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WINNING THE WAR ON CANCER AND MEDICARE: PHYSICIAN PRACTICE EXPENSES

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

SPECIAL HEARINGS

MAY 7, 1997—WASHINGTON, DC
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WINNING THE WAR ON CANCER: PROGRESS AND PROGNOSIS

WEDNESDAY, MAY 7, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:20 a.m., in room SH–216, Hart Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Cochran, Faircloth, Harkin, and Reid.

NONDEPARTMENTAL WITNESSES

PANEL 1—SENATE CANCER COALITION

STATEMENTS OF:

SENATOR CONNIE MACK, COCHAIR

SENATOR DIANNE FEINSTEIN, COCHAIR

OPENING STATEMENT OF SENATOR SPECTER

Senator SPECTER. This room, Senate Hart 216, is the major hearing room in the U.S. Senate, and there are many hearings of significance in this room, but I believe today we have a special hearing as we commemorate the 25th anniversary of the National Cancer Act and talk about where we have been, what we have accomplished, but more importantly, perhaps, what remains to be done.

The President and the Congress came to agreement on Friday on the general outline of a budget, and I believe that is a great step forward for America, so that the people of this country can see that at least sometimes there is agreement in Washington, DC.

We have a budget of $1,700 billion, and I am personally convinced that we have the funding to do what is necessary on medical research with the National Institutes of Health and the focus on cancer with particularity, and it is a matter of applying those resources.

Early this year, a group of us joined together—Senator Mack was a principal sponsor, Senator Feinstein, I, others—in setting a target of doubling NIH funding over the next 5 years. That is a very, very ambitious target, but it is one that I think we can meet.

Senator Harkin, who cochairs this subcommittee and I, set our mark on a 7½-percent increase for National Institutes of Health this year, which is another high mark, $952 million.

We have had increases in NIH funding consistently during my tenure here. Lots of cuts in the budget, but the National Institutes of Health has been funded with increases whether the chairman was Senator Weicker or Senator Lawton Chiles or Senator Tom Harkin, or, since I have become the chairman we have made those increases year by year, and we have a very, very strong case because of the advances which have been made by the NIH in so many diseases.

Cancer strikes 1.2 million Americans a year. In 1971 the words, "you have cancer," was tantamount to a death sentence. Well, it is still a very significant pronouncement to hear. Testicular cancer death rates have dropped some 66 percent since the early seventies. Hodgkin's Disease death rates have dropped 57 percent. Survival for bone cancer grew from 20 percent to 60 percent, and the death rate for childhood leukemia is down 52 percent.

While we have those statistical improvements, there is a great deal to be concerned about today. Cancer is the second leading cause of death in the United States, accounting for 24 percent of the total deaths. There were 1,252,000 new cancer cases in 1995, the last statistical year available, 547,000 deaths in that year. More than 7 million people have cancer in the United States, and cancer has the highest rate among African-American men.

I personally have been the beneficiary of the advances in technology. I had some mild symptoms, found out I had meningioma. The initial diagnosis was much tougher, so I know what it is like to hear the alleged death sentence, and it all worked out fine. When I had an MRI, I did not know until I had my own MRI that we have only had the MRI since 1984, and we really can do much, much more if we establish our priorities.

PREPARED STATEMENT

We have a very distinguished list of witnesses today. These are the impediments to testimony in this room. There is no unlimited right to speak, as there is on the Senate floor, and the green light goes on for 5 minutes, and we would appreciate if our witnesses can complete their testimony within that limit, but if you go over that is all right, especially for my senatorial colleagues, but today all the witnesses are Senators.

At this time I will put my formal statement into the record without objection.

[The statement follows:]

PREPARED STATEMENT OF SENATOR SPECTER

Just over 25 years ago the Congress and the President enacted the National Cancer Act. This legislation catalyzed an unprecedented effort in science and technology to overcome a disease that strikes 1.2 million Americans each year. In 1971, the words: "you have cancer" was tantamount to a death sentence. Today, because of the national cancer program, that is becoming less so. Since the early seventies:

—Testicular cancer death rates have dropped 66 percent;
—Hodgkin's disease death rates have dropped 57 percent;
—Five year survival rates for bone cancer have improved from 20 percent to 60 percent; and
—The death rate for childhood leukemia is down 52 percent.

I can personally attest to the miracles of modern medicine and the return on our investment in research. Three years ago, an MRI detected a benign tumor at the outer edge of my brain. The tumor was removed by conventional surgery with five

days of hospitalization and five more weeks of recuperation. Last June, a follow-up MRI detected a small amount of tissue remaining from the previous tumor . On October 11 of last year, it was treated with high-powered, focused radiation from the "gamma knife." I entered the University of Pittsburgh medical center in the morning, and left that same afternoon, ready to resume my regular schedule. Like the MRI, the gamma knife is a recent invention, coming into widespread use.

What we have accomplished as a nation in battling cancer in the past 25 years has been a lasting legacy for all people. The advent of genetic therapy, new diagnostic techniques like MRI and CT scans, and high-tech surgical techniques are just some of the new weapons in our collective arsenal against cancer. But we still have many more steps, both big and small, to accomplish the objective of striking down the death sentence of cancer.

This subcommittee has the primary responsibility for funding the war on cancer. Over the past 25 years, we have appropriated $31.5 billion to the National Cancer Institute. Like the Chairmen who served before me, including Senator Harkin, I hold this responsibility with highest regard.

On January 21, I joined with my colleague, Senator Mack, in introducing Senate Resolution 15 which aims for a doubling of NIH funding over the next 5 years. While committed to this goal, I recognize its ambitious nature and am working with my colleagues on alternative methods of financing in order to reach this objective. Toward this end, on March 13, Senator Harkin and I introduced S. 441, a bill to establish a National Fund For Health Research. Monies from the Fund would provide the NIH with up to $6 billion more annually through a small assessment on health insurance premiums. We have gotten a good response to this proposal and I am optimistic that we can make progress.

In the meantime, I have expressed publicly a commitment to a 7.5-percent increase for NIH, or $952 million, and I will be looking closely at the budget agreement to ensure that it is sufficient for this subcommittee to support our top priorities, not only in medical research, but in education as well.

We have assembled here today three panels representing leaders from the public and private sector, physicians, scientists, and cancer patients who wish to bear witness to the progress and to the opportunities that remain to be pursued. It is an impressive array of witnesses with heartfelt interests, not only for themselves, but for all people. I look forward to hearing your testimony.

SUMMARY STATEMENT OF SENATOR MACK

Senator SPECTER. We are here today to hear first from the distinguished cochairs of the Senate cancer coalition. I guess we are proceeding with—I do not know why this has listed Senator Connie Mack first, but Senator, the floor is yours.

Senator MACK. Thank you, Senator Specter, for convening this hearing today.

I want to express my appreciation to Senator Reid and Senator Faircloth for being here as well. This is an important day for many of us, because it does focus the attention of the country once again on the disease of cancer.

I want to, Senator Specter, express my deep appreciation to you and to Senator Harkin. Regardless of whether you were chairman or ranking member or vice versa, the two of you have made a commitment to the National Institutes of Health which has been second to none.

I had the opportunity the other day to speak with some folks in the pharmaceutical field, and the comment was made that knowledge drives investment, that as we expand the base of knowledge, ideas are developed to the point that investors see opportunities to move into new pharmaceuticals, the potential for a cure, so it is the development of knowledge that is so vital, and it is the investment that we make as a country in the National Institutes of Health through basic research that develops this expanding base of knowl-

edge which drives investment which will eventually lead us to a cure.

We are today in a sense celebrating what has been accomplished over the last 25 years, and a great deal has been accomplished. Senator Specter made the comment a moment ago about his experience with cancer and the impact of technology which became available in 1984. There are literally hundreds, if not thousands of examples of what has been developed over the last 25 years from the standpoint of technology.

I come to this hearing this morning, though, wanting to emphasize the personal side of this. Sometimes I guess I have in working with Dianne Feinstein, Senator Feinstein over these last several years with the cancer coalition we have had an opportunity, I think, Dianne, to really make more and more of our fellow citizens aware of the disease.

We have played our part, if you will, in making America more knowledgeable about the disease. We know that if people are made aware of the signs of the early stages of cancer that truly lives can be saved. That information has been developed as a result of our commitment this last 25 years through the efforts of the Congress and NIH.

I would just say to everyone that we should focus today on the future and the lives that can be saved. My own personal experience is one that began in the early 1960's, when my younger brother, Michael, was diagnosed with melanoma, and Arlen, when you mentioned hearing those words that somebody had been diagnosed with cancer, clearly in those days it was a foregone conclusion in everyone's mind that Michael would die, and truly he was diagnosed in his early twenties, told he had 6 months to live. He was a fighter, and he lived for 12 years, and the impact he had on people's lives those 12 years cannot be measured.

When I ran for the Congress in 1982 I dedicated my political career to my brother, to Michael. I think in 1982, when I expressed those words, I really had no idea as to how to go about playing a role in the fight against cancer. I now know that in fact, at least in my mind, it is possible to find a cure for cancer, and that we could eradicate cancer.

Think about what has been going through people's minds years ago when the pursuit of ridding the world of polio. I am sure there were plenty who said it could never be done, but look at the impact on the world and on our country and on our society today because of the fact that polio has been eradicated.

Norman Schwarzkopf in this room, at a hearing that was held by Senator Hatfield and Senator Cohen—as a matter of fact, their last hearing—Senator, or, excuse me, Norman Schwarzkopf was here and he was testifying on behalf of those who have been engaged in this fight against cancer, and he is a prostate cancer survivor. He said the American people would not stand for military operation which, like the battle against cancer, has taken 25 years and claimed 10 million lives.

He in essence went on to say that one day when the American people fully understand what we are capable of doing they are going to be mad as hell that we have not acted faster, that we have not provided more resources to fight this disease.

Travis Roy was at that hearing as well. Travis Roy was a starter for the Boston University hockey team and while this is not cancer, it, I think, goes to indicate that—someone said to me earlier this morning, we are not here solely for investments in the National Institutes of Health for cancer only. We want to see the investment in the National Institutes of Health doubled because we believe that this investment in basic research can have an effect in all kinds of diseases.

This individual suffered a spinal cord injury which paralyzed him from the neck down. His comment to us that day was his hope was that one day I simply want to be able to hug my mother, and if he had made that statement 25 years ago, most of us would have concluded that there was no way that that could possibly happen.

I think what has changed now, why this fight is different, is because most of us honestly believe that we have developed to the point that we can develop technology in the future that in fact can cure so many of these diseases that are affecting our loved ones.

PREPARED STATEMENT

So again I thank the chairman for allowing me to go on beyond the assigned time and I commend you and compliment you for the work you are doing, and indicate to you that Senator Feinstein and I and others will work with you to make sure that over this 5 years that we double the investments of NIH.

Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Mack.

[The statement follows:]

PREPARED STATEMENT OF SENATOR CONNIE MACK

Mr. Chairman, thank you for the opportunity to testify at this important hearing.

This year marks the 25th Anniversary of the National Cancer Act. With the signing of this historic legislation by President Richard Nixon, America officially declared a "war on cancer."

I believe the most significant benefits of the National Cancer Act can be summed up in these words—hope and opportunity.

Twenty-five years ago, when patients were told they had cancer, they were also told there was not much hope for survival.

Today, thanks to the scientists at the National Institutes of Health and in academic research centers throughout our nation, patients have a realistic hope of beating cancer. Overall cancer death rates have fallen. New technologies for the detection and diagnosis of cancer are being developed at a rapid pace. The Human Genome Project is progressing ahead of schedule, and it is leading biomedical research in to a revolutionary era. Cancer patients have immediate access to information about new methods of treatment, including clinical trials. America has led the world in the development of more targeted, and less toxic, ways to treat cancer.

And so today, as we commemorate the 25th anniversary of the passage of the National Cancer Act, there is indeed great cause to celebrate the scientific advancements which now bring hope to patients throughout the world who are diagnosed with cancer.

Now, it is up to Congress and the Administration, along with our friends in the patient community, to take advantage of the opportunity to build upon this foundation and conquer this horrible disease.

Our scientific base of knowledge is such that now is the time for a bold, new commitment to finding the cure for cancer and other diseases. We now have the opportunity to make scientific breakthroughs which, only a decade ago, would have seemed impossible. Scientists have identified key research areas where they are poised to make significant advances including the biology of brain disorders; new preventive strategies against disease; the development of new therapeutics such as genetic medicine; new approaches to our understanding of cell and protein structure through 3-D modeling, and state-of-the-art instrumentation and computers.

The question is whether the Congress will provide the necessary resources to take advantage of these and other scientific opportunities.

I have introduced a Senate resolution to double funding for the National Institutes of Health over the next five years. I realize how difficult this will be to achieve. It will mean tough choices. Spending on some government programs will undoubtedly have to be reduced.

But I am convinced that Americans are willing to make this commitment, and they are looking to Congress for the leadership necessary to achieve this ambitious goal.

What could it mean to average Americans if we doubled our commitment to biomedical research?

I think back to a hearing of the Senate Committees on Appropriations and Aging which took place last year. One of the witnesses who testified was a brave young man from Maine named Travis Roy. All his life, Travis dreamed of being a professional hockey player. He had the God-given talent and the strong desire to achieve his goal. He qualified as a starter for the Boston University hockey team. Eleven seconds into his first game, he suffered an injury which left him paralyzed from the neck down.

Travis Roy knows his dream of being a professional hockey player is probably gone. Now, he has a new goal. As he told those of us who were there, "One day, I simply want to be able to hug my mother."

A decade ago, doctors could not offer Travis much hope. Today, given the outstanding progress that has been made in spinal cord rejuvenation research, doctors are able give him a realistic sense that he can, one day, achieve this new goal.

The challenge before us is great. But America has always responded when our people are behind the challenge. America landed a man on the moon. We pioneered computer technology. America won the cold war. Now, it is time for America to win the war on cancer and other diseases.

We have the knowledge. We have the technology. We have the support of the American people.

Now is the time for leadership. Now is the time for action.

SUMMARY STATEMENT OF SENATOR FEINSTEIN

Senator SPECTER. We now turn to the distinguished Senator from California, Senator Feinstein.

Senator FEINSTEIN. Thank you, Mr. Chairman, Senator Faircloth, Senator Reid. I am very pleased to be here. It has been a great pleasure for me to work with Connie Mack. We have held four hearings in the cancer coalition. I think they have been useful.

We have done some work on genetics to prevent any insurance company from discriminating against anyone in their policy on the basis of genetics. That is now part of legislation that Congress passed, the law of the land.

We held hearings on environmental risk factors, breast cancer, and tamoxifen.

I think, Mr. Chairman, the good news is the American Cancer Society's finding that shows that for the first time since 1900 the death rates of cancer are on the decline. That is good news. There is a lot of bad news. Part of it is that cancer kills half-a-million Americans a year, that it will overtake heart disease by the year 2000.

Lung cancer remains the No. 1 killer of women and breast cancer the No. 2 killer, now impacting more and more younger women.

Since the signing of the National Cancer Act in 1971 we have spent $25 billion on cancer research and yet we still do not have a cure or, in so many cases, a cause.

In 1996 the National Cancer Institute could fund only 26 percent of its grant applications. That is down from 32 percent in 1992 so they were actually able to fund fewer grant requests.

Only 3 cents of every health care dollar is used in this country for medical research, and NIH's budget is less than 1 percent of the Federal budget, and yet we find in independent polls that 75 percent of the American people would pay more if their dollars were used for research.

A recent poll this year in California found that 59 percent—this is a proposition 13 State—59 percent of the people polled support more taxes if those dollars go for this kind of research.

I want to just speak about three efforts that are going to take place. Senator Mack and I have joined together in a bill that will create a tax checkoff for cancer research. Studies show that 60 percent of Americans would contribute to medical research in this way. If the average contribution were just $10, $410 million could be raised through a tax checkoff. If the average contribution, which has been average in other areas, were $23, $1.1 billion for research could be raised in this way.

I know both Senator Mack and I cordially invite the three Senators on the dias to become cosponsors of this legislation. We believe its time has come.

This week, I will also introduce a bill to create some consistent coverage of screening mammography for women over the age of 40 in commercial insurance, in Medicare and Medicaid, consistent with the guidelines of the American Cancer Society and the National Cancer Institute. Lack of insurance coverage is a major obstacle in getting regular mammography screening for women.

The third piece of legislation that I will introduce this week, and again I would urge people to join with me, is a breast cancer stamp. This initiative is supported by a host of cancer institutions, and I would like to ask that their names be incorporated in my written remarks, if I might.

Senator SPECTER. Without objection, they will be incorporated.

Senator FEINSTEIN. Essentially, what we are asking is that the U.S. Postal Service create, instead of a 32 cent stamp, an additional stamp, a 33 cent stamp, and that that 1 cent go for breast cancer research. Research has shown that this could produce anywhere from $60 million to $300 million a year. If just 10 percent of those who buy first-class stamps were to buy the breast cancer stamp, this would mean an additional $60 million a year.

So these three initiatives are going to be taking place this week, and I would very much hope that every Member would support them.

Also, Senator D'Amato has authored legislation, of which I am an original cosponsor, which would end the drive-through mastectomies and set into law the proviso that hospital stays should only be determined by the physician in consultation with the patient, not by insurance companies.

I was appalled to learn from a California constituent who had a mastectomy at 11:30 a.m., and was pushed out the door at 4:30 that afternoon, virtually unable to stand, not really understanding even where she was. This kind of medical care has got to end.

PREPARED STATEMENT

So I see my time is up. I really want to thank you. This is so important. I think it is the one thing that all Americans agree on.

They want to see their Federal Government doing more research to end life-taking disease, and I thank you very much, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Feinstein.

[The statement follows:]

PREPARED STATEMENT OF SENATOR DIANNE FEINSTEIN

Thank you for giving me the opportunity to appear before you this morning. In looking at where we are as a nation in terms of health care, there is hardly a higher calling than the goal of eradicating one of humankind's most dreaded and most devastating diseases—cancer. As Co-Chair of the Senate Cancer Coalition along with my colleague Senator Mack, I have made cancer research one of my top priorities.

Even though earlier this year the American Cancer Society announced new data showing that for the first time since 1900, overall cancer death rates have shown a sustained decline, we all know that death rates for some cancers, like cancer of the pancreas and chronic leukemia in the elderly, are going up. We know that childhood cancer has risen 11 percent over the past decade.

Cancer kills half a million Americans per year. It will overtake heart disease as the leading cause of death of Americans by 2000. This year, 44,190 people will die from breast cancer, the second major cause of cancer death in women. Lung cancer rates continue to rise; lung cancer accounts for 29 percent of all cancer deaths. Virtually every family is touched by cancer at some time. Every person fears it. We cannot rest until we have found a cure for cancer. And I for one will not.

There are several issues I would like to highlight today.

REDOUBLE RESEARCH EFFORTS

This subcommittee has given important support to cancer research over the years and I know you agree that we must not let federal health research decline. Since the signing of the National Cancer Act in 1971, we have spent over $25 billion on cancer research, but we do not have a cure.

The facts tell us a sad story:

In 1996, the National Cancer Institute could only fund 26 percent of grant applications, a rate that has dropped from 32 percent in 1992. This low funding rates leaves a vast wealth of knowledge unobtained, many questions unanswered.

Only 3 cents of every health care dollar spent in this country is used for research. NIH's budget is less than 1 percent of the federal budget.

As managed health care insurance expands and plans choose not to affiliate with academic medical centers, our research institutions are rapidly losing revenues that have traditionally provided core support for research.

Biomedical science—and especially cancer research—is on the cutting edge of many important discoveries, a time when we should be nourishing our research base, not starving it, to maximize these explosions in scientific knowledge. For example, we have made revolutionary advances in understanding genetics in recent years that help us better understand why cells become cancerous.

A June 1995 national survey by Research America found that 75 percent of the public would pay more for medical research. 94 percent of Americans believe it is important for the United States to maintain its role as a world leader in medical research. A May 1996 poll found that 59 percent of Californians would pay more in taxes to support medical research.

The United States has always been the world's leader in developing sophisticated treatments for illnesses and diseases, in making breakthrough medical discoveries and in improving human life expectancy. We cannot backslide.

FEINSTEIN EFFORTS

I have taken a number of steps to address the scourge of cancer.

Tax checkoff.—This week, Senator Mack and I will introduce a bill to create a tax checkoff on tax returns so that citizens can contribute to a Cancer Research Trust Fund. Studies show that 60 percent of Americans would contribute to medical research in this way and that if the average contribution were just $10, $410 million could be raised.

Mammography Coverage.—This week, I will also introduce a bill to create some consistent insurance coverage of screening mammography for all women over age 40 in commercial insurance, Medicare and Medicaid, consistent with the guidelines of the American Cancer Society and the National Cancer Institute. Lack of insur-

ance coverage is a major obstacle to getting regular screening mammographies, studies show, and mammograms save lives.

Breast Cancer Stamp.—I will also introduce a bill requiring the U.S. Postal Service to create a new stamp, adding 1 cent to the price of a normal, first-class, 32-cent stamp, and directing USPS to transfer the funds to the NIH and the Defense Department for breast cancer research.

Senate Cancer Coalition.—Senator Mack and I have held several hearings on cancer including a hearing on genetic testing for cancer, one on the status of breast cancer research, one on the drug tamoxifen, and one on environmental risk factors for cancer. At the March 6 hearing on environmental risk factors, several witnesses presented compelling testimony about the geographic disparities in cancer rates and pressed the need for more research. They called for better coordination among the 14 federal offices that sponsor environmental health research.

Clinical Trials Database.—On January 21, along with Senator Snowe, I introduced S. 87, a bill to set up a toll-free service so that people with life-threatening diseases and the medical community can conveniently find out what research projects are underway. This database is needed so that people—often people in desperate, life-threatening situations, people who have tried everything—can easily find possible new treatments. Getting information on health research projects should not require a "fishing expedition" of futile calls, "good connections," computer sophistication or access to top-flight university medical schools to find out about research on treatments of disease.

Mastectomy, Reconstruction Coverage.—With Senator D'Amato, I have introduced S. 249, the Women's Health and Cancer Rights Act of 1997, to require insurance plans to cover medically-necessary hospital stays, the length of which would be determined by the physician, in consultation with the patient. The bill also requires plans to cover breast reconstruction after a mastectomy and for all cancers, to cover second opinions by specialists, whether the initial diagnosis is positive or negative.

Anti-Discrimination Now Law.—Last year, Senator Mack and I introduced the Genetic Fairness Act, and with others, we succeeded in including in the Health Insurance Portability Act, now law, a provision prohibiting insurers from denying insurance on the basis of genetic information.

I salute you for holding this hearing this morning. Hearing from this distinguished list of witnesses, who have been personally touched by cancer, can communicate to the public most graphically the need to make cancer research funding a top priority of this government. In this difficult budget climate, let us pledge to work together toward that end.

OPENING REMARKS OF SENATOR REID

Senator SPECTER. Senator Reid, do you have an opening statement?

Senator REID. Mr. Chairman, I have a number of things I would like to say. First of all, I would be happy to be joined as a sponsor of the resolution—your legislation, I am sorry, to have a tax check-off. I think that is excellent.

My only suggestion with your breast cancer stamp is, I think it should be on all stamps. I do not think it should be a choice. I think it should be a penny on every stamp. It should go to medical research generally, but that lacking, I will join you in having a special stamp, which I think is better than nothing, but not much.

Senator FEINSTEIN. Thank you.

Senator REID. Mr. Chairman, I think that I would first like to extend my appreciation to you for the panels that you have gotten together today. Like happens around here, we have a vote scheduled at 10 o'clock so we will not be able to join in all of these.

I appreciate the leadership of Senators Mack and Feinstein. I think it is commendable that you have done the things you have already done and I think, Senator Mack, I would say that as I was waiting to hear you testify I was thinking about how, as a young boy, I was frightened to death of polio.

I lived in a small rural community, was always worried about polio. There was a man in town that had a real—he was hunchbacked and grossly handicapped, and he had had polio as a young boy.

The same feelings that I had as a boy are now present with cancer. You know, prostate cancer, one out of every five men, people around the family and friends dying, getting sick with cancer, and I believe, as do you, that we can do better.

In testimony we will hear today—I have reviewed the testimony. The experts that will testify say we are very close with all of our gene research to finding some breakthroughs not only to finding better ways of treatment, maybe, to stop cancer. One part of the testimony today talks about a vaccine for some type of brain cancer that they think is going to work.

So I again commend you for your leadership. Senator Specter, thank you very much for convening this hearing, and I will close by saying that, Senator Feinstein, I think it is important that we do not talk about all the negative things, as you started off by indicating there is good news. There is good news with the work that is being done on cancer research, and even though there is a lot more to do, we have made significant progress.

Senator SPECTER. Thank you very much, Senator Reid.

OPENING REMARKS OF SENATOR LAUCH FAIRCLOTH

Senator SPECTER. Senator Faircloth, do you have an opening statement?

Senator FAIRCLOTH. Yes; I do have a very brief one, and again I want to thank you for having the hearing and the panel that you have put together here. It will certainly attract attention to something that we all feel very strongly about.

Much progress has been made, as we all know, since President Nixon signed the National Cancer Act 25 years ago. In the 1990's we have seen some very encouraging news in that the overall mortality rate for cancer for the first time has begun to drop since 1990.

But I am old enough to remember when cancer—as Senator Mack mentioned earlier that when his brother was 20 years old—that it was a death sentence. In the thirties and forties when someone had cancer and even into the fifties it was an automatic death sentence. There really was not anything they could do. They just tried to make people comfortable and watched them slowly die, and that was it. So we have done a lot, but we need to do a lot more to eradicate the disease.

But I am especially proud that so much of the research and finding a cure for cancer has taken place in North Carolina. Duke University especially has had a lead role and was named a comprehensive cancer center in 1973 by the National Cancer Institute.

Today, clinics at Duke have more than 100,000 cancer patient visitors each year. I am proud of what they have been able to do. I want to commend the panel for coming here this morning and meeting here to share their experience and knowledge.

It is a tremendous help when people such as Mr. Donaldson and Mr. Palmer come and show their support, and it encourages all Americans to use early detection and prevention and methods that

are available to us today. I think so many younger people tend to forget when these methods of detection were not available. You just simply went on until the cancer broke through somewhere and you were too far gone to do anything about it.

So I want to thank you, Senator Specter, and all of the panelists, for what they have done to bring this to the forefront of the American people. I thank you.

Senator SPECTER. Thank you very much.

Senator MACK. Mr. Chairman, if I could just make one comment with respect to what Senator Reid said a moment ago, he is absolutely right to focus us on the positive.

I am reminded that my wife, Priscilla, who is a breast cancer survivor, just about I guess 10 days ago, 2 weeks ago had a luncheon here in Washington. It was a luncheon of survivors. The message is that in fact you can beat the disease, that, for example, in certain types of breast cancer, if detected early, 94 percent curable.

So you are absolutely right, we need to keep people focused on the idea that if you catch the disease early you can whip it. So thank you for raising that point.

Senator SPECTER. Thank you, Senator Mack. We do have a vote at 10 o'clock. My suggestion would be that we limit our questions to one for the two panels here on the first round.

I am frequently asked a question, and was this morning earlier, what can be done in a practical sense to increase funding for cancer, increase funding for the National Institutes of Health, and I would be interested in a response from Senator Feinstein and Senator Mack, and the response that I give is to contact your Member of the House and your Member in the Senate and to get your peers to do the same thing.

It is much more effective if you are going to try to influence the Member from Congress in Wisconsin illustratively to have people from that district contact him. I still have 160,000 unanswered letters from one of the Supreme Court hearings from out of State. I answer all the ones from in-State, but get somebody in-State and in the district to do so.

When the 104th Congress came in in 1995 and we had a new attitude in the House, the funding for the National Institutes of Health was cut by more than $900 million, and when the matter came to the Senate on the budget resolution a characteristic for the majority to have the amendment offered, and there was a Hatfield-Specter-Kassebaum—Senator Hatfield as chairman of the Appropriations Committee, I as chairman of the subcommittee, and Senator Nancy Kassebaum, she chaired the authorizing committee, and we reinstated those funds.

One of the difficulties, and I think this has to be talked about and pressed, is the necessity for a center in the Senate and the House. We do not have Senator Hatfield any more, and we do not have Senator Kassebaum any more, and that puts a greater obligation on the part of the American people to tell their elected representatives where their priorities are.

We have enough money to do the job if we establish the priorities. Senator Feinstein, I would appreciate your thinking as to how we can raise enough money in the Federal budget. What action would you recommend?

Senator FEINSTEIN. The first thing I think of is, will money really help, will money really solve the problem, and my answer to that is a resounding yes, because I really believe that cancer is going to be solved, and we are going to find the cause, and we are going to find a cure, and that is solidly dependent on research, and I think what has been done in genetic research today, the research that is going on on environmental risk factors for cancer, are really vital.

The immunological studies that are going on that can produce changes in the immune system to ward off cancer cells I think is extraordinarily important, and if you think about it, Government is really where the great bulk of this money has to come from. I also believe that the kinds of individual initiatives, whether it is a breast cancer stamp, a tax checkoff, other things that we can think of to encourage the private contribution to this kind of major research is also critical.

But you are right, Senator, people have to rally and say, we want you to do this, so that there is that solid bulwark of support to increase the appropriations.

Senator SPECTER. Senator Mack, what is your best recommendation?

Senator MACK. I would build on your recommendation, and you are exactly right, we all know that with all of the different issues and problems facing our country, if we do not get focused on something it is very hard to move something here.

So I think what we have to decide, those of us who have been interested in this issue, is really what is kind of like our No. 1, No. 2, and No. 3, what are our top priorities, and I think that the No. 1 top priority, frankly, is the doubling of research over 5 years. That ought to become the mantra, if you will.

If we can communicate a clear message to those who are interested in this fight, then I think it is easier for them to deliver a clear message to their representative about what to support.

And of course I would say that I think the key thing to do is doubling the research in 5 years. That ought to be the message we deliver. That ought to be the message we encourage people back home to deliver to their representatives.

Senator SPECTER. Senator Reid.

Senator REID. I think that is commendable. If you look at the number of grants that now are able to be filled, it is I think 26 percent. It was 32 percent, or a number similar to that. If we double the funding maybe half the research grants requested would be able to be met, which would be a significant increase.

So other than that, Mr. Chairman, I have no further questions.

Senator SPECTER. Thank you, Senator Reid.

Senator REID. Senator Faircloth.

Senator FAIRCLOTH. I do not have any questions. Thank you, Mr. Chairman.

Senator SPECTER. Thank you very much, Senator Feinstein. Senator Mack, we will see you at the vote.

PANEL 2

STATEMENTS OF:

RICHARD KLAUSNER, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE

SHERRY LANSING, CHAIRMAN AND CEO, PARAMOUNT PICTURES CORP., INTRODUCED BY HELENE G. BROWN, DIRECTOR OF COMMUNITY APPLICATIONS OF RESEARCH, JONSSON COMPREHENSIVE CANCER CENTER AT UCLA

SAM DONALDSON, ABC NEWS

ELLEN SIGAL, CHAIRMAN, FRIENDS OF CANCER RESEARCH

INTRODUCTION OF PANEL

Senator SPECTER. I would like to call our second panel. Dr. Richard Klausner, Ms. Helene Brown, who will introduce Ms. Sherry Lansing, Mr. Sam Donaldson, and Ms. Ellen Sigal.

We are going to lead our testimony today with Dr. Richard Klausner, who is the Director of the National Cancer Institute. He took that job on August 1 of this year. Since 1984 he has been Chief of the Cell Biology and Metabolism Branch of the National Institute of Child Health and Human Development. Dr. Klausner was an undergraduate at Yale, medical degree at Duke University, well-known for his contributions to multiple aspects of cell and molecular biology.

Welcome, Dr. Klausner. The floor is yours.

SUMMARY STATEMENT OF DR. KLAUSNER

Dr. KLAUSNER. Good morning, Senator Specter. As you said, I am Richard Klausner. I am Director of the National Cancer Institute, actually since almost 2 years ago. I am pleased once again to have the honor of appearing before your subcommittee.

After 20 years of our war on cancer, we have as you have said some victories to report. Some cancers previously carrying a rapid and inevitable death sentence are now, incredibly, curable and, as we have heard, the overall mortality rate from cancer, the overall rate is falling, yet as we sit here this morning over 450 Americans will be newly diagnosed with cancer, and over 150 will die.

The progress we have made is a direct result of research which has begun to eliminate the causes of cancer, allowing effective prevention for some cancers, the development of vastly improved methods of early detection and diagnosis, and producing new therapies with increasingly real and measurable efficacy.

The good news is that we have tested the very premise of the war that this Nation has supported. That premise is that progress is predicated on research, and we have found that premise to hold true, but as the grim statistics and the stories of tens of millions of survivors, the stories of their families and friends, and the stories of those who have not survived tell us, we have a long way to go.

I believe, however, we are at a turning point in this war. It is hard to adequately describe the profound advances in the science of cancer research and in the revolutionary technologies that have given us the power to attach these diseases in ways we could not imagine just a few years ago.

All cancers, we now know, arise because of a slow accumulation of changes in a small number of the hundred thousand or so instructions that determine the behavior of each cell. There is no one cause of these changes, and there is no one cause of cancer. Chemicals like those found in tobacco smoke, viruses, radiation, sunlight, and the inevitable mistakes made each time one of the hundreds of trillions of cells in our body have to copy the DNA in which those instructions are written all contribute to cancer.

Identifying the causes is the key to prevention. Diet, exercise, hormones, and our genetic makeup in ways often still mysterious profoundly modify the risk of cancer. But cancer is not something that just happens. It does not happen at the moment one receives that awful diagnosis. It arises out of a long process that we are now beginning to unravel.

All cancer evolves from precancer, and we now can begin to design how to detect and how to treat not cancer, but precancer.

Let me give you an example. Colorectal cancer is the second most common killer from cancer in the United States. 145,000 new cases this year. In the vast majority of cases there is a loss of one of those instructions, one specific gene product which we call APC, and this happens in 85 percent of those cases, and very early.

This gene was actually discovered by studying a very rare familial syndrome of hereditary cancer. This molecular change results in the activation of another gene, one which encodes an enzyme which actually is inhibited by anti-inflammatories such as aspirin.

This, coupled with epidemiologic observations that anti-inflammatories may reduce the risk of colorectal cancer is leading to the search for new and more effective drugs that inhibit this enzyme, and clinical trials are aimed at such specific targets in hopes of preventing the development and recurrence of this cancer. This is the type of process we are ready for for all cancers, for new preventions, and new therapies.

Will it work? We do not know, but we will not know unless we try, and we will not know what to try unless we capture the opportunities that our new discoveries are daily yielding.

We can, I am convinced, as you have heard, develop new ways to predict the behavior of each cancer and determine how to design and target therapies the way we do with antibiotics, with anti-cholesterol-lowering drugs, and with the new protease inhibitors for HIV.

Some of these new strategies are aimed at getting cancer cells to commit suicide, others at slowing down the motor that drive cancer cells, others at getting the immune system to recognize and attack cancer cells, others at attacking the unique ways that cancer develops its own blood supply to supply its own nutrients. All of this is based on specific knowledge.

Imagine engineering a virus, engineering it to only kill cancer cells. Such a virus has been made. It is now being tested. It is being tested in clinical trials.

This year, 20,000 patients will be enrolled into one of over 700 NCI-sponsored clinical trials. These clinical trials are the only way to test therapies and preventions of tomorrow which must replace the inadequate approaches we have today.

Despite the enormous size of this process, only 2 percent of adults with cancer enter into clinical trials, limiting our ability to test promising leads, and limiting the speed with which we get these answers.

Senator SPECTER. Dr. Klausner, we are about to come to a vote. If you would summarize it, I would appreciate it.

Dr. KLAUSNER. This is a time in cancer research, as I know you have heard me say, that many of us approach with extraordinary optimism. We know the road to take. We do not know how long that road is going to be.

PREPARED STATEMENT

We at the NCI have been planning with all of our communities about how we must be prepared to make new investments in the extraordinary opportunities now available. The challenge before us is to step up to these new opportunities to make sure that however long that road is we travel on it at full speed.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF RICHARD D. KLAUSNER, M.D.

Good morning, Senator Specter. I am Dr. Richard Klausner, Director of the National Cancer Institute. I am pleased to have the honor of appearing before the Subcommittee today.

After twenty years of our "War on Cancer," we have some victories to report—some cancers, previously carrying a rapid death sentence are now, incredibly, curable—overall cancer mortality rates are, for the first time, beginning to fall.

Yet, as we sit here this morning, over 450 people will be newly diagnosed with cancer and over 150 more Americans will die. The progress we have made is a direct result of research which has begun to illuminate the causes of cancer—allowing effective prevention for some cancers, development of vastly improved methods of early detection and diagnosis and producing new therapies of increasing efficacy. The good news is that we have tested the very premise of the war which this Nation has supported—the premise that progress is predicated on research—and found that premise to hold true. But as the grim statistics and the stories of the tens of millions of survivors and families and friends of survivors and of those who have not survived tell us, we have a long way to go.

I believe we are at a defining point in this war. It is hard to adequately describe the profound advances in the science of cancer research and in the revolutionary technologies that give us powerful tools to attack these diseases—but let me try.

All cancer arises because of the slow accumulation of changes in the set of the 80–100,000 instructions that determine the behavior of each of our cells. There is no one cause of these changes and no one cause of cancer. Chemicals, like those found in tobacco smoke, viruses, radiation, sunlight and the inevitable mistakes made each time each cell copies the DNA on which those instructions are written, all contribute to cancer. Identifying cause is the key to prevention. Diet, exercise, hormones and our genetic makeup, in ways still mysterious, profoundly modify the risks of cancer.

Cancer is not something that just happens—it arises out of a long process that we are only now actually unravelling. All cancer evolves from pre-cancer and we can now begin to design how to detect and treat pre-cancer. Let me give you an example. Colorectal cancer is the second most common cancer killer. In the vast majority of cases, there is a loss of the function of one specific gene product called APC. This was actually discovered by studying a relatively uncommon hereditary colon cancer syndrome. This molecular change results in the activation of another gene which instructs the cells to make an enzyme that is one of the targets of anti-inflammatory drugs like aspirin. This, coupled with observations that aspirin and other anti-inflammatories may prevent colon cancer, is leading to the search for new and more effective drugs and to clinical trials that are aimed at this specific target in hopes of preventing the development or recurrence of this cancer. This is the type of process that we are ready to repeat for new preventions and new therapies not blind guesses but targeted choices based upon real knowledge of the machinery of each

cancer. Will it work? We will not know if we do not try and we will not know what to try if we do not capture the opportunities for discovery.

We can, I am convinced, develop new ways to predict the behavior of each cancer, whether it needs to be treated, whether it will respond to therapy and what therapy will actually work. This is the new promise of molecular diagnostics. The explosion of new ideas about the specific machinery of cancer cells is beginning to result in the design of therapies against cancer much like the use of antibiotics, anti-cholesterol agents and the new anti-HIV drugs. Some of these new strategies are based on turning off the motors that make cancer cells grow, some are based on strategies to trick cancer cells to commit suicide, some on harnessing the immune system to seek out and destroy cancer cells and some on destroying the unique ways that cancers assure their own blood supply. All of these are based on specific knowledge about cancer That is where the research is taking us.

One recent therapeutic advance illustrates how cancer therapy is being altered by our new understanding of the molecular characteristics of cancer. Researchers at the NCI, in collaboration with extramural investigators, have been testing new treatment regimens for a particularly aggressive form of lymphoma. A 5-drug regimen resulted in an apparent cure, or long-term remission in about 50 percent of the patients. The remainder either failed to respond or rapidly relapsed. What was different? In virtually all of the relapsed patients, their cancer cells harbored a mutation in the p53 gene, a gene whose loss of function is implicated in over 50 percent of all human cancer. What had been called one cancer was clearly at least two distinct diseases. Recently, the investigators evaluated a newer regimen with three additional drugs and have observed long-term remission, hopefully cure, in 90 percent of all of these patients. This example illustrates a principle that is guiding a transformation in oncology. We can begin to identify the defining characteristics of any cancer. It is this set of alterations that will define the actual targets for therapy.

Imagine engineering a virus to only kill tumor cells—a virus tailored to recognize a gene altered in 50 percent of all human cancers. It has been done and is now being tested in clinical trials. This year, 20,000 new patients will be enrolled onto one of over 500 NCI-sponsored clinical trials This is the only way to test the therapies and preventions of tomorrow which must replace the inadequate therapies of today. Despite the size of our national clinical trials system, only 2 percent of cancer patients enter clinical trials limiting the number of promising leads tested and the speed with which we answer critical questions.

This is a time in cancer research that all of us approach with a new optimism. We know the road to take. Unfortunately, we don't know how long that road is. We, at the National Cancer Institute, have been planning for how we must be prepared to make new investments in the extraordinary opportunities now available. The challenge before all of us is to step up to these new opportunities to make sure at, however long the road is, it is one we travel at full speed.

Mr. Chairman, that concludes my prepared testimony. I would be pleased to answer any questions.

NEWLY DIAGNOSED CANCER CASES

Senator SPECTER. Thank you, Dr. Klausner. You talk about 450 newly diagnosed cancer cases. I would add an addendum at this point that those who are diagnosed do not have to accept that.

I was diagnosed and told I had 3 to 6 weeks to live, and I did not accept that. We got a second opinion and moved promptly, and I do believe the doctor was wrong. It was not true, and I do believe, and I think it is important for patients to take a very active role in their own care and to undertake some substantial studies.

Just another parenthetical note. I took a look at what is called the gamma knife and had to talk to about 35 doctors around the world, and a lot of doctors did not like the idea because it was not conventional, but there is a big body of opinion out there on the periphery which says it is a good thing, so that a patient ought to be a real activist. I might say, even if you are dealing with lawyers. [Laughter.]

SUMMARY STATEMENT OF HELENE G. BROWN

We will turn now to Ms. Helene Brown, who will introduce Ms. Sherry Lansing.

Ms. Brown has been a leading activist in the fight against cancer, responsible for implementing the mass media approach to the promotion of the new pap smear in the 1950's and 1960's.

Ms. Brown, why do we not turn to you, and I will introduce Ms. Lansing myself. [Laughter.]

Ms. BROWN. Somehow, Senator Specter, I expected that. [Laughter.]

Senator SPECTER. Well, I had not, but it seemed to me a good thing to do.

Ms. BROWN. Thank you.

Senator Specter, Senator Reid and guests here today, I come as a spokesman for 15 million donors to the American Cancer Society, the voluntary arm in the community supporting cancer research as well as the things you just spoke of, Senator Specter, lifestyle changes, the way in which patients can, indeed, help themselves.

There are three points that I will make, and you do not have to fuss with your lights because I will be way under the 5-minute period of time, but first the majority of people in this country have forever given charitably to cancer research, to cancer causes.

They do that with what we call leftover dollars, if you will, not to denigrate the money but to indicate that they think of it as a charity, and what I would like to do today, what the 15 million people out there would like to do and all of us on these panels, is to turn away from Congress looking at cancer research as if it is a charity and look at it better as an investment, because we know what kind of an enormous and beautiful investment it is.

Congress knew this in 1930, 1937 when the first cancer act was passed, and again in 1971, when the next cancer act was passed. The result is that since the 1930's life expectancy has moved from about 48 years to approximately 78 years. Now, if that is not one beautiful investment in our country, I do not know what is.

The pharmaceutical industry in this Nation depends upon the basic science research that is brought about by Government, and in our view Government is here to do what the private sector cannot or will not do, and voluntarily they have never given enough money to do the kind of work that we can get done through the doubling of the cancer research budget by the National Cancer Institute, by you, Senator Specter, and the Congressmen that you represent.

Last, I want to simply say that the monumental explosion of knowledge that Dr. Klausner has just described to us is something that has never happened before, only since what we used to call the golden age of medicine. That was when we discovered antibiotics and immunizations. There have been several references made to that this morning.

This is indeed, in our opinion, the second golden age of medicine that is about to come upon us. A doubling of this research budget within the next 5 years will give us the investment in the pharmaceutical industry, in business, in parents, in children, in the collec-

tion of taxes and the buying of stamps and all of this that we think will make an enormous difference in this country.

PREPARED STATEMENT

Senator Specter, we join you, Senator Mack, Senator Feinstein, in stepping up to the plate. We need a home run in this, and to make this the mantra of the country, the highest priority possible, is what we are asking of you today.

Thank you so much for listening to us.

[The statement follows:]

PREPARED STATEMENT OF HELENE G. BROWN

Mr. Chairman and members of the committee: In most of the country, people believe that cancer research is a charity that one contributes to with leftover dollars. In the hall of Congress, you and we know better. History tells us that voluntarily people have never and will never give enough to support the level of scientific discovery that we have witnessed in the past several decades. Congress knew that in the 1930's, when Federal expenditures for scientific advancement began in earnest. Now life expectancy has increase from 48 years at the turn of the century to the 78 years that it is today.

We know cancer research to be a major contributor to one of the most successful business in America, the pharmaceutical industry. We know that in recent years cancer research has succeeded in saving more young lives and that the years of life saved of a young person add considerably to our gross national product, to our collection of taxes, to the growth of families, of business, of talent, of scientists, and yes, of our future politicians and a future President.

We, in this room, know of the potential that is now within reach in genetic discovery because of what your federal funding has accomplished in the past. We now know that all diseases have a genetic component. Cystic fibrosis is viewed as having a 75-percent dependence on genetic makeup, adult diabetes may be 50 percent attributable to genes, and AIDS may be as little as 1 percent genetically based. So, as much as we know and will know about genes and how they cause cancer, we also know that treatments will necessarily be combined to include lifestyle changes and medicine, along with the results of the study of epidemiology (the study of that which causes cancer in our lifestyle, like smoking, or in our surroundings, like ionizing radiation) in order to prevent cancer as well as to cure it. And please do not forget that an ounce of prevention is still worth a pound of cure.

We all know that our expectations and limitations are totally and fully dependent on money. In the final analysis that's where the rubber hits the road. If we fund cancer research by doubling the current budget, we will get there and we will get there sooner. If we do not accept that challenge, we will literally cripple a monumental effort with every indication of a monumental payoff that will impact your life, mine, and that of all our children and grandchildren. I do not want that pox on my house. And I do not believe you want it on yours. Please double this budget as soon as you can * * * it is not a question of should it be but when will it be?

Please accept my appreciation for this time before you and your patience with these candid remarks.

Senator SPECTER. Thank you, Ms. Brown.

As I had said earlier, we have a vote on. We vote at irregular times in the Senate, and votes take precedence over every other activity, and so I am going to excuse myself for a few moments. I should be back within 10 minutes, and we will resume at that time.

[A brief recess was taken.]

SUMMARY STATEMENT OF SHERRY LANSING

Senator SPECTER. Our hearing will resume, and we will proceed with the testimony of Ms. Sherry Lansing, the chairman and CEO of the motion picture group, Paramount Pictures Corp. She had previously had her own independent production company at Para-

mount, and has had an illustrious career in the industry, movies, and television, in 1980 was president of production at 20th Century Fox, the first woman to hold that position in the industry.

She has had a long list of extraordinary achievements in the industry, "Indecent Proposal," "Fatal Attraction," "Black Rain," "The Accused," and the list too long to enumerate—so we now turn to you, Ms. Lansing. Thank you for joining us, and the floor is yours.

Ms. LANSING. Thank you. Thank you, Mr. Chairman and members of the committee. It is truly an honor for me to testify before you today, and I come here because I believe so deeply in the importance of cancer research.

I have had a long and personal history with this disease. Over 30 years ago I remember attending a black tie event which was to raise funds for cancer research. At that time, a very articulate representative from the American Cancer Society got up to speak. He spoke about the horrors of cancer, about the nature of the disease and the advances that were being made.

I barely listened. I was having too good a time, and I simply did not want to be interrupted. I certainly did not want to think about anything as unpleasant as disease or sickness. He then said that one out of three people get cancer. Turn to your right. Turn to your left. One of you will get cancer.

At that time, that statistic held absolutely no meaning for me. I could not relate to it. I did not have cancer, and no one I knew had cancer. It was simply somebody else's problem.

Then, several months later, my mother, Margot, called and she told me she was not feeling well. She had a distended stomach. I laughed, and I told her it must be all the good food that she was eating. No doubt she had just been careless in watching her weight.

Margot went to numerous doctors as the pain continued. One doctor told her that it was diverticulitis. Medicine was prescribed, but it just did not seem to do any good.

Still, I did not take it too seriously. My mother was such a healthy and such a happy woman. She was so very young and so very vital. Nothing bad could happen to her. Nothing bad could happen to me.

As the pain persisted, my mother went to a specialist at the University of Chicago, and we were told that my mother, Margot, had ovarian cancer. Turn to your right. Turn to your left. One out of three people get cancer. Turn to your right. Turn to your left. One of you will get cancer.

Suddenly, that statistic was no longer a remote and a meaningless one. Suddenly my family was no longer invincible, because that statistic had become a chilling reality.

For the next 18 months, I watched as my mother struggled to defeat this disease. I watched the pain, the false hopes, the humiliation, and I watched as the cancer ate her body. My mother's will to live could not stop this disease. No amount of positive thinking could save her. No amount of love could prevent her death.

I hate cancer. I hate it in a way that I have never hated anything in my entire life. It causes incredible pain and suffering in an almost random way. It knows no class barriers, no race, no reli-

gion or gender. Rich or poor, we get it. Rich or poor, we die the same.

Throughout the years, cancer has struck my loved ones, my friends, and my professional associates. I sometimes feel as if cancer is really a plague, as I pick up one phone call after another and I learn of another friend who has been struck by this disease, but that is just what it is, a disease. As in the case of other diseases that used to cause fear, it can and it will be cured.

I, too, remember when we were all growing up and you were afraid to go to the beach because you were afraid you would get polio. Similar stories abound about tuberculosis and smallpox, and some day, I know, in the not-too-distant future we will be sitting around and we will telling stories about the big C, and in that not-too-distant future we will no longer hate cancer and we will no longer be frightened by it. It will no longer hold power over us, because it will no longer exist.

So I come to you today to ask you to try to finally put an end to this disease. This year, nearly 1.4 million Americans will be diagnosed with cancer, and about 560,000 will die of it, more than 1,500 every day. These statistics are simply unbearable when you realize that cancer research, when pursued aggressively, can help diagnose, treat, cure, and prevent this terrible disease.

Hollywood obviously has not been immune to cancer. In February, following a meeting with Vice President Gore and NCI Director Rick Klausner, my colleagues and I formed the creative community task force which will work in conjunction with Friends of Cancer Research.

This task force, which Jack Valenti and I chair, includes all the senior executives at the major studios and broadcast networks, as well as independent producers, writers, actors, and directors.

Our task force agenda is an aggressive one. First, we are committed to use our television, film, and other programming to communicate what actions people can actually take to fight cancer, actions such as supporting cancer research, modifying diet, and scheduling regular diagnostic exams.

At the request of the Vice President, we also are evaluating how our industry, as well as the Government, can help in the fight against teen smoking.

Second, we will be public advocates for cancer research ourselves. We have visibility and the opportunity to talk to the public about these issues in the media. The task force will become an important, visible voice, similar to the AIDS lobby. We intend to mobilize the public as well as the Government for increased emphasis on cancer awareness and cancer research.

I do not want my mother to have died in vain. I do not want my friends and my associates to have died in vain. I want, as we all want, to defeat and eradicate this disease.

So in closing, Mr. Chairman, I would like to thank you for your leadership in the area of biomedical research. You are one of the original cosponsors of Senate Resolution 15, introduced as well by Senator Mack, which calls for the doubling in Federal funding for cancer research over the next 5 years.

PREPARED STATEMENT

I sincerely hope that all of your colleagues will join you in supporting this goal, and so it is in that spirit that I thank you for your time and for the privilege of testifying before you.

Senator SPECTER. Thank you very much, Ms. Lansing.

[The statement follows:]

PREPARED STATEMENT OF SHERRY LANSING

Mr. Chairman and members of the committee, it is an honor for me to testify before you today; I do so because I believe so deeply in the importance of cancer research.

I have had a long and personal history with this disease. Over 30 years ago I remember attending a black tie event to raise funds for cancer research. At that time, a very articulate representative from the American Cancer Society got up to speak. He spoke about the horrors of cancer, about the nature of the disease and the advances that were being made. I barely listened. I was having too good a time and I didn't want to be interrupted. I certainly didn't want to think about anything as unpleasant as disease or sickness. He then said that one out of three people get cancer. Turn to your right, turn to your left * * * one of you will get cancer. That statistic held absolutely no meaning for me, I couldn't relate to it. I didn't have cancer. No one I knew had cancer. It was simply someone else's problem.

Then, several months later my mother Margot called and told me that she wasn't feeling well. She had a distended stomach. I laughed and told her it must be all the good food she was eating—no doubt, she has been careless in watching her weight. Margot went to numerous doctors as the pain continued. One told her it was diverticulitis. Medicine was prescribed, but it didn't seem to do any good. Still I didn't take it too seriously. My mother was such a health and happy woman. She was so very young—so very vital. Nothing bad could happen to her—nothing bad could happen to me.

As the pain persisted, my mother went to a specialist at the University of Chicago, and we were told that my mother Margot had ovarian cancer. Turn to your right, turn to your left * * * one out of three people get cancer. Turn to your right * * * turn to your left, one of you will get cancer. Suddenly that statistic was no longer a remote and meaningless one * * * suddenly my family was no longer invincible, that statistic has become a chilling reality.

For the next 18 months I watched my mother struggle to defeat this disease. I watched the pain, the false hopes, the humiliation and I watched as the cancer ate her body. My mother's will to live could not stop the disease. No amount of positive thinking could save her. No amount of love could prevent her death.

I hate cancer. I hate it in a way I've never hated anything in my life. It causes incredible pain and suffering in an almost random way. It knows no class barriers, no race or religion or gender. Rich or poor we get it. Rich or poor we die the same. Throughout the years cancer has struck my loved ones, my friends and my professional associates. I often feel as if cancer is really a plague as I pick up one phone call after another and learn of another friend who has been struck by this disease.

But that's just what it is, a disease. And as in the cases of other diseases that used to cause fear, it can and will be cured. Remember when we were all growing up and you couldn't go to the beach because you could get polio? Similar stories abound about tuberculosis and small pox. And someday in the not too distant future we will all be sitting around and telling stories about the big C. And in that not too distant future, we will no longer hate cancer or be frightened by it. It will no longer hold power over us because it will no longer exist.

And so I come before you today to ask you to try to finally put an end to this disease. This year, nearly 1.4 million Americans will be diagnosed with cancer, and about 560,000 will die of it—more than 1,500 every day. These statistics are unbearable when you realize that cancer research—if pursued aggressively—can help diagnose, treat, cure, and prevent this terrible disease.

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In closing Mr. Chairman, I would like to commend you for your leadership in the area of biomedical research. You were one of the original cosponsors of Senate Resolution 15, introduced by Senator Mack, which calls for a doubling in federal funding for cancer research over the next 5 year. I hope that your colleagues will join with you to support this goal.

And it is in that I thank you for your time and for the privilege of testifying before you all.

SUMMARY STATEMENT OF SAM DONALDSON

Senator SPECTER. We turn now to Mr. Sam Donaldson, distinguished broadcast journalist, a 29-year veteran of ABC News, coanchor of "Primetime Live," and "This Week," a long list of accomplishments. It is a special pleasure for me to welcome Mr. Donaldson here, because this will give me a chance to question him. [Laughter.]

Mr. DONALDSON. I trust you will show me the same deference that I have shown you when you have come to "This Week," Senator. [Laughter.]

Senator SPECTER. No; I am going to be a lot nicer to you. [Laughter.]

I am not sure, but I think this hearing was scheduled before I was on "This Week" recently, and I have to say that on one occasion Sam let me finish an answer. [Laughter.]

So that may have been in anticipation.

We have been joined by our distinguished colleague, Senator Cochran. I had a brief chat with Thad at the last vote, and he said, is Donaldson really going to be there, and I said, yeah, and when Senator Cochran's turn comes you will see a distinguished trial lawyer in operation. [Laughter.]

Well, we welcome you here, Sam. You have had your own experiences and become an outstanding advocate and focused a lot of public attention, and we look forward to your testimony.

Mr. DONALDSON. Senator Specter, thank you for holding this hearing.

Now, you said that Senators Hatfield and Kassebaum are no longer with us in the Senate, that is true, but you are here, and you are on the large side of this one, and we appreciate that very much.

Senator Cochran, thank you for coming today, too. I know that you know something about cancer and that you, too, are on the right side of the Pearly Gates—not yet literally, you understand. [Laughter.]

In January 1988 a wart on my ankle which I had had for years and years and years did not look right. I went to the doctor. He

said, we have got to have this off, and I do not want to frighten you, but we have to check it to see whether it is melanoma.

Well, he frightened me, and they sent the tissue to three separate laboratories. The first one said it was not, and the doctor said, I do not know, we had better check this some more, and all three said that it had not turned.

Well, I went home happy and go-lucky, jaunting, arrogant as usual, and then in the summer of 1995 I felt a lump in my groin in the shower, and to me it had come up overnight. Well, I knew that was not good, and I went to the doctor, another one, and he said, what is this on your ankle? I said, it is a scar. It did not matter. I told him the story and he said, well, I do not want to scare you, but we are going to have to take a look at this.

Well, he scared me. They did take a look. The biopsy said it was melanoma. I went home that night and I sat down with my wife, and I think I am pretty well informed as a layman, and I said, dear, I think we have about 3 to 6 months. I knew something only casually about melanoma, and I knew it was sort of a Tyrannosaurus rex, normally not responsive to chemotherapy or radiation, and I was sad. I have been very lucky. Very lucky. I have enjoyed my life, and I did not particularly want to leave it.

They sent me out to NCI, I thought as a consultation to see Dr. Steven Rosenberg. He looked at my scans. It had not spread, apparently. He examined me, he sat down with me and he said, "you know, I think you have a good chance of leading a long, healthy life," and I blurted out, "I don't believe you." So here is one of the foremost cancer authorities in the world, and I am setting myself up as his master. Well, he said, no, I really think so, and we can take care of it here.

I said, well, I am not eligible. He said, you are. You are eligible for a tissue protocol, and I said, Steve—and we were on a first-name basis now—I had better be eligible, absolutely. Never mind the melanoma, my press colleagues will kill us if I am here inappropriately.

They removed what turned out to be one lymph node. The involvement of only one lymph node in stage 3 in my case means that I am in a 50–50 bracket statistically. About 50 percent of the time people like me see it come back, usually then in the soft organs, and now it is desperate; 50 percent of the time we never see it again.

I do not know which category I am in. I know which category I would like to be in. I have tried to learn something about the disease, and also selfishly what is in store.

In 1984, before then, the cure rate for metastasized melanoma was zero. In that year, Dr. Rosenberg, having tried 66 times and failed, with the 67th patient he is free of it for 12 years now, and he has freed others, and other great research institutions have, but it took money to go through those first 66.

We did a program on cancer, and I discovered to my horror that doctors tell us we have therapies in the laboratory that work on the rats. Now, they may not work on human beings. Many of them do not. Some of them do, and we cannot test them on human beings because we do not have the money.

Well, I thought that is a little silly. I discovered we have only at least, as of last November, one national breast cancer protocol, and only one national prostate cancer protocol. Why don't we have more? We don't have the money, is the answer.

Well, ladies and gentlemen, I know that all of you are pressed by special interest good causes. Ours is not the only worthy cause that you have to deal with as custodians of the public purse, but to think that this disease, which kills 560,000 Americans every year, is something that we could conquer sooner if we had more research dollars to increase the trials and therapies that work in the laboratory, to increase national trials so that we will have a better idea of how to do it, is something that really is a little silly.

I want to close not only by saying to Senator Harkin, thank you for coming—I know you have been a champion of this cause, too—I want to close by saying something pretty harsh, and I do not mean to be, but I thought Senator Specter in one of his opening statements was exactly right. He answered the letters from Pennsylvania first. That is his constituency. That is frankly—and again, forgive me, but maybe your reelection counts on.

Senator SPECTER. Not a total irrelevancy.

Mr. DONALDSON. I want to say to you that when you mark up this fall, I want you to feel, and I know I am preaching to the choir, but I want your colleagues to feel that among all the worthy causes there are just too many letters out there from the cancer people not to answer, because my old friend, and I mean that sincerely, Ronald Reagan got it right. You do not have to make them see the light. You just have to make them feel the heat.

Thank you.

Senator SPECTER. Thank you very much, Sam. Thank you very much indeed.

REMARKS OF SENATOR HARKIN

We have been joined by the distinguished ranking member, Senator Harkin, and I would turn now to Senator Harkin for an opening statement or whatever comments he chooses to make at this stage.

Senator HARKIN. Mr. Chairman, thank you, and I apologize to this panel, and I already did to Senator Mack and Senator Feinstein, for not being here earlier. It just so happened that this morning was the markup of the Individuals With Disabilities Education Act and months of negotiations.

We finally pulled it together and we are able to get it out of committee, so I had to be present at another committee, at least up until this moment, but I did not want to miss the opportunity to be here, and I am sorry I missed some of the testimony here, but I will read it, I can assure you.

Just picking up on what Mr. Donaldson said, it really does come down to resources and focus. I have often said that—President Nixon declared war on cancer. The war on cancer was what, in 1972, or 1971, and we declared war and beat a hasty retreat, and that has just been the sum and substance of it.

We have made great progress. I have been an eyewitness to some of the progress that has been made. People are living longer that have cancer. There is more hope for people out there, but it still

is a killer, and it is still taking too many lives every year, and the mortality rate is still exorbitant.

We have some promising new therapies. The whole gene program, gene therapy I think holds a lot of progress, but we are not going to get there if we keep muddling along like we have been doing in terms of the finances.

I do not know what everyone else said, but I just happened to hear what Sam Donaldson said, and he is right. You know, I always think of it like this. You say, well, how much money do you need, and I say, I do not know, but I always look upon the research, Dr. Klausner, and we have talked about this before. It is like you have got 10 doors, and those doors are all closed, and the answer may lie behind one of those doors.

Well, if you are going to open 1 out of 10 doors your chances, your odds are what, 10 to 1, 9 to 1 that you are not going to find it. Those are overwhelming odds.

Right now, we are funding 2 out of 10, 2½ out of 10, something like that, of—and those are the research proposals that have gone through the peer review process, and poor Dr. Klausner, he can only fund 2½ out of 10. That is about 25, 26 percent I think last year, if I am not mistaken, so there is another eight doors that are being shut that we do not know what is behind those doors.

Now, there are a lot of young people out there, I know, I see them, that are in colleges, sometimes they are in high schools now, they are interested in this area, they are interested in the biology, they are interested in the chemistry of it, they are interested in the medical approach, they are interested in the gene research approach, but they have to be realistic.

They are looking ahead and they say, my odds that I am going to be a great scientist and I am going to put in for a grant, and my odds are only 1 in 4 that I am going to get approved, and if I get approved 1 year I may not get approved the next year, and sometimes this research has to take a long period of time, well, that can dissuade me from following that course of study.

I am going to get on my soap box here. I did not mean to, but you asked me to make an opening statement, and I will.

Senator SPECTER. Or briefly a closing statement. [Laughter.]

Senator HARKIN. You see, here is another thing to keep in mind, and I am going to use this opportunity to say this again. During the gulf war we saw all of these great TV pictures of these smart bombs that went down the chimney and these missiles that intercepted these other missiles. We knocked out what was it, we knocked out 3,000-some tanks and we only lost 7, and this was wonderful. I mean, all this wonderful technology that we have. As far back as I have been able to research the Department of Defense spends 15 cents of every $1 on research, 15 cents of every $1 on research.

One other thing to keep in mind. In the last 4 years, in the last 48 months, we have spent more money, your money, taxpayers' money in 4 years, Sam, we have spent more money on military research and development than we have on all medical research since the turn of the century. I say that to people and they say, you must be nuts, Harkin. I say no, you check it out. I am right. You add it up. In 4 years.

Sure, that is why we have got smart bombs and missiles. Thank God they protect us, and I am not downgrading it, but if you want the smart missile or the smart bomb that is going to knock out that cancer you have got to put those kind of resources there now.

And when we spend as much money as we spend on health care in this country, and we do not put 1 penny out of every $1—we do not even put 1 penny out of $1 into medical research. What do we expect? We are going to keep doing just what we have been doing in the past, and we are not going to find the interventions, the causes, and the cures.

So that is why I have pushed for so long, first with Senator Hatfield, now, God bless him, with Senator Specter, to try to get it in people's minds in this country that when you spend $1 on health care some of that ought to go to research. We only ask for 1 penny. My God, you would think the sky is going to fall.

I have had some of the largest managed care organizations in America, supposedly there to help the health of America, say that they are going to fall on their sword to defeat us on this bill, to try to get 1 penny out of every $1 to put into medical research.

Insurance companies—oh, no, we can't have that. Well, I will tell you, it is time that we have a policy in this country that out of every $1 that an American spends on health care, some of that is going to go to research. We only ask for 1 penny. That would only give us a 50-percent increase to NIH. We cannot even get that through.

So you are right. I did not mean to go off, but you pulled my chain when you started talking about resources, because that is what it adds up to, and we have got to get those resources, and we have to have a dedicated fund of money.

I talked about a trust fund that Senator Specter and I have talked about, where some of that money would come from a health care bill. If we put 15 cents out of every $1 that goes into defense into research, my God, we ought to be able to take 1 or 2 cents out of every $1 for health care and put that into research, and then—then we would win the war on cancer.

Thank you very much, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin.

Senator Cochran, would you care to make an opening statement?

Senator COCHRAN. No, Mr. Chairman. I am here to learn from the witnesses and I just want to express my sincere appreciation to all of them who have come here today to help us understand how important it is that we move as quickly as we can to do more in the research area to try to find the answers and to try to find the cures that we know are out there to save the lives that are very important to all of us.

Thank you very much.

Senator SPECTER. Thank you very much, Senator Cochran.

SUMMARY STATEMENT OF ELLEN SIGAL

We now turn to Dr. Ellen Sigal, Presidential appointee to the National Cancer Advisory Board and chair of its Budget and Planning Committee which oversees the board's $2 billion budget.

Dr. Sigal has had a very distinguished career, and is a very, very strong advocate in the fight against cancer, and I want to thank

Dr. Sigal for helping us organize today's hearing. She was really instrumental, along with Bettilou Taylor and Craig Higgins, and we are going to have a field hearing commemorating the 25th anniversary of the National Cancer Act in Los Angeles on May 29, and so we will be paying tribute again to the same lives, so we very much appreciate your help, and we welcome you here, Dr. Sigal, and the floor is yours.

Dr. SIGAL. Thank you, Senator Specter, and thank you for your leadership and support for cancer research. It is deeply valued. Thank you, Senator Harkin and Senator Cochran for being here to listen.

My advocacy is based on a personal and very tragic loss. It is the loss of my younger sister to breast cancer 11 years ago. I will never forget my niece's first birthday party. My sister had breast cancer, and she was undergoing chemotherapy, and when we came to New York to help her prepare for the party her hair fell out that day, the very day of her daughter's first birthday party, and it was 10, or 11 o'clock in the morning, and we had—no, she was not prepared. She was told her hair was going to come out eventually but not that quickly, and I remember desperately going out to find a turban or a scarf, or to do something to protect her so she could have pictures with her daughter on her first birthday party.

She fought valiantly. She underwent every treatment imaginable for this disease. When the disease progressed, her only option was a bone marrow transplant. At the time there was a very high fatality, and she felt she had no other choice because it was certain death.

However, they knew that fatality was high, and I was with her when the psychologist had advised her to take a video of herself for her daughter in case she did not make it, and she recorded a video saying goodbye to her daughter. We thought she would make it. We hoped she would, but indeed she did not, so we have the video.

So yes, we speak with great passion, because it is our sisters, it is our brothers, it is our children, it is our fathers and mothers that we are talking about. I do not think there is a family in the United States that has not been hit by this disease or affected by it, and so there is great passion and great hope in this community.

The burden is felt by all, disproportionately among the minorities. It is more pronounced on our poor, but there is no one that is exempt from this, and you know this on this panel.

We are at a point where there is no stopping us now. There is great progress on this disease. We have enormous leadership. We are so lucky at the National Cancer Institute to have someone as brilliant and gifted as Dr. Klausner. It is his vision. It is his inspiration. It is the opportunity. It is the ability now, and it is the time to get something done.

It is all over. It is pervasive. It is in the communities. It is at our cancer centers. We know now that we can, indeed, do something. There is focus and there is opportunity. What is stopping us? It is money. We are spending $2.4 billion a year on this disease. It is not enough. That is the equivalent of a half-a-tank of gas a year, or $10 per person.

I would challenge you to look at any witness here today or cancer survivor in the eye and tell them that their quality of life and their prospects for cure and their chance of survival is worth the cost of two fast food meals. We cannot do this.

The cancer community is organized. We are together. We are not going to pit breast cancer against prostate cancer against ovarian cancer. We are speaking with one voice. We need more money for this. We can make a difference, and we need you. We need your support. We need your leadership, because this is extremely important to all of us. There is no family in this country that is not affected, and we have the opportunity, and now we need your leadership.

PREPARED STATEMENT

We are very pleased about Senator Mack's resolution and Senator Specter, your support for it, for doubling the NIH, and I would say thank you, and I would only say this is a good start.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ELLEN SIGAL

Mr. Chairman and members of the Committee, I deeply appreciate the attention you are giving today to the topic of cancer research. Mr. Chairman, I salute you for your leadership, Friends of Cancer Research was proud to honor you earlier this year. I would also like to acknowledge the long-time support of Senator Connie Mack and his wife, Priscilla. They have personally experienced the burden of cancer and are passionate advocates for change.

You will hear news of medical science here today, and you will hear budget numbers. But for me and for many of the witnesses today, this issue is rooted in personal experience. I lost my own sister to breast cancer. I would venture to say that nearly everyone in this room has lost someone close to them because of cancer. And that is why we are here today.

We speak with passion about this subject because it is our lives and the lives of our fathers and daughters, our husbands, and our friends that we are fighting for—the lives of half a million Americans a year. These are young people as well as old, cut down in the fullness of life, their contributions to their families and the world cut short by this merciless disease, a disease that does not discriminate, but strikes indiscriminately, rich and poor, people of all races and ethnicities, famous people and common people alike.

We are here because a cause which some called hopeless now shines with opportunity, as the mysteries of the human genome yield to brilliant research and astonishing breakthroughs. We are here because we believe that we now have the tools we need to make further gains—gains that will save lives and alleviate suffering and possibly transform our understanding of cancer. All that we lack is the money to pursue them with the vigor and passion that this cause deserves.

Some 25 years ago a Committee of Congress came together, much as you have today, to determine what should be done about this devastating disease. In their wisdom and in cooperation with President Nixon, a bipartisan Congress enacted the National Cancer Act. Now, 25 years later, thanks to that caring and compassionate Congress, who could not sit by and watch this disease destroy families nationwide, the overall cancer death rate in the United States is going down. It has declined 2.6 percent and is falling for colon and rectum cancers, breast cancer, lung cancer, prostate cancer and cancer for children due to progress in prevention and research. For men it is down 4.3 percent and for women 1.1 percent.

But despite Congress' action a quarter-century ago, 1.4 million people will be diagnosed with cancer, and about 560,000 will die this year alone. That is more than 1,500 people a day. In fact, one of every four deaths in the United States is from cancer. Yet we spend only $2.4 billion in finding a cure, improving treatments and diagnosis, and preventing cancer—that breaks down to $10.40 per person per year. I lost my sister and many dear friends to cancer, and I believe it is inexcusable that a disease that costs this country $104 billion annually to treat those afflicted only spends the equivalent of half a tank of gas per person to eradicate this disease. I

challenge you to look any witness here today or cancer survivor in the eye and tell them their quality of life, their prospects for cure, their chance of survival is worth only the cost of two fast-food meals.

Like the Congress 25 years ago, this Congress has an opportunity to provide increased funding for cancer research that will benefit generations of Americans for years to come. Scientists have opened the black box on cancer and are beginning to understand what causes this disease and what treatments offer the best prospects for success. Of the 10 million survivors of cancer alive today, the majority have been cancer-free for 5 years because of new discoveries in research that diagnose the cancer earlier, that treat the cancer more directly with fewer overall toxic effects on the body, and that enable the cancer patient to live a higher quality of life.

We are not often confronted with an opportunity to make a decision that will save millions of lives and improve the quality of living for millions of people currently living. But we have that opportunity today. It will take the cooperation of government, public advocacy groups like those represented here today, and survivors. You hold the key to the resources that will unlock the door to new treatment and cures for cancer.

I urge your support for a level of investment that will make that happen, and in particular I want to commend Senator Mack for his resolution—which I know you have co-sponsored, Mr. Chairman. On behalf of all the cancer survivors, I urge you to at a minimum double the federal funding for biomedical research over the next 5 years.

FUNDING NEEDED TO FIGHT CANCER

Senator SPECTER. Thank you very much, Dr. Sigal.

We are now going to have a 5-minute round for questions for the panel.

Dr. Klausner, I'll begin with you. You are the head man. When we had a hearing in early February I asked you how much money could be usefully spent. I take a look at the statistics on grants. There were 4,185 grants for fiscal year 1997. There were 10 years ago 3,732 grants, so we are 453 up. That is not very much over a 10-year period.

You talk about resources, and when I commented earlier about getting the people in your districts and your States to write your elected representatives, I am a U.S. Senator and I am also a Pennsylvania Senator, and when Sam Donaldson refers to election, that is a thought which occasionally crosses the mind of 535 people up here on Capitol Hill.

A lot of people write me letters from all over, and I am glad to get them, but they would be a lot more effective in their district, and people do not think when they come to visit us and they ask for advice. Take a look at the people who voted against it. They are all on the record, and get people in their districts to tell them.

If I get a dozen letters from Pennsylvania with 12 million people that is a trend. That is a matter of significance.

So Dr. Klausner, you have had several additional months, February, March, April, 3 additional months. You will be in next week for the NIH hearings. How much money, not would you like to have, but could you usefully use to fight cancer?

Dr. KLAUSNER. Sir, you are asking my professional judgment as to what we can use?

Senator SPECTER. Well, I am sure I would get it whether I asked for it or not.

Dr. KLAUSNER. Well, of course, as you know, I am asked by law to provide a professional judgment budget, which we have done, created a whole new budget to outlay very explicitly what we be-

lieve the needs and the opportunities are, and exactly what those investments would mean.

We asked in that for an immediate about 20-percent increase in the budget to allow us to find what we believe are the immediately accessible and achievable opportunities, and my feeling is, is that in order to achieve these opportunities, as we have laid out in the NCI bypass budget, we really see the opportunities. We actually see the only way to prevent the tragic inability to step up to the opportunities, and Senator Harkin said young people are saying this is not for me. This is a disaster.

Senator SPECTER. Dr. Klausner, I ask you for your view because there is a lot of filtering. After you put your figures in they go to NIH generally, and there is a lot of filtering in the Office of Management and Budget, and a lot of times we have witnesses come into the appropriations process who tell us one thing, and then they meet us in the back room and they tell us something else.

Dr. KLAUSNER. Senator, again, I am in the unusual situation that the law allows the NCI Director to directly produce a bypass budget to go to both the Congress and the President. We have done that and have created that. It is in this document, that lays out a very explicit plan for how to spend what we ask for in 1 year.

Senator SPECTER. We will have a chance to do this further next Tuesday. I want to observe the time limit, because we are going to have some time problems. We have to conclude a little in advance of noon.

Dr. Sigal raised her hand, and I will call on her last.

Ms. Lansing and Mr. Donaldson. I was glad to hear Ms. Lansing comment about what her industry could do and what your industry could do, Mr. Donaldson, and I would urge you to do all you can to tell the American people about the support we need.

Dr. Sigal, on my time the final word is yours.

Dr. SIGAL. Thank you, Senator Specter. I just want to tell you that I serve on the National Cancer Advisory Board. I see the grants—that is our statutory responsibility—that are not funded, the science that is not funded. We can do much more. There is good science out there.

I also serve on the board of cancer centers. There is an enormous opportunity. That additional funding, and as I said earlier, double would be a good start, but we could productively over time use a lot more money.

Senator SPECTER. Thank you very much, Dr. Sigal.

We turn now to Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

We know about the bypass budget, and the 20-percent increase is what you said you could use immediately to actually get out to the grants that have come through. I just want to say again, Dr. Sigal—and I am sort of combining two here—you talked about you do not want to pit breast cancer against prostate cancer against brain cancer, et cetera. You see, that is the problem that Senator Specter and I have, and all of us, and Senator Cochran, that we have on this committee.

It is not pitting one cancer against another. It is pitting this research against education, Head Start programs, low-income heating energy programs for elderly who are poor, Pell grants for college

students. And what else is there? We have got more than I can even remember when I chaired the subcommittee.

Senator SPECTER. School-to-Work, drug education.

Senator HARKIN. Drug education.

Senator SPECTER. Therapy.

Senator HARKIN. Yes; everything.

So we get one bundle of money. And so it is pitted against that.

Thus, why I encourage you, I plead with all of you, we need a dedicated source of revenue so that we are not pitting this against everything else.

I have worked with Arlen Specter a long time. I know he agonizes over it, just like I do, trying to figure out how we are going to fund these things. Every time you go down and put a tank of gas in your car, some of that money goes into a trust fund. Every time you buy an airline ticket, some of that money goes into a fund, to help make safer airways and airports and things like that.

Yet every time you buy Blue Cross/Blue Shield, Aetna, or whatever else health plan you have gone to, not 1 cent of that goes for research. And I am saying that has to change in our society. That is why I make that point, Ms. Lansing.

Ms. LANSING. And I think we all agree with you 100 percent. I certainly do not want to take something away from something else. But I do not think that we have ever been at this point in cancer research, where we are so close to finding cures, to finding a way to control the disease. And I think you could look at what happened with AIDS and see where the money that went to research really did produce results, where people are now not dying from AIDS, and they are finding ways to live with it.

I can only say to you that—you know, I heard Senator Feinstein speak about various ways so that we could get alternate income in, you know, the idea of the stamp, the idea of checking your income tax form. And on behalf of the people in Hollywood, these are the kind of things we want to do.

Senator HARKIN. Ms. Lansing, excuse me. I am all for the stamp. I am one of the supporters of it. At the most, that is going to raise about $30 million.

Ms. LANSING. But it is something.

Senator HARKIN. That is nothing.

Ms. LANSING. But do not we have to start thinking of alternate things like that? I mean if you are saying to me——

Senator HARKIN. Fine. You can think of that. I am just telling you that that $30 million is like spitting in the ocean. I am sorry, I just have to tell you that. I am all for it. I would get a dollar anywhere I can. But the stamp is not going to do it.

We are talking about increasing it by billions of dollars a year, not a few million dollars a year.

Ms. Brown.

Ms. BROWN. Senator Harkin, you were gone when I spoke, but I am here as a spokesperson for the American Cancer Society. We are the group with the constituency out there. They are willing to pay more in the taxes to put it into medical research.

Senator HARKIN. Absolutely.

Ms. BROWN. They are, I will bet you dollars to donuts, that your 10 cents, 15 cents of every health care will be important. What we

have to beg you to do is to turn a deaf ear to the lobby that says, "no."

In all of World War II, in all of Vietnam, in all of Korea, in all of the gulf war, we have not lost nearly as many as we lose in 1 year to cancer.

Now, you found the money for the Persian Gulf war. You found the money for Vietnam. You found the money for the other wars. It seems to me that what we have to do in support of you is to step up to the plate and say to the Blue Cross and to the other insurers, put some money where the rubber hits the road. They are making money from health care. I will tell you, an ounce of prevention still is worth a pound of cure.

And what we are here to express to you is the feeling of all of your constituents. We want this No. 1 on your agenda. So if you will say no, we will say yes.

Senator HARKIN. Some of us have been saying no.

Did you have something, Sam, that you wanted to say?

Mr. DONALDSON. This is a national emergency. And if you put it on that basis, Americans will respond. Because it is not something esoteric. Scientists tell us that if we do not get a hold of the hole in the ozone layer, it may kill us all. But it is not something people understand. Their mother did not die immediately, that they can see, from the hole in the ozone layer. But their mother died of cancer. Their best friend has it. They themselves may have it.

Now, you gentlemen are on the right track. Here is the question I would like you to put to Dr. Klausner. Not how much money can you use. He has got many considerations, as you well know far better than I, in how he has to frame his answer. Put the door question to him. Dr. Klausner, if we open all 10 doors, how much money would that take?

He is freed now from having to worry about the other considerations and the other people that he has to worry about.

Senator SPECTER. Dr. Klausner, would you answer Senator Donaldson's question? [Laughter.]

Mr. DONALDSON. Dr. Klausner, if these grant requests, that have gone through peer review, that show some promise, and not someone saying let us flap a bed sheet at the aurora borealis, were all funded, all 10 doors, how much money, sir?

Dr. KLAUSNER. We believe that to do that would require a doubling of the NCI budget in 3 years.

Mr. DONALDSON. Then let us do it. Then let us do it.

Ms. LANSING. Three years, not five.

Senator HARKIN. OK. The other thing, Dr. Klausner, is this a doubling, but not a one-shot deal. This has to be something that we know is going to be there for these young people to say, hey, I want to get involved in that. I want to spend the next 10 years or 20 years of my life in this kind of research. We have got to hold that out there that that money is going to be there.

If it is just up to the appropriations process, and we are battling this and battling that and maybe it is there and maybe it is not, but if we had that dedicated source of revenue that is going to be there, that can double it, and it will be there for the next 20 years.

Mr. DONALDSON. Americans will support it.

Senator HARKIN. I believe they will, Sam, but, darn it, you have got too many people around here who say, we do not want to raise another tax on anybody around here. And I am telling you that I believe the American people would pay that penny. They would pay 2 cents of every health care dollar if they knew that that was going to medical research.

Mr. DONALDSON. You do these things better than I do every day.

Senator HARKIN. I do not think so.

Mr. DONALDSON. We can roll over the people who say no, because we have the numbers. Not because of me. We have the numbers out there; 10 million cancer survivors. If you took a show of hands in this room—and I am not suggesting it—of people who have cancer or whose family members have died of cancer, or whose friends, almost every hand—probably every hand would go up.

We have got the shock power. How many divisions has the Pope? How many divisions do the cancer people have? We have unlimited divisions. And we will get behind you through perhaps a march on Washington that many of us are contemplating.

Senator HARKIN. How many people in the audience have had a family member who has had cancer, how many people? [A show of hands.]

Mr. DONALDSON. My mother died of it. My brother of it.

Ms. LANSING. Well, there you are. That is what we are talking about.

Mr. DONALDSON. I do not want to die of it, but I may.

Senator SPECTER. We are going to have to move on.

Senator HARKIN. Ms. Lansing.

Ms. LANSING. I think we are all saying the same thing. You know that the constituents, the American people, will support this. We all, you know, in my industry try and make it more visible, try and draw more attention to it, but this is a national emergency. And we are at a time like we have never been before in cancer research and we have to do something about it.

Senator SPECTER. I am reluctant to cut off this very important dialog, but we have six more witnesses and we have to finish shortly before noon. And we had made you a senator, Sam, to ask Dr. Klausner. I did not know we were giving you the chairmanship to get the show of hands. [Laughter.]

Mr. DONALDSON. Excuse me, Senator. I sometimes take the bit in my teeth. And I apologize.

Senator SPECTER. Senator Cochran.

Senator COCHRAN. Well, we all know the cost in lives. We also are aware that cancer costs $100 billion every year. And that is an astounding amount of money to lose. When we can invest more, we will save more, not just lives, but money as well. So you were talking about the dollars-and-cents aspect of this.

And I think Senator Harkin touched on an aspect, too, that cannot be overlooked and should not be underemphasized in all of this, and that is doing more to try to attract into the research field medical doctors and others who can help us find the answer.

We had a hearing here last year—Dr. Klausner, I think, was in one of the panels—we were talking about orphan drug research, for example, and the difficulty of not only getting dollars, but getting

people to commit themselves to those areas of research that are also very important.

But we are limited, I think, in terms of the number of people who are engaged in this. And that limits how much money may be effectively used in a research project. You do not have the people there to use the money and do the things that you know need to be done.

What is the answer to that? Is there a proposal that we have before us in terms of research, scholarships or incentives that we can build into the system that will help us do a better job of getting people into these fields?

Dr. Klausner.

Dr. KLAUSNER. Yes; we do. Part of this is to significantly increase the amount of money for training, but also to protect people who want to do research from the forces that are preventing them from doing research. With the changing health care system, clinical researchers are in danger. They cannot spend the time doing clinical research. That is part of this budget request.

But I can tell you the people who want to do research, who want to participate in preventing and curing cancer are there. They want to do it. The most painful thing, as we have all talked about, is the number of times, constantly, that we have to say no.

Senator COCHRAN. Dr. Sigal, would you add to that or comment?

Dr. SIGAL. Young people today who are inspired, who are brilliant, who can make a difference have to rethink whether they can dedicate their lives. They have to feed their families. They have to know that there are resources available. There is the will. There is the opportunity. There are the scientists. There are the brilliant minds that are ready to make a commitment. But they cannot and will not make a commitment to this disease and research if there is no funding.

It is what we do well in government. It is what we do well at the National Cancer Institute. And it is where we can make a difference. There are too many millions of lives dependent upon it, and we can do that.

Senator COCHRAN. Thank you very much.

Thank you, Mr. Chairman, for your leadership in this area and for having this hearing and for doing all that you are doing to try to generate support for this new initiative.

Senator SPECTER. Well, thank you very much, Senator Cochran.

Senator Cochran has been on the subcommittee, and he is No. 1 in line to become the next chairman of the appropriations committee.

I would like now to turn to our next panel. Thank you very much, Mr. Donaldson, Ms. Brown, Dr. Sigal, Ms. Lansing, and Dr. Klausner.

PANEL 3

STATEMENTS OF:

DONALD S. COFFEY, Ph.D., M.D., PRESIDENT-ELECT, AMERICAN ASSOCIATION FOR CANCER RESEARCH

ARNOLD PALMER, PROFESSIONAL GOLFER, ARNOLD PALMER ENTERPRISES

TONI M. SHAHEEN, BREAST CANCER SURVIVOR, MANMOUTH BEACH, NJ, INTRODUCED BY AMY LANGER, EXECUTIVE DIRECTOR, NATIONAL ALLIANCE OF BREAST CANCER ORGANIZATIONS

KEITH L. BLACK, M.D., PROFESSOR, DEPARTMENT OF SURGERY, UNIVERSITY OF CALIFORNIA, LOS ANGELES

CHARLES A. COLTMAN, JR., M.D., PRESIDENT AND CEO, CANCER THERAPY AND RESEARCH FOUNDATION OF SOUTH TEXAS AND DIRECTOR OF THE SAN ANTONIO CANCER INSTITUTE

SUMMARY STATEMENT OF DR. DONALD S. COFFEY

Senator SPECTER. I will turn now to Dr. Don Coffey, Mr. Arnold Palmer, Ms. Amy Langer, Ms. Toni Shaheen, Dr. Keith Black, and Dr. Charles Coltman.

We begin with Dr. Don Coffey, who is the president-elect of the American Association for Cancer Research [AACR], and is a professor of urology, oncology, pharmacology, and molecular sciences at the Johns Hopkins University School of Medicine. For 19 years, Dr. Coffey served as a member of the National Prostatic Cancer Program of the National Cancer Institute, and as national chairman from 1984 to 1988.

Welcome, Dr. Coffey. We are going to be compelled to pay a little more attention to the time lines. And we have changed the timing from 5 minutes to 4 minutes, because we want to hear from everybody and we want to leave some time for questions.

Dr. Coffey, the floor is yours.

Dr. COFFEY. Senators Specter, Harkin, and Cochran, I am speaking to three heroes of medical research, and I have very little that I can really tell you that you do not already know. In fact, I thought Senator Harkin had given my speech, so I had to quickly rewrite another one.

But on the serious side, let me start out by saying that there are three or four things that burn their images into my mind. And one of them was when I was a young schoolchild in Bristol, VA-TN, looking into a mirror into the face and the eyes of a young boy in an iron lung, like being in a coffin, and helping him to breath, and he succumbed to this. An epidemic of polio swept through Wythville, VA, and they were rerouting traffic around U.S. 11 outside of Wythville.

Well, another thing that really burned into my mind when, 40 years later, I stood in Baltimore and watched four large dump trucks hauling all the iron lungs—75 iron lungs—to the trash dump because they were obsolete. And this came because my father stood on the corner ringing bells, he thought research would do this, raising money. We got those little pieces of blue cardboard and put our dimes in it.

But it was really Senator Cochran who really—and people like this—who led the fight in Congress to eradicate this. And you know what you had to do to do that, and I salute you, sir, for that.

Now, years later, as a young engineer in 1957, working in military research with the Westinghouse Corp., we were stunned when we found out that the Russians had put their research money into space efforts and a satellite had gone up. Well, over night—they did not say how much money we could use—it was not the March of Dimes, it was the march of dollars. And it was absolutely overwhelming.

And then, again, many years later, I stood in Florida in the night and watched this scientific marvel hauling American astronauts to the moon and a car to drive around when they got on the moon. Is this a good country or what? I could not believe it.

Well, in 1971, President Nixon pledged and made a contract with America to eradicate prostate cancer. And it was never a war. It was only a skirmish. And even though that chart looks great over there, it would not buy two bombers—the one over there that shows all the appropriations—it would not buy two bombers for this war. And still six cancers were cured. But one-fourth die.

Now, I want to show you on this chart over here, this is what is going to happen while this session is going on. Seven people are going to be murdered in this 2½ hours of this session, shown on the bottom in red. Eleven of these people are going to die of AIDS while this conference is going on. And 161 are going to die from cancer.

Now, this is equivalent—and I want this in our minds as we leave this meeting—to five jumbo jets, fully loaded, crashing every day, year in and year out—that is what it would take to kill this number of people. Those five jumbo jets are falling behind the mountains and we do not see them. It is terrorism from within. But if it hits you or your family, you certainly know what we are talking about.

And on the next chart, I want to show you what the real problem is; 1 penny out of every $10 goes for cancer research; 1 penny out of every $10. Even if we doubled that—that little red dot down there in the corner is the penny—even if we doubled that, that would not be one-third of what we are spending on our space effort.

Now, I am all for the space effort, but we can spend one-third of that amount here.

Now, as president of the AACR, the American Association for Cancer Research, which is the largest research organization in the world and the oldest one in cancer research, I tell you, ideas abound. And let me just end with this. Three-fourths of the cup is empty. There is no doubt about it in research. They are not being funded.

One of those yellow dots on that chart is Janet Luke. And 11 days ago, I stood by her coffin. She is a young nurse. She is 29 years old. And in 3 years of pain and suffering, she succumbed to cancer. Standing by her coffin was her little son, who had the same look in his eye as that little kid in that iron lung—bewilderment and fear.

PREPARED STATEMENT

And I will tell you, we can do better than that. And if we cannot get four bombers in this war, let us surrender. And I think we can

do it. And we are not going to surrender. And we are going to do it one way or the other.

And I want to salute you three Senators, who helped us do it. You have all sorts of good ideas. We stand behind you. We will charge up that hill with you. I swear we will.

Thank you very much.

Senator SPECTER. Thank you very much, Dr. Coffey. Those charts—we have had a lot of charts around here. I have not seen one more impressive than the 161 cancer deaths. If we keep talking too long, there will be more.

[The statement follows:]

PREPARED STATEMENT OF DR. DONALD S. COFFEY

As a young, grade-school student in Bristol Virginia-Tennessee, I watched in horror as a young child, who was locked alive in a metal, mechanical coffin, struggled to breathe while afflicted with poliomyelitis. An epidemic of polio was sweeping through the neighboring city of Wythville, Virginia. We all stood by, helpless and frightened, as this unknown killer maimed its victims. Our national leaders rallied to control this scourge, but they did not know how. Neither the source nor the identity of this menace was known. We had to attack polio with research; it was our only hope. People collected donations for a cure, standing on street corners ringing bells. Children in school were given cards in which to place their dimes in rows? and the March of Dimes was initiated. America and the world had had enough of polio. The collected research funds worked. Fifty years later, I stood in Baltimore and watched dump trucks hauling the last obsolete and unneeded iron lungs off to the trash dump. A tear of relief and of pride in America rolled silently down my cheek as I witnessed the end of polio—conquered by research.

Earlier, I was a young engineer, working in military-related research with the Westinghouse Corporation in Baltimore. In October 1957, we awakened to the startling news that the then feared Russians had silently invested their research in space and had beat America into orbit. To catch up would require more than a march of dimes; this would require a march of dollars. We got it. Almost two decades later, I stood in the Florida night and watched an unimaginable miracle as the United States launched a gigantic scientific marvel carrying American astronauts and a car to drive around on the lunar surface. Was this a great country or what?

Then, in 1972, we launched another great endeavor—a War on Cancer. President Nixon pledged the full resources of our government to conquer this dreaded disease. Unfortunately, only limited research funding trickled out that could support only a small skirmish, and not a real war. This was not an American-style effort to go to the moon, to crack the atom, or to fight a Gulf War. This effort could only support a few thousand investigators to fight only a limited engagement. Still, six cancers were essentially cured, including those that primarily affect young people, such as leukemia and testicular cancer. However, today the big six cancer killers (lung, breast, colon, prostate, bladder, and brain cancer) continue to ravage the bodies of their victims. Now, 25 years after this country pledged to go to war against cancer, one half of all American men and one third of all American women will be struck by the horror of being diagnosed with cancer during their lifetimes. One fourth of all Americans will one day die from this most unpleasant and painful form of death. During the approximately 2½ hour period that this Senate hearing will be in session, 161 Americans will die from cancer, compared with 11 who will die from AIDS and 7 who will be murdered. It would take 5 Boeing 747 jumbo jets crashing every day for a year to equal the half million Americans who die each year from cancer. This number of cancer deaths per year exceeds all U.S. combat deaths in all of the wars in this century. This carnage on our people from cancer must stop, and it will, because of research funded by this Congress. In the past, medical research has conquered the pain of amputation, surgery, and dental procedures, as well as infectious diseases such as typhoid fever and pneumonia; one day, medical research will conquer AIDS and cancer. We have already proved that we can cure six cancers through medical research; now it is tune to eradicate the other major cancers. However, this will be slow to be realized at the current funding levels, when only one penny out of every ten tax dollars is spent to research this tremendously costly disease. If we doubled our effort on cancer today, it would still cost less than one-third of our space effort and only one-twentieth of the cost of the Gulf War. Taxpayers

are far more endangered by a "berserk" cancer cell than by a bullet from an enemy, and they want to be protected against cancer.

As a scientist at Johns Hopkins University who has dedicated his life's effort to cancer research, and as the elected President of the American Association for Cancer Research which is the largest organization of laboratory and clinical cancer investigators in the world, I can assure you that exciting scientific opportunities abound. No one can predict when or where cures or successful prevention strategies will originate, but all agree that they will only come from funding a large base of investigations. At present the cancer research cup is three-fourths empty. Of every 100 grants approved for funding after critical peer review, less than 25 will receive funding. The other 75 unfunded projects represent lost opportunity, valuable time in the fight against cancer, and more lives lost.

On April 26th, I stood by the graveside of my friend, Janet Luke, a young nurse who was just 29 years old when she died after suffering for 3 years from the pain and ravages of cancer. By her coffin stood her husband, Markham, who is in training as a physician-scientist, and her 3-year old son, Matthew. I just know that one can do better than this. It would take only a fraction of the effort that got Americans to the moon, and it would save so many. We have had enough of the suffering and death from cancer. Together, with your support of cancer research, we can conquer cancer. It is time to make a commitment to the American people to wage a Real War on Cancer. Thank you for listening to their pleas through my inadequate words.

SUMMARY STATEMENT OF ARNOLD PALMER

Senator SPECTER. It is a special pleasure for me now to turn to a very distinguished American and a distinguished Pennsylvanian, Mr. Arnold Palmer, an immortal in the golf world. They brought the statistics up, Arnie: 92 championships in professional competition, 61 of those in the USPGA Tour, 4 Masters Tournaments, 2 British Opens. He is a native of Latrobe, PA. He is a father of a breast cancer survivor and someone who has been diagnosed with prostate cancer himself a few years ago.

Many of us tried to persuade Arnie Palmer to run for Governor. I am just glad no one has tried to persuade him to run for Senator, at least not my seat. [Laughter.]

We are delighted to have you here, Mr. Palmer, and the floor is yours.

Mr. PALMER. Thank you, Senator. I had a speech here that was going to last about 1½ hours, but I saw I was only allowed 3 to 4 minutes, so I will make it very quick.

I am not an expert in cancer. I have had. I know how it feels. And I have very strongly felt that we have people, doctors, and researchers. And if you gentlemen can find the moneys to fund those researchers, we can really prevent a lot of the cancers that are happening before they happen.

I have a lot of things here. I was going to talk about how I found out about cancer and how I found out I had it. And you know about those things. But we talk about PSA and we talk about breast cancer and all the cancers—and we are together and we want this to be cured. We want it to be cured before it happens. And I think that that is possible, with research.

My purpose here is more not to tell you about cancer and not to tell you that what I know about it, but to call it to the attention of the American people. And if I can do that, then I will feel like I have really helped.

I was taking a physical. And I have been taking physicals for 35 years. And the doctors have been fantastic. And at one point, about 2½ years ago, they said that my PSA was rising. Well, let me just

say something about PSA's. I went to the Mayo Clinic to be operated on for prostate cancer. And the doctor told me the night before he operated on me that if it had not been for the PSA, they would not be operating on me that next morning, simply because the digital testing was not satisfactory and they would have not known that I had cancer without PSA testing. And, of course, that led to further screening and a final operation.

So I cannot get into the facts about bombers and all the things, the wars, and all the things that have happened. But I have a lot of friends that have had cancer, including a daughter. And I will do whatever I have to do to call attention to research and further development for the cure of cancers—and I would like to say that before the fact.

PREPARED STATEMENT

And I have been told by doctors who I have talked to that that is very possible, with the dollars for research. And what can happen is something that I would just like to see it happen.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF ARNOLD PALMER

Mr. Chairman and Members of the Committee, it is an honor for me to testify today before this group. I want to personally thank you for your attention to the topic of cancer and your support for research that can save the lives of literally millions of people.

I consider myself a direct beneficiary of progress made in research to date. Just a few short months ago, when I arrived from Florida for the PGA Tour Player Awards Dinner in California, I had a message to call my wife, Winnie, who is here with me today When I heard Winnie's voice, I knew right away—the doctor had diagnosed me with prostate cancer.

Five days later I was operated on at the Mayo Clinic. My surgery coincided with the first round of the Bob Hope Chrysler Classic—a tournament I won five times over the years, most recently in 1973. From the moment of diagnosis, I was determined to defeat this challenge the same way I had won tournaments in the past—facing the challenge head on.

While I am not a medical man, I want men nationwide to understand that prostate cancer is not a death sentence. It's not the end of life—not even the end of golf. And research truly is the key. People need to understand the possibilities of having cancer and the great possibility of cures for cancer.

I am living proof. For a year and a half before I was diagnosed, I knew I had a high level of risk for prostate cancer because of a simple blood test that checks for a protein that is an indicator of the disease. This test called a PSA—Prostate Specific Antigen—is a recent research discovery that can alert men that they are at risk for this deadly disease. My doctor caught my cancer early because of better detection methods—methods that were not available to men just a few short years ago.

But this test is not perfect. An elevated PSA may mean cancer is growing, or it may not be significant at all. In fact, my doctors monitored my PSA level for several months, and took 12 biopsies before diagnosing me with prostate cancer. Clearly, we need more research to give doctors better detection tools. And once cancer is detected, we need more research to help us better understand which men are at risk of dying from prostate cancer and which may not need treatment at all.

Prostate cancer is now the most common cancer in American men. This year alone, over 200,000 new cases of prostate cancer will be diagnosed, and 42,000 men will die. Current studies show that prostate cancer is found mainly in men over age 55, and it is more common in black men than in white men. But doctors cannot explain why one man gets prostate cancer and another does not.

Thanks to important research conducted around the country, men today have better chances of having this disease detected and treated than ever before. The death rates from the disease are already going down.

But that is just the start. Not enough is known about prostate cancer. More funding for cancer research is desperately needed to determine which treatments are best for older and younger men and men in "different stages" of the disease, and to identity new drugs to control or prevent prostate and other types of cancers.

Now, I am not interested in being a hero over this sort of thing. But my daughter is a breast cancer survivor, and as you are well aware, a cure for prostate cancer may come from research being conducted in any number of other related areas. If I can help raise awareness that discoveries in cancer research are and will continue to improve detection methods, treatment options and the general quality of life for men, women, and children, I am happy to do that. And I want to join in with the other witnesses here today to say that we are only part of the way there. I am not here today to pit one cancer against another, but to ask you to provide increased funding for the whole cancer program.

As you might guess after being operated on and resting for several weeks, I was real anxious to return to the golf course. And I am happy to report that just 42 days after my surgery, I swung my first golf club. Two short months after surgery I competed in my own Bay Hill Invitational. And as I set out to do from the start, on April 9, I played my 43rd consecutive Masters.

I have always felt that on the golf course the key to success is preparation and persistence plus a little luck. This is as true of cancer research as it is of golf. You have in your hands a chance to support more research and more clinical trials that will increase what we know about the disease and save millions of lives. Increased funding for all cancer research is truly the key, and I urge you to provide it.

CANCER SURVIVOR

Senator SPECTER. Well, thank you very much, Mr. Palmer. Your presence here today is very significant. Americans pay particular attention to our heroes. And when it comes from Arnie Palmer, a lot of people will listen to it. So we thank you for joining us.

Mr. PALMER. Well, if you saw the mail that I received, you would not believe it.

Senator SPECTER. No; I would believe it.

Mr. PALMER. It was fantastic. I had one that I will relate to you. This is a little off the subject, but it is on the subject. I had a letter from an older man. And he said that he had gone through the same thing that I had and that he was doing very well and he was playing golf again. And he said that the only thing that he had noticed was that his sex life was not the same as it was before. He said, but it is good enough. He says, it is not bad for an 88-year-old. [Laughter.]

Senator SPECTER. I think probably Mr. Palmer only you could get away with that. [Laughter.]

SUMMARY STATEMENT OF AMY LANGER

Now I want to turn to Ms. Amy Langer, executive director of the National Alliance of Breast Cancer Organizations. She is a 12-year breast cancer survivor and serves as a lay member of the Board of Scientific Advisers of the National Cancer Institute. We welcome you here, Ms. Langer, and the floor is yours.

Ms. LANGER. Thank you very much, Mr. Chairman, for your attention to this issue, and for the actions we are very hopeful you will take.

You have started my remarks for me. I am a 12-year breast cancer survivor, and it is my privilege to appear here before you with these expert colleagues and also to introduce Toni Shaheen, a fellow breast cancer survivor who is here today to speak from the heart.

As I am sure you know, usually my role is limited to breast cancer issues, but today those issues form a part of a larger problem that you have the tools to repair. The many mysteries yet to be unraveled about how cancer works and how it chooses its enemies are exemplified by breast cancer, a single disease among hundreds of cancers but the most common form of cancer in women in this country.

Because of America's familiarity with and fear of this disease, when women become breast cancer patients they are astonished that many vast questions remain unanswered, among them how soon will we know how to prevent breast cancer? So far, prevention research is still in progress, stalled, undernourished, or the source of conflicting information.

When will we have true early detection? We cannot yet diagnose breast cancer cells gone wrong until they cluster in billions, forming masses big enough to image but also to spread and kill.

When can we design the right treatment for each patient? As good as many breast cancer treatments are, we still cannot predict which patients should receive what treatments or how much of them, so that thousands of women are routinely overtreated with drugs they do not need, and others live unprotected, their cancers ready to resume control.

And can we ever promise a certain cure? Although an increasing portion of breast cancer survivors remain cancer free, physicians cannot honestly reassure us that we can take a deep breath, have our families, make our plans, smell the roses without the constant counterpoint of cancer that could return.

You have heard today what I feel, too. We need a shift in national values, a reaffirmation and an unwavering commitment to bring resources to the fight against breast cancer, and we need increased funding for basic and clinical research and all cancers, and a plan to prioritize transitional activities that will have an immediate impact on prevention and treatment.

We need a scientific environment that attracts the best minds and nurtures their explorations. We need science to be responsive to priorities of cancer patients and survivors, their needs, perceptions, hopes, and fears.

Ms. Shaheen captures this paradox, a strong and admirable woman who is cancer-free because of advances in treatment but not worry-free, because research has not advanced enough. I am honored to introduce Toni Shaheen.

SUMMARY STATEMENT OF TONI SHAHEEN

Senator SPECTER. We welcome you here, Ms. Shaheen. You, too, are a breast cancer survivor, cancer-free, according to the information provided to me, for 6 months after and during a lumpectomy, lymph node removal, radiation and hormonal treatments, and subsequently stem cell transplants. Quite a sequence.

Unfortunately, according to what I have learned here you lost your identical twin sister, Regina, through breast cancer in 1966, and you are an outstanding advocate, and we welcome you here and look forward to your testimony.

Ms. SHAHEEN. It is an honor for me to testify here today with the other supporters of Friends of Cancer Research.

The best way for me to express the importance of cancer research is to share with you my family's experience with cancer. My first encounter with this disease began in 1989 when my identical twin sister Jeannie was diagnosed with breast cancer. She was 36 years old. Her initial treatment at the time was a lumpectomy followed by radiation and mild chemotherapy.

Just 2 years later, in 1991 I was also diagnosed with breast cancer, but in those 2 years clinical research had opened up new protocols for women diagnosed with breast cancer. I had a lumpectomy and lymph node removal followed by radiation without chemotherapy. Subsequent to the radiation treatment I received various hormonal treatments.

About the same time my sister, Jeannie, found a second tumor in her other breast, and she had another lumpectomy, lymph node removal and radiation. Chemotherapy followed, and over the course of the next 4½ years Jeannie was continually on and off chemotherapy.

In October 1994 on the advice of her doctors, Jeannie began an even more aggressive approach, a regimen of high dosage chemotherapy and a bone marrow transplant.

Being twins, my sister and I were very close, and I found it devastating to see her undergo the effects of the high dosage chemotherapy. It was evident to me that research was needed to make lifesaving treatments less toxic and painful for patients.

At that time, I told my husband that I would never have that done, that I am not as strong as Jeannie. In January 1996 however, we realized that various hormonal treatments I had been taking were not effective, and my doctor had recommended more aggressive therapy for me also. My options were to begin traditional chemotherapy regimen or to begin high dose chemotherapy combined with a new treatment, a peripheral stem cell transplant, which was a much less risky procedure than a bone marrow transplant.

Having seen what my twin sister had gone through, I did not think I could do the high dosage chemotherapy, or high dosage treatment. With her encouragement and support, however, I started my preparation for the high dosage chemotherapy in February 1996. I was still in the early stages of my treatment when Jeannie died in May 1996. She was only 42 years old.

In the summer of 1996 I began the stem cell harvesting process. This was followed by three different cycles of high dosage chemotherapy treatment and the stem cell transplants. I was released from Columbia Presbyterian Hospital following my third cycle of high dosage chemotherapy on November 8, 1996.

To my surprise the stem cell transplant program was not nearly as harsh for me as the bone marrow transplant had been for my sister just 2 years earlier. Within those 2 short years, the advances made in breast cancer treatment, which were made possible by cancer research, meant a great deal to me.

I rebounded quicker after the stem cell transplant and was home sooner from the hospital than would have been possible with a bone marrow transplant, but the treatment was still devastating to my physical well-being. I look forward to the day when cancer

treatment will not subject a person to the rigors of chemotherapy, a day that I truly hope is not too distant in the future.

I have a 32-year-old sister and a 14-year-old daughter, both of whom have seen what my twin sister and I have gone through, and I would love to live to see the day when advances in cancer treatment reach the point that neither my sister nor daughter will ever have to deal with this disease.

I remain optimistic that with continued research if I ever have a relapse there will be something new for me. I am presently taking a drug which has had some success in treating osteoporosis and which may also be beneficial in preventing bone metastasis. This drug and many other new drugs presently being tested were not available for my sister just a few short years ago, so as you can see we are moving forward, but it can never be too fast for me and for others like me.

Being able to testify before you on this particular day is very special for me, for tomorrow is the first anniversary of the day we laid my sister to rest. It is not easy, losing someone you love to this disease, and it is especially difficult for my parents.

PREPARED STATEMENT

I do not want my family to have to go through this again, and that is why I will be speaking out for the need for cancer research for as long as it takes to conquer this disease. I believe that we are at a point in time that we are very close to conquering this disease. That is why I am asking the Senate to at the very least double the budget for cancer research over the next 5 years.

Thank you.

Senator SPECTER. Thank you very much, Ms. Shaheen, for that very moving testimony.

[The statement follows:]

PREPARED STATEMENT OF TONI M. SHAHEEN

It is an honor for me to testify here today. The best way for me to express the importance of cancer research is to share with you my family's experiences with cancer. My first encounter with this disease began in 1989 when my identical twin sister, Jeanne, was diagnosed with breast cancer. She was 36 years old. Her initial treatment at that time was a lumpectomy, followed by radiation and mild chemotherapy.

Just two years later, in 1991, I was also diagnosed with breast cancer, but in those 2 years, clinical research had opened up new protocols for women diagnosed with breast cancer. I had a lumpectomy and lymph node removal, followed by radiation, without chemotherapy. Subsequent to the radiation treatment, I received various hormonal treatments.

At about the same time, my sister, Jeanne, found a second tumor in her other breast. She had another lumpectomy, lymph node removal and radiation. Chemotherapy followed, and over the course of the next four and one half years Jeanne was continually on and off chemotherapy. In October 1994 on the advice of her doctors Jeanne began an even more aggressive approach, a regimen of high dosage chemotherapy and a bone marrow transplant.

Being twins, my sister and I were very close, and I found it devastating to see her undergoing the effects of the high dosage chemotherapy treatment It was evident to me that research was needed to make life saving treatments less toxic and painful for patients. At that time I told my husband: "I will never have that done. I am not as strong as Jeanne."

In January 1996, however, we realized that the various hormonal treatments I had been taking were not effective. My doctor recommended more aggressive therapy for me also.

My options were to begin a traditional chemotherapy regimen, or to begin high dosage chemotherapy with a new treatment—a peripheral stem cell transplant, which was a much less risky procedure than a bone marrow transplant. Having seen what my twin sister had gone through I did not think I could do the high dosage treatment. With her encouragement and support, however, I started my preparation for the high dosage chemotherapy in February 1996. I was still in the early stages of my treatment when Jeanne died in May 1996. She was only 42 years old.

In the summer of 1961 began the stem cell harvesting process. This was followed by three different cycles of high dosage chemotherapy treatment and stem cell transplants. I was released from Columbia Presbyterian Hospital following my third cycle of high dosage chemotherapy on November 8, 1996. To my surprise, the stem cell transplant program was not nearly as harsh for me as the bone marrow transplant had been for my sister just two years earlier. Within those two short years, the advances made in breast cancer treatment, which were made possible by cancer research, meant a great deal to me. I rebounded quicker after the stem cell transplant, and was home sooner from the hospital, than would have been possible with a bone marrow transplant. But the treatment was still devastating to my physical well being. I look forward to the day when cancer treatment will not subject a person to the rigors of chemotherapy, a day that I truly hope is not too distant in the future. I have a 31 year old sister, and a fourteen year old daughter, both of whom have seen what my twin sister and I have gone through. I would love to live to see the day when advances in cancer treatment reach the point that neither my sister nor daughter will ever have to deal with this disease.

I remain optimistic that with continued research, if I ever have a relapse there will be something new for me. I am presently taking a drug which has had some success in treating osteoporosis, and which may also be beneficial in preventing bone metastasis. This drug, and many other new drugs presently being tested, were not available for my sister just a few short years ago. So, as you can see, we are moving forward, but it can never be too fast for me, and for others like me.

Being able to testify before you on this particular day is very special to me, for tomorrow is the first anniversary of the day we laid my sister to rest. It is not easy losing someone you love to this disease, and it was especially difficult for my parents. I do not want my family to have to go though this again. That is why I will be speaking out on the need for cancer research for as long as it takes to conquer this disease.

SUMMARY STATEMENT OF DR. KEITH BLACK

Senator SPECTER. We turn now to Dr. Keith Black, professor in the Department of Surgery, Division of Neurosurgery at the University of California at Los Angeles. He has served as UCLA's head of neurosurgical oncology. He is now codirector of the comprehensive brain tumor program on the Brain Committee for the Southwest Oncology Group and National Clinical Research Group, and he is a member of the Board of Scientific Councils for the National Institute of Neurological Disorders and Stroke at NIH.

Welcome, Dr. Black. We look forward to your testimony.

Dr. BLACK. Thank you, Senator Specter, distinguished Senators. Let me first express my gratitude for the opportunity to testify before your prestigious committee.

As a physician specializing in the treatment of cancer I know of no disease that can strike a patient more tragically than cancer. However, I can tell you with absolute certainty that the medical and scientific communities are on the verge of major breakthroughs in our ability to control this dreadful disease.

Unfortunately, I can also tell you with absolute certainty that tens of thousands of Americans will die because critical research remains unfunded, slowing the development of new lifesaving treatments by years.

Never in the history of mankind have we had such an opportunity in medicine. We are literally witnessing an explosion in our

understanding of cancer. Every week, new genes which regulate the process of cancer are being discovered.

We now have an incredible knowledge of what regulates cancer, what makes a cancer cell a cancer cell, what cancer cells need to thrive, what signals cancer cells to self-destruct and die. We also have a remarkable ability now to manipulate genes within cells, to actually direct cells to do what we want them to do.

This combination of increased knowledge and powerful new techniques to manipulate cells provides opportunities we could only dream of just a few years ago. Let me give you just one example of how we are now using this new knowledge.

I specialize in the treatment of malignant brain tumors. The most common brain tumor, the malignant glioma, is responsible for 15,000 deaths in the United States each year. The median survival time from diagnosis to death without treatment is 12 to 16 weeks. With conventional cancer treatments, including surgery, radiation therapy, and chemotherapy, the median survival is 38 weeks.

Because of new research findings we now know that malignant brain tumors are able to grow and escape destruction by our immune system because they release a protein that turns off the immune system. This protein is called TGF beta.

We were able to take tumor cells and genetically engineer the cells in our laboratory so that they could no longer make TGF beta, thereby uncloaking these tumor cells to the immune system.

We showed in laboratory experiments that rats with untreated brain tumors all died within 25 days. However, rats treated with the genetically modified vaccine all survived. Rats given the vaccine were able to develop immunity against their cancers and completely eradicate the tumors.

Based on these studies, we now have a clinical trial where tumor cells are removed during surgery, genetically engineered, then reinjected into patients with brain cancer. Some 6 weeks ago, we treated our first patient with the vaccine, a 36-year-old man with three children whose brain tumor was growing despite two surgeries and radiation therapy. His tumor appears to have stabilized now after the first vaccine injection.

This is just one of literally hundreds of novel approaches now being developed for the treatment of cancer. When plans to start this clinical trial were first announced a year ago, my office received over 2,000 phone calls, faxes and e-mails from desperate patients hoping to participate in this trial because they had failed conventional treatments.

Due in part to limited funding the trial could start only 6 weeks ago, I would venture that most of the patients who called my office have now died. Even with the study underway, only 12 patients can be entered into the trial out of potentially thousands who could be treated. This is the painful reality, knowing that our patients will die because our country has not made cancer research a higher priority.

PREPARED STATEMENT

Our national budget for cancer research should be twice current funding levels. We no longer wonder if we will find a cure for cancer, but when. America has an incredible opportunity to conquer

this deadly disease. Increasing funds for cancer research now could accelerate this process by years, saving tens of thousands of American lives.

Thank you.

Senator SPECTER. Thank you very much, Dr. Black. I will have a question for you when the dialog begins.

[The statement follows:]

PREPARED STATEMENT OF KEITH L. BLACK, M.D.

Senator Specter and distinguished Senators, let me first express my gratitude for the opportunity to testify before your prestigious committee.

As a physician specializing in the treatment of cancer, I have had to watch hundreds of patients die from cancer because current treatments have limited benefit. I know of no disease that can strike a patient more tragically than cancer. However, I can tell you with absolute certainty that the medical and scientific community are on the verge of major breakthroughs in our ability to control this dreadful disease. Unfortunately, I can also tell you with absolute certainty that tens of thousands of Americans will die because critical research remains unfunded or underfunded, slowing the development of new lifesaving treatments by years.

Never in the history of mankind have we had such an opportunity in medicine. We are literally witnessing an explosion in our understanding of cancer. Every week, new genes which regulate the process of cancer are being discovered. We now have an incredible knowledge of cancer, what makes a cancer cell a cancer cell, what cancer cells need to thrive, and what signals cancer cells to self-destruct and die. With more research our knowledge will be even greater. We also now have the remarkable ability to manipulate genes within cells, to actually direct cells to do what he want them to do. This process, one of many new treatments we now have, is called Gene Therapy.

This combination of increased knowledge and powerful new techniques to manipulate cells provides opportunities we could only dream of just 5 years ago. Let me give you just one example of how we are now using this new knowledge: I specialize in the treatment of malignant brain tumors. The most common brain tumor, the malignant glioma is responsible for 15,000 deaths in the United States each year. The median survival time from diagnosis to death without treatment is 12 to 16 weeks. With conventional cancer treatments, including surgery, radiation, and chemotherapy, the median survival is 38 weeks.

Because of new research findings, we now know that malignant brain tumors are able to grow in the brain and escape destruction by our immune system because they release a protein into the brain which suppresses or "turns off" the immune system. This protein is called Transforming Growth Factor Beta, (TGFb).

We are able to take tumor cells and genetically engineer them in our lab so that they can no longer make TGFb, thereby uncloaking these tumor cells to the immune system. We've shown in lab experiments that rats with untreated brain tumors all died. However, rats with brain tumors treated with the genetically modified vaccine all survived. We found that rats given the vaccine were able to develop immunity against these tumors and their brain cancer was completely eradicated. Based on these studies, we now have a clinical trial where tumor cells are removed from patients during surgery, genetically engineered to make a cancer vaccine, and then reinjected into patients with brain cancer.

Six weeks we treated the first patient with the vaccine, a 36-year-old man with three young children whose brain tumor was growing, despite two brain surgeries and radiation therapy. His tumor appeared to have stabilized after his first vaccine injection.

This is just one of literally hundreds of novel approaches now under development for the treatment of cancer. When plans to start this experimental trial were first announced a year ago, my office received over 2,000 phone calls, faxes, and e-mails from desperate patients hoping to participate in this trial because they had failed conventional treatments. Due partially to limited funding the trial started just 6 weeks ago. I would venture that most of the patients who called my office have now died. Even with the study underway, only 12 patients can be entered into the trial, out of potentially thousands who could be treated. This is the most painful reality, knowing that our patients will die because our country has not made cancer research a higher priority.

To continue rapid progress requires increased funding for not only basic research to continue our understanding of cancer, but also for the translation of research into

clinical trials for patient care. Our national budget for cancer research should be at least twice the current funding levels. We no longer wonder if we will find a cure for cancer but when. America has an incredible opportunity to conquer this deadly disease. Increasing funds for cancer research could now accelerate by years the development of new and more effective treatments for cancer, literally saving tens of thousands of American lives.

Thank you.

SUMMARY STATEMENT OF DR. CHARLES A. COLTMAN, JR.

Senator SPECTER. We now turn to our final witness, Dr. Charles Coltman, president and CEO of the Cancer Therapy and Research Foundation of Southwest Texas, as well as director of the San Antonio Cancer Institute and chairman of the Southwest Oncology Group.

He is a graduate of the University of Pittsburgh School of Medicine, and now is a professor at the University of Texas Health Science Center at San Antonio. We welcome you here, Dr. Coltman, and look forward to your testimony.

Dr. COLTMAN. Senator Specter, honorable members of the committee, it is my high privilege to speak on behalf of the subject near and dear to my heart. I have been in the care of patients with cancer and in cancer clinical trials for the past 34 years.

I chair the Southwest Oncology Group, the largest National Cancer Institute-supported clinical cancer research organization in the country. In 1996, this group enrolled 6,359 patients to therapeutic cancer research clinical trials from all 50 States and completed randomization of 18,867 normal, healthy men into an intergroup prostate cancer prevention trial.

Clinical trials are always designed to improve the outcomes of patients with cancer. However, only 2 to 3 percent of all eligible patients in this country are treated on these cutting-edge clinical trials. It is clear that this number must increase dramatically in order for us to be able to translate the monumental advances emanating from the basic research laboratories into effective diagnosis, prevention and treatment strategies for patients with and at high risk for cancer.

This low accrual is related to multiple factors. First, managed care has a negative impact related to its refusal to reimburse for the clinical care aspects of patients on cancer clinical trials. During my presentation to the President's cancer panel in San Antonio in September I shared three thoughts as to what the panel should be asking as they pursued the question of managed care's role in the war on cancer:

Should managed care bear a portion of the cost of clinical research as a form of R&D?

What State or Federal legislation is needed to assure that managed care patients have access to cancer clinical research?

Will there be any future for cancer clinical research when the managed care tidal wave finally reaches Chicago and New York?

The NCI-Department of Defense and the NCI-Department of Veterans Affairs interagency agreements are superb models of what needs to be done for the rest of managed care.

Second, the Southwest Oncology Group is outstripping its financial support at its current rate of accrual. Even if the managed care problem were resolved, there must be more money to support clini-

cal research to translate this plethora of science into patients with cancer.

As director of the San Antonio Cancer Institute, an NCI-designated comprehensive cancer center in San Antonio, recently one of my investigators had an astonishingly productive breast cancer program project grant which received a priority score of one point below the line. While this grant will undoubtedly be funded by exception, it is representative of a nationwide problem of insufficient funds to support truly outstanding research.

The following is a quote from another cancer director who, like me, is also cooperative group chairman:

BREAKTHROUGH

We never know where the next breakthrough will come from. Every time we discover a new gene we also have a new marker for early diagnosis, a new predictor of response to therapy, a new target for chemo prevention as well as for cancer treatment.

Every discovery in a cancer center provides fuel for the cooperative group program and requires affirmation in large clinical trials. Thus, the universe of cancer research is a continuum, where improved funding for any of it impacts all of it, and improved funding for all of it will hasten the pace of discovery throughout.

PREPARED STATEMENT

Finally, I would like to paraphrase a futurist that I recently heard: The present is obsolete. The future has already been discovered in the laboratories of molecular biologists throughout this country. We must search among those discoveries for the keys to cancer cures.

We are confronted with insurmountable opportunities. These new tools will change the rules of the game. We should not manage change. We should love change. We should make change our best friend, as all those involved in cancer research and Congress must do every day.

Thank you for your attention.

[The statement follows:]

PREPARED STATEMENT OF CHARLES A. COLTMAN, JR., M.D.

Senator Specter, honorable Members of the Committee, is my high privilege to speak on behalf of a subject near and dear to my heart. I have been involved in the care of patients with cancer and in cancer clinical trials for the past 34 years.

I chair the Southwest Oncology Group, the largest National Cancer Institute-supported cancer clinical research organization. In 1996, this Group enrolled 6,359 patients to therapeutic cancer clinical trials from all 50 states (Appendix 1), and completed the randomization of 18,867 normal, healthy men into the intergroup Prostate Cancer Prevention Trial.

Cancer clinical trials are always designed to improve the outcomes of cancer patients. However, only 2 to 3 percent of all eligible cancer patients in this country are treated on these cutting edge trials. It is clear that this number must increase dramatically in order for us to be able to translate the monumentary advances emanating from the basic cancer research laboratories into effective diagnosis, prevention and treatment strategies for patients with and at high risk for cancer.

This low accrual is related to multiple factors: First, managed care has had a negative impact related to its refusal to reimburse for the clinical care aspects of patients on cancer clinical trials. During my presentation to the President's Cancer Panel in San Antonio in September (Appendix 2), I shared three thoughts as to what the Panel should be asking as they pursue the question of "Managed Care's Role in the War on Cancer."

"Should managed care bear a portion of the costs of clinical research as a form of R&D?"

"What State or Federal legislation is needed to assure that managed care patients have access to cancer clinical research?"

"Will there be any future for cancer clinical research when the managed care tidal wave finally reaches Chicago and New York?"

The NCI-Department of Defense and the NCI-Department of Veterans Affairs Interagency Agreements are superb models of what needs to be done for the rest of managed care.

Second, the Southwest Oncology Group is outstripping its financial support at its current rate of accrual. Even if the managed care problem was resolved, there must be more money to support clinical research to translate this plethora of science to patients with cancer.

I am also Director of the San Antonio Cancer Institute, a National Cancer Institute-designated Comprehensive Cancer Center (Appendix 3). A recent astonishingly productive Breast Cancer Program Project Grant received a priority score one point below the pay line. While this grant will undoubtedly be funded by exception, it is representative of a nationwide problem of insufficient funds to support truly outstanding research.

The following quote is from another Cancer Center Director, Dr. Richard L. Schilsky:

"We never know where the next breakthrough will come from. Every time eve discover a new gene, we also have a new marker for early diagnosis, a new predictor of response to therapy, a new target for chemoprevention, as well as for cancer treatment. Every discovery in a Cancer Center provides fuel for the Cooperative Group program, and requires affirmation in large clinical trials. Thus, the universe of cancer research is a continuum, (where) improved funding for any of it, impacts all of it, and improved funding for all of it will hasten the pace of discovery throughout."

Finally, I would like to paraphrase a futurist that I recently heard:

"The present is obsolete."

"The future has already been discovered" in the laboratories of molecular biologists throughout this country! We must search among those discoveries for the keys to cancer cures.

"We are confronted with insurmountable opportunities!"

"These new tools will change the rules of the game!"

"We should not manage change, we should love change and make change our best friend", as all those involved in cancer research and the Congress must do every day.—Don Burrus.

Thank you for your attention.

TESTING

Senator SPECTER. Thank you very much, Dr. Coltman.

The issue of testing is so very, very important. And you have highlighted that, Mr. Palmer, with your comment about the PSA. And we are trying to work hard to popularize testing on all lines as a method of prevention.

Senator Dole had wanted to be here today, because he recently had an operation for prostate cancer. And he has a way of characterizing the situation, which is really unique. He came back as majority leader at a Republican luncheon, where we had a caucus, announce his successful operation and he said it strikes one man out of nine, so you eight guys are safe. [Laughter.]

And he turned to Senator Stevens, Ted Stevens, who had just had an operation for prostate cancer, he said, you eight are safe, and he turned over to Strom and he said, and Strom is too old to get cancer anyway. [Laughter.]

But I thought that his focus in his own lighthearted way was very effective. And the testing is so very vital. And I think your voice today is a very important one on that.

Dr. Black, let me turn to you in the very limited time we have. There are lots of questions I have for everybody, but I am especially concerned with the research you are doing on brain cancer.

There is a fine line as to what is not malignant and what is, as I have had some occasion to take a look at the pathology. It is tough to figure some of that out as to what the doctors classify as No. 1 and No. 2 and different categories. But I am concerned to hear about the lack of money for the clinical application.

Now, where does that fit in to what we can do? How can this subcommittee and then, ultimately, the Congress help on the funding for those kinds of trials, those kinds of experimental operations? You do not have enough money to do it. That does not quite fit into the research. How can we help you?

Dr. BLACK. Well, Senator, I think it is important to increase funding both for basic research to increase our knowledge of cancer, but it is also critical to increase funding for what we call translational research—bringing the research from the laboratory bench to the bedside, so that we can carry these technologies very rapidly into clinical care. This is a very critical issue: How do we get research from the laboratory into our patient armamentarium?

Senator SPECTER. Well, we will pursue that. Dr. Klausner will be in on Tuesday when we have the NIH hearings. And I now know a new term, "translational research."

In my limited time, I want to come to you, Dr. Coltman, on your comment about managed health care. That is a subject which is being very, very closely followed by the Congress now. And we legislated against drive-by deliveries last year. And there is some legislation up as to drive-by mastectomies. And pretty soon we may legislate on everything. There may not be a need for any medical judgments. We may handle it all right in the Congress. And I do say that facetiously, because we really do not want to micromanage or meddle.

But on managed care, we are looking at a lot of ways to try to make these medical decisions not exclusively financial decisions. And you say they are not bearing their fair share in cancer clinical trials. I would like a brief explanation today as to what you think we ought to do on that subject, if we should legislate, and if so, how, and perhaps a followup at a later time. Because we are going to be getting into that field and we want to do it right. We want to do it in a very limited way.

But what is the essence of your thought as to how Congress might act?

Dr. COLTMAN. Let me just start by saying that managed care is not a totally evil organization. They do a lot of good things. But the fact is that all of their contracts have built into them that they will not pay for research, and that includes clinical research. So any time you take a laboratory tool and take it into clinical research to use it on patients, which of course is the only way you can validate the concept from the laboratory, it requires patients.

They repeatedly refuse to pay for those clinical care aspects—that is, the hospitalization that might be necessary in a phase 1 or 2 clinical trial—when a patient is getting a new agent for the first time. And that is the major impediment. It goes on to phase 3 clinical trials—large clinical trials that impact on all sorts of malignant diseases. The accrual to those clinical trials is impeded by that particular aspect of refusal to pay for quote, "research." It is not laboratory research, it is research involving humans.

Senator SPECTER. Well, Dr. Coltman, we would like your advice as to how we might legislate in the field, if you think that would be wise.

We have questions for Ms. Langer and Ms. Shaheen, but we just do not have time to put them to you.

One final question, where is the touch of your Southern accent from, Dr. Coffey?

Dr. COFFEY. Bristol, TN-VA, a State-line city.

Senator SPECTER. Senator Harkin.

Senator HARKIN. I want to thank, first of all, the panel for being here and for your testimonies.

I want to pick up in one area. I do not know who to direct this to. Maybe Dr. Coffey. I do not know. But also for the benefit of Dr. Klausner, who will be here again next week. Just listening here and in some experiences that I have had in the past, and not only experiences, but being on this committee for a number of years, I am concerned that there is evolving, I think, what I would call a disturbing and I think somewhat inaccurate perception that the process of new discovery, Dr. Black, is a one-way street. It starts in the laboratory and it goes to the bedside for clinical trials.

Now, Dr. Coltman just touched on that. And that is what got me thinking about this. However, I understand a lot of discoveries are made by clinical scientists who are observing diseases out there.

Dr. BLACK. Absolutely.

Senator HARKIN. And some of these are no less profound than what is happening in the laboratory. And yet, to move this kind of research from the clinical arena to the laboratory bench seems not to be working too well. I guess what I would say is, as it was put to me one time, the path to discovery is multifaceted. And it really is a two-way street between the laboratory and the bedside, and the bedside to laboratory.

And yet, this kind of highly innovative type of research does not seem to compete in this present environment that we have. I do not know how we move in that direction. And that is something I wanted to ask Dr. Klausner next week, and perhaps we will talk about it again. And just listening to this, I am sorry to have to say this, but listening to a couple of you talking about going from the laboratory to the clinic—well, wait, there is another pathway to this, too, and that is from the clinical to the laboratory also.

Now, Dr. Klausner just testified—I just read—he said that only 2 percent of cancer patients are in clinical trials. Now, that is from the laboratory to the bedside. That is woefully inadequate. Then how about the other end? How about the doctors who are out there, Dr. Coltman, that you are talking about, and getting that back to the laboratory for them to look at it?

That does not seem to be working too well. So I just throw that question out there for digestion.

Dr. COFFEY. I would like to comment if you would allow me.

Senator HARKIN. Yes; Dr. Coffey.

Dr. COFFEY. Special projects on research excellence, called SPORE grants, were put forth by Congress toward the NCI to address this very problem. And in those research operations, you have to have both the clinical and basic plan the grant, plan the

experiments, in a two-way street. These have been highly successful. And Dr. Klausner can tell you about it.

Unfortunately, let me just give you one example. In the prostate, many, several dozens of these grants came in. They could only fund two of them in the first go-around. One of those SPORE grants from Harvard had three Academy of Science members on it that did not get funded. The one from M.D. Anderson, which had the winner of the George Bush Award, did not get funded. The Mayo Clinic did not. These were beautiful grants. And each one of them was the size of a New York telephone directory.

So when I hear statements made that all the good grants and ideas are being funded, they are not. And in this area of SPORE's, just what you are talking about is happening and it is working.

Senator HARKIN. Did you have something, Mr. Palmer?

Mr. PALMER. I did.

Senator HARKIN. I think Dr. Coltman wanted to respond first.

Dr. COLTMAN. Senator Harkin, there is absolutely no question that this is a two-way street. We are emphasizing this plethora of science that is standing there, waiting to be translated into patients. And we have a critical lack of funding to support that translational research into patients. But there is no question that the clinical scientists of this country, of which I represent a diminishing few, are engaged in feeding back and interacting at cancer centers throughout this country.

The interaction between the clinicians and the basic science is the essence of centeredness of the National Cancer Institute-supported cancer centers. And it happens every day. We do not happen to be focusing on that today, but it is a critical aspect.

But in order to assure the supply of young scientists, we must have a training program available and grant support to support the physician-scientists, who are out there, the next generation of Chuck Coltmans, who are prepared to take the ideas in both directions. And we need support for those young clinical investigators.

Senator HARKIN. Mr. Palmer?

Mr. PALMER. I was only going to bring up the fact that in the case of prostate cancer, Medicare, for an example, does not cover a PSA until it is diagnosed.

Senator HARKIN. I did not know that.

Mr. PALMER. And a lot of the insurance companies will not cover PSA's under their medical insurance coverage.

Senator HARKIN. That is crazy. I was not aware of that. That is ridiculous.

Senator SPECTER. Well, along the same line, on your time, Senator Harkin, since it is gone——

Senator HARKIN. I can see my red light is up.

Senator SPECTER. On your time, since it is gone, Medicare does not cover PSA's either.

Senator HARKIN. That is what he just said.

Senator SPECTER. Oh, I see.

Senator HARKIN. He said Medicare and the insurance companies.

Senator SPECTER. OK, and insurance. Or cholesterol testing. When you see the kind of funds we have to allocate, it is just, I think, shocking that you sort of throw away the people on Medi-

care. Never mind. Too old. No cholesterol testing. No PSA. We really have to change that. And we will.

Senator HARKIN. On that last question I asked, I really want to pursue that. If you have any other, Dr. Coltman, Dr. Coffey and Dr. Klausner, next week when we come up, I would like to kind of delve into this a little bit more, about how we get that two-way street going a little bit better.

Senator SPECTER. Thank you very much, Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you, Dr. Black, Dr. Coltman, Ms. Langer, Ms. Sheehan, Mr. Palmer, and Dr. Coffey. I think it has been a very productive session, and we are going to do this again in Los Angeles on the 29th of May.

Thank you all. That concludes our hearing. The subcommittee will recess and reconvene at the call of the Chair.

[Whereupon, at 11:55 a.m., Wednesday, May 7, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

WINNING THE WAR ON CANCER: PROGRESS AND PROGNOSIS

THURSDAY, MAY 29, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Beverly Hills, CA

The subcommittee met at 10:18 a.m., in the Beverly Hills City Hall council chambers, Beverly Hills, CA, Hon. Arlen Specter (chairman) presiding.

Present: Senator Specter.

NONDEPARTMENTAL WITNESSES

STATEMENT OF SHERMAN BLOCK, SHERIFF, LOS ANGELES, CA

OPENING STATEMENT OF HON. ARLEN SPECTER

Senator SPECTER. We will now proceed with the hearing of the Appropriations Subcommittee on Labor, Health and Human Services, and Education. This is part two of our subcommittee's hearings on the National Cancer Act, as we celebrate the 25th anniversary of that historic legislation and the massive efforts which we have made to try to conquer cancer.

We have scheduled this hearing in Beverly Hills, quite candidly, because when Hollywood speaks, the world listens; when Washington speaks, occasionally the world snoozes. And we have an issue which requires a tremendous public focus if we are to move ahead on the war against cancer.

This is very current subject, because funding for the National Institutes of Health and the war on cancer at this moment is very much in doubt. And that has been occasioned by the fact that in the budget resolution passed last week by the U.S. Senate, the account for health services has been reduced by $100 million. And in Washington, we sometimes have double speak and sometimes triple speak and sometimes quadruple speak. But last week, it is a little hard to quantify it, and I will tell you exactly why.

The U.S. Senate passed a sense of the Senate resolution, to add $2 billion to the National Institutes of Health; this followed pronouncements by many of us on the need to increase funding for NIH.

But this is a meaningless gesture unless there is a specific offset specifying where the money is going to come from. So Senator Tom Harkin and I—Senator Harkin is my counterpart, and we work on

a bipartisan basis, and that is the only way anything ever gets done in Washington, is when Democrats and Republicans work together—Senator Tom Harkin and I introduced an amendment to add $1.1 billion to NIH, with a specific offset.

And it was a modest offset—four-tenths of 1 percent on discretionary nondefense spending. So a little bit would be taken in a lot of places to have the funding to add to the National Institutes of Health. And that amendment was defeated, 63 to 37. I thought it very important, in my capacity as chairman of the subcommittee, to lay it right on the line so that the American people would know exactly what was going on. Because there is a need for significant increases in cancer funding, and heart disease, and Alzheimer's, and many, many other very, very important areas of medical research. I did not want to see a situation prevail, where America thought there was a $2 billion increase, but it was meaningless, on a sense of the Senate resolution.

So, ladies and gentlemen, our work is cut out for us, in terms of what we must do. And this hearing takes on added significance, as we want to focus the attention of the American people on the need for funding of the National Institutes of Health.

I am personally convinced that we have the resources in the Federal budget to take care of America's needs if we establish our priorities properly. We have a Federal budget of $1.7 trillion. Now, that is a staggering, incomprehensible sum of money. If you take a large room this size, there would not be enough space to stuff $10,000 bills into this room and occupy that kind of a budget.

In the last 2 years, Senator Harkin and I consolidated or eliminated 134 programs from our subcommittee to save $1.5 billion, allowing us to put more resources into NIH and into education, which I personally consider the two top priorities in America today. And yet, the headlines of the day are troublesome. The lead story in this morning's USA Today has this headline: "$30 billion war on cancer, a bust."

And a new study is now out from Dr. John Bailar and Dr. Kevin Gornick of the University of Chicago, published in the New England Journal of Medicine, which raises real questions about the success of the war on cancer, and raising real questions about allocations of resources, as to whether it all ought to be in research, or so much in research, or in prevention, with prevention resources having increased from 5 to 10 percent. These are real issues which we are going to have to tackle, and our subcommittee will have a hearing at a very early date, to assess the most effective way to deal with this issue.

We have a very, very distinguished panel today. It has been assembled with great effort. We will give the kudos at the conclusion of the hearing, but now I want to move as promptly as possible to our very distinguished witness list.

I would like to start off with the distinguished sheriff of Los Angeles County, Mr. Sherman Block, a member of the department since 1956. He was sworn in as the 29th sheriff in 1982, having been appointed by unanimous decision of the Los Angeles County Board of Supervisors. He is now in his fourth elected term of office. He commands the largest sheriff's department in the world, supervising more than 12,000 personnel.

On a personal note, Sheriff Block and I were reminiscing about a hearing which the Judiciary Committee held, which I chaired here in Los Angeles in 1985, when we moved ahead with the armed career criminal bill, my legislation moving the Federal Government into the fight against street crime.

Sheriff Block, we welcome you here. And it is appropriate for me to say at this time that we would appreciate having statements within a 5-minute limitation. The green light will go on to start, the yellow with 1 minute remaining, and the red when time has expired. All statements will be made a part of the record. To the extent that we can stay within the time limits, it would be appreciated. If you go over, it is not like arguing in the Supreme Court of the United States, where they cut you off in midsyllable.

Sheriff Block, the floor is yours.

SUMMARY STATEMENT OF SHERMAN BLOCK

Mr. BLOCK. Thank you, Mr. Chairman. It is an honor for me to testify today. And I want to personally thank you for your attention to the topic of cancer, and your support for research that can save the lives of literally millions of people.

I am proud to testify here today, because I have survived cancer not once, but twice; 6½ years ago, my doctor, while doing a routine examination, determined that something was not quite right during a digital exam. He detected a soft spot. My PSA was not highly elevated, but a biopsy turned up prostate cancer. I was 66 at the time. And my first reaction to the word "cancer" was, am I going to die? But how could I, with a family and so much left to do?

I had surgery at USC's Norris Cancer Hospital and Research Institute. And because my cancer was detected early, I have been prostate cancer-free ever since. Having battled cancer once, 4 years ago this June, I was shocked to find a lump between my neck and left shoulder as I shaved for work one morning. The lump, which was the size of a golf ball, or perhaps even larger, turned out to be high-grade, fast-moving, non-Hodgkin's lymphoma, according to my doctor. I was stunned and somewhat devastated. I had conquered the prostate cancer at 66, but here I was at 68, and considered a high-risk patient because of my age.

The doctors told me straight out that the chemotherapy alone might kill me, but that without the chemotherapy, I would certainly die in 3 to 6 months. This time, I was certainly concerned, but not fearful. I underwent 7 months of chemotherapy. And thanks to innovations in research, I was able to tolerate the chemotherapy and actually go to work every day except for 2 during that 7-month period. New drugs greatly minimized the side effects previously caused by chemotherapy, like nausea and a susceptibility to infection, which would have prevented me from holding my position as sheriff.

As head of the Nation's largest sheriff's department for 15 years, I was very public about my cancer diagnosis, treatment, and progress from the start. As a result, the community saw the progress I was making each month, and many strangers with similar diagnoses called me for counsel and advice. They saw me on my good days and my bad days. And I felt real good about the informa-

tion I was able to share with these folks, and to help ease their concerns.

Prostate cancer, of course, is now the most common cancer among American men. This year alone, over 200,000 new cases of prostate cancer will be diagnosed and 42,000 men will die. And there will be an estimated 61,000 new cases of lymphoma in 1997. And since the early 1970's, incident rates have increased more than 80 percent. And an estimated 25,280 deaths from non-Hodgkin's lymphoma are expected in 1997; 4,800 in California alone. That is 13 fatalities per day from just one type of cancer.

There are fewer than 10 people a day who die from all homicides in California. Cancer, of course, is one of the biggest societal menaces we currently face, and we need to find the resources to put this hazard to rest.

At a recent event, I listened to a large number of women of color express their fear of getting annual checkups. Their fear was that they might find something wrong, and since they were breadwinners, they feared losing their jobs because of a cancer diagnosis. We need to increase the funding for research, and get the information out to these and other women that cancer is not a death sentence. Research has and will continue to make early detection and better treatments possible.

Like myself, thanks to research, many of these women may be able to keep their jobs once diagnosed with cancer, because of improved treatments that are gentler on our bodies.

We also need to make sure that the health care systems that many of these women and others depend on, like managed care, provide access to the most innovative treatment and trials. All Americans should have the chance to receive the best and most cutting-edge care available.

PREPARED STATEMENT

I will continue my work as a cancer advocate in my community, to make sure that people know of all the opportunities to lead a productive life with cancer. But you have in your hands a chance to support more research and more clinical trials that will increase what we already know about the disease and save millions of lives. Increased funding for all cancer research is truly the key. And I urge you to provide it.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF SHERIFF SHERMAN BLOCK

Mr. Chairman, it is an honor for me to testify today. I want to personally thank you for your attention to the topic of cancer and your support for research that can save the lives of literally millions of people.

I am proud to testify here today, because I have survived cancer not once, but twice. Six and half years ago, my doctor, while doing a digital exam, determined something was just not quite right. He detected a soft spot. My PSA was not highly elevated, but a biopsy turned up prostate cancer. I was 66 at the time, and my first reaction to the word cancer was "I am going to die." But how could I with a family and so much left to do? I had surgery at USC's Norris Cancer Hospital & Research Institute, and because my cancer was detected early, I have been prostate cancer-free ever since.

Having battled cancer once, four years ago June, I was shocked to find a lump between my neck and left shoulder as I shaved for work one morning. The lump, which was the size of a golf ball or even larger, turned out to be a high-grade, fast-

moving non-Hodgkins lymphoma according to my doctor. I was stunned and somewhat devastated. I had conquered the prostate cancer at 66, but here I was 68 this time, and considered a high-risk patient because of my age. The doctors told me straight out that the chemotherapy alone might kill me, but that without the chemo I would certainly die in 3 to 6 months. This time I was concerned, but not fearful. I underwent 7 months of chemotherapy. And thanks to innovations in research, I was able to tolerate the chemotherapy and go to work every day, except for two. New drugs greatly minimized the side effects of previously caused by chemotherapy, like nausea and vomiting and a susceptibility to infections, which would have prevented me from holding my position as Sheriff.

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At a recent event, I listened to a large number of women of color express their fear of getting annual check-ups. Their fear was not the fear of finding something wrong, but many were the breadwinners and feared losing their job because of a cancer diagnosis. We need to increase the funding for research and get the information out to these and other women that cancer is not a death sentence. Research has and will continue to make early detection and better treatments possible. Like me, thanks to research many of these women may be able to keep their jobs once diagnosed with cancer because of improved treatments that are gentler on our bodies. We also need to make sure that that health care systems that many of these women and others depend on, like managed care, provide access to the most innovative treatments and trials. All Americans should have the choice to receive the best and most cutting edge care available.

I will continue my work as a cancer advocate in my community to make sure that people know of all the opportunities to lead a productive life with cancer. But you have in your hands a chance to support more research and more clinical trials that will increase what we know about the disease and save millions of lives. Increased funding for all cancer research is truly the key, and I urge you to provide it.

MAMMOGRAMS

Senator SPECTER. Thank you very much, Sheriff Block. When you comment about the diagnoses for women and the concern factor, we are trying very hard to make mammograms available throughout the land. And we recently had quite a controversy on the issue of mammograms for women 40 to 49, with an NIH panel in January, raising a doubt about that subject. And this subcommittee held hearings, and we brought the issue to a head. And a group of specialists concluded that the mammograms were warranted for women 40 to 49.

There was a concern expressed as to what the impact of what happened when a question was raised, as to whether that would discourage so many women from having mammograms. But, ultimately, it turns on a question of resources. And that is a decision, as a matter of public policy, the Congress has to decide. We need the best scientific evidence, but then, when it comes to the allocation of funding, that is for the Appropriations Committee to decide and the full Congress.

So we thank you for your testimony.

STATEMENT OF SALLY FIELD, ACTRESS, LOS ANGELES, CA

Senator SPECTER. I would like to turn now to a very distinguished actress, Ms. Sally Field, two-time Academy Award winner for her performance in the films "Places in the Heart," and "Norma Rae;" recipient of an Emmy Award for her title role as a young woman with multiple personalities in the television special "Cybil." Her film credits are very long and include such hits as "Forest Gump" and "Mrs. Doubtfire."

We welcome you here, Ms. Field, and look forward to your testimony.

Ms. FIELD. Thank you. Mr. Chairman, I want to thank you for inviting me to testify here today. I am personally grateful for your attention to this topic that affects so many of us and our families and our lives.

In my family, frankly, I always thought we were immune to cancer, because I was not aware of any family member who had been stricken. All my life, if there was a hidden monster, I feared it was heart disease and not cancer. My family had a predisposition to heart disease, and I have always been very concerned for my health and that of my sons. But that all changed this last year, when two of my very closest family members were both diagnosed with and treated for cancer.

Out of respect for their privacy, I will not go into detail. I only bring it up to make to point that you never know when, who or why cancer will strike. Yet, when it does, it turns your life and your family's life upside down.

While I am not a cancer expert, I do know that many cancers can be prevented. Medical research over the last 25 years has given insights into how to prevent certain cancers altogether. This year alone, 174,000 cancer deaths are expected to be caused by tobacco use. They could have been prevented.

A like number of cancer deaths will be caused by poor nutrition and dietary factors. As many as 900,000 nonfatal skin cancers, preventable by protection from the sun, will be diagnosed this year. We need to do a better job of getting information out to the public on cancers that are preventable, and we must make it a national priority to increase funding to determine the underlying causes of other cancers killing and afflicting our family and friends.

Research has made the detection of cancers at an early stage possible as well. I am very grateful that early detection helped those people that I love so dearly detect their cancers and get treatment at the earliest possible stage. But we need to make sure all Americans take advantage of regular screening examinations to help detect cancer of the breast, tongue, mouth, colon, prostate, and others. Survival for these and other cancers is 80 percent if caught early. We must ensure that all Americans get access to screening. We cannot afford not to.

We need your support, Mr. Chairman, to help fund research in prevention, detection and treatment. Because, as we identify the diseases earlier, our doctors are going to need the best tools and information available to treat them. They can only come if our legislators stand up for the 10 million cancer survivors, their families and friends, and appropriate more money to cancer research now.

PREPARED STATEMENT

Can there be any American who has not been in some way touched by cancer? I come here before you today with a message of urgency. I know my family is not immune to cancer. And I see the great potential for improved prevention, detection, treatment, and cure for all cancers. We cannot stand silent as this disease devastates our lives. Please double the budget for cancer research, for our families and friends today who are surviving, and for our children, God forbid, who may be stricken unexpectedly tomorrow.

[The statement follows:]

PREPARED STATEMENT OF SALLY FIELD

Mr. Chairman, I want to thank you for inviting me to testify here today. I am personally grateful for your attention to this topic that affects so many of our lives.

In my own family, frankly, I always thought we were immune to cancer, because I wasn't aware of any family members who had been stricken. All of my life, if there was a hidden monster I feared, it was heart disease. My family had a predisposition for heart disease, and I have always been gravely concerned for my health and that of my sons.

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PSA

Senator SPECTER. Thank you very much, Ms. Field, for that very poignant and moving testimony.

We are going to have questions for the panel when everybody concludes, but may I ask if either of the two family matters that you referred benefited from early detection?

Ms. FIELD. I believe their lives, at this point, were saved from that. They both received very early detection. They were both operated on, and right now they are cancer-free.

Senator SPECTER. That is a message which needs to go out very forcefully. Sheriff Block testified about his PSA, a very good detection for prostate cancer—methods—mammograms for breast cancer, and so on. So I think that is something to be underscored early and often.

STATEMENT OF STEPHEN J. FORMAN, M.D., DIRECTOR, DEPARTMENT OF HEMATOLOGY AND BONE MARROW TRANSPLANTATION, STAFF PHYSICIAN, DEPARTMENT OF MEDICAL ONCOLOGY AND THERAPEUTICS RESEARCH, CITY OF HOPE NATIONAL MEDICAL CENTER, DUARTE, CA

ACCOMPANIED BY:

SHARI KAHANE, CANCER SURVIVOR
YOCHEVED ROSENTHAL, CANCER SURVIVOR
CINDY LADIN, CANCER SURVIVOR
ANISSA AYALA, CANCER SURVIVOR
ROBIN FRASIER, CANCER SURVIVOR
MUSHTAQUE JIVANI, CANCER SURVIVOR

SUMMARY STATEMENT OF DR. STEPHEN J. FORMAN

Senator SPECTER. I now turn to Dr. Stephen Forman, director of the department of hematology and bone marrow transplantation at the City of Hope National Medical Center, and president of the City of Hope Oncology Network. He is the principal investigator with the $14 million, 5-year National Cancer Institute bone marrow transplant project grant, and is an international leader in the field of bone marrow transplantation.

Dr. Forman, welcome, and the floor is yours.

Dr. FORMAN. Thank you, Senator Specter.

Before I start, I would like to address the article that you held up that was in the newspaper today and try to put it in context. Cancer has had 3 million years of evolution to evolve to the state where it is a human problem. We have had 30 years of research to address it. It would be naive to think that we could solve all those problems in 30 years, given what we have been up against in nature.

Senator SPECTER. How many years has it been evolving; you say 30 million?

Dr. FORMAN. Well, I think 3 million years of evolution, to have——

Senator SPECTER. Why do you pick 3 million?

Dr. FORMAN. Because I think the species has been evolving over that long a period of time. I think the problems that exist, the ways that cells have figured out to get around our therapeutics, have had that long a time to evolve and confront us with a very large problem.

So to think that in 30 years we will have figured out all the secrets that a cell holds would be naive.

Senator SPECTER. So you want to be put down for funding for research? [Laughter.]

Dr. FORMAN. Yes; I do. But I also want to address the issue of prevention. Prevention that we can address now is only possible be-

cause of the last 30 years of cancer research. One cannot simply go out and make a statement that we want to prevent it without knowing more about the cancer cell and how to prevent. All of the innovations that we are ready to make in terms cancer prevention are on the basis of the research that we have done in the last 30 years.

Senator SPECTER. Well, Dr. Forman, since I have taken up most of your time, we are going to reset the clock for you.

Dr. FORMAN. Thank you very much. [Laughter.]

Thank you, Senator Specter, for the opportunity to appear before you today.

As you know, I am physician in chief at the City of Hope National Medical Center, one of the National Cancer Institutes' designated clinical cancer research centers. I am the principal investigator on a grant which supports the work of many dedicated scientists and physicians whose task it is to improve our understanding and the therapeutics of cancer; in particular, leukemia, lymphoma and breast cancer. I have been caring for patients for over 20 years and conducting research for that same amount of time.

I would like to make two points about cancer research that I think are important this morning. First, the progress that has been made in cancer treatment over the last two decades has been remarkable. And I say very appreciatively, on behalf of my colleagues and our patients, that we could not have made many of the advances without the Federal Government's funding of cancer research. However, the major obstacle to more rapid progress in the fight is limited funding. For years, I have sat on panels where excellent research projects were turned down for lack of funding.

It is not the absence of ideas that limits the pace at which we can save lives, it is the absence of funding for those ideas. And idea unexplored is a life lost.

Second, a new and significant threat to cancer research has emerged in the form of managed care. Successful cancer treatment has been a trusting and committed partnership between physicians, patients, and scientists. The current system threatens the involvement of patients and discourages the testing of new ideas. It is this partnership which has led to breakthroughs made in the laboratories, which have been turned into treatments that have saved thousands.

Under managed care, patients for whom there is no alternative but cutting-edge medical treatment are being refused these treatments because they are considered by some investigational. Flatly said, many of these companies do not pay for innovative therapies despite the potential for a better outcome.

The real illness is a system which considers physicians as vendors, patients as customers, cancer as a product line, and scientists as a drag on that bottom line.

Now, I decided, Senator Specter, not to use my time today to give you dry statistics, but rather to introduce you to six individuals who are living today thanks to basic and clinical research, thanks to their courage to participate in clinical trials, and thanks to their ability to have access to those trials. Despite the paper this morning, none of them, not one, would be alive were it not for the sup-

port for Federal cancer research that has been done in breast cancer, leukemia and lymphoma.

Let me introduce them to you. Shari Kahane, if you would stand.

Shari is a physician, who developed breast cancer—advanced breast cancer—4 years ago. She is alive today because of research that helped us understand the difference between her breast cancer and that which occurs in other women, and the specific need for more innovative and intensive therapy. Studies which have been done in cancer pharmacology, genetics, and stem cell biology, were combined to develop a new therapy for breast cancer.

She is alive to continue her work on behalf of other women with breast cancer, and is alive to raise her children, because we had the funding to combine research from different areas and to advance treatment. She is one of thousands of women who are alive today because of this kind of research.

Yocheved Rosenthal. Yocheved was diagnosed with leukemia at the time of the birth of one of her children. The moment that a new life was entering the world, hers was on the line. She needed a transplant, but transplant was fraught with dangers, despite our efforts to make it safer. With funding from the Federal Government, we were able to offer her clinical research trials, each of which were designed to decrease complications and prevent the disease from coming back.

One of those complications was pneumonia. In those days, it claimed one in five patients undergoing that kind of transplant. An NCI-funded study, however, helped us develop a therapy that has nearly eliminated this as a complication. Yocheved had a long and arduous battle, but she has recovered. And she and her husband adopted another child, who has become a special part of their family.

Cindy Ladin. Cindy had a disease called chronic myelogenous leukemia [CML]. When I began my work in oncology 20 years ago, all patients with CML died. That was before the development of transplantation, which has cured many other patients with incurable diseases. It is the single most complicated therapy we do in oncology. And it is dependent upon research knowledge that we derive from diverse fields in immunology, tumor biology, radiation biology, and immunogenetics.

Cindy needed a transplant, but had no donor in her family. Fortunately, she benefited from the laboratory work that showed that the genes that control our immune response allow us to identify donors in the general population—in this room. This ability to apply research knowledge from one area to another has meant the difference between life and death. In this case, it led to the development of the National Marrow Donor Program, a registry with 3 million people who have helped save many lives.

In Cindy's case, after 1 year of searching, a woman in New Hampshire was found to be a match. Because of those scientific achievements, all of which were federally supported, and a Samaritan donor, Cindy is alive, in remission, living a normal life, a mother to her children, a wife to her husband.

Anissa Ayala. Anissa also had CML, but did not have a family donor. But unlike Cindy, no one could be found in the registries. However, research which was then being performed about stem

cells showed that these cells are also present in the umbilical cords of new-born babies. Therefore, after her father had his vasectomy reversed, her mother, at age 43, became pregnant and gave birth to a baby girl, who miraculously was a match. Anissa underwent transplantation utilizing cells that were collected from the umbilical cord in the hour of her sister's birth. That was 5 years ago. The sister became a donor within the first minutes of her life.

Robin Frasier. Like the others whom I have introduced you to, Robin Frasier had a form of leukemia for which there was no curative therapy. And she had no donor of any kind. However, laboratory studies at that time were helping us understand the molecular abnormalities present in her leukemia. Other research which was also government funded, showed us how therapy with interferon can sometimes lead to remissions of her disease.

Five years ago, Robin underwent transplantation utilizing her own bone marrow that had been put into remission. She was one of the first patients in the whole world to undergo such a therapy. Without the work of investigators and laboratories working together, she would not be alive today, she would not be practicing medicine, she would not have seen her children married, nor her grandchildren born.

Mushtaque Jivani. Mushtaque holds a very special place in the world of cancer research and marrow transplantation, because he is the longest living transplant patient in the City of Hope's program, having been transplanted over 20 years ago for treatment of leukemia. At that time, the therapy was just developing, and the scientists in laboratories to help design it were not sure of its outcome. The heroism he showed in trusting scientists and physicians to develop a therapy to treat his fatal disease is one reason he is here today. Another is that there was funding to do that research. And the third is that the medical care system allowed him access to these approaches.

In closing, Senator Specter, I appreciate your allowing me the opportunity to be here today. It says in the Hebrew Talmud that he who saves a life saves the whole world. You should not underestimate for a moment the role that the Federal Government has had in funding cancer research has had on supporting that observation.

PREPARED STATEMENT

On behalf of my scientific and clinical colleagues, on behalf of the patients standing before you, and on behalf of those who love them and still have them in their lives, we all thank you for your efforts on their behalf, and I would ask their families to now stand with them. [Applause.]

[The statement follows:]

PREPARED STATEMENT OF STEPHEN J. FORMAN, M.D.

Thank you, Senator Specter, for the opportunity to speak to you and your committee concerning the important issue of cancer research and the saving of lives from this disease. By way of introduction, I am Dr. Stephen Forman, physician-in-chief at City of Hope National Medical Center, which is designated by the National Cancer Institute as a Clinical Cancer Research Center. I direct the Department of Hematology and Bone Marrow Transplantation and am a staff physician in the department of Medical Oncology and Therapeutics Research. I am also principal investigator on a five-year, $14 million NCI program project grant on transplantation for leu-

kemia and lymphoma, a grant which supports many clinical and basic investigators devoted to basic cancer research and innovative cancer therapy.

For 20 years, my colleagues at City of Hope and I have been involved in research, both in the laboratory and at the patient bedside, which has focused on understanding cancer in humans and developing ways to control it and ameliorate the suffering it causes. When I first began my work, very few, if any, patients for whom I cared survived. They all succumbed to the disease. This was a driving force in my choosing a career dedicated to the development of innovative therapies that translate into extending and saving lives from cancer.

I am proud to say that the medical community has made great advances in the past two decades thanks to the partnership between physicians, patients, and the scientific community. This progress is directly attributable to the linkage there has been between basic research into, for instance, the nature of the cancer cell, as well as the testing of new research knowledge in clinical trials.

This progress is also directly attributable to the funding that there has been for such basic and applied research. We could not have made the advances we have without the federal government's funding of cancer research. I want to acknowledge that, to express my appreciation for it—and to emphasize that continued progress will depend upon continued federal support for cancer research.

The reality is that limited funding for cancer research is the major obstacle to more rapid progress in the fight against this disease. For many years, my colleagues and I have served on research panels where excellent proposals are turned down for lack of funding—with the result that promising research goes undone. It is not the absence of ideas that limits the pace at which we can save lives from cancer, it is the absence of funding to examine and test new ideas. An idea unexplored is a life lost.

The critical factor of funding is of particular importance now as molecular genetics and the immunology of malignancy are just beginning to provide remarkable new information, important to all of us.

What is sometimes difficult to understand is that it often requires progress in diverse fields of study to develop a therapy that is the difference between a patient living or dying—a person who may be our parent, our friend, our co-worker, our spouse, or our child. The path to a breakthrough may start in a distant place and take a course we can't foretell. Sometimes it begins on a blackboard in a laboratory that leads to a proposal to a research organization, to the funding of a young postdoctoral fellow whose energy is matched by his creativity, which leads to a laboratory experiment whose implications are noted by a physician investigator who works with that scientist to develop a therapy and a trial which is then offered to a patient who comes to us for help.

I decided, today, not to present to you cold statistics about such patients, but rather to introduce you to some of these individuals; people who would have been doomed by their disease were it not for research studies that not only saved their lives but became the basis for therapies that have helped others.

As I introduce each of these six people and ask her or him to stand, please be aware, Senator Specter, that the person you see is alive before you today because of funded basic and translational medical research and because they had access to investigational therapies.

SHARI KAHANE

Shari Kahane is a physician who developed advanced breast cancer four years ago. She is alive today because of research that helped us understand the difference between her breast cancer and that which occurs in other women and the specific need for a more innovative and intensive therapy. Studies which were done in cancer pharmacology, cancer genetics, and stem cell biology were combined to develop a new transplant therapy for breast cancer.

Dr. Kahane is able to continue her work on behalf of other women with breast cancer—and is alive to raise her children—because we had the funding to combine research from different areas to advance treatment.

YOCHEVED ROSENTHAL

Yocheved Rosenthal was diagnosed with leukemia at the time of the birth of one of her children. As a new life entered the world, her life was on the line. Yocheved needed a bone marrow transplant from a family donor. Despite our tireless efforts to improve the procedure and make it safer, transplantation from donors is fraught with danger. With funding from the federal government, she was able to enter several innovative trials, each designed to decrease complications and reduce the chances that the disease would come back.

One of the major complications that faced Yocheved and other patients was pneumonia. At that time, pneumonia claimed one out of every five patients who was transplanted. However, an NCI funded study helped us develop a therapy that has nearly eliminated post-BMT pneumonia.

Yocheved had a long and arduous battle, but she has recovered. Her life was saved, and in turn she has saved another life by adopting an unwanted child who has joined her family—providing a son to her and her husband and a brother to her other children.

CINDY LADIN

Cindy Ladin had a disease called chronic myelogenous leukemia. When I began my work in oncology, there was no cure for CML. All patients with the disease died. That was before the development of bone marrow transplantation—which has cured many patients with otherwise incurable diseases. BMT is the single most complicated therapy we do in medical oncology and it is dependent upon basic laboratory research knowledge derived from many fields including immunology, tumor biology, radiation biology and immunogenetics.

Cindy needed a BMT but she had no donor within her family. Fortunately, though, she benefited from laboratory work that had studied the genes which control our immune response—this research proved to be useful in identifying bone marrow matches from the general population. Again, this ability to apply research knowledge from one area to a different area has meant the difference between life and death for many people. In this case, it led to the development of the National Marrow Donor Program, a registry in which there are currently nearly 3 million volunteer marrow donors.

In Cindy's case, after a year of searching, a woman in New Hampshire was found to be a match and, although she had never met Cindy, she felt the need to give. They met for the first time one year after transplant. Because of scientific achievements and a Samaritan donor, Cindy is alive, in remission, and leading a normal life as mother to her children and wife to her husband, Hal.

ANISSA AYALA

Anissa Ayala is someone who taught us what the combination of scientific investigation and hope can achieve. Like Cindy Ladin, she had CML and did not have a family donor. Unlike Cindy, however, none could be found for her in the national registries.

However, research which was being performed at that time showed that stem cells that we have in our bodies are also present in the umbilical cord of newborn babies. Therefore, after a reversal of her father's vasectomy, at age 43 her mother gave birth to a baby girl who, miraculously, was a match to her. Anissa underwent transplantation utilizing cells that we collected from the umbilical cord of her newborn sister. Her sister became a donor within minutes of her birth.

That was five years ago.

ROBIN FRASIER

Robin Frasier also had a disease for which no curative therapy other than transplant was known to exist but, unlike Cindy and Anissa, did not have a donor of any kind.

However, studies by scientists such as Dr. Owen Witte and others helped us understand the molecular abnormalities present in the form of leukemia she had. Other research, which was also federal government funded, showed us how therapy with Interferon can, in some patients, lead to remissions of the disease and offer opportunity for a transplant.

Five years ago, Robin underwent transplant utilizing her own bone marrow that had been put into remission by Interferon. At that time, she was among the first patients in the world to undergo such a therapy. Without the work of many investigators and laboratories working together to develop a therapy for an otherwise incurable disease, Robin would not be alive today. She would not be practicing medicine. She would not have seen her children married and she would not have reveled in the birth of her grandchildren.

MUSHTAQUE JIVANI

Mushtaque Jivani holds a very special place in the world of cancer therapy and marrow transplantation. He is the longest living transplant patient in our program, having had a transplant 20 years ago for treatment of leukemia. At that time, the

therapy was just developing and the scientists in the laboratories that helped design it were not completely certain of its outcome. The heroism Mushtaque showed in trusting scientists and physicians to develop the therapy to treat his fatal disease is one reason he is here today. Another reason is that there was funding for those scientists and physicians to follow where their intuition and intellect led them. It is upon Mushtaque's shoulders that all transplant patients stand because the success we had with his disease is what led to the development of curative therapies for all of the patients you see here today and who are represented in many other cancer centers around the United States.

Each of the people I have been privileged to introduce to you are unique and special to us. Sadly, I could tell you stories of other patients who, because of our ignorance, I am unable to introduce you to; for each of the patients you see here today, there are others, had we known what we know today, would be alive to join us. For us, every breakthrough has an exhilaration that we can use to save a life but also the realization that had we only known sooner, how much more we could have done for others. It is clear to me, in talking with colleagues around the world, that there are very exciting, compelling ideas yet to be tested that wait in line for funding to allow them to do their work. In some cases, good ideas will never be funded, young investigators will be discouraged, and we all lose in that process.

It says in the Hebrew Talmud that "He who saves a life saves the whole world". In the people I have had the privilege of introducing to you today, we all see the truth of that. Children keep their parents and parents do not lose their children, husbands their wives, each other, brothers and sisters and communities, their friends and colleagues.

While the six people you see standing before you now, Senator Specter, represent the success that can flow from funded research, I must tell you that I am worried. This is a difficult time for cancer research. Not only is funding limited, but the current health care system of managed care is a very reluctant partner in this process. Some in managed care think of physicians as vendors, patients as customers, and scientists as a drag on their bottom line. The current system implies that we know all we need to know—an attitude that robs future patients of the hope that research brings.

In the current environment, none of the patients you see here today would probably be able to get authorization for the therapy that saved their lives, regardless of its rationale or the hope it provides. In this callous environment, it is vitally important not only that research funding is adequate, but that the health care system does not deny patients access to something that may save their lives just because it is investigational. People with potentially fatal diseases should not have to battle both their disease and a system that bars them from access to what might help them.

In closing, Senator Specter, I want again to express my appreciation for this opportunity to testify and for the federal government's support of cancer research. I hope that you understand, by the presence of these very heroic people with me today, how critical and personal is our challenge.

Thank you.

FUNDING

Senator SPECTER. Dr. Forman, that is indeed impressive. And you have offered a fair amount to refute the headline in the USA Today on the questions raised. And we will discuss that when we conclude the panel. And it is very impressive indeed.

When you talk about funding, we have increased funding on NIH and on cancer. It has gone up exponentially, to now $2.3 billion, out of the $12.7 billion in NIH. And those increases have come in the last 15 years, notwithstanding budget cuts in almost every other area, regardless of Democratic or Republican administrations.

When Senator Weicker chaired the subcommittee, funding went up. When Senator Chiles, now Governor Chiles, chaired the subcommittee, funding went up. When Senator Harkin chaired the subcommittee, funding went up. And in my first 2 years as chair, the funding has gone up. I am determined to see it go up again. But we have our work cut out for us, because the overall budget

allocation for health has been cut by $100 million for the next fiscal year. It is important to put our spending priorities back on track.

Dr. FORMAN. We would be privileged to help you.

Senator SPECTER. Good.

STATEMENT OF DIANE KEATON, ACTRESS, LOS ANGELES, CA

Senator SPECTER. We turn now to a very distinguished actress, director and producer, Ms. Diane Keaton. Her acting career spans some 25 movie greats. She received an Academy Award for her spectacular role in "Annie Hall," in the "Godfather" trilogy. She has a recent smash hit, the "First Wives Club." She had her performance in "Marvin's Room", which earned her an Academy Award nomination.

And I withstood the temptation to ask Dr. Forman how the patient in "Marvin's Room" bears on this issue, but we will let you take it up if you choose to, Ms. Keaton. We are delighted to have you here, and the floor is yours.

Ms. KEATON. Thank you very much.

Chairman Specter, of course it is an honor to testify before you today. I think I speak for a lot of people about my experience with cancer. It started when my grandmother Keaton got colon cancer, which metastasized into her liver and took her life. Then my mother's father, who I never met, died of lung cancer. Then Grammy Hall had a breast removed. Then Auntie Martha had a form of skin cancer which forced her to have her nose literally taken off her face.

But the worst of all happened when my sister Robin called me in Rome, where I was shooting "Godfather Part 3", and told me dad had a brain tumor, something called a glioma, and it looked bad. It was bad. We did all the things we were told to do. We went to UCLA. That always sounds good. He was put on some experimental treatment, which used a combination of chemotherapy, special chemotherapy, and radiation.

These so-called therapies, which were developed to prolong life, were terrifying. The cumbersome machine, baking 200 RAD's twice a day into my father's head for 5 weeks, and his odd courage while living under the rein of a tumor, rapidly enveloping his frontal lobe, seemed impossible to believe. After dad prematurely flunked the program, he was driven home in an ambulance to be more comfortable. For my family, an air of disbelief about dad's future filled our lives with the depressing kind of hope, a stagnant hope, and basically it was a hope of no hopes.

My sisters, Robin and Dorrie, and my mother, Dorothy, and I ritualistically watched for any improvement. He might get better; you never know. But dad was looking more wounded, more broken, more like the dozens of dazed birds, who, over the years, had flown into mom's plate glass window, never knowing what hit them.

My father's failure to live up to the program's requirements was obvious, as he gently reeled through the kitchen, his 6-foot frame barely held up under the uneasy steps his skinny legs took him. Soon he stopped walking altogether. Dad's death was devastating. I am not ashamed to say that it was the most overwhelmingly sad experience of my life. But I am ashamed to say that in the wake of dad's death, I developed a terrible, horrible fear of cancer. This

fear kind of shut me down. I tried very hard to keep cancer out of my life. But, of course, it would not go away.

After dad's death, I directed my first feature. It was about a family struggling with the loss of a mother who succumbs to cancer. Two years later, I played the part of Bessie, in "Marvin's Room", who learns she has leukemia, and more than likely will die from cancer. Spending 3 months of my life pretending to be somebody who has cancer was not fun. It was not fun. But beyond the suffering required of the part came a kind of guilty joy, knowing that the movie would end and I did not have to live with cancer on my back anymore.

But it did not go away. The fear kept creeping back in the form it always takes with me—avoidance. Do not go to the doctor, do not get a mammogram, do not even read about ovarian cancer; you might get it.

I know that there are millions of people like me who wake up in the middle of the night in a panic, convinced that they have cancer; then get up in the morning and do nothing about it. Like me, they know cancer has had the last say all too often. It is everywhere. It is lurking behind every corner you turn. It is secretly waiting to jump out at you in order to take your life away. You do not fight cancer. What is the point?

Not only does cancer frequently kill the people who have it, but it also crushes the fighting spirit in those of us who are too afraid to even think about the word in connection with ourselves. And that is what fear can do to you. It can squelch your curiosity. It can strip you of your courage. It can eat your soul. But, most importantly, it can tear away at your ability to hope. And without hope, where does the motivation to fight back come from?

Now, I do not know how many of you know Sherry Lansing, but she is a very persuasive person. She is seductively persuasive. We had lunch several months ago to celebrate our good fortune with the success of the "First Wive's Club." At some point, you know, I brought up the name of the mutual acquaintance who had recently been diagnosed with a brain tumor; 1½ hours later, Sherry had convinced me to testify before you today. Now that is an amazing sell job. Because this is the last place I want to be. [Laughter.]

Since fear obviously is at the core of my speech, I figured I would just pick out a few of the terrifying highlights that I forced myself to read in preparation to come to you today, in hopes that you, Senator Specter—and now I know you—are not like me, too scared to fight cancer. OK, here we go. I know you have heard this before, but I am going to say it, because it just floored me. OK.

One-half of all American men and one-third of all American women will be struck by the horror of being diagnosed with cancer during their lives, one-fourth of all Americans will one day die from cancer; more than 1,500 people every day die from cancer, and during this period that this Senate hearing is in session, 161 Americans will have died from cancer.

The number of cancer deaths per year exceeds all U.S. combat deaths in all wars of this century. And listen to this one—this is the one that got me—it would take five Boeing 747 jumbo jets crashing every day for a year to equal the half-million Americans who die each year from cancer. Now that one really got me. I mean,

pick your favorite fear, double, triple, quadruple the likelihood that cancer is going to get you instead.

And, finally, this: Obviously, if we doubled our effort on cancer research today, it would still cost less than one-third of our space efforts and only one-twentieth of the cost of the gulf war. I mean, to me, this is not right. This does not cut it. And even I know that. Even me, in my fear-ridden stupor, I know that that is not good enough. We all deserve a better effort. We have got to keep trying and keep spending time, effort and most importantly, the big M, money, to destroy the big C, cancer.

I am just saying, to me, do not wait. Do not wait until the day it strikes you or your family or somebody you care about. Because then it is going to be too late. So let us spend now for the future—yours, ours, and everyone's.

Senator SPECTER. Thank you very much. [Applause.]

Thank you very much, Ms. Keaton. May I ask how old your father was?

Ms. KEATON. He was 68.

Senator SPECTER. Well, I had been on the subcommittee for more than a decade when I insisted on an MRI. I had no discernible symptoms, according to the doctors. My shirts were a little tight and I had light pains running up and down the side of my head. All sorts of tests did not show anything, but I knew about an MRI and I said I wanted the one. They said, well, you do not need one. I said, but I want one. They said, well, you are not going to have one. And I insisted and I got one.

And I am aware of the fact that I am in a little better position to insist than most people. And the MRI showed a meningioma, which was benign. But I was shocked to learn that we only have had the MRI since 1984. And without going into any detail, my own personal experience brought me into contact with many, many details of the evolving wonders of research, which I had been voting for, for more than a decade. So it comes very close to home when it is in your head, or in your heart, or in your family.

Ms. KEATON. Thank you.

Senator SPECTER. Thank you.

STATEMENT OF OLIVIA NEWTON-JOHN, ACTRESS, BEVERLY HILLS, CA

Senator SPECTER. We now turn to Ms. Olivia Newton-John, an accomplished actress and recording star, recognized throughout her musical career with numerous awards, including the Country Music Association's top female vocalist of the year; honored at Buckingham Palace by Queen Elizabeth II, where she received the prestigious Order of the British Empire. She is best known, perhaps, for her starring role in "Grease."

In June 1992, she became the spokesperson and goodwill ambassador for the Children's Health and Environmental Coalition. And last October, she hosted a cable special, "Lifetime Applauds the Fight Against Breast Cancer."

Welcome, Ms. Newton-John, and we look forward to your testimony.

Ms. NEWTON-JOHN. Thank you. I am very pleased to be here and be a part of this panel this morning. In fact, I am pleased to be

anywhere, for I am one of the lucky ones. I am a survivor of breast cancer, and not everyone is as lucky as I am.

I think that if you told me a few years ago that I would be discussing something so personal in public, something so intimate as this, I would have cringed. But I know that I need to speak out and something must be done. In 1992, I was diagnosed with breast cancer. There is no history of breast cancer in my family. I was, I thought, a very healthy person. So if it can happen to me, it can happen to anybody.

My treatment was a modified radical mastectomy, and I had reconstruction on the table, followed by a 6-month course of chemotherapy. Now, 5 years away from surgery and chemotherapy and breathing a little easier, I am really examining what caused my cancer. I did not smoke or drink. I exercised, and I always ate plenty of my fruits and vegetables. But maybe, was it in my fruits and vegetables, in the enormous amounts of pesticides sprayed on our crops? Is it in the polluted air that I breathe when I am running? Is it in the water I drink, from the estrogen-mimicking hormones from plastics?

I understand that the Government has spent more than one-quarter of a billion dollars since the official war on cancer began under President Nixon. Some two decades into this war, we still do not have a cure for the most common forms of the disease. In addition, scientists cannot tell us why cancer continues to strike in children, why more and more women are diagnosed with breast cancer, and why more young men are acquiring testicular cancer.

Of course, we need to allocate more money to cancer research, and we do need more effective treatments for the 1.5 million people who will be diagnosed this year. But we must be careful to insist that a large part of whatever moneys are allocated be spent on figuring out how to prevent this disease and why is it happening.

It is clear that doctors do not know why most women get breast cancer. Like me, they have none of the known risks of the disease. Inherited genetic defects only account for about 1 in 10 cases. And experts can only explain about 25 percent of these cases.

Since 1971, scientists have known that cancer is caused by changed genes which control cell growth. But my question is, what causes this gene to mutate in the first place? What triggers it?

I believe we need to be looking for the causes in our environment. We know for a fact that smoking can cause lung cancer. We need to spend research money finding these links in your daily lives.

There are two key environmental problems that may be linked to breast cancer. First, radiation. Everything from nuclear fallout to routine x rays. And, second, carcinogens and toxic chemicals found in pesticides, fuels, plastics, and even some therapeutic drugs. We simply must find funds for the research that will give us the answer to these life and death questions.

I was relatively young when I was diagnosed. And a mammogram missed my tumor. And we all have to remember that mammograms, even when done properly and in the best institutions, simply do not prevent cancer; they only detect it after the disease is there. And for women like me, mammograms can miss tumors. It missed mine.

I am first a mother, a survivor, and a woman who cares for the planet very much. And we are poisoning our Mother Earth, and we are poisoning ourselves. And there is recent evidence in animals and wildlife that indicates that a number of widely used pesticides, fuels and plastics and drugs can disturb the body's hormones. And these disturbances could also be keys to hormonal cancers.

Despite the obvious importance of hormone-disrupting materials, the Federal Government has spent relatively modest amounts of money on this issue. Not only must more money be allocated to cancer overall, but this additional money must be spent on efforts to understand the causes of and to prevent the disease.

As a mother, I am deeply concerned that we are failing to protect our children. My dear friends, Nancy and Jim Chuda, lost their daughter, Collette, at 5 years old, to Wilm's tumor. This is a cancer that has been shown to increase in children whose parents have had workplace exposure to some pesticides. And because of this personal experience, I am the national spokesperson for CHEC, the Children's Health and Environmental Coalition, a national movement on behalf of children's environmental health.

PREPARED STATEMENT

I am not a scientist. I am a concerned mother and a citizen. And the main reason I am here is to say that we need to spend whatever it takes to stop cancer. And I know that with additional support from the government and the private sector, we can all make this happen. So that when my daughter looks at me and says, mummy, am I going to get breast cancer, I can say, no. [Applause.]

[The statement follows:]

PREPARED STATEMENT OF OLIVIA NEWTON-JOHN

I am very pleased to be here and be a part of this panel this morning—I am very pleased to be anywhere, for I am one of the lucky ones. I am a survivor of breast cancer. Not everyone is as lucky as I am.

I think that had you told me a few years ago that I would be discussing something so personal in public, something so intimate as this, I would have cringed.

In 1992 I was diagnosed with breast cancer. My treatment was a modified radical mastectomy with no lymph gland involvement and I had reconstruction on the table * * * followed by a 6-month course of chemotherapy.

Five years away from surgery and chemotherapy, and breathing a little easier, I am really examining what caused my cancer. I didn't smoke or drink. I exercised and always ate fruits and vegetables. Was it in my vegetables from the enormous amounts of pesticides sprayed on our crops? Was it in the polluted air that I breathe when I go running? Was it in the water I drank, from the estrogen mimicking hormones from plastics?

I understand that the government has spent more than a quarter billion dollars, since the official War on Cancer began, under President Nixon. Some two decades into this War, we still do not have a cure for the most common forms of the disease. In addition, scientists can't tell us why cancer continues to strike in children, why more and more women are diagnosed with breast cancer, and why more young men are acquiring testicular cancer.

Of course, we need to allocate more money to cancer research. And we do need more effective treatments for the one and a half million people who will be diagnosed this year. But, we must be careful to insist that a large part of whatever new monies are allocated be spent on figuring out how to prevent this disease.

It is clear that doctors don't know why most women get breast cancer. Like me, they have none of the known risks for the disease. Inherited genetic defects only account for about 1 in 10 cases. Experts can only explain about 25 percent of the cases.

Since 1971, scientists have known that cancer is caused by a change in genes which controls cell growth. But my question is, what causes this gene to mutate in

the first place? What triggers it? I believe we need to be looking for the causes in our environment. We know for a fact that smoking can cause lung cancer. We need to spend research money finding links in our daily lives.

There are two key environmental problems that may be linked to breast cancer. First, radiation—everything from nuclear fallout to routine x rays and secondly, carcinogens found in pesticides, fuels, plastics and even some therapeutic drugs. We simply must find funds for the research that will give us the answers to these life and death questions.

I was relatively young when I was diagnosed. And a mammogram missed my tumor. We all have to remember that mammograms, even when done properly and in the best institutions, simply can not prevent breast cancer—and for women like me, mammograms can miss tumors like they missed mine.

I am first a mother, a survivor and a woman who cares for the planet so very much and we are poisoning ourselves and our earth. There is recent evidence in animals and wildlife that indicates that a number of widely used pesticides, fuels, plastics, and drugs, can disturb the body's hormones. These disturbances could also be key to hormonal cancers.

Despite the obvious importance of hormone disrupting materials, the federal government has spent relatively modest amounts of money on this issue. Not only must more money be allocated to cancer over all, but this additional money must be spent on efforts to understand the causes of and to prevent the disease.

As a mother, I am deeply concerned that we are failing to protect our children. My dear friends Nancy and Jim Chuda lost their precious daughter, Collete, at age 5 to Wilm's tumor. This is a cancer that has been shown to be increased in children whose parents have had workplace exposure to some pesticides. Because of this personal experience I have been involved in CHEC, (Children's Health & Environmental Coalition) a national movement on behalf of children's environmental health.

I am not a scientist, I am a concerned mother and citizen and the main reason I am here is to say that we need to spend whatever it takes to stop cancer and I know that with additional support from the government and the private sector we can all make this happen so that when my daughter looks at me and says "Mummy am I going to get breast cancer?" I can say "no."

IMPROVING MAMMOGRAMS

Senator SPECTER. Very impressive. Very impressive. How old is your daughter, Ms. Newton-John?

Ms. NEWTON-JOHN. She is 11.

Senator SPECTER. When you talk about mammograms and mammograms missing something, a lot of work is being undertaken to try to improve mammograms. And of course, for the past several years, we have enlisted the CIA to help—on their detection of piercing the clouds, with their special equipment—the program is called missiles to mammograms—to use that technology.

For the last 2 years, I chaired the Intelligence Committee as well as this subcommittee, and we brought some extra funding in. Dr. John Deutch, the Director, was willing to put an extra $2 million from his funds into trying to improve mammogram detection, with the special techniques which the CIA had developed.

Dr. Forman, I am going to ask your patients to come forward. We have rearranged the hearing room a little bit. I would like to hear from them. It is a little unusual, but I think that they might have something to add, which goes to the issue, which is very topical today, as to what Dr. Bailar has had to say about research not being significant.

So would, at this time, Ms. Shari Kahane, Ms. Rosenthal, Ms. Ladin, Ms. Ayala, and Ms. Frasier come forward. We do not intend to put you on the spot, and we know you are not prepared to testify, but I think it might be useful.

And Mr. Jivani.

Dr. Forman, I would like to have you give us some insights, to the extent you can, on the benefits of research, which is essentially what Dr. Bailar is contesting, as to how it works out in an application with your own patients who are here today, and perhaps hear a word or two from them on what has happened to them.

Dr. FORMAN. I think in each case that I introduced each person to you today, we used something in their care that was derived from a laboratory that was researching cancer.

Senator SPECTER. Something that was successful on the cancer research?

Dr. FORMAN. The phrase we use is translational research, taking observations in a laboratory and trying to figure out how they can be incorporated into diagnosis, prevention, or therapeutics.

Senator SPECTER. May we start with the gentleman who is the longest survivor, 20 years, as articulated by you.

Sheriff Block, could you hand him your microphone? Craig Higgins is ahead of me, as is Bettilou Taylor, as usual, our committee staff. Tell us a little bit about your case. When did you first know you had the problem, and what did you do about it?

STATEMENT OF MUSHTAQUE JIVANI

Mr. JIVANI. OK, I was going to school in Indiana, in 1976, and I was sick and diagnosed with leukemia.

Senator SPECTER. And could you state your name, please, for the record.

Mr. JIVANI. My name is Mushtaque Jivani.

Dr. Forman told me that you are going to die today, tomorrow or in a week, and he recommended I go home and see my family, because there was no treatment at the time in Indiana. I called my brother here, and he said why do not we bring you to California, Los Angeles, and we try something. And it happened that they called the City of Hope, and they admitted me the very next day. I went through the chemotherapy and then the bone marrow transplant.

Senator SPECTER. And you came from?

Mr. JIVANI. I came from Pakistan.

Senator SPECTER. Pakistan.

Mr. JIVANI. I was going to school in Indiana.

At that time, I had my transplant in December 1976. They just started the unit there, and I was like the fourth or fifth transplant patient at that time. Everything was new. I had to take a chance of going through it. Things have changed since then.

Senator SPECTER. Dr. Forman, would you give us an insight as to what research did for this gentleman, the cancer research?

Dr. FORMAN. The research that we utilized was to figure out how we could transplant marrow from one individual to another and have it take. He received a transplant from his brother, who we, through laboratory tests that had been worked out, was found to be a match. If we could not identify the match, we could not have identified that he could have a transplant from a donor.

He was then able to endure very high doses of radiation and chemotherapy to kill the cancer and have his own marrow and immune system replaced by someone else's.

Senator SPECTER. I would like to go into more detail, but I want to hear from the others, too. And if we might move to Ms. Shari Kahane, who is a physician, and developed advanced breast cancer 4 years ago. What do you mean by advanced breast cancer? Do you mean it could have been detected earlier and was not?

Dr. FORMAN. I think the biology of her particular cancer was very aggressive. So, at time of diagnosis, we knew it was extensive.

Senator SPECTER. Research developed an understanding as to the difference between her breast cancer and that which occurs in other women, according to your testimony, and the specific need for more innovative and intensive therapy. What did the research do specifically there?

Dr. FORMAN. It showed us that if we could use the chemotherapy available at that time, her chances of survival were 20 percent. And by using innovative methods of cancer therapy that had been developed on research protocols, we were able to intensify the therapy and increase the survival to 70 percent.

STATEMENT OF DR. SHARI KAHANE

Senator SPECTER. Dr. Kahane, let us hear from you. You are a physician yourself.

Dr. KAHANE. Yes, Mr. Specter.

Senator SPECTER. How did you first discover your breast cancer? What happened to you? How were you treated?

Dr. KAHANE. First, I would like to thank you very much for being able to listen to us. I truly appreciate it.

My breast cancer was misdiagnosed for a long time by several physicians. I had been nursing my son, who is here with me today, and it was missed for a long time. Like Ms. Newton-John, it did not show up on mammography. And at the time of diagnosis, it was extensive.

Senator SPECTER. Did not show up on mammography?

Dr. KAHANE. It did not show up.

Senator SPECTER. Do you know why?

Dr. KAHANE. I had been nursing a child, and it was thought at that point that mammography was difficult, in that women such as myself, who were young and had what would be classified as dense breasts. At the time, I was told by several community oncologists and the surgeon that basically I would be lucky to live 2 years.

Senator SPECTER. And that was 4 years ago?

Dr. KAHANE. That was almost 4 years ago.

Senator SPECTER. And how are you now?

Dr. KAHANE. No evidence of cancer.

We six here are the lucky ones. We have had access to treatment that 5, 10 years ago, might not have been available to save our lives. There are many patients out there who do not have access to clinical trials, because they are not aware of what is out there. And I really believe that, in addition to research, we need to work to educate patients so that they can have access to clinical trials.

Senator SPECTER. Thank you very much, Dr. Kahane.

I would like to hear more, but I would also like to hear from others here.

Ms. Rosenthal, diagnosed with leukemia at the time of the birth of one of her children. Leukemia has always been, Dr. Forman, an

especially dreaded form of cancer, if you can distinguish among dreaded forms of cancer. Tell us a little bit about her case and what happened exactly with respect to the research which was of assistance.

Dr. FORMAN. When one uses the phrase "acute leukemia," it means that life is on the line at that moment. Prior to therapies, patients would die within weeks. The research that she benefited from was that a transplant is a dangerous thing, and that we had funding from the Government to look at ways to reduce the complications. She was on that trial. She avoided many of the complications, and she looks like any normal person you might see anyplace.

What, in essence, the research did was spare her the complications of an intensive therapy designed to cure her leukemia.

Senator SPECTER. And how are you today? How is she today?

Dr. FORMAN. I will let her speak for herself.

STATEMENT OF YOCHEVED ROSENTHAL

Ms. ROSENTHAL. I am fine, thank you.

Mr. Specter, one thing that Dr. Forman may not remember about my specific case, where I specifically benefited from research that was done right at that moment, was one part of having a transplant is you need to have a bronchoscopy and find out if you are a carrier of CMV. CMV is an infection that can potentially cause pneumonia.

Prior to my transplant, just within weeks prior, there was no medication to treat CMV. Right before I went in for my transplant, there was a new medication that was developed thanks to research, called cyclovir. And I benefited from that because I was CMV-positive. And had I gotten CMV pneumonia, I would not be here today if not for the research that helped develop that medication.

Senator SPECTER. And where did you find your donor?

Ms. ROSENTHAL. My sister.

Senator SPECTER. Ms. Keaton, do you have any special advice from "Marvin's Room" as to how to find donors?

Ms. KEATON. How to do what?

Senator SPECTER. Find donors. Last week you did.

Ms. KEATON. Find donors. In "Marvin's Room," there was no donor for her. She just—it did not work out for her.

Senator SPECTER. OK.

And Ms. Cindy Ladin, chronic leukemia. When you began your work in oncology, Dr. Forman, there was no cure for CML. Tell us a little bit about what the research did there.

Dr. FORMAN. The trials we did in transplantation for CML were to convert it from a disease that was uniformly fatal to one where up to 80 percent of the patients can be cured under the age of 50, who have a donor in their family. Cindy did not have a donor in her family. But there was a lot of research being done on how our immune system works. And one of the offshoots of that research was the ability to identify donors. There is potentially a donor in this room for other patients around the country.

We used that information to try to find a donor for Cindy.

Senator SPECTER. How frequently do—is there failure because you cannot find a donor? It must happen all the time.

Dr. FORMAN. It happens disappointingly frequently.

Senator SPECTER. What are the mechanisms set up to try to find donors or have a reserve of donors?

Dr. FORMAN. In the United States, there is the National Marrow Donor Program, which is also federally funded and it exists in Minneapolis, MN.

Senator SPECTER. And that is the organ donor organization?

Dr. FORMAN. That is for bone marrow.

Senator SPECTER. And bone marrow as well?

Dr. FORMAN. Yes; it is administrated under UNIS and the Federal Government. There are international registries, and we in fact have used marrows that we have gotten from Europe, South America, the Orient, Canada, and England.

Senator SPECTER. Well, that is a repository which could certainly use more publicity and more support.

Dr. FORMAN. Thank you.

STATEMENT OF ANISSA AYALA

Senator SPECTER. May we hear from Ms. Ladin?

Ms. AYALA. Hi.

Senator SPECTER. How do you feel?

Ms. AYALA. I feel terrific. Thank you. I am celebrating my fifth anniversary in October of this year. And I thank God for all the research that has been done that I have been able to come as far as I have. When I was first diagnosed in 1991, I had two small children, who are now, as you can see—one is 11 and one is 8. And thanks to the research that Dr. Forman and his group have done, I am here to be able to celebrate with my children on the fifth anniversary.

Senator SPECTER. Well, thank you very much.

Ms. Newton-John, we know you have to depart, and we thank you very much for being with us.

Ms. NEWTON-JOHN. Thank you very much. I am doing a documentary on breast cancer, so it is for a very good reason. But thank you very much for listening.

Senator SPECTER. Well, leave very promptly then.

Ms. NEWTON-JOHN. Thank you very much for listening.

Senator SPECTER. Thank you. Thank you very much. [Applause.]

Anissa Ayala. A combination of scientific investigation and hope.

Ms. Ayala, may we hear from you? What was your situation and how are you feeling?

Ms. AYALA. I am doing great today. I am celebrating my sixth anniversary coming up in June. And I was diagnosed in 1988, when I was 16 years old. I had CML. That is what my diagnosis was. At that time, I was given 3 to 5 years to live, without a marrow transplant. I only had one sibling at that time. We tested him. He was not a match.

And from that point, we went to the National Marrow Donor Program, and tried to locate a donor. Unfortunately, for 1½ years, we did not find a donor. And at that time, my parents went through extreme measures to try to conceive another child to see if that child could possibly be a match for myself. At that time, my disease was treatable through an experimental drug, called interferon, that would hopefully hold off my disease for a period of time.

And I was on that until my sister was born. She was a perfect match at the time of her birth. They did save the cord blood, and at the time of my transplant—why they save the cord blood was because she would not have to be large enough—she would not have to be as large to donate the marrow needed for me.

So, at 14 months, my sister went in. She donated her marrow. I also received the umbilical cord blood that was frozen up until that time. And so I received the cord and marrow transplant, and I am here today, thank God.

Senator SPECTER. Well, you have a miraculous story. According to the information that Dr. Forman has given, a reversal of your father's vasectomy.

Ms. AYALA. Right, after 17 years.

Senator SPECTER. Your mother gave birth at the age of 43——

Ms. AYALA. Correct.

Senator SPECTER [continuing]. To a sister who was a match for you.

Ms. AYALA. Right. And the odds of that are one in four.

Senator SPECTER. Boy, you sure got a good doctor.

Ms. AYALA. I do. He is great. Thank you.

Senator SPECTER. And Robin Frasier had a disease for which no curative therapy, other than transplant, was known to exist. Tell us about Robin Frasier's case, Dr. Forman, in a little more detail.

Dr. FORMAN. Robin had a disease for which, as you pointed out, there was no cure except a transplant. But she had no donor in the family or the registry. We were able to use a medicine, called interferon, to clean up her marrow, if you will, of leukemia cells, and then take it out, remove it from her, put it in the freezer, so that we could transplant her utilizing the normal cells that we could find in her marrow. At the time that we did that, there were very few, if any, other people who had undergone therapy in that exact situation.

Had we not known from research that these cells even existed in the leukemia marrow, we would not have been able to harvest them for the transplant. And I think it is Robin's trust in the system, in research and us that led her to that therapy.

Senator SPECTER. And she was one of the first patients in the world to undergo this particular kind of therapy?

Dr. FORMAN. That is correct.

Senator SPECTER. How are you feeling today?

STATEMENT OF DR. ROBIN FRASIER

Dr. FRASIER. I feel wonderful and very grateful to Dr. Forman.

I am a physician as well, and when I was in medical school, I treated a lot of patients with CML. That is to say, I held their hands while they died, and I thought that that would be my case when I got my diagnosis.

Senator SPECTER. And you are the beneficiary of the research and a good doctor.

Dr. FRASIER. Absolutely.

Senator SPECTER. Well, it is very impressive. I think we have heard from all of your patients now, Dr. Forman.

Dr. FORMAN. Yes.

Senator SPECTER. Well, thank you all very much. It is important testimony. And my colleagues will be reviewing it on the subcommittee and the full committee, and I am going to make a special floor statement on it to summarize—Bettilou Taylor and Craig Higgins will summarize it, but I will make the floor statement to acquaint others with exactly what you have accomplished. It is very impressive.

So thank you very much, Sheriff Block, Ms. Field, Dr. Forman, Ms. Keaton.

Thank you very much.

Dr. FRASIER. May I say one other thing?

Senator SPECTER. Sure.

Dr. FRASIER. I would like to point out that I have had two grandchildren born since I was ill. And both of them have had cord blood stored just in case this should ever be a problem.

Senator SPECTER. How old are your grandchildren?

Dr. FRASIER. One is 14 months old. I have three others that are older: one is 4½, a 15-year-old, and an 8-year-old.

Senator SPECTER. OK, thank you very much. I appreciate it very much. I would like to move now to panel 2. [Applause.]

STATEMENT OF HAROLD P. FREEMAN, M.D., DIRECTOR, DEPARTMENT OF SURGERY, HARLEM HOSPITAL CENTER, NEW YORK, NY

Senator SPECTER. We turn first to Dr. Harold Freeman, director of the Department of Surgery at Harlem Hospital Center, and professor of clinical surgery at Columbia University College of Physicians in New York City. He is the chief architect of the American Cancer Society's initiative on cancer for the poor.

Recognizing his contributions, in 1990 the American Cancer Society established the Harold P. Freeman Award, given annually to individuals who have made outstanding contributions in the fight against cancer for the poor. He was appointed by President Bush as chairman of the President's cancer panel in 1991, and reappointed to the position by President Clinton in 1994.

Dr. Freeman, in a very bipartisan sense, welcome. The floor is yours.

Dr. FREEMAN. Thank you. It is an honor to be here, Senator, and I am going to spend my 5 minutes talking about the effect of managed care on the war against cancer.

As chairman of the President's cancer panel I have had the opportunity to look at this over the past year. The panel has had hearings in four American cities in the four quadrants of America, and I have heard the testimony of people, not only consumers but scientists, and we have a deep concern about what this system has caused.

Indeed, we know that cost is fairly well under control under this system. However, there is a concern that managed care is controlling cost but at very high price to the American people. The system we believe at this point of evolution could be better characterized as a managed cost system, in contradistinction from a managed-care system. The system pays for what it defines as medical care, which often is different from what doctors believe should be done, and will not pay for other care. Also it will not pay for research and for training of scientists.

The previous system, which was traditional health care, paid for research, and it paid for training, and to a certain extent helped to pay for indigent care, so the shift from traditional health care at fee for service, although the other system had its problems, has left us with a situation where there is a threat to this system with respect for paying for research and for training and for indigent care.

There are certain points I want to make in this short period of time that we consider problematical with the managed care system. No. 1, often it denies reimbursement for services provided under a so-called research protocol, even though the services would have been granted as regular care, but once it is classified as research, many of the managed care companies do not pay for the service.

In many instances we found that there was diminished patient access to clinical trials, patients being shifted to gatekeepers and generalists instead of being examined by a specialist, which they should be examined by, and often patients are referred away from the research centers to get cheaper care elsewhere.

Researchers themselves are under duress. Sometimes ethical considerations occur where a researcher has to relate to a cost concern of a company rather than the human concerns of those patients. There is less time for physicians to do research, as they are being forced to spend less time with patients and have to be accountable for money rather than care.

One of the threats that I think is extraordinarily important to bring to the table is that, as you know, we have developed the highest and most advanced system of medical care in the history of this planet, and we should all be proud of it. Medical care and research are at the highest level in this country compared to anywhere else in the world, but these research institutions, Senator, I believe are being threatened by this new system.

The academic medical centers are being squeezed by lack of reimbursement for services, by cutting reimbursement for services, by increased overhead with the need to develop higher infrastructures to satisfy the managed care movement, by decreased referrals, as I said, to the outside, which the companies do not wish to send these patients to the research centers themselves.

Another area of concern is that we are spending less money under this new system for training and education, and I think the young scientist is rather threatened in this change. The managed care companies will not pay for research nor for training.

Also, the percentage of research that is being done in the centers is more and more being taken up by pharmaceutical and by medical companies as opposed to investigative simulated research, which has been so important.

So in general I would summarize by saying that we have a system that is undergoing change from traditional health care to so-called managed care, which has so far emphasized managed costs. We have a system where the managed care companies are taking significant money out of the system to be distributed to stockholders and CEO's and not putting money back in for the research, as was done in the previous system. This is a dangerous change.

The question is, Senator, what does it profit this Nation to manage the cost of medical care if it loses its great research and teaching potential in the process?

If managed care will not pay for this, who will? Should not the research and development be at built-in expense to the managed care companies? If an automobile company builds a car, as General Motors does, you pay a part of the research for the next year's car when you pay for that car. Why should this system not do the same thing?

A final concern is that the system called managed care gives less favorable outcomes to certain segments of the population, the poor and the less educated. People who have money and education tend to get into research protocols at a greater rate than the poor and the people who are less educated. The system does nothing to confront the problem of the 41 million uninsured American people who do not get care at all until it is too late.

PREPARED STATEMENT

So we conclude in general that we are shifting to a system that has controlled cost to a large extent, but I believe at too high a price for the American people.

Thank you very much.

[The statement follows:]

PREPARED STATEMENT OF HAROLD FREEMAN, M.D.

MANAGED CARE'S ROLE IN THE WAR ON CANCER: FINDINGS FROM 1996

During 1996, it was the intent of the President's Cancer Panel to hear first-hand, in four distinct regions of the country, how changes in health care delivery are impacting the National Cancer Program and the reduction of the burden of cancer on the American people. Our primary objective throughout this process was to determine if and how the shift to a managed care system dominated by the notion of "managed cost" is impacting the process of bringing cancer advances to individual patients and to the public as a whole. This process, as defined by the Panel, embraces the whole spectrum of cancer research, application in trials, and finally to the delivery of enhanced cancer care. Clinical research, even narrowly defined, cannot be isolated from its application in cancer care and all the issues associated with assuring that the cancer care provided is the best that science has to offer.

Funding for clinical cancer research has traditionally been derived from a variety of sources, with a significant portion, perhaps even half, coming from "premium" dollars paid by individual and corporate subscribers to health insurance companies. These dollars, as well as State and Federal payments for services to Medicaid and Medicare beneficiaries, have traditionally flowed to academic medical centers and other health care organizations and provided the funding required for additional investments in clinical cancer research, education, and training. They have also provided the basis for indigent care in many parts of this Nation.

These sources of funding are shifting or disappearing altogether as our health care system changes and Federal support decreases. Various health care providers, but particularly managed care organizations, have responded by instituting policies that curtail costs through restricting health services utilization, negotiating provider contracts that may not cover the providers' costs, capping costs, and denying reimbursement for services provided in connection with research initiatives. In response, many health care institutions are adopting cost effectiveness as a standard of success and re-engineering key processes to enhance efficiency and improve outcomes. More clinical trial support by pharmaceutical and biotechnology companies is also being provided.

Coping with the demands of the changing health care systems at the institutional level requires new case management systems, clinical research cost information systems, as well as intensified clinical trial review processes. The intent of these changes is beneficial for all participants in the process. However, building these core

resources is expensive and, with declining revenues from patient care, reinvestment in clinical infrastructure may be out of reach for many centers.

Many providers are increasing the number of patients they see and decreasing the amount of time they spend with each patient in order to maintain the same level of revenue needed to fund clinical research efforts. Other institutions are severely curtailing non-patient associated costs, including training and education. In this scenario, teaching will suffer most, since no one wants to pay for it. And from an ethical perspective, physicians are also facing the increasing challenge of maintaining their roles as patient advocates while contracting with managed care organizations governed by economic motivations.

There was consensus that managed care organizations rarely approve reimbursement for phase I clinical trials, that phase II trials are occasionally approved, and that while phase III trials are frequently approved, more time and documentation is needed to obtain such approval. In all fairness, however, the fee-for-service policies which formerly dominated the health care system also carried specific prohibitions against participation in clinical investigations. But, it is also true that those policies allowed much greater physician discretion in requesting medical care deemed necessary for the welfare of the patient. Such decisions are now impacted by cost limitations, gatekeeper review and, in some cases, blanket policies prohibiting reimbursement of any care associated with research efforts even if the same or similar services would have been provided as part of a "standard" cancer therapy in the absence of an experimental component.

These issues impact whether patients are offered the best and most appropriate cancer care, but also impact the validity of clinical study outcomes. If the only trials that can be supported become those that are most easy to finance, for example, shorter outpatient trials, how will that impact progress toward ongoing aggressive fast moving disease that requires inpatient support? If personal ability to pay for health care or intellectual capacity to challenge the decisions of health care providers become the criteria for entry into clinical trials, can the results of those trials be extrapolated to the underserved of this nation, or in a worst case scenario, will access to appropriately designed cancer therapy become a privilege of the "rich and well connected?" We clearly need strategies to ensure that appropriate cancer care remains easily and widely available and that a meaningful clinical research agenda continues to exist at all levels and that all the beneficiaries of clinical research share the burden of its cost.

On a positive note, there are mature managed care organizations plans which are committed to the support of clinical research. And, despite many of the concerns heard by the Panel, on a system-wide basis, managed care—not managed cost—could ultimately lead to significant positive benefits, such as greater emphasis on prevention, development of better research guidelines and protocols, clearer measurement of outcomes, greater consistency across health care delivery systems, and improved affordability.

We must not overlook these opportunities in a rush to single out managed care as the cause for all that ails us. Access, cost containment, and quality of care are currently the competing priorities with which we are struggling to achieve a balance. This balance is essential, since without high-quality, accessible clinical research, progress in the war on cancer will be undermined. And we cannot forget to bring our focus back to those we are serving; we must remain humane and caring at all times to the cancer patients' needs.

MANAGED CARE

Senator SPECTER. Thank you, Dr. Freeman. You articulate it very well when you characterize it as managed cost as distinct from managed care. This is something that we are really wrestling with in the Congress at the present time, and are looking for answers. We had the so-called gag rule, which is really managed care telling family physicians not to refer to specialists, and we have changed that in the Medicare system.

We had hearings in this subcommittee. Last year we had an amendment by Senator Wyden which passed by a big vote in the Senate but did not get enacted into law. I then scheduled a hearing last November and the head of the Health Care Financing Administration came in and said, well, we plan to change the gag rule

next year. My response was that we should not wait until next year.

It happened to be November 13, and I counted the days remaining in the year. There were 48 of them, and I said a lot can happen in 48 days or 48 hours or 48 minutes, and I commented that the President had opposed the gag rule 5 months earlier, and I know the President was really in charge of HCFA the last time I looked; as a result, HCFA did change the gag rule just 12 days later, on November 25, 1996.

I have taken up with Secretary Shalala the issue of managed care having a share in graduate medical care, because they do not have any now, and we are looking for answers.

When you say that it denies referrals away from research centers, could you particularize that a little more?

Dr. FREEMAN. Yes; the testimony that we heard, Senator, indicated that throughout the country—and the four regions that we explored, there was a tendency particularly on the west coast where the managed care system is more highly developed, that there was a tendency for the managed care companies, many of which are for-profit companies, not to wish to send their patients to the medical centers, the academic medical centers where the cost is a bit higher, but it is a cost that the American society needs to pay to keep its advances going.

Senator SPECTER. So it is not only for the patients, but it is for the ongoing research.

Dr. FREEMAN. Yes; that is the key issue, is not only patients being harmed, perhaps, but research centers threatened for their very existence, and I think this is a major issue to be considered, that we have major academic centers that are being squeezed and threatened to the point where they may not exist in the future.

Senator SPECTER. Well, Senator Harkin and I have introduced legislation, Senate bill 441, where 1 percent of insurance premiums would go to support medical research. We are trying to add on the private sector. That would be about $6 billion for biomedical research. We are very concerned about the problem, Dr. Freeman, and I would like to pursue it with you in terms of what suggestions you might have as to how we solve it.

I do not have to tell you that we do not have all the answers in Washington. We need help from the professionals, who see it day-in and day-out.

Dr. FREEMAN. Senator, we are completing a report to the President, perhaps within the next 30 days, and if you wish I will be happy to send you that report.

Senator SPECTER. I would like to see it. Perhaps I can read it faster than he can.

Dr. FREEMAN. Yes.

Senator SPECTER. I would like to see it.

Dr. FREEMAN. Very likely—thank you.

STATEMENT OF JACK KLUGMAN, ACTOR, MALIBU, CA

Senator SPECTER. We turn now to a very distinguished Philadelphian, Mr. Jack Klugman. One of the reasons for coming here today is to bring him back to south Philadelphia. [Laughter.]

We need his presence in my home town, and he has enjoyed tremendous success in films, television, theater, attended Carnegie Tech in Pittsburgh on the GI bill after his service in World War II, a three-time Emmy Award winner, including two for his role in the hit comedy series "The Odd Couple."

They have taken your "Odd Couple" and have applied it indiscriminately, Mr. Klugman. Now Hatch and Kennedy are being called "The Odd Couple" I think. I think you may have a cause of action. You might be able to win a lawsuit on that if you challenge it.

Senator Hatch said recently in one of his speeches, when Kennedy and I are on the same bill everybody figures one of us has not read it.

So your odd couple scenario has gained great fame. We appreciate your being here, Mr. Klugman, and look forward to your testimony.

Mr. KLUGMAN. Whenever I get that many compliments I always wish, as LBJ said, that my mother and father were here, my father because he would have enjoyed it, my mother because she would have believed it. [Laughter.]

Really, it is an honor to be here, Senator. When I told Sherry Lansing that I would be honored to appear before you, she sent me an enormous packet of very valuable information about cancer research, facts and figures and statistics which definitely prove the need and the value of cancer research. But now I am here, and I know you have heard all these figures over and over again, so I am going to throw as few statistics as possible, and I am going to jump right into the fire and get personal.

But the one word I did not see in the packet is the word, "miracle," and research can perform miracles. For instance, it is a miracle that research can have a doctor or a scientist know something about a disease on Friday that he did not know the preceding Monday. It is miraculous that a doctor can cure a cancer in 1997 that was incurable in 1987, and he only has one tool that helps him to do that: research, the only tool.

My father died in 1934, when I was 12 years old. My mother went to visit him in the hospital and he said to my mother, he said: "take me out of here, they do not listen to me, they are not helping me." He was in a ward with 30 other people, big wards in those days. He died 2 days later, and throughout the years, when people ask me what did my father die from, I really answer very bitterly, he died from poverty.

But as years went along I had to appear before—I spoke at the graduation, at Mount Sinai, of doctors, and I went over what my father had said. I was going to use the poverty line, but I realize what he said was, "they do not listen to me." It does not cost anything to listen.

And he said, "they are not helping me." But my older brother had assured me that doctors had done everything they possibly could, so he did not die from poverty, and he did not die from indifference, and he did not die from negligence. He died from ignorance. Because if the same doctors treated him today for the same illness, I was told that they could guarantee him a minimum of 20

more years of quality life. You see, the flip side of ignorance is knowledge.

I am living proof of why increased investment in cancer research is so critical. In 1997, this year, almost 11,000 new cases of larynx cancer will be diagnosed, almost 9,000 new cases in men alone, and 4,230 people will die from this devastating disease.

A little over 8 years ago they performed a partial laryngectomy on me, brought on by cancer caused by smoking, but I know that is a different congressional committee.

Senator SPECTER. Not really.

Mr. KLUGMAN. Not really? Well, let me get into that.

Senator SPECTER. Go ahead.

Mr. KLUGMAN. That light is going to go on.

Had I had the same illness 20 years ago, just 12 years previous, the doctors would have taken out my entire larynx and left me with a hole in my throat, and I would be talking to you on the bubble, or maybe with one of those vibrators, and the quality of my life would be gone because I would not be able to act any more, and that has always been my main love.

But because it was a partial, because of research they had found out how to just take out my right chord and not take the entire amount. I exercised vocally for 4 years, very hard, and now my voice is stronger, not prettier, but it is stronger, and last year—last year Tony Randall and I performed a play, "The Odd Couple", on stage in London in the most beautiful theater in the world, the Royal Haymarket Theater. We had a 4-month engagement. I did not miss one performance, and we played to standing ovations. [Applause.]

So the quality in my cup runneth over, and I swear, you ain't heard nothing yet. I am 75, and I am going on.

PREPARED STATEMENT

So Mr. Chairman, I beg you—I beg you today to commit to a doubling of the budget for the National Cancer Institute, and that will make sure that the best care is available to all people. We must stop equating money with human life. That really is an insult to human life.

Thank you. [Applause.]

[The statement follows:]

PREPARED STATEMENT OF JACK KLUGMAN

When I told Sherry Lansing that I would be honored to appear before this distinguished panel, she sent me an enormous packet of valuable information about cancer research. Facts and figures and statistics which definitely prove the need and value of cancer research. Now I know you have heard these figures over and over again, so I will limit the amount of statistics I throw at you. Instead, I'll jump right into the fire and get personal.

You see, the one word I didn't see in the packet was the word miracle. And research can perform miracles. For instance it is miraculous that a scientist can know more about a disease on Friday than he did the preceding Monday. Or that a doctor can cure an illness in 1997 that was incurable in 1987. And the only tool that helps him to do that is research. The only tool.

My father died in 1934. I was twelve. My mother and I went to visit him in the hospital. He was in a ward with thirty other patients. He said to my mother, "take me out of here. They don't listen to me. They are not helping me." Two days later he died. I never forgot the size of that ward. And for years, when anyone asked me what my father died from, I always answered angrily, "poverty."

But a few years ago, I realized I was wrong. He said, "they don't listen to me." Well it doesn't cost anything to listen. And he said, "they are not helping me." My older brother assured me that the doctor did everything he could. So my father didn't die from indifference. And he didn't die from negligence. He died from ignorance. If the same doctors treated my father for the same illness today, I was told he could be guaranteed at least twenty more years of quality life because of research. The flip side of ignorance is knowledge.

I am living proof of why increased investment in cancer research is so critical. In 1997, 10,900 new cases of larynx cancer will be diagnosed. 8,900 new cases in men alone. And 4,230 people will die from this devastating disease.

A little over eight years ago they performed a partial larynectomy on me brought on by cancer caused by smoking cigarettes. (but I understand that's for a different congressional committee).

Had I had the same illness twenty years ago, the doctors would have taken out my entire larynx and left me with a hole in my throat. And I never would have been able to act again. And since acting has always been my main love, my love would have lost all of its quality. But because of the partial, I was able to do vocal exercises that made my voice stronger. (not prettier, but stronger!) As a result, last year, Tony Randall and I did the play, "The Odd Couple" in London at the most beautiful theater in the world. The Royal Haymarket. We had a four month run and I never missed a performance. And we played to standing ovations. And so, ladies and gentlemen, the quality in my cup now runneth over. And you ain't heard nothin yet!

Mr. Chairman, I beg you today to commit to a doubling of the budget for the National Cancer Institute and to help make sure that the best care is available to all people.

We must stop equating money with human life. It's an insult to human life.

ABDOMINAL CANCER

Senator SPECTER. Mr. Klugman, may I ask you what your father died of?

Mr. KLUGMAN. He had abdominal cancer, which could have been taken today, I understand, because they caught it early. He was in hospital for such a long time. They just did not know what to do. He had been in there about 5 weeks.

Senator SPECTER. Was he in the old Jewish hospital?

Mr. KLUGMAN. Mount Sinai. You are too young to remember this ward, 30, 35 people on the ward, but they were taking care of him. The thing is, you hear what you want to hear.

Senator SPECTER. Well, you had two very powerful characterizations. He died from poverty, and then you said he died from ignorance, and I think both are appropriate. In America, no one should die from poverty. We have great wealth if we apply it properly.

And smoking, would you tell us a little more about that?

Mr. KLUGMAN. Well, I used to smoke, you know. That is the way it started. You were talking about Joe Camel now. That is how I started. There used to be a program called the Lucky Strike Hit Parade. This was many years ago, almost 60 years ago. They would have 10 songs, the top 10. If you wrote in the top three songs that you guessed would be the top three, they would send you a free carton of Luckys. Well, it was easy when the same songs were on top for 6 weeks, so all the guys are on the corner—and I am talking about 50, 60 guys. We would fill it out.

Senator SPECTER. Where did you live in south Philadelphia?

Mr. KLUGMAN. Seventh and Morris. We would send it in, and they would send us a carton of cigarettes, so we said, what suckers these people are. What fools. We got' em, boy. We did not realize that we were being hooked, and that is what they do with Joe Camel, and they have been doing it for years, something like 60 years, and that is what got me hooked on it.

Senator SPECTER. Seventh and Morris, was that not just around the corner from Frank Rizzo?

Mr. KLUGMAN. Yes.

Senator SPECTER. Did you know Rizzo?

Mr. KLUGMAN. Yes; I knew him quite well—quite well, quite a character.

Senator SPECTER. But he did not smoke.

Mr. KLUGMAN. I did not know that. If he did not, he was the only one in south Philadelphia, I will tell you that. If they had known they would have thrown him out. [Laughter.]

Senator SPECTER. Well, thank you very much for your testimony, Mr. Klugman. You have given some good verbiage for the Congressional Record. We will put it in.

STATEMENT OF JUDD ROSE, ABC NEWS CORRESPONDENT, "PRIME TIME LIVE," NEW YORK, NY

Senator SPECTER. We turn now to Mr. Judd Rose, a correspondent with ABC News, "Prime Time Live," since May 1989, prior to that a Washington-based correspondent for "Nightline," Emmy Award winner for his contributions to "Nightline's" coverage of the Philippine President Marcos, extensive experience in TV and radio, reported on some of the most significant news stories of the day, including the San Francisco earthquake, or one of the recent San Francisco earthquakes, the crash of Pan Am 103, and the U.S. invasion of Panama.

Thank you for joining us, Judd, and the floor is yours.

Mr. ROSE. Thank you, Mr. Chairman, and like everyone who has preceded me today, I appreciate the opportunity to speak here about a subject that is very important to me, and I appreciate the fact that you are interested in a subject that is important to so many of us.

You just cited all of my years as a reporter. In those years I have always gone by the rule that I am not the story, and I think that that is a rule that is being broken a lot these days, but I have always tried to adhere to that. But last fall, when my friend and colleague Sam Donaldson, who had gotten through a bout with melanoma cancer, came to me and suggested that we get together and do an hour on "Prime Time Live" television about our stories and then talk about other people and what they dealt with, I broke my rule and we went on the air with that last October.

The response that we got, both Sam and I, was phenomenal. He received thousands of letters, e-mails, phone calls, faxes. I received hundreds. Clearly, what we did touched people out there, and I am very proud that we did that.

What we also learned, among many things, in doing that hour was that there are many potential treatments for brain tumors and other kinds of cancers that are being worked on now that in fact could be ready in a very short time if the money is there to pay for the research. I will get back to that in 1 minute, but obviously I am not here today as a medical expert or a scientist. I am neither of those. All I know is basically what I have reported on, and been told by other people, but I am here as a survivor, so I would like to tell you briefly about my story.

In the fall of 1993 I was 39 years old and, like one of the other people here testified today, Olivia Newton-John, I did not smoke, I did not drink, other than the occasional beer—I was a pretty healthy guy, so that was the way I proceeded.

In the fall of 1993 I started getting dizzy spells. They did not last very long, but they were frequent, and then I started losing my balance, again not in a serious way, but enough so that I noticed it.

I went to my doctor, and I was diagnosed as having an inner ear infection, and so I took the medication. It did not seem to help at all. Finally, after a few months I went and got an MRI, and after the MRI it was clear something was going on in my brain and, after consulting with several neurologists, I got a biopsy which showed that I had a grade II astrocytoma, a brain tumor.

Senator SPECTER. You had a biopsy before surgery?

Mr. ROSE. Yes; In fact, surgery, when they took a look they realized that surgery was not an option, because it had grown in a place where they could not operate. Surgery was not an option, chemotherapy was not an option because all of the doctors that I spoke with told me that what they had available for my type of brain tumor was not really very effective and they had terrible side effects.

So basically it came down to radiation, and they were going to hold that unless and until my tumor began to grow. A grade II tumor, as you may know, it means that it is there but it is not necessarily growing at that particular point.

So I did not have a lot of options, and finally when the tumor did begin to grow late in 1994 radiation was really my only choice, and I began a 6-week course of radiation at Memorial Sloan-Kettering Hospital in New York, which as far as I can tell is about the best in the country for that sort of thing.

I went in there for 6 weeks, every day of the week for 6 weeks, and by the time I was finished, of course, like everybody who goes through this I was bald. I used to have a big bushy head of hair. I was bald, and I was bloated from this huge amount of steroids that I had been taking, and I was bed-ridden for more than 1 month after the radiation ended, because it depletes your energy in such a way that you cannot get out of bed. You cannot literally get up on your feet.

It is one of those things where you think to yourself at the time, the cure is worse than the disease. Of course, I realize that is not the case, but you get the idea.

For months after that—and we are talking now about the spring of 1995—I had to walk around with a cane. I wanted to get back on the air. That was my job, and I wanted to get back to it, and I probably got back to it a little too early, but I felt that I wanted to show the people I work for that I was not damaged goods.

I looked like I had put on an enormous amount of weight because of the bloating from the steroids. I bought a wig to put on my bald head, and I looked like a guy with a wig, and I did not have the stamina, but I did go back to work finally.

Of course, as soon as I did go back on camera, anybody who did not know at that time that I had a brain tumor knew as soon as they saw it. I looked like a very sick guy.

I am not complaining, you understand. The radiation, as it happens, ended up saving my life. I stopped getting the radiation at the end of January 1995, but it continued to work in my brain for at least a year after that, and my tumor today has been reduced down to a little tiny, microscopic speck, so I am today pretty much like my own self, just with a lot less hair, and I guess at my age, which is 42, I should not be worried about that.

At the same time, even though I managed to survive, I have to stress how critical it is that we continue to search for new treatments that will reduce the damage that I suffered and so many people suffer in worse ways from the treatments we get.

Obviously, research is the key, and like Mr. Klugman I am not going to bore you with a lot of numbers, but I do want to give you a few important ones from the brain tumor side of this issue.

Some 17,600 Americans will be diagnosed with a brain tumor this year alone, and also this year 13,200 of us will die from a brain tumor. It does not take a mathematician to see that those are not great odds.

For brain cancer patients, it sounds like good news. The chance of survival for brain cancer patients, survival 5 years after diagnosis, that keeps going up, actually: 18 percent survival in the sixties, 20 percent in the seventies, 25 percent in the eighties, and just about 30 percent survival rate now.

That is good, obviously, but it is not good enough. We need more money for more research that will greatly improve the odds for those with brain tumors and, of course, all other types of cancer.

I can tell you from the reporting that Sam Donaldson and I did for that show last year that we saw just a few of these remarkable treatments that are in fact going on at UCLA Medical Center. There is—of course, you have heard of gene therapy, and they have been doing a protocol with gene therapy.

There is another thing called RMP–7, which they have been experimenting with, which would allow the administering of medicines to a brain tumor that cannot get in there now. All kinds of things are going on, but of course without the funding to keep those experiments going, they will not. They will not go forward. That is a risk we just cannot take.

Senator SPECTER. Mr. Rose, the biopsy that they did, how did they do the biopsy?

Mr. ROSE. My biopsy was a stereotactic biopsy, in other words, needle biopsy.

Senator SPECTER. And what was the finding on that?

Mr. ROSE. I had a grade II astrocytoma.

Senator SPECTER. What does that mean?

Mr. ROSE. An astrocytoma is a type of brain tumor that is—obviously all brain tumors are serious. Mine was not as bad as some. Grade II, as I said, means that it is not growing.

Brain tumors are graded I through IV. You may know this. People say was it malignant, was it benign. Well, they do not really talk about tumors that way in the world of doctors. It is I through IV.

I is basically just what children get, if children get a brain tumor, that is a I. II, what I had, you have a tumor, but it is not growing at that particular point, and hopefully can be controlled

with whatever treatment. III means it is growing and you have to do something, and do it quickly. IV basically means it is terminal.

I had a II, which was sort of on the bad side. Then it began to grow, and since radiation, it is now on the good side, I would say. It has shrunk down to such a small point.

Obviously, listening to all of the other people who are testifying here today, my story is not incredibly different from all the others. I want to repeat the point that some of them made that this affects all of us. Everyone at least knows somebody who has cancer.

PREPARED STATEMENT

Let me tell you that the same month that I was diagnosed, I found out that my mother had breast cancer, and she died a few months later. It is too late for her, but my survival, the survival of all of these people and countless others, it depends on you and the decisions of this committee. I ask for your help, and I thank you for your time.

[The statement follows:]

PREPARED STATEMENT OF JUDD ROSE

Mr. Chairman, I am pleased to testify at this special hearing on research. I want to personally thank you for your attention to the topic of cancer, which affects the lives of millions of Americans, their friends, and families each year.

I am not a very public person about my private life. But I am here today to share with you how progress in cancer research has made it possible for me to continue my work and my passion despite a terminal cancer diagnosis over four years ago.

In the fall of 1993 I started having dizzy spells. My equilibrium and balance were out of synch as well. I was originally diagnosed with an inner ear infection, but the symptoms kept getting worse and not improving. Finally, I consulted some of New York's top neurologists. My worst fear was confirmed: I was diagnosed with a brain tumor, also known as a Grade II astrocytoma.

I was stunned. At that moment, I wasn't depressed or angry, just shocked. I was always a pretty healthy guy.

Because of the tumor's location, surgery was out of the question. So I began various types of treatments, including radiation, chemotherapy, and steroids.

I won't lie to you, the treatments that saved my life were not pleasant. I lost my hair and experienced severe bloating throughout my body. I cannot stress enough how critical it is that we continue to search for new treatments that will minimize the effects on our bodies. Research certainly holds the key to discovering gentler antibodies that can destroy the disease with as little impact as possible on our bodies, minds, and lives.

But I also don't kid myself in that the discoveries made to date from research in the last 25 years have saved my life.

Some 17,600 Americans will be diagnosed with a brain tumor in 1997. And 13,200 people will die of brain tumors the same year. I'm not a mathematician, but I can understand that those aren't great odds.

Brain cancer patients are given a 29-percent chance of survival 5 years after diagnosis. The survival rate has continually gone up from 18 percent in the 1960's, 20 percent in the 1970's, 25 percent in the 1980's, and now almost 30 percent in the 1990's. But unless there is an infusion of funding into cancer research, brain tumor patients only expect a 30-percent chance of survival—and that is unacceptable. More money for increased research will greatly improve the hope and opportunities for those newly diagnosed with a brain tumor and other types of cancer.

Since 1996 my tumor has shrunk, and I am symptom-free. I am coming up on my fifth year as a survivor—an extremely significant benchmark for cancer survivors. But for others as well as myself, I want to be sure cancer researchers have the full support of the U.S. Congress to take advantage of every research opportunity that presents itself.

We cannot rest until the budget for cancer research is doubled.

I lost my mother to cancer. We have all lost a friend or family member. My survival depends on you and the decisions of this Committee. I am confident you will strive to help those of us afflicted by this terrible disease.

PUBLIC IMPACT

Senator SPECTER. Well, we can work together, Mr. Rose. Some might say that ABC–TV has more currency, more distribution, more impact than the Congressional Record. I am not too sure.

Mr. ROSE. Well, certainly. We are planning a sequel, if you will.

Senator SPECTER. OK, good. Our appropriations process tops you, notwithstanding the power of ABC and Disney, but our public impact is not quite as great as ABC.

Thank you for your testimony.

Mr. ROSE. Thank you.

STATEMENT OF STEVEN WEBER, ACTOR, BEVERLY HILLS, CA

Senator SPECTER. I would like to turn to Mr. Steven Weber, an accomplished dramatic and comedy actor perhaps best known as the character, Brian Hackett, on the NBC comedy "Wings," recently seen on the ABC miniseries, Stephen King's "The Shining," also starred in such films as "Leaving Las Vegas," "Hamburger Hill," and in addition to his career in television and film he has performed in the theater, making his Broadway debut in 1985 in "The Real Thing."

Welcome, Mr. Weber. We look forward to your testimony.

Mr. WEBER. Thank you, Mr. Chairman. This is just a brief story about a surviving family.

In 1958, a daughter was born to a couple. Two years later a son was born, and they lived as most families live. They tried in the most basic ways to simply be happy. The parents worked to support their children and themselves, to provide a home, food, and as many comforts as they could.

Time, of course, passed, as the parents grew older they continued to do what most parents seek to do, to watch their children grow into strong, healthy teenagers, to hopefully become wise and sensitive adults, and perhaps to go on to have children of their own, and above all to keep the family strong and close.

But, of course, the unforeseen happens. In 1990 the daughter, who was born in 1958, died at age 32 of complications stemming from lymphoma. She left a family that has not recovered from her loss, a family that simply wanted to live, as most families want to live, unburdened by hardship, illness, and pain.

The family that survived her did not understand why she had died, nor do they understand it now. They watched and listened to doctors who tried to explain the complicated puzzle that is cancer. They struggled to understand why they had to literally stand helplessly by while the girl was overtaken by the disease.

They felt ignorant, ashamed, embarrassed that they should be so ill-equipped to deal with the situation, and in the end they felt the leaden weight of her loss, the finality of her absence, and they were left with the image of the beautiful young woman's eyes wide with terror as infection swept through her lungs, smothering her.

The doctors had done all they could for her, and despite the breakthroughs in treatments and research, the care shown by the physicians and specialists, all working under endless pressure of trying to help people desperate to simply live, it still was not enough.

Cancer, of course, still tears families apart and destroys the most basic dreams that we all have. So this is what is left for those who are powerless, the surviving families who do not themselves have the direct resources to take action against cancer, who have to stand helplessly by and watch their daughters, their fathers, their mothers, their sons, their friends, their sisters slip from their grasp utterly and forever.

This is what is left for the surviving families, to beg those who have the power to wield it forcefully and wisely and to commit themselves to the eradication of this most formidable destroyer of families.

And so, Mr. Chairman, I beg you on behalf of my sister, Abby Weber, who was born in 1958 and who in 1990 died of cancer at age 32, to please continue your generous and necessary efforts to fund cancer research. Millions of families depend on you to simply live.

Thank you.

Senator SPECTER. Thank you very much, Mr. Weber. [Applause.]

That is a very powerful, real life situation. A longstanding friend of mine, Dick Buterra, who is in the audience today, has a somewhat similar personal experience with a daughter, and of course the power is greatest when it is personal, very obviously, and when we juggle all the figures in Washington they tend not to be too personal.

We talked about a balanced budget. That is an important objective, but the step beyond that is to assess priorities, and as Dick Buterra says when he talks about many of the other ailments—and there is fierce competition for these NIH dollars among heart disease and cancer and Alzheimer's and AIDS. Those other people, most of them are living, but in cancer they are not. They are not breathing—or hearing disorders, or what-have-you. We have to make this impact felt on the decisionmakers, and I am one of them, and I have a key position.

I am determined to raise NIH funding—I set a target of providing a 7½-percent increase this year, which would be $952 million, and I am not quite sure at this point how I am going to get there from here, but I am determined to get there. Hearings like this and airing the kinds of personal experiences we have heard today are very powerful driving forces.

In your field you have a lot of powers, and cameras have enormous power, because they tell the story on television. People watch television, and Members of Congress watch television and hear from people who do. Hollywood talks and people listen, very much so.

STATEMENT OF DR. OWEN W. WITTE, PROFESSOR OF MICROBIOLOGY AND DEVELOPMENTAL IMMUNOLOGY, UCLA, INVESTIGATOR, HOWARD HUGHES MEDICAL INSTITUTE, LOS ANGELES, CA

Senator SPECTER. We turn now to Dr. Witte, professor of microbiology and molecular genetics, first incumbent of the president's chair in developmental immunology at Howard Hughes Memorial Institute at UCLA, a recipient of numerous awards for leukemia and cancer research, a graduate of Cornell and Stanford University School of Medicine, completed his postdoctoral research at the Center for Cancer Research at MIT not too long ago.

What comes after post doctoral research? I ask that because Joan and I have a son who is just working on his postdoctoral research. We thought when he had his Ph.D., he was there, but where else do you fellows and women go?

Dr. WITTE. If the budget of NIH is increased sufficiently there will be jobs out there for the Ph.D.'s and postdoctoral fellows that we are training currently.

Senator SPECTER. Our son has no interest in a job. [Laughter.] That is not where he wants to go.

Dr. WITTE. Send him to my lab for a couple of years. It will shape him up.

Senator SPECTER. OK. He is on his way.

Dr. Witte, we thank you for being here, and we have not started your clock yet.

Dr. WITTE. OK. Thank you very much.

Senator SPECTER. So the whole time is yours.

Dr. WITTE. I just want to connect with some of the other testimony we heard this morning and to a comment you made, which is that people talk about research, we talk about new therapies, we talk about advances. Who does the research? Where do the new medicines and therapies come from?

It connects to your comment where you said the two things you are most interested in are (1) advancing the research agenda in the NIH budget, and (2) education, and they are intimately related, and that is what I would like to speak to today about.

I have had the privilege of being supported by the National Institutes of Health, and in particular the National Cancer Institute, for over 17 years. My own research and work in the area of human leukemia has helped to define the genetic basis of this group of diseases and provided new insights useful in diagnosis and therapy. In fact, I was delighted that some of the things we worked on a decade ago have come to be borne out in some of the stories you heard today from Dr. Forman and his patients.

As many witnesses have testified, the National Institutes of Health funding is the most critical resource available to move our knowledge forward in the fight against these dreaded diseases. We really could put a great deal more money to use immediately on needed and valuable research projects.

Today I would like to focus on an item of great concern to me as an educator and a medical researcher. A not-so-obvious benefit to added research funding is the impact it has on the overall process of education for the next generation of scientists. The excitement caused by the revolution in molecular biology and biotechnology has led to direct advances in biomedical research. It has also not surprisingly resulted in a dramatic surge in the number of students enrolled in our colleges and universities who major in these subject areas.

At the University of California, Los Angeles, as one example, within the last 5 years we have seen a huge increase in the number of majors in such disciplines as biochemistry, microbiology, neurosciences, cell biology, and molecular biology. Currently, there are over 5,000 students enrolled in these areas of study at UCLA. A little simple math across the board of the number of people inter-

ested in these subject areas around the country comes to an impressive figure.

These students that are interested in these careers in biotechnology and biomedicine get this excitement both from what is going on in the field, as well as from the lay press. In fact, I think it is hard to find a week that either Time, Newsweek, or other major periodicals do not have a lead story about what is going on in biomedicine, cancer, and other subjects.

Now, the hands-on doings of science is a critical component of science training. Students in our classes want to work with the advanced technologies necessary to study the important biological processes associated with cancer and other diseases and then apply this knowledge as they move from college into further professional training—that would be your son—or the job market.

They want to participate in this biological revolution that will carry us into the 21st century, and at the same time our biotechnology, pharmaceutical, and health care industries want better-trained graduates competing for the broad range of jobs they can provide.

Now, I believe that NIH funding will support not only this critical research agenda to press forward on the causation of disease and new therapies, but simultaneously provide the educational framework for the efficient framework of new generations of scientists. This will occur by increasing the opportunities for practical experience before they leave their undergraduate training and continuing on to graduate school and post doctoral training.

Our faculty that teach this group of students must also be critical to practitioners of the art of science, so if we view our colleges and universities as providers of opportunity, we must face the issue that classroom teaching alone is not sufficient to ensure that the most competitive group of young biological science graduates will be the next generation of professionals working to define a knowledge of disease and new cures for such diseases.

PREPARED STATEMENT

So in summary, Mr. Chairman, the increase in funding for the National Institutes of Health will ensure faster progress toward the treatment of these dreaded diseases and also ensure the quality and training of and opportunity for thousands of students who wish to participate in the biotechnology and biomedical revolutions.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF OWEN WITTE

Good morning, Senator Specter and other distinguished members. My name is Owen Witte; I am a professor at the University of California, Los Angeles, and an investigator at the Howard Hughes Medical Institute. I am pleased to be present and to provide my testimony concerning the benefits of increased research funding through our National Institutes of Health.

I have had the privilege of being supported by NIH, in particular the National Cancer Institute, for over 17 years. My own research experience and work in the area of human leukemias and immunology has helped to define the genetic basis of this group of diseases and provided, I believe, new insights useful in diagnosis and therapy. As many other witnesses have and will testify, NIH funding is the most critical component to move our knowledge forward in the fight against these

dreaded diseases. We could put a great deal more money to use immediately on needed and valuable research projects.

Today I would like to focus on an item of great concern to me as an educator and a professor. A not-so-obvious benefit to added research funding is the impact it has on the overall process of education for our next generation of scientists. The excitement caused by the revolution in molecular biology and biotechnology has led to direct advances in biomedical research. It has also, not surprisingly, resulted in a dramatic surge in the number of students enrolled in our colleges and universities who major in these subject areas. At the University of California, Los Angeles, we have seen a dramatic increase in the number of majors within the last five years. The number of students declaring themselves interested in careers in biotechnology and biomedicine has more than doubled. The tremendous public interest in this subject area, as seen in the lay press and professional science magazines, goes hand-in-hand with this increased excitement.

If our colleges and universities are to provide the appropriate training for these students, we must not only develop the didactic curriculum for lecture and seminar groups, but also provide substantive early research experiences in the professional research laboratory. Most students get the science bug sometime during junior high or high school, but they only really experience science when they have the opportunity to conduct science themselves.

The "hands on" doing of science is a critical component of science training. Students in our classes want to work with the advanced technology necessary to study the important biological processes associated with cancer and other diseases and then apply this knowledge as they move from college into professional training for the job market. They want to participate in the biological revolution that will carry us into the 21st century. At the same time, our biotechnology, pharmaceutical, and health care industries want better-trained graduates competing for the broad range of job opportunities they can provide.

Increased NIH funding will support not only the critical research agenda to press forward on defining the causation of disease and new therapies, but will simultaneously provide the educational framework for the efficient training of new generations of scientists. This will occur by increasing the opportunities for practical on-the job experience during the undergraduate years.

The faculty that teach this group of our brightest students must also be critical practitioners of the art of science. If we view our colleges and universities as providers of opportunity, we must face the issue that classroom teaching alone is not sufficient to ensure that the most competitive group of young biological science graduates will be the next generation of professionals working to define a knowledge of disease and our new cures for such diseases.

In summary, Mr. Chairman, an increase in funding for the National Institutes of Health will ensure faster progress toward the treatment of dreaded diseases and ensure the quality training of and opportunity for thousands of young students who wish to participate in the biotechnology and biomedical revolutions. Thank you for your attention. I would be happy to answer any questions.

MOLECULAR GENETICS

Senator SPECTER. Thank you very much, Dr. Witte.

Would you amplify on exactly what molecular genetics is?

Dr. WITTE. It is the study of how genes influence either processes of life or, in the case of diseases like cancer, how they influence the progression of disease, and it is really an explosive area of research, and what we know about cancer causation today really can be lumped under that heading of molecular genetics.

Senator SPECTER. How is that distinguished from microbiology?

Dr. WITTE. Microbiology would include the study of microorganisms, but as we heard earlier today, controlling a cytomegalovirus [CMV] infection in a cancer patient is just as important to the outcome of that patient's life as is treating the primary cancer, so it is hard to segregate cancer research from any of these disciplines, and in fact we utilize all of those disciplines in our approach to studying cancer.

Senator SPECTER. How would you quantify, if you can, the progress made on finding a cure for cancer? I realize that is a very broad question.

You have Dr. Bailar articulating the conclusions, which we see in the morning's press, and I have not had a chance to read his report, and I suppose you have not either, because it is hot off the press. How would you respond to what Dr. Bailar has said in terms of progress which you have seen on trying to find the cause of cancer with your microbiology, or molecular genetics, or whatever else there is in the field?

Dr. WITTE. This morning we heard from many people who said they neither smoked nor drank or did anything to any excess, and we heard about cancer in children. There is much in cancer for which there is no appropriate preventive cause of action. Cancer happens. It happens based on genetic principles as well as things in our environment. That is undeniable by any study, not just the latest study.

What I sense and what I see is that the progress we make in cancer research is hard to predict down the line, and in fact some of the spectacular results we saw today of people standing and testifying about their disease and treatment—Dr. Forman—relates to things that at the time we study them we had no idea there would come to this conclusion.

In fact, the particular piece of work that I did over a decade ago was to define the molecular genetic change in the type of leukemia that one of the women today spoke of, called chronic myelogenous leukemia. It actually comes from something called the Philadelphia chromosome, which you may have heard about. It is the only cytogenetic event——

Senator SPECTER. Why is it called the Philadelphia chromosome? Is that like the Philadelphia lawyer?

Dr. WITTE. No; it is actually like the Philadelphia Philadelphia in Pennsylvania, because Peter Noel, the man who first described that, was working at the University of Pennsylvania.

The convention to name chromosomal abnormalities after cities started and stopped with the Philadelphia chromosome. They now have boring numbers that nobody will remember.

But as a young assistant professor at UCLA, without meaning to we actually stumbled upon the molecular key to what happened in that disease.

From that point, my laboratory, in cooperation with biotechnology companies, developed improved diagnostics which are used, I am sure to this day to monitor patients such as Dr. Forman's to look for residual disease and an increase in disease, and subsequently new therapies for this disease based on a knowledge of how the stem cell, a particular cell in the bone marrow works, and how it is affected by it.

So I do not think what is in that article about preventing cancer makes a lot of sense for people who have cancer currently. I think we need to face the reality.

Senator SPECTER. Well, what do you think Dr. Bailar's point is? It is difficult for you to put yourself inside his head, but——

Dr. WITTE. I do not know him and I do not know the study.

Senator SPECTER. What do you think his point is here?

Dr. WITTE. I think his point is that there are some preventable causes of cancer. I think smoking is one.

Senator SPECTER. Well, OK, so we ought to do more on cancer prevention. Smoking, the environmental factors, detection, early detection, but he fairly slams research very, very hard.

Dr. WITTE. Well, having not read his study and only the excerpts from the USA Today I think probably I should reserve judgment.

Senator SPECTER. He came to the conclusion back in 1986. Now he says it again, on a study that he made up through 1982.

Dr. Freeman, do you have any thinking as to whether—we are going to ask him to come in and testify in Washington.

Dr. FREEMAN. Yes; I think it would be fair to let him say what he really wants to say. I have read the article, and I have it in my bag right here, and I do believe that the headline that you read does not depict the article.

Senator SPECTER. Well, that is the first time that has ever happened. [Laughter.]

Dr. FREEMAN. They have taken a sort of editorial view and try to make a more sensational headline. I think you can disagree with Dr. Bailar or you can agree, but it is true, however, that the greatest impact that you can have on an emanating cancer would be prevention.

If no one smoked, about one-third of cancers, people who die now would not die. If we could improve education with diet, another third probably would not die.

But it is not an either-or, Senator. If Dr. Bailar is saying it is prevention or treatment, then I would disagree with him firmly. We need to go into research for treatment. We have made great breakthroughs. We have people here who represent those breakthroughs.

Senator SPECTER. Does his article say, as depicted in the USA Today, that we are not getting value for our research dollar?

Dr. FREEMAN. There is an implication that we should have shifted the money more toward research, in his article.

Senator SPECTER. Away from research?

Dr. FREEMAN. If you had a limited amount of money, he believes you should shift it more toward prevention as opposed to treatment research, but I think you need to read the article. The newspaper is a bit unfair to Dr. Bailar.

On balance, there is a need to prevent cancer, and there is a need to do research to advance treatments for cancer. We have made great advances in pediatric cancer and Hodgkins disease, certainly the lymphomas, testicular cancer. Truly, those are diseases where not many people are affected.

We have not gotten to colon cancer. We have not gotten to breast cancer in the way that we have to.

Senator SPECTER. We have not gotten as far on colon cancer and breast cancer?

Dr. FREEMAN. As far as being able to treat them for cure.

Senator SPECTER. Contrasted with the other types of cancer?

Dr. FREEMAN. Yes; that is correct.

Senator SPECTER. Why are we behind on breast cancer?

Dr. FREEMAN. Because we have not done enough research.

Senator SPECTER. That is a field which at least recently has come under intense scrutiny, deservedly so.

Dr. FREEMAN. Yes.

Senator SPECTER. In my position I have a lot of complaints about the money we are spending on breast cancer, the money we are spending on AIDS, believe it or not. People are showing me statistics about how many people have AIDS and how many women have breast cancer, how many people have other kinds of ailments. Of course, you can get the statistics arrayed in virtually any line, but should we be spending more money on research on breast cancer?

I asked Dr. Klausner the question on one of our recent hearings that we had on the mammograms, for women between ages 40 and 49, how much do you need? How much do you want? What is the figure? I have not really gotten that figure here, because I think there are some of us who would spend whatever it takes, like Elizabeth Crew's book, "Whatever it Takes," might even get foreign contributions for whatever it takes.

Dr. FREEMAN. Yes; well, Senator, that is a tough question, but there is good and bad in targeting research toward one disease. It may very well be that the answer to breast cancer may come from another line of research. We have to deal with the fundamental changes that take place called carcinogenesis, and that might occur in a laboratory of a doctor who is dealing with a different disease.

Senator SPECTER. You are gesturing toward Dr. Witte.

Dr. FREEMAN. Yes.

Senator SPECTER. More money for Dr. Witte?

Dr. FREEMAN. Well, perhaps so, but my point is that it is a controversial issue as to whether you should target money on a certain site as opposed to putting the money on the very basic research that might affect all sites.

Senator SPECTER. Well, thank you very much, Dr. Freeman, Mr. Klugman, Mr. Rose, Mr. Weber, Dr. Witte, and special thanks to Ms. Sherry Lansing, chairman and CEO of Paramount Pictures Corp. [Applause.]

She has had an illustrious career, is having an illustrious career, and we very much appreciate the work that Dr. Helen Segal has done, presidential appointee to the National Cancer Advisory Board and chair of its budget and planning committee which oversees the board's $2 billion budget. Special thanks to Ms. Helene Brown, a leading advocate, activist in the fight against cancer, and responsible for implementing the mass media approach for many items going all the way back into the fifties and sixties on the new pap smear. [Applause.]

SUBCOMMITTEE RECESS

I have been at quite a few hearings, and this is one of the best. I will be sharing this with our colleagues on the subcommittee, the full committee, and the full Congress, so we thank you very much for coming. [Applause.]

That concludes our hearing. The subcommittee will recess and reconvene at the call of the Chair.

[Whereupon, at 12:13 p.m., Thursday, May 29, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

MEDICARE: PHYSICIAN PRACTICE EXPENSES AND WINNING THE WAR ON CANCER

THURSDAY, JUNE 19, 1997

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2:53 p.m., in room SD–124, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF KATHLEEN A. BUTO, ASSOCIATE ADMINISTRATOR FOR POLICY

OPENING REMARKS OF SENATOR SPECTER

Senator SPECTER. Good afternoon, ladies and gentlemen. We will proceed with the Subcommittee on Labor, Health and Human Services, and Education. I regret our late start. We have on the floor the intelligence authorization bill, and it was necessary for me to be there, and as sometimes happens in the Senate we are in the midst of a vote now, so I voted and came right over. We are soon going to have a second vote and then a third vote, so I am going to have to return there in about 15 minutes. We have a great many witnesses on important subjects, so we will do the best we can to try to conclude the hearing. We had scheduled it from 2:30 to 4, and whether we will be able to maintain that schedule, I do not know, but we will proceed.

PREPARED STATEMENT

I have a lengthy statement which will be made part of the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

The Senate Appropriations Subcommittee on Labor, Health and Human Services and Education will come to order. Today we will have three panels to discuss separate, but equally important, topics.

We will first hear from the Associate Administrator for Policy of the Health Care Financing Administration followed by a distinguished group of medical professionals to discuss the impact of proposed Medicare "practice expense" regulations, that could result in dramatic changes in payments to various providers. These regulations, scheduled to take effect January 1, 1998, are required by legislation passed by Congress in 1994 to adjust Medicare reimbursement to physicians to better reflect the actual practice expense costs.

There has been a great deal of controversy about the accuracy of the data used by the Health Care Financing Administration in developing the new system of calculating physician overhead costs. It has taken the Health Care Financing Administration a long time to issue these regulations. Many physician groups, including the AMA, have been critical of the short time they have been given to analyze the new proposals. Certain specialists are facing severe reductions in Medicare reimbursements, that when combined with other fee schedule changes being contemplated by Congress, could adversely effect quality of care and access to care by senior citizens.

Even as these regulations are being published for a 60-day comment period, the authorizing Committees are considering changes to the law as part of reconciliation legislation which is on a fast track in Congress. This hearing provides not only the first opportunity to discuss the proposed regulations, but also to assess the impact, feasibility, and cost to this Committee of possible legislative changes requiring the collection of new data.

The final panel will continue our ongoing series of testimony examining the national War on Cancer and its progress and prognosis after 25 years of effort. On two previous occasions, once here and once in Los Angeles, we heard compelling testimony from individuals who have survived cancer and who called for more cancer research. On the morning of our Los Angeles hearing, May 29, the USA Today newspaper ran a front page story: "$30 Billion War on Cancer a Bust?", based on an article in the New England Journal of Medicine that critiques the priorities given to prevention research verses treatment research in the War on Cancer. Our panel will feature Dr. John Bailar of the University of Chicago, chief author of that article, and Dr. Richard Klausner, Director of the National Cancer Institute and as such, stands as the commander in chief in the War on Cancer.

SUMMARY STATEMENT OF HON. KATHLEEN BUTO

Senator SPECTER. We will proceed now to hear Ms. Kathleen Buto, Associate Administrator for Policy of the Health Care Financing Administration. And to the extent you can focus, Ms. Buto, in the 5 minutes you have allotted to you as to what is happening with the schedule of physician payments due on May 1 and what the proposals are for HCFA to act on that, there are some proposals now pending to give a year's delay, and what would that mean and what can we expect from HCFA.

Thank you for joining us. The floor is yours.

Ms. BUTO. Thank you very much, Mr. Chairman. I am pleased to be here today to discuss our proposals for implementing the fee schedule, the relative-value-based practice expense portion of the fee schedule. I have a lengthier statement which is being submitted for the record. I am going to really respond very directly to your comments and first announce that the proposed rule was published in the Federal Register on Wednesday. It does some very important things to begin to change and make more accurate the relative overhead payments or the overhead cost payments.

Senator SPECTER. Any coincidence of that publication yesterday with this hearing today?

Ms. BUTO. No; quite frankly, we have been working toward a May 1 date, as you noted, and it has just taken us longer than that to get this work completed. So there was really no connection.

Senator SPECTER. No connection. OK.

PHYSICIAN PRACTICE EXPENSE

Ms. BUTO. We actually put the reg on Federal Register display on Friday the 13th, an auspicious date, but it has been out in the public domain since last week.

The way physicians are now paid, we have a fee schedule where the work part of the fee schedule is based on physicians' estimates of their time, skill, and effort typically required for the service. But practice expenses and malpractice values in our fee schedule are based on our old historical reasonable charge system. These are historical charges without a direct relationship to actual costs.

The inequity in the current system could be seen by comparing practice expense payments, these overhead payments, for the most common office visit with, for example, triple heart bypass surgery. Medicare pays almost 100 times more for the physicians' practice expense, this overhead payment, for bypass surgery than for an office visit. This would be about $1,400 in overhead payments to the surgeon compared to about only $14 for the office visit overhead. Most observers agree that the relative values here for practice expenses are out of line for both services, and our analysis suggests that the ratio should be closer to 18 times as great for heart bypass overhead costs as for the office visit, not 100 to 1 as currently is the case.

So as you pointed out, we have issued a proposed rule. The rule is supposed to go into effect for fee schedule payments beginning January 1, 1998. As you noted, the Congress is considering a number of proposals, both the House and Senate, to look at an extended implementation schedule for the fee schedule. As currently in law, the fee schedule changes would go into effect in one fell swoop beginning January 1, 1998, the original fee schedule provisions involving the work portion that is now on a relative value basis.

Senator SPECTER. So you are prepared to have the schedules go into effect January 1, 1998?

Ms. BUTO. We are prepared to do that. The proposal is put forward with that schedule still in mind because we do not know ultimately what the legislation will say. However, I want to add that the administration is working with the committees to look at an extended implementation schedule, and we want to work productively. We agree that in many ways this kind of an extension would allow the changes to go in more gradually.

Senator SPECTER. Do you favor an extension?

Ms. BUTO. We do. We favor an extended implementation schedule.

I want to just point out a couple of things about the way we did the fee schedule. We used extensively the physician community to help us derive these values. The values are complicated. I will not go into them here because my testimony more specifically lays out how direct costs and indirect costs are computed and what they are and so on. But we did calculate these values using more than 170 physicians, 15 expert panels, and we included in those panels, in addition to the 170 physicians, practice managers and nonphysicians such as registered nurses who would have knowledge of the staffing and overhead costs associated for each procedure.

I should point out there are about 7,000 procedures that had to be costed, if you will. In addition to that, since they are in office and out of office, we are talking in the neighborhood of 14,000 distinct prices or costs that had to be associated with these fees. So it is a fairly complicated process.

Senator SPECTER. Was the questionnaire of any value to you?

Ms. BUTO. The questionnaire, the survey that we commissioned ABT Associates to put out, which they did last year, turned out to be very disappointing. We got about a 20-percent response rate from physicians, and found that we could not use it. Our hope was that it would help us to make that judgment about the right share between indirect costs and direct costs for each of the procedures.

Senator SPECTER. My question was was it of any value to you?

PREPARED STATEMENT

Ms. BUTO. Well, it was valuable in that we thought we could get more information than we did. I think if we had not undertaken the survey we might be under the illusion that we could do a major survey. We now think major survey is not the way to go in developing the methodology for indirect costs and that we ought to use more accounting-based methods for doing that, and that is what we have proposed in the proposed rule.

Senator SPECTER. Ms. Buto, would you mind staying with us? We have five chairs here. What I would like to do now is call the doctors, because I think we are going to have some interchange, and we will use the question and answer session as we move through the doctors.

[The statement follows:]

PREPARED STATEMENT OF HON. KATHLEEN A. BUTO

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am pleased to be here today to discuss the Health Care Financing Administration's proposed plans for implementing the practice expense relative value requirements which Congress mandated for physician services under the Medicare fee schedule. Research performed by the Physician Payment Review Commission (PPRC) and recommendations made in their 1993 annual report to the Congress documented the need to change the current practice expense RVU system and the significant redistributions that would occur under the new system. Following the PPRC recommendations, Congress passed legislation requiring HCFA to implement a resource-based practice expense relative value system beginning in 1998. The intent of the new system is to create a more equitable system for physician reimbursement which better reflects the relative cost of the resources that are involved when a physician performs a service.

BACKGROUND

Medicare's physician fee schedule, implemented beginning January 1, 1992, established relative values for three components of each physicians' service: physician work, practice expenses, and malpractice insurance. The sum of these three components represents the total relative value for a service; this total relative value is used in conjunction with a conversion factor to establish the Medicare fee schedule amount for the service. The relative size of the three components varies for each service, but on average, physician work represents 54 percent of the overall relative value, practice expenses 41 percent and malpractice insurance 5 percent.

The relative values for physician work were based on physicians' estimates of the physician time and effort typically needed to perform each service. Practice expense and malpractice expense relative value units, however, were constructed based on allowed charges under the old reasonable charge system of paying physicians. Rel-

ative values for these components thus largely reflect historical charge values, without a direct and explicit relationship to resources used.

One example of the inequity in the current system can be seen by comparing practice expense RVU's that Medicare currently pays for the most common office visit and for triple heart by-pass surgery. Under the existing system, Medicare pays almost 100 times more for the physician's practice expense (overhead) for a by-pass surgery than for an office visit. In other words, a physician practicing in an office would have to do almost 100 office visits to receive the same amount of practice expense as performing one by-pass surgery in a hospital. Most observers would agree that the "relative" values for practice expense is out of line for both services. Our analyses suggest that a ration of about 18 visits to 1 heart by-pass procedure is more appropriate, not 100 to 1.

PROPOSED RESOURCE-BASED PRACTICE EXPENSE RVU

To replace the current system of paying for practice expenses, Section 121 of the Social Security Act Amendments of 1994 requires the Secretary of Health and Human Services to develop and implement, effective January 1, 1998, a system of resource-based practice expense relative value units for each physicians' service. The law requires that the methodology recognize the staff, equipment, and supplies used in the provision of medical and surgical services in various settings.

Let me also point out that our task is to develop a set of "relative" values for practice expenses. That is, we need to determine the resource inputs for one procedure relative to another. Our task is not to measure the actual practice costs of any individual physician as we are not designing a cost-based reimbursement system.

We closely followed the statutory provisions in designing the resource-based practice expense relative value system. The approach we are using is one in which we divide practice costs into direct and indirect practice expense. Direct costs are the specific resource inputs, such as clinical and non-clinical labor, medical supplies, and equipment, that can be identified for a specific service. Indirect costs are overhead costs that do not obviously relate to specific services but under the fee schedule must be allocated to individual services. Indirect costs include rent, utilities, office equipment, accounting and legal fees, and similar general expenses. Relative value units are derived separately for direct costs and for indirect costs and then summed to create practice expense relative value units. We have proceeded by attempting to identify all the specific direct costs for individual services and have used an allocation method to attribute indirect costs to individual services. As we developed our approach, we sought input from researchers expert in relevant methodologies and from staff of the PPRC.

We have attempted to treat as many physician practice costs as possible as direct costs, explicitly linked to specific services and thus not requiring allocation. For hospital based services, we have even included as direct costs the many office expenses such as services of the receptionist to set up the appointment, the office billing and collection costs. In the aggregate, our estimates are that direct expenses are approximately 55 percent of total practice expenses while indirect expense are about 45 percent.

The data to establish the direct practice expense relative value units come from resource profiles furnished by expert clinical panels composed of practicing physicians, practice managers and other nonphysicians, such as registered nurses. These practitioners served on 15 Clinical Practice Expert Panels (CPEP's), each generally consisting of 12 to 15 members. These panels estimated the typical amounts of nonphysician staff time, including both clinical and non-clinical staff, medical supplies, and medical equipment expended in the provision of each physician service.

Because the physician practice incurs different costs in the office and non-office setting, the CPEP's reported direct service inputs for both settings when appropriate. The direct costs for each service were determined by applying national standardized wages or prices to the service inputs.

There has been much misinformation claiming that this new system is not based on accurate data. I wish to be very clear on this point: We obtained data about the direct resource inputs from the physician community. We asked physicians participating on the CPEP's to determine what supplies and equipment are used for the procedure and how long they are used. We asked the number and kinds of staff needed and the time they spend on procedures. We asked physicians how much staff time it takes to do the paperwork, appointments, billing, authorizations, reports and correspondence. We obtained all of these estimates from physicians who perform the procedures, their nurses and clinical assistants and the administrators who manage clinics and practices. We added up the costs of the supplies, equipment and staff to determine the other direct expense for each service. As I will explain below, we

then allocated part of the overhead (rent, heat, lights, automobile, etc.) to each code since all codes must have overhead components.

The allocation of indirect expenses to particular services is a standard problem in accounting for all industries. The task we face is to determine how much indirect expenses such as rent and utilities should be associated with a particular procedure. Unlike direct expenses where the resource inputs can be specifically linked to particular services, indirect expenses by their nature cannot be linked to specific services. The issue of how much rent or expenses for utilities that physician's practice incurs should be allocated to a by-pass surgery or an office visit requires some type of allocation method. No survey or study could determine the indirect costs of any of the more than 7,000 individual procedures.

No universally accepted method for allocation of indirect expenses exists. Accountants look for reasonable proxies and available data. For example, a reasonable case can be made that the amount of rent and utilities associated with particular procedures should depend on the amount of time the physician or his staff spend doing the procedure. Preliminary impacts we released to the physician community in January of this year were based on allocating indirect expenses using these two approaches.

We have continued to review those approaches to allocating indirect expenses as well as consider other alternatives. However, basically all the approaches we considered utilized formula-based methods in which indirect practice relative values are assigned to individual codes based on some factor, such as physician time, nonphysician time, direct practice expenses, or some combination of these factors. Our Notice of Proposed Rulemaking selects a method of allocating indirect costs that is driven by direct costs, an allocation method that we believe is sound. The proposed rule also discusses other options and why they were not selected.

Also, I wish to set the record straight about a survey of physicians that we started but subsequently canceled. We initiated the survey to obtain data on aggregate practice costs and case mix of physician practices. However, we canceled the survey due to unacceptably low response rates. If the survey response rate had been adequate, it might have provided additional data on indirect costs for the entire practice that would have allowed estimation of econometric cost functions which, if they yielded plausible estimates, would have provided an alternative approach to the allocation of indirect costs to particular procedures. However, the survey itself would not have determined the indirect costs of particular procedures, nor would it have been a source of data for individual procedures. The bottom line is that regardless of the physician practice cost data source, we still have to select a method for allocating indirect costs to individual procedures.

We believe that the methodology we have used is fundamentally sound and that the data are not fundamentally flawed. We believe that our results are the best that can be achieved, given the information that is, or would likely, become available. However, we recognize that the proposed values do contain some anomalies, as one would expect with any effort of this magnitude. A purpose of the proposed rule is to solicit procedure-specific comments from physicians about the practice expense relative value units. We plan to refine the proposed values in response to comments received.

IMPACT ON PHYSICIANS

The statute requires that the new system be implemented in a budget-neutral way. This means that there will be both winners and losers. The general pattern of winners and losers by specialty is similar to the winners and losers in the 1993 PPRC report, although the magnitudes differ somewhat.

The new system shifts practice expense RVU's from services performed in the hospital setting to services performed in the office setting. Physicians in specialties which tend to perform more services in offices gain and specialties who work mostly in hospitals experience reductions. Specialties that divide their time between the office and the hospital would experience modest increases or decreases.

Hospital based surgical specialists are likely to see the greatest payment reduction. They would still receive payments for practice expenses covering the direct costs of the resource inputs they incur for services performed in the hospital, as well as direct expense payments for pre- and post-operative care provided in their offices, and payment for indirect costs for direct costs in both the hospital and office setting.

Let me explain why the proposed system would result in a significant shift from hospital based to office based services. Inpatient hospital surgery provides a good example. A surgeon, while performing a 3-vessel bypass, may provide hours of difficult work. Since bypass surgery is always performed in a hospital, the hospital provides the staff, medical equipment and supplies provided during the entire hos-

pitalization which are all covered under the prospective payment system of reimbursement to the hospital. The surgeon incurs indirect costs such as setting up appointments, the expense of post-operative visits, and the administrative expense of creating a single patient record, obtaining approvals from third party payers and sending a single bill.

Compare this to the primary care physician who incurs all direct costs for services performed in "his" office. The physician who removes three skin lesions from three patients in the office incurs indirect costs such as rent and the costs of maintaining an office, the administrative cost of creating three records and sending three bills, the cost of the clinical staff to prepare instruments and assist in three different procedures, the costs of other staff, supplies and equipment to do the service, and the cost of providing follow-up visits.

We believe that the redistributions resulting from resource-based practice expenses could be difficult for physicians in some specialties. For this reason we will work with the Congress to change the law so that resource-based practice expense payments would be phased in gradually. The statute does not provide for such a transition. The phased-in implementation schedule will allow us to refine the application of our methodology to ease the inequities this legislation was intended to address.

In order to implement a new system by the statutory effective date, the Health Care Financing Administration will publish an NPRM this month. The proposed rule will have a formal 60 day comment period. We believe that prior consultations with physician groups and specialty societies were very comprehensive and contributed greatly to more accurate relative values for practice expenses. However, we think there may be anomalies in some of the values and we will be looking for precise code specific comments from physicians on these points.

PRACTITIONER INVOLVEMENT

Not only have we sought to keep the physician community involved and informed on the progress of this initiative throughout the process, we have obtained the direct cost data for this new system from them. The data to create the resource-based practice expense RVU's came primarily from two sources, both of which were provided by physicians. In 1996 HCFA convened the 15 CPEP's of practicing physicians, non-physician clinicians, and practice managers, including 180 members from more than 61 specialties and subspecialties, to provide data on direct expenses for about 6,000 CPT codes. The panelists were nominated by national specialty societies. Ultimately, the American Medical Association's 1996 Socioeconomic Survey data were used to divide practice expense relative values into direct and indirect cost portions. These data are collected annually from 4,000 practicing physicians.

In addition, HCFA held five open but formal meetings with a broad array of physician specialty groups. The purpose of these meetings was to solicit physician input and provide them with project updates. At the January 1997 meeting HCFA released (1) preliminary impacts by physician specialty for several different models under consideration, and (2) preliminary resource-based practice expense relative value units for the top 200 procedure codes. Shortly thereafter, HCFA made available the underlying direct cost data which provided the basis for the calculations. Thus, in making this information available prior to publication of the proposed rule, HCFA has allowed extended time of nearly 6 months for medical organizations to analyze and provide input into the process. HCFA staff accepted numerous invitations to meet with representatives of segments of the medical profession and we expect to continue meeting with the profession at appropriate times.

CONCLUSION

We are confident that our basic methodology for implementation of resource-based practice expense is sound and we are prepared to implement the legislation in January 1998 as required. We conducted extensive consultations with physician groups and specialty societies. This process contributed significantly to the development of more accurate relative values for practice expenses. Certainly, we are receptive to additional consultations and refinements that will improve upon the provisions of our proposed rule. Finally, we understand the difficulties that the proposed changes present for some specialty groups. We look forward to working with the Congress on the gradual phase-in of the new resource-based practice payment system.

NONDEPARTMENTAL WITNESSES

PANEL 1

STATEMENTS OF:

CHRISTINE GOERTZ, VICE PRESIDENT OF RESEARCH, POLICY AND INFORMATION SERVICES, AMERICAN CHIROPRACTIC ASSOCIATION

JAY H. KLEIMAN, GOVERNMENTAL RELATIONS COMMITTEE, AMERICAN COLLEGE OF CARDIOLOGY

ALAN R. NELSON, CHIEF EXECUTIVE OFFICER, AMERICAN SOCIETY OF INTERNAL MEDICINE

DONALD H. SMITH, IMMEDIATE PAST PRESIDENT, AMERICAN SOCIETY OF GENERAL SURGEONS

REMARKS OF SENATOR SPECTER

Senator SPECTER. Would Dr. Christine Goertz, Dr. Kleiman, Dr. Nelson, and Dr. Smith come forward at this time? And we begin with Dr. Christine Goertz, vice president of the research policy and information services for the American Chiropractic Association, former assistant professor at Northwestern College of Chiropractic, and coprincipal investigator of the treatment of hypertension with alternative therapy study, former chair of the Minnesota Chiropractor Association's legislation and National Health Care Committee.

Dr. Goertz, welcome. Thank you for joining us, and I look forward to your testimony. I regret the 5-minute time limit, but I also regret even more that that is customary.

SUMMARY STATEMENT OF CHRISTINE GOERTZ

Dr. GOERTZ. Thank you, Chairman Specter and members of the committee. It is a pleasure to be here this afternoon. It is an honor for me to be given the opportunity to testify before this committee, and it is a special privilege for me to have my son Nathan with me today. Thank you.

Senator SPECTER. Where is Nathan?

Dr. GOERTZ. He is the short one right there, I think the only 10-year-old in the room.

I was asked by this committee to testify regarding the status of HCFA's current proposal to reform Medicare payment to physicians for their practice expense costs. It is my opinion and the opinion of the American Chiropractic Association that the resource-based methodology used by HCFA to calculate practice expense is basically sound, and that the new fee schedule should go into effect in January 1998, as scheduled. Under the new system proposed by HCFA, practice expense will be more fairly allocated to those who primarily provide office-based services, and, therefore, are financially responsible for their own overhead expenses.

For example, 76 percent of chiropractic physicians are in a solo private practice. Less than 9 percent of doctors of chiropractic practice in urban areas of more than 1 million residents and nearly half practice in communities of less than 50,000. A national survey showed that the mean practice expense for doctors of chiropractic is just under 60 percent of their average gross income at present.

While on average, the practice expense under the current Medicare system comprises about 40 percent of the fee for any given CPT or HCPCS code that is reimbursed under the fee schedule, right now for the three codes the doctors of chiropractic are allowed reimbursement for under the system, the practice expense comprises only 30.3 percent of the total RVU's that have been allocated to those codes. Thus, the actual practice expense for doctors of chiropractic is approximately twice the practice expense that is reimbursable by Medicare at this present time.

Although doctors of chiropractic are slated for an increase of approximately 15 percent in total reimbursement for Medicare services, under the proposed resource-based practice expense system the total impact on the net income of the profession is relatively small on average. Basically doctors of chiropractic see about 8.4 percent of their income is derived from Medicare fees. According to HCFA's estimates under implementation of the fee schedule, as outlined in the preliminary rule that was released yesterday, the average net yearly income of doctors of chiropractic would change from just under $94,000 to just over $95,000, resulting in an increase of just over $1,000 annually.

Now, it has been intimated by some during the debate that has led up to this testimony today that the increases projected for nonmedical providers, nonmedical doctors such as chiropractors, account somehow for the losses that are projected for some of the other groups, and I want to make the point that this is just simply not the case. According to HCFA, reimbursement from nonmedical doctors such as podiatrists, chiropractors, and optometrists comprise about 4 percent of the fee schedule. They eliminated our increase that would only make a 2-percent difference to all of the other groups.

NEW PAYMENT SYSTEM

For example, HCFA has projected that under the new payment system reimbursement for a CABG, or coronary bypass procedure, would fall to approximately $1,770. If they eliminated all nonmedical doctors from the system, it would make a difference of only $16 in a CABG. It would increase to $1,786 for the procedure.

The projected reallocation assigned to chiropractic alone has an almost insignificant——

Senator SPECTER. Ms. Buto, would you focus on this, because I am going to ask you in a moment whether you agree with this? Go ahead, Doctor Goertz.

PREPARED STATEMENT

Dr. GOERTZ. In summary, we believe that any delay in the implementation of the practice expense is unwarranted; that the current system is unfair to those who primarily provide office-based serv-

ices, and are responsible for their own overhead; and that this burden is felt especially by practitioners who are in solo practice. We also believe that it is unlikely that a delay in implementation would lead to significantly better data or significantly improved methodology for arriving at practice expense.

Thank you.

Senator SPECTER. Thank you very much, Dr. Goertz.

[The statement follows:]

PREPARED STATEMENT BY CHRISTINE GOERTZ, D.C.

Chairman Specter, Senator Harkin, Members of the Committee and ladies and gentlemen present, good afternoon.

My name is Dr. Christine Goertz, Vice President of Research, Policy and Information Services for the American Chiropractic Association. I earned my doctor of chiropractic degree from Northwestern College of Chiropractic in Bloomington, Minnesota and I am currently a doctoral student at the University of Minnesota's Institute for Health Services Research. It is an honor for me to be given the opportunity to testify before this Committee, and a privilege to have my son Nathan present here today.

I was asked by this Committee to testify regarding the status of HCFA's current proposal to reform Medicare payments to physicians for their practice expense costs. It is my opinion and the opinion of the American Chiropractic Association, that the resource-based methodology used by HCFA to calculate practice expense is basically sound and that the new fee schedule should go into effect in January of 1998, as scheduled.

Under the new system proposed by HCFA, practice expense will be more fairly allocated to those who primarily provide office-based services and, therefore, are financially responsible for overhead expenses. For example, 76 percent of chiropractic physicians are in a solo private practice. Less than nine percent of Doctors of chiropractic practice in urban areas of more than one million residents and nearly half percent of Doctors of chiropractic practice in communities of less than 50,000. A recent national survey showed that mean practice expense for doctors of chiropractic is just under 60 percent of average gross income. On average, practice expense under the current system comprises approximately 40 percent of the fee for any given CPT/HCPCS code reimbursed under the Medicare Fee Schedule. However, the practice expense allocated to the only three CPT codes that can be used by doctors of chiropractic under the Medicare payment system comprises only 30.3 percent of the total RVU's allocated to those codes. Thus, actual practice expense for chiropractic physicians is approximately twice the practice expense reimbursable by Medicare at the present time.

Although doctors of chiropractic are slated for an increase of approximately 15 percent in total reimbursement for Medicare services under the proposed resource-based practice expense system, the total impact on net income for the profession is relatively small. The percentage of income received by doctors of chiropractic from Medicare patient fees in 1995 was 8.4 percent. According to HCFA's estimates, under implementation of the fee schedule as outlined in the preliminary rule, the average net yearly income of doctors of chiropractic would change from $93,956 to $95,032, resulting in an increase of $1,076 annually.

It has been intimated by some during the debate leading up to this testimony that the increases projected for non-medical providers, such as doctors of chiropractic, account for the losses forecasted for surgical groups. This is simply not true. According to HCFA, reimbursement for non-medical doctors such as podiatrists, chiropractors, and optometrists comprise approximately four percent of the Medicare fee schedule. In fact, elimination of the increase projected for all of these provider groups would only reduce surgical losses by two percent. As an example, HCFA has projected that under the new payment system, reimbursement for a CABG or coronary bypass procedure would fall to approximately $1,770. Elimination of the increases assigned to all non-medical doctors would raise this to $1,786, a difference of only $16. The projected reallocation assigned to chiropractic alone would have significantly less than a one half of one percent impact on the changes estimated for surgical and other groups.

In summary, any delay in the implementation of the practice expense is unwarranted. The current system is unfair to those who primarily provide office-based services and are responsible for their own overhead. The burden is felt especially by those practitioners commonly in solo practice. Further, it is unlikely that delay

would lead to better data or a significantly improved methodology for arriving at practice expense values.

Thank you for your time.

SUMMARY STATEMENT OF DR. J.H. KLEIMAN

Senator SPECTER. We now turn to Dr. J.H. Kleiman, assistant professor of clinical medicine at Northwestern University and attending physician at St. Joseph's Hospital in Chicago; a graduate of the University of Michigan's Medical School, Dr. Kleiman is the immediate past medical director for interventional cardiovascular service with St. Joseph's Hospital and serves on the Governmental Relations Committee of the American College of Cardiology. And one other background credit, he and I have mothers who are sisters, so I have known Dr. Kleiman since shortly before he was born. [Laughter.]

I can personally attest to his competence in many lines.

Dr. Kleiman, welcome, and you have 5 minutes.

Dr. KLEIMAN. Thank you, Mr. Chairman and members of the subcommittee. I am Dr. Jay Kleiman, a cardiologist and member of the American College of Cardiology. I would like to thank you for the opportunity to testify before you today on behalf of the Practice Expense Coalition.

I have practiced clinical cardiology for more than 20 years, and during this time have cared for numerous Medicare patients in both academic training institutions and in large community teaching hospitals. I want to share with you the deep concerns of members of the Practice Expense Coalition and the American College of Cardiology regarding changes in the practice expense component of the Medicare fee schedule recently proposed by the Health Care Financing Administration.

The concerns of the 40 organizations comprising the coalition are shared by the American Medical Association and groups representing hospitals and academic medical centers. We strongly believe that implementation of these changes will cause serious deterioration in the quality of care available to seniors. The data on which this schedule is based are badly flawed, and must be revisited.

One week ago HCFA made public its notice of proposed rulemaking, which includes resource-based practice expense relative value units. It does not create reimbursement equity within the community of medicine. HCFA's proposal produces new and damaging distortions that will become effective January 1, 1998, unless Congress takes immediate action.

HCFA has used questionable methodology and inconsistent data. It has made inaccurate assumptions in allocating the proportion of direct and indirect practice expenses. HCFA has incorrectly stated that physicians practicing primarily outside the office in the office in the hospital setting incur very limited practice expenses. They have failed to take into account staff and supply costs which are incurred independent of where the physician is practicing. HCFA admits that there is no correct way to allocate indirect costs with their existing data, so they have arbitrarily ascribed indirect procedure costs based on what they believe is fair rather than on sound data, or more importantly, sound cost accounting principles.

The practice expense component for procedures performed in the hospital begin significantly before a patient enters the hospital. It ends long after the patient is discharged. Medicare patients, in particular, need repetition of instructions and high levels of reassurance to support them through angioplasties, hip pinnings, bypass surgeries, gastrointestinal endoscopies, and numerous other interventional procedures.

In fact, the overhead expenses related to providing these progressively more intense support services have increased. Some 10 years ago, two secretarial persons were able to support my cardiology practice. Now, five staff members are required, including a nurse clinical specialist, to provide the same number of physicians with support.

CORONARY ANGIOPLASTY

For example, services related to coronary angioplasty include detailed outpatient preoperative teaching; dietary instruction, covering low-salt regimens to prevent heart failure; dietary instructions, covering low-fat regimens needed to slow further hardening of the arteries; education and laboratory monitoring of anticoagulation therapies; monitoring and refilling prescriptions, for an average of six medications per patient; and stenographic support to provide multiple letters to primary care physicians. Staff must be constantly available. My expenses continue whether I am in or out of the office. In addition, specialists providing high tech, intense, and often emergency care must maintain mobile telephone, pager, and answering service capabilities to provide immediate 24-hour access.

In its proposed rule, HCFA has made a number of arbitrary assumptions and edits to its incomplete data. For example, HCFA staff thought the amount of administrative time required for many services seemed excessive. They are proposing to cap the time allowed for these services at a midlevel office visit. In addition, HCFA assumes that there are economies of scale when a diagnostic test such as an echocardiogram is done in conjunction with an office visit. They propose to cut the practice expense payment for the diagnostic office test by 50 percent in that instance. It makes no sense that the economies gained for administrative staff time would amount to 50 percent of the costs associated with a complex test such as an echocardiogram. These tests require the services of highly trained clinical technicians, as well as payment for expensive, state-of-the-art equipment.

I anticipate that the negative fallout of HCFA's proposal will spread far beyond the physician community to all patients, not just Medicare beneficiaries. Logic dictates that reductions of this magnitude cannot fail to have an administrative effect on physician practices. These will be translated into delays at every level. Patients will have less time with the doctor and longer waiting times.

The drop in reimbursement will also delay acquisition of new and improved technologies which enhance medical care and ultimately save lives. They will add financial pressure to teaching facilities. They will target services provided to patients in the hospital, where these patients are the sickest and need the care most. At a time when quality considerations have generated bipartisan legislation to assure patient access to specialists, HCFA's proposal will impede

such access. Importantly, their effect will inevitably be compounded by similar adjustments from private insurance carriers.

Mr. Chairman, we urge Congress to delay the implementation date for resource-based relative values for 1 year; to redirect HCFA to develop new and verifiable methodologies based on generally accepted accounting principles to determine these values; and to phase in the changes over 3 years. Although some have argued that the distortions of the new practice expense values could be mitigated by a transition, transition alone will not correct or prevent the profoundly adverse effects of changes based on flawed data which grossly undervalue the overhead costs of an array and tests of procedure.

PREPARED STATEMENT

Transition to a payment system built on incorrect data and faulty assumptions will not protect patients, hospitals, and academic medical centers from harm. HCFA must give Congress the opportunity to restudy this issue and to get it right. We encourage this subcommittee to provide the appropriate financial support to HCFA to ensure that congressional mandates can be met in a way that protects the Medicare constituency.

Mr. Chairman, I appreciate the opportunity to speak before the subcommittee, and I thank you.

Senator SPECTER. Thank you very much, Dr. Kleiman. Thank you very much, indeed.

[The statement follows:]

PREPARED STATEMENT OF JAY KLEIMAN, M.D., F.A.C.C.

INTRODUCTION

Mr. Chairman and members of the subcommittee, I am Dr. Jay Kleiman, a cardiologist and member of the American College of Cardiology. I would like to thank you for the opportunity to testify before you today on behalf of the Practice Expense Coalition.

I have practiced clinical cardiology for more than 20 years and during this time have cared for numerous Medicare patients in both academic training institutions and in large community teaching hospitals. I want to share with you today the deep concerns of the members of the Practice Expense Coalition and the American College of Cardiology regarding changes in the practice expense component of the Medicare fee schedule recently proposed by the Health Care Financing Administration (HCFA). We share our concerns with the American Hospital Association, the Association of American Medical Colleges, the Medical Group Management Association, the Association of Academic Medical Centers, the American Medical Association, and the American College of Surgeons. We strongly believe that implementation of these changes will cause serious deterioration of the quality of care available to seniors. The data on which this schedule is based is badly flawed and must be revisited.

HISTORY

In 1994, Congress mandated that reimbursement for physician practice expenses (or overhead costs) be converted from a charge basis to a resource basis by 1998. To develop new practice expense relative values in accordance with the mandate, HCFA convened a series of Clinical Practice Expert Panels (CPEPs) to develop estimates of direct practice expenses for about 300 current procedural terminology (CPT) "reference" codes. HCFA also was to conduct a complex national survey of physician practices in order to collect data on total practice expenses, including both direct (expenses directly related to the performance of a specific medical procedure, i.e., cost of supplies) and indirect (expenses that cannot be traced to a particular service, i.e., rent) practice expenses. Unfortunately this survey was very cumbersome. In September 1996 the survey was abandoned due to low response rates,

leaving HCFA without a major source of data on how practice expenses are distributed across specialities and divided into direct and indirect expenses. Furthermore, the CPEP data have never been released in a readable format nor validated by HCFA. Despite these events, HCFA is still under a congressional mandate to produce a resource-based payment system for the practice expense component of the Medicare fee schedule for implementation on Jan. 1, 1998.

HCFA'S PROPOSED RULE

On June 12, 1997, HCFA made public its notice of proposed rulemaking (NPRM) of policy changes affecting the Medicare Fee Schedule, including resource-based practice expense relative value units. It does not create reimbursement equity within the community of medicine. HCFA's proposal produces new and damaging distortions.

It is clear from the proposed rule and comments by HCFA staff that even the CPEP process was flawed. Until this time, we were under the impression that HCFA believed that the CPEP data was the strongest component of their study. HCFA had to go through several steps to "normalize" the data. Agency staff acknowledge that they could only describe a few of the numerous edits made to the CPEP data before it was usable. In fact, HCFA had to construct a whole new "simplified data set" from which to develop the proposed relative value units. HCFA staff have been unable to say when this "simplified data set" will be available for review by the public. However, they imply that these data are essential to evaluating the proposed values.

Using questionable methodology and inconsistent data, HCFA has made an important assumption concerning the proportion of direct and indirect practice expenses. HCFA has stated that physicians practicing primarily outside the office incur very limited practice expenses. However, HCFA has failed to take into account labor and supply costs which are incurred independent of where the physician practices. Furthermore, HCFA does admit that there is no correct way to allocate indirect costs with their existing data. They have arbitrarily allocated indirect procedure expenses based on what they believe is fair, rather than on data or sound accounting principles.

The practice expense component for procedures performed in the hospital begins significantly before a patient enters the hospital and ends long after the patient is discharged. Medicare patients, in particular, need repetition of instructions and high levels of reassurance to support them through angioplasties, hip pinnings, bypass surgeries, gastrointestinal endoscopies, and numerous other interventional procedures. Thus, overhead expenses related to providing progressively more intense support services have increased. For example, such services related to coronary angioplasty could include dietary instructions covering low-salt and low-fat regimes, education and laboratory monitoring of anti-coagulation therapies, and monitoring and refilling prescriptions for an average of six medications per patient. Staff must be constantly available. I do not close my office when I go to the hospital. My expenses continue. In addition, specialists providing high-tech, intense, and often emergency care, must maintain a mobile telephone, pager, and answering service capabilities to provide immediate 24-hour access.

HCFA claims that the current system is inequitable and does not reflect the actual cost of providing services. For example, it states that "a family physician would have to perform approximately 100 mid-level office visits to receive the same amount of practice expense reimbursement as a thoracic surgeon receives for one triple bypass operation." This claim has absolutely nothing to do with the costs physicians incur.

This comparison is like comparing the costs of car makers and bicycle manufacturers. The car maker sells fewer, more expensive units but more overhead is put into the price of each car. The bicycle manufacturer sells many more inexpensive units, but the amount of overhead per unit is smaller. Should the payment to the bicycle maker go up just because he has to sell more units to recover his costs?

HCFA does not identify the costs of the family physician, nor does it identify the costs of the thoracic surgeon. In fact, HCFA's data is incomplete and lacks clinical validation. It cannot realistically sort out what those different costs really are. HCFA's proposal would reduce its practice expense reimbursement for a three-vessel open heart surgery by 35 percent down to $400. Surgical payments cover a full 90 days of care, not just the hospital procedure. HCFA has not validated its proposed values against data on actual practice costs of a typical cardiac surgeon.

In its proposed rule, HCFA seems to have made a number of assumptions and edits to its incomplete data which are completely arbitrary. For example, HCFA staff thought that the input on administrative staff time for many services seemed

excessive, so they are proposing to cap the time allowed for those services to the time allowed for a mid-level office visit. In addition, HCFA assumes economies of scale when a diagnostic test is done in conjunction with an office visit and proposes to cut the already reduced practice expense payment for the diagnostic test by another 50 percent in that instance. Does it make sense that the economies gained for administrative staff time (scheduling, reception, billing) would amount to 50 percent of the costs associated with a complex diagnostic test requiring the services of a highly trained clinical technician as well as an expensive piece of state-of-the-art technology?

CONSEQUENCES

If rational allocation of Medicare resources to physicians was the only issue, that would be reason enough for Congress to act. However, the negative fallout will spread far beyond the physician community to all patients, not just Medicare beneficiaries, if HCFA's proposal is allowed to take effect on Jan. 1, 1998. Logic dictates that reductions of this magnitude cannot fail to have an administrative effect on physician practices. These adjustments cannot be to the patient's benefit. Patients will be less satisfied with the care they receive and can expect to experience delays at every level including appointments, test results and longer waiting room times. In my office, I know that the patients who are calling have potentially life-threatening problems. This makes the first person who answers the phone the most important person in a cardiologist's office. I am concerned that these inevitable administrative reductions will have an adverse effect on the well-being of my patients.

A precipitous drop in reimbursement will delay acquisition of new and improved technologies that will enhance medical care and save lives. In some cases, physicians may have to stop providing certain services, and care will become fragmented as patients are forced to go elsewhere for those tests. It will add financial pressure to teaching facilities, which not only train the next generation of physicians, but also often reach out to underserved communities. These reductions also target services provided to patients in the hospital, those who are sickest and need care the most. At a time when quality considerations have generated bipartisan legislation to assure patient access to the services of specialists, HCFA's proposal will lessen such access, both in the short-term and for the future. Moreover, an extreme reduction in Medicare reimbursement to specialists will be compounded by similar adjustments from private insurance carriers. These reductions will likely be even more severe in the inner city and rural areas due to their already limited resources. Congress could not have foreseen nor intended these outcomes.

ACTION

The HCFA practice expense methodology is based on neither a reasonable definition of resource-based practice expenses nor sufficiently accurate data to trust the results. We urge Congress to delay the implementation date for resource-based relative values until Jan. 1, 1999, redirect HCFA to develop new and verifiable methodologies based on generally accepted accounting principles to determine these values, and phase-in the changes over three years. Many argue that the distortions in the proposed practice expense relative values could be mitigated by a transition. But a transition alone will not correct or prevent the adverse effects of changes based on flawed data.

CONCLUSION

Implementation or transition to a payment system built on incorrect data and faulty assumptions will not protect patients, hospitals and academic medical centers from harm. HCFA must be given the opportunity by Congress to restudy this issue and get it right. We encourage this subcommittee to provide the appropriate financial support to HCFA to ensure that congressional mandates can be met.

Mr. Chairman, your leadership in health care is widely recognized within the physician community, and we thank you for your attention to this important issue. I appreciated having the opportunity to speak before the Subcommittee.

SUMMARY STATEMENT OF DR. ALAN NELSON

Senator SPECTER. We will turn now to Dr. Alan Nelson, CEO of the American Society of Internal Medicine. He previously practiced internal medicine in Salt Lake City, where he was clinical professor at the University of Utah; past Chair of the Board of Trustees

of the AMA; and a member of the first National Professional Standards Review Council.

Thank you very much for joining us, Dr. Nelson, and the floor is yours.

Dr. NELSON. Thank you, Mr. Chairman.

My hope is that today's hearing will bring some balance to what has become a very contentious debate. Unfortunately, the way the data has been framed to date has put Congress in the position of having to choose between surgical specialists and primary care physicians. There is an alternative that does not require that Congress make such a choice, however. The bill reported out of the Finance Committee yesterday is a win-win compromise that responds to the legitimate concerns of both primary care doctors and surgical specialists. The bill would begin to make some modest improvements in 1998 in payments for primary care services whose practice expenses are undervalued under the current charge-based formula. But it would also give the critics of the current rule-making process much of what they have asked for.

Under the Finance Committee proposal, no specialty would be subjected to extreme cuts in 1998. Another year would be provided to refine the data. The Secretary of HHS would be required to consult with a panel of physicians and other experts and provide for additional data collection if appropriate. The General Accounting Office would conduct a thorough examination of the proposed rule. Resource-based practice expenses would be phased in over 4 years to limit the amount of redistribution that will occur in any 1 year.

But the Finance Committee alternative also responds to the concerns expressed by primary care physicians about the unfairness of the current payment methodology by beginning at 10 percent of the transition to resource-based payments in 1998, and by requiring the full implementation to occur no later than January 1, 2001. The bill recognizes that we do not need another huge study to begin correcting inequities. The recently released notice of proposed rulemaking adds to the growing body of data in support of the need to improve payments for primary care services, but it is not necessary to rely on the specific data and methodology used in the proposed rule to begin the transition.

SURGICAL PROCEDURES OVERVALUED

It is important to keep in mind that the existing flawed and inequitable charge-based methodology has already been in effect for 6 years, and that this formula perpetuates inequities that have existed since the Medicare Program was enacted in 1965. I do not believe that any honest assessment of the practice expense issue could deny that the practice expenses of primary care services are undervalued, and that those of many surgical procedures are overvalued. At least five different studies, each using different methodologies and sources of data, all concluded that the current practice expense methodology systematically undervalues primary care services.

There are serious inequities that the Finance Committee proposal would begin to address. There simply is no other proposal on the table that is responsive to the concerns of both primary care physicians and surgical specialists. The bills reported by the House

authorizing committees would begin and complete the transition a year later than the Finance Committee alternative. They would do nothing to begin correcting in 1998 the inequities in payments that have disadvantaged primary care.

The Finance Committee bill provides that appropriate level of direction to HHS on how the proposed rule should be improved. I caution this committee not to include language in the appropriation bill that would force HHS to use a single methodology to the exclusion of all others, or that would require that the agency start all over in developing an approach to resource-based practice expense methodologies.

We have no objection to including any additional data on actual costs to the extent that it is feasible to collect such data. But we would be concerned about any directive language that could delay implementation of the final rule by requiring a massive and costly new study of practice expenses, one that the Physician Payment Review Commission has said is not needed.

By no means is ASIM suggesting that the proposed rule is perfect. Far from it. To the extent that other sources of data on practice expense costs exist, Health and Human Services should consider such data and make revisions as appropriate. But we firmly believe that the needed improvements can readily be accomplished with an additional year. No further delay beyond that is appropriate. And we also firmly believe that although the data and methodology can be improved, Congress should not direct that Health and Human Services start over again from scratch and dismiss the data and analyses that are conducted to date.

PREPARED STATEMENT

I urge the members of the committee to express your strong support for the alternative reported yesterday out of the Finance Committee. Congress does not have to choose between providing more time and direction to Health and Human Services on improving the proposed rule, or making incremental improvements in payments for undervalued primary care services. The Finance Committee proposal is the only one under consideration that satisfies both objectives.

Thank you.

Senator SPECTER. Thank you very much, Dr. Nelson.

[The statement follows:]

PREPARED STATEMENT OF ALAN R. NELSON, M.D.

I am Alan R. Nelson, MD, executive vice president of the American Society of Internal Medicine. I appreciate the opportunity to share with you the perspectives of internists on HCFA's proposed rule on practice expenses, and on the ongoing debate in Congress on this important issue.

My hope is that today's hearing will bring some balance to what has become a very contentious debate. No one likes to put Congress in the position of having to adjudicate a fight between warring factions of physicians. Unfortunately, the way that the debate has been framed to date has put Congress in the position of having to choose between surgical specialists and primary care physicians. Clearly, any proposal that would redistribute payments among physicians—and, therefore, produce winners and losers—is going to produce some degree of division within medicine. But there is an alternative that does not require that Congress choose between voting with the surgeons or with the primary care physicians. This alternative is the one proposed by Senator Roth, chairman of the Finance Committee, in his mark on Medicare budget reconciliation.

A better alternative

The Finance Committee chairman's alternative would give the critics of the current rule-making process most of what they have asked for. They have expressed concern about "extreme cuts" in payments. Under this alternative, no specialty would be subjected to extreme cuts in 1998.

They have asked for another year to work with HCFA to improve the data and methodology used in the proposed rule. This alternative would give them another year to refine the data.

They have asked that Congress provide more direction to HCFA on how the study should be conducted. The alternative would provide appropriate direction to HCFA on improving the data used to develop the proposed rule, with Congress' own General Accounting Office being given a major role in reviewing the data and methodology used by HCFA.

The critics have asked that Congress direct HCFA to consult more with physicians. More consultation with physiclans would be mandated.

They have asked that resource-based practice expenses be phased in over several years to limit the amount of redistribution that will occur in any one year. The alternative provides for a four-year transition.

But the Finance Committee alternative also responds to the concerns expressed by primary care physicians about the unfairness of the current payment methodology, by beginning 10 percent of the transition to resource-based payments in 1998. This modest transition would represent a good faith effort by Congress to begin honoring the commitment it made in 1994, when it enacted legislation that required implementation of resource-based practice expense payments in 1998.

The Finance Committee alternative recognizes that it doesn't take another study to begin correcting inequities that have been long-documented in every major study of this issue. Studies that support this conclusion include the Harvard RBRVS study (1990, 1991), Physician Payment Review Commission (1991, 1992), Health Economics Research (1996), Pope and Burge (1996), and now the Abt study cited in the proposed rule (1997). The recently-released notice of proposed rulemaking adds to the growing body of data in support of the need to improve payments for primary care services, but it is not necessary to rely on the specific data and methodology used in the proposed rule to begin the transition. The modest amount of the transition that would occur under the Finance Committee in 1998 is actually far less than the studies suggest is appropriate. In addition, it is important to keep in mind that the existing flawed and inequitable charge-based methodology has already been in effect for 6 years, and that this formula perpetuated inequities that have existed since the Medicare Program was enacted in 1965. Even under the chairman's mark, full implementation of resource-based practice expenses would not occur until 2001—9 years after implementation of resource-based payments for physician work, and 7 years since Congress enacted legislation in 1994 calling for resource-based practice expense payments. It is simply not reasonable to delay implementation further so that another study can be done to confirm what we already know: that the current charge-based formula is inherently unfair and needs correction.

I don't believe that any honest assessment of the practice expense issue could deny that primary care services are undervalued, and many surgical procedures overvalued, under the existing charge-based practice expense methodology. There may be legitimate differences of opinion on the best methodologies and sources of data to be used in developing resource-based payments. But even though the studies cited above used different methodologies and sources of data, they all agree that the current practice expense methodology systematically undervalues primary care services. Further, common sense tells us that the differences between what Medicare allows for the practice expenses of many surgical procedures, compared with those of primary care services, just isn't right. Under the current charge-based methodology, an internist would have to provide 115 established patient office visits to receive the amount of reimbursement for practice expenses that a surgeon gets for a single coronary bypass graft. Yet the internist assumes the entire overhead costs of the office visit, while most of the direct costs of the surgical procedure are borne by the hospital, not the surgeon.

It is this kind of serious inequity that the Finance Committee proposal would begin to address. But it does so in a way that requires only very modest adjustments in existing payment levels, until such time as the final rule is ready to be implemented. As a result, no specialty would gain or lose more than 3 percent in 1998 as a result of the 10 percent transition to resource-based practice expenses.

There simply is no other proposal on the table that is responsive to the concerns of both primary care physicians and surgical specialists. The bills reported by the House Commerce and Ways and Means Committee would not start the transition until 1999, a year later than under the Finance Committee's proposal, and would

also mandate that full implementation occur a year later (2002) than under the Finance Committee proposal (2001). By beginning and completing the transition a year later than the Finance Committee alternative, the House version allows for the existing inequities to remain in effect for a longer period of time. It does nothing to begin correcting in 1998 the inequities in payments that have disadvantaged primary care.

I urge the members of this committee to express your strong support for the alternative being offered by Sena or Roth.

Direction to HCFA

Many of you are also being asked to support legislation that would direct HCFA on how to collect and analyze the data on resource-based practice expenses. Although some direction to HCFA may be appropriate, I caution this committee not to include language in the appropriations bill that would force HCFA to use a single methodology to the exclusion to all others, or that would require that the agency start all over in developing an approach to resources-based practice expense methodologies.

The argument of those who are seeking to direct how HCFA conducts its study is that the current methodology is fundamentally flawed. As explained more fully below, ASIM believes that although improvements in the existing methodology and data may be appropriate, it is not necessary to reject all of the work that has been done to date. The objective should be to refine and improve upon the existing data including incorporating additional data as necessary and feasible, rather than throwing out everything that has been done to date.

ASIM would be especially concerned about any language that requires that HCFA conduct a detailed cost accounting of physician practices. We have no objection to including any additional data on actual cost, to the extent that it is feasible to collect such data. But we would be concerned about any directive language that could delay implementation of the final rule even further by requiring a massive new study of practice expenses.

The Secretary has already attempted to conduct a detailed survey on practice costs, but was forced to abandon it because of an inadequate response rate. Development and implementation of a new survey could take several more years, with no guarantee that it would produce sufficient responses. A mandate that would implicitly require a new survey could make it impossible for the Secretary to meet a January 1, 1999 implementation date. Further, it is difficult to justify mandating a detailed cost accounting survey that would cost millions of taxpayers' dollars—especially one that may not be necessary or even feasible.

Congress should also not enact legislation that would rule out using other sources of data—such as existing data on indirect costs and estimates from clinical practice expert panels—that the Physician Payment Review Commission has reported can produce accurate practice expense relative value units (RVU's). Although it is appropriate to require that HCFA consider additional data, to the extent that such data can practically be collected, it is inappropriate for Congress to mandate that HCFA disregard source of existing data, including some of the sources of data used in the proposed rule.

ASIM is concerned that if Congress establishes requirements and a timetable that may be impossible for Health and Human Services to meet, this will virtually guarantee that some physician groups will seek an additional delay next year, on the grounds that HCFA failed to meet statutory requirements. HCFA should be held accountable. But the requirements placed on the agency must themselves be realistic.

The committee should consider the question of what is driving the requests that Congress provide more direction to HCFA. To the extent that the requests are simply for HCFA to consider additional data within the one year extension likely to be granted by Congress before the rule is implemented, then this is appropriate. But some of the requests may be motivated more by the desire to require that HCFA go through so many hurdles that RBPE's may never be implemented. One must question whether there is any amount of data that will convince those who expect to see reduced fees under RBPEs to accept the inevitability of the required redistribution.

Preliminary analysis of the proposed rule

During the 60-day comment period, and during any extended comment period that Congress may grant, ASIM plans to conduct a rigorous evaluation of the methodology used by HCFA in the proposed rule. Although we expect to recommend improvements in HCFA's data and methodology, we believe that some of the data used may well prove to be valid and appropriate.

The recommendations from the Clinical Practice Expert Panels on direct costs are among the sources of duties that should be considered in developing resource-based practice expense RVUs. ASIM recently surveyed 185 internists on the clinical and administrative staff times associated with evaluation and management services. Approximately 30 percent responded. Although we are still analyzing the response, it appears that for most of the codes, the respondents agreed with the CPEP data. Although admittedly a relatively small sample, this suggests that it would be inappropriate to simply reject all the CPEP data as being "fundamentally flawed" as some have alleged.

The proposed rule allocates indirect costs on the basis of direct costs—i.e., the higher the direct costs, the higher the indirect costs. ASIM will be submitting comments to HCFA on the appropriateness of this methodology. We concur with HCFA's view, however, that existing sources of data can be used to determine indirect costs—a view also shared by the Physician Payment Review Commission. We also concur with HCFA's view that "by definition, it is not possible to directly survey [indirect] costs associated with specific procedures." This is because the indirect costs of running an office—utilities, rent, general administrative salary costs—are by definition not attributable to a specific procedure. Therefore, some method of allocating those costs to a given procedure must be selected. Among the options that are available are to allocate them based on physician time, staff time, or on the basis of the direct costs as HCFA has proposed. It is misleading to suggest that use of these allocation methodologies represent an arbitrary "proxy" for actual data on the indirect costs of each procedure, since there simply is no feasible way to collect the actual indirect costs that are attributable to each procedure.

By no means is ASIM suggesting that HCFA's proposed rule is perfect—far from it. To the extent that other sources of data on practice costs exist, HCFA should consider such data and make revisions as appropriate. The agency should also consider analyses that suggest that the estimates from the Clinical Practice Expert Analyses need to be revised in some cases. It should consider alternatives to the approach it recommends on indirect costs. It should consider collecting additional data on actual costs, to the extent that it is feasible to collect such data. It should consult more regularly with physicians and other technical experts.

But ASIM believes that the kinds of improvements and refinements that are needed can readily be accomplished with an additional year—no further delay is appropriate. We also firmly believe that although the data and methodology can be improved, Congress should not direct that HCFA start over from scratch and dismiss the data and analyses that it has conducted to date.

Conclusion

In conclusion, ASIM urges the committee:

1. To strongly support the proposal from Senator Roth for a four-year transition to RBPEs, with 10 percent of the transition beginning in 1998. Congress does not need to choose between providing more time to reexamine the data used by HCFA before the final rule is implemented, and beginning to make improvements in payments for primary care services in 1998. The Roth proposal is the only one on the table that does both.

2. To assure that any direction that is given to HCFA on how the study should be conducted does not lead to additional delay in implementation of RBPE's, require the collection of data that are not feasible or practicable to obtain; or set up a series of impractical conditions that HCFA will not be able to meet. If some additional direction is given, it should emphasize to the agency the importance of consulting with physicians and other experts, and of being open to considering the collection of additional sources of data, to the extent practicable.

3. To make it clear that Congress expects that HCFA will make a concerted effort to consider comments on improving the data and methodology used in developing the proposed rule, both during the current 60 day comment period and during any extension that Congress will provide. HCFA should not be required, however, to disregard all of the analysis and data it has collected to date.

Congress has an opportunity to come up with a winning approach that begins to address the serious inequities created by the existing flawed formula, while at the same time assuring that HCFA publishes and implements a final rule that is based on the best available data. We urge you not to turn back the clock on correcting the inequities in payments that have disadvantaged primary care services, by improving requirements that will further delay or even indefinitely postpone resource-based practice expenses.

I'd be pleased to answer any of your questions.

SUMMARY STATEMENT OF DR. DONALD H. SMITH

Senator SPECTER. We will now turn to Dr. Donald Smith, immediate past-president of the American Society of General Surgeons, and vice chairman of the Pennsylvania delegation to the American Medical Association. He is a graduate of Lehigh and Jefferson Medical College. He has been chief of the Division of General Surgery at Easton Hospital; clinical assistant professor at Hahneman, and has maintained a general practice in Easton over the years.

Dr. Smith, we welcome you here and look forward to your testimony.

Dr. SMITH. Thank you very much, Mr. Chairman. I would like to thank you for convening this hearing, and for giving me the opportunity to testify with respect to the Health Care Financing Administration's plans to revise the practice expense component. Having practiced in Easton for over 26 years, and having served as a spokesperson for general surgeons throughout this country for the past year, I believe I can lend some real world perspectives to this subject.

When Congress directed HCFA in 1994 to develop these expense relative values, they specifically asked that the new relative values recognize the staff equipment, equipment, and supplies used in the provision of these services. Clearly congressional intent was for HCFA to construct the values using data generated by actual resources involved in the provision of these services, rather than the off-the-shelf estimates that are currently in use.

Unfortunately, the proposed rule unveiled a few days ago is not based on a methodology that we agree with, because it does not measure the actual resources consumed in the provision of a Medicare procedure, and again, we believe is based on estimates extrapolated from various data and theoretical sources. It is inconceivable that a sound practice expense methodology using actual data could produce the payment reductions of the magnitude proposed by HCFA for these various specialties. In fact, some of the proposed reductions appear to assume that certain specialties have only minimal practice expenses.

In my own specialty, HCFA's proposal would reduce overall payments to general surgeons by 9 percent. This is compared to an earlier plan that called for reductions of as much as 19 percent. The fact that there is such a wide variation tells us that HCFA is simply massaging statistics rather than employing the sound cost accounting principles that we think are necessary, and that we believe have been referenced earlier in the discussion.

Perhaps the most egregious example has already been related dealing with the thoracic surgeons or the cardiac surgeons by reducing their payments by 32 percent, which contrasted with national data that shows that practice expenses for surgeons on the average are about 41 percent of their total revenues.

Mr. Chairman, we know that the surgeon is not going to perform as many procedures as office visits by a family physician, thank God, but consider the different requirements for office expense to care for an established patient with a midlevel problem contrasted with the multiple pre- and postoperative office visits, scheduling, family and physician contacts, billing, rent, and ancillary office

staff involvement in caring for an elderly patient undergoing a major operation that may last for several hours, with postoperative attention often lasting several weeks. I would just make the point that the office meter never stops running for the general surgeon, either.

Sound accounting principles, not to mention logic, call for the overhead costs of the family physician to be spread over many more encounters with the patient, while the payment to the surgeon is and appropriately should be on fewer, far more complex patients. In my estimation, examples such as these demonstrate what the American Medical Association, the American College of Surgeons, and many specialists have identified.

The methodology that HCFA is proposing to use, we believe is fatally flawed. It is unrealistic, and not the product of actual measurement of multiple resources, but simply more of the theoretical or estimated inaccurate data that prompted the 1994 mandate from Congress. More to the point, I seriously doubt that the intent of Congress was to eliminate payments for legitimate payments, anymore than to base the entire resource-based relative value system on erroneous estimates and theories in the late 1980's.

I recognize that HCFA made an effort to collect data, but they never completed it. Using the clinical practice expert panels, of which many physicians were composed, they asked physicians to try and evaluate procedures with which they were not familiar—point No. 1. What has not been said is the physician survey took 24 hours to complete, and explains, I think readily, why only a small percentage of these surveys were reported. In all candor, Mr. Chairman, there must be a better way to get a fair and equitable handle on this aspect of a physician's practice.

Unfortunately, what HCFA has proposed will have far-reaching effects beyond the Medicare Program. As you know, most insurance companies utilize some form of the Medicare relative values in developing their own payment schedules. Thus, the true impact of this proposal is really not known. However, it could be very substantial, and it seems unwise to cause such a major disruption in the health care delivery system using what we believe is spotty research.

More importantly, this impact could be devastating on one of the most vulnerable segments of our population, our senior citizens. No one knows for certain how physicians will adjust to these charges. A reduction of this magnitude when coupled with other changes Congress is now contemplating could dramatically restrict access to and for Medicare patients.

Every time payment reductions to physicians occurs, organized medicine cries access to quality health care will suffer. But as you well know, little change has occurred up till the present time. Coupled with other proposals for the Medicare conversion factor in 1998 and payments for needed assistance at surgery, general surgeons could see reduction in their Medicare income this year of 25 to 30 percent. And I would only ask is this the threshold that truly limits access to care.

Last, we must not overlook the impact this change has on academic health centers which rely heavily on faculty practices to train medical students and generate the revenue needed to support

medical research. As someone who has a long-standing record of support for medical research, you should be aware that if this change is implemented, it will result in dramatic reductions in research and training at institutions in your home State of Pennsylvania.

PREPARED STATEMENT

In closing, Mr. Chairman, I urge you and your colleagues to adopt the recommendations of the American Society of General Surgeons and our colleagues in the Practice Expense Coalition to stop the current rulemaking process and allow sufficient time for accurate methodology to be developed, as well as a reasonable time for comment and refinement of that methodology. Instruct HCFA to assemble experts that they will require in cost accounting and to develop mechanisms for collecting actual data on physician practice expenses which can be validated and regularly reported in their progress reports to Congress, and to provide for an appropriate 3-year transition.

Mr. Chairman, let me conclude by saying that the Medicare Program is not the place to road-test a very risky theoretical scheme.

Thank you, sir.

Senator SPECTER. Thank you very much, Dr. Smith.

[The statement follows:]

PREPARED STATEMENT OF DONALD H. SMITH, M.D., F.A.C.S.

Mr. Chairman and members of the committee: I am Donald H. Smith, M.D., F.A.C.S., the Immediate Past President of the American Society of General Surgeons. By way of background, ASGS is a national society exclusively representing 4,000 practicing General Surgeons who currently make up its membership and all 28,500 board-certified General Surgeons in the U.S. The Society focuses on educational and socioeconomic issues affecting the practice of general surgery as well as the interests of surgical patients regarding cost, access and quality of care.

Mr. Chairman, I would like to thank you for convening this hearing and for giving me the opportunity to testify with respect to the Health Care Financing Administration's (HCFA) plans to revise the practice expense component of the Medicare fee schedule. Having practiced in Easton, Pennsylvania for over 26 years, I believe I can lend some "real world" perspectives to the subject.

In 1994, Congress directed HCFA to develop resource-based practice expense relative values for each procedure and service provided under Medicare. In so doing, the statute specifically directed that the new relative values "recognize the staff, equipment and supplies used in the provision of medical and surgical services in various settings." Clearly, congressional intent was for HCFA to construct the practice expense values using data generated by actual resources involved in the provision of physician services, rather than the "off-the-shelf" estimates currently in use. Unfortunately, the proposed rule HCFA unveiled a few days ago is not based on a methodology that measures the actual resources consumed in the provision of a Medicare procedure or service, but rather on estimates extrapolated from various data and theoretical sources. It is inconceivable that a sound practice expense methodology using actual data could produce payment reductions of the magnitude proposed by HCFA. In fact, some of the proposed reductions appear to assume that certain specialties have only minimal practice expenses.

In my own specialty, HCFA's proposal would reduce overall payments to General Surgeons by 9 percent, compared to an earlier HCFA plan that called for reductions of as much as 19 percent The fact that there is such a wide variation tells me that HCFA is simply massaging statistics, rather than employing sound cost accounting principles. Perhaps the most egregious example relates to payments to our colleagues for cardiac surgical procedures, where HCFA would reduce payments by 32 percent. Contrast this with national data which shows that practice expenses for surgeons, on average, account for 41 percent of total physician revenues. In other words, HCFA would eliminate reimbursement for three-fourths of that specialty's overhead costs.

Yet another example of how HCFA has missed the mark is contained in the agency's own press release that accompanied this new proposal. HCFA calls it inequitable that a family physician has to perform about 100 mid-level office visits to receive the same amount of practice expense reimbursement as a thoracic surgeon receives for one triple bypass operation. Mr. Chairman, we know that the surgeon is not going to perform as many bypass procedures as the number of office visits by a family physician. Sound accounting principles, not to mention simple logic, call for the overhead costs of the family physician to be spread over more encounters with the patient, while the surgeon's payment is concentrated on fewer patients.

In my estimation, examples such as these demonstrate that the methodology HCFA is proposing to use is fatally flawed, unrealistic and not the product of an actual measuring of the multiple resources required to provide a quality surgical service. More to the point, I seriously doubt that this was the intent of Congress to eliminate payments for legitimate practice expenses.

While I recognize that HCFA made an effort to collect data through Clinical Practice Expert Panels, or CPEPs, and through the use of a survey of selected physician practices, neither of these tasks were completed.

In fact, the survey instrument took more than 24 hours to complete and was so complex that only 27 percent of the practices selected responded. In all candor, Mr. Chairman, there must be a better way to get a fair and equitable handle on this aspect of a physician's practice.

To construct a new set of values, HCFA relies primarily on data derived from the clinical practice expert panels. But a review of those findings suggest that they contain a number of errors. In addition, HCFA has no indirect cost data and thus has no way to validate its proposed methodology. In its proposed rule, HCFA admits that "refinements" will have to be made after the rule is implemented.

Unfortunately, what HCFA has proposed will have far reaching effects beyond the Medicare Program. As you know, most insurance companies utilize some form of the Medicare relative values in developing their payment schedules. Thus, the true impact of this proposal is really not known at this time. However, it could be very substantial. It seems unwise to cause such a major disruption in the health care delivery system using spotty research.

More importantly, the impact this could have on one of the most vulnerable segments of our population—our senior citizens—is unknown. No one knows for certain how physicians will adjust to these changes. A reduction of this magnitude, when coupled with other changes Congress is now contemplating, could dramatically restrict access for Medicare patients. Some surgeons certainly would leave the field and others may eliminate the necessary clinical support they now have in their practices. In surgery, for example, a substantial portion of the pre- and post-operative care is provided by the nursing staff. Currently surgery is paid a "global fee". This covers the pre-, the operative, and the post-operative care. If you take away a substantial portion of the relative value units, it would seem that the quality of all of those services currently in the global fee would have to suffer—as will the patients' access to quality surgical care.

Last, we must not overlook the impact this change would have on academic health centers, which rely heavily on physician faculty practices to help train medical students and generate the revenue needed to support medical research. As someone who has a long standing record of support for medical research, you should be aware that if this change is implemented, it will result in dramatic reductions in research and training at institutions such as the University of Pittsburgh and the Hershey Medical Center.

In closing Mr. Chairman, I urge you and your colleagues to adopt the recommendations of ASGS and our colleagues in the Practice Expense Coalition to:

—stop the current rule making process, and allow sufficient time for accurate methodology to be developed as well as a reasonable time for comment and refinement;

—instruct HCFA to assemble experts in cost accounting and to develop mechanisms for collecting actual data on physician practice expenses which can be validated, and regularly report their progress to Congress; and

—provide for a three-year transition to the new payment schedule.

Mr. Chairman, let me conclude by saying that the Medicare program is not the place to road test this very risky theoretical scheme.

PREPARED STATEMENT OF LARRY FITZGERALD

Senator SPECTER. The subcommittee has also received a statement from Larry L. Fitzgerald of the University of Pittsburgh, the statement will be placed in the record at this point.

[The statement follows:]

PREPARED STATEMENT OF LARRY FITZGERALD

RVU IMPACT STUDY

We have performed an analysis of the impact of the proposed reduction to the RBRVS system for the computation of practice expense on the University of Pittsburgh Physicians. Collectively the University of Pittsburgh Physicians represent the faculty physicians of the University of Pittsburgh Medical Center. The estimated impact to our faculty physicians is a decrease in net Medicare revenue (collections) of 11 percent ($3 million annually).

Please recognize that other payors such as Worker's Compensation, auto insurance and many of the managed care companies follow the Medicare rule. The ultimate overall impact on the net revenue could be a reduction of as much as $15 million on an annual basis. Needless to say this is potential revenue loss and a great concern to our practice plans and it has the potential of impacting negatively on services made available to the Medicare recipients in Western Pennsylvania and their health and well-being.

QUESTIONS FROM WITNESSES AND OTHERS IN THE PROFESSION ASKED OF HCFA

Senator SPECTER. We have 2 minutes left on the clock for the vote which started a few minutes ago, and there is a 5-minute grace period, which I can make with about 90 seconds to spare if I leave immediately. I want to thank you very much for coming in, and I express my regret that other committee members were not present because they were over there voting, and they are not quite able to come back.

What I would like to do is a little different procedure here. What I would customarily do is have a dialog for about one-half hour. But I cannot do that because of time constraints and I have to go vote. You have not had a chance to review the 400 pages which were made available on Friday and filed formally yesterday. What I would like you to do is to frame questions which you would like this subcommittee to ask HCFA, and we will frame questions in addition.

Again, I express my regrets, but these schedules are very, very difficult. But I did want to have this hearing at this point. I had expected we would be pressing HCFA as to why nothing had been filed, but not coincidentally something has been filed. So we will proceed as I have just outlined.

I will return as soon as I can to hear the next panel. Thank you all very much.

[The following questions by witnesses and others in the profession as what ought to be asked of HCFA to respond to. The questions were not asked at the hearing but were submitted to HCFA for response subsequent to the hearing:]

I. QUESTIONS PERTAINING TO RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS (RVU'S) SUBMITTED BY AMERICAN SOCIETY OF GENERAL SURGEONS

Question. In the absence of specific data, it is difficult to analyze HCFA's June 18 proposed rule on practice expenses. Would HCFA provide the Subcommittee with

the data used to develop the proposed rule? Will the agency also make the data available for review by the medical and surgical community?

Answer. The Abt data, which includes the resource inputs per code furnished by the Clinical Practice Expert Panels (CPEP's) and then priced using national standardized prices, was made available to the medical and surgical community following a meeting on January 22, 1997, with the physician specialty groups. As explained in the June 18, Notice of Proposed Rulemaking (NPRM), the physician community will also be able to gain access to this data through the HCFA Home page or to purchase it from the National Technical Information Service. HCFA will provide this extensive data set, on diskette, to the subcommittee.

Question. HCFA has analyzed the impact the proposed rule would have on each specialty on physicians' income. Would HCFA provide the Subcommittee with its best analysis of what impact the proposed rule is likely to have on Medicare enrollees? In particular, focus on how the proposed rule might affect access, including the availability of care in rural areas.

Answer. Although changes in physician payments when the physician fee schedule was implemented in 1992 were large, we detected no problems with beneficiary access to care. We do not expect problems with beneficiary access to care as a result of the change to resource-based practice expenses. Because some specialties will experience large changes, we favor a transition to resource-based practice expenses. A four-year transition (1992–1996) was used for the implementation of the work component of the physician fee schedule.

Resource-based practice expenses should not have any particular geographic impact. That is, resource based expenses affect the relative value of the procedure in all areas. Geographic differences across areas are recognized by the geographic practice cost adjustment which applies to whatever relative value is used. We should note that a larger mix of primary care services are performed in rural areas. Since the proposed resource-based practice expense produces significant increases in payments for evaluation and management services and other office based procedures commonly furnished in rural areas, access to care by beneficiaries in rural areas should not be adversely affected and could be enhanced.

Question. Earlier this year, HCFA was reviewing options where Medicare reimbursement for some procedures was below the Medicaid reimbursement. Are there any instances where that occurs under the proposed rule? If so, would you provide the Subcommittee with a list of procedures where that occurs?

Answer. We have not conducted a comparative analysis of Medicaid payment rates and Medicare payment rates per code and, therefore, cannot provide a list of procedures or services where the proposed Medicare payment rate, adjusted for the resource-based practice expenses, is less than the corresponding Medicaid rate.

Question. Those initial options were viewed by many to be seriously flawed since they were derived from studies and extrapolation rather than actual data. What have you done since then to gather actual data? How can Congress be assured that your current proposal has validity?

Answer. We obtained actual data about the direct resource inputs from the physician community. We asked CPEP participants to determine the number and kinds of staff needed and the time these staff spend on procedures. We asked about the supplies and equipment for the procedure and how long they are used. We asked physicians how much staff time it takes to do the paperwork, appointments, billing, authorizations, reports and correspondence. We added up the costs of staff, supplies and equipment to determine the direct expense for each service. We then allocated the indirect expenses (i.e., rent, utilities, automobile, other expenses) to each code.

The data we are using to determine the direct nonphysician direct inputs expended in the provision of physician services are then priced using national data and used to establish the direct practice expense RVU's. These data were obtained from the CPEP's whose members were predominantly physicians but included other practitioners and practice managers. We have continued to use this data set because it is the best available source of data on direct resources and expenses. As explained in detail in the NPRM, our medical staff have applied individual tests of data reasonableness to the CPEP data to eliminate data anomalies and to ensure internal data consistency.

The options we have presented in our NPRM differ significantly from any of the four options that we shared with the physician specialty groups in January 1997 predominantly with respect to the methods used to allocate indirect expense to individual physician services. The options presented in January employed methods that allocated indirect costs (RVU's) to individual codes based on either physician time or nonphysician staff time. In the NPRM, indirect costs (RVU's) are allocated to individual codes based on the sum of the physician work RVU, malpractice RVU, and the direct practice expense RVU. We believe this is consistent with a standard ac-

counting approach and also consistent with recommendations from the Physician Payment Review Commission.

Question. The proposed rule calls for a 32-percent reduction in total allowed charges for cardiac surgery. Since practice expenses account for about 41 percent of practice costs, how does HCFA justify a reduction of this magnitude—about three-fourths—against allowed charges?

Answer. The reduction for cardiac surgery can be understood in context of a typical high volume procedure, bypass surgery (code 33512) that is performed by cardiac surgeons. Currently, the national fee schedule (without any geographic adjustment) for this code is $2,748 and this amount is lowered to $1,770 under the resource-based practice expense system, a 36 percent reduction. Current analysis shows that a primary care physician must perform over 100 mid-level office visits to receive the same amount of practice expense payments that the cardiac surgeon receives through the current practice expense payment for a three vessel bypass surgery. Under the resource-based practice expense RVU system, a primary care physician must perform 18 mid-level office visits to receive the same amount of practice expense payments that the cardiac surgeon will receive for a three vessel bypass surgery.

For the hospital surgical procedure, the physician utilizes medical supplies, medical equipment and nonphysician clinical staff, whose costs are recognized, by law and implementing regulations, as paid only through the prospective payment made to the hospital. Thus, these services cannot be paid again through the practice expense payment.

Question. What is HCFA's estimate of actual practice expenses that would be covered for the average physician practice in each specialty, assuming that Medicare were the sole payer? This is especially important because many insurance companies will follow HCFA's lead in setting reimbursement levels?

Answer. We have analyzed, by specialty, the impact of the resource-based practice expense RVU's on physician's net incomes. However, we have not analyzed the percent of the actual practice expenses covered for the average physician. One of the difficulties with this type of analysis is that we do not have the specific procedure mix of the typical specialist across all payers. Moreover, we believe the statutory mandate was to develop a fee schedule where payments are based on the resources required to perform each service.

We do not believe there is a statutory requirement or expectation that the new resource based practice expense payments return a fixed percentage of "costs" to each specialty. In fact, we would expect the opposite to occur—that practice expense payments would increase or decrease by specialty based on the specific mix of services performed and the resources required to produce the service. In any case, there are no "cost report" data available that we know of that would enable us to compute these type of statistics. (We do not believe that current expenditures are an accurate estimate of "costs." "Cost data" for other settings typically refers to audited cost reports in which expenditures have been audited for reasonableness or for other criteria or limits).

Question. If the proposed values did not cover roughly the same proportion of each specialty's practice expenses, would they be truly resource-based?

Answer. Yes, as explained for question 6.

Question. If HCFA cannot estimate the proportion of each specialty's practice expenses that would be covered by the proposed values, how can the agency be confident that those values are fair and accurate?

Answer. We are charged by law with designing a resource-based relative value system not a system of cost reimbursement for physicians' services. Consistent with the statutory requirement, our focus has been on developing payments that reflect the relative resources to perform each service, not to return a specific percent of current expenditures to each specialty.

Question. What information does HCFA have about urban-rural differences in the utilization of medical equipment per unit of time? What is the risk that the relative values being proposed by HCFA will underpay rural practices for costs of their equipment because it is not possible or practical for them to match HCFA's assumed machine capacity?

Answer. The fee schedule represents relative resources required to perform a service for the "typical practice". Other adjustments, such as the geographic practice cost indices and the health professional shortage area bonus have been established by Congress to account for differences between geographic areas.

We acknowledge in the NPRM that there is no source of data on utilization levels of equipment across all procedures and all payers. We have made requests to the medical community for this information, but it has not been provided. Certainly, the pricing of medical equipment is critical for those specialties that are significant

users of medical equipment, such as radiology and ophthalmology. However, for almost all other specialities, medical equipment in the aggregate represents less than 10 percent of total direct practice costs.

Question. HCFA has estimated that the indirect costs of a practice average about 55 percent of total costs in a charge-based system. Yet with respect to surgical practices, the proposed rule does not appear to make any allowance for continuing indirect costs of maintaining an office and support staff during the time the surgeon is performing work in the hospital or operating room. Please explain HCFA's assumptions on these aspects of practice expenses, and how those costs are accounted for.

Answer. First, neither of these statements is correct. We estimate from the AMA SMS data that the indirect costs, which are costs other than clinical and administrative labor, medical equipment and medical supplies, are approximately 45 percent of total costs. Further, we do recognize the practice's indirect costs when the surgeon is performing surgery in the hospital. We allocate indirect costs to the specific code based on the sum of the physicians' work, the direct practice expense and the malpractice expense relative value for that code. Furthermore, office staff is likely performing direct labor for other physician services while the physician is performing tasks in the hospital.

QUESTIONS FROM PANEL 1

PENDING LEGISLATION

Question. What is your assessment of the additional House and Commerce Committee and Senate Finance Committee provisions calling for new studies and reviews of the data?

Answer. We firmly believe that we have sufficient data to establish resource-based practice expense RVU's. We are very supportive of a well defined refinement process during which physician panels can address concerns that code-specific RVU's are missing key inputs or the RVU's are inconsistent with the values of other codes in the same family or codes of other specialties. In the proposed rule, we asked for comments from physicians regarding the refinement process.

Question. You have already spent nearly $3 million on data development contracts; how much more do you estimate it would cost to implement the new House and Senate provisions under consideration, and could you absorb the cost within your fiscal year 1998 budget request?

Answer. The proposed legislation requires that we use, to the maximum extent practicable, generally accepted cost accounting principles; use actual data on equipment utilization and other key assumptions. We believe we have most of the data we need to establish resource based relative values in accordance with the proposed legislation. Information we don't have, such as actual equipment utilization, will be requested as part of the notice of pre-rulemaking we plan to publish in September of this year.

From the comments we have received so far on our June 18, 1997 proposal in the Federal Register, some physicians have told us they have information about equipment utilization in their practices. We plan to request this and other information so we can incorporate it into the proposed notice which the legislation mandates we publish by May 1, 1998.

An additional provision of the proposed legislation requires that the Secretary develop a refinement process for each of the years of implementation of the new relative values. HCFA is well on the way in developing a refinement and validation process. In the Fall of this year, we will be conducting a series of validation panels to review the practice expense data on about 300 of the most frequently performed procedures. Members of the validation panels will be comprised, in part, by physicians nominated by their specialty societies. Although we haven't scheduled additional validation and refinement activities as yet, we expect to ask for comments about how this process should work in our notice of pre-rulemaking.

IMPACT ON HOSPITALS

Question. Have you looked at the impact of your practice expense regulations on major medical centers across the country?

Answer. In our impact analysis, we did not examine the impact of the practice expense regulations on major medical centers. Our national claims data is not structured in a format to allow us to readily perform an analysis by medical center.

RELIABILITY OF DATA

Question. Ms. Buto, in Dr. Kleiman's testimony, he states that the data you are relying on for the practice expense regulations, developed by Clinical Practice Expert Panels, has neither been released in a readable format nor validated by HCFA. Are you working with the interested groups to resolve these concerns, and won't more time be needed than the 60-day comment period allowed by the proposed rule?

Answer. The Abt data, which includes the resource inputs per code furnished by the CPEP's and then priced using national standardized prices, is available to the medical community. The data that were used to determine the relative values were widely distributed in January to the medical community. The physician community can gain access to the final data through the HCFA Home Page or can purchase it from the National Technical Information Service.

The current law requires us to implement the resource-based practice expense system in 1998. We cannot extend the comment period and also met the deadline imposed by the current law.

Question. What is your response to Dr. Kleiman's recommendation, made on behalf of the 40 health organizations that are members of the Practice Expense Coalition, that Congress should delay implementation of the regulations until January 1, 1999 and redirect your agency "to develop new and verifiable methodologies based on generally accepted accounting principles?"

Answer. We are working with Congress to pass legislation allowing for a phased-in implementation schedule. There are different opinions in Congress on when changes should first take place. A phased-in implementation strategy will ease the impact of these changes, which otherwise will take place at the same time as the President's proposal for a single conversion factor. Phased-in implementation also will allow us to work with physician groups to refine the relative values for specific codes. However, we are confident that our methodology is sound.

LAG TIME GETTING OUT REGULATIONS

Question. Ms. Buto, Congress enacted the legislation requiring your agency to implement physician practice expense regulations on October 1994, and provided a lead-time of 3 years and 2 months for development of the regulations before going into effect on January 1, 1998. Why has it taken 2 years and 8 months to publish the proposed rule in yesterday's Federal Register?

Answer. The law requires us to develop the resource-based practice expense RVU system based on the staff, the medical supplies and the medical equipment for the service furnished in various settings.

To develop this system, we had to collect data on resource inputs at the code level. This type of data was not available. Consequently, we published a request for proposal (RFP) and asked the research community to submit proposals following the design elements and the criteria in the RFP.

The RFP was published in the Commerce Business Daily in November 1994. The proposals were submitted with respect to the RFP in January 1995 and, in March 1995, the contract was awarded to Abt Associates. Under the contract, Abt was to perform data collection activities. Code-specific data on the direct service resource inputs was collected through two rounds of the CPEP's. The first round of CPEP's was held in February 1996 and the second round was held in June 1996. Abt provided the complete draft CPEP data set to us in January 1997. These data were used to derive the direct component of the proposed relative values.

Question. Do you feel that interested parties are being given sufficient time to analyze these regulations and provide informed comments before a final rule is issued this fall?

Answer. In order to meet the deadlines required under current law, we are giving the medical community and public 60 days to comment on the NPRM. During the life of the Abt contract, we have conducted numerous public meetings with the medical community. In January of this year, we conducted a meeting at HCFA's headquarters during which we provided an overview of the proposed methodology and various options being considered, such as whether the CPEP data should be linked or unlinked and how indirect costs (RVU's) should be allocated to individual procedure codes. We also shared impacts by physician specialty on four options that were being considered.

Question. Would you prefer an extension of time to further refine the regulations?

Answer. We plan to seek input from the physician community and refine the procedure-specific relative values whether resource-based practice expense relative values are implemented next year or in a later year.

Question. Why did it take 6 months after enactment of this law to award the initial contract with Abt Associates to put together the data collection survey for developing these regulations?

Answer. See response to question 1 under this subsection. The time frame for awarding a contract is governed by the competitive procurement rules that apply to all government agencies.

Question. Why did it take another full year to develop the survey and get it approved by OMB?

Answer. The survey of practice costs was a very comprehensive survey of physician practice costs and the procedure mix of the practice. Because of its complexity and range, we asked Abt to solicit comments from the medical community. As noted below, the design of the survey itself and the review and feedback from the medical community took 5 months and the clearance by OMB took nearly an equivalent time.

In June 1995, HCFA scheduled a public meeting with the specialty societies to discuss the overview of the project and the planned data collection strategies. Comments were also solicited on the practice cost survey. After considering the comments of outside researchers, medical specialty societies and HCFA, Abt finalized the survey design in September 1995. In October 1995, the package for clearance of the Survey was sent to the Department and OMB. OMB approved the survey in February 1996. The first mailing of the survey began April 1996.

Question. When the survey was finally canceled in September 1996, due to lack of an adequate response from the physician community, do you feel 18 months had been wasted?

Answer. We have always attempted to have as many options as possible. If the survey had been successful, we would have been able to consider more options for measuring and allocating indirect costs. This experience has been invaluable to us. We do not believe a survey of this type is feasible. We are confident we can use the existing data and more standard accounting methods to allocate indirect costs.

Question. Why weren't the regulations put out months ago?

Answer. Under the timetables that we had presented to the AMA and the physician specialty groups as far back as April 1996, we had advised the medical community that we would publish a NPRM in the first half of 1997. Thus, the publication of the NPRM was not significantly delayed even from the perspective of the earliest projections.

ADDITIONAL QUESTIONS ON PRACTICE EXPENSE FOR SENATOR SPECTER

Question. It strikes me that the study of physician practice expenses and how to fairly reimburse physicians for those expenses boils down to an accounting exercise. Did HCFA utilize generally accepted accounting principles in collecting its data?

Answer. We believe that we used generally accepted accounting principles in our method to develop practice expense relative values. We divided practice costs into direct and indirect costs attempting to identify as many costs as possible as direct costs. We obtained itemized direct inputs for each procedure from the physician community. We then priced these inputs using standard pricing data. Indirect expenses, which by definition cannot be directly measured at an individual service level, were allocated in relation to total direct expenses, a commonly accepted accounting practice in cost accounting.

Question. Please describe which accounting experts were consulted in this study and what aspects of the study did they consult on?

Answer. HCFA staff have extensive experience and familiarity with cost accounting. For many years HCFA payment systems have been based on cost accounting methodologies.

The RFP also required Abt Associates to assemble several Technical Expert Groups to provide technical advice on the CPEP process and the survey. The TEG's included clinicians, and researchers, including economists and accountants. Included on the TEG were a number of participants who have done work in this area either for HCFA or specialty societies, including Allen Dobson, Ph.D., Daniel Dunn, Ph.D., Henry Miller, Ph.D., and Gregory Pope, M.S.

Abt Associates engaged subcontractors to provide technical expertise on the design of the survey instrument itself. These subcontractors included the Medical Group Management Association, and Rod Nelson, a CPA and the owner of a firm that specializes in costing physician practice activities. MGMA had experience with physician practice surveys including knowledge of accounting information that physician practices could provide.

Question. I'm not an accountant, but it would seem that there are some fundamental issues that would impact your proposal.

—(a) For example, how did HCFA's study consider and reconcile the differences in practice expenses incurred by a specialist physician practicing at a major research and teaching institution versus a physician in the same specialty who practices independently?

—(b) In conducting your study, how did you collect and consider detailed information about the different practice expense structures faced by physicians in these rather different practice settings?

Answer. A relative value scale requires the development of one number for a procedure, regardless of the various setting in which the service may be furnished. This is a fundamental premise upon which the entire physician fee schedule is premised. The same issues are involved for the physician "work" for a procedure. The relative value for physician work, as well as practice expenses, are based on the resources for the "typical" patient. Separate adjustments under the fee schedule are made for differences across geographic areas.

However, in developing relative values for a "typical" patient for procedure, we sought input from a wide mix of physician practices. One of the objectives of the CPEP process was to assemble a panel of physicians and practice administrators that represent the variation in physician practices in terms of size, geographic location (urban vs. rural), and teaching/nonteaching characteristics. Thus, the CPEP's consisted of both academic and nonacademic physicians and each contributed to identifying the typical kinds of resources involved in providing a different code both in and out of the physician's office.

Standard prices were assigned to labor input components principally using data from the Bureau of Labor Statistics (BLS). Data from the University of Texas Medical Branch and the Current Population Survey were used as supplements to BLS data. Prices for medical supplies were obtained from published catalogues, contacts with medical suppliers, and CPEP members. Prices for medical equipment were obtained from medical equipment suppliers (and allocated to individual replications of services using a relatively straight-forward technique).

Question. I understand that the purpose of the proposed Abt Associates survey of physician practice expenses was to understand the actual realities of expenses being incurred by physicians in the operation of their practices.

—(a) In suspending the Abt study, how can HCFA now assure Congress that its proposal is based on "real", rather than hypothetical information?

—(b) Please explain how you were able to get real, reliable and relevant data in lieu of the originally planned study.

Answer. We are able to calculate resource-based practice expense RVU's without the survey. First, we used the AMA SMS data from approximately 4,000 physician practices to determine the division, in the aggregate, between direct and indirect costs. The definition of direct costs we used for this calculation is the same definition of direct costs used by the CPEP's.

We relied on the CPEP's to provide us with "real" data on the resource inputs, such as labor staff, medical supplies and medical equipment, associated with individual services. This information came from physicians, practice managers and others who are actively practicing medicine. In addition, prior to the CPEP sessions, participants were provided with a list of the procedure codes they were to analyze so they could consult with others about what resources were required when those services were performed. These inputs were used to generate the direct practice expense RVU's.

Question. How does HCFA propose to measure changes and collect information in the future about practice expenses, to ensure, for example, that changes which occur in the practice expenses being incurred by physicians are adequately considered in future policy decision? Have these changes been though through?

Answer. We are considering these matters as part of how we will structure the refinement process. It is clear that there will be significant physician involvement in the refinement process. We have already had and will continue to have discussions with the AMA and the physician specialty groups about these issues.

Question. What about things like indirect expenses, say electric utilities? How did HCFA's approach capture basic things like the allocation of an electric bill to many physicians of different specialties practicing in a large building? Without a mechanism to meter each physician's electricity usage separately, how would you know how much it cost each practice to operate?

—(a) Did HCFA's study allocate these items on a "per physician" basis, or did it consider the "actual consumption" of electricity and its cost for each different type of physician or procedure performed?

—(b) So if in the same building you had a radiologist providing services that consume large amounts of electricity next to a primary care physician who consumes much less energy resources, how did the study consider these differences and build them into the reimbursement proposal?

Answer. It was not feasible to attempt to collect data at this level of detail. We did collect information on staff, equipment and supplies required for each service. Other costs, such as electricity, heat, telephones, etc. are considered to be indirect costs and allocated to individual codes on the basis of the sum of the physician work, direct practice expense and malpractice value for the code. This is consistent with a standard accounting approach.

Question. What do you feel are the major weaknesses in the approach used by HCFA to study this issue? What allowances have been made to deal with these weaknesses to ensure that we do not make an error in establishing policy?

Answer. We recognize there are some specific areas where additional work is needed and have asked the public to share their comments and views with us. One of the areas is the pricing of medical equipment. As we mentioned earlier, the pricing of medical equipment is not a significant issue for most specialties since it represents less than 10 percent of total direct costs (which is about 2 percent of total payments). However, medical equipment pricing is a more significant issue for some specialties (i.e. radiology) and we need to further examine the implications of a single uniform approach for these specialties. The other major issues are the process by which the practice expense RVU's are refined and the magnitude of the redistribution for certain specialties. We are supportive of a multi-year transition so that the changes do not occur in a single year.

II. Questions Pertaining to Radiosurgery

Question. It is our understanding that HCFA proposes to reduce the Medicare reimbursement for radiosurgery to begin October 1, 1997, but is willing to work with providers to review cost data. Should the current reimbursement rates be maintained until the cost of the review is completed?

Will your review of cost data differentiate between clinically different technology in the radiosurgery area?

Concerns have been expressed that severe reductions in Medicare gamma knife reimbursement could force many patients back to traditional surgical approaches at high cost to the government and potentially resulting in harm to patients due to complications from needless surgical intervention. Have you investigated these concerns, and if so, what have you found out?

Can you give us any assurances that no action will be taken on Medicare reimbursement that could result in limiting patient access to gamma knife treatment, which could be the only option for patients unable to withstand conventional surgery?

Answer. This is not an issue for payment under the physician fee schedule. Rather, it is an issue for the DRG payments to hospitals.

The most recent Medicare data indicate that hospital charges associated with stereotactic radiosurgery cases are substantially lower than the charges for other cases in the relevant DRG's. For example, in DRG 1 (Craniotomy)—which contains most of the radiosurgery cases—the average charges for the radiosurgery cases are approximately $16,400 compared to approximately $27,800 for DRG 1 overall, and the lengths of stay are about 3 and 10 days, respectively. Thus, we believe that these cases are being overpaid. As a result, we are proposing to move these cases to DRG's 7 and 8 (Peripheral and Cranial Nerve and Other Nervous System Procedures, with and without CC), with average charges of $20,500 and $8,240, respectively.

The analysis above is based on hospital charge data from the standard 10 percent sample of Medicare cases that we use in assessing DRG issues. We have indicated our willingness to examine a full 100 percent sample of all radiosurgery cases before making a final decision about DRG assignment. We intend to complete this analysis before publication of the fiscal year 1998 hospital payment rates that are scheduled to take effect on October 1, 1997.

Because current ICD–9 codes do not discriminate between the "gamma knife" procedure and other radiosurgery, there is no way to discriminate between these types of cases in the Medicare database. Any expansion of the coding would have to be accomplished through the ICD–9 Coordination Committee process and could not take effect any earlier than October 1, 1998.

We do not believe that the proposed reductions in payment for radiosurgery cases would jeopardize patients or limit their access to appropriate care. A basic principle

of the hospital prospective payment system is that payment is based on an averaging process, as each DRG contains a range of patient costs and lengths of stay. Payment in excess of cost in one DRG may offset costs in excess of payment in another DRG. For cases that would now fall into DRG 7 (which contains nearly 6 times as many patients as DRG 8), radiosurgery cases would continue to be somewhat overpaid in the aggregate, since average charges for radiosurgery cases are lower than for other cases in the same DRG. Similarly, cases that fall into DRG 8 would likely be underpaid as a whole. Particularly in view of the large profit margins hospitals now enjoy on Medicare patients, we do not believe it is necessary to continue to overpay all radiosurgery cases to ensure that hospitals provide appropriate care, including gamma knife treatment, to Medicare beneficiaries. We note that a hospital may not refuse to provide a covered service to a Medicare beneficiary if it provides that service to other patients.

III. TEMPLE UNIVERSITY HOSPITAL VENTILATION REHABILITATION DEMONSTRATION

Question. Ms. Buto, I understand that your agency has been working with Temple University Hospital on a Medicare demonstration project for ventilator-dependent rehabilitation patients to devise a workable solution for permanent fund for the unit. What is the status of these discussions? Will HCFA extend the demonstration project for another year while a permanent fix is developed? Would the Administration support legislation to permanently extend this project?

Answer. Temple University's ventilator rehabilitation unit (VRU) was part of a HCFA demonstration project from July 1, 1991 through June 30, 1997. Because of Temple's excellent outcomes in this area, HCFA has worked with Temple for the past three years to find a way for Temple's VRU to become permanently eligible for Medicare funding. As of yet, no mutually agreeable solution has been found. HCFA cannot extend the Temple VRU demonstration project for another year under its own authority because the demonstration project is not budget neutral. We would oppose the creation of a new class of providers for ventilator-rehabilitation units since the demonstration project showed that the quality of care across these institutions varies widely, but we would not oppose permanent continuation of the two sites in the original demonstration project which have consistently demonstrated high quality care, Temple University and the Mayo Clinic.

PANEL 2

STATEMENTS OF:

JOHN C. BAILAR III, M.D., Ph.D., DEPARTMENT OF HEALTH STUDIES, UNIVERSITY OF CHICAGO

RICHARD KLAUSNER, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE

Senator SPECTER. Our hearing will resume.

We have with us two very distinguished doctors and researchers, Dr. Klausner and Dr. Bailar. We will begin with Dr. John Bailar, chair and professor of the Department of Health Studies, University of Chicago, graduate of Yale University School of Medicine, who began his career with the National Cancer Institute, and has written extensively on progress in the war against cancer. The full statement that I had prepared will be made a part of the record.

As I said earlier, regrettably we are under time constraints. We have a recent headline from USA Today, "$30 Billion War on Cancer a Bust?" That frames the issue about as well as anything.

Dr. Bailar, the floor is yours.

SUMMARY STATEMENT OF JOHN BAILAR, M.D.

Dr. BAILAR. Thank you, Mr. Chairman. I did not write that headline. I would not have written that. I think there are some things that we need to be concerned about, but that is a statement I think that is inappropriate.

In 1986, Dr. Elaine Smith and I reported that cancer mortality had climbed slowly but steadily over several decades, and we concluded that the war against cancer should be judged a qualified failure. My current work with Dr. Heather Gornik finds little reason to modify that conclusion. The cancer mortality rate, adjusted for changes in the population, including changes in the risk of death from other causes, continued to grow by about 1 percent per year until very recently. Mortality has now plateaued and started to decline slightly, but the 1994 cancer death rate was still about 6 percent higher than that of 1970. We expect a slow and partial decline to continue, primarily because of the delayed effects of reductions in tobacco usage several years ago.

Of course, cancer is a collection of many different diseases, and the risk of death from some forms has been declining, while it has been growing for others. These changes in cancer mortality, both up and down, have been largely a result of changes in the occurrence of cancer, sometimes in earlier detection, rather than a result of the development of improved treatments.

We are not questioning the value of treatment. Treatments presently available are already curing about one-half of all patients, and the best of modern medicine has much to offer those who cannot be cured. In short, this is not a dispute over whether the glass is half full or half empty. We agree that it is half full. The problem is that it is the same half full that it was several decades ago. There is no substitute for a major reduction in cancer mortality rates, a reduction which has not yet occurred despite decades of targeted research focused mostly on treatment.

I am convinced, as I was in 1986, that a major emphasis on cancer research must be shifted from treatment to prevention. The principal counter argument to a new focus on prevention, as expressed to us, has been that success in treatment is near. We are almost there, we hear. Persistence will pay off, we have been told time and time again. I have heard this argument for 41 years, since I entered cancer research in 1956. I heard it again repeatedly and stridently after Dr. Smith and I published our paper in 1986. If there are no changes in the broad direction of our national cancer research strategy, I expect to hear it again in another 10 years and 20 years and beyond. The cure is just around the corner argument may have been old in 1956; it is most certainly old now.

Why the relative lack of prevention research? We have heard arguments that cancer research organizations are dependent on proposals submitted by investigators. That is, of course, true, but the agencies are far from helpless in this matter. In short, prevention research could be moved ahead broadly and effectively, if the will were there.

Another recent advance for the dominance of treatment research is the need to deal with the life-threatening problems of cancer patients now and in the future. We wholeheartedly agree that these patients must not be abandoned, and that a vigorous program of research on cancer treatment should continue, though the level of effort must be balanced with investment in a prompt major expansion of cancer prevention research initiatives.

PREPARED STATEMENT

It is time for all of us to stop dreaming and to devise new and realistic strategies to concur this disease. Prevention is the key to future progress against cancer, and we hope that this Congress will employ effective means to support research toward that end.

Thank you, sir.

Senator SPECTER. Thank you very much, Dr. Bailar.

[The statement follows:]

PREPARED STATEMENT OF JOHN C. BAILAR, M.D.

Good afternoon. My name is John C. Bailar, III. I am Professor and Chair of the Department of Health Studies at the University of Chicago. I am here to talk about work I have recently done with my colleague Dr. Heather Gornik on trends in cancer mortality

I am a retired commissioned officer of the U.S. Public Health Service. I worked at the National Cancer Institute in Bethesda for 22 years, and since then I have held academic appointments at Harvard, McGill University, and now the University of Chicago, where I am Professor and Chair of the Department of Health Studies. For six years I was Editor-in-Chief of The Journal of the National Cancer Institute. For 11 years I was the statistical consultant for The New England Journal of Medicine, and more recently I have been a member of the Editorial Board of that journal. I have an MD degree (Yale, 1955) and a Ph.D. in statistics (American University, 1973). I have a license (presently inactive) to practice medicine in D.C. I was a MacArthur Fellow from 1990 to 1995, and I have been elected to both the Institute of Medicine and the International Statistical Institute. I have published about 250 scientific papers of various kinds, as well as several books. My 40-plus year career has been devoted to the interpretation of statistical evidence in medicine, with special emphasis on cancer.

A report of my research with Dr. Gornik was published recently (May 29, 1997) in The New England Journal of Medicine. In 1986 I published a similar article in the same journal with Dr. Elaine Smith (314:1226–1232; May 8, 1986). Both papers are included here as attachments. The data are not in need of any revision, and our interpretation is up to date, so Dr. Gornik and I will use this statement to address some misunderstandings of our paper and to comment on some of the rebuttals that have been offered.

In 1986, Dr. Smith and I found that cancer mortality rates had climbed slowly but steadily over decades, and we concluded that the war on cancer, at that time, should be judged a qualified failure. Our current study finds little reason to modify that conclusion. The cancer mortality rate (adjusted for changes in the population, including changes in the risk of death from other causes) continued to grow slowly but steadily, at a rate of about 1 percent per year, until very recently. The cancer mortality rate has now plateaued and has started to decline slightly (by a total of 1 percent during the three year period 1991–94), but the 1994 cancer death rate was still 6 percent higher than that of 1970. We believe that the present decline will continue (though still at a slow rate), primarily due to the delayed effects of reductions in tobacco usage several decades ago.

This six percent increase is a serious matter; it corresponds to more than 30,000 cancer deaths per year beyond what the rates of 1970 would have caused, even after adjustment for increases due to growth and aging of the population, and declines in deaths from other fatal conditions.

Though there has been much interest in our findings and conclusions, we have not heard any serious questions about the data we present. All of the questions have been related to our interpretation and conclusions, rather than the data. But we believe that the data almost speak for themselves: the cancer death rate was increasing until quite recently, and the small downturn now observed is largely a result of decreased cancer incidence (primarily of lung cancer in men, reflecting their turning away from tobacco several decades ago) and in some cases, earlier detection. On the national level, treatment has had little impact on total cancer mortality.

Changes in the death rate for all forms of cancer combined do not tell the whole story. Cancer is a collection of many different diseases, and the risk of death from some forms has been declining, while it has been growing for others. Our analyses indicate that these changes in cancer mortality, both up and down, have been largely a result of changes in the occurrence of cancer, and sometimes in the earlier detection of the disease, rather than a result of the development of improved treat-

ments. Despite some clear successes in treatment, which we will return to, it is disappointing that the risk of death from cancer is now so much higher than it was at the time of passage of the National Cancer Act of 1971, and indeed higher than it was at the time of the 1986 paper I published with Dr. Smith.

We conclude that past efforts, focused largely on treatment, have not been generally successful, that there is now reason for skepticism about whether they will ever be successful, and that it is time to get serious about cancer prevention, so that treatment will be needed much less often. Large decreases in the incidence of some forms of cancer have been occurring with little intervention by the medical and public health establishment, and targeted efforts to continue and extend these welcome but unintended changes may produce great benefits. Tobacco-related cancers are an exception, but the efforts even there fall far short of advertising and other efforts to promote tobacco use.

We now turn to some of the misinterpretations of our study.

First, we are not questioning the value of treatment for cancer. Treatments presently available in hospitals nationwide are already curing about half of all cancers, and we should make maximum use of whatever is known to work. And, the best of modern medicine has much to offer all cancer patients—even those who cannot be cured of their disease. There is no question that knowledgeable medical care can be of great value to a cancer patient even when the cancer cannot be kept in check indefinitely and will ultimately causes the patient's demise.

We have consistently tried to keep these advantages of present cancer therapies in clear focus. In short, this not a dispute over whether the glass is half empty or half full; we all agree that it is half full. The problem is that it is the same half full that it was several decades ago. National progress in reducing cancer death rates has been spotty and, overall, not very successful.

We also emphasize that we are not attacking any persons. I know many cancer research investigators, and they are uniformly dedicated and honest scientists who are fully committed to the public welfare. Unfortunately, many of them are also wrong, to the extent that they continue to believe that the present division of effort between research on cancer treatment and on cancer prevention is the best way to deal with this dread disease.

We have been accused of unjustified, even destructive, pessimism, but the real pathology here is unjustified optimism. While false hope may have its uses, it can waste resources and, more importantly, direct attention away from what really needs to be done, whether at the conference table of our leaders in medical research or at the bedside of a patient. In some ways, Dr. Gornik and I feel that our role has become similar to that of the independent accountant, a part of whose job is to curb the excesses of company managers who are fundamentally sincere, but desperately want to find good news to sustain themselves, their company, and their stockholders. Similarly, it seems that cancer research managers and investigators have consistently, though sincerely, overstated their progress and underestimated the problems that remain, while the public has been sustained more by hope than by accomplishment.

What are the successes? First, there has been marvelous progress in reducing the cancer death rate among children and young adults. Cancer mortality of persons under the age of 15 is only half of what it was in 1970, and is still declining. We might all agree that if we must begin reducing the death rate in one place, cancer in children is that place. To put these data in perspective, however, cancer deaths before the age of 15 now make up only about one-third of 1 percent of total cancer mortality in the U.S., and complete elimination of cancer at these young ages would have little impact on the national death toll.

In addition to more effective care of cancers of children and young adults, there have been major successes in treatment of some cancers in adults, such as Hodgkin's disease and cancer of the testis, but all of these, too, are relatively uncommon. For example in 1993, deaths due to Hodgkin's disease and testicular cancer combined accounted for less than one-half of 1 percent of total cancer deaths in the United States. Past successes of treatment for these particular forms of cancer are reflected in the present death rate, but further progress can have little further effect on the national cancer burden.

In addition to these individual treatment victories, there have been major advances in the palliation of most cancers. Cancer patients can now live better lives, and in many cases, longer lives, than in decades past. There is no question that it is better to have cancer in 1997, even incurable cancer, than it was 20 or 30 years ago. This is a very important improvement.

More broadly, the national dedication to cancer research has produced major advances in related fields of medical science, including virology, immunology, genetics, and molecular biology, and these have important clinical applications to other dis-

eases. It was no accident that the first major successes in research on AIDS were at the US National Cancer Institute, where investigators had the knowledge, skills, and facilities to deal with dangerous viruses. There have also been important advances in medical imaging technologies and other kinds of technology as a result of decades of dedication to cancer research.

However encouraging these advances may be, improvements in scientific knowledge and even in palliation are not what we set out to do in the ongoing war against cancer, nor should they be our present goal. There is no substitute for a major reduction in cancer mortality rates—a reduction which has not yet occurred despite decades of targeted research.

The principal-counter argument that we have heard is that success in treatment is near. "We are almost there," we hear, "Success is just out of reach" or "just around the bend." Persistence will pay off, we have been told, time and time again.

I have heard this argument for forty-one years, since I entered cancer research in 1956. I heard it again, repeatedly and stridently, after Dr. Smith and I published our paper in 1986. And if there are no changes in the broad direction of our national cancer research strategy, I expect to hear it again in another 10 years * * * in 20 years * * * and even beyond, as Dr. Gornik continues our work. The "cure is just around the corner" argument may have been old in 1956, and it is most certainly old now, as cancer mortality remains near its all time high. Remember interferon? Remember interleukin–2? Remember the monthly, sometimes weekly, fanfare about great new advances against cancer?

Another argument brought forward in response to our data is that the lack of progress in reducing cancer mortality is because major advances in treatment have been offset by large increases in cancer incidence—increases that reflect new exposures to carcinogens. But this argument in fact supports our conclusion. An increase in the true incidence of cancer is an unmistakable flag of trouble that merits the immediate and broad concern of the cancer research establishment and the reallocation of substantial support to characterize, understand, and interrupt the increase. Even if increases in incidence have been largely contained by improvements in treatment, we still have an obligation to identify and attempt to control the causes of the increase. In any event, few persons who have had cancer would argue against the statement that prevention would have been better for them than treatment, which, regardless of ultimate effectiveness, is at best inconvenient, and at worst, leaves the patient with painful, life-altering, and disabling problems, many of which are permanent.

Why the relative lack of prevention research? We have heard arguments that cancer research organizations are dependent on proposals submitted by investigators. That is of course true, but the agencies are far from helpless in this matter. For example, NIH is divided into institutes precisely to assure attention to specific areas of great public concern than might otherwise be under-studied. These institutes have intramural as well as extramural programs, in part so that all important matters can be covered without regard to what is proposed by independent investigators. Requests for Applications and Requests for Proposals, with special funding limited to defined narrow areas of investigation, are remarkably effective in capturing and directing the attention of investigators. NIH staff can provide targeted training, equipment, and other encouragement where they feel that encouragement is necessary.

Another reason advanced for the dominance of treatment research is the need to deal with the life-threatening problems of cancer patients who need care now, or who will need it in the years before a national prevention program could become effective, or who will continue to get cancer for reasons that remain beyond prevention. We wholeheartedly agree that these patients must not be abandoned, and that a vigorous program of research on cancer treatment should continue, though the level of effort must be balanced with investment in the expansion of prevention research.

A prompt, major expansion of cancer prevention research initiatives at the National Cancer Institute and elsewhere is feasible as well as needed. This change may be difficult and painful for both investigators and institutions that have been dedicated to research on treatment, but it is possible if we all have the will to make it work.

We have not addressed the issue of the overall budget for cancer research in this country. Instead, we are arguing for a new balance between prevention and treatment within the constraints of whatever budget is provided. We have heard some critics say that our findings should drive a massive expansion of the cancer research budget. That may be the best way to go. However, we are not certain that anyone would be harmed by substantial reallocations within the present NCI budget. We understand the argument that one cannot predict where the next important re-

search finding will emerge, but we are not convinced there will ever be such an advance. Further, while all funded research is judged to be promising, some projects are readily identified as more promising than others. We trust that decisions to reduce research on cancer treatment, if necessary, will result in a leaner program that is more focused on what is most likely to pay off.

We believe that Congress recognizes the need for a shift of attention to prevention. After more than 20 years of little change, the Public Health Service Act (Section 417B(d)) was modified in 1993 to require a reluctant NCI to devote at least 10 percent of its budget to a range of specified cancer control activities by 1996. This requirement is being met on paper, but we have no way to tell how much of the apparent change is real, as opposed to relabeling of ongoing work, and even the full 10 percent would still be far too low.

What figure would be optimum? We cannot be sure; Dr. Gornik and I have been working alone, without even grant support, and we have not had the resources for a full analysis. However, it appears that the treatment: prevention ratio has been about 4:1 exclusive of administrative costs and research that is so basic that no direct implications for prevention or treatment can be discerned (though relabeling of applied research as basic may again be a problem). My initial guess is that this should be partially reversed, to a ratio of at least 1:2 in favor of prevention, but this (or any other) figure requires detailed and entirely unbiased consideration by a panel of experts.

After decades of tenacious dedication to treatment research, it is time for all of us to stop dreaming and to devise new and realistic strategies to conquer this dread disease. Prevention is the key to future progress against cancer, and we hope that this nation will find effective ways to support research toward that end.

Thank you.

SUMMARY STATEMENT OF DR. RICHARD KLAUSNER

Senator SPECTER. We now turn to Dr. Richard Klausner, Director of the National Cancer Institute since August 1, 1995. Since 1984 he has been the Chief of Cell Biology at the Metabolism Branch of the National Institute of Child Health and Human Development. A graduate of Duke University School of Medicine, he began his research career in NIH in 1979.

Welcome Dr. Klausner. The floor is yours.

Dr. KLAUSNER. Thank you, Senator Specter.

I am pleased to have this opportunity to discuss progress and to respond to the article "Cancer Undefeated." I want to make eight brief points.

MORTALITY RATES

First is one overarching message that we all agree on. Overall cancer mortality rates which had been rising all century have finally begun to fall. The 1- to 3-percent drop in age-adjusted mortality rates is just a beginning, representing thousands of lives saved per year that would have been lost.

Second, to understand why mortality rates are changing, we must move away from lumping all cancers together, and rather examine each, for each is a different disease. We can look at four examples.

Lung cancer.—The No. 1 killer, has a death rate that is finally falling in men and in women under 65. The reason is indeed prevention, and a drop in smoking rates.

Gastric cancer.—This has plummeted from the No. 1 killer early in the century to the No. 8 now, and in fact, none of us really know why.

Colorectal cancer.—This is the No. 2 cancer killer. Its mortality has been falling for 20 years, due largely to early detection. We believe that the recent evidence of a 30- to 35-percent reduction in

mortality following adjuvant treatment of moderately advanced disease is and will continue to contribute to the drop in mortality from this cancer.

Breast cancer.—There is a significant recent decline in mortality that is likely the result of both early detection and the widespread use of adjuvant treatment. All of the data suggest that it is the latter, that is, treatment that explains the bulk of this effect.

Third, we must take our victories against cancer where we can. For that reason, a balanced approach to prevention, detection, treatment, and the science that underlies all of them must remain the driving principle of the NCI. Indeed, prevention and treatment are often not readily separated. Prevention is a high priority to the NCI. Prevention research does and must include research into causes of cancer, or else we cannot prevent it; identifying who is at risk from which cancer; conducting prevention research; and direct prevention interventions. It this year will amount to $911 million, or 38 percent of our budget.

Research into early detection of cancer crosses the line between prevention and treatment. Early detection is of no benefit unless you have effective treatment. Our investment in treatment-oriented research, in contrast to what Dr. Bailar says, amounts to $845 million, 35 percent of our budget. The remaining 27 percent of our budget is targeted to cancer biology training and education, which I consider to be part of the foundation for prevention, treatment, or detection.

Senator SPECTER. How much of the budget is for prevention, would you say, Dr. Klausner?

Dr. KLAUSNER. If we define prevention as identifying causes of cancer, as identifying who is at risk for cancer, conducting what we call strictly prevention research, and direct prevention interventions, it amounts to 38 percent of our budget, and I would be happy to provide you with the details of those numbers.

Senator SPECTER. Identifying the cause of cancer, who is at risk, intervention, prevention——

Dr. KLAUSNER. Yes, both prevention research, and direct prevention interventions. For example, there is a new burgeoning of clinical trials where we are now testing a whole variety of prevention interventions, from behavior research to new drugs. Many of those drugs began as treatment drugs.

Senator SPECTER. OK.

CANCER PREVENTION REVIEW

Dr. KLAUSNER. Since I became Director 2 years ago, I have commissioned a series of critical external reviews, and 2 days ago I received the first-ever comprehensive report from a very eminent panel of our country's cancer prevention researchers that will help guide the invigoration of our cancer prevention programs.

Fourth, progress is dependent upon knowledge. Our investment in understanding the causes and characteristics of cancer is essential if we are to develop effective interventions, regardless of whether they are treatment or prevention.

Fifth, progress takes time. The pace of progress against cancer frustrates all of us. Whether we like it or not, to move from an insider in observation to a tested successful human intervention

takes time, and there will always be a lag between our investment and the payoff we are now actually beginning to see.

Six, success is measured in multiple ways. While the reduction in cancer mortality should be our ultimate goal, there have been critical advances in the quality of life for the 8.1 million cancer survivors; longer survival time after diagnosis, time to spend with family and community; less destructive and disfiguring surgery, so that people who would have lost their voices can speak, people who would have lost their limbs can walk, and many others can keep the function of their bowel and bladder; better control of pain and disabilities. These are all advances that benefit people, advances that should not be dismissed.

Seven, the drop in mortality that we have recently seen can be viewed as a fork in the road of our progress against cancer. What do we do with this fork? I agree with Yogi Berra. When you come to a fork in the road, take it. This year, over 1.3 million Americans will be diagnosed with cancer. While some significant fraction of these cases are a failure of prevention, even if all tobacco use stopped today, even if all of us instantly adopted a perfect diet, we would still be confronted with an enormous number of people who would be diagnosed with cancer. These people cannot and will not be written off because we have chosen one fork in the road and decided that if you slip past prevention you are out of luck. Our broad-based approach is working. It would be foolish to abandon it.

And eighth, it is dangerous to make predictions, especially about the future. While the past is prologue to the future, the future is not easily predicted by the past. Before all of our breakthroughs critics pronounced that we will never fly, never wipe out smallpox or polio, or never cure a child with leukemia. While cancer is still clearly undefeated, defeatism is simply not supported by the current evidence. The promise of ideal and total prevention of cancer may well contain as much hype as Dr. Bailar sees in the overpromise of cure.

PREPARED STATEMENT

I believe that we can and must do better in our fight against cancer. The past 2 years, I have worked to bring a spirit of reevaluation and of real change to the NCI, to ensure that our investment in understanding the causes and nature of cancer are optimally linked to the development of new strategies for prevention, detection, diagnosis, and treatment which this collection of complex diseases demands.

Senator, I thank you very much for having the opportunity to appear before you today.

[The statement follows:]

PREPARED STATEMENT OF RICHARD D. KLAUSNER, M.D.

Senator Specter, Members of the Committee—I am Richard Klausner, Director of the National Cancer Institute. I am pleased to have this opportunity to discuss progress against cancer and to respond to the recent article in the New England Journal of Medicine entitled "Cancer Undefeated." I wish to make eight brief points.

First, there is one overarching message that we all agree on: overall cancer mortality rates, which had been rising all century, have finally begun to fall. The 1–3 percent drop in age-adjusted mortality rates is, we hope, just a beginning—representing thousands of lives saved per year that would have been lost.

Second, to understand why mortality rates are changing, we must move away from lumping all cancers together and rather examine each cancer, for each is a different disease or, indeed, a different set of diseases. Let us look at four examples.

—(1) *Lung Cancer.*—This is the No. 1 killer whose death rate is finally dropping in men and in women under 65 and the reason is clear: the drop in smoking that began after the first Surgeon General's report in 1964.

—(2) *Gastric Cancer.*—This has plummeted from the No. 1 killer in 1900 to No. 8 now, and we don't know why.

—(3) *Colorectal cancer.*—This is the No. 2 cancer killer. Its mortality has been falling for 20 years due largely to early detection, and we believe that recent evidence of a 30-percent reduction in mortality following adjuvant treatment of moderately advanced disease is and will continue to contribute to the drop in mortality from this cancer.

—(4) *Breast cancer.*—The significant recent decline in mortality is likely the result of both early detection and today's almost universal use of adjuvant treatment. I believe it is the latter that explains the bulk of the effect.

Third, we must take our victories against cancer where we can. For that reason, a balanced and constantly re-evaluated approach to prevention, detection, and treatment must remain the driving principle of the National Cancer Institute.

Currently, we do have a large investment in prevention. This does and must include research into the causes of cancer, identifying who is at risk for which cancer, conducting prevention research and prevention interventions, and amounts to $911 million or 38 percent of our budget.

Research into detection of cancer crosses the line between prevention and treatment. Early detection is of no benefit without effective treatment. Our investment in treatment-oriented research amounts to $845 million or 35 percent of our budget.

The remaining 27 percent of our budget is targeted to cancer biology, training, and education which I consider to be part of the necessary foundation for prevention, detection, or treatment. Since I became director, I have commissioned a series of critical external reviews and two days ago, I received a comprehensive report from a very eminent panel of our country's cancer prevention researchers that will help guide the invigoration of our cancer prevention programs.

Fourth, progress is dependent upon knowledge. Our investment in understanding the causes and characteristics of cancer is essential if we are to develop effective interventions—regardless of whether they are aimed at prevention or treatment.

Painstaking molecular, genetic and epidemiologic studies in colorectal cancer are revealing real targets for preventing the development of polyps, the precursors of colon cancer, and preventing their progression to cancer. Cellular and molecular studies of the hormone-dependent growth of breast and prostate cancer are allowing the design of specific antagonists that are providing the first preventives now being tested for these cancers.

Fifth, progress takes time. The pace of progress against cancer frustrates all of us. Whether we like it or not, to move from an insight or an observation to a tested successful human intervention takes time, and this is why there will always be a lag between our investment, the development of the critical knowledge base, and the pay-off that we are finally seeing.

Childhood leukemia was not cured overnight. It took decades from the first tentative use of anti-metabolites and genotoxic drugs to achieve our current 70–80 percent cure rate.

Sixth, success is measured in multiple ways. While the reduction in cancer mortality should be our ultimate goal, there have been critical advances in the quality of life for our 8.1 million cancer survivors. Longer survival time after diagnosis—time to spend with family and community, less destructive and disfiguring surgery, so that people who would have lost their voices can speak, those who would have lost limbs can walk, and many others can keep the function of their bowel and bladder, better control of pain and other disabilities—these are all advances that benefit people, advances that should not be dismissed.

Seventh, the drop in mortality can be viewed as a fork in the road of our progress against cancer. What do we do at this fork? I agree with Yogi Berra "When you come to a fork in the road, take it." This year, over 1.3 million Americans will be diagnosed with cancer. While some significant fraction of these cases are a failure of prevention, even if all tobacco use stopped today, even if all of us instantly adopted a "perfect" diet (recognizing that we don't know for sure what the preventive efficacy is of changing diet), we would still be confronted with an enormous number of people who will be diagnosed with cancer. These people cannot and will not be written off because we have chosen one fork in the road and decided that if you slip past prevention, you're out of luck. Our broad-based approach is working. It would be foolish to abandon it.

Eighth, it is dangerous to make predictions, especially about the future. While the past is prologue to the future, the future is not easily predicted by the past. Before all of our breakthroughs, critics pronounced that we will never fly, never wipe out smallpox or polio, or never cure a child with leukemia. While cancer is clearly still undefeated, defeatism is simply not supported by our current data. The promise of ideal and total prevention of cancer may well contain as much hype as Dr. Bailar sees in the over promise of cure. I believe that we can and must do much better in our fight against cancer. For the past two years, I have worked to bring a spirit of re-evaluation and change to the NCI to assure that our investment in understanding the causes and nature of cancer are optimally linked to the development of new strategies for prevention, detection, diagnosis and treatment which this collection of complex diseases demands.

Thank you Senator Specter, for asking me to appear before you today. I would be pleased to answer any questions.

PERCENT OF BUDGET

Senator SPECTER. Thank you, Dr. Klausner.

Dr. Bailar, you say you disagree with this headline, "$30 billion war on cancer a bust," but you call it a qualified failure. A qualified failure, as distinguished from an unqualified failure. I am not saying you are wrong, but I have seen few headlines about me that I like or anything that I have said that I like. I do not know if the headline is too far off as a real attention-grabber.

The information submitted some time ago by the NCI on percentages, and I am going to ask you about this in a minute, Dr. Klausner, is 11.53 percent spent for prevention. If you have not seen it, let me have it made available to you.

Dr. KLAUSNER. I have it here.

Senator SPECTER. Dr. Klausner now identifies a number of prevention items which he says totals 38 percent. I would be interested, Dr. Bailar, in your evaluation as to whether those are really prevention items?

Dr. BAILAR. I would not classify all of this as prevention the way I define it. You could take a very comprehensive definition and smuggle these in. I would not, for example, include all of the work on the causes of cancer. Understanding causes of cancer will not lead directly to saving any lives. It may help in identifying carcinogenic agents that should be removed, but much of it is focused on molecular processes that might be of equal value in treatment or in other ways.

Similarly, some of the work on who is at risk of cancer I think is not directly related to prevention unless those risk factors are going to be modifiable. My figure is a good bit less than 38 percent.

Senator SPECTER. What would your figure be?

Dr. BAILAR. My figure would be on the order of 10 percent.

On the other hand, I would be more generous than Dr. Klausner in the proportion of the budget targeted to cancer biology, training, and education, which underlies everything. He mentioned 27 percent. I might say 40 percent.

And I would not touch that 40 percent.

CANCER PREVENTION PERCENTAGE

Senator SPECTER. Dr. Klausner, how do you interpolate or justify your current 38 percent estimate with the category which you provided the committee some time ago, at 11.53 percent?

Dr. KLAUSNER. In talking about trying to understand what is needed for prevention, I strongly disagree with Dr. Bailar. I think the idea of preventing something you do not know the cause of——

Senator SPECTER. Before you disagree with him, answer my question about 38 versus 11.5 percent.

Dr. KLAUSNER. If we have the same table, it is broken into epidemiology, causation——

Senator SPECTER. Well, that is why I wanted to give you my sheet.

Dr. KLAUSNER. OK. The epidemiology, causation and carcinogenesis portion is 28 percent.

Senator SPECTER. Please do not read the whole chapter. Take my percent. Well, I have got a sheet here that has 11.53 percent. Take a look at that, and I again ask you what is the explanation for the difference between that document you provided a long time ago and the 38 percent on prevention you are testifying about now?

Dr. KLAUSNER. There is a mandated line in the budget called cancer prevention and control, which is to be approximately 10 percent.

Senator SPECTER. Who says it is to be approximately 10 percent?

Dr. KLAUSNER. Ten percent is according to legislation. It is determined in the law that 10 percent should be in cancer prevention and control.

Senator SPECTER. Only 10 percent or a minimum of 10 percent?

Dr. KLAUSNER. It is a minimum of 10 percent.

Senator SPECTER. It could be more?

Dr. KLAUSNER. That is right. And above this, sir, is called cancer causation, which is 27 percent.

Senator SPECTER. OK. So why did you say cancer prevention was 11.3 and now say it is 38?

Dr. KLAUSNER. Because when you add the about 10 percent for cancer prevention and control, plus the 28 percent here listed as cancer causation—that adds up to 38 percent. This budget table was based upon reporting as we were asked for this, based upon budget authorities.

Senator SPECTER. But if you thought cancer research was really cancer prevention, you could have put it in earlier?

Dr. KLAUSNER. Yes; I think it was for answering a different question, but yes. We called it cancer causation—asking what we are investing for our ability to intervene in cancer, I think requires an investment in understanding the causes of cancer.

Senator SPECTER. Now, Dr. Bailar, what would you recommend as activities that NCI ought to undertake for prevention research?

Dr. BAILAR. It would be largely an expansion of activities already underway. One is to identify and remove known carcinogens, so that the cancer never gets started, never gets a toehold. A second broad area is strengthening natural defenses against cancer. This may be the most important overall impact of the gross elements of diet—proportions of the major dietary fractions, as opposed to trace contaminants.

A third area is what is called hemoprevention. That is the development of drugs and drug-like materials that one can take over a lifetime to interrupt the development and progress of a malignant neoplasm. As I say, all of these things are in progress. I think they

are being done well. But I am calling for a very substantial expansion in these.

I might add, sir, I take strong exception to the notion that we must understand causation, that we must approach it as if our understanding is necessary for any effective action. This has not been true in a wide range of medical advances. We knew about the beneficial effects of vaccination and immunization, put them to good use before we knew how they worked. The same is true of antibiotics. The early years of the antibiotic era, we saved thousands, perhaps millions, of lives, without knowing how antibiotics really worked. We knew that they did work.

Dietary diseases is another example. We were able to block the development of beri-beri, rickets, scurvy, and pellagra without knowing the basic biology behind those. Even in lung cancer, we knew that smoking was a very serious health threat, that it caused most lung cancers, before we knew anything about how it worked. So, in summary, I would say that we do not, in general, need to know about causation in order to undertake effective action.

I am not arguing against research on causation, but I think it has to be kept in this kind of context.

BREAST CANCER ACTION PLAN

Senator SPECTER. Dr. Klausner, we have had some discussions about the breast cancer action plan. And I know that there are many who think that research is the only real line. We have had the mobile mammograms, which came to Philadelphia. And some people said, we really ought not to be investing in that kind of detection. And there has been some revision in what was in the last appropriations bill on the breast cancer action plan, a fair amount of which is devoted to prevention.

Will the prevention aspects that are in the breast cancer action plan be carried out under whatever arrangement has been worked out? I have not yet resolved that with Secretary Shalala. I wrote to her months ago, and have not had a formal response to that. What is happening there?

Dr. KLAUSNER. The action plan, of course, sits in the Secretary's Office, in the Office of Women's Health. And we have, and remain, available, and have been working very closely with Dr. Blumenthal in order to help facilitate the type of activities that Dr. Blumenthal and the action plan and that planning process wants to do.

You are right, most are prevention. And we are working very closely on—I think there are 15 projects that were identified. Most of which are involved with prevention and education outreach, that the NCI staff and expertise and mechanisms are made available to help with the Office of Women's Health studies.

Senator SPECTER. As I understand it, there was some concern that that money ought to be going to research—we talked about that at an earlier hearing. Do you think it ought to be maintained in the prevention category?

Dr. KLAUSNER. Oh, yes, I am very comfortable with these 15 projects that were identified, and we are working on them.

Senator SPECTER. And while it is not a part of the breast cancer action plan, mobile mammography—digital, as I understand it—came to Philadelphia. It seems to me that when you talk about pre-

vention, it does have multiple meanings—education of women, making services available in the inner city, as we had with Temple University Hospital. Now, that is not research, but is that money well spent in your opinion?

OUTREACH

Dr. KLAUSNER. I think it is. And we do much of that. I mean outreach is very important, and education. And I think this discussion about prevention is a very interesting one. There are many ways to think about prevention. You have to define what is it you are preventing. One can prevent the first molecular change by preventing exposure to a carcinogen. Not all of these molecular changes that lead to cancer come from the outside. Those that do, you try to stop. There is also prevention, preventing the cancer from developing, or preventing the cancer from ever expanding or spreading.

As we learn more about cancer, in fact, I think this knowledge will have the most impact in prevention. But what it will do is greatly increase our definition and understanding about multiple places where we can prevent what we want to prevent, as Dr. Bailar says, which is death from cancer.

Senator SPECTER. Well, I am going to have to excuse myself in a moment or two, but I want to ask you one more question, Dr. Klausner, that we have talked about before; have you committed yourself to funding for clinical evaluation of MRI imaging in breast cancer?

Dr. KLAUSNER. Yes; we have.

Senator SPECTER. That is something that I am particularly interested in, because I had the benefit of an MRI myself. And you learn most, I suppose, when you are most directly involved.

Senator Harkin is going to take over and preside. And, as I said earlier, I had commitments that I am going to be late for now. We have been very fortunate in having great experts here, such as Dr. Bailar. You came from Chicago today?

Dr. BAILAR. Yes.

CANCER

Senator SPECTER. Our schedule around here is just extraordinary, with so many things we have to do. I consider the work of this subcommittee a very, very high priority. And cancer is right at the top of the list, as we try to get additional funding for NIH. I thank Dr. Varmus for taking my personal call on what the MRI is doing in heart conditions now. I think you are doing phenomenal work.

I compliment you again, Dr. Klausner, and, Dr. Varmus, Director of NIH. Senator Harkin and I are determined to find extra money for NIH somehow, although we are not sure where. It may be from Riggs National Bank at gunpoint. [Laughter.]

Senator Harkin agrees, as a coconspirator, an active coconspirator—we are determined to find you the money.

Senator HARKIN. I am driving the getaway car, you are doing the stickup.

Senator SPECTER. OK. [Laughter.].

And, Dr. Bailar, I compliment you on producing that headline, whether you agree with it or not. Because I think that the debate is really very good. And I know your qualifications as a researcher, and I admire them. And I believe growth comes out of controversy.

It stimulates thinking. I am just sorry we cannot do more today. I know that Senator Harkin will have very incisive questions, and will move the ball along tremendously.

Thank you very much. I yield now to my distinguished colleague, who has had very substantial experience presiding over this subcommittee, as its previous chairman.

Thank you.

Dr. KLAUSNER. Thank you, Senator.

Dr. BAILAR. Thank you.

Senator HARKIN [presiding]. I knew if I waited long enough, I would get it back. [Laughter.]

First of all, I apologize for being late and not hearing your testimony, but I have read it over. And I really do not have a lot of incisive questions at all. I just have a couple of issues that I want to cover.

I agree with Senator Specter, Dr. Bailar and Dr. Klausner, I agree that it is good to have this debate. I think we ought to be taking a look at this. The headline in the USA Today: "$30 billion war on cancer a bust." I mean it is pretty provocative. I know you did not write the headline, but it is a provocative headline and it gets people thinking. And maybe we all ought to think about this, what direction we ought to go in.

So I agree with Senator Specter in that regard, that out of this could come a good dialog and debate and discussion about what avenues of research we ought to be pursuing.

Now, I am all for prevention. And I think my history in legislation has been one of promoting more prevention in a lot of programs. I guess the one thing I just have to ask, Dr. Bailar, if you are going to talk about prevention, though, you have got to talk about what to prevent—what is causing cancer. That is a very simple straightforward question. What causes cancer?

Dr. BAILAR. That is an extremely complicated, technical kind of question, as you recognize.

Senator HARKIN. Yes.

Dr. BAILAR. On the other hand, as I have already sort of flagged, I am not sure that we have to understand the causes in order to prevent cancer. If we are going to identify specific carcinogens and remove them from the environment, yes. But strengthening body defenses in one way or another—the cancer chemopreventive agents that I talked about—can act, I think, without any real understanding of the individual causes of each form of cancer.

That is one of their glories, that you do not have to deal with cancer—I suspect, in the long run, we will find—that you do not have to deal with cancer as a collection of 100, 200, 300, or 400 diseases if we can work effectively along those avenues of attack.

Senator HARKIN. But it seems to me, if we do not know the cause, how are we going to prevent it? If we did not know the cause of smallpox, we could not prevent it. If we did not know the cause of polio, we could not prevent it. If we are out there flailing around, we could come up with all kind of crazy things. I would like to get

a better understanding of how are you going to have a preventative scheme if we do not have some better understanding of the cause.

Dr. BAILAR. Senator, we were preventing smallpox before we knew the cause.

Senator HARKIN. We were?

VACCINATION

Dr. BAILAR. A century or more before we knew about the smallpox virus, vaccination was being effective in saving very large numbers of lives. Acute clinical observation showed that persons who had been infected with a related disease, called cowpox, simply did not get smallpox. And that was the original source of this notion of vaccination, which——

Senator HARKIN. OK, you may have bested me there. How about polio?

Dr. BAILAR. Polio, we did know about the virus at the time the vaccine was developed.

Senator HARKIN. It seemed to me we had to find out what kind of virus it was. And there was a lot of research—I happen to know a little bit about this—which Dr. John Enders and others did at Harvard, to find the intervention. But, first, they had to understand what was causing it, it would seem to me.

Dr. BAILAR. Well, polio may be a good example of that.

Senator HARKIN. OK, so we are even on it. OK, we are even. [Laughter.]

Let me see if I can think of another one here.

Dr. BAILAR. Maybe I can give you one.

Senator HARKIN. OK.

Dr. BAILAR. Scurvy.

Senator HARKIN. What?

Dr. BAILAR. Scurvy. Which used to be very devastating in navies and other populations that were away from fresh fruits and vegetables for long periods of time.

Senator HARKIN. I have read my history, yes.

Dr. BAILAR. And an English naval surgeon, John Lent, discovered that giving sailors lime juice would prevent scurvy.

Senator HARKIN. OK.

Dr. BAILAR. He did not have the foggiest idea what was going on, but it worked.

Senator HARKIN. OK, fine. I believe that is a good approach. I have had some arguments with NIH about an approach, about looking at different ways of saying, OK, if you have a group of people out there and they have had spontaneous remissions of cancer, we ought to get a matrix done of who they are, what they have come from, what they have done, to see if there is connecting points. We have talked about that before. I have talked about that before.

But it seems to me, with cancer, though, since there are so many different forms and varieties and how it starts and how it spreads, can you show me or can you give me any idea of any study that has been done to show where, if you do A, B, and C, you are not going to get cancer? Or if you do this or if you do not do this, the results will be different?

Dr. BAILAR. I think the——

Senator HARKIN. I know of no valid scientific study that shows that. And I do not know how you would ever set one up.

Dr. BAILAR. I think the history of our understanding about the relation between cigarette smoking and lung cancer is an example of that. It was clear that there was a cause-and-effect relation before 1964, at the time of the first Surgeon General's report. Nobody knew what the cause was. There was educated guessing that it was tar or nicotine or possibly just the heat that was in the tobacco smoke that might damage cells. But we did not know what was going on at the molecular or cellular level.

What we knew was that if you get people to stop smoking, that the rate of lung cancer would, in time, start going down. And that has happened.

Senator HARKIN. OK. We know that smoking does cause lung cancer.

Dr. BAILAR. Yes.

Senator HARKIN. But we also know—I have known people that smoked all their life and never got lung cancer.

Dr. BAILAR. Yes.

Senator HARKIN. So something else is going on. I mean I can take some people that live an awful lifestyle, they drink, they smoke, they eat the worst possible kind of foods, they are exposed to all the worst kinds of chemicals, they never get cancer. I can show you people that live virtuous lives, never drink, never smoke, eat the best kinds of foods—vegetarians—and they get cancer. See, I do not know of any—what is the word I am looking for—any cohort of individuals that you can point to, that because they lived a certain way, ate a certain way, did not do this or did this, were immune from cancer.

Dr. BAILAR. I agree with you. And I am not sure to what extent this is a result of just random chance—luck—that it affects groups of people. You may have a group of persons in whom the risk of cancer, person by person, is increased, perhaps quite a lot, but still not 100 percent, so some will get the disease and some will not. There may also be some element, a substantial element, of individual variation in risk that we do not know about and might be able to exploit if we did know.

There has been research to try to identify reasons why some people are at high risk and others are not. I do not think it has been applied across the board in the way that it might. But there certainly are some kinds of cancer where we know a good bit about the risk of individuals, you know, as opposed to their neighbors or even their close relatives.

Senator HARKIN. I tend to agree to a certain amount that diet does have something to do with it. There seems to be a lot of evidence out there about that—not firm, but some. And you can look at other societies and other countries, where they have a different diet than ours, and their incidence of certain kinds of cancer are less than ours.

Dr. BAILAR. Yes.

Senator HARKIN. And we know that.

Dr. BAILAR. Yes.

SKIN CANCER

Senator HARKIN. But it is just like skin cancer. They say to use a sunscreen and do not go out in the sun. Yet there are countries, high altitude, where people live at very high altitudes, exposed to extremely high amounts of ultraviolet radiation, and never get skin cancer.

Dr. BAILAR. Yes; the evidence is actually stronger than what you have indicated. There have been a number of studies now of populations that have migrated from one area to another. And what is generally found is that within 15 to 25 years, those who migrate begin to acquire the cancer risks of the place they went to.

Senator HARKIN. I understand that.

Dr. BAILAR. They have been compared with siblings and others who stayed back in the country of origin, and it takes about that long before there are major changes in cancer risk. I think that is abundant evidence that there is something in our environment, very broadly defined, that is determining most of our cancer risk. We do not know what it is in most cases.

Senator HARKIN. Why is it that, in certain places, the incidence of skin cancer has gone up? And people say, well, it is sunlight exposure. Yet, you get to the higher reaches of Tibet and Nepal and places like that, where people are living at 12,000 to 15,000 feet, with absolutely no interference between them and ultraviolet radiation, and they do not have that problem. Why is that?

Dr. BAILAR. Well, first, I think they do have the problem. It may not be as great as it is here.

Senator HARKIN. No; it is certainly not.

Dr. BAILAR. It looks like a small problem because large parts of those populations do not live to the ages where skin cancer would be common. Beyond that, they have darker skin than most people of Western European origin, and the skin pigmentation may be important in this. I suspect that there has been some degree of natural selection. That is, their ancestors, who moved to the high altitudes, with very intense exposure to ultraviolet light. Not all survived to reproduce and have children because of the skin cancers and other conditions that might be related to that exposure, so that their descendants are more resistant.

It is possible to spin out a number of theories about this, I am sure.

Senator HARKIN. Could it be possible, Dr. Bailar, that 100 years ago, 150 years ago, our ancestors, my grandparents and great grandparents, that had they lived beyond the age of 50 years, that there might have been a lot more cancer in those days than we are having today?

Dr. BAILAR. I am sure that there would have been. I would like to just inject here that the figures that I have been talking about—I believe all the figures that Dr. Klausner has talked about here and elsewhere—have been what is called age adjusted to remove the effect of the changing age distribution of the population at the same time to remove the effect of changes in other causes of death.

Senator HARKIN. But that is comparing today.

Dr. BAILAR. No; it is comparing over time.

Senator HARKIN. I do not understand that.

Dr. BAILAR. The age adjustment says if you had a population under a certain set of cancer risks, with the age distribution in a specific standard that you choose, what would have happened? So that your great grandfather, whoever, from an earlier era, was in a population that was, on the whole, a great deal younger. Now, the question the age adjustment asks is, what happens if we allow those people to get older—to have the current age distribution or the age distribution in 1990 or whatever, what would we be observing?

Senator HARKIN. I guess some of that data I would not trust. Because I have some personal knowledge of deaths that occurred in older times and records were not kept that well. And people died of the consumption. They did not know what it was. And they died of the ills. And, you know, who knows what it was? And so I do not accept a lot of that data of previous times.

Dr. BAILAR. I agree, sir. And I do not myself go back beyond 1950 in any of this.

Senator HARKIN. Yes; that is getting into pretty modern times. I am just saying I am not certain how long the plague of cancer has been with us. That is my point.

Dr. BAILAR. From antiquity.

Senator HARKIN. Well, I think so.

Dr. BAILAR. Egyptian mummies have had evidence of cancer.

Senator HARKIN. And I think so. And I am just saying, if people lived longer, maybe the incidence would have been just as high then as it is today. I do not know.

Dr. BAILAR. Yes, sir.

PREVENTION

Senator HARKIN. I have no way of knowing that. My basic premise, getting back, is that I am all for prevention. But it seems to me we still have to—how are you going to prevent what you do not know is causing something? You can take shots in the dark, and that is fine. And we can take a shot in the dark. We can all change our lifestyle and change our diets and hope for the best. I think changing our diets would help us live better. It would help us feel better. We would have better lives. We would be healthier. Our hearts would be better. And we would probably live longer, and we would have a better life.

But I am not so certain in my own mind that that alone is where we ought to focus as much resources as I think you are wanting us to focus in the fight against cancer. And that is what I am concerned about. I want to find out what is the root cause. What is causing those cells to go haywire? I think if we find that out, then it seems to me that is when we can start finding out the cures and the preventions of them.

Dr. BAILAR. With respect to diet, we already have a good many indications that a class of vegetables that includes cauliflower, broccoli, brussels sprouts, and so forth is in some way, somewhat protective. Now, that may be information that could be more thoroughly checked. I do not regard it as absolutely established. But if we learn that there is that kind of correlation, if it appears on further study to be cause and effect, there is something that we could

recommend right now in a much more vigorous way than we can, without understanding the mechanisms.

I am not opposed, sir, to understanding mechanisms, but I think we ought to get on with what we can do now, whether it is in terms of implementation or research, based on these kinds of hints that I have mentioned.

Senator HARKIN. Well, I think there is room for that.

I do not know the discrepancy, Dr. Klausner, between your figures and Dr. Bailar's, in terms of what percent of NCI funding goes for prevention. I do not know what that is all about. You are saying 38, you are saying 10, I do not know what that is all about.

Dr. KLAUSNER. Well, you heard it. Dr. Bailar thinks that doing research into the cause of cancer, whether that is doing research to originally identifying that tobacco is a cause of cancer—this idea that cause only means molecular cause or subatomic cause and cellular cause. What you do is you look for mechanisms at the level of cause that tells you how to effectively intervene. It is an operational definition.

The reality is that the more we know about the components of tobacco, the better we are at effecting the prevention that Dr. Bailar would like us to do. Even with tobacco, knowing that nicotine is in tobacco delivery systems and that is addictive is extremely important in effective prevention. Remember, we have known that tobacco has been the cause of cancer for quite some time. The first case-controlled study was in 1939, published in Germany.

But, actually, what you have to do to effect that prevention is very difficult. And the more we understand about who is at risk and why, including aspects of the mechanism, gives us more and more powerful tools at intervening, whether it is intervening with addiction, intervening behaviorally. This all takes research.

If we try to turn this discussion into this type of black and white, you either just prevent sort of magically, whether you know or do not know, or you need to know down to the quarks—we are not saying that. What we are saying is that the way scientists work is you establish definitively connections that allow you to predictably act. Whether that means you totally understand mechanism or very vaguely understand mechanism, but understand enough of what your intervention is, whether it is prevention or treatment, that it be predictable in terms of its outcome. That is what science does for you. And it is a complete continuum.

CHEMOPREVENTION

Dr. Bailar mentioned chemopreventions, as if we would just throw chemicals at people without knowing why and how they work. Now, there are chemicals that we would give to people because of observational studies, such as aspirin or nonsteroidal anti-inflammatories, to prevent cancer. But I will tell you that that is a great example of studying the molecular mechanisms, which gives us what appears to be the precise molecular target of aspirin in that pathway—an enzyme we think is called Cox-2; we think that is the precise target; we think we can prove it—now allows us to say, well, aspirin does it.

Since that is not a specific inhibitor, only an inhibitor of that enzyme, if that is the enzyme that gave that observational effect, knowing that connection allows us now to design and test, which we are now doing, chemopreventative agents to prevent colon cancer. That may well be one, two, or five steps better than this sort of—the information we get out of these observational studies. And it is just another example that what we want to do, we want to do well, and we want to make sure that we optimize it.

It is true what Dr. Bailar said, we did not know how antibiotics worked when they were discovered. But we very quickly learned about their structure, where they are made and how they work. And that allowed us to develop the enormous explosion of antibiotics. So it is true, it is not a black and white; we need to know how everything works. But all of our history tells us, the better we know how it works, the better we can intervene, with fewer side effects and directed at the people that most need it. And that is really what we are talking about.

I mean the more I listen to Dr. Bailar, as he has said to me, the less we seem to disagree. We need to know things to the point where we can successfully intervene.

Senator HARKIN. I do not know if I have any followup to that—other than I know a lot of people are frustrated, me included, because we are not getting some of the answers. But, again, I would submit, perhaps, Dr. Bailar, something that Senator Specter mentioned, and that is that we declared war on cancer in 1971?

Dr. BAILAR. 1971.

Senator HARKIN. And we immediately beat a hasty retreat. And so if the war on cancer is a bust, it is because we never really fought it. People say $30 billion is a lot of money. You know, in the scheme of things, it really is not.

Dr. BAILAR. I agree.

Senator HARKIN. And I keep pointing out, and I keep pointing out to a lot of people I see—those who watched the gulf war on television and saw all those smart bombs go down those chimneys and all those missiles intercepting missiles and all those wonderful things we have to protect our country and keep us free—it is wonderful. It came about because of military research.

In the last 5 years—Dr. Klausner is getting sick of hearing me say this—I say it everywhere I go—you could spread the gospel; you could spread the word—in the last 5 years, we have spent more money out of this Congress on military research and development than we have on all biomedical research since the turn of the century—cancer, Alzheimer's, diabetes, heart, polio, everything. Add it all up. More in 5 years—and I can show you the numbers, I have got them—5 years, more on the military than we have on all biomedical research since the turn of the century.

And we have got smart missiles and we have got smart bombs; we can do anything. But just think what we could do, instead of opening—what is it now—one out of four doors—if we could open four out of five. Then maybe we could start making some advance on this.

So I do not know if the war has been a bust, I just do not think we ever really fought it. We just kept kind of low-level combat going on that does not win anything. It just sort of keeps it going.

And we have had some success. People do live longer. We have had some successes in certain forms of cancer. There is no doubt about it—that some early intervention programs and chemo and others—radiation therapy and other drugs have certainly kept people alive longer and added to the quality of their life.

I am sorry, I have to go. I am sorry to have to abruptly end this like this, but thank you both very much. I appreciate it.

Dr. KLAUSNER. Thank you.

Dr. BAILAR. Thank you, Senator Harkin.

Senator HARKIN. Thank you, Dr. Bailar, and thank you, Dr. Klausner.

CONCLUSION OF HEARINGS

Senator HARKIN. That concludes our hearing, the subcommittee will stand in recess awaiting the call of the Chair.

[Whereupon, at 4:33 p.m., Thursday, June 19, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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