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FIGHTING PROSTATE CANCER: ARE WE DOING ENOUGH?

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

SEPTEMBER 23, 1999

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FIGHTING PROSTATE CANCER: ARE WE DOING ENOUGH?

THURSDAY, SEPTEMBER 23, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Morella, Shays, McHugh, Horn, Mica, Barr, Terry, Biggert, Vitter, Waxman, Owens, Maloney, Norton, Cummings, Kucinich, Turner, and Schakowsky.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; James Wilson, chief counsel; David Kass, deputy counsel and parliamentarian; Carla J. Martin, chief clerk; Lisa Smith Arafune, deputy chief clerk; Heather Bailey, legislative assistant; Robert Briggs and Michael Canty, staff assistants; Robin Butler, office manager; S. Elizabeth Clay, professional staff member; Mark Corallo, director of communications; Corinne Zaccagnini, systems administrator; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Kristin Amerling and Sarah Despres, minority counsels; Ellen Rayner, minority chief clerk; and Jean Gosa, minority staff assistant.

Mr. BURTON. The committee will come to order, and a quorum being present, the Committee on Government Reform will start its business.

I ask unanimous consent that all Members' and witnesses' written opening statements be included in the record. Without objection, so ordered.

I ask unanimous consent that all exhibits and materials referenced to be included in the record. Without objection, so ordered.

And if our first panel, Senator Dole, if you would like to come forward, sir, and our good friend, the great Congressman from California and, Mrs. Gallo, would you come forward. Duke, I am surprised you are not out flying a plane this morning.

Mr. CUNNINGHAM. Tomorrow.

Mr. BURTON. You are going to fly tomorrow? For those of you who don't know, Duke was an Ace in Vietnam. And of course we know that Senator Dole was not only a great Senator but a war hero as well.

We are here this morning to talk about a disease that will affect over 175,000 men this year, prostate cancer. In fact, unless we change course, one in five men will develop prostate cancer during their lifetime. Today, 101 Americans will die each day from pros-

tate cancer. That is 37,000 men this year that will be killed by this dreaded disease.

Prostate cancer affects more men than any other cancer except skin cancer, and it is the second leading cause of cancer-related deaths in men. We have a slide that shows this.

The National Institutes of Health reports to Congress, and they state that despite advances over the past decade our treatments for prostate cancer are inadequate, the side effects of treatment are unacceptable, and troubling questions remain about the relative benefit of early detection for the disease.

We are here today to talk about what the current level of knowledge is in preventing prostate cancer. We will also talk about current treatment options and research that will develop better and more compassionate treatments for men to choose. It is a travesty for a man to be forced to choose to save his life by choosing a treatment that has a good chance of leaving him impotent or incontinent for the rest of his life.

I am pleased to have three colleagues and friends joining us for the first panel today. Senator Dole is a true American hero. He was elected by the people of Kansas to the House of Representatives in 1960. He retired in 1996 after serving four terms in the House and five terms in the Senate and being elected Senate Majority Leader in 1984. He has continued as one of the Nation's leaders now as an advocate saving the lives of men with early detection testing for prostate cancer and access to better care.

After testifying, Senator Dole will be visiting the confidential prostate specific antigen screening that is taking place here in the Rayburn Building this morning and on the Senate side this afternoon. I hope all of my colleagues and the staff will take the time for screening today.

Most of us keep a close eye on our cholesterol levels and on our blood pressure, but are we watchful about our PSAs? This is a simple blood test which has been shown to be a valuable indicator to the possibility of prostate cancer and we should all pay attention to this.

Congressman Randy "Duke" Cunningham was re-elected to the House of Representatives in 1998 for his fifth term. Gosh, has it been that long? Five terms? I understand that Duke may have to leave early since he is a member of the Appropriations Subcommittee on Labor, Health and Human Services and Education, one of the cardinal committees. We do not want him to miss the markup that is happening concurrent with our hearing. We will benefit greatly by Duke sharing his personal story of dealing with prostate cancer, and we look forward to working with Duke on prostate legislation.

Additionally, we are delighted that Mrs. Betty Gallo, whose husband Dean was a friend of mine, is joining us to share her perspectives as the wife of a prostate cancer victim, Congressman Dean Gallo. She will share their story and discuss the work of the Dean and Betty Gallo Prostate Cancer Institute of New Jersey, including the role of nutrition in preventing prostate cancer.

Dr. Jeremy Geffen, board certified in medical oncology and internal medicine and executive director of the Geffen Cancer Center and Research Institute, will lead the second panel. In addition to

his extensive training in oncology and hematology, Dr. Geffen is also trained in the medical and spiritual traditions of the East. He will share with us his perspectives in the reality of treating prostate cancer in a compassionate manner. In politics there is more than one philosophy or school of thought. This freedom to be diverse is one of the greatest benefits of democracy and the same is true in medicine.

Dr. Konrad Kail is a naturopathic physician from Phoenix, AZ and a member of the new Advisory Council on Complemental and Alternative Medicine. He will discuss natural approaches to treating cancer and interactions between the naturopathic medical community and conventional oncologists.

Dr. Sophie Chen is an associate professor at the New York Medical College and will discuss Chinese botanicals and their use in the treatment of prostate cancer. Dr. Chen patented PC SPEC, a Chinese botanical that research indicates may slow the growth of cancer cells.

Dr. Alan Thornton is the chief advisor to the Midwest Proton Radiation Institute at Indiana University in the great State of Indiana, and he will provide testimony on the benefits offered prostate cancer patients by proton therapy. Dr. Richard Kaplan, a leading expert on prostate cancer, will present testimony on behalf of the National Cancer Institute. Dr. Andrew von Eschenbach of the Anderson Cancer Treatment Center will present testimony on behalf of the American Cancer Society. And Dr. Ian Thompson from the University of Texas Health Science Center at San Antonio will testify about research in preventing prostate cancer.

There has been a lot of progress in prostate cancer. Today we will hear about that progress. But are we doing enough and are we spending enough?

Is the funding of research at the National Institutes of Health adequate and properly focussed to get viable, effective, and compassionate treatments for prostate cancer? Are we looking enough into the natural approaches to healing? Are we looking closely enough at the emotional and psychological-physiological issues that arise as men and their families face prostate cancer? Are we moving forward in getting real answers about the nutritional aspects of cancer prevention, including organic and plant based diets and the role of dietary supplements? Are we looking at the role of pain management issues, including complementary approaches like meditation, guided imagery, acupuncture, aroma therapy, and music therapy? Is the spending on prostate cancer in line with the spending for other diseases that affect the comparable number of individuals?

This is very interesting, and I want to put this slide up there right now. I hope everybody can see this. When we calculated this, the disparity was shocking. I was not aware of this and I don't think any Member of Congress is. In fiscal year 1999 for HIV/AIDS, the National Institutes of Health is spending on average $44,960 for each new case of AIDS in the United States this year just for research alone. That is almost $45,000 for research on AIDS for each case. And that is not talking about all the treatments, just for research alone.

In cardiovascular disease the National Institutes of Health is spending $2,019.69 per new case, and in the case of prostate can-

cer, that is going to affect 175,000 men this year, they are devoting $941. Now, I want you to know that I think AIDS is a tragic thing for anyone to have to deal with, and we should pay attention to that and we should appropriate money for research, but the disparity is unconscionable. We have a lot of other diseases that are extremely important to the American people and to spend $45,000 for each new case of AIDS on research and less than $1,000 on research for prostate cancer just does not make any sense.

In our June hearing we asked the National Cancer Institute to provide us a list of all the new drugs, devices, and treatments available in Canada and Europe that are not currently available here. Just yesterday, we received a letter that lists six chemotherapy drugs available and an explanation that so far they haven't been able to compile the rest of the requested information. We were told at the June hearing that the National Cancer Institute staff stays in communication with international experts. If they cannot even provide a list of the existing international alternative advances in cancer detection and treatment, how can they be taking advantage of these advances in research and moving to increase America's access to them? The Congress and the American taxpayer have entrusted the National Cancer Institute with over $3 billion to fight cancer this year alone. I said in the past that the less than 1 percent of the NCI budget that is being spent on complementary and alternative medicine is not enough considering that over 50 percent of cancer patients use these therapies. I will reiterate my request again to the National Cancer Institute to step up to the research plate and set aside a larger percentage of research funds for this necessary research.

The time for watchful waiting in prostate cancer research is over. We as a government have to join organizations like CapCURE, the National Prostate Cancer Coalition, Men's Health Network, U.S. 2, and the American Foundation for Urologic Disease to get answers to the questions of how to prevent cancer, how to detect cancer as early as possible, and how to treat prostate cancer with effective compassionate treatments. Then we must empower men with this knowledge so that 101 men do not die each day from prostate cancer.

The hearing record will remain open until October 7th for those who would like to make some statements in addition to what they are going to say today. Let me end up by saying that I hope those who are here from the National Cancer Institute and the National Institutes of Health will address this disparity in funding for HIV and prostate cancer. And we are talking not about overall; we are talking about $45,000 per HIV patient, new HIV patient for research alone, not for the cure or helping those people. And less than $1,000 for prostate cancer. That just doesn't make any sense. I now recognize my colleague from California.

[The prepared statement of Hon. Dan Burton follows:]

Opening Statement
Chairman Dan Burton
Committee on Government Reform

"Fighting Prostate Cancer: Are We Doing Enough?"

Thursday, September 23, 1999
10:00 AM
2154 Rayburn House Office Building
Washington, DC 20515

We are here this morning to talk about a disease that will affect over 175,000 men this year – prostate cancer. In fact, unless we change courses, one in five men will develop prostate cancer during their lifetime. Today, 101 American men will die from prostate cancer. That is 37,000 men this year that will be killed by prostate cancer.

Prostate cancer affects more men than any other cancer except skin cancer. And it is the second leading cause of cancer-related deaths in men.

The National Institutes of Health's (NIH) report to Congress states:

> *"Despite advances over the past decade, our treatments for prostate cancer are inadequate, the side effects of treatment are unacceptable, and troubling questions remain about the relative benefit of early detection for the disease."*

We are here today to talk about what the current level of knowledge is in preventing prostate cancer. We will also talk about current treatment options, and research that will develop better and more compassionate treatments for men to choose.

It is a travesty for a man to be forced to choose to save his life by choosing a treatment that has a good chance of leaving him impotent or incontinent for the rest of that life.

I am pleased to have three colleagues and friends joining us for the first panel today.

Senator Bob Dole is joining us today. Bob Dole was elected by the people of Kansas to the House of Representatives in 1960. They kept him in office until 1996, when he retired after serving four terms in the house and five terms in the Senate and being elected Senate Majority leader in 1984. He has continued as one of the nation's leaders, now as an advocate saving the lives of men with early detection testing for prostate cancer and access to better care.

After testifying, Senator Dole will be visiting the Confidential Prostate Specfic-Antigen (PSA) Screening that is taking place here in the Rayburn Building this morning and on the Senate side this afternoon. I am encouraging all of my colleagues and staff to take the time for screening today.

Most of us keep a close eye on our cholesterol levels and our blood pressure, but are we as watchful about our PSA's? This simple blood test has been shown to be a valuable indicator to the possibility of prostate cancer and we should all pay attention to this.

Congressman Randy "Duke" Cunningham was reelected to the House of Representatives in 1998 for his fifth term. I understand that Duke may have to leave early since he is a member of the Labor, Health and Human Services Appropriations Subcommittee. We do not want him to miss the mark up that is happening concurrent to our hearing. We will benefit greatly by Duke sharing his personal story of dealing with prostate cancer and we look forward to working with Duke on Prostate legislation.

Additionally, we are delighted that Mrs. Betty Gallo is joining us to share her perspectives as the wife of a prostate cancer victim – the late Congressman Dean Gallo. She will share their story and discuss the work of the Dean and Betty Gallo Prostate Cancer Institute of New Jersey, including the role of nutrition in preventing prostate cancer.

Dr. Jeremy Geffen, board-certified in medical oncology and internal medicine, and Executive Director of the Geffen Cancer Center and Research Institute will lead the second panel. In addition to his extensive training in oncology and hematology, Dr. Geffen is also trained in the medical and spiritual traditions of the East. He will share with us his perspectives in the reality of treating prostate cancer in a compassionate manner.

In politics there is more than one philosophy or school of thought. This freedom to be diverse is one of the greatest benefits of democracy. The same is true in medicine.

Dr. Konrad Kail, is a naturopathic physician from Phoenix, Arizona and a member of the new National Advisory Council on Complementary and Alternative Medicine. He will discuss natural approaches to treating cancer and interactions between the naturopathic medical community and conventional oncologists.

Dr. Sophie Chen, an associate professor at the New York Medical College, will discuss Chinese botanicals and their use in the treatment of prostate cancer. Dr. Chen patented PC SPES, a Chinese botanical that research indicates may slow the growth of cancer cells.

Dr. Allan Thornton is the Chief Advisor to the Midwest Proton Radiation Institute at Indiana University. He will provide testimony on the benefits offered prostate cancer patients by proton therapy.

Dr. Richard Kaplan, a leading expert on prostate cancer, will present testimony on behalf of the National Cancer Institute (NCI).

Dr. Andrew vonEschenbach of MD Anderson Cancer Treatment Center will present testimony on behalf of the American Cancer Society.

Dr. Ian Thompson from the University of Texas Health Science Center at San Antonio will testify about research in preventing prostate cancer.

There has been a lot of progress in prostate cancer. Today we will hear about that progress. But are we doing enough? Is the funding of research at the National Institutes of Health adequate and properly focused to get viable, effective, and compassionate treatments for prostate cancer? Are we looking enough into natural approaches to healing? Are we looking closely enough at the emotional and psychosocial issues that arise as men and their families face prostate cancer? Are we moving forward from looking at, to getting real answers, in the nutritional aspects of cancer prevention, including organic and plant-based diets and the role of dietary supplements including selenium and Vitamin E?

Are we looking at pain management issues, including complementary approaches like meditation, guided imagery, acupuncture, Qi-gong, aromatherapy, and music therapy?

Is the spending on prostate cancer in line with the spending for other diseases that affect a comparable number of individuals? When we calculated this, the disparity was shocking. In Fiscal Year 1999, for HIV/AIDS, the NIH is spending on average $44,960 per each new case of HIV/AIDS in the United States this year in research. In cardiovascular disease, the NIH is spending $2019.69 per new case of cardiovascular disease. And in prostate cancer in America, the National Institutes of Health is devoting $941.44 on average for each new case of prostate cancer in the United States. It is no wonder we do not have better treatments, given the disparity in funding.

In our June hearing, we asked the NCI to provide us a list of all the new drugs, devices and treatments available in Canada and Europe that are not currently available here. Just yesterday we received a letter that lists six chemotherapy drugs available and an explanation that so far, they have not been able to compile the rest of the requested information. We were told at the June hearing, that NCI staff stays in communication with international experts. If they cannot even provide a list of the existing international and alternative advances in cancer detection and treatment, how can they be taking advantage of these advances in research and moving to increase American's access to them? The Congress and the American taxpayer have entrusted the National Cancer Institute with over three billion dollars to fight cancer this year alone. I have said in the past that the less than one percent of the NCI budget that is being spent on complementary and alternative medicine is not enough considering that over fifty percent of cancer patients use these therapies. I will reiterate my request again to the NCI to step up to the research plate and set aside a larger percentage of research funds for this necessary research.

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The hearing record will remain open until October 7, 1999 for those would like to make a statement.

Cancer Death Rates in Men
Rate per 100,000 male population
80
60
40
20
0
1930
1940
1950
1960
1970
1980
1990
Stomach
Prostate
Colon &Rectum
Lung & Bronchus
Pancreas
Liver

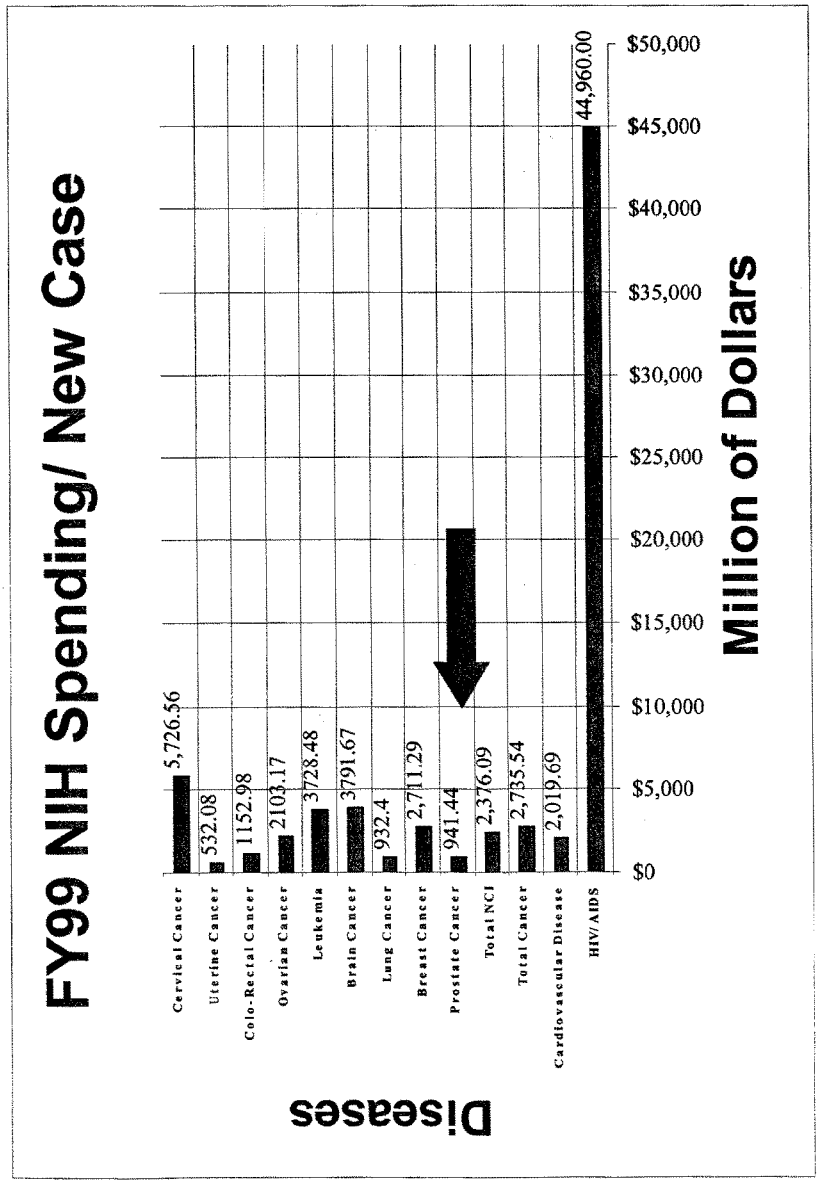
National Institutes of Health

"Despite advances over the past decade, our treatments for prostate cancer are inadequate, the side effects of treatment are unacceptable, and troubling questions remain about the relative benefit of early detection for the disease."

Disease Incidence and NIH Spending By Disease

Disease[i]	Estimated New Cases in 1999	Estimated Deaths in 1999	FY 1998[ii] Actual	FY 1999 Estimate	FY2000 Estimate	1999 Spending Per New Case[iii]	1999 Spending Per Death[iv]
Total NIH[v]	--	--	13,647,843,000	15,652,386,000	15,969,786,000	--	--
HIV/AIDS	40,000	17,047	1602.8	1798.4	1833.8	44,960.00	105,496.57
Cardiovascular Disease	650,000	700,000	1164.5	1312.8	1350.3	2,019.69	1875.43
Total Cancer	1,221,880	563,100	2,940.0	3364.5	3446.0	2,735.54	5,974.95
Total NCI	--	--	2547.3	2903.3	2972.9	2,376.09	5,155.92
Prostate Cancer	179,300	37,000	113.6	168.8	177.0	941.44	4,562.16
Breast Cancer	176,300	43,700	430.1	478.0	501.0	2,711.29	1,093.82
Lung Cancer	171,600	158,900	152.4	160.0	163.8	932.40	1006.92
Brain Cancer	16,800	13,100	59.1	63.7	65.3	3791.67	4862.59
Leukemia	30,200	22,100	109.0	112.6	115.3	3728.48	5095.02
Ovarian Cancer	25,200	14,500	49.1	53.0	54.7	2103.17	3655.17
Colo-Rectal Cancer	132,700	57,100	141.7	153.0	156.7	1152.98	2679.51
Uterine Cancer	37,400	6,400	18.9	19.9	20.6	532.08	3109.37
Cervical Cancer	12,800	4,800	68.7	73.3	75.2	5,726.56	16,666.67

[i] All Figures Provided by the Department of Health and Humans Services, September 1999
[ii] All Dollars Other That NIH Total Budget in Millions unless otherwise noted.
[iii] In Actual Dollars
[iv] In Actual Dollars
[v] Total NIH Budget in Actual Dollars.


FY99 NIH Spending/ New Case
Diseases
Cervical Cancer
Uterine Cancer
Colo-Rectal Cancer
Ovarian Cancer
Leukemia
Brain Cancer
Lung Cancer
Breast Cancer
Prostate Cancer
Total NCI
Total Cancer
Cardiovascular Disease
HIV/AIDS
5,726.56
532.08
1152.98
2103.17
3728.48
3791.67
932.4
2,711.29
941.44
2,376.09
2,735.54
2,019.69
44,960.00
$0
$5,000
$10,000
$15,000
$20,000
$25,000
$30,000
$35,000
$40,000
$45,000
$50,000
Million of Dollars

Mr. WAXMAN. Thank you, Mr. Chairman. I am pleased that we are having a hearing on the important issue of prostate cancer. Except for skin cancer, prostate cancer is the most commonly diagnosed cancer in American men, and this year alone an estimated 37,000 American men will die of the disease.

We face many challenges relating to prostate cancer. Questions remain unresolved about the causes and biology of prostate cancer and about why there are racial differences in the incident rates. We must concentrate our efforts on developing the most effective prevention, detection, and treatment approaches. We must also work to ensure that all men have access to appropriate treatment and to accurate information about their treatment options.

As we face these challenges, it is important that we keep an open mind about innovative and unconventional approaches to prostate cancer treatment and prevention. At the same time, we must promote thorough testing and review of these approaches to avoid unnecessary harm and expense to consumers.

Some of today's witnesses will share their personal experiences with prostate cancer. Others will highlight ongoing efforts to advance prostate cancer prevention, detection, and treatment. This discussion will increase our understanding of the options currently available to men who are diagnosed with prostate cancer and of the research efforts we should continue to explore.

I look forward to their testimony. I want to explain to witnesses that many of us have conflicts in our schedule, and I know I won't be able to be here for the full hearing but I will have an opportunity to review the record and the statements that will be submitted. So, while many of our colleagues are not present, we are making an important record today that will be shared with all of our colleagues and others interested in this field.

I particularly want to recognize and welcome Senator Dole. He and I have had an opportunity to work together over the years, and he has been a tremendous champion for research and trying to fight this and other diseases, and for making sure that people have access to care. He has my undying admiration and respect for the work he has done in this and many other areas.

I am pleased we have our other colleague and spouse of our former colleague with us as well.

Mr. Chairman, I appreciate the fact that we are holding this hearing. It is important that we pursue this issue and I look forward to the testimony.

[The prepared statement of Hon. Henry A. Waxman follows:]

STATEMENT OF REP. HENRY A. WAXMAN

Mr. Chairman, we all agree on the importance of prostate cancer research. But I am troubled by the comparison you made at the beginning of this hearing.

For some time, there have been comparisons made between AIDS research funding and other diseases. The argument is always: "We're spending too much on AIDS and not enough on these other diseases."

At the end of the day, this is a counterproductive argument. It focuses on cutting the pie in different size pieces, instead of making the pie bigger. It chooses winners and losers based on a simplistic formula: "dollars to deaths" or "dollars to victims."

In fact, the National Academies of Science issued a report last year on this question, entitled "Scientific Opportunities and Public Needs." The Academies concluded that NIH chooses its research priorities based on science, not politics. It found that it emphasizes public health need, not public relations. I want to submit the executive summary of this report for the hearing record.

The Acadamies did, however, call for a more formal mechanism for public input. That's why NIH Director Varmus has created a new Council of Public Representatives (COPR). The Council advises Dr. Varmus on research priorities and NIH policy. Again, I want to submit for the record the announcement of the Council's formation and its public web site.

Let me make a final point. The NIH uses science, not politics, to guide its funding decisions. As Congresswoman Morella pointed out, Congress must work on doubling NIH's budget, not micromanaging scientists. In the case of medical research, a rising tide does indeed lift all boats -- and that is the position of almost every patient advocacy and scientific society in the country.

Scientific Opportunities and Public Needs

INSTITUTE OF MEDICINE

Scientific Opportunities and Public Needs

Improving Priority Setting and Public Input at the National Institutes of Health

Committee on the NIH Research Priority-Setting Process

Health Sciences Policy Program

Health Sciences Section

INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1998

Executive Summary

The National Institutes of Health (NIH) is the leading federal agency supporting research related to improving the nation's health. The scientists and clinicians whom it has helped train and support have consistently been at the forefront of research discoveries that have advanced fundamental knowledge of human biology and of better ways to treat or prevent disease and promote good health. Over the past 50 years, NIH as an institution has played a major role in the explosion of knowledge that has amounted to a revolution in biology.

NIH's success has earned it steadily increasing budgets even when the overall federal budget has been tight, as it has been in recent years. Although the NIH budget for the current fiscal year (1998) is more than $13 billion and both the administration and the U.S. Congress have promised a substantial increase for 1999, it will never be large enough to meet every need or fund every promising lead. Choices must be made and priorities must be set.

Concerns about priority setting in the allocation of NIH research funding come from several sources. First, some members of Congress believe that there should be more of a correlation between the allocation of funding by disease and the distribution of disease burdens and costs in the population. Second, more and more disease-specific interest groups have begun campaigning for increases in NIH funding related to particular diseases. Additionally, many of these groups do not feel that NIH listens or responds to their inputs. Finally, the leadership of the health committees in Congress has become increasingly uncomfortable with intervening in research priority setting at NIH, for example, by mandating specific funding set-asides, new programs or institutions focused on specific diseases, or the use of particular research mechanisms or by trying to

push research advances in specific areas in other ways. For these reasons, this committee has been asked to evaluate the processes for setting priorities at NIH, particularly NIH's mechanisms for obtaining public input and the role of Congress in directing the allocation of funding among areas of research.

In setting priorities, NIH must also adapt to a changing policy environment. Despite having a growing budget, scientific research opportunities have grown even more rapidly, as has awareness of health problems as the population ages and as globalization exposes the U.S. population to emerging or reemerging infectious diseases.

To meet the expectations of the American people and fulfill the agency's mission, NIH's leaders must pursue many objectives. Two of the most important are (1) to identify the public's health needs, reducing the burdens of illness by developing better methods of prevention, diagnosis, treatment, and rehabilitation, and (2) to extend the basic knowledge base to lead to even better methods in the future. These two objectives are complementary and must be pursued with equal intensities if NIH is going to be successful. A third important objective is to communicate to the public and health providers the current state of scientific knowledge and the implications of research advances for improving the nation's health. Box 1 describes some of NIH's constituencies.

BOX 1 NIH Constituencies

NIH interacts with various external constituencies who have a stake in research priority setting. These include:

- research scientists in universities, colleges, medical centers, and other research institutions outside NIH who conduct most of the research funded by NIH;
- clinicians who apply research results and who can help identify research needs (physicians, including specialized physicians, nurses, dentists, pharmacists, social workers, psychologists, public health practitioners, and other allied health practitioners);
- organized voluntary groups and individuals active in advocating for those with specific diseases or medical conditions;
- organizations and individuals who represent population groups with special health problems (members of particular ethnic groups, low-income populations, women, elderly people, children, etc.);
- Congress, which provides NIH with the authority and funding to carry out its mission, which oversees its effectiveness, and with which NIH must maintain good communication about priorities; and
- media who communicate research results and NIH activities and who thus play an important role in helping the public understand the research enterprise.

Identifying the burden of illness, however, is not a straightforward task. As indicated in the NIH booklet "Setting Research Priorities at the National Institutes of Health" (National Institutes of Health, 1997b) (referred to hereafter as Setting Research Priorities), there are many ways to measure the burden of disease because the problem can be analyzed and interpreted from many different perspectives. These are all relevant because the concept of the burden of disease is very broad.

