly increases. Diet appears to be the main factor in this rise in incidence of the disease. Research is currently focused on whether it is the fat and high carbohydrate content of the American diet which leads to this increased risk, or the lack of protective factors such as soy products and other substances in the typical diet of Orientals. Recent research has established that soy products can actually inhibit the growth of prostate cancer.

4. What do you believe the impact in the growth of managed care will be to prostate cancer screening?

We have already begun to experience the impact of managed care on prostate cancer screening. In the attempt to control healthcare dollars, screening programs are trimmed. However, I believe that when the definitive evidence exists to support the value of early detection, the impact will be minimal.

With personal greetings, I am

Sincerely yours,

E. DAVID CRAWFORD, M.D.
*Professor of Surgery,
 Division of Urology.*

RESPONSES FROM WALTER REED ARMY MEDICAL CENTER

(1) How prevalent is training to surgeons in the prostate treatment arena? Could you tell us how surgeons are trained in the new and developing treatment options available?

All urologic surgeons are exposed to, and trained in, the diagnosis and treatment of all diseases of the prostate. As far as prostate cancer is concerned radical prostatectomy is in the armamentarium of most urologists. Certainly during residency and fellowships in this area the procedures are well taught. Only a few training programs have cryotherapy (freezing of a cancerous prostate), but the efficacy of this procedure is debatable. In the area of brachytherapy (placement of radioactive seed within a cancerous prostate), only a few training programs have urologists as co-managers of this therapy. Certainly, a close relationship is essential among urologists, radiologists, and medical oncologists, if our patients are to receive optimal benefit from their treatment.

On another note, the decrease in reimbursement rates for certain complicated procedures may well lead to many physicians doing less of these procedures with concomitant decrease in their operative skills. There must be a serious re-examination of reimbursement for surgical procedures.

(2) You mentioned some "government imposed" barriers to treatment advances for prostate cancer, what are other barriers that you could identify at this time?

There are several barriers to treatment advances that are under the government's control, as I noted in my testimony. These is a lack of Medicare coverage for some medications, e.g., anti-androgens which are increasingly used in neo-adjuvant therapy, a delay in implementing Medicare coverage for PSA tests, and a lack of adequate spending on prostate cancer research.

Another significant barrier, I believe, is the confusion about diagnosis and treatment of prostate cancer. Granted that PSA screening/detection has not been subjected to clinical trials, and medical groups that seek to discourage men from screening/detection or treatment are well-intentioned; however, these groups are causing some men who might benefit from subsequent treatment to refrain from being tested. This approach seems to me to be trying to turn the clock back on the progress we have made in PSA detection. It would be appropriate, I believe, for us to continue to refine the precision of our diagnostic techniques. Rather than discourage men from finding out if they have prostate cancer, we should be expending this energy on responding to those who are detected with the disease, improving our capacity to predict the course of the disease, and educating patients on their treatment options.

In addition, private insurance coverage needs to become as complete as we would like Medicare coverage to become. New disease management approaches that can improve patient care for prostate cancer in managed care plans can benefit patients only if full range of treatment options are available under the plan. This combinations of more comprehensive coverage with improved management of treatment, and greater adaptability of treatment to the needs of patients, can go a long way to resolve the concerns of some of the late witnesses at this hearing about the potential for inappropriate patients care. As Medicare shifts from being a payer for care to a purchaser of managed care plans, the quality of care for Medicare patients will

rest increasingly on the breadth of coverage and the sophistication of management tools employed by the managed care plans.

On another issue, I suppose the restrictions imposed by the FDA relating to new products, etc. are somewhat of a barrier, but those barriers are placed as appropriate safety measures. Reimbursement by the government for procedures tend to be a barrier. Because each individual Medicare area handles some of these situations differently, it would be more appropriate if a uniform federal policy were established by HCFA, as far as Medicare payments are concerned. This certainly would be to the advantage of most physicians and could help avoid the many controversies that arise when decisions are made by an inexperienced administrator in a local area.

Last, increased research funding is imperative. Prostate cancer in many instances is a slow and insidious disease, however, it is going to affect more and more men, especially since life expectancy is increasing. Also, it will take years to realize effects of diagnosis and treatment regimens. In addition, research into dietary regimens and preventive measures must be funded. Many private companies cannot afford to spend scarce research funding in those two areas. In summation there needs to be more funding for prostate cancer work.

DEPARTMENT OF VETERANS AFFAIRS,
Washington, DC,
October 30, 1997.

Hon. CHARLES E., GRASSLEY,
Chairman, Special Committee on Aging,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Enclosed are the Department's responses to post-hearing questions posed in connection with the September 23, 1997, hearing on prostate cancer.

We appreciate the opportunity to submit this information for the record.

Sincerely yours,

HERSEL W. GOBER,
Acting Secretary.

Enclosure.

HEARING ON PROSTATE CANCER

Question 1: Once the physician has explained the value of the DRE and PSA tests and the potential benefits and risks of screening, what percentage of those patients then choose to undergo the tests?

Answer: We do not have information regarding what percentage of VA patients choose to be screened for prostate cancer subsequent to physician counseling. Current data systems cannot capture information to that degree of specificity. However, there is some evidence available from the medical literature, and VA patients should likely behave in a similar fashion.

Chadwick et al. (Lancet 1991; 338:613-616) invited 814 men to participate in a community prostate cancer screening program of rectal examination, prostate-specific antigen (PSA), and ultrasonography testing. Nearly one-fifth of the patients chose not to attend, and an additional 24 percent attended but were not screened (presumably on the basis of patient preference rather than physician choice). Thus, in an environment wherein specific patient counseling was not employed, between 40 and 45 percent of patients did not complete the recommended course of screening, and even in those cases wherein PSA levels were abnormal, about 10 percent chose not to complete the diagnostic workup.

The Patient Outcome Research Team (PORT) on Prostate Disease, commissioned by the Agency for Health Care Policy and Research, has reviewed the issue of patients' decisions in the context of prostate cancer. They have developed a Shared Decision-making Program to explain the nature of the PSA test and what is known of treatment outcomes for prostate cancer. Subsequently, the PORT produced an informational patient videotape addressing those issues, and studied its use in patient decision-making (Flood et al, J Gen Intern Med 1996; 11:342-9). They found that patients' knowledge of the natural history of prostate cancer, efficacy of current treatment, and predictive value of PSA testing was quite poor, and that viewing the tape significantly improved their understanding. Further, patient preference for testing was influenced by the information presented. Patients who viewed the videotapes were less inclined to have PSA screening and choose active treatment for cancer than a group viewing a "control" informational videotape prepared by a pharma-

ceutical company. For the subset of approximately 200 men selected from those attending a general medicine clinic, the patients' stated likelihood of selecting PSA screening decreased from 67 percent to 30 percent; actual requests for PSA testing decreased from 23 percent to 12 percent. Thus it appears that provision of objective evidence in an unbiased fashion results in both improved knowledge and a decrease of patient enthusiasm for screening and for some current active treatments.

Question 2: Will you identify some of the advantages and disadvantages of this patient-doctor consultation prior to their decision?

Answer: Advantages of counseling:

(a) The patient has the information provided by a knowledgeable clinician who is familiar with the patient's medical history, risk factors, etc., and the patient is thus not subject to a "one size fits all" approach.

(b) In a formalized "one-on-one" environment, the provider has an ethical obligation to provide care that is in the patient's own best interest and not in the interest of the physician or an organizational system of care.

(c) Information is provided in a context that encourages the patient to ask questions that address his own particular concerns, given the observation that patients often view risks and benefits differently from one another, and very differently from clinicians.

(d) This provides the best circumstances for patient involvement and shared decision-making, an approach which comports with current ethical and legal views of the patient-physician relationship.

Disadvantages:

(a) Not all clinicians are likely to be equally well informed.

(b) Not all clinicians have equal opportunity and/or willingness to take the time that such discussion may require.

(c) Some clinicians have strong beliefs in their preferred approach, and may not provide an objective and unbiased presentation of all the facts.

DARTMOUTH-HITCHCOCK MEDICAL CENTER,
Lebanon, NH, October 30, 1997.

Hon. CHARLES E. GRASSLEY,
Chairman, Special Committee on Aging,
U.S. Senate, Washington, DC.

DEAR SENATOR GRASSLEY, I am replying to the questions that you posed in your letter of October 10, 1997 in follow-up to the Senate hearing on prostate cancer screening.

Question. Regarding your concerns about the lack of evidence that screening alters the death rate, aren't we better off erring on the side of caution and supporting screening? What reasons would you offer why we shouldn't?

Answer. This question uncovers a basic dichotomy in the medical profession. Some physicians feel that the best way to serve the patient's interests is to do something that is unproved until there is proof that it is harmful. Others feel that the "cautious" approach is to wait until there is proof of effectiveness. When the evidence is weak, as in the case of prostate cancer screening, reasonable people can disagree strongly because they differ in their fundamental philosophy.

The decision to undergo screening involves deciding if the potential benefits of screening outweigh its potential harms. If screening and the subsequent diagnosis and treatment of suspected prostate cancer did not lead to harm, it would be reasonable to "bet" that current studies of screening and treatment will show a reduction in the death rate from prostate cancer. Unfortunately, we already know that treatment can cause major problems. In one study of Medicare patients who underwent radical prostatectomy, 30 percent had to use some sort of device (catheter, pad, or diaper) to deal with incontinence of urine. Only 10 percent of the patients had erections that were firm enough for sexual intercourse. So, the studies of screening and treatment must show that screening has substantial benefits in order to outweigh the known harms.

Of course, some patients won't see the potential harms in the same light. A man is who no longer sexually active will see the threat of sexual dysfunction differently than a man who is sexually active. Therefore, I and others advocate a process in which the physician takes the time to inform the patient about the known harms and potential benefits of screening, diagnosis, and treatment and helps the patient to come to an informed decision that takes into account his feelings about the potential harms.

The organizations that I represent, the American College of Physicians and the U.S. Preventive Services Task Force, recommend against routine screening and

favor an individualized approach. The American Cancer Society has moderated its position, which used to favor routine annual screening, so that it now recommends "offering" screening together with informing the patient of the potential benefits and harms. So, there is considerable doubt about the wisdom of recommending routine screening, as distinct from individualizing the decision so that it reflects the patient's feelings and concerns.

Question. I understand your position is based on a lack of scientific evidence. Could you comment on what is going on now that will give us the evidence that we need?

Answer. I am not the best person to answer this question. I know that there are some randomized clinical trials of screening and some trials of radical treatment, but I don't know any details. I believe that Dr. Holohan would have addressed this question in his testimony. Dr. John Feussner, Assistant Secretary for Medical Research in the Department of Veterans Affairs, knows exactly what studies are underway and what they are designed to measure.

Very truly yours,

HAROLD C. SOX, M.D., FACP,
*Professor of Medicine and Chair of the Department,
Dartmouth Medical School.*

PREPARED STATEMENT OF THE AMERICAN UROLOGICAL ASSOCIATION

The American Urological Association (AUA) appreciates the opportunity to submit this statement regarding early detection and treatment of prostate cancer on behalf of the 9,200 urologists that we represent and the patients they see.

The American Cancer Society estimates that this year approximately 210,000 new prostate cancers will be diagnosed and almost 42,000 men will succumb to prostate cancer. This disease is currently the most common malignancy in men in the United States and, in its terminal phases, causes severe pain and suffering due to metastasis and the eventual involvement of other major organs. Prostate cancer is a major killer of adult men and is increasing in frequency.

Developing effective modes of early detection and proper treatment are crucial to saving thousands of men from the agony prostate cancer can inflict. The AUA believes Congress should take the following steps to best combat this deadly and elusive disease.

1. Support for NIH. There have been many advances in the early detection, treatment and cure of prostate cancer. Support for these advances has mainly come from the National Institutes of Health (NIH). Without support from NIH, this disease's impact would be even more devastating. Therefore, the AUA requests that Congress increase funding for prostate cancer research, especially at the National Cancer Institute (NCI) and National Institutes of Diabetes, Digestive and Kidney Diseases (NIDDK). The AUA requests support be given to NCI so the Institute can commit at least \$100 million for prostate cancer research in fiscal year 1998. The full array of NCI programs must be supported, including centers of excellence, clinical trials, individual research grants, and research training. The AUA recommends that research for prostate cancer be brought into equilibrium with breast cancer research as soon as possible. According to AUA estimates, in 1997 the NCI spent \$221 for each diagnosed case of prostate cancer, \$1,833 for each new breast cancer case and \$3,282 for each new AIDS diagnosis.

Also, a key part of the effort to combat prostate cancer is to increase our understanding of the basic science of the prostate which is one of the vital functions of the NIDDK. The NIDDK plays a significant leadership role in funding basic and clinical research on all prostate diseases. We recommend that prostate research in the urology program at NIDDK be granted an additional \$20 million. These new funds would strengthen work to evaluate factors that affect the regulation of prostate growth.

2. Medicare coverage for prostate cancer early detection. The AUA applauds Congress for legislating Medicare coverage of PSA testing and other early detection of prostate cancer tools through the Balanced Budget Act of 1997. Starting January 1, 2000, Medicare will pay for annual PSA blood tests and digital rectal exams for Medicare beneficiaries aged 50 and older. Though this law is beneficial and will save many lives through early detection, the AUA requests that this legislation go into effect as soon as January 1, 1998. By moving up the effective date of this law, even more lives can be saved as men who currently show no symptoms of prostate cancer now can be diagnosed using PSA and treated at an early stage of the disease.

The AUA urges careful consideration of these recommendations and is available to answer any questions the Special Committee may have.

PREPARED STATEMENT OF BETTY I. GALLO

I am Betty Gallo, wife of the late Congressman Dean A. Gallo (11th District) of New Jersey.

My husband, Dean, died of prostate cancer on November 6, 1994. Dean was diagnosed with advanced stage prostate cancer in February, 1992. At that time his PSA (prostate specific antigen) blood test was 883, his cancer had spread into his bones and he had a life expectancy of 3-6 months. Through the use of combined hormonal therapy and participation in clinical trials through the National Cancer Institute, he survived a miraculous 2½ years with a good quality of life until his last six months.

Dean had always had annual physicals. During his physical in March of 1991, the physician performed a DRE (digital rectal examination). The PSA test was not being used as a normal diagnostic tool for the early detection of prostate cancer at that time. In August, 1991, Dean began complaining of back and shoulder pains. He felt that these problems were because of his height, because he was walking a great deal, and because he was getting older. I kept encouraging him to see a doctor, but he ignored my suggestions.

Finally, the pain became so intense that Dean made an appointment with his chiropractor. With no relief from the pain, he then visited his orthopedist, Dr. David Feldman. Cortisone injections provided little relief. Dr. Feldman then ordered a bone scan. The prostate cancer throughout Dean's body made the bone scan light up like a Christmas tree.

From that time on, Dean and I waged a battle with prostate cancer and PSA numbers. We lived by the results of the PSA levels. Sometimes it went up . . . sometimes it went down . . . Our moods were reflected by the PSA tests results.

I can only say that the one positive result of this disease was that it brought us closer together than we could ever have imagined. Our love was indestructible. We fought the battle of prostate cancer together. We vowed that when the battle was won we would advocate for early detection and increased awareness and research funding for prostate cancer.

Although Dean is no longer with us, I am keeping our vow. I admired and respected Dean and the way he endured the cancer, following his doctor's orders "to a tee", and maintaining his work schedule in Congress until the pain rendered him unable to continue. In fact, the majority of his colleagues did not know of his disease until he was about to retire. Dean Gallo will always be the person I will try to emulate because of the noble way he fought the prostate cancer.

It is my belief that if the PSA blood test had been used along with the DRE during Dean's annual physicals, he would be here with us today. The medical expenses for Dean in the 2½ years were close to \$1 million. A tremendous amount of money could be saved if prostate cancer is detected and treated in its earliest and most curable stages. Men would have longer lives and they and their families would not have to endure the emotional pain of the disease. I cannot impress upon this Committee the importance of early detection with regard to the survival rate, cost factor and quality of life for prostate cancer patients and their families. Prostate cancer not only affects the man, but his family, and future generations.

The Committee must ensure that cancer patients have reimbursements for all approved cancer therapies. Dean was fortunate enough to have his medical expenses fully covered by insurance. The fear of how to pay for approved cancer therapies should not be a part of the struggle that families are confronted with in their battles with life threatening diseases such as cancer.

I thank the Committee for allowing me to present this testimony.