> When applied to illness, the burden includes the heavy load borne by society in providing services to prevent, cure, and care for the sick. It also includes the substantial losses of output to the economy due to disease, disability, and death. The burden on the family in caring for and accommodating a sick member of the household can also be severe. Finally, there is the burden of pain, discomfort, and suffering of each sick person and that of anguish and grief of relatives and friends (Institute of Medicine, 1976:2).

Assessing the burden of disease takes into account the fact that the benefits of past research have not reached everyone, indicated by significant differentials in disease rates and outcomes among different socioeconomic and ethnic groups. Also, about half the nation's health care costs result from unhealthy behaviors and environments, which pose major research challenges. In addition, state-of-the-art screening, diagnostic procedures, and treatments are not reaching everyone, resulting in unnecessary burdens of undetected or poorly treated diseases, and patient and provider knowledge could be improved through education. All of these factors must be weighed and balanced in the priority-setting process.

The committee assessed NIH's priority-setting process in light of the agency's mission and objectives and the changing policy environment. Are the criteria adequate? Is the process for implementing them working? Given the objective of responding to health needs as well as scientific opportunity, in conjunction with the expansion of organized disease-specific interest groups, are the mechanisms for public input adequate, or can they be changed to increase the complementarity between NIH's goals of responding to health needs and scientific opportunity? Can Congress, the holder of the public purse strings, be assured that NIH has a rigorous process for priority setting in which the full range of considerations is taken into account in planning programs and allocating funding?

The committee concludes that NIH's system for setting priorities has generally served NIH and the nation well in supporting research to improve human health, but some changes would strengthen it, especially in mechanisms for exchanging information and concerns with interested individuals and groups. The process by which NIH sets its research priorities should more fully engage the public (i.e., the public should have greater opportunity to learn about and provide input into the priority-setting process) in a process that is led by the director, guided by reasonable criteria, and well informed by robust analyses of health statistics. The process should be open and understandable, include multi-

year strategic planning, and give appropriate consideration to the competing needs of scientific opportunity and disease burden. Effective implementation of such a process would improve public access to the process and limit the need for congressional directives.

CRITERIA FOR PRIORITY SETTING

The committee reviewed the major criteria that NIH uses in its overall priority setting. These criteria were explicitly laid out in Setting Research Priorities, and the committee concluded that they are generally reasonable and useful both for allocating research resources and for enabling organized interest groups, members of Congress, and members of the public to understand and evaluate NIH's program. The criteria are

- public health needs,
- scientific quality of the research,
- potential for scientific progress (the existence of promising pathways and qualified investigators),
- portfolio diversification along the broad and expanding frontiers of research, and
- adequate support of infrastructure (human capital, equipment and instrumentation, and facilities).

The committee wants to be sure, however, that the conceptualization of the first criterion, public health needs, be broadened beyond the medical model implied in the discussion of the criterion in the booklet to include the preservation and maintenance of health and function.

Recommendation 1. **The committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.**

To enhance the legitimacy of and support for its priority-setting and resource allocation processes, NIH should work to increase the level of understanding of its criteria by the general public and of how they are implemented and should engage in regular evaluations of how the criteria are used and of their impacts. The Setting Research Priorities booklet and other documents are not as effective at gaining public understanding as they could be, for example, in informing citizens who are concerned about health and particular diseases about how they can become involved (an issue addressed more fully below in the section Mechanisms for Public Input).

Recommendation 2. **NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.**

The committee found that some of the information needed for priority setting, especially data on disease burden and costs, is obtained rather informally and concluded that NIH should be more systematic in obtaining and analyzing such data. It should be kept in mind, however, that there is no simple metric for the use of these data, and the relationship between such data and allocations of research funding will not be simple because health problems are not equally ripe for research advances.

Recommendation 3. **In setting priorities, NIH should strengthen its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.**

Individuals and groups concerned about specific health problems or health research often use NIH-generated data on spending by specific disease or area of research to assess the overall research portfolio. The data are not of the quality that they could be, however, and NIH should work to improve the data and to better explain the data to the public. Calculations of spending by disease should include not only all research directly related to the disease but also research projects on fundamental areas indirectly related to that disease. Users of the data should know that such calculations reflect the best estimates of all NIH spending in particular areas and that fundamental science is essential to understanding the etiology and progression of disease.

NIH should also collect and analyze data on health research spending by others, such as other federal agencies, industry, nonprofit health organizations that fund research, foundations, or other countries. This should help identify gaps, overlaps, and opportunities for joint efforts and ensure that NIH invests wisely in areas and approaches that no one else is funding, provides the appropriate coordination, and supports the training of personnel and the other infrastructure needed in the national research enterprise.

Recommendation 4. **NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.**

PRIORITY-SETTING PROCESSES

Priority setting is decentralized at NIH, which is appropriate for a research organization in which those closest to a problem are in the best position to de-

cide on approaches and in which expertise is highly specialized. The priority-setting processes also vary from institute to institute and from area to area within institutes. Some such variation is appropriate, because the institutes vary in their missions, histories, leadership, sizes, and complexities. The committee did find that some institutes and programs have priority-setting processes that incorporate a broader range of inputs and views, including those of nonresearchers and nonclinicians.

More recently, NIH has been making decisions on priorities and funding allocations that are more centralized than in the past; that is, NIH is looking across traditionally independent institutes and centers and focusing on certain crosscutting needs and opportunities where joint or unified action is desirable. This trend stems from the growing realization that common biological processes underlie diseases that were previously seen as different or that important diseases and other health problems are more complex than was previously thought, affect more organs and processes than was previously realized, and happen to be addressed in more than one institute.

The committee concluded that the Office of the Director of NIH needs an increased capacity to analyze such crosscutting needs and opportunities and to interact with the public (the latter process-related issue is addressed separately below). Improvement requires a more central role for the NIH director and more uniformity in the data and analyses presented to the Office of the Director.

> ***Recommendation 5.*** **In exercising the overall authority to oversee and coordinate the priority-setting process, the NIH director should receive from the directors of all of the institutes and centers multiyear strategic plans, including budget scenarios, in a standard format on an annual basis.**

In any organization, change toward centralization raises concerns about accountability. As the authority of the director is strengthened, greater accountability of the director's office could be achieved through a strengthened Advisory Committee to the Director, one that is more actively engaged in the NIH priority-setting process and that has a broader base of membership, especially among its public members.

> ***Recommendation 6.*** **The director of NIH should increase the involvement of the Advisory Committee to the Director in the priority-setting process. The diversity of the committee's membership should be increased, particularly with respect to its public members.**

MECHANISMS FOR PUBLIC INPUT

Although a major criterion in research priority setting is public health needs, the committee found that NIH's interaction with various kinds of publics is generally weak compared with NIH's interaction with the research community. This is especially true for the Office of the Director of NIH, which does not have adequate channels through which members of the public can express their concerns to NIH or through which they can receive information about the broad scope of effort being made in the fields with which they are concerned.

This structural weakness has important complications: first, because patient advocacy groups have become better organized and more proactive on behalf of their interests and have greatly increased their appeals to Congress to intervene to adjust NIH research priorities; second, because congressional leaders have expressed a strong desire to avoid mandates and earmarks in favor of particular diseases and to let NIH set research priorities; and third, because the NIH director has increased his role in priority setting (partly by exercising additional authorities granted to him by Congress). This confluence of events highlights the need for improved communication between the public and NIH.

NIH should engage the public to a greater extent in informing the process by which NIH sets its research priorities. The following three recommendations are intended to provide the public with more opportunities to present their views regarding research needs and to receive information about research and the priority-setting process at NIH.

> ***Recommendation 7.*** **NIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The director's Office of Public Liaison should review and evaluate these mechanisms and identify best practices.**

The Offices of Public Liaison are meant to serve several purposes: (1) they provide an easily identifiable point of contact for individuals and groups who have an interest or concern; (2) they are a place where members of Congress can refer constituents who want to obtain information or to raise concerns; and (3) they conduct an active program of outreach to and interaction with constituency groups. The NIH director's Office of Public Liaison will oversee and coordinate the institutes' Offices of Public Liaison, serve as a point of contact for individuals or groups who are dealing with crosscutting issues or who do not have a specific institute to contact, and staff the Director's Council of Public Representatives (discussed below).

Recommendation 8. **The director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH director, to facilitate interactions between NIH and the general public.**

The Director's Council of Public Representatives—an advisory group made up of citizens who are either patients, family members of patients, or advocates for patients—serves to elevate public input into the priority-setting process to the highest level of NIH in a systematic and periodic manner. Importantly, the Council will not set priorities regarding the NIH budget or its research programs. That is, it is not intended to serve as a forum for advocacy groups to lobby the NIH director for research dollars. Rather, it is intended to serve as a mechanism for NIH to receive valuable and thoughtful perspectives on its research programs from those who are in some way affected by disease and disability and who are therefore advocates for a healthy NIH and for NIH to provide information about its research and priority-setting process as part of a two-way exchange of information.

Together with the Offices of Public Liaison, the Director's Council of Public Representatives would permit continual interaction between NIH and the public. The Council would allow the NIH director to hear periodically from representatives of a spectrum of interest groups; the Offices of Public Liaison, which would be staff offices that function on a daily basis, unlike the Council, would provide information to and receive input from interested groups and congressional offices and would staff the Council in the Office of the Director. Figure 1 shows the proposed placement of the Offices of Public Liaison and the Director's Council of Public Representatives within the current organization at NIH.

Recommendation 9. **The public membership of NIH policy and program advisory groups should be selected to represent a broad range of public constituencies.**

NIH has long-standing mechanisms by which to include public or lay members on top-level advisory bodies. In the institutes, these councils provide advice and guidance on their research programs and funding decisions by providing the second layer of review (the first being peer review through the study sections). Thus, public representatives play a role in the priority-setting process and provide advice on funding decisions. NIH also reserves slots for public members on the Advisory Committee to the Director. It does not appear, however, that advocates for patients or special populations are regularly considered for these advisory committee memberships, despite numerous examples of cases in which such arrangements have been constructive and positive. Not using this mechanism to receive public input is a missed opportunity and has resulted in the perception of some groups that NIH does not encourage public input at the highest levels of its advisory processes.

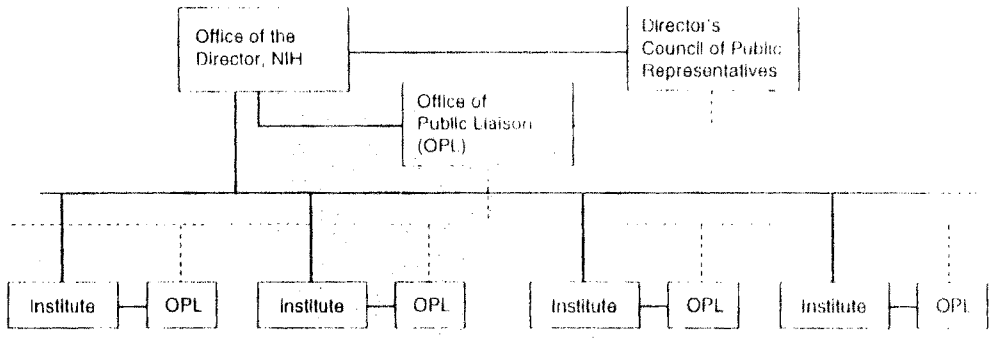


FIGURE 1 Proposed placement of the Offices of Public Liaison and the Director's Council of Public Representatives within the current organization at NIH

These recommendations are not intended to replace the existing criteria for priority setting. They are intended to enhance and reinforce existing NIH mechanisms through which the voices of the public can be heard in a constructive and open manner. The committee believes that public input, which has been important in sustaining the growth and stature of NIH, is an important component of the priority-setting process and, if used wisely by NIH when setting research priorities, will make for a stronger and more responsive NIH. It also believes that although implementation of these recommendations will not supersede or remove the potential for appeals to Congress, their enactment will reduce the need for such appeals.

The new organizational mechanisms proposed to improve public input have the potential to increase, in the short term, organizational costs and complexity. In the long run, however, the committee believes that the contribution made by these offices and the Council will prove to be cost-effective in terms of carrying out NIH's mission to improve health through research and will contribute to overall goodwill on the part of the public and Congress toward NIH.

CONGRESSIONAL ROLE

Congress has always taken a special interest in NIH and has usually provided for larger budgets than administrations request. Congress has also often directed NIH in fairly specific ways, requiring the establishment of research programs, setting aside specific amounts of funding for research on designated problems, mandating the creation of research centers, institutes, or other specific mechanisms, and so forth.

Congress has the authority and the responsibility to intervene if it thinks that NIH is neglecting an opportunity or is not responsive to a need. Members of Congress recognize that it would be better for NIH to make the detailed decisions on how to approach problems.

The committee believes that if NIH revises its priority-setting system in the ways recommended above, Congress will be more likely to grant NIH (which, it is hoped, will be informed by stronger public input) the primary role in setting its research priorities. The text of the report includes some guidelines first offered by an Institute of Medicine committee in 1984 for Congress to use in deciding whether to mandate major organizational changes.

> ***Recommendation 10.*** **The U.S. Congress should use its authority to mandate specific research programs, establish levels of funding for them, and implement new organizational entities only when other approaches have proven inadequate. NIH should provide Congress with analyses of how NIH is responding to requests for such major changes and whether these requests can be addressed within existing mechanisms.**

If NIH is to have more autonomy in organizing and managing its research programs, it is incumbent on the agency to engage in periodic reviews of its organizational structure and planning and budgeting systems and to explain the results to Congress and the public.

Recommendation 11. **The director of NIH should periodically review and report on the organizational structure of NIH, in light of changes in science and the health needs of the public.**

The committee questions whether NIH, especially the Office of the Director, has adequate resources to operate an effective priority-setting system. Providing the Office of the Director of NIH with adequate resources for analysis and interface with the public would make research priority setting more effective.

Recommendation 12. **Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.**

BOX 2 The Committee's Recommendations

Criteria for Priority Setting

Recommendation 1. The committee generally supports the criteria that NIH uses for priority setting and recommends that NIH continue to use these criteria in a balanced way to cover the full spectrum of research related to human health.

Recommendation 2. NIH should make clear its mechanisms for implementing its criteria for setting priorities and should evaluate their use and effectiveness.

Recommendation 3. In setting priorities, NIH should strengthen its analysis and use of health data, such as burdens and costs of diseases, and of data on the impact of research on the health of the public.

Recommendation 4. NIH should improve the quality and analysis of its data on funding by disease and should include both direct and related expenditures.

Priority-Setting Processes

Recommendation 5. In exercising the overall authority to oversee and coordinate the priority-setting process, the NIH director should receive from the directors of all of the institutes and centers multiyear strategic plans, including budget scenarios, in a standard format on an annual basis.

Continued

BOX 2 *Continued*

Recommendation 6. The director of NIH should increase the involvement of the Advisory Committee to the Director in the priority-setting process. The diversity of the committee's membership should be increased, particularly with respect to its public members.

Mechanisms for Public Input

NIH should engage the public to a greater extent in informing the process by which NIH sets its research priorities, as illustrated by the following:

Recommendation 7. NIH should establish an Office of Public Liaison in the Office of the Director and, where offices performing such a function are not already in place, in each institute. These offices should document, in a standard format, their public outreach, input, and response mechanisms. The director's Office of Public Liaison should review and evaluate these mechanisms and identify best practices.

Recommendation 8. The director of NIH should establish and appropriately staff a Director's Council of Public Representatives, chaired by the NIH director, to facilitate interactions between NIH and the general public.

Recommendation 9. The public membership of NIH policy and program advisory groups should be selected to represent a broad range of public constituencies.

Congressional Action

Recommendation 10. The U.S. Congress should use its authority to mandate specific research programs, establish levels of funding for them, and implement new organizational entities only when other approaches have proven inadequate. NIH should provide Congress with analyses of how NIH is responding to requests for such major changes and whether these requests can be addressed within existing mechanisms.

Recommendation 11. The director of NIH should periodically review and report on the organizational structure of NIH, in light of changes in science and the health needs of the public.

Recommendation 12. Congress should adjust the levels of funding for research management and support so that NIH can implement improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.

Study Faults the Way NIH Sets Budget Priorities

Political Pressure to Combat 'Pet' Diseases Cited as Influence on Funding Decisions

By Rick Weiss
Washington Post Staff Writer

The National Institutes of Health needs to be more scientifically rigorous in how it chooses spending priorities for its rapidly growing research budget, according to an independent report critical of the recent politicization of the agency's appropriations process.

The report, released yesterday by the Institute of Medicine (IOM), an arm of the National Academy of Sciences, also recommends that NIH develop a formal mechanism for giving patient advocates and other nonscientists more direct influence over how much money gets spent on various diseases.

An organized system of advocacy would serve the public better than the current one, in which various groups compete in a desperate effort to get Congress to earmark spending for "pet" diseases, the report said.

The 119-page report, "Scientific Opportunities and Public Needs," does not cite specific instances of inappropriate spending by the $13.6 billion agency—the nation's largest single funder of biomedical research. But it warns that NIH stands to lose its historically high credibility if it does not do a better job of justifying its spending decisions.

"There are some celebrated examples where very effective and forceful lobbying and political pressure have affected resource allocations," said Leon Rosenberg, the Princeton University biology professor who chaired the IOM advisory committee that authored the report. "Breast cancer and AIDS are two very clear examples."

On paper, at least, NIH has a commendable system for assigning spending priorities, the report says. That system calls for an emphasis on diseases that have the greatest public health impact (as measured, for example, by the number who die from that disease or the total cost of caring for patients); the potential for progress in a given field; the scientific quality of the proposed research; the proposed work's contribution toward the maintenance of a "diversified research portfolio" at NIH; and the availability of scientists, equipment and facilities appropriate to that line of research.

But, the report concludes, NIH does not hew to those rules. Critics in Congress have estimated, for example, that NIH spends $110 a year on AIDS for every death from that disease, but only $10 in cancer research per death from cancer and $2 in stroke research per death.

Concerns have mounted as advocacy groups have perfected their lobbying acumen. The NIH budget has increased by 80 percent since 1990—compared with a 48 percent increase in the rest of the nondefense discretionary budget—yet earmarked increases for specific diseases have in some years outpaced the agency's budget growth, forcing real losses in other areas of inquiry.

In one effective campaign last fall, a coalition persuaded the Senate to approve a Parkinson's disease package for 1998 that will require NIH to spend $100 million on research centers, training grants and other activities to help people with that disease, which affects perhaps 1 million Americans. After the spending dust settled, Sens. Dan Coats (R-Ind.) and Bill Frist (R-Tenn.) called for an IOM assessment of NIH's budget process.

The report does not conclude that NIH spending should simply be pegged to cold indicators such as numbers of people affected. Rather it suggests that NIH consider data on the total burden that each disease inflicts upon the nation—medically, economically, psychologically and otherwise—as a major factor.

Rosenberg said NIH leaders in the past balked at that prospect, saying there is a shortage of such data. In fact, he said, that information is available, though imperfect, and its use would "enhance the legitimacy" of NIH's priority-setting process.

The report does not dispute Congress's authority to intervene in NIH's ranking of priorities, but it suggests the agency would find itself less prone to such machinations if it offered better documentation for its decisions.

The report also calls for creation of advisory committees within each of NIH's 21 institutes and centers—including the office of NIH Director Harold Varmus, which is cited as being especially inaccessible—through which patient advocates could make their wishes known.

Varmus promised in a statement that he will review the report "in detail" over the next several months. He repeatedly has emphasized that basic research in one field often spurs advances in others.

Research Spending

A federal report criticized the National Institutes of Health for being too politicized in deciding how to use research dollars. Below is 1996 NIH spending on research related to the 10 most lethal diseases.

Condition	1994 deaths	Annual cost*	1996 spending
Heart disease	732,400	$126 billion	$852 million
Cancer	534,300	$96 billion	$2,571 million
Stroke	153,300	$30 billion	$120 million
Chronic lung disease	101,600	$28 billion	$62 million
Pneumonia, influenza	81,500	$22 billion	$62 million
Diabetes	56,700	$92 billion	$299 million
HIV, AIDS	42,100	$10 billion**	$1,411 million
Chronic liver disease	25,400	$3 billion	$170 million
Kidney disease	23,000	$40 billion	$327 million
Septicemia	20,400	$4 billion **	$11 million

* Total economic impact figures taken from various years between 1985 and 1992.
** Includes only direct medical costs
SOURCE: Institute of Medicine

THE WASHINGTON POST

COP Democrats Spar Over Census Funding, Sampling Issues

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NIH NEWS RELEASE

NATIONAL INSTITUTES OF HEALTH — Office of the Director

FOR IMMEDIATE RELEASE
Friday, April 16, 1999

Contact: Anne Thomas
(301) 496-4461

NIH Names 20 Members to First Council of Public Representatives

First meeting set for April 21 at NIH

NIH Director Dr. Harold Varmus has named the 20 members of NIH's first Council of Public Representatives (COPR). The COPR (pronounced "copper"), a new advisory committee to the NIH Director, will be a forum for discussing issues affecting the broad development of NIH policy and research programs. COPR members will also advise the NIH Director on increasing public understanding of the NIH and public participation in NIH activities.

"It is extremely gratifying that this broadly experienced and diverse group of interested citizens has agreed to help NIH enlarge its engagement with the general public," Dr. Varmus said. "The NIH is a public institution and our research is having a great impact on the lives of all Americans. The COPR will help us enrich our already extensive interactions with the public by bringing us a greater diversity of perspectives and ideas, and by helping us ensure that more Americans understand the NIH and its work."

The members are (in alphabetical order):

Michael D. Anderson, Oklahoma City, OK
Theodore Castele, Cleveland, OH
Robin Chin, Providence, RI
Luz Claudio, New York, NY
M. desVignes-Kendrick, Houston, TX
Melanie C. Dreher, Iowa City, IA
Pam Fernandes, Needham, MA
David Frohnmayer, Eugene, OR
Vicki Kalabokes, San Rafael, CA
Barbara B. Lackritz, St. Louis, MO
Joan Lancaster, Johnson City, TN
Debra Lappin, Englewood, CO
Lydia Lewis, Chicago, IL
Roland McFarland, Beverly Hills, CA
Isaac D. Montoya, Houston, TX
Rosemary B. Quigley, Ann Arbor, MI
Maurice F. Rabb, Schaumberg, IL
Robert J. Roehr, Washington, DC
Thomas Vaalburg, Holland, MI
Douglas Q.L. Yee, Honolulu, HI

The group selected for the initial COPR has multicultural and geographical diversity, includes men and women from their 20's to their 70's, has personal and professional experience with a broad span of disease conditions and physical and mental disabilities, and includes many who work with and understand the problems of the medically underserved. Among the members are patients, patient advocates, caretakers, and volunteers; scientists and health care professionals; students of science, law, and public health; professional communicators of health, medicine, and science; and individuals in public service, academia, or professional societies involving the medical field.

Members have been appointed to terms initially running from April 21, 1999, to March 31, 2000.

Each member has agreed to subordinate his or her individual interest or involvement in specific diseases or programs and to come to the table ready to think globally about broad, cross-cutting matters of importance to the NIH and society.

The first COPR meeting will be April 21, 1999, in Bldg. 31C, Conference Room 10, on the NIH campus in Bethesda, Maryland, starting at 8:30 a.m. The meeting is open to the public, subject to space available, and will be broadcast on the Internet for public viewing. Information on Internet access is available at http://videocast.nih.gov.

Topics for the first meeting include: models of public participation in NIH activities, patient access to clinical trials, the clinical trials database required by the FDA Modernization Act of 1997, and health disparities among various populations. A meeting agenda is posted on the Internet at http://www.nih.gov/welcome/publicliaison/get-involved/copr/042199/agenda.html.

Establishment of the COPR to facilitate interaction between NIH and the public was among the recommendations of the 1998 Institute of Medicine report, "Scientific Opportunities and Public Needs." NIH has already implemented other recommendations of the IOM report, including establishing an Office of Public Liaison in each Institute and in the Office of the Director.

Selection of the first COPR members followed a two-month, nationwide, public call for nominations (published in the Federal Register on November 19, 1998) that attracted well over 200 applications. The selection process was designed with advice from a group of 23 members of the public who met at NIH in September 1998 to develop eligibility criteria for nominees. These advisors also identified characteristics important for ensuring that the COPR reflects the breadth and diversity of publics interested in the NIH, recommended that NIH involve the public in review of the applications, and said the NIH Director should be the selecting official. Dr. Varmus made the final selection after extensive and deliberative review.

Dr. Varmus has invited applicants not selected for the first COPR to become "COPR Associates," and to serve as links between the NIH and the public. COPR Associates might be asked to comment or advise on COPR agenda items or to serve in the future on COPR or other NIH committees.

The COPR will meet approximately twice a year, usually at NIH. In future years, members will serve overlapping terms of up to three years, as do members of other NIH advisory committees.

Attachment: Biographies of First NIH Director's Council of Public Representatives Members

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Encouraging and coordinating public participation in NIH activities.

The Key is 'Public Participation'

The NIH Offices of Public Liaison work closely with the Director's Council of Public Representatives (COPR) to encourage and coordinate public participation in NIH activities. Public liaison offices are located in each of the 25 Institutes and Centers that comprise NIH, as well as in the office of the NIH Director.

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Los Angeles Times
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Wednesday, August 18, 1999

National Desk

AIDS Research Yields Bounty of Science Advances

MARLENE CIMONS
TIMES STAFF WRITER

WASHINGTON -- This winter, when the nation is in the achy, feverish throes of its annual influenza epidemic, Americans will have a new drug to ease their suffering.

Just approved by the Food and Drug Administration, the flu medicine is the first in a new generation of drugs that owe their development to a massive federal investment in AIDS, the deadly disease that attacks the body's immune system.

Fueled by almost $15 billion in federal funds and the energy of thousands of researchers around the world, scientists have waged an intense and unprecedented campaign to unravel the mysteries of AIDS, which has killed 411,000 Americans.

From the beginning, those scientific efforts--supported by the gay and minority communities hardest hit by the disease--have come under attack from advocates for spending research money on other diseases that kill or afflict more people.

AIDS commands a federal research investment of $1.5 billion a year. By contrast, Alzheimer's disease gets $400 million annually, even though it affects 4 million Americans, three times the number of AIDS cases.

In the latest salvo, the New England Journal of Medicine suggested in a study reported in June that federal funding should reflect "the burden of disease on society."

Now, AIDS researchers are fighting back, arguing that, in fact, their work has

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(Publication page references are not available for this document.)

produced a bounty of unexpected--and unappreciated--scientific advances well beyond the scope of AIDS.

Drug companies need no convincing. They are already lining up at the lab door, eager to turn discoveries into profits. In the next few years, scientists hope that new insights from AIDS research will allow them to develop drugs to combat everything from cancers to the common cold. In the meantime, drug companies and researchers alike are taking heart from new treatments--thanks to AIDS research--for chronic viral diseases, historically among the toughest to cure.

In eight months, a new drug for hepatitis B has become the most valuable treatment for that liver-destroying disease, which afflicts 1 million Americans. Made by Glaxo Wellcome Inc., lamivudine, also known as 3TC, got its start as an AIDS treatment.

The flu medicine is not a vaccine, giving doctors a new weapon to treat flu: a drug to be administered after the illness occurs.

And Dr. Robert C. Gallo, who with French scientist Dr. Luc Montagnier discovered the human immunodeficiency virus, hopes to begin human testing soon on a new drug that destroys cancers in the laboratory and shows potential against certain blood disorders.

"AIDS brought an amazing level of scientific brain power . . . that has brought benefits way beyond HIV," said Jeffrey Levi, a longtime AIDS policy analyst who is an assistant research professor at the George Washington University School of Public Health here.

"Scientists were excited," he added. "A lot of them wanted to find the cure and win the Nobel Prize. It stimulated a whole lot of new research."

In studying AIDS, researchers set out to explore the insidious way in which HIV infects cells and erodes the immune system, unleashing a range of illnesses from pneumonia to blindness to cancer. This track--looking for patterns in how the virus operates--has led to a wealth of scientific information applicable to numerous fields, including virology, microbiology, neurology, genetics and, of course, immunology.

"It has been the real coming of age of immunology," said Dr. Anthony Fauci, one of the country's leading AIDS researchers.

One key scientific discovery of the AIDS epidemic was that doctors could slow

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the progress of the disease by interrupting the virus at different stages of reproduction, suppressing its growth. AZT, approved in 1987, worked by curbing HIV's production of a key enzyme, reverse transcriptase, needed to help the virus integrate itself within human cells.

As they began to accumulate more knowledge about how HIV worked, researchers discovered that the more such "hits" a virus took during different stages of replication, the better the chances to slow or halt its spread and resulting damage. This led to the development of powerful protease inhibitors and other drugs that deliver a one-two punch at different phases in HIV's cycle.

Now, the same principle is being applied to other viruses, often with surprising success.

AIDS "gave us the confidence to try," said Dr. Vicki Sato, a scientist with Vertex Pharmaceuticals, of Cambridge, Mass., a firm involved in research on drugs to combat hepatitis C. "Before, many drug companies were scared off."

Both hepatitis C and hepatitis B are prime candidates for this drug approach and with a huge potential market. More than 1 million Americans are infected with hepatitis B; nearly 3 million Americans carry the hepatitis C virus. Over time, a chronic infection with either results in liver damage, liver failure and a deadly form of liver cancer.

Like HIV, hepatitis C makes a protease enzyme that is necessary for viral replication. And hepatitis B makes an enzyme that is similar to HIV's reverse transcriptase.

Vertex Pharmaceuticals also is studying the workings of another hepatitis C enzyme, helicase, with the hope of finding new compounds to inhibit it.

The same approach recently has been applied to viruses that cause acute infections. Even with these, the idea of disrupting the action of the virus shows big promise.

The newest flu drug, for example, Relenza (zanamivir), which was approved by the FDA in July, inhibits an enzyme produced by the two major flu virus strains. Called neuraminidase, the enzyme is vital to the flu virus's ability to spread through the body.

Although the drug offers only modest improvement--it shortens the duration of illness by about 36 hours--it "opens the door to better drugs that will do the

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same thing," Fauci said.

Fauci, who is director of the National Institute of Allergy and Infectious Diseases, said that scientists always had believed in theory that viruses could be attacked where they replicate. But that there was little enthusiasm for investing in that approach before the AIDS epidemic. Most medical researchers now believe it is the way to go, he said, now and in the future.

"We thought that in theory it could be done--but few people were doing it," he said. "It was almost a cottage-type industry before AIDS. AIDS really jump-started the field."

Beyond treatment for chronic viral infections, researchers arelooking to other areas for future breakthroughs. Among those thought to be the most promising: blood disorders, autoimmune disorders, genetic conditions and cancers where both viruses and the immune system are believed to play a role, such as cervical cancer, non-Hodgkins' lymphoma and Kaposi's sarcoma.

Gallo, now director of the Institute of Human Virology at the University of Maryland, has found several naturally occurring substances produced by the body's immune system that he believes fight HIV and possibly other illnesses.

He found one such substance while studying Kaposi's sarcoma. One of the curiosities of Kaposi's, a form of skin cancer, is that it afflicts many more men than women. In trying to figure out why, Gallo found a protein in the urine of pregnant women, produced early in pregnancy, that kills cancer cells.

Dubbed "Maternin," the substance has not yet been tested in humans, although Gallo said that he hopes clinical trials can begin by the end of the year. If it is found to be effective, Maternin could be used to help fight blood disorders and some cancers.

The progress in converting the lessons learned from AIDS research to other diseases is unlikely to quiet the periodic complaints of those who believe AIDS has been singled out for special funding attention over the years.

For example, AIDS research funds currently dwarf those for such diseases as breast cancer, which strikes 180,000 women a year and has a federal research budget of $380 million, one-fourth that of AIDS.

But the New England Journal of Medicine study also acknowledged that "different measures of the burden" can yield "different conclusions" about

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spending decisions.

Many AIDS researchers have insisted all along that AIDS research would produce benefits beyond the treatment of this disease. In the early days their predictions "were as much based on hope as on sound experience," Levi said. "But, in this case, they turned out to be right."

---- INDEX REFERENCES ----

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Mr. BURTON. Thank you, Mr. Waxman. Do any other Members have a comment they would like to make an opening statement? Mrs. Morella?

Mrs. MORELLA. Thanks, Mr. Chairman. I want to thank you for holding this hearing today to examine the current status of prostate cancer issues, including prevention, early detection, treatment, and research.

As you listen to the compelling statements of our panels, particularly Senator Dole, our colleague Duke Cunningham, and Mrs. Gallo. I served with your late husband and have great, great respect and love for him, I appreciate the three of you coming to discuss this with us. Indeed we must keep in mind that prostate cancer is the most frequently diagnosed nonskin cancer, the second leading cause of cancer deaths among men, second only to lung cancer. In fact, prostate cancer is the most common type of cancer in men in the United States.

The statistics are one out of every six men will develop prostate cancer at some point during his life. African-American men have the highest incidence of prostate cancer in the world. There are many parallels I find between prostate cancer in men and breast cancer in women. Like breast cancer in women, the risk of having prostate cancer increases with age. The American Cancer Society estimates that 180,000 new cases of prostate cancer will be diagnosed in 1999. It kills 37,000 men each year. Breast cancer kills over 46,000 women. Prostate cancer is the second leading cause of cancer death in men. Breast cancer is the second leading cause of death in women after lung cancer.

Although testing for early detection for prostate cancer has become more common, too many lives are still lost to this disease, and I think it is critical that American men use every means available to fight prostate cancer, including regular testing and medical examinations.

I know Senator Dole is going to be chairing a luncheon panel in the Senate at noon as part of Prostate Cancer Awareness Week to further educate men about this disease. Free, confidential prostate cancer screenings will be offered immediately after the luncheon until 3:30 this afternoon. I encourage the men in this room and others to take advantage of this opportunity because it was through a similar Capitol Hill screening that I eventually discovered that I have osteoporosis. So one never knows.

In conclusion, Mr. Chairman, I have been a strong supporter of increasing the Federal Government's commitment to biomedical research. In particular, I was leading an effort to double the funding for the National Institutes of Health over the next 5 years and we are working toward that goal. Funding biomedical research through the NIH is today's investment in America's future. We must continue our commitment now if we are to find better ways to fight prostate cancer and to ensure the future health of our Nation.

Recently, I attended the opening of an expanded Department of Defense Prostate Cancer Research Center in Rockville, MD. This is a wonderful partnership with NIH in Bethesda, and will also work with other departments and even the private sector in prevention, early detection, and a cure for prostate cancer.

I just want to mention one comment, Mr. Chairman, and that is I would be very much against pitting one disease against another. I mean, I think you have to be very careful when you look at the kind of money that goes into AIDS and you don't want it to be in combat with breast cancer, prostate cancer, whatever it may be.

But I really look forward to the discussion today and the testimony of our witnesses. Thank you very much.

Mr. BURTON. Before I yield to my next colleague, let me just say that they are spending $2,700 for every new case of breast cancer research, and I have had that happen in my family. And while you cannot make everything equal and you should not, I think that we ought to seriously look at why some are getting a great deal more attention, huge quantities more of money per case for research than others. I think it is a question that at least needs to be answered.

Mr. Horn.

Mr. HORN. Thank you, Mr. Chairman. I appreciate you setting up this hearing. My wife has had breast cancer and I have had prostate cancer, and I have a daughter who heads an anticancer foundation. So the family is deeply involved.

And I think Senator, you and I had the same doctor, Dr. McLeod, who is an outstanding surgeon. We are very lucky that we had his talents work on both of us and a lot of other Members of the House. We have an alumni group, a McLeod alumni group. They ought to make him a General with all the lives he has saved.

I thank you for being here, you and Mr. Cunningham, and, Mrs. Gallo, I had great affection for your husband. He was a wonderful Member. Thank you very much and we will maybe get results as a result of this hearing.

Mr. BURTON. Thank you, Mr. Horn. I neglected to alternate back to our colleagues on the other side of the aisle, so I will yield to two of them in a row. First, Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman. I want to begin by stating my appreciation to the Chair and to our ranking member, Mr. Waxman, for their ongoing commitment on matters of health, and over the years I think we have seen great leadership from many members of this committee on health issues and our American community, and we see our congressional community represented here by Senator Dole, Congressman Cunningham, and Mrs. Gallo.

It takes great courage to share your experience with us and to share with the people of the United States the things that can be done to protect their families through early protection through perhaps raising health issues to a higher priority on this Nation's agenda through addressing it with funding and new strategies.

So thanks to all of you, to my good friend Senator Dole for his willingness to come forward and to Mr. Cunningham for his never-ending insight into matters, which makes all in Congress very grateful, and to Mrs. Gallo for sharing your husband's career with this Congress and for your willingness to come back here and talk about what can be done to help other Americans who have struggled with this. Thanks to all of you and again thanks to the Chair.

Mr. BURTON. Thank you. Mrs. Maloney.

Mrs. MALONEY. Thank you, Mr. Chairman. And thank you very, very much for having this hearing and for our distinguished guests, distinguished panel. And until we come up with a cure, the only thing that we really have is preventive screening and early detection. And all of your speaking out on this disease, particularly Mr. Dole, have hopefully brought more people to doctors for screening.

As we sit here today, Supreme Court justice Ruth Bader Ginsberg, who is just 66 years old, is undergoing colon cancer treatment and, like many other women and men, she was misdiagnosed for several months. Very often, women and men over age 50 are not advised to get tested for cancer despite their risk. Routine screening really should be taking place between ages 50 and 65.

I am glad that we are focusing on prostate cancer, but really it should be interrelated with all cancers, many cancers are interrelated. And I want to mention a bill, along with the cochair of the Women's Caucus Sue Kelly, we have put forward, and it is a cancer screening bill.

One of the bills that I authored with Mrs. Morella and others that was part of the balanced budget amendment was the Breast Cancer Early Detection Act, which allowed for annual mammograms for women on Medicare, and we are pleased that this became part of the law of this country. But what about men and women who are at threat for prostate cancer—prostate cancer for Medicare was also covered but what about below the age of 65, at the age of 50, when most cancers could begin and when screenings should likewise be taking place?

Our bipartisan bill, the Cancer Screening Coverage Act, would help ensure preventive care—that it becomes, you know, part of our routine health care and it would have insurance coverage for prostate cancer, breast cancer, cervical cancer, and colorectal cancer. And we do not need to or we shouldn't be looking at cancer with a body part by body part perspective.

I am glad that we are focussing on prostate cancer here today, but how many of you are aware that colon cancer is the second leading cancer killer just behind lung cancer. And so I just want to say that the American Cancer Society and many others have endorsed this bill and they say that people who do not receive screening tests because their doctors do not encourage it, and if you ask doctors why is it not encouraged it is because it is not covered. So it is important that screening, when it is advisable or necessary, is covered.

I thank the chairman for organizing this and our distinguished panel for being here.

Mr. BURTON. Thank you, Mrs. Maloney. Mrs. Biggert.

Mrs. BIGGERT. Thank you. I am particularly eager to hear from our distinguished witnesses, particularly Senator Dole and our colleague Congressman Cunningham, so I would ask unanimous consent to submit my opening statement for the record.

[The prepared statement of Hon. Judy Biggert follows:]

Opening Statement of Representative Judy Biggert (R-IL)
Committee on Government Reform
Hearing on Prostate Cancer
September 23, 1999

Good Morning, Mr. Chairman. Thank you for holding this important hearing on prostate cancer.

Americans are fortunate to have access to the highest quality health care in the world. This can be seen in the progress made this century in combating and, in some cases, eradicating diseases. However, there are still many afflictions – such as the one we are talking about today – that continue to have a devastating impact on individuals and the country as a whole.

Cancer of the prostate is one of the most common cancers among American men, affecting about one in five men during the course of a lifetime. An estimated 37,000 to 39,000 men will die this year of this affliction. These men are our brothers, fathers, sons and husbands. This disease has touched almost every American family.

Prostate cancer is an urgent problem that demands Congress' immediate action. I firmly believe the lifesaving biomedical research carried out by the National Institutes of Health (NIH) is the key to helping us understand the cause of this disease, as well as for developing effective treatments and a possible cure.

I am pleased that Congress has made a strong commitment to double NIH's budget over the next few years. I am particularly proud of the substantial funding increase NIH received in fiscal year 1999. Despite this financial progress, however, I am troubled that support for prostate cancer research lags far behind other diseases.

The scarcity of funding for prostate cancer research creates a vicious cycle. Due to a lack of adequate funding, young and established researchers are drawn to more profitable avenues of investigation; private enterprise views the field as too risky for investment; and ideas that might lead to a cure are conceived but never completed. This is unacceptable and more should and can be done.

Today's hearing provides us an opportunity to find out what more Congress can be doing to help those in need. We will hear from individuals directly impacted by this disease, as well as from experts in the area of prostate cancer research and treatment.

I am particularly eager to hear from two of our distinguished witnesses, Senator Bob Dole and our colleague, Congressman Duke Cunningham. Their first-hand insights into this disease and its impact will be very compelling.

Again, Mr. Chairman, I thank you for holding this important hearing. I look forward to working with you, the individuals and entities here today, as well as my colleagues here in Congress to strengthen prostate cancer research and prevention programs.

Thank you.

Mr. BURTON. Without objection, so ordered. Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman. I want to commend you on organizing this hearing. It is a very important subject. And I want to thank Senator Dole for his leadership. It took a lot of gutsiness to make those commercials, Senator. It meant a whole lot to the cause that you spoke out on behalf of.

Our second panel has two distinguished professionals from Texas today, so I think we have a good second panel, Dr. von Eschenbach and Dr. Thompson.

Mr. BURTON. There is one from Indiana as well.

Mr. TURNER. So we are in for a good hearing today. Thank you, Mr. Chairman.

Mr. BURTON. Thank you. Mr. Terry, do you have any comments? Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to just take this moment to thank our panel for being here. In my district, we have one of the greatest hospitals in the world, Johns Hopkins, and some of probably the greatest experts in this area in prostate cancer, whom I have gotten to know very well. But at the same time, we have one of the highest death rates from prostate cancer.

I have said it often, when I go to the bank on Saturdays it is not unusual for me to run into someone, Mr. Chairman, who is about to undergo some type of prostate surgery or has just come through it or is recovering from it.

And so I want to thank our panel for what you are doing. So often, I think what happens is that we in government and those not in government who speak out on these issues wonder what effect what we do has. I mean we always wonder. But I can tell you that it has had a profound impact to raise this issue to a level where people can talk about it. I think it was Congresswoman Maxine Waters who said: "Secrets kill. Keeping things hidden and not dealing with them and not bringing them out kill."

And so, I too join the voices of my colleagues to say thank you, simply thank you, for those you will never meet. For those who have been touched by seeing you on C–SPAN or hearing you all testify at a hearing like this. But touching their lives because when you open the door and break down the walls of discussion, then you also break down the walls so that people can get the kind of diagnosis and treatment that they need.

And so I thank you. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Vitter, no comment? Ms. Norton.

Ms. NORTON. Thank you, Mr. Chairman. May I thank you for organizing this hearing about a form of cancer that I think needs very special awareness.

If I may, I would like to thank Senator Dole first for his work on behalf of the District as head of the Federal City Council. The Senator was most gracious as the District was coming out of crisis to offer his extraordinary and unique leadership. That leadership has been felt and the District, its residents, and its elected officials are most grateful to you for your work.

I share with the Senator what has been his lifelong habit of not speaking much about his own personal life and struggles. I am sometimes squeamish when I hear people talk much about them-

selves and what they have gone through physically or mentally, but I must say that I have come to believe that there are some conditions where to hear from a person who is very distinguished and very admired is to render a unique service. To talk about a disease like prostate cancer to people, I have in mind men who are reluctant even to go to the doctor, is to do something that doctors cannot do, that Members of Congress cannot do, that only someone whom they respect, whom they know would not be inclined to simply speak about himself for the sake of hearing—telling about himself, that person gets the attention in a way nobody else does, and that person can save lives.

And I submit to you without being able to document it that I believe that Senator Bob Dole has saved lives by having the guts to go on television and talk personally about prostate cancer.

And I must thank you, Senator, as well because not only is that the case for men in general who go only at the last minute and perhaps because they think it is a sign of weakness even to go to the doctor when they have a cold, but for many men, especially African-American men where prostate cancer is out of control, the whole notion of going about this disease simply was off the radar and off the table. To hear a man whom they regard as manly speak about this disease has had an effect which I think we will never know, but I think all of us should be grateful for, and I want to express my gratitude personally to the Senator here this morning.

Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Ms. Norton. Well, without further ado we will start with Senator Dole. We really do appreciate you being here. We appreciate all of you being here. I would just like to say that I have known a lot of people who had some kind of prostate problems that led to prostate cancer and they were very reluctant to even talk about it to anybody. And I think because of you and others like you, Mr. Cunningham, Mrs. Gallo, and others, I think that people are now willing to talk about it and look into it. And thanks to you very much, Mr. Dole.

STATEMENTS OF HON. BOB DOLE, FORMER SENATOR OF THE U.S. CONGRESS; HON. RANDY "DUKE" CUNNINGHAM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA; AND MRS. BETTY GALLO, VICE PRESIDENT, DEAN AND BETTY GALLO CANCER RESEARCH FOUNDATION

Senator DOLE. Well, thank you, Mr. Chairman and members of the committee. I really appreciate this opportunity. It is good to be back on the Hill. And I know the experts are lined up behind us. We are here to sort of set the stage and then they can make very appropriate statements.

But I think it is true that not many people like to talk about their own problems, whether it is an illness or anything else. We go through life and some people have some problems, some people have other problems, and that is all a part of life. But this is Prostate Cancer Awareness Week, and for the past 8 years, I have been speaking out on prostate cancer.

When it was diagnosed, I recall some difference in my staff. Maybe I should just have it done quietly and nobody would know about it because it might make people think that I wasn't going to

be able to carry out my job and all these things. But it occurs to me that maybe just sending a signal might encourage others to do the same. And since that time, I have literally talked to hundreds of men—in fact I was coming out of the hotel this morning, we are living there temporarily while they are fixing up our apartment, the doorman stopped me and said, "You know, I have prostate cancer." This was less than an hour ago. And can we talk about it? And I said, yes, I am going to be here for a couple of months. And so he has some good new theory that he doesn't have to have an operation. Maybe there is an option that I am not aware of.

The point is that it is out there. It is every day. It affects Republicans and Democrats, liberals, conservatives, black, white, yellow, brown, whatever. It doesn't spare anybody. And the case that I remember is Senator Sparky Matsunaga, who was one of my colleagues. We served together in the House and then in the Senate, and then of course he died of prostate cancer, which spread throughout his body.

I remember talking to Dean shortly before his death, and I must say he was a man of great courage. His spirits were good. He understood what was about to happen. And it is great that Betty is carrying on with the foundation to help others.

One thing that we have done, and I found it to be very good policy and might also be good politics, but at the Kansas State Fair, we have a screening booth, the Bob Dole screening booth. We have mammograms and PSA tests and we got the cooperation of the State Urological Society and generally some of the drug companies to help underwrite part of it. That ended as soon as I left the Senate, I might add. But we are still doing that. We are still finding the funds. It is a good way because some people will not go to the doctor, particularly men. It takes about two laps around the midway to get them in that little booth there for that blood test, which is painless, and we discovered even in our small state we do about 3,000 PSAs during that week and maybe 100 cases of cancer, prostate cancer that could be treated because there is early detection.

We hope to do this at both national conventions next year in Philadelphia. We are working with some doctors to see if we can, because we will have a lot of opinion makers there, there will be a lot of people at the Democratic Convention and Republican Convention that people will listen to and we think it is a great opportunity just to spread the word. We did it at the Republican Convention in 1996. There wasn't much else going on. About the most exciting thing that happened were the PSA tests. But in any event, we think it is an opportunity and I know there is certainly enough support for it there.

I think it is fair to say that almost every family in America has been touched by cancer. And when you hear the word "cancer," it scares a lot of people, and men are not any different than women. As I said, I think I have talked to, I don't know, hundreds of men because their son asked me to call or the wife asked me to call or the mother, whoever, and just say that there is life after prostate cancer, as Cliff knows and others in the Congress. Suddenly your whole perspective changes when you hear the word, and again when it is determined by biopsy after the PSA test, what the cancer may be. I share the view that it is not just prostate cancer, it

is cancer across the board. Great progress is being made and I commend those who are making that progress. But it seems to me that early detection is, of course, the key.

As I said, it was about 8 years ago and I have been in great health since that time. I have made a commercial or two and I must say I got a lot of ridicule for one. But I think when you look at the 30 million men that may be benefited, you have to take a little heat sometime. Most of it came from the misinformed media. They are generally misinformed when it comes to some of these issues, and it seemed to me a little unfair, because there are 30 million men and their wives who would be affected by the message I was trying to send without endorsing any products. I don't endorse any products and don't intend to endorse any products and I didn't keep any money. There was no monetary motivation. But I must say some of the reaction, not from the people but from the media, was a little distressing.

But so what I think some of us can do is encourage others, as Eleanor said, and others have said, encourage others to see their doctor. For some reason men just don't want to see their doctor. If you look at percentages of men versus women, and you are the experts, doctor visits are much higher among women, and they do it on an annual basis. For some reason, men, they don't want to go to the doctor, they don't think they are ever going to be sick and so they put it off and put it off and put it off. My father was a good example of that. He would go to our little hospital and maybe spend all night with a patient, but he would never want to go to the hospital himself. And I am sure there are others like that and some women like that too, but primarily men.

I think the early detection message is the important one. It is like anything else. If you find what the problem is early, you can deal with it. And I think the options are changing. You are going to hear some of the new options available. Eight years ago, when I went out to see Dr. McLeod, a fantastic and a very good person, a good surgeon, I was told there were two options: Surgery and radiation. And I explored both, because I didn't know much about what was happening. And none of this sounded very appealing to me, but I finally decided and I was 68 years old at the time—so to get to the point where maybe watchful waiting, maybe you don't do anything—but I was in good health physically and I finally decided to do the radical prostatectomy. But other men, 68, 70, and older, may have other health problems and doctors don't want to chance surgery. If you have got other health problems you may not want surgery. My point is that the more effective treatment options available, the more men will be cured of prostate cancer, and that is where the role of Congress and the administration come in.

And I might say just looking at the figures that are over there, I think about 9 years ago, maybe 7 years ago, Mr. Chairman, the amount spent for prostate cancer on a Federal level was hardly anything. And I must say that Senator Stevens, who has gone through the same procedure at Walter Reed Hospital, is on the Appropriations Committee, sort of made it a crusade to see that we couldn't spend a little more for prostate cancer research. And that is why we have, even though it is not as high as some of the others, certainly much higher than it was just a few years ago.

Now the way our system works, at least the way it worked when I left here 3 years ago, is that if Medicare adequately reimburses a treatment, it is widely available. If you are going to get treatment, going to get paid for it, it is going to be there. And every day there is a scientist looking for the cure for cancer or looking for a new treatment option. Companies invest large sums of capital in this endeavor, and we all hope that there will be a cure. We all hope the government will have the wisdom to recognize it when they see it. Is our government prepared to take the necessary steps so that when a new technology for treatment becomes available, patients with the disease can have access to it?

I mean, if you have a new treatment option that has been demonstrated effective and safe and you can't get access to it because you don't have the money and Medicare doesn't cover it, of course that is a problem. Brachytherapy is an example where the role of Medicare reimbursement is critical. It is an innovative treatment option for prostate cancer where radioactive seeds are implanted in the prostate to destroy the cancer. For some patients it is a minimally invasive procedure done on an outpatient basis. You are in and out of the hospital. You don't stay as you do with the surgery and all the other things. It has shown to treat some forms of prostate cancer. Now, I am not here advocating. I am just saying this is one new option.

This procedure is reimbursed by Medicare currently, but a proposed change in the regulation will reduce the rates of reimbursement dramatically, in effect making this treatment unavailable. And I agree with everybody here, you have to find a way to stop some of the increased costs and you have to make certain changes. But I think this is one area that at least ought to be addressed. You have to determine how it is going to affect patients who could benefit from this procedure. Is this really the type of decision-making which the government needs to involve itself? Maybe it ought to be left to physicians and others to make that choice.

There is another new treatment—there are probably others we are going to hear about, ones that I haven't heard about, later from the other panel. Cryosurgery is another treatment option where the prostate is frozen to prevent the growth of cancer. And again this is a sort of noninvasive procedure. I think you maybe stay overnight in the hospital. There is no blood shed. It is just frozen and it took over 3 years to receive Medicare reimbursement for that procedure. And again you kind of wonder, well, maybe if you are too old or your health is not good enough for surgery, you reject radiation, are these other options available? And if so, are they covered and should they be covered? That is a decision that doctors and patients and the marketplace have to make. As I said, I am an advocate for solvency of Medicare, but I think our health care system continues to change with all this new technology. We have to keep up with it. Medicare was passed originally in 1964, so maybe we haven't kept abreast of all the technology and I think we do need to take a look at these options.

The private sector is always looking for new therapies and new options because they are more cost effective in many cases and you could go back and look at some of the options here that are probably more cost-effective and less demanding on the patient.

I know that Congress is considering a number of Medicare reforms. I am not here lobbying for anything except we have got to keep in mind in 11 years we are going to have 77 million baby boomers descend on us and there is going to be a big, big demand out there and the money has to come from somewhere and we have got to have priorities. I am certain there are people in this committee on a bipartisan basis who are going to be looking at that very carefully.

I think a successful Medicare program will mean that when an individual receives a diagnosis of cancer or any other serious disease, his life doesn't have to flash in front of him. He or she will understand that there is going to be some protection, some way they can receive treatment. I am just here to underscore the importance of communication. The thing that I have learned over the years as sort of a spokesperson for prostate cancer, and there are a number of them, but is that most people do not understand, they do not know what to do.

It is pretty hard for somebody to do the right thing if they do not know what the right thing is. The right thing obviously is to see your doctor, and even some doctors there is not enough communication between the doctor and the patient. I have been speaking to medical groups urging doctors to be more forthcoming. If you don't ask the patient the right questions you are not going to find out what the problem is because sometimes patients, we all tend to be very shy. We don't go in there and lay out our soul because we are in a doctor's office. The doctor has to sort of draw it out of some of us, and I think that is very important.

Last week or in fact this past Sunday, my wife was off somewhere doing what she's doing, and so I was reading the Washingtonian, and I just happened to read a story, which probably should be made part of the record—that costs money, but it is called "Under the Knife." You may know David Dorsen. I don't know David Dorsen, but I called him on the telephone after I read the story. It is the story of a 62-year-old man—I think that is the right age—who discovers he has prostate cancer and he doesn't know how to deal with it. He is in a state of denial. He doesn't think it is real. He doesn't understand the different options and they go through the options. He keeps it from his wife. He does not discuss it with his wife. And of course that leads to a rather tense situation, until he finally faces up to reality that this has to be dealt with.

And then the story sort of goes on in how he dealt with it and how successful it was, and so he feels very good about it. But I think it is the kind of story that if all men could read it, they would be a little more apt to go visit their doctors. So I would at least call it to the attention of the committee and I told Mr. Dorsen it is the kind of thing that ought to be circulated at State fairs, anywhere people have a chance to pick up information.

Again, I want to thank all the committee and the chairman for holding this hearing. I hope in 10, 20 years, we may not have prostate cancer, many of these diseases will be gone. And those of us who have had the successful operation, radiation, cryosurgery, or Brachytherapy, whatever, I think have some responsibility to encourage our friends and encourage our neighbors.

I think that is just the way it is, and I think most of us will do that and by spreading the word and getting good information, not trying to prescribe anything, I think we will be able to reach out to more and more men. So thank you very much and I appreciate this opportunity.

[The prepared statement of Hon. Bob Dole follows:]

STATEMENT OF SENATOR BOB DOLE
U. S. HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM
SEPTEMBER 23, 1999

THANK YOU FOR INVITING ME THIS MORNING TO TALK ON BEHALF OF PROSTATE CANCER SURVIVORS. MANY OF YOU ARE PROBABLY AWARE THAT THIS IS PROSTATE CANCER AWARENESS WEEK. AND, TO ADVOCATE AWARENESS, A PROSTATE CANCER SCREENING IS OCCURRING THIS MORNING IN THE RAYBURN BUILDING, ROOM B344, AND THIS AFTERNOON IN THE SENATE, IN THE HART BUILDING, ROOM 124. AND, I ENCOURAGE ANY MEN IN THE AUDIENCE TODAY WHO ARE OVER 40 TO TAKE ADVANTAGE OF THIS FREE TEST.

AN UNFORTUNATE FACT OF LIFE IS THAT ALMOST ALL FAMILIES IN AMERICA HAVE BEEN TOUCHED BY CANCER. MY FAMILY HAS. AND, I HAVE. YOU CAN HAVE MANY ACCOMPLISHMENTS, BE VERY SUCCESSFUL IN MANY WAYS, BE BLESSED WITH FAMILY AND FRIENDS, AND SUDDENLY HAVE YOUR WHOLE PERSPECTIVE CHANGED BY HEARING YOUR DOCTOR SAY JUST THREE LITTLE WORDS, "YOU HAVE CANCER."

FOR THOSE HERE, WHO HAVE HAD THAT EXPERIENCE, I DON'T NEED TO DESCRIBE THE DISBELIEF AND FEAR THAT ONE SIMULTANEOUSLY EXPERIENCES. BUT, SINCE WE'RE STILL HERE, WE ALL KNOW THAT THERE IS SOMETHING ELSE - HOPE AND THE STRENGTH TO FIGHT BACK. OF COURSE, NOT EVERYONE TRIUMPHS, BUT FORTUNATELY MORE AND MORE EVERY YEAR DO SUCCEED.

THAT SUCCESS IS WHAT I AM HERE TO TALK ABOUT. OVER EIGHT YEARS AGO, I WAS DIAGNOSED WITH PROSTATE CANCER. I WAS LUCKY ENOUGH TO HAVE HAD THE DISEASE DIAGNOSED EARLY AND TREATED PROMPTLY THROUGH SURGERY.

EIGHT YEARS LATER, I AM HAPPY TO SAY I AM CANCER FREE. SINCE THE TIME OF MY DIAGNOSIS, I HAVE TRIED TO SPEAK OUT AS MUCH AS POSSIBLE ABOUT THE VALUE AND IMPORTANCE OF EARLY DETECTION. I TRULY BELIEVED THEN, AND CONTINUE TO BELIEVE TODAY, THAT EARLY DETECTION MAY HAVE SAVED MY LIFE. THE CANCER WAS FOUND WHEN IT WAS STILL CONTAINED WITHIN THE PROSTATE GLAND.

WHILE MY MESSAGE OF THE IMPORTANCE OF EARLY DETECTION IS ONE THAT I WILL CONTINUE TO DELIVER, I WOULD LIKE TO TAKE A MOMENT TO TALK ABOUT TREATMENT OPTIONS.

EIGHT YEARS AGO, MY DOCTOR TOLD ME I HAD TWO TREATMENT OPTIONS - SURGERY OR RADIATION. AFTER DISCUSSING THE SIDE EFFECTS OF BOTH - NONE OF WHICH SOUNDED VERY APPEALING - I MADE THE DECISION TO HAVE SURGERY. I WAS 68 YEARS OLD AT THE TIME. AND, OTHER THAN THE PROSTATE CANCER, IN VERY GOOD HEALTH. MY DOCTOR BELIEVED I COULD WITHSTAND THE SURGERY.

BUT, MANY MEN WITH PROSTATE CANCER HAVE OTHER HEALTH PROBLEMS, OR ARE OVER 70 WHEN MANY DOCTORS DON'T WANT TO CHANCE SURGERY. MY POINT IS, THE MORE EFFECTIVE TREATMENT OPTIONS AVAILABLE, THE MORE MEN WILL BE CURED OF PROSTATE CANCER. AND, THAT IS WHERE THE ROLE OF CONGRESS AND THE ADMINISTRATION COME IN.

THE WAY OUR SYSTEM WORKS IS THAT IF MEDICARE ADEQUATELY REIMBURSES A TREATMENT, IT IS WIDELY AVAILABLE. EVERY DAY THERE IS A SCIENTIST LOOKING FOR THE CURE FOR CANCER, OR LOOKING FOR A NEW TREATMENT OPTION. COMPANIES INVEST LARGE SUMS OF CAPITAL IN THIS ENDEAVOR. WE ALL HOPE THERE WILL BE A CURE.

AND, WE ALL HOPE THE GOVERNMENT WILL HAVE THE WISDOM TO RECOGNIZE IT WHEN WE SEE IT. IS OUR GOVERNMENT PREPARED TO TAKE THE NECESSARY STEPS SO THAT WHEN A NEW TECHNOLOGY FOR TREATMENT BECOMES AVAILABLE, PATIENTS WITH THE DISEASE CAN ACCESS IT.

BRACHYTHERAPY IS ONE EXAMPLE WHERE THE ROLE OF MEDICARE REIMBURSEMENT IS CRITICAL. BRACHYTHERAPY IS AN INNOVATIVE TREATMENT OPTION FOR PROSTATE CANCER WHERE RADIOACTIVE SEEDS ARE IMPLANTED INTO THE PROSTATE TO DESTROY THE CANCER. FOR SOME PATIENTS, THIS MINIMALLY INVASIVE PROCEDURE, DONE ON AN OUTPATIENT BASIS, HAS SHOWN TO TREAT SOME FORMS OF PROSTATE CANCER.

FORTUNATELY, THIS PROCEDURE IS REIMBURSED BY MEDICARE CURRENTLY. BUT, A PROPOSED CHANGE IN THE REGULATION WILL REDUCE THE RATE OF REIMBURSEMENT DRAMATICALLY, IN EFFECT, MAKING THIS TREATMENT OPTION UNAVAILABLE. HOW WILL THAT AFFECT PATIENTS WHO COULD GREATLY BENEFIT FROM THIS PROCEDURE? IS THIS REALLY THE TYPE OF DECISION MAKING IN WHICH THE GOVERNMENT NEEDS TO INVOLVE ITSELF?

CRYOSURGERY IS ANOTHER TREATMENT OPTION WHERE THE PROSTATE IS FROZEN TO PREVENT THE GROWTH OF CANCER. IT TOOK OVER THREE YEARS TO RECEIVE MEDICARE REIMBURSEMENT FOR THAT PROCEDURE. I WONDER HOW MANY PROSTATE CANCER PATIENTS COULD HAVE BENEFITTED FROM THIS MINIMALLY INVASIVE PROCEDURE, BUT COULDN'T BECAUSE OF THE GOVERNMENT'S REIMBURSEMENT POLICIES.

IN MY OPINION, THAT IS THE DECISION OF DOCTORS, PATIENTS, AND THE MARKET PLACE. I HAVE BEEN A LONG TIME ADVOCATE OF MEDICARE SOLVENCY. BUT, I ALSO BELIEVE THAT AS OUR HEALTH CARE SYSTEM CONTINUES TO EVOLVE AND CHANGE, POLICY MAKERS MUST ENCOURAGE INNOVATION. AND, THE WAY TO DO THAT IS TO MAKE OPTIONS WIDELY AVAILABLE THROUGH REIMBURSEMENT POLICIES.

THE PRIVATE SECTOR READILY ACCEPTS NEW THERAPIES, PARTLY BECAUSE THEY ARE COST EFFECTIVE, BUT MOSTLY BECAUSE CONSUMERS IN THE MARKET DEMAND THEM. AS THE BABY BOOMERS AGE, I BELIEVE MEDICARE WILL FEEL THE SAME PRESSURE FROM ITS CONSUMERS.

I KNOW THAT CONGRESS IS CONSIDERING A VARIETY OF MEDICARE REFORM PROPOSALS. IN JUST 11 YEARS, THE COUNTRY'S 77 MILLION BABY BOOMERS START BECOMING MEDICARE ELIGIBLE. I THINK THE IMPACT OF THEIR DEMAND IS NOT TO BE UNDERESTIMATED. MEDICARE IS GOING TO HAVE TO DELIVER, JUST AS EVERY OTHER SERVICE HAS THAT BOOMERS HAVE DEMANDED. PLEASE KEEP THAT IN MIND WHEN ATTEMPTING TO MODERNIZE MEDICARE. THAT WILL MEAN KEEPING PACE THE SCIENCE AND TECHNOLOGY THAT MANY OF THE BABY BOOMERS HAVE DEVELOPED.

A SUCCESSFUL MEDICARE PROGRAM WILL MEAN THAT WHEN AN INDIVIDUAL RECEIVES A DIAGNOSIS OF CANCER OR ANY OTHER SERIOUS DISEASE, HIS LIFE DOESN'T HAVE TO FLASH IN FRONT OF HIM. THERE WILL BE PLENTY OF HOPE BECAUSE MANY OPTIONS ARE OUT THERE TO SUCCESSFULLY TACKLE THE DISEASE.

THANK YOU FOR YOUR TIME TODAY.

Mr. BURTON. Well, thank you very much, Senator Dole. I know there are great demands on your time and we appreciate it.

Senator DOLE. I am unemployed.

Mr. BURTON. Give our regards to your wife. I understand she is doing some important things right now.

Senator DOLE. Send money. Thank you.

Mr. BURTON. One of my heroes is Duke Cunningham. He was an Ace in Vietnam and has been a hero here in the Congress as well. Duke would you like to go next?

Mr. CUNNINGHAM. Thank you, Mr. Chairman and Mr. Waxman and panel.

Mrs. Gallo, unlike Strom Thurmond, I didn't know Abraham Lincoln, but I did know your husband and he reminded me a lot of my dad. He was a big, assuming guy and I can still remember his smile. We all miss him. And I would say to my former colleague, Senator Dole, the day after I found out I had prostate cancer, I called Bob Dole. I think that the amount of information that we put out and the knowledge and that call was probably the most helpful that I had, because today there is not a day goes by that I don't have somebody call me and say Duke, can I talk to you about prostate cancer because they don't know. You become an automatic expert on the issue because you read, you study, you do everything that you possibly can.

We are having a markup in Labor-HHS and I am proud to say that last year we increased medical research by 15 percent. This year, medical research is going to exceed 8.5 percent. I believe in it. I would invite each of you to sit in on a panel. Actually it is very difficult. John Porter, the chairman, asked me to chair a couple of the hearings and I told him I would never do it again because we had about 16 children that had exotic diseases and one of them looked up and said, "Mr. Congressman, you are the only person that can save my life." I had to shut down the hearing. It is just too hard. So medical research is very, very important.

While we talk here today, four men will die, just in the time that we talk, an equal number of breast cancer surgeries. I don't know why I am teary. I am happy. I am the luckiest guy in the whole world. But it is very—something that happens and it is difficult.

On May 10, 1972, I was coming down in a parachute over North Vietnam and it is something that always happens to the other guy that gets shot down. It is not Duke Cunningham. I am invincible. And the realization that you are coming down over North Vietnam and going to die or be a prisoner, there was no white scarf and no Bentsen and Hedges coming out. But the most scared individual you would ever imagine, that is not second to a doctor looking you in the face and saying, Duke, you have got cancer.

The first is denial, no, it can't be me. You have the wrong test. I am invincible. It happens to the other person. I can't have cancer. I am Duke Cunningham; I just can't have it. And the next thing is to find out everything you can and say, OK, Doc, what do I have to do?

I called two people. I called Father George from Georgetown University, a good hunting buddy of mine, and I called my friend, Senator Dole. And I want to tell you some of the things that you go through in this.

First of all, early detection, as Senator Dole has talked about, is the most important thing. Dr. Christiansen, my surgeon, told me about a lady that had four lumps in her breast. All were benign. She was a soccer mom and she got a fifth lump. She, like most moms, are busier than we are, they are taking their children to school, they are taking them for soccer, the piano lessons, cooking dinner, and all the other things. She let it go for over a year.

This lady is now going through chemo, she had a mastectomy, and they don't know if she is going to exist anymore. She is fighting for life itself. Not just life, but the quality of life and what those people can be giving back to their children.

In my case, I had an annual physical. Dr. Christiansen, who—I am very fortunate, Bob, the Navy, and we are going to beat Army this year in football, but the Navy doctors have been in the Capitol for the history of Congress, and Dr. Eisold is no exception.

I had my annual physical. I had a prostate check. They found no cancer. But because of a blood test called a PSA, there had been, and it really wasn't that high, but there was a delta between what it was last year and it had gone up slightly, Dr. Eisold said, "Let's do a sonogram." They found no cancer on the prostate.

They then said, "Let's do an MRI." They found no cancer. Dr. Eisold said, "Duke, we want you to go out to Bethesda and have a biopsy." I would tell the panel, I would rather fly over Hanoi again and get shot down again than get a shot. You can imagine when the doctor said he was going to use a needle that big in my prostate, I said "Doc, I ain't going. You told me I don't have cancer." Probably, like Steve went through, the night before, I am a coward when it comes to shots, and I sweated bullets thinking, man, this thing is going to hurt so bad.

I want to tell the panel, first of all, it doesn't hurt. You sit there and you wait, and it sounds like a cap gun goes off, and you say, is that all there is to it? You say, I know the next one is going to hurt. But it doesn't. You go through. But unfortunately when Dr. Eisold called me and said, Duke, I have some bad news for you, he said, in two of the eight biopsies you have a low-grade cancer.

The next that I had never heard, he said Gleason. I said who is that? Jackie Gleason? He said no, Gleason is the aggressiveness of a cancer, a 10 being the highest and the lower numbers the least aggressive. I had a 4. He said, well, Duke, you can go for years by just observing this and watching it, and you don't have to have surgery or the other things for a while.

I said wait a minute, Doc, you told me I have an enemy inside of me, an enemy more deadly than any MIG that I ever shot down, that this guy is going to try to sneak up on you. I said, is it in the lining of the prostate? Is it in the center? He said, statistically you can go for a long time.

The next thing is to find out the information and the different options that you have. Is it cryogenics? There had not been enough information at that time, so I chose not to. What about radiation? And then the doctor goes through the different side effects—incontinence, where you can't control your bladder because when they remove the prostate, they have to detach the urethra and reattach it to the bladder. Sometimes you end up incontinent. The next

thing is impotence, a pretty serious thing for a man and for his family.

You go through the different choices of what you have, and I chose, like Senator Dole, to go through the surgery. I said, I want it out. I told Dr. Christiansen, I don't care if it takes you 40 hours, you protect those nerves.

And I am happy to say I don't need Viagra. I appreciate your calling. This was one Member of Congress that saluted, what you did on TV, and didn't criticize Senator Dole because—for us that are trying to get the information out and know that it is important to do that.

The second thing that Senator Dole mentioned that I think is very, very important, it is very, very difficult to go to your wife and say, sweetheart, I may be impotent after the surgery. I may be incontinent, and we may have to live with that.

My wife looked at me and said, sweetheart, I will support you all the way. She supported me 100 percent whatever those decisions were, and you need to bring in the family as well. Those things are very, very important.

But something else that I found in my studies, Mike Milton, who was famous for another reason, has invested millions of dollars into prostate cancer. I met with Mike and he has put out a diet book. And I spoke—I see Mrs. Holmes Norton—I spoke the day before yesterday at a hospital in D.C. right down by the air force base there, Bolling Air Force Base. D.C. has the highest prostate cancer rate in the United States, and among African Americans, it is even higher, prostate cancer. And they have done studies, and the reason I bring it up, on diet, that people that are African Americans that come directly from the continent have a less incidence of prostate cancer. But once they come to the United States, and the same is true with Asians, once they come to the United States, their incidence goes up.

There are a lot of studies that say it is diet, the fatty foods and so on. So my mom was right, you need to eat your veggies and those things. But that kind of information, is very, very important.

I would like to address another subject real quickly. I think it is a good question to ask as far as the disparity between the amount spent on prostate cancer versus other diseases, but I want to tell you something. Many of us went out with Dr. Varmus and Dr. Klausner—Dr. Varmus, head of NIH, and Dr. Klausner in cancer research. I saw an African American lady that had Parkinson's, that they implanted an electrode into her brain. She had been in a wheelchair, couldn't eat and walk, had been taken away from her family. We asked what happened to her, because the film ended.

She ran down the center of the aisle, jumped in front of us and started talking to us. That kind of medical research in those things.

I met an AIDS patient that contacted AIDS in 1989. He said, Duke, the only thing I thought about was death. Every morning I woke up, I only thought about dying.

You know that since they have had some of these new research techniques, that he has bought stocks and bonds, he has bought a new home, that he has hope?

Ovarian cancer, I know Mrs. Ginsburg, you talked about, with colon cancer, for the first time NIH is identifying PSA-type markers for ovarian cancer, and they have never had that before.

So support the medical research that comes in. I would say that Senator Stevens and Jerry Lewis on the House side, we have put more money into breast and prostate cancer in the military. We have a captured force there, and we can look and make those kinds of studies. It is important.

I would say, also, I think it is time that many of us do believe that we need HMO reform, because some HMOs don't do PSA's and the other things. Some of the veterans hospitals don't have those, Mr. Waxman. I would tell you there are two bills out there—Norwood is one bill, and the other one is, I think, Dr. Coburn—but take a look at them. It is time to put doctors in charge of our health care again. But it is not time to put trial lawyers into the driver's seat, in the Democrat bill, which is why we oppose that kind of HMO reform. Unlimited lawsuits is just not going to work, and it will drive more people out of the issue.

But I want to thank the panel for having this hearing, and Senator Dole, and also Mrs. Gallo. Thank you.

Mr. BURTON. Thank you, Duke.

[The prepared statement of Hon. Randy "Duke" Cunningham follows:]

RANDY "DUKE" CUNNINGHAM
51st DISTRICT, CALIFORNIA

COMMITTEE ON APPROPRIATIONS

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Statement by the
Honorable Randy "Duke" Cunningham
before the
House Committee on Government Reform
hearing on government programs on
Prostate Cancer
September 23, 1999 at 10:00 a.m. in
2154 Rayburn House Office Building

Mr. Chairman Burton, Ranking Member Waxman, members of the Committee, it is an honor for me to be here today to talk about my personal experience with prostate cancer and discuss the importance of research, prevention, and early detection and treatment of this disease.

Just over one year ago, I was diagnosed with prostate cancer.

During my annual examination my doctor noticed a slight elevation in the readings of a Prostate Specific Antigen (PSA) test. However, it was only after a prostate biopsy that it was determined that I had cancer. Following the diagnosis, with my family, we decided that I should go ahead and have surgery.

Mr. Chairman, I am fortunate that my cancer was detected early, that I had a doctor who was familiar with PSA test results, and that I had healthcare coverage for my treatments. In my case, and in the cases of thousands of men, early detection and treatment have meant the difference between life and death.

Unfortunately, the national statistics for prostate cancer are not as promising for everyone else. We're not screening enough. Our tests are not good enough. And the available therapies have too many side effects for too many men and their families.

Prostate cancer results in more than 40,000 deaths each year. It is the leading cancer diagnosed and second leading cause of cancer-related deaths in American men.

In the time that I will testify here today, two more men will be diagnosed with prostate cancer.

During this hearing, four more men will die of prostate cancer.

Yet these cold numbers do little to convey the fear and uncertainty experienced by the men, our fathers, brothers, uncles or grandfathers, who are diagnosed with prostate cancer. They do not describe the impact that prostate cancer has upon a man's family and loved ones. Every day, too many men in the United States hear the life-changing words. "You have prostate cancer."

What steps can men take to keep this from happening?

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It is believed that a good course of action to prevent prostate cancer includes exercise, a diet low in fat and consisting mostly of vegetables, fruits, and grains. Results of several studies suggest that men who eat a lot of fat in their diet have a greater chance of developing prostate cancer. Recent research also suggests that a diet high in calcium and low in fructose (fruit sugar) can increase a man's prostate cancer risk. In addition, I have been told from several sources that cooked tomatoes are particularly good to help combat cancer.

In short, our mothers were right. We should eat our vegetables.

However, diet and exercise are no replacement for annual examinations and early detection. Early detection is most important if men have the risk factors associated with prostate cancer.

Cancers found early, by either PSA blood test or physical examinations, are, on average, smaller and have spread less than cancers discovered because of symptoms they cause. And since prostate cancer is such a slow growing cancer, men who are diagnosed with prostate cancer that has not spread beyond the prostate gland face a survival rate of nearly 100 percent.

But even with all of our knowledge about this terrible disease we still have far too many questions.

** Why are African-Americans diagnosed with prostate cancer 35% more frequently then Caucasians and twice as likely to die?

** Why are more and more men in their 40's and 50's battling prostate cancer?

** Are the reports of more aggressive cancers in younger men a trend, or simply the result of greater detection and heightened awareness?

These are just some reasons why we need a greater national investment in medical research, and specifically prostate cancer research. The National Prostate Cancer Coalition has identified new or underfunded research opportunities totaling nearly $500 million in 1999. These include:

- Chemotherapies that destroy cancer cells and halt the progression of disease
- Vaccines and other stimulators of the immune system
- Drug therapies that can destroy a tumor by shrinking its blood supply
- Treatments that can turn cancerous prostate cells back into normal cells
- Therapies that could hasten a cancerous cell's death -- that kills cancer faster then it can spread
- Radiobiology and radiology treatments
- Tumor molecular biology, including the molecular "fingerprinting" of disease
- Genetics that may help stop the disease at its earliest stages
- And nutrition, vitamins and alternative therapies that may impede or reverse the progression of disease.

These are just a few of the opportunities that modern technology has identified.

Yet, just as important are the projects and opportunities that we have not identified, that are yet to be discovered. In my congressional district in San Diego, I am fortunate to represent some of America's finest medical researchers and biotechnology companies. These companies are on the cutting edge of today's biotech revolution . . . discovering and bringing to market new medicines, new therapies, and new treatments to prevent and cure disease.

As I have toured these companies, I have seen the future of medical research. It is a future where gene therapies will treat diseases before symptoms develop, where disease detection will find cancer cells in their earliest stages, and where the pain and suffering of debilitating disease is a thing of the past.

But it is a future that will only happen if we invest in medical research now.

The Prostate Cancer Research Program in the Department of the Army received approximately $60 million for its peer reviewed research in 1999. However, more money is needed to advance our research to find cures.

The other primary source of funding is the National Institutes of Health. I am a proud original cosponsor of the Biomedical Revitalization Resolution of 1999 (H.Res. 89), introduced by Rep. George Gekas (R-PA). This resolution expresses the sense of Congress that we should increase our investment in NIH by $2 billion this year, and double NIH in 5 years.

It is that goal of doubling that I am pursuing through my role on the Appropriations Subcommittee on Labor, Health and Human Services, and Education. As all members of this body know, last year Congress was able to enact an historic 15 percent increase for NIH. That down payment was only the first of five needed to double NIH spending.

Unfortunately, the Clinton-Gore FY 2000 budget provides only a meager 2% increase to NIH. Were Congress to enact the President's budget, we would cut new research grants by 25 percent. More to the point, the Clinton-Gore budget raises the white flag in our war on cancer, raises the white flag in the war on heart disease, on arthritis, and on so many other conditions that we are fighting.

The Clinton-Gore plan is risky and wrong for America. We will do better.

Finally, I want to bring to the attention of the Committee legislation that is pending in the Subcommittee on the Postal Service. On July 20, 1999, I introduced the Stamp out Prostate Cancer Act (H.R. 2562). This bill will allow individuals the opportunity to contribute to prostate cancer research through the voluntary purchase a specially priced U. S. postage stamps. I hope that the members of the Committee here today will join me in supporting this effort.

Again, I want to thank you for this opportunity to testify on this important issue, and thank you for holding this important hearing.

Mr. CUNNINGHAM. Can I mention one other thing real quick?

This stamp on cancer awareness, breast cancer, this stamp right here, does not add to medical research for cancer. We have a bill that does. Like in breast cancer, we would like to propose, this is a 4-year committee, and you can act on it, Mr. Chairman—that we would like to bring forward a stamp that actually—I think we have to get every Member of Congress in their campaigns to use that stamp, the breast cancer stamp, that goes for medical research. I know I would.

Mr. BURTON. We will see if we can't talk to the Postmaster General about that.

Mrs. Gallo, we have about 12 minutes, I think, before the vote. Would you like for us to come back after the vote to hear your testimony, or you would like to do it now?

Mrs. GALLO. Whatever is easiest for the committee.

Mr. BURTON. Why don't we recess for the vote and come back, and then—we appreciate it.

Senator Dole, will you be able to stick with us for a while or do you have to leave?

Senator DOLE. I will be here for a while.

Mr. BURTON. We will be back as soon as the vote is over because we have some questions for you. Thank you.

[Recess.]

Mr. BURTON. If we could get the witnesses to once again take their seats, we will have witnesses coming back. We just finished our second vote. Because we have that good-looking Senator Robert Dole with us—I know he has some time constraints, as well as the other panelists—I thought we would go ahead and get started.

While we are waiting on Mrs. Gallo, let me just ask Senator Dole a question or two, if it is all right, Senator.

You spoke about the emotional side of facing cancer, the disbelief, fear, hope and so forth. How did you and your wife cope with this when you first found out about it?

Senator DOLE. Well, I think a little like Duke Cunningham said.

First of all, you think it must be a mistake. It can't be my biopsy, because I don't have prostate cancer. But then there is the realization that it is there and then you have to decide how to deal with it. So we went to—I learned a lot more about it since the operation than I knew before the operation. I am not saying I might have picked a different route, but I don't know. We were a little panicky, and we went out to Walter Reed Hospital, and they talked to both of us about side effects and all the other things.

But once you make a decision, that is it. Then you just do the best you can.

Mr. BURTON. It sounds like you handled it pretty well. Was it kind of like when you realized all the severity of your wounds when you were in World War II?

Senator DOLE. I guess I had great faith in medicine and doctors, and I think they certainly played a major role in my life from way back when I was 19 years of age.

But I think the important thing is—we were just visiting here while you were voting—how do we get the information out there? How do we get the average guy on the street, who may be walking around with a PSA of 10, 12—and that is not foolproof, it may not

make any difference, but how do we get him to understand that it is important to go to the doctor?

We have all the experts here today, and they can tell us about all the options, but there has to be some way for that information to leave this room and get out to the average guy on the street in Indiana or Kansas or California or wherever.

Mr. BURTON. I wish we had a lot more coverage today than we have. We have print media here that will probably be talking about it. We need to really work on getting the message out.

You have been very helpful in that regard. We will see if we can't be of assistance too.

Senator DOLE. I need to speak at noon.

Mr. WAXMAN. I thought the Senator had mentioned he had to be at this luncheon at noon. Would you allow me to ask a question or two?

Mr. BURTON. If Mrs. Gallo doesn't mind, would you mind if we ask a few questions of the Senator?

OK.

Mr. WAXMAN. Senator Dole, you have been a very important force in raising awareness, public awareness, about prostate cancer and all the related problems; and I want to congratulate you and express my appreciation to you in that regard.

You are also spokesman for the product Viagra. That product was approved by the Food and Drug Administration where they evaluated numerous randomized placebo controlled trials involving more than 3,000 men; and then FDA published information on potential side effects of this product and other interactions Viagra might have with other substances.

But there are some herbal products being advertised on the Internet, and they are being called alternatives to Viagra. One product, for example, says they are 100 percent herbal sensation, touted as the herbal Viagra, and they make a number of claims that the product will relieve lack of desire, impotency, orgasm dysfunction. Additionally, they state it will help relieve prostate problems, lower cholesterol, help urinary function. They say you don't need a prescription. There are no side effects; there are only positive things from using this drug.

If Pfizer were to make some of these claims, they would have to extensively prove them to protect the public health, but for some of these herbal products, there are no FDA approvals, because it is not a drug, they say, and they cite no clinical studies to support their claims. There is only testimony, always of users.

I would like to know how you feel about that and whether it is a concern and whether we ought to have more scrutiny over these kinds of products?

Senator DOLE. I must say I think the first part of this, I almost got into this by accident. I was talking to Larry King one time in the Green Room, I learned not to do that since, just visiting before the show, and I was telling him about this trial I was in, this protocol, and it turned out to be Viagra. Of course, Larry made a mental note of that and raised it publicly on the show about 2 minutes later.

So, with you, I have had people send me these things. They have heard about what I have been doing; this is better, do this, do this,

do this. It seems to me there ought to be some basis for all the claims that are made. At least it ought to say at the bottom it may not help, but it won't do you any harm. There ought to be something there.

Mr. WAXMAN. What assurances would you want to have before you would feel comfortable in promoting any kind of product like that?

Senator DOLE. I don't promote that product. I have some stuff called Macho Man, somebody sent me a case of it in the mail. I would be happy to bring it up here and distribute it.

Mr. BURTON. You think we need that, do you?

Senator DOLE. They make a lot of claims, but I don't have any information at all, whether it is, because they don't have to comply with any regulation. They don't have to satisfy that it is safe and effective.

Mr. WAXMAN. Do you think the Congress and the regulators should require some substantiation before claims to consumers are made about the effect of these products?

Senator DOLE. I think it would be helpful. I know it is a very tough issue when you get into vitamins and everything else and herbal remedies. At least there ought to be some determination that it is not going to hurt someone. I don't know how you do that. Aside from whether it is doing all the things you read off, I think that is probably mostly hype, would be my guess.

They also had different herbal remedies for brain power. I got a case of that the other day. Just take a couple of drops a day and your brain functions, which is different than it has been.

Mr. WAXMAN. The way the Congress decided to deal with the issue is, we said if it is a claim about just your general good health, you can go ahead and make it. But if it is a claim you are going to cure a disease, there automatically should be more substantiation because then it gets to be close to a drug.

Senator DOLE. I agree.

Mr. WAXMAN. You agree with that kind of distinction?

Senator DOLE. We are talking about health and new technology, new options for all these different things, not just cancer, but everything else. We have to be very careful. We are dealing with consumers, a lot of people that don't have information, are not sophisticated; and they pick up some magazine, they will read all these things and they are going to head for the store.

In fact, there was one last night on TV that I am going to check out myself, not about any of this, but about your general energy. We will see what happens.

Thank you.

Mr. WAXMAN. Thank you very much.

Mr. BURTON. Mr. Horn, do you have any questions briefly for the Senator?

Mr. HORN. Well, let me make one point. We named some colleagues that really have helped in getting the money for cancer research—you, Senator Stevens and so forth on your side. I want to say Jack Murtha, when he was the chairman of the Defense Appropriations Committee pumped millions of dollars into the Defense Department to face up finally to both breast cancer and prostate cancer, and he felt with the military having women in the services

and breast cancer being the plague that it is, that that ought to be done. I think he can take great pride in what has happened in the grants over there.

One of them I am aware of, at UCLA, the person had been denied a grant by NIH, and why? Because they had never had a grant from NIH. Now, if that wasn't a catch-22, I don't know what is. But the military has made some real progress in research with the grants given to the Department of Defense.

Senator DOLE. Steve, I appreciate that. I think it is fair to say the record is pretty clear, this is a nonpartisan-bipartisan area, where you have got, in this case, men on both sides of the aisle who have had the problem.

I remember getting a very irate letter from a lady in Kansas after we appropriated money for prostate cancer research. This is after my operation, but she concluded this was to help me, and I advised her that it was too late to help me, but it might help her grandson. So there is misinformation or noninformation or whatever. But certainly in the Congress, it has had across-the-board support.

Mr. BURTON. Mr. Turner.

Mr. TURNER. No questions.

Mr. BURTON. Mr. Ose.

Mr. OSE. I do want to say hello to the Senator.

Senator DOLE. Good to see you again. Good to see you here.

Mr. BURTON. Mr. Owens, do you have a comment?

Mr. OWENS. No.

Senator DOLE. I watch him on the Late Show. I watch C–SPAN at night.

Mr. BURTON. You do? I may have to get on there more often.

Mr. Barr.

Mr. BARR. No questions. No, thank you, Mr. Chairman.

Mr. BURTON. I had a lot of questions for you, Senator, but I think you covered just about everything. We really appreciate you and your wife and how you represent all these issues to the country. You are a real credit to America.

Senator DOLE. On Sunday, for example, I will be in Des Moines, IA. I am not a candidate——

Mr. BURTON. Are you sure?

Senator DOLE. But there is going to be a Walk for Prostate Cancer to raise money for prostate cancer.

So it is happening. All these things are happening, so there is more awareness. A lot of it is being done by men who have been through the process, radiation, whatever treatment they might have had. So I think the word is getting out.

But certainly this hearing will be helpful and what you do individually will be helpful as you go back to your districts, town meetings, whatever. Thank you.

Mr. BURTON. Thank you, Senator.

Mrs. Gallo, thank you for your patience. Once again we really appreciated your husband, serving with him and traveling with him. He was a fine fellow. We appreciate what you are doing by carrying on his memory with this Institute.

Mrs. GALLO.

Mrs. GALLO. Thank you very much, Mr. Chairman. I want to thank the committee for allowing me to testify today, especially before the people who knew and worked with Dean in Congress. That is why it is nice to be here, because I am talking to people who really knew him. So if I can use him as "a poster child"—for prostate cancer, I think that is very important. You put a face with the disease, and this is exactly what I am trying to do.

I want to give you a little background on what happened to Dean with regard to prostate cancer. Back in March 1991, he had his normal physical in Congress, and about August 1991, he started with a backache. Of course, as is typical of men, they don't go to the doctor, and I kept bugging him. Finally, in February 1992 he went to an orthopedist, who gave him cortisone shots. Didn't work. They gave him a bone scan, and he called me up and said, "Honey, I have got prostate cancer." I responded, "What? What is prostate cancer?" Not knowing what I was getting myself into and how my life was going to change at that point. He said his bone scan lit up like a Christmas tree.

I am not sure if everyone is aware of the PSA test. A normal PSA, the prostate specific antigen, is usually 1 to 4. Dean's PSA was 883. He was already in the advanced stages of prostate cancer; it had already metastasized to his bones.

His prognosis was only 3 to 6 months. This was back in 1992, and, as you all know, he was in Congress until 1994.

Dean went to his urologist where we lived in Morris County. He said, what can you do for me? The doctor said they could remove his testicles, because the testosterone is what causes the cancer cells to grow. I said to him, I think before we go to that extreme, I would like to look at other options.

Because he was down here in Washington most of the time and we did not have a cancer institute in New Jersey, he decided to go to the National Institutes of Health. Dean was treated by Dr. Charles Myers and was actually one of the first two people on a protocol called suramin, which—I don't know if you remember Bill Bixby, they tried it on him when he had prostate cancer, but unfortunately, it had already advanced to his organs.

With that, Dean's PSA did come down between 1992 and 1993. In January, it was 3.5. People in Congress at the time did not realize Dean was sick with prostate cancer. In fact, Senator Dole made a comment: Do you say anything? Will people look at you differently? And that is what Dean's concern was. He loved his constituents and didn't want them to feel sorry for him because he was going through this process of dealing with cancer.

So for the following couple of years he seemed to be doing OK. He was on different protocols. One of the things you live by is the PSA. He would get it checked every month, and sometimes it would be up, sometimes it would go down; and then you have to decide, if it went up, what were you going to do next.

I am sorry, I am just trying to gather myself here.

Finally, what happened was, toward the fall of 1994, as you all recall, Dean had decided to retire from Congress. He had very bad bone pain, and it couldn't be controlled at that point. So he decided not to run for re-election in November.

When Dean left Congress, he decided to try to work harder on the cancer, which he did, but unfortunately, the pain was so much out of control that there wasn't too much more they could do for him. Unfortunately, in October 1994, he fell and broke his shoulder, which put him in the hospital.

The bone pain was so excruciating, it was very difficult to treat it. Most of the time, they treat bone pain with morphine, and from what I understand, that doesn't always take the pain away like it should.

Unfortunately, the cancer was so well advanced that he died on November 6, 1994. All I can say is that Dean and I had the best 2½ years of our 8-year relationship when he had the cancer. It brought us much closer together and created a love that I may never know again. I saw a very warm and loving side of Dean that I may have never known had he not had cancer.

When Dean was diagnosed, we started going to church and we believed that the Lord would get us through the tough times. Dean was a wonderful, strong individual, and he put up an incredible fight. I truly believe the support system was part of what helped him through that tough time.

If the PSA had been available when Dean had his yearly physical, maybe Dean would have been diagnosed in the early stages rather than the advanced stages in 1992. If we had had more funding for prostate cancer at that point, and research, perhaps Dean would have survived.

We do need more money for prostate cancer research. If we don't have the funding, we can't attract the scientists to come and do research in this field. Prostate cancer, as Chairman Burton had remarked, has the highest incidence rate in the Nation.

We need the funding, to be able to prevent or possibly cure this disease. We need the FDA to find a better approach to move the approval process which affects the public. We also need to focus on research for pain management. As I said before, the bone pain is horrible. We need to look at how to improve the quality of life, not always the quantity of life.

We need more studies and funding for complementary and alternative medicines. I have seen that people that have been on some kind of complementary or alternative medicines, along with standard chemotherapy, seem to do a little better.

I feel nutrition is a very important part, of prevention and the treatment of prostate cancer. I feel it helps to build the immune system and keep it healthy when the body is being fed the toxins to destroy the cancer cells.

Dean had a nutritionist come in before he passed away, and unfortunately, I wish I had done it sooner. I think it would have helped him to survive or possibly do better with his chemotherapy treatments.

Unfortunately, the other point with nutrition is, our foods do not have the nutrients like they used to because we process the foods for shelf life. We lose a lot of our nutrients, so that is why the supplements are so important.

Today, prostate cancer is no longer an older man's disease; 30 to 40 percent of men over 50 will be diagnosed with prostate cancer. A prime example is my husband's doctor, Dr. Charles Myers, who

treated my husband. To me he was my hero because he kept Dean alive for 2½ years and Dr. Myers was just diagnosed a couple of months ago with prostate cancer.

Since Dean's death, I have become a prostate cancer advocate. I have worked with the American Cancer Society and developed a prostate task force to educate the community. I have worked with the American Foundation of Urologic Disease. I am also a founding and present board member of the National Prostate Cancer Coalition, and I also work with the Men's Health Network.

I have also testified at the State level for two bills. One was to name June as Prostate Cancer Awareness Month in memory of Dean, and the other was for insurance coverage for the PSA and the digital rectal exam.

One concern which is important that Senator Dole mentioned before, is the funding for medication for the patients. I think Congressman Cunningham referred to that also—that the medications are so expensive and even some of the treatments they have to go through, the patients can't always afford them. I think that is one area we need to have more money available to them, whether it be through Medicare or their own insurance companies.

I know the patients that come to the Cancer Institute where I work, there are certain parts that are not always paid for, like some of their visits and whatnot. It becomes very costly when you are treating any kind of cancer or any kind of disease.

I am currently working at the Cancer Institute of New Jersey, which is the State's only NCI-designated center. I am director of advocacy and fund-raising for the Dean and Betty Gallo Prostate Cancer Center, which was just recently created in memory of Dean. Dean was very helpful in getting the initial funding to build the Cancer Institute of New Jersey. I am also on the scientific review board at the Cancer Institute.

With regard to the Prostate Cancer Center, our intention is to create more programs, bring in more research funding, and do education and awareness. We want to make this a premier center in memory of Dean.

One of the programs I am involved with that I am bringing on board to the Prostate Cancer Center which, I am vice chair of, is the 100 Black Men Prostate Cancer Initiative. We are planning to screen the underserved population in the 21 counties of the State of New Jersey by the year 2001. We are doing an educational part to educate the underserved on prostate cancer, and are doing screenings.

Advocacy is really important. Part of what when Senator Dole mentioned is getting out there to get out the word. It is groups like the National Prostate Cancer Coalition, the "us too" groups, and the grassroots that gets out there and tells people how important it is to have early detection and education on prostate cancer. That is the only way you are going to stop it from going into the advanced stages like Dean.

It has been almost 5 years since Dean's death. My mind knows time, but my heart doesn't. My goal is to prevent others from suffering from prostate cancer the way Dean and his family did. This is a family disease.

I want to advocate the importance of early detection, awareness, and education. In doing so, I know when I leave this Earth, I will have made a difference, as Dean had, and I know we will be together again.

Thank you.

[The prepared statement of Mrs. Gallo follows:]

THE DEAN AND BETTY GALLO PROSTATE CANCER CENTER
AT THE CANCER INSTITUTE OF NEW JERSEY

I want to thank Chairman and the Committee for allowing me to testify.

I am Betty Gallo the wife of your Colleague the late Congressman Dean Gallo 11th District of New Jersey. I am the Director of Advocacy Fundraising for The Dean and Betty Gallo Prostate Cancer Center of The Cancer Institute of New Jersey. I am also a founding and present Board member of the National Prostate Cancer Coalition.

Dean served in Congress from 1985 to 1994. Dean died of prostate cancer on November 4, 1994. In August 1991, my husband Dean started to complain of a backache. I asked him repeatedly to see a doctor, he then went to a chiropractor but got no relief. The chiropractor recommended that Dean see an orthopedist, who gave him several cortisone shots. Dean felt a little relief, but not a lot.

The doctor then ordered a bone scan. On February 10, 1992 our whole life changed, Dean told me he had prostate cancer. He said his bone scan lit up like a Christmas tree. We didn't have a clue about what was going to happen next. Dean had a biopsy and Prostate Specific Antigen (PSA) Blood test. The biopsy showed cancer activity and his PSA was 883. When Dean told me this, the first thing I did was pray.

Deans urologist recommended and orchiectomy, an operation to remove his testes so that his body would no longer produce the male hormone testosterone, which stimulates cancer growth. I thought before we went to that extreme we should check out alternative treatments. At this time, I was not aware that Dean's condition was so far advanced that he should have survived only three to six months.

Since Dean was in Washington most of the week and since New Jersey did not have a Cancer Institute we decided on the National Institute of Health. Dean said Dr. Charles Myers who started Dean on a new protocol suramin and combined hormonal therapy, his PSA level soon began to drop. By January 1993 Deans PSA was down to 3, and he said to me "Honey, I can't believe I have cancer because I have no pain.

In the fall of 1993 Dean's PSA level went up and down as he participated in several other NIH treatment protocols. Dean had a lot of pain in July of 1994, the beginning of August they decided to give Dean an injection of strontium, a radioactive compound that was to help in treating bone pain. It did the complete opposite to Dean and created more pain. Dean was hospitalized on September 10, 1994 and then released September 13, 1999 during that time we tried different diets, vitamins and herbal teas. We had the church elders come in and pray over Dean and we also changed doctors.

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On October 12, 1994 Dean fell and broke his shoulder. The next couple of weeks we up and down, I never gave up hope that something would turn this around. Dean was so good about trying to fight this disease, it was never easy.

On October 26, 1994 former President Bush came to New Jersey for an event honoring Dean's retirement from Congress. Unfortunately, Dean could not attend. The President came to the hospital prior to the event to see Dean. The Telephone Company had hooked up a special line so Dean could hear the whole event from his hospital room. It was a wonderful tribute, but that night Dean was put on oxygen.

A few days later my pastor came to see Dean, later in the cafeteria I told the pastor that I had spoke to the Lord after Dean was diagnosed and the Lord had promised he would heal him. The pastor said to me "The Lord does not always heal physically, but spiritually. The next three days Dean was very quiet. On Thursday, November 3, 1994 Dean was very upset. He said to me "Honey I can not do this anymore, I want to die and be with the Lord." I said "Whatever you want, I am here for you. "I told the nurses to call the rest of the family. A couple of hours later, Dean turned to me and said, " How long is this going to take?' I didn't know what to say. I wished I had a heavenly telephone so I could find out for him. It was a humorous moment in a very sad situation.

The next day, Dean was in tremendous pain. It was horrible. I just wanted him to stop suffering. The last thing Dean said was, " Jesus, please take me know." At 11:30AM Sunday, November 6, 1994, Dean drew his last breath. He had gone to be with the Lord.

The last two and a half years from diagnose to his death was the best years of our relationship. We were so close with our love and with the Lord. Our faith is what got us through such a devastating situation and kept us going. From the time Dean was diagnosed, the one thing he and I began to do was go to church. Dean had a very busy schedule, but he tried to make Sunday morning church a priority unless there was an obligation he just could not miss.

It is almost five years since his death. My mind knows time, but my heart doesn't. I still miss him, as much today.

Since the death of my husband, I have become a prostate cancer advocate. The results of what I have done is as follows.

In June of 1995, I became a volunteer with the American Cancer Society (ACS), Morris Unit in New Jersey. I served as Honorary Chairperson of the Dean Gallo Memorial Sports Tournament to raise funds for prostate cancer treatment. I formed a county level Task Force to bring education and awareness about prostate cancer to the community and is also on the ACS, State Prostate Cancer Task Force.

I also became involved with the American Foundation of Urologic Disease (AFUD) in January 1996 and was featured in their ***Urology*** magazine which was introduced at the American Urologic Association Convention in Orlando, Florida. Through AFUD, I sponsored the Dean Gallo Scholarship supporting a student at a medical school in New Jersey conducting prostate cancer research. For my efforts, I received the AFUD 1997 Presidential Award in New Orleans.

I testified before the New Jersey Legislature to name June Prostate Cancer Awareness Month in memory of Congressman Gallo. I also testified in support of a NJ bill that called for insurance coverage of Prostate Specific Antigen (PSA) and the Digital Rectal Exam (DRE).

I am a founding board member of the National Prostate Cancer Coalition formed on July 20, 1996 in Los Colinas, Texas and is still on the board. I currently work for The Cancer Institute of New Jersey, the states first and only National Cancer Institute (NCI) designated center, since October 1997 as a Development Associate and Advocate. As of October 1998 I am now the Director of Advocacy and Fundraising for The Dean and Betty Gallo Prostate Cancer Center at The Cancer Institute of New Jersey. I created this prostate cancer center in memory of my husband Congressman Dean Gallo.

I am Vice-Chair of the "100 Black Men" Organization Prostate Cancer Initiative. This program is to reach out to the underserved population for education, early detection and awareness. The goal of the program is to be screening the 21 Counties of New Jersey by the year 2002.

I received The Advocacy Award from The Zonta Club of Morristown, New Jersey on 4/28/99 for my advocacy work at the State and Federal level. I also received The Award of Excellence from the "100 Black Men" Organization on 5/20/99. I received this award for my work with the organization on outreach and prevention to the underserved community on prostate cancer.

I have been featured in ***Family Circle, Men's Health and The ABC's of Prostate Cancer.*** I have also collaborated with Immunex, Jannsen and Schering Plough prostate cancer awareness programs. I have appeared on Health Watch (NJN), Nightly News with Peter Jennings, and numerous radio talk shows.

With regard to research and access to treatment we need much more funding. It takes time to get the research to the clinics, this is called Translational research. For example at The Cancer Institute of New Jersey (CINJ) we may have six protocols, but if there was more funding we could double our protocols. As a public policy issue the National Prostate Cancer Coalition is to change this.

We need to speed up the process for funding. With funding we can do much more research to prevent or possibly cure this disease. We need the FDA to find a better approach to move the approval process, which is most effective to the public. As far as innovative new treatments all National Cancer Institutes are doing that. We need more funding to enable more scientist to do prostate research. We also need to be doing more studies, on complementary and alternative medicines. I feel that this can be used in conjunction with standard treatment. It may help to lessen side effects and the chemotherapy may be more effective.

Nutrition plays a very important part in the prevention and treatment of prostate cancer. I feel that building the immune system is so important. People who include nutrition in their diet respond and tolerate chemotherapy much better. You need something to keep the healthy cells going which the toxins are getting rid of the cancerous cells. I did have a nutritionists evaluate Dean, and put him on certain vitamins and herbs toward the end. I wish we had began with the nutritionist when he was first diagnosed. We need supplements because our foods are processed that the nutrients are lost from our foods. The incident rate of prostate cancer is high nationally. The statistics are 30-40% of men over 50 will be diagnosed with prostate cancer. It is no long an older man's disease.

My goal is to help prevent others from suffering from prostate cancer the way Dean did by advocating the importance of early detection, awareness and education. In doing, so I know that when I leave this earth, I will have a difference, as did my husband and that we will again be together.

Mr. BURTON. Thank you for that very moving testimony. We really appreciate it. I know it was difficult for you.

You mentioned the incredible pain that Dean was suffering, and it was treated, I guess, by morphine primarily?

Mrs. GALLO. Primarily. They also put him on this protocol called strontium, which unfortunately I have a very tough time with, because most of the men on it die from it. I think that is what happened with Dean, it hits the immune system.

Mr. BURTON. Were you offered anything as an alternative, like acupuncture, or any other complementary treatments that might have helped?

Mrs. GALLO. Not at that time. Unfortunately, I wasn't that well educated to realize that may have been very helpful. I think now—as time has gone on, I realize patients are beginning to use that. I think it is helping a lot of patients.

Mr. BURTON. I see. I don't know, do you know if any of that is paid for by any of the insurance plans?

Mrs. GALLO. Probably not. I think most of them are not. A lot of patients try to do something to help their chemotherapy. I think some of the complementary medicines out there you have to be concerned about, such as the herbal medicines. One of our scientists, doctors, had done research on the PC SPES, which is used to bring the PSA down. It does work, but the only problem is you have to monitor it.

I do believe you need some kind of regulations when it comes to any kind of herbal medications. You don't want the person to get really ill if it is not monitored. I think it is important to have alternative medicines cancer patients, because they feel it does help to heal the good cells and keep them going. I have seen people who have done that and they have done very well with their chemotherapy.

Mr. BURTON. Let me just ask you one or two more questions. Did the spirituality that you were active in with Dean, did that really help?

Mrs. GALLO. The spirituality with Dean and me was incredible. I didn't really touch on that as much. I put it in my testimony. But Dean and I did start going to church, every Sunday, I had never given up hope that Dean was going to survive. Up until the week before he died, I was not going to let this man die. I was going to do everything humanly possible.

On that Sunday I had said to my pastor that I had spoken to the Lord 2 years ago and he promised he was going to heal Dean. He said to me, the Lord doesn't always heal physically, he heals spiritually. That is exactly what he had done with Dean.

I will give you a for-instance. We had been engaged a year. I wanted to give Dean something for our anniversary of being engaged, and I bought him this cross. He had been in the hospital at this time because he had a hip replacement. I went in and gave him the present, and he opened it. I didn't buy him a chain because I didn't know if he would wear it. He was not a real big jewelry person. Dean started to cry. He put the cross around his neck, and he wore it until the day he died.

Another thing, along that note was, he died on Sunday, but on the previous Thursday he was in excruciating pain. I went in, and

he said, honey, I can't do this anymore. I want to die and be with the Lord. I just looked at him. I had no clue what was happening at that point. I am sure, knowing Dean you knew he wanted to know what was going on next. So finally he looked at me 2 hours later and he said, honey, how long is this going to take? I am looking at him, I don't know. Do I have a heavenly contact somewhere? I had no clue what was happening at this point.

On that Friday, one of the last things he said before they put him into a comatose like state, which is when they brought up his morphine count and also gave him Ativan to relax him, he said, Jesus, please take me now.

So my pastor was right in the fact God had healed him spiritually, and I guess that is what I felt my mission to him was, to bring him to the peace he had when he passed away.

Mr. BURTON. Did you get any nutritional advice from the oncologist that was working with Dean?

Mrs. GALLO. I actually got a nutritionist to come in to evaluate Dean. She gave a regimen of different vitamins he should be taking and some changes in his diet. This was toward the end. Again, I was learning so much in the process of dealing with this disease. I really wish I had done it sooner, because I think it really had some good merit to it.

I think one of the interesting parts is green tea which seems to be helpful in even preventing cancer, and when you have cancer, it supposedly helps to maybe not let it spread further. There are still some studies being done with that. Green tea seems to be one of the areas that they are saying has some credence to it.

Mr. BURTON. But the oncologist wasn't one of those who recommended any kind of nutrition?

Mrs. GALLO. No.

Mr. BURTON. I see my colleague is on the phone here. Let me ask him one more question and then yield to him and then go to the next panel.

Did anybody ever talk to you about why African American men get—you said you worked with them a little bit—get and die more from prostate cancer?

Mrs. GALLO. Part of it is, I think, the culture. Part of it is the fact a lot of them don't have insurance and their fear of medical community. These are the three areas. One of the reasons I have gotten involved with the "100 Black Men," is because they do have the ability to bring us into the community to educate them so they are not as afraid of the medical community and are willing to get tested for prostate cancer.

Mr. BURTON. Mr. Barr, do you have any questions?

Mr. BARR. No, Mr. Chairman. I appreciate the testimony.

Mr. BURTON. I want to thank you very much, Mrs. Gallo, for being with us. Continue your good work. If we can be of any help, let us know.

Mrs. GALLO. If I can be of any help, I am here to help.

Mr. BURTON. And we all miss Dean.

Mrs. GALLO. I do too. Thank you.

Mr. BURTON. Would the next panel come up, the experts. We appreciate your being so patient. We will try not to keep you too long.

I can't recall when we have had so much knowledge and talent at that table at one time. I only regret that more of my colleagues are not here. I am sure there will be more coming back and forth, running from different meetings. So I apologize for that.

Dr. Geffen, I have been instructed to ask you if you have an opening statement and let you start off, if you would like.

STATEMENTS OF JEREMY GEFFEN, M.D., GEFFEN CANCER CENTER AND RESEARCH INSTITUTE; KONRAD KAIL, M.D., PHOENIX, AZ; SOPHIE CHEN, Ph.D., BRANDER CANCER RESEARCH INSTITUTE, NEW YORK MEDICAL COLLEGE; ALLAN THORNTON, M.D., INDIANA UNIVERSITY; RICHARD KAPLAN, M.D., NATIONAL CANCER INSTITUTE, ACCOMPANIED BY JEFFREY WHITE, M.D., DIRECTOR, NCI'S OFFICE OF CANCER COMPLEMENTARY AND ALTERNATIVE MEDICINE; ANDREW C. VON ESCHENBACH, M.D., AMERICAN CANCER SOCIETY; AND DR. IAN THOMPSON, COL.M.C., UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Dr. GEFFEN. Good afternoon. I am honored and privileged to be here today and to have the opportunity to speak with you about a subject that I care very deeply about, namely the journey through cancer in general, and prostate cancer specifically.

Like so many others, I have been touched by this disease in many ways, including through members of my own family. I spent 14 years studying and training to become a medical oncologist at some of the finest universities and medical centers in the United States, and have also been fortunate to have studied medical and spiritual traditions in other parts of the world. For the past 10 years, I have also had the privilege of serving as physician, guide, mentor, coach, and friend to thousands of cancer patients and their family members, many of whom were dealing with the often formidable challenges associated with prostate cancer.

Along the way, I have learned one lesson over and over and over again that I believe lies at the heart of what patients and families experience on their journey through cancer. That lesson is very simple, yet profound, and it is this: Cancer often challenges the mind, heart, and spirit of patients and their family members, as deeply, if not more deeply, than it challenges the physical body.

Unfortunately, even tragically, this simple lesson is often overlooked in the compelling search for newer and better ways to diagnose and treat cancer.

The urgent drive to eradicate illness has caused Western medicine, which we are so richly blessed to have, to focus almost exclusively on the physical dimensions of disease, rather than on caring for the whole person who has the disease. This is especially true in the field of oncology.

With respect to prostate cancer, for example, as we have heard today, we typically speak of incidence and mortality rates, PSA screening programs and Gleason scores. We talk of radical versus nerve-sparing prostatectomies, external beam versus seed implant radiation therapy, and things like simple versus total androgen deprivation therapy. In recent years, we have also started to talk about the role of diet, nutrition, and alternative and complementary therapies in cancer prevention and treatment.

This is the language of prostate cancer, and it is also the language that physicians, researchers, and legislators tend to use when we talk about where the field is today and where it should be going in the future. If we listen carefully to all of this language, however, and if we have the courage to really hear, we will notice something that is almost always glaring in its omission: namely, the mind, heart, and spirit of the men who are going through the nightmare of prostate cancer, and the spouses and family members who are going through it with them.

Make no mistake, aggressively pursuing all avenues of research in early diagnosis, prevention, and treatment of cancer is a vitally, critically important task. However, technological breakthroughs in science and medicine, no matter how breathtaking or spectacular, will never fully resolve the enormous spectrum of challenges encountered by people with cancer.

And in a similar vein, as valuable as they are—undoubtedly valuable—neither will diets, herbs, vitamins, antioxidants, exercise programs or other similar regimens. Focusing primarily on treating the physical body ignores the profoundly important mental, emotional, and spiritual dimensions of this disease, and it also ignores the important inner healing potential that lies within all of us.

Thus, as radical as it may seem, I have one simple message that I would like to bring to this committee. I believe it is time for our medical and health care system to make a firm, uncompromising, and unwavering commitment to honor and embrace every single dimension of who we all are as human beings, particularly in the care of people with cancer. At our cancer center in Florida, we have implemented a unique program which, along with high-tech conventional medical cancer treatments, is designed explicitly to accomplish this very goal. The program, which has seven levels, addresses each and every aspect of the healing process that patients encounter on the journey through cancer.

Very briefly, the seven levels are as follows: First is education and information, which is designed to give patients answers to the urgent, pressing questions which they have about their disease and treatment options.

Next is psychosocial support, which focuses on the need and benefits of having a strong support network on the journey through cancer as well as the journey through life.

Third is what we call the body as garden, which encourages patients to think of their body as a garden that can be cultivated and nurtured rather than as a machine that is simply to be fixed by the doctor. This level of the program is where we also explore the vast array of alternative and complementary therapies which can definitely help facilitate this process.

The fourth level of the program is called emotional healing, and here we help patients and family members deal with the difficult and at times overwhelming emotional challenges encountered on the journey through cancer.

Fifth is the nature of mind, which helps patients gain an understanding of how their own thoughts and beliefs, and the meaning they give to events, including cancer, profoundly influences their day-to-day experience of life and their treatment process.

Sixth is life assessment, which helps patients understand and connect more deeply to their life's deepest meaning and purpose and to their most important goals and priorities for the coming year.

And last, No. 7, is the nature of spirit, which teaches patients to connect with the nonphysical, timeless, dimensionless, and profoundly healing spiritual aspect of life that we all share.

Years and years of experience have proven to me that these are the seven areas of care that all patients need, in addition to the very best that high-tech conventional medicine has to offer. I believe that our challenge and our opportunity is to find a way to make them available to every man, woman, and child in America who has cancer. Thank you.

[The prepared statement of Dr. Geffen follows:]

United States House of Representatives

Committee on Government Reform

Hearing: Fighting Prostate Cancer:
Are We Doing Our Best?

September 23, 1999

Testimony of:

Jeremy R. Geffen, MD, FACP
Geffen Cancer Center and Research Institute
Vero Beach, Florida

Good morning.

I am honored and privileged to be here today, and to have the opportunity to speak with you about a subject that I care deeply about; namely, the journey through cancer in general, and prostate cancer specifically.

Like so many others, I have been touched by this disease in many ways, including through members of my own family. I spent fourteen years studying and training to become a medical oncologist at some of the finest universities and medical centers in the United States, and have also been fortunate to have studied medical and spiritual traditions in other parts of the world. For the past ten years I have also had the privilege of serving as physician, guide, mentor, coach, and friend to thousands of cancer patients and their family members, many of whom were dealing with the often formidable challenges associated with prostate cancer.

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> ***Cancer often challenges the mind, heart, and spirit of patients and their family members as deeply—if not more deeply—than it challenges the physical body.***

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The urgent drive to eradicate illness has caused western medicine—which we are richly blessed to have—to focus almost exclusively on the *physical* dimensions of disease, rather than on caring for the *whole person who has the disease*. And this is especially true in the field of oncology.

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Make no mistake: aggressively pursuing all avenues of research in early diagnosis, prevention and treatment of cancer is a vitally important task. However, technological breakthroughs in science and medicine, no matter how breathtaking or spectacular, will never fully resolve the enormous spectrum of challenges encountered by people with cancer. And, as valuable as they are, neither will diets, herbs, vitamins, antioxidants, exercise programs, and other similar regimens. Focusing primarily on treating the physical body ignores the profoundly important mental, emotional, and spiritual dimensions of this disease, and it also ignores the important inner healing potential that lies within all of us.

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2. Psychosocial Support, which focuses on the need and benefits of having a strong support network on the journey through cancer, as well as the journey through life;
3. The Body as Garden, which encourages patients to think of their body as a garden that can be cultivated and nurtured, rather than as a machine that is simply to be "fixed" by the doctor. This level of the program also explores the vast array of alternative and complementary therapies which can help facilitate this process;
4. Emotional Healing, which helps patients and family members deal with the difficult and at times overwhelming emotional challenges encountered on the journey through cancer;
5. The Nature of Mind, which helps patients gain an understanding of how their thoughts and beliefs, and the *meaning* they give to events, including cancer, profoundly influences their day to day experience of life, and their treatment process;
6. Life Assessment, which helps patients understand and connect more deeply to their life's deepest meaning and purpose, and to their most important goals and priorities for the coming year; and
7. The Nature of Spirit, which teaches patients to connect with the non-physical, timeless, dimensionless, and profoundly healing spiritual aspect of life that we all share.

Years of experience have proven to me that these are the seven areas of care that all patients need—in addition to the very best that high-tech, conventional medicine has to offer. Our challenge, and our opportunity, is to find a way to make them available to every man, woman and child in America who has cancer.

Thank you.

Mr. BURTON. Thank you, Doctor. We will take a look at your book. I presume what you just talked about is in your book.

Dr. GEFFEN. That is right.

Mr. BURTON. Hopefully it will help give us a more in-depth understanding of how to deal with it. My mom and dad died of cancer last October and November, and my wife has had breast cancer for 5 years, so this is the kind of literature that we have in the house all the time.

Dr. Kail, would you like to go next, sir?

Dr. KAIL. I want to thank Chairman Burton and the members of the committee for holding this hearing on one of the leading forms of cancer affecting U.S. males. I am a licensed naturopathic physician and a physician's assistant.

Mr. BURTON. Doctor, this is going to be for the record and it will be disseminated to the Congress. So we need you to talk straight into the microphone.

Dr. KAIL. I have a private practice in Phoenix, AZ, and serve as the chairman of the board of the Southwest College of Naturopathic Medicine and Health Sciences. I am here as a representative of the American Association of Naturopathic Physicians. I formerly was on their board of directors and I participate in several other alternative medicine organizations. I am currently a naturopathic physician representative to the advisory council of the newly created NIH Center for Complementary and Alternative Medicine, and I am serving as the first NCCAM advisory council liaison to the National Institutes of Health advisory panel as well.

I attended the last NCAP meeting and was pleasantly surprised at the high level of interest among conventional cancer specialists with alternative medical therapies. Admittedly, they had little knowledge about how they worked, but they were interested in the outcomes that they were observing.

I hope that this will eventually become part of the day-to-day course of medical events, but as of this reading, most alternative treatments are not even considered as an option in looking at the list of medical events that can happen in regard to this.

My written statement refers to several things: The similarities and differences in the training of naturopathic and allopathic physicians, the medical philosophy that is different and why that creates barriers to integrating this into care, and we are also going to talk about some of the things you can do to deal with prostate cancers and what we can do to get by the barriers to care.

I had some slides prepared. This first slide looks at some of the differences in training as far as specifics and some of the softer areas of clinical science that we have specific education in.

Next slide.

The next slide shows more equivalence of our education. If you look at the top three schools, they are all naturopathic colleges and the bottom three schools are well-known medical universities. The main information here is that our total number of hours is basically the same in basic sciences and clinical sciences. You can see that in allopathic medical sciences we are just a little bit short and of course the naturopathic medical sciences, if you will, don't show any representation at all in the allopathic venues.

Next slide.

This is even a bigger discrepancy when you look at some of the things that were allowed to counseling and therapeutic nutrition. The other differences that come other than our education involve philosophy and the types of therapeutics. Natural therapeutic modalities include five basic types: Nutrition, botanical medicine, energy medicine, physical medicine, psychological medicine, and minor surgeries, which sometimes includes home birthing. And in some jurisdictions, naturopathic physicians can write prescriptions and dispense medications as well.

As to our philosophy, the next slide please, one of the concepts that we hold as naturopathic physicians is the concept of the vital force, that each person has in them a force that innately tries to optimize conditioning and functioning. We view health as more than the absence of disease but a balance of a variety of forces moving toward the optimal condition.

Next slide.

Toxification is one factor that opposes this natural inclination toward optimal. Toxification is the concept that dysfunction of metabolic processes to detoxify internally generated or ingested xenobiotics is a progenitor and aggravator of disease and this is an event that can be measured. Internal cleansing via detoxification protocols to simulate liver and other organ functions result in a lower level of internal toxic burning and hence facilitate healing.

Next slide, please.

There are basic tenets of care that are shared by most healing traditions. The healthy lifestyle and treating the whole person in the context of their environment are the things that might be unique to us.

Next slide.

Naturopathic health care services are focused in a different area. Our fortes are treatment of preclinical disease and chronic disease management.

Next slide, please.

Diagnosis is around health risks, tissue function, and finally gets to pathology. But we think it is very important if you want to look at prevention that you look at the things that precede disease. Your risk goes up; your function goes down.

Next slide.

Outcomes are based—hopefully, therapeutics are based on outcomes. We review the medical literature. We develop the protocol. We track our outcomes. We refine the protocol.

Next slide.

Studies have shown potential savings could be great. And this is looking at naturopathic patients who were 50 percent lower or discontinue conventional medication; 16 percent forgo a surgery procedure, 96 percent get educated well at home, and 92 percent as a result of that change their lifestyle.

Next slide, please.

If you look at likelihood of use of therapies when conventional therapies fail, of course supplements and diet lead the pack, but increase likelihood when other things fail.

Epidemiology, there are a couple of points on here that are important. First, that 80 percent of cancers are slow growing and 20

percent of prostate enlargement is cancer. The rest of the demographics you are familiar with.

Next slide.

If you look between 1983 and 1991, new cases increased dramatically. But if you look at deaths due to cancer and percentage of deaths, they are actually modest increases and actually decrease in percentage of deaths. This reflects earlier intervention due to better diagnosis. This is the result of people getting those PSA tests out there.

Next slide.

This is probably the most dramatic slide I can show you, and that is that this cries for conservative treatment. In one study that is treated here only 8.5 percent of the people followed for over 10 years died from their cancer, 47 percent of those people died from other causes. The survival rate was 86.8 percent with no treatment at all compared to survival rates of 65 and 83 percent with irradiation and prostatectomy. The mean survival time of 10 years was found in 85 to 90 percent of the patients involved. This cries for conservative treatment.

Next slide.

Some basic approaches that are different between allopathic and alternative medicine. Allopathic medicine with regards to cancer focuses on decreasing the cancer mass while alternative methods focuses on increasing host survival. Allopathic usually are single modality. There are some multimodality uses, but by and large all alternatives are multimodality. The agents are noninvasive and conventional agents reduce host defenses where CAM agents build them. The best I can say is that the best outcomes are an integration of both.

If we can go through the next slide quickly. If you look at utilization of therapies, chronic conditions basically are treated better by alternative medicine than possibly conventional medicine. If you go to the next slide you will see efficacy. With cancer in particular, you find that alternative methods are on a par with conventional methods. In other words, alternative treatment alone doesn't do any better than conventional treatment alone. It is when you do both together that you get a synergistic effect and actually do better.

Next slide.

Primary cancer therapy for alternatives is avoidance xeno biotics, lifestyle modification, detoxification, energy balancing, optimizing function, relaxation, and visualization.

Secondary therapies include antioxidants, immune modulation, endocrine modulation, and specific therapy as to tissue types.

Next slide.

Nutrition is a big part of that. This is also part of prevention as well as treatment. There are several things listed there that are very useful. The big ones of course are modified citrus pectin seems to prevent metastases, and IV vitamin C seems to be very promising.

Botanical medicines have specific indications for treating prostate cancer. They either block estrogen or follow stimulating hormone or somehow have a direct effect.

Next slide.

There are a whole bunch of other agents that have indirect effects, or are more suited for specific treatment of symptoms.

Next slide, please.

There are also other therapies that are less formal and secondary that are also very usual. As you can see there is a wide variety. Homeopathic medicine is very noninvasive and we have reviewed some cases at the NIH which are very dramatic in homeopathic response to cancers. Dendritic cell therapy and some others are very important.

Next slide.

Basically our modalities are inexpensive, they are easily managed at home, they have less side effects, and do result in better outcome than conventional medicine, and they do result in better quality of life for patients that have them.

Next slide.

Barriers to integration. There are two big barriers. One is 46 percent of HMOs actively discourage patients from using alternatives. This makes it real hard for people to go see a doctor of their own. Another big barrier that is not stated here is Federal policy and this has to do with entitlements. If you are not entitled—if you look at the language of entitlement of virtually every Federal program, there is no language that enables alternative participation.

Other barriers to integration—next slide. This has to do with the practitioners in the allopathic community. There is lack of information about training of the providers in the alternative community. There is lack of information about alternative therapeutic modalities. There is lack of information about interaction with allopathic therapeutics. And in general there is a fear of liability with conventional physicians comanaging patients with alternative physicians.

Part of this is due to the training that they receive. The next slide please. You will see that a survey that I did of conventional medical colleges that were training in alternative methods we found that out of 26 schools we surveyed, 9 responded. But as you can see the quality of the courses here were less than desirable. They are basically survey courses. There is no place where conventional physicians can get formal information that is quality information about alternative modalities without going to school.

Some things to facilitate integration. I will be brief. This is my last slide. Public demand for CAM health care services is forcing these things. The public is driving this boat. I think that is why we are all sitting here. Inclusion of CAM providers into third-party reimbursed multispecialty care networks forces communication. I am in many of these. I have to communicate with the primary care doctors as part of my consultation, and as a result of that, we are getting to know each other and we trust each other's therapeutics more and we interact more for the benefit of the patient.

Integration training. There is a leg that can be done on both sides of the fence to help people understand each other better. The NIH, of course, National Center for Complementary and Alternative Medicine is a big step forward; however I want to put this in context. Even though their funding went from approximately $19 million to $50 million last year it still represents only one-third of 1 percent of the total NIH budget. I think that is a very dramatic place to state where alternative medicine is in the conven-

tional community, certainly within the research community. It is the smallest, tiniest little consideration out there. I think if you look at the Federal Government in general that reflect business, the same attitude.

Potential cost savings is so great, and the plan for integration is so necessary, that there are several alternative medicine organizations that have been working on a national plan to address the Federal public policy issues in regards to this. I have a copy of the plan that has been put together by these organizations here with me. I would like to see it entered into the record. I would also ask that you and other members of the committee or committee staff review the document and submit comments, criticisms, and suggestions for improvement to the organizations who are leading this effort.

I think if you read this, the magnitude of this document will suggest there are some very solid and good ways without a lot of funding, with just entitlement and other things, that we can do to greatly accelerate this process of integration which I believe again shows the best outcomes for all those concerned. I thank the committee for your time.

[The prepared statement of Dr. Kail follows:]

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

Government Reform Committee
United States House of Representatives
September 23, 1999

Fighting Prostate Cancer: Are We Doing Enough ?

Statement of Dr. Konrad Kail, N.D.,PA-C

I want to thank Chairman Burton and the other members of the Government Reform Committee for holding this hearing on one of the leading forms of cancers affecting US males, and the roles of allopathic and naturopathic medical therapies for the prevention and treatment of prostate cancer.

I am a licensed Naturopathic Physician and Physician's Assistant and have been in active clinical practice for over 15 years. I am co-owner of Naturopathic Family Care, Inc., in Phoenix, Arizona and serve on the Board of Directors of the Southwest College of Naturopathic Medicine. I am here as a representative of the American Association of Naturopathic Physicians (AANP). I formerly served on the Board of Directors of the AANP. I also currently serve as a naturopathic physician representative on the Advisory Council for the newly created NIH Center for Complementary and Alternative Medicine, and am serving as the first NCCAM Advisory Council liaison to the NIH National Cancer Advisory Panel (NCAP). I attended the latest NCAP meeting and was pleasantly surprised with the high level of professional interest among conventional cancer specialists with alternative medical therapies for the treatment of cancers. Hopefully, this top level of professional interest in complementary and alternative medical therapies for the prevention and treatment of all cancers, and for prostate cancer, will eventually be effectively integrated into the to the day-to-day course of medical care throughout the United States.

Naturopathic physicians can play an active role in the treatment of prostate cancer. The rest of my written statement presents information which addresses (1) the similarities and differences in the training of naturopathic and allopathic medical doctors; (2) the medical philosophy of naturopathic physicians in the treatment of prostate cancer; (3) the scientific studies on naturopathic therapies for treatment of prostate cancers; and, (4) the integration and the barriers to integration of allopathic oncology and naturopathic medical therapies and practices that give rise to today's hearing on whether we are doing enough in the fight against prostate cancer. I will now orally summarize this information for you and the members of the committee.

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NATUROPATHIC MEDICINE AND PROSTATE CANCER

INTEGRATING WITH ALLOPATHIC MEDICINE

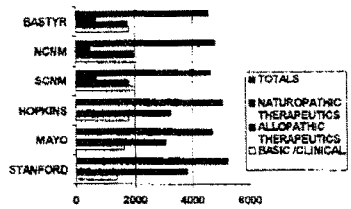
TESTIMONY BEFORE THE HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT
9/23/99

KONRAD KAIL, N.D., PA-C.

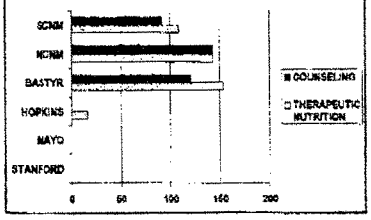
Naturopathic Physicians

- Specific Training in Preventive Medicine
  - Health Risk Analysis, Tissue Function Evaluation, Health Maintenance
- Specific Training in a variety of Natural Therapeutics
- Specific Training in Lifestyle Modification
- Specific Training in Patient Education and Motivation

MEDICAL SCHOOL CURRICULA COMPARISON (CLASS ROOM HOURS)



COUNSELING AND THERAPEUTIC NUTRITION (CLASS ROOM HOURS)



THE VITAL FORCE

This describes the energy essential for life, the innate life principle, or the inherent power within every living organism.

Naturopathic Doctors seek to support the vital force

PHILOSOPHY

- Health is normal and harmonious vibration of the elements and forces composing the human entity on the physical, mental, and moral planes of being, in conformity with the constructive principle in nature applied to individual life--Lindlahr, Philosophy of Natural Therapeutics

DETOXIFICATION

- The concept that dysfunction of metabolic processes to detoxify internally generated or ingested xenobiotics is a progenitor and aggravator of disease and can be measured.
- Internal cleansing via detoxification protocols to stimulate liver and other organ functions results in a lower level of internal toxic burden and hence facilitates healing.

TENETS OF CARE

- HEALING POWER OF NATURE
- DO NO HARM
- TREAT THE CAUSE
- TREAT THE WHOLE PERSON
- TEACH HEALTHY LIFESTYLE

Naturopathic Healthcare Services

- Diagnosis and Treatment of **Pre-Clinical Disease** and **Chronic Disease** Management are emphasized
- Based on **Risk Analysis** and **Organ Function Evaluation**
- Less Expensive, Less Invasive, More Natural Therapeutics
- Requires Education and Motivation of the Patient

DIAGNOSIS

- HEALTH RISK
- TISSUE FUNCTION
- PATHOLOGY

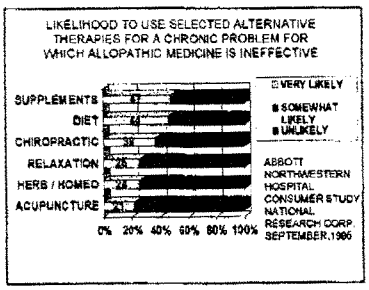
OUTCOMES BASED THERAPEUTICS

- REVIEW MEDICAL LITERATURE
- DEVELOP THERAPEUTIC PROTOCOL
- IMPLEMENT PROTOCOL IN PATIENT CARE
- TRACK OUTCOMES
- MODIFY PROTOCOL BASED ON OUTCOMES

POTENTIAL COST SAVINGS IN NATUROPATHIC CARE

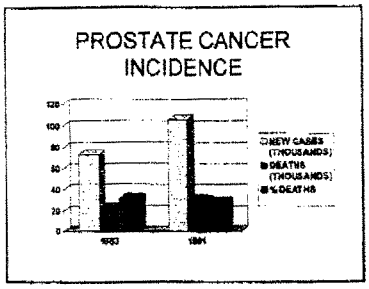
- LOWERED OR DISCONTINUED CONVENTIONAL Rx 49%
- FORGONE SURGERY OR PROCEDURE 16%
- HOMECARE EDUCATION GOOD-EXCELLENT 96%
- EFFECT ON LIFESTYLE GOOD-EXCELLENT 92%

• NATUROPATHIC PATIENT SURVEY PILOT PIHCP, JOHN WEEKS, 1996



PROSTATE CANCER EPIDEMIOLOGY

- 20% OF PROSTATE ENLARGEMENT IS CANCER
- MOST COMMON CANCER IN MALES
- 21% OF ALL CANCERS DIAGNOSED
- >50% OF MALES > 70 YRS.
- RARE IN ORIENTALS
- PREVALENT IN BLACKS
- 80% OF CANCERS ARE SLOW GROWING
- 30,000 DEATHS/YR.



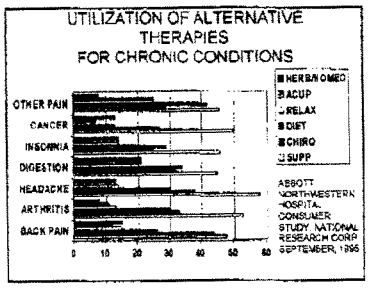
CONSERVATIVE TREATMENT

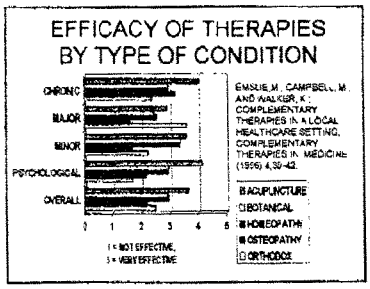
- 223 PATIENTS WITH CAP FOLLOWED FOR 10 YEARS
- ONLY TREATED IF SYMPTOMS OR EVIDENCE OF AGGRESSIVE GROWTH
- 8.5% DIED FROM CAP. 47% DIE FROM OTHER CAUSES
- SURVIVAL RATE 86.8% WITH NO TREATMENT COMPARED TO 65%-83% WITH IRRADIATION AND PROSTATECTOMY
- MEAN SURVIVAL TIME OF 10 YEARS FOUND IN 85% TO 90%

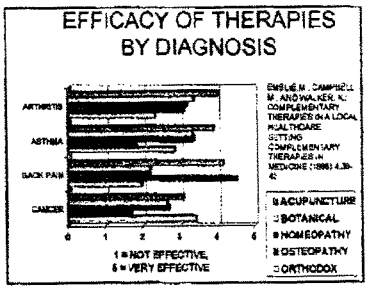
COMPARISON OF APPROACHES TO TREATMENT

ALLOPATHIC	CAM
• FOCUSED ON DECREASING CANCER MASS	• FOCUSED ON INCREASING HOST SURVIVAL
• SINGLE MODALITY USE	• MULTI-MODALITY USE
• AGENTS ARE INVASIVE	• AGENTS ARE NON-INVASIVE
• AGENTS REDUCE HOST DEFENSES	• AGENTS ARE RELATIVELY NON-TOXIC AND BUILD IMMUNE RESPONSE

The best outcomes are achieved using an integration of both approaches!







PRIMARY CANCER THERAPY

- AVOIDANCE OF XENOBIOTICS
- LIFESTYLE MODIFICATION
- DETOXIFICATION
- ENERGY BALANCING
- OPTIMIZING FUNCTION
- RELAXATION / VISUALIZATION

SECONDARY CANCER THERAPY

- ANTIOXIDATION
- IMMUNE MODULATION
- ENDOCRINE MODULATION
- SPECIFIC THERAPY AS TO TISSUE TYPE

NUTRITION

- HIGH PROTEIN AND VEGETABLES
- VERY LOW FAT (<25 GRAMS/DAY)
- AVOID LECTINS FOR SEROTYPES
- FRESH GARLIC (10 TIMES MORE POTENT THAN CAPSULES)
- OMEGA 3 AND 6 FATS
  - FISH AND FLAX (OMEGA 3)
  - EVENING PRIMROSE OIL, BLACK CURRANT OIL, BORAGE OIL (OMEGA 6)
- MODIFIED CITRUS PECTIN (PREVENTS METASTASES)
- ANTIOXIDANT VITAMINS
  - VITAMIN C
  - VITAMIN E
  - BETA CAROTENE

BOTANICAL MEDICINES

- SERENOA (SAW PALMETTO) AND PYGEUM AFRICANUS
  - BLOCK ESTROGEN AND PROGESTERONE
  - INHIBIT ANDROGEN BINDING
- LITHOSPERMA (STONE SEED)
  - BLOCKS GONADOTROPIC HORMONE
  - DECREASES FOLLICLE STIMULATING HORMONE (FSH)
- FENUGREEK AND VITEX AGNUS CASTUS
  - DECREASE FSH AND ESTROGEN
- URTICA DIOICA
  - BINDS LECTINS

LESS SPECIFIC BOTANICAL MEDICINES

- HOXSEY FORMULA
- PHYTOLACCA DECANDRA (POKEWEED)
- VINCA ROSA (PERIWINKLE)
- VISCUM ALBUM (MISTLETOE)
- COLCHICUN AUTUMNALE
- CONIUM MACULATUM
- BERBERIS AQUAFOLIUM(OREGON GRAPE)
- ECHINACEA ANGUSTIFOLIA
- DIGITALIS PURPUREA
- ARCTIUM LAPPA (BURDOCK)

OTHER THERAPIES

- RELAXATION, VISUALIZATION
- HYDROTHERAPY
- HOMEOPATHIC MEDICINE
- ACUPUNCTURE
- BCG AND STAPHAGE LYSATE
  - THYMUS
  - ELEUTHROCOCCUS SENTICOUS (SIBERIAN GINSENG)
- GALVANIC CURRENT
- INVESTIGATIONAL THERAPIES

NATUROPATHIC TREATMENT MODALITIES

- EFFECTIVE
- COST LESS
- NON-INVASIVE
- EASILY MANAGED AT HOME
- LESS SIDE EFFECTS
- ENHANCE BIOCHEMISTRY AND PHYSIOLOGY
- ENHANCE CONVENTIONAL THERAPEUTICS

BARRIERS TO INTEGRATION

- 46% OF HMO'S ACTIVELY DISCOURAGE PATIENTS FROM USING ONE OR MORE ALTERNATIVE THERAPIES
- 31% DISCOURAGE HERBAL MEDICINE
- 24% DISCOURAGE HYPNOSIS AND ACUPUNCTURE
- 14% DISCOURAGE MENTAL IMAGERY
- 7% DISCOURAGE CHIROPRACTIC AND WEIGHT LOSS PROGRAMS
- 3% DISCOURAGE RELAXATION THERAPY

Decision Resources report, "Self Treatment in Managed Care. HMO Involvement in CTC and Alternative Therapies," March/April, 1997

BARRIERS TO INTEGRATION

- LACK OF INFORMATION ABOUT TRAINING OF PROVIDERS
- LACK OF INFORMATION ABOUT THERAPEUTIC MODALITIES
- LACK OF INFORMATION ABOUT INTERACTIONS WITH ALLOPATHIC THERAPEUTICS
- FEAR OF LIABILITY

ALTERNATIVE MEDICAL TRAINING IN ALLOPATHIC MEDICAL SCHOOLS

- 9 RESPONSES OUT OF 26 MEDICAL SCHOOLS SURVEYED
- 9/9 COURSES ELECTIVE (10-80 HRS.)
- 4/9 HAD INSTRUCTORS WHO CLAIMED TO PRACTICE THE MODALITY
- 3/9 TAUGHT A MAJOR ALTERNATIVE MODALITY
- 2/9 HAD INSTRUCTORS WITH A STANDARDIZED CREDENTIAL
- 1/9 OFFERED SOME CERTIFICATION

INTEGRATION FACILITATORS

- PUBLIC DEMAND FOR CAM HEALTHCARE SERVICES
- INCLUSION OF CAM PROVIDERS INTO THIRD PARTY REIMBURSED MULTISPECIALTY CARE NETWORKS
- INTEGRATION TRAINING
- NIH NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE (NCCAM)
- NATIONAL PLAN FOR INTEGRATION

Kruzel, Tom, Protocol Journal of Botanical Medicine; Vol. 2, no. 3, Pgs. 176-183.

Cancer of the Prostate - A Naturopathic Perspective

The prostate gland acts as the male genitourinary systems first line of defense against infection as well as in the packaging and delivery of sperm. The gland is composed of fibromuscular and glandular tissue, is approximately the size of a chestnut and lies between the bladder and external urethra, anterior to the rectum. The urethra, the conduit through which the urine flows, passes through the prostate gland at the portion closest to the bladder outlet. It is at this point where the ejaculatory ducts enter the urethra for the packaging of sperm prior to ejaculation. The prostate gland is composed of four parts. The peripheral zone, the central zone, a transitional zone which is near the opening for the ejaculatory ducts and the periurethral zone or that portion which lies adjacent to the urethra.

The prostate secretes a thin, milky white fluid both prior to and following ejaculation. This fluid is high in citric acid, calcium, acid phosphatase and zinc and acts to sterilize the urethra as well as provide nutrients for the spermatozoa. The ejaculate also contains fructose which acts as a nutrient for sperm, prostaglandin's, phosphorylcholine, fibrinogen and coagulating substances.

Enlargement of the prostate gland is caused by an abnormal over-growth or swelling of tissue, termed hyperplasia. When this occurs a blocking of the urethra or opening from the bladder takes place. This will happen regardless of whether the growth is associated with benign prostatic hypertrophy (BPH), prostatitis or cancer. Additionally, because of the close proximity of the bladder sphincter to the prostate, symptoms of frequency and urgency to urinate will occur due to prostatic irritation. Because nodular hyperplasia associated with BPH or prostatitis takes place primarily in the region surrounding the urethra, urinary obstruction can occur with little overall glandular enlargement. On the other hand, if the urethral obstruction occurs due to enlargement of the peripheral regions, a significant amount of abnormal tissue must be present in order for the symptoms of urinary obstruction to occur. Most prostate cancers arise in the peripheral zone away from the urethra and therefore symptoms of urinary obstruction develop later on. If the symptoms of obstruction are due to cancer of the prostate (CAP) it generally means that there is a significant amount present. Symptoms most often encountered will be a painless hematuria or irregular urination (dysuria) due to obstruction. Pyuria, or white blood cells in the urine, may also be present if there is an infection.

Cancer of the prostate is responsible for upwards of 30,000 deaths every year in the United States. It is the most commonly found cancer in males over 50 years of age

and is the most common cancer afflicting men, accounting for 21% of all cancers diagnosed. The incidence of cancer of the prostate increases until greater than 50 % of men over age 70 years will have some histologic evidence of prostate cancer. Only about a third of these cancers become clinically manifest in this age group. In 1983 there were 73,000 new cases of CAP and 23,300 deaths reported from this disease. The number of new cases jumped to 106,000 in 1991 with a reported 30,000 deaths for this period. While the total number of CAP cases increased by 33,000, the percentage of those dying from CAP decreased from 31.9% in 1983 to 28.3% by 1991. The continued decrease in the percentage of deaths due to CAP probably reflects the results of careful screening and early intervention.

Prostate cancer is extremely rare in Orientals and very prevalent in blacks, especially those who live in the United States. A correlation with environment has been noted in that men from cultures with low incidences of CAP show higher incidences of prostate cancer if they move to the United States.

Approximately 20% of all prostate enlargements are the result of cancer. About 80% of these cancers are of the slow growing variety, do not metastasize readily and often cause little if any problem. A smaller percentage of these cancers may spread quickly depending upon the type and location of the lesion. Prostatic cancer arises primarily in the peripheral zone, that area which is most affected by the male hormone testosterone. In conventional medicine it is felt that most prostate cancers will metastasize given enough time and no treatment, with dissemination occurring through the lymphatics and bloodstream. The primary area of metastases is to the bones, especially those of the lumbar vertebrae and lymph nodes of the pelvis. Spread to the abdominal viscera is rare.

Pre-cancerous lesions

A study reported to the American Urological Association showed the incidence of pre cancerous prostate gland lesions range from 22% to 41% in males between the ages of 30 and 49 years with the percentages increasing with age. Another study conducted in England supports these findings. These statistics suggest that pre-cancerous lesions of the prostate are more prevalent than previously thought.

Until recently it has been assumed that pre-cancerous lesions would become clinically significant with time, leading to the development of CAP and higher morbidity and mortality. There is still some uncertainty however, as to the natural history of the development of cancer of the prostate from the atypical hyperplasia commonly found in a significant percentage of men. Some of the difficulties in establishing the diagnosis of

prostatic cancer are encountered with lesions such as prostatic intraepithelial neoplasia (PIN) and small acinar lesions or atypical adenomatous hyperplasia (AAH). While these particular lesions are more often found with CAP, finding them does not always mean that CAP will develop. Atrophy associated with an aging prostate gland is commonly encountered and often mistaken for CAP. This is especially true following needle biopsy used to establish the diagnosis, as this form of sampling may not provide enough material for full evaluation. Variants of prostatic hyperplasia such as acinar hyperplasia, basal cell hyperplasia, and cribiform hyperplasia occur frequently, and may be misinterpreted as CAP. Additionally, nonspecific granulomatous prostatitis, the most common form of prostatitis, can mimic CAP in a large percentage of cases.

In part due to these findings some discussion as to the significance of pre-malignant lesions has ensued. Elevated serum Prostatic Specific Antigen (PSA) levels have been associated with prostatic intraepithelial neoplasia (PIN) as well as prostatitis and BPH. As the natural history of PIN has not been fully determined, it is not known if this lesion is a precursor to CAP or if it will regress with proper treatment. PIN satisfies several criteria for classification as a pre malignant lesion and is more often than not seen along with or just prior to development of carcinoma of the prostate. These lesions are also found to be more prevalent in the peripheral zone, the area where CAP usually arises.

Another view can be taken that the prostate gland is a dynamically functioning organ which is responsive to the environment in which it exists. An example would be its response to infection during which there is an intense tissue inflammatory reaction resulting in hyperplasia and destruction as well as a proliferation of white blood cells, often appearing similar to CAP. Upon resolution of the infection a normalization of tissue and function usually occurs. Secondly, while it has been supposed that pre-malignant lesions would turn cancerous, the larger number of these lesions found in younger age groups suggests that this is either a normal variation or part of the dynamic of tissue growth and proliferation and cellular death. In other words, the prostate gland goes through changes similar to any other organ system and has the ability to repair and normalize function.

Pre-cancerous lesions may therefore present a problem diagnostically. They may predispose the patient to the development of CAP, but also may represent a stage in the natural history of the gland, and with proper treatment, revert to a more normal tissue. Second opinions therefore are recommended for someone presented with a diagnosis of CAP or a pre-cancerous finding on biopsy.

While the number of cases of prostate cancer has risen dramatically over the past 10 years the percentage of deaths compared to new cases has dropped. In part, the

increase in the number of new cases is explained by the advent of newer diagnostic techniques such as serum Prostatic Specific Antigen, transrectal ultrasound and needle biopsy. Additionally, an increased physician and public awareness has also lead to earlier screening and detection of cancerous lesions which would otherwise have gone undetected until later in the course of the disease.

CAP Staging

There are generally 4 stages of classification of prostate cancer, each with sub grading. These are used to differentiate the lesion further and to aid in determining the prognosis and potential for metastasis. A further system of grading tumors frequently used is the Gleason system. A Gleason score of 2 to 10 is employed in order to aid in predicting the tumors metastatic potential. The higher the score, the greater liklihood of metastasis.

Stage A tumors are confined to the prostate gland. These are often not palpable on rectal exam and are usually an incidental finding on biopsy or surgery for BPH. They can be further classified into lesions which are localized or diffuse throughout the gland. Tumors of at least stage A2 must be present in order for the serum PSA to be elevated.

Stage B tumors are also confined to the prostate gland but are palpable on rectal exam. Often these lesions are visible with ultrasound examination. Tumors which lie near the apex or base of the gland have a greater likelihood of metastases. This is due to their close proximity to the prostate capsule and the weakness in these regions.

Stage C tumors have left the confines of the prostate gland and have invaded the soft tissues which surround it. Tumor spread involves the seminal vesicles, bladder neck, urethral muscle or surrounding fatty tissue in the absence of treatment. Spread to these regions is often followed by a more distant metastases within 5 years.

Stage D tumors have invaded the pelvic lymph nodes which are abundant around the prostate gland, as well as the bones in the lumbosacral region. This means that distant metastases has occurred and eventually the cancer will show up in other areas of the body. This form of metastases is the most common.

Causes of CAP

As with other cancers, the precise cause of carcinoma of the prostate is unknown. A number of epidemiological factors have been noted which are thought to contribute to a higher incidence of prostatic cancer. The persons age, race, endocrine system, diet and environment all play a role in development of cancer of the prostate, but it is usually a combination of several or all of these which contribute to its development.

The predisposing factors, as well as the course of the disease, will vary from person to person.

Age

The risk of prostate cancer increases steadily after age 40 until a peak incidence is reached about age 80. Pre-malignant changes seen in younger men often do not become apparent until much later in life, thus contributing to the increasing incidence seen with aging. As there are a number of factors involved with the development of CAP, aging alone does not necessarily mean that one will develop the disease.

Hormones

Hormone levels certainly influence the course of cancer once it has become established, and is also thought to be involved in its origin. The higher incidences of cancer found as the male population ages is related to the changes in the levels of testosterone, dihydrotestosterone and estrogen that normally accompany aging. In eunuchs a very low incidence of prostate cancer is found, due to the almost total absence of testosterone.

While serum testosterone levels decline with age, they remain high within the prostate gland, suggesting an intracellularly controlled mechanism. Because of this a shift in the testosterone/dihydrotestosterone ratio occurs leading to an androgen imbalance. Under the action of the enzyme 5-alpha reductase, testosterone is converted to its more potent form dihydrotestosterone, which results in a higher rate of tissue proliferation. In patients with CAP, a reduction in androgen levels results in a decrease of tumor size which suggests a direct relationship between testosterone and tumor growth. However, a direct correlation between serum testosterone levels and tumor reduction is not always seen due to intracellular factors. Secondly, as testosterone levels decrease, the ratio of testosterone to estrogen increases which can contribute to the prostatic enlargement found with benign prostatic hypertrophy. Estrogen seems to have a more profound effect on the cells which line the prostatic urethra causing more growth. Estrogen also affects the prostate gland by suppressing the release of pituitary gonadotrophin releasing hormone (GRH), the hormone which stimulates the production of testosterone by the testicles and adrenal glands. Estrogens are used in treatment of prostatic cancer to lower testosterone levels with some success.

It has been suggested that hormonal factors may be affecting the prostate as early as puberty. Males who enter puberty later seem to have higher incidences of prostatic cancer. Further, prostatic cancer patients generally report greater levels of sexual activity than counterparts who do not have cancer.

Genetics

Genetic factors seem to play a role as there are higher incidences of CAP in some families than others, especially if there is a father or brother with the disease. An early onset of the disease, in males less than 55 years old, suggests that a familial predisposition is more likely. Black American males show a 50% higher incidence than whites. As of yet, a specific gene for predisposition to CAP has not been identified.

Diet

Populations with diets high in animal fats and refined sugar and lower in fiber and vegetable intake have much higher incidences of cancer of the prostate. High animal fat intakes, as well as with the development of obesity, has been shown to have one of the strongest associations with prostate cancer. Men from cultures traditionally with low incidences of CAP, who migrate to the United States, develop the cancer at rates comparable to those of their American counterparts. If however, they retain their native diets, the incidence does not increase as much. A number of epidemiological studies have shown, with all other contributing factors being equal, that diets high in fiber, fruits and vegetables result in a lower incidence of prostate as well as other cancers.

Environment

Environmental factors play a variety of roles in the development of CAP. Often it is several factors which contribute over a period of time, but some seem to play a greater role than others. It has been noted that there are higher rates of prostatic cancer in males who are exposed to chemical toxins. Occupations in industries such as petrochemical, rubber and textile are among the highest in number of CAP cases. Urban, as opposed to rural areas, have higher incidences of CAP which is felt to be due to air and other pollutants.

Cadmium has also been implicated in cancer of the prostate as a much higher incidence is found in men who work with batteries. Zinc is normally found in high concentrations in the prostate gland and will be displaced by cadmium.

While viruses are implicated in other types of cancers, a direct relationship with prostatic carcinoma has not been found. Viral particles have been found, however, in electron microscopic examination of cancerous prostatic tissue. A relationship between previous gonorrhea and Chlamydial infections and higher incidence of cancer have also been suggested. Usually these infections are frequent in occurrence, cause persistent symptomology or have been poorly treated resulting in chronic prostate problems.

Vasectomy

Several studies have suggested that men who have undergone vasectomy have increased risks of developing prostate as well as testicular cancer. The production of allosperm antibodies, which are formed following the procedure, has been proposed as a

mechanism for lowered immune response and the body's subsequent inability to destroy cancerous cells.

Other studies have not shown the same correlation and the matter remains unresolved.

Monitoring the Patient With CAP

The laboratory evaluation of CAP relies primarily on 2 tests, the Prostatic Specific Antigen [PSA] and the Prostatic Acid Phosphatase [PAP]. Ultrasound examination provides some information as to the location of the tumor and is sometimes helpful to evaluate its size following therapy. Neuroendocrine parameters found to be associated with other cancers are also being looked at in relation to CAP. Plasma chromogranin A, neurone-specific enolase, substance P, calcitonin, somatostatin, neurotensin and bombesin levels are being studied to determine if their levels may aid in early detection, evaluation and staging of CAP. To date they have shown little promise.

A review of cases where digital rectal exam and ultrasound screening were done concluded that they alone have not produced any significant decrease in CAP deaths in men over 70 years of age. Therefore a combination of different tests is used by physicians in order to evaluate the disease.

Prostatic specific antigen (PSA) is a glycoprotein which is particular to prostatic epithelial cells. Increases are found with prostate cancer, benign prostatic hypertrophy (BPH), prostatitis and prostatic interepithelial neoplasia. With BPH and prostatitis, levels will vary from one blood draw to the next, depending on the degree of involvement or level of inflammation. Additionally, age related changes in PSA values have been noted suggesting that different reference ranges be adopted depending upon the persons age.

A correlation between prostate tumor size (volume) and increase in serum PSA levels have been demonstrated in a number of studies. Tumor size greater than stage A1 in CAP is necessary to elevate PSA in most cases. In general, patients with increased PSA levels, without evidence of an enlarged prostate gland, should be suspected to have at least a grade A2 CAP. Prostatic specific antigen levels drop after prostatectomy or successful treatment of the cancer, prostatic hypertrophy or inflammation.

Prostatic specific antigen levels are not specific for CAP but are much more sensitive for prostate enlargement than acid phosphatase. Serum levels greater than 15 suggest a large tumor while those greater than 50 suggest an advanced cancer or metastases. Because of this the PSA has become a good screening test, along with digital rectal examination, for prostate gland abnormalities, as well as for following the course of therapy.

Acid phosphatase is found primarily in the prostate gland, as well in smaller amounts in other tissues. Prostatic acid phosphatase (PAP) is produced by the epithelial cells and secreted into the glandular lumen. High amounts of PAP are found in seminal fluid.

A major limitation in the evaluation of prostate cancer is the ability to quantitate the extent and progression of the disease. Prostatic acid phosphatase, while more specific than prostatic specific antigen (PSA) for cancer of the prostate, isn't as sensitive and is only increased if the tumor is a stage C or greater with metastases. Therefore, PAP is not utilized as often by clinicians and not recommended as a screening test.

The value of PAP lies in its ability to help determine tumor staging, monitoring of therapy and prognosis. While the majority of CAP are slow growing, those that aren't tend to metastasize quickly, especially once outside the prostate capsule. In general, a persistent decrease by 50% from the mean PAP value is suggestive of a favorable response to treatment. A return to the reference range of the PAP also indicates a favorable response to treatment and a better prognosis. Patients who had a normalization of PAP after therapy had a significantly longer survival rate than those who did not.

Ultrasound examination is most often done to determine the location of the prostatic mass in order to obtain a more accurate biopsy. Occasionally it is useful in assessing treatment. It does not differentiate the type of tumor which is something only a biopsy can do.

Generally, I obtain a baseline PSA, Acid Phosphatase and serum testosterone level at the first visit in order to establish a base line. I may also obtain an Anti Malignin Antibody [AMA] if the patient has not had a biopsy of the prostate to obtain the diagnosis. The AMA helps to determine if the tumor is malignant and the patients level of immune response. The AMA can be monitored throughout the therapy to assess its efficacy. The PSA should be repeated at frequent intervals initially [every 2 to 3 months], then less so as the cancer is controlled. An initial increase in the PSA is not unusual before it starts to stabilize and decrease. The patient should be warned about this as an increasing PSA can cause much anxiety.

Treatments

Watchful Waiting

Depending upon which physician you consult, a variety of opinions and philosophies as to whether or not to treat the cancer aggressively will be found. Some physicians express the view that watchful waiting is the wrong approach in men younger than 65 because of the potential to metastases, while others do not share this view based

on statistical evidence and a lack of knowledge of the natural progression of CAP. Some physicians however, citing the decrease in mortality from CAP, and studies which suggest that no treatment is as effective as surgery, take the view that frequent screening is not needed and may in fact lead to needless diagnostic procedures and patient anxiety.

In older men it is felt that since a large percentage of them do not manifest symptoms of the disease, and the treatment causes higher morbidity and mortality, that CAP should be left untreated because they are more likely to die of other diseases long before the cancer manifests. In a number of studies there have been no significant differences in survival rates between patients treated with orchiectomy or estrogen therapy alone, or in combination with one another as compared to no treatment at all. In one study, 223 patients diagnosed with early stage CAP were followed for 10 years and examined by PSA and bone scan every 6 months for the first 2 years and yearly afterward. The patients were treated only if they developed symptoms of CAP or if evidence of aggressive tumor growth. After 10 years only 19 of the 223 patients (8.5%) died from CAP with 105 dying of other causes (47%). Those with localized tumors had a much better prognosis than those with poorly differentiated tumors or with metastases. The survival rate was 86.8% with no treatment compared to 65% to 83% for those who underwent irradiation or prostatectomy. This suggests that treatment may even have a negative effect on survival.

In several other studies done on men with well and moderately differentiated prostate cancers a mean survival time of 10 years was found in 85% to 90% . These statistics are common and are derived from populations which are receiving no therapy whatsoever, not even natural therapies.

A watchful waiting program, monitored by your physician, offers the opportunity to persue a natural medication program before having to resort to surgical or radiation therapy. If this is coupled with the use of diet and nutritional changes, the chances of having to undergo surgery diminish.

Herbal medicines:

Herbal medicines have long been a main stay in the treatment of cancer in general and in particular for prostate cancer. As a general rule, herbal medicines are not specific for the different types of tumors encountered but rather act as an overall immune system stimulant. (In contrast, chemotherapy, the "big gun" of conventional medicine has shown dismal results.) Certain herbal medications tend to have an affinity for particular tumor types and can also be selected based upon their specific indications.

Herbal medications perform a variety of functions when attacking cancerous tissue. They act to stimulate production and activation of both T & B cell systems of the

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Herbal medications perform a variety of functions when attacking cancerous tissue. They act to stimulate production and activation of both T & B cell systems of the

lymphocytic variety of white blood cells. Additionally, the different components contained in herbal preparations will adhere to the tumor cell surface making it easier for the lymphocytes to attach and destroy the cell. Certain components of herbal medicines will enter the tumor cell and disrupt its function making it more vulnerable to destruction by the immune system. Many chemotherapeutic agents such as vincristine and taxol are derivatives of botanical medicines. Lastly, botanical medicines have built in check and balance systems which make it less likely for them to become toxic and thus harmful to healthy tissues.

Specifically for cancer of the prostate, the components of the herb Serenoa serulatta/repens [Saw Palmetto] and Pygeum africanus are the mainstay of any herbal medicine program for cancer. Serenoa blocks the conversion of testosterone to its more potent form dihydrotestosterone by inhibiting the enzymes 5-alpha reductase and 3-ketosteroid reductase. This results in decreased swelling and thus increased blood flow to the prostate.

Additionally, Serenoa extract has been shown to reduce cholesterol levels within the prostate gland. This is of significance since higher levels of cholesterol are found in cancerous prostate glands than non-cancerous ones.

Serenoa (Saw Palmetto) has also been found to have antiestrogenic effects upon the prostate gland. Serenoa was found to lower the number of cytosol and nuclear receptors for both estrogen and progesterone. While there was no effect on the number of cytosol androgen receptor sites, following the use of Serenoa, a lower number were found on the nuclear membrane. Therefore it is concluded that Serenoa blocks estrogen and progesterone as well as competitively blocking androgen binding to the nuclear envelope.

Lithospermum, or stone seed, has been found to block gonadotrophic hormone and its effect on the anterior pituitary. It decreases follicle stimulating hormone [FSH] which is needed to increase estrogen and testosterone levels. Because these hormones are involved with tumor proliferation and prostatic enlargement, a reduction in PSA values are seen following administration of Lithospermum. Another commonly found herb, Fenugreek, also decreases FSH and estrogen levels. Vitex Agnus Castus, an herbal medication often used for women during menopause, decreases FSH and estrogen levels as well.

Urtica dioca has been used in the treatment of BPH with some success, especially in the early stages. It has now been shown that its' action on the prostate gland is by lectin binding, suggesting that Urtica may also be effective against prostate cancer, especially those confined to the periurethral and transitional zones.

Less specifically but equally important are the use of medicines such as Phytolacca decandra [Polk weed], Vinca rosa [Periwinkle], Viscum album [Mistle toe], Colchicum autumnale, Conium maculatum, Berberis aquifolium [Oregon Grape], Echinacea angustifolia, Digitalis purpuria and Arctium lappa [Burdock]. These, along with others, have been found to effectively treat cancer of the prostate and when used along with a holistically oriented program, have equal or improved survival rates over conventional therapy.

I will often use the Hoxsey formula as a base prescription to be taken 2 to 4 times daily in addition to the other botanical medicines I prescribe. Besides being an overall immune stimulator, it enhances lymph flow and helps with an overall detoxification of the body. Additionally, I put the person on an herbal anticoagulant formula if they are not taking modified citrus pectin as there is less likelihood of metastases in patients on anticoagulant therapy. If I am doing electrotherapy, I will use an additional formula containing Red Clover along with some Digitalis.

Nutritional:

Along with any treatment program for cancer, including conventional medical therapies, the nutritional aspects are important to address. This is especially true if the person is undergoing therapy which acts to destroy the tumor by exogenous means such as chemotherapy or radiation.

An overall balanced diet which is high in protein and vegetables, lower in calories and very low in fat (less than 25 grams per day) and cholesterol is needed to maintain a healthy internal environment. Additionally, we have found that a specific diet based upon the persons Serotype, can enhance the immune response to the tumor. A Serotype diet, as per D'Adamo, can also be used by the physician to recommend specific foods which have a propensity to attacking certain cancer cells.

Garlic (Allium sativum), in its natural clove form, helps supply the body with vitamins and minerals but most importantly helps to prevent infection as well as enhance t-cell binding to cancerous cells. Allium sativum also disrupts the metabolism of the cancerous cell by disrupting its ability to produce lactic acid. Garlic in capsule form is often found clinically to be less potent than fresh garlic, requiring ten times the amount to achieve the same effect. Some studies suggest that some, but not all, immune enhancing activities of garlic may be preserved by the deodorizing process.

Fish oils, olive oil and high amounts of Evening Primrose oil (EPO) or Eicosapentanoic acid (EPA) act to reduce thrombus formation thus lowering the potential for tumor and thrombus spread. Decreased thrombus formation has been linked with better survival rates in cancer patients due to the inability of the cancer to spread by this

route. This may be the reason that shark cartilage/oil therapy has been shown to prevent tumor metastasis. Research suggests that shark cartilage/oil prevents thrombus formation, thus making it difficult for the tumor to spread. This also has the effect of isolating the tumor, making it easier for the immune system to destroy it.

More recently, modified citrus pectin (MCP), but not citrus pectin (CP), has been shown to combine with a variety of galactose-specific proteins on cancer cell surfaces. MCP inhibits metastases in rat CAP by adhering to the cancer cell surface thus making it unavailable for aggregation and adhesion needed for metastases. The studies show that MCP does not inhibit the cancer growth but makes it difficult to spread. MCP has been shown to affect not only the metastases of human prostate adenocarcinoma, but human breast cancer, malignant melanoma, and laryngeal epidermoid carcinoma as well.

Antioxidants such as Vitamin C, E, and beta carotene should be taken in large doses as they eliminate free radical formation and enhance cellular oxidation. Intravenous administration of them may be needed initially, especially if the person has undergone chemotherapy or radiation. It has been my experience that the person who has opted for radiation or chemotherapy does not suffer their effects as severely if they are receiving antioxidant therapy.

Other Naturopathic Therapies

Certainly with any treatment of cancer the overall needs of the individual must be addressed. These include physical, mental/emotional and even spiritual needs. Simply treating the disease without addressing the whole person makes any therapy less effective.

Patients with cancer are often found to possess what is termed a "cancer personality". They are often encumbered with excesses of guilt, worry, frustrations and suppressed anger. It is not unusual to find a person with cancer who is trapped in a living situation which is unbearable for them, or to find they have never learned to "loosen up" and relax or is a "type A" or high achiever personality. There are a variety of factors which contribute and must be addressed through self help groups, counseling or psychotherapy. Statistically, those patients with the best outlooks concerning their cancers have the longest survival rates, regardless of the therapy that they are undergoing.

Hydrotherapy, or the use of hot and cold water, is also useful in the treatment of cancer of the prostate. Specifically, many naturopathic physicians use the constitutional hydrotherapy technique developed by Henry Lindlahr M.D. and refined by O.G. Carrol N.D. and others. Constitutional hydrotherapy uses a combination of hot and cold applications coupled with a mild electrical current to induce a healing reaction by the patients' immune system. Hydrotherapy has been shown to increase the circulating white

blood cell count for up to 36 hours following treatment. Further, it improves oxygenation to the affected tissues, higher oxygen levels making it difficult for cancer cells to survive. In addition, the increase in body temperature accelerates immune system function.

Homeopathic medicine is an integral part of any treatment plan for CAP as it helps the body adjust to the ravages of the disease and stimulates the immune system. My own personal preference is for using homeopathic medicines, but acupuncture also provides the energetic boost needed for balancing of the body and stimulation of the immune system.

An immune therapy which shows promise utilizes BCG (bacillus Calmette-Gue'rin) or Staphysage lysate. Injected intradermally, these vaccines act to stimulate lymphocyte production and thus enhancing the immune response. Along with this therapy I will also give the patient thymus extract and Eleuthrococcus senticosus to help boost production.

Electrical current in the form of positive galvanism, applied transrectally, has been used in the treatment of CAP as well as BPH. A steady current of 1 to 5 milliamps for 10 to 15 minutes creates an acidic environment within the prostate gland, oxygenating the tissues and increasing the white blood cell count. This treatment must be coupled with anticoagulant and antioxidant therapy. During and following a series of treatments, protomorphogen therapy helps the growth of healthy prostate tissue.

With natural treatment for CAP it is important to remember that the therapy will have its ups and downs. Because tumor response to treatment is usually measured by the PSA, it is important to remember that this test reflects changes in tissue inflammation as well as in new and cancerous tissue growth. Therefore, a slight rise initially in the PSA may not necessarily be a bad sign but a reflection of the healing process. Also, during the course of treatment a leveling out of, or slight rise in the PSA, may be seen. In my experience, a slight rise in the PSA soon after initiation of natural therapies is usually followed by a decrease. Continued elevations should alert the clinician to make medication changes in order to reverse the trend.

Treatment of cancer of the prostate is one of the diseases in which naturopathic medicine can have a high rate of success. What is required is commitment on the part of the patient and physician to follow through with the therapeutic program. The physician must be aware of the aspects of the pathophysiology of the disease as well as the psychological aspects of the patient. A diagnosis of cancer has a tremendous psychological impact and the physician must be sensitive to the patient's needs while maintaining objectivity. Educating the patient as well as informing them at every junction of the therapeutic process will help allay fears and make for better patient

compliance. Additionally, the patient must be helped to understand that they must make a total commitment to their health and well being in order for the treatment to ultimately be successful. There are no "quick fixes" but the rewards are great.

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Naturopathic and Major Medical Schools
Comparative Curricula

	Southwest College of Naturopathic Medicine	National College of Naturopathic Medicine	Bastyr University (Naturopathic) (Medicine)	Johns Hopkins	Mayo	Stanford
Basic and Clinical Sciences Anatomy, Cell Biology, Physiology, Pathology, Neuroanatomy, Clinical Diagnosis, Histology, Genetics, Biochemistry, Pharmacology, Lab Diagnosis, Pharmacognosy, Bio-statistics, Epidemiology, Public Health, History, Philosophy, Ethics, Research, and other coursework.	1942	2070	1815	1794	1640	1401
Clerkships and Allopathic Therapeutics Lecture and clinical instruction in Dermatology, Family Medicine, Psychiatry, Medicine, Radiology, Pediatrics, Obstetrics, Gynecology, Neurology, Surgery*, Opthamology, and clinical electives.	1810	1974	1782	3250	3080	3840
Naturopathic Therapeutics Botanical Medicine, Homeopathic Medicine, Acupuncture/Oriental Medicine, Hydrotherapy, Preventive Medicine, Naturopathic Manipulation	704	492	704	0	0	0
Therapeutic Nutrition	109	144	154	17	elective	elective
Counseling	92	144	121	0	0	0
TOTALS	4657	4824	4576	5071	4720	5241

* Naturopathic physicians study minor surgery only.

Sources: Academic offices of Southwest College, National College, and Bastyr University.
1988 *Curriculum Directory* of the Association of American Medical Colleges.

For more information contact: American Association of Nat[illegible] Seattle, Washington 98102 [illegible]

Mr. BURTON. Thank you. We will review that followup on that and I have some questions for you too on the record when we get to that.

Dr. Chen.

Dr. CHEN. Mr. Chairman, and members of the committee, thank you for your invitation to testify today. It is my honor to present to you information on scientific research on botanicals for treatment of prostate cancer.

I appear before you today as a medical researcher. I got into this field because of personal experience with family members who had prostate cancer. In the past 10 years, we have learned that the fight against cancer requires multiple interventions and efforts. The good news I can say today is there are botanicals that can be beneficial for cancer treatment and for prevention. The bad news is we do not have enough clinical studies and there is still a long way to go.

One role for botanicals is that they can serve as complementary medicine to enhance the conventional therapies. They will not be a replacement for cancer therapy at this point. There are large numbers of botanical components that have been identified as antioxidants, immune stimulants, and others and are shown to be preventive for prostate cancer. These include selenium, vitamin E, green tea extract, lycopene from tomatoes, soy products, and PC SPES.

It is postulated that the reason Asian men and women have a lower incident rate of prostate and breast cancer is because their diet is rich in botanicals.

I feel the more we study these compounds, the better we can utilize them to help patients. Here I would like to discuss PC SPES, which has been studied at many different prestigious laboratories and hospitals across the United States. To my knowledge, more than 1,000 men are taking PC SPES at the recommendation and suggestion of their physicians. PC SPES is a standardized botanical formulation composed of seven purified Chinese herbs and one American herbal extract. The preparation is based on a patented formulation which I developed. The laboratory data so far has shown that it can inhibit prostate cancer cell growth in a test tube. It can also induce them to go suicidal.

Two different animal studies confirm the laboratory finding and show a 50 percent reduction in prostate tumor incident rate, in tumor volume and in metastasis.

At the present time there are several clinical trials in phase two. Two of them have been reported recently. Dr. Eric Small from the University of California San Francisco found that 61 advanced stage prostate cancer patients responded to PC SPES; 27 of them belong to the group of hormone sensitive and they responded 100 percent. The other 34 hormone failure patients responded with 57 percent. He also found some reduction in the pain of those patients.

A separate study by German physician Dr. Ben Pfeifer with a team studied 16 hormone refracture patients. They also had failed the conventional therapy and were at the end of their life. The response rate among this group was about 70 percent and the quality of life was found to be profoundly improved. Those data were preliminary. There are some side effects that need to be investigated.

We need more funding and more studies to conclude these exciting results and hope we can help more prostate cancer patients using this new approach with multiple components based on scientific studies.

In conclusion, I would like to suggest that Congress consider fully refunding and expanding the budget for the National Center for Complementary and Alternative Medicine and the Office of Dietary Supplement at the NIH to undertake clinical studies on botanicals which show promise for prostate cancer treatment. I also would like to suggest that the Congress can promote and encourage more clinical research on botanicals by the NCI. Thank you for your time.

[The prepared statement of Dr. Chen follows:]

TESTIMONY OF DR. SOPHIE CHEN, PH.D.
BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON GOVERNMENT REFORM
THURSDAY SEPTEMBER 23, 1999 ON PROSTATE CANCER

Mr. Chairman and Members of the Committee:

Thank you for your invitation to testify today. It is my honor to present to you information on scientific research on botanicals for treating prostate cancer. I appear before your committee today as a research scientist affiliated with New York Medical College. I am not here on behalf of any business organization.

We have learned that the fight against cancer requires a multi-dimensional intervention. The good news is that there are botanicals that can be beneficial for cancer treatment and prevention. The bad news is that we still have a long way to go and much more clinical research is needed. One role for botanicals is that they can serve as complementary medicine to enhance conventional therapies. They are not a replacement for conventional cancer treatment.

There are vast numbers of natural compounds in the field of natural products including dietary supplements that possess anti-oxidative properties and are shown to be preventive for prostate cancer. They include selenium (reference1), Vitamin E (reference2), green tea extract (references 3-4), lycopene from tomato (reference 5), soy product (reference 6) and PC SPES (references 7-19). It is postulated that the reason men and women in Asia have lower incidence of breast and prostate cancers is due to the diet rich in botanicals. The more we study these botanicals, the better we can utilize them effectively. Specifically, I would like to discuss PC SPES which has been studied at various

prestigious laboratories and hospitals across the nation, and has shown some great promise. To my knowledge, over one thousand men are taking it at the recommendation and suggestion of their physicians.

PC SPES, is a standardized botanical formulation composed of seven purified Chinese herbs (Dendrantherma morifolium, Ganoderma lucidium, Glycyrrhiza uralensis, Isatis indigotica, Panax pseudo-ginseng, Robdosia rubescens, Scutellaria baicalensis) and one American herbal extract, Saw Palmetto. This dietary supplement is based on a botanical composition I developed and patented. The American herb, Serenoa repens (Saw Palmetto), has been shown to decrease PSA level caused by prostate inflammation and to be useful in treating benign prostate hyperplasia (BPH, reference 20). As members of the Committee may be aware Saw Palmetto extract is sold as a dietary supplement for prostate gland support. The original Chinese concept for development of herbal medicine is to combine non-toxic phyto-chemicals from each herb empirically and create a mixture that can act synergistically to

benefit human health and improve the wellbeing of patients.

The laboratory data published in peer reviewed journals on PC SPES shows that it can:

(l) inhibit the growth of various cancer cell lines including prostate cancer cells (both hormone- sensitive and hormone- insensitive);

(2) induce cancer cell apoptosis which is also called "programmed cell death"- type of a cell death induced by most conventional anticancer drugs;

(3) block prostate cancer cell proliferation (arresting cells in G_1 phase) and;

(4) reduce cellular levels of bcl-2, bcl-6, PSA, androgen receptor and PCNA.

These changes reflect decreased cancer cell proliferation and increased sensitivity to apoptosis. These in turn lead to a reduction or elimination of prostate cancer cell stimulation by testosterone, an androgen hormone.

Animal studies further show:

(1) a 50% reduction in tumor incidence, tumor volume and lung metastasis in Copenhagen rats that were injected with highly metastatic prostate cancer cell line (mat-ly-leu); and `

(2) a 50% reduction in tumor volume in triple immune deficiency mice (nude mice) that were inoculated with hormone-insensitive human prostate cancer cell (DU 145).

These laboratory studies suggest a potential role for PC SPES in treating metastatic prostate cancer. Its role in human metastatic prostate cancer still awaits study in a clinical setting.

Funded by the CaPCURE Foundation, preliminary results of a clinical study for sixty-one patients conducted at the University of California, San Francisco by Dr. Eric Small, showed that all twenty-seven hormone naïve patients had a greater than 50% decrease in PSA; nineteen of thirty-four hormone-resistant patients also had a larger than 50% decrease in PSA (response rate 56%). Furthermore, half of sixteen hormone-sensitive patients who were evaluated showed a decrease in cancer with ultrasound, two of the twelve patients available for bone scans also showed a clear improvement. In some patients, pain was lessened (Urology Times: Vol. 27, No. 8, August, 1999).

A separate German study headed by Dr. Ben Pfeifer (in press, British Journal of Urology, 1999) also showed comparable results with twelve of sixteen hormone-resistant patients who failed all conventional therapies (D3 and D4 stages) had a

greater than 50% decrease in PSA (70% response) in five months. An improvement in their quality of life was also observed. The main side effects included loss of libido, gynecomastia, and a potentially increased risk in vein thrombosis. These phenomena are similar to the estrogenic effects caused by synthetic drugs but to a lesser extent. The estrogenic effect of PC SPES is estimated to be about one million times less than that of estrogen (estradiol) based on extrapolation of data published by Dr. DiPaola in NEJM, 339:785-91.

In conclusion, preliminary clinical studies suggests PC SPES may be beneficial to prostate cancer patients. In order to determine its clinical efficacy and any adverse effects, double blind and randomized clinical studies are needed. It is also necessary to study the mechanism of action of this botanical supplement and its possible synergy and interaction with conventional anti-tumor agents. Along those lines, I would like to make the following suggestions:

1) That Congress consider fully funding and expanding the budget for the National Center for Complementary and Alternative Medicine and the Office of Dietary Supplements at NIH to undertake clinical studies on botanicals for prostate cancer;

2) Promote and encourage more clinical research on botanicals by the National Cancer Institute.

Thank you.

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Postdoctoral	Cornell University, Chemistry Department, 1973-1977
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M.S.	University of Idaho, Chemistry Department, 1968
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EXPERIENCE:

1993-Present	Board of Directors, International Medical Research, Inc.
1996-Present	Research Associate Professor, New York Medical College
1997-Present	Director, NovaSpes Research Lab
1991-95	Secretary, Chinese-American Chemical Society
1987-93	Group Leader, Bayer USA, Hematology Department
1986-88	Co-director, Technicon-China Joint Venture Research Laboratory
1986-87	Adjunct Assistant Professor, New York University School of Dentistry, Department of Biochemistry
1982-87	Group Leader, Technicon Instruments Corporation, Advance Research Department
1978-82	Senior Biophysicist, Merck Sharp and Dohmes Research Laboratory, Inflammation and Arthritis Department

HONORS

Graduated first in the class of 1966 (National Normal Taiwan University), 1968 (University of Idaho)

SCIENTIFIC AWARDS

Recipient of Miles Outstanding Scientific Award 1991
Recipient of Miles Technical Achievement Award 1992
Recipient of CaPCURE Scientific Award 1998

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Mr. BURTON. Thank you, Dr. Chen. We will have some questions for you and NIH about your findings in just a little bit.

Dr. Kaplan, would you rather someone else go first?

Dr. KAPLAN. I thought that Dr. Thornton was going ahead of me.

Mr. BURTON. Dr. Thornton.

Dr. THORNTON. Thank you, Congressman Burton, for the opportunity to speak before you and your committee this morning. I serve as the chief advisor for the Midwest Proton Radiation Institute, and my current faculty position is as a member of the Department of Radiation Oncology at Massachusetts General Hospital and a member of the Harvard Medical School. I have prepared a brief summary of prostate cancer and then I will focus on proton therapy.

In general, cancer of the prostate is common in men of developed countries second only to lung cancer in incidence. The current incidence is greater than 75 per 100,000 with an annual incidence of new cases of 120,000 in this country. The tumor is more common in men of African-American ancestry and increases in incidence with age.

Most cases of prostate cancer are composed of what is known as adenocarcinoma cells, a pattern that is seen on pathologic specimens under the microscope. A small percentage of these cells are transitional tumors, which are much more aggressive.

Importantly, the degree of differentiation of the tumor as seen under the microscope when the tumor is first diagnosed is the single most important factor to determining survival and how aggressive the tumor will be.

The cancer of the prostate usually spreads, that is metastasizes, by passage through the lymph system to lymph nodes, that is one mechanism; second, by direct extension to tissues around the prostate gland; and also by direct invasion into the blood vessels and thereafter into other organs throughout the body. The tumor may spread to bones, which we have heard about today, where severe pain and fracture may occur, as well as to the liver, to the lungs, but rarely the brain. Patients often live for significant periods of time after the tumor has spread subject to prolonged pain and compromise of quality of life due to these bone and organ metastases.

Fortunately, many prostate tumors are now detected at an early age due to the development of PSA antigen test which we have been hearing about today, which was developed in the 1980's. Formerly, patients were not diagnosed until changes in either the urine stream or frequency prompted a rectal exam. With sensitive PSA screening, a significant number of patients, now thought more than 50 percent, present with early stage disease, which represents a clear pattern shift, disease diagnosed prior to the likely spread of the tumor. This offers potential for long-term control and cure to increasing numbers of American people if the control of the tumor in the prostate gland can be realized.

The current therapeutic options as standardly recognized include surgery, radiation, and we have heard cryotherapy for very early stage disease. Hormonal therapy alone is effective therapy only for very early cases in elderly men who are thought too senior for either radiation or surgery. Chemotherapy has thus far been relatively unsuccessful in affecting this tumor. Surgery is reserved for

men with tumor confined to the prostate gland and it is usually designed for men with lower grade—that is less likely to spread—types of tumors. Men must be healthy in order to tolerate the surgery and they must recognize that over 50 percent of the time they will lose sexual function and may lose control of their bladder function.

Radiation is an effective alternative to surgery for prostate cancer supported by the consensus development conference of the NIH in 1988. Radiation has the advantage of less toxicity with greater likelihood of preservation of sexual function and bladder function. It is also used widely for men with more advanced tumors, those who have a higher likelihood of spread of their tumors, or those who are thought not suitable for surgical rejection.

However, conventional radiation, which is known as photon or x-ray radiation, that is available in most community hospitals and most university hospitals, cannot be aimed to selectively treat only the prostate gland and not the adjacent rectum and bladder. Therefore, the doses that can be safely delivered with conventional photon radiation are limited.

Proton therapy involves the precise delivery of high doses of radiation with particle beams from hydrogen atoms, the hydrogen atom nuclei, designed to treat only the prostate gland and involved tissues around the gland. This therapy for prostate patients is predicated on the knowledge that prostate cancer remains localized for a significant length of time in the earlier stages of the disease. However, we know from very elegant Canadian studies by Juanita Crook in 1987 that over 38 percent of men will still harbor tumor cells within their prostate glands after conventional radiation.

Of great significance is the knowledge that patients whose biopsies are positive after this treatment will have over a 70 percent likelihood of going on to develop metastatic disease. However this represents an incurable situation for these patients. However, if the biopsy is negative after radiation, then only 25 percent of the patient will develop metastatic disease and will likely be cured. Therefore, effective control of the tumor within the prostate is the key to long-term control and the cure of this otherwise relentless disease.

Proton therapy has been used for many years, since 1962, for the treatment of tumors at the base of skull, inaccessible to neurosurgeons. Cure rates with tumors at the base of brain have been increased by 35 percent at the Massachusetts General Hospital in Boston, working in conjunction with the Harvard Cyclotron Laboratory. The physics and computer dosimetry of proton therapy has been developed to a very sophisticated degree, spurring increasing elegance of conventional therapies as well.

Figure 1—and I have but one slide here—graphically demonstrates the high degree of concentration of protons in the prostate gland as viewed horizontally on a CT scan, which is known as computerized tomography scan. The concentric colored lines represent the areas treated by the protons with very high degrees of concentration. Volumes outside these lines receive only 20 percent of the prescribed dose. If you look carefully, you will see a crescent-shaped white line which represents the anterior wall of the rectum,

which is a very sensitive structure and this is largely untreated and spared with protons.

Currently only two centers exist in the United States to treat patients with proton therapy: Massachusetts General Hospital in Boston and Loma Linda Medical Center in Los Angeles. No center exists to treat patients in the Midwest, who must travel great distances and stay for an average of 2 months of proton treatment in either Boston or L.A.

The Midwest Proton Radiation Institute, a consortium of Midwest universities led by Indiana University, is seeking to convert an existing accelerator at the Indiana University Bloomington campus into a facility for the treatment of prostate cancers using proton therapy. Recognizing the need to provide access to this type of cancer treatment to patients in the Midwest, the House Labor, Health and Human Services, Education Appropriations Subcommittee in the 1999 committee report accompanying the appropriations bill, encouraged the NCI to assist with the conversion of an accelerator for proton therapy treatments in a location not currently served by two existing facilities. The MPRI clearly fits this outline and MPRI sponsors, led by Indiana University, submitted an application to the NCI earlier this year to seek assistance with the conversion of this accelerator at the cyclotron facility for proton therapy treatments. To date, NCI has not reviewed the application.

I ask your committee to inquire of the agency its plans for responding to the language in the House report supporting the establishment of a proton therapy facility in the Midwest and how that agency plans to specifically address the proposal put forth by Indiana University. It is our hope that congressional support for prostate cancer will include assistance to the Midwest Proton Therapy Institute so that the proven benefits of proton therapy may be available to patients throughout the United States with more equitable regional access.

We appreciate the opportunity to review the effectiveness of proton therapy for prostate cancer with this committee. Thank you.

[The prepared statement of Dr. Thornton follows:]

Proton Therapy for Prostate Cancer

TESTIMONY

BEFORE THE HOUSE GOVERNMENT REFORM COMMITTEE

DR. ALLAN THORNTON
CHIEF ADVISOR, MIDWEST PROTON RADIATION INSTITUTE

SEPTEMBER 23, 1999

Overview of prostate cancer

Cancer of the prostate is common in men of developed countries, second only to lung cancer in incidence. Approximately 120,000 new cases are diagnosed per year with an incidence greater than 75 per 100,000. The tumor is more common in men of African-American ancestry, and increases in incidence with age.

Pathology

Most cases of prostate cancer are comprised of adenocarcinoma – a pattern of appearance under the microscope suggesting gland development. A small percentage (2%) are transitional-cell tumors that are much more aggressive. Degree of differentiation (appearance of the cells under the microscope suggesting mature cells) is the single most important factor in determining how aggressive the tumor will be.

Routes of spread

Cancer of the prostate usually spreads (metastasizes) by passage through the lymph system to lymph nodes, by direct extension to tissues around the prostate gland, and also by blood vessel invasion. Prostate tumors may spread to bones, where severe pain and fracture may occur, as well as to the liver, lungs, and rarely brain. Patients often live for significant periods of time after the tumor has spread, subject to prolonged pain and quality of life compromise due to these bone and organ metastases.

Diagnosis

Fortunately, many prostate tumors are now detected at an early stage due to the development of the PSA (prostate specific antigen) biochemical blood test, developed during the 1980's and currently widely available. Formerly, patients were not diagnosed until changes in the urine stream and frequency prompted a rectal exam. With sensitive PSA screening, a significant number of patients (>50%) present with early-stage disease – disease diagnosed prior to the likely spread of the tumor outside of the prostate gland. This offers the potential for long-term control and cure to increasing numbers of American men, if control of the tumor in the prostate gland can be achieved.

Therapeutic Options

Either surgery or radiation is the only effective therapy for prostate cancer. Hormonal therapy alone is effective therapy only for very early cases in elderly men, thought too senior for either surgery or radiation. Chemotherapy has been unsuccessful in affecting this tumor.

Surgery is reserved for only those men with tumor confined to the prostate gland, and is usually designed for men with lower-grade (less likely to spread) tumors. Men must be healthy in order to tolerate the surgery, and they must recognize that over 50% of the time they will lose sexual function and may lose control of their bladder function.

Radiation is an effective alternative to surgery for prostate cancer supported by the Consensus Development Conference of the National Institutes of Health in 1988. Radiation has the advantage of less toxicity with greater likelihood of preservation of sexual function and bladder function. It is also used widely for men with more advanced tumors, who have a higher likelihood of spread of their tumors, and are thought not suitable for surgical resection.

However, conventional radiation (photon or x-ray) that is available in most community hospitals and most university hospitals can not be aimed with sufficient accuracy to selectively treat only the prostate gland, and not the adjacent rectum and bladder. Therefore, the doses that can be safely delivered with conventional photon radiation are limited.

Proton therapy efforts

Proton therapy involves the precise delivery of high doses of radiation with particle beams from hydrogen atom nuclei designed to treat only the prostate gland and involved tissues surrounding the gland.

This therapy for prostate patients is predicated on the knowledge that prostate cancer remains localized for a significant length of time in the earlier stages of the disease. However, we know from Canadian studies (Crook et al, 1997) that over 38% of men will still harbor tumor cells within their prostate glands after conventional (photon) irradiation currently available in North America. Of great significance is the knowledge that patients whose biopsies are positive have a 70% likelihood of developing metastatic disease (disease that leaves the prostate and spreads elsewhere in the body) (Kuban et al, 1991). This is an incurable situation for these patients. However, if the biopsy is negative, only 25% of patients will develop metastatic disease, and will likely be cured. Therefore, effective control of the tumor in the prostate is the key to long-term control and cure of this, otherwise, relentless disease.

Proton therapy has been used for many years (since 1962) for the treatment of tumors at the base of skull, inaccessible to neurosurgeons. Cure rates for tumors at the base of the brain have been increased by over 35% with the use of proton therapy, work pioneered at the Massachusetts General Hospital in Boston. The physics and computer dosimetry of proton therapy has been developed to a very sophisticated degree, spurring increasing elegance of conventional therapy. **Figure 1** graphically demonstrates the high-degree of concentration of the protons in the prostate gland, as viewed horizontally on a CT (computerized tomography) slice. The concentric lines represent the areas treated with protons. Volumes outside the lines receive less than 20% of the prescribed dose.

Currently, only 2 centers in the United States exist to treat patients with proton therapy – Massachusetts General Hospital (Boston) and Loma Linda Medical Center (Los Angeles). No center exists to serve patients in the Midwest, who must travel great distances and stay for an average of 2 months of daily proton treatment in either Boston or Los Angeles.

The Midwest Proton Radiation Institute (MPRI), a consortium of midwestern universities led by Indiana University, is seeking to convert an accelerator at the IU-Bloomington campus into a facility for the treatment of prostate cancer using proton therapy. Recognizing the need to provide access to this type of cancer treatment to patients in the midwest, the House Labor-HHS-Education appropriations subcommittee, in the 1999 committee report accompanying the appropriations bill, encouraged the National Cancer Institute (NCI) to assist with the conversion of an accelerator for proton therapy treatments in a location not currently served by the two existing facilities.

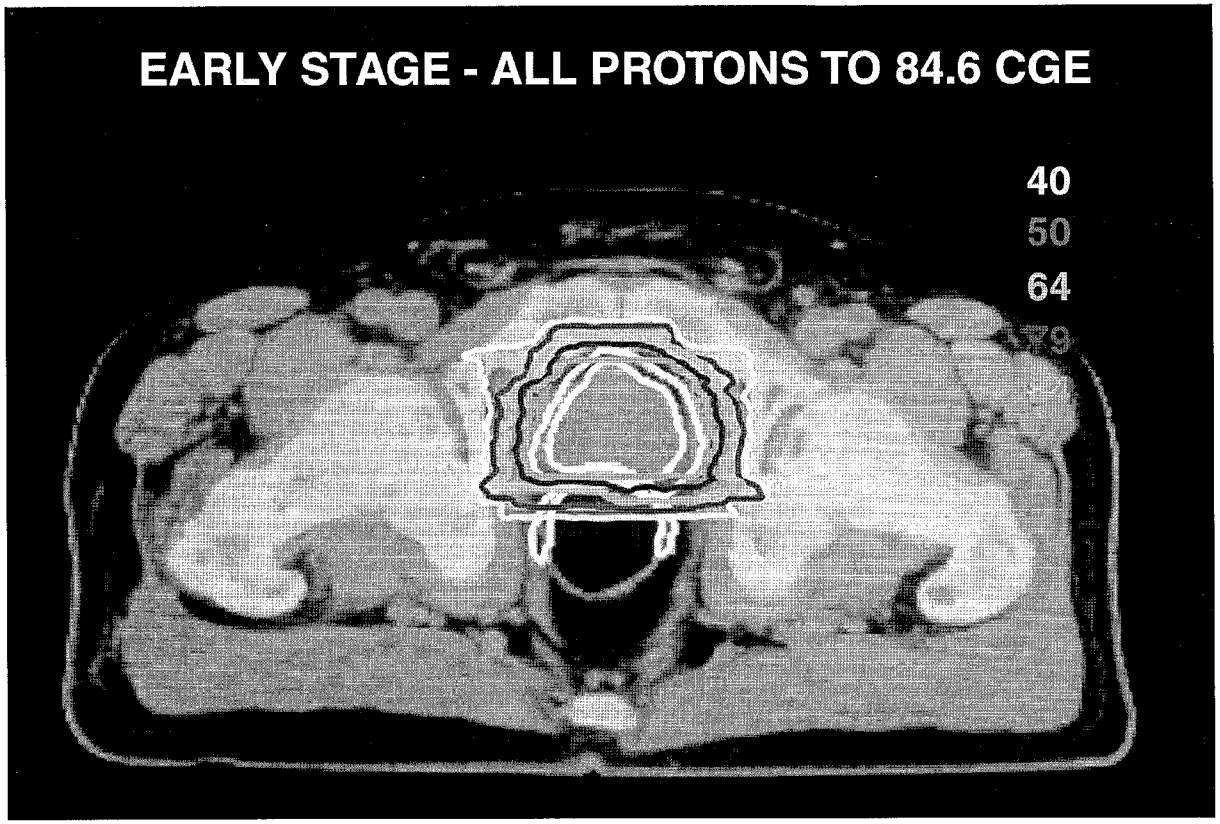
The MPRI clearly fits this outline and MPRI sponsors, led by Indiana University, submitted an application to the NCI earlier this year to seek assistance with the conversion of the accelerator at the cyclotron facility for proton therapy treatments at the site. To date, NCI has not reviewed the application. I ask your committee to inquire of the agency its plans for responding to the language in the House report supporting the establishment of a proton therapy facility in the midwest and how that agency plans to specifically address the proposal put forward by Indiana University.

Conclusion

It is our hope that Congressional support for prostate cancer will include assistance to the Midwest Proton Radiotherapy Institute (MPRI) so that the proven benefits of proton therapy may be available to patients throughout the United States with more equitable regional access. We appreciate the opportunity to review the effectiveness of proton therapy for prostate cancer with this committee.

Figure 1

Axial Slice of Prostate Gland with Proton Isodose Distribution demonstrating high-degree of conformality of dose.


EARLY STAGE - ALL PROTONS TO 84.6 CGE
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79

Mr. BURTON. That was one of the slickist bits of lobbying I have ever seen, it was well done.

Dr. Kaplan, are you next?

Dr. KAPLAN. Congressman Burton and members of the committee, I coordinate NCI's extramural clinical research on prostate cancer treatment. I am accompanied by Dr. Jeffrey White, who is directly behind me, the Director of the NCI's Office of Cancer Complementary and Alternative Medicine. I am pleased to appear before you to describe NCI's prostate cancer research program and our interest in complementary and alternative approaches to prostate and other cancers.

The Congress has asked NIH to make prostate cancer a top priority in allocating funding increases to accelerate spending on prostate cancer and to consult closely with the research community. We have undertaken a vigorous effort to respond in all of these areas.

Prostate cancer has risen in clinical and research importance in the last decade faster than any other neoplasm. Some of the many factors responsible for this are greatly improved methods to identify the disease before it causes symptoms; major public awareness campaigns, including the sorts of things that Senator Dole has had such an impact on; some modest improvements in surgery, radiation, and hormonal therapy that have rendered management options more acceptable; and important new research opportunities.

When Dr. Klausner assumed leadership of the NCI he envisioned a new strategy of evaluating the entire research portfolio for a particular disease from the ground up and structuring future efforts according to the insight and advice of the entire extramural research community and of stakeholders, including patients, advocacy and patient support organizations, and professional societies.

This new process called a Progress Review Group [PRG], was initiated in prostate cancer and breast cancer and it was extremely productive. The Prostate Cancer PRG laid out a framework for planning and identified a number of particularly important problems and potentially productive areas of research. There are about 20 new NCI initiatives outlined in the reports that we have provided, but I would like to go through some examples.

The following sequence of three initiatives taken together should speed the development of new interventions, that is to say treatments, of any type from initial work in the laboratory, or animal, all the way into definitive testing in men with cancer. The RAID and RAPID programs, as they are called, are intended to expedite new agent development by moving novel molecules toward clinical trials. Often there is a catch-22. Many scientists don't have the resources to do all the required animal testing or drug formulation before tests in humans can begin. At the same time it is not easy to get a pharmaceutical or biotech industry partner to commit such resources until an agent is further along.

This is where RAID and RAPID can step in. Independent investigators are given access on a competitive basis to NCI's own preclinical drug development resources and expertise. They are assisted with necessary development steps to enable investigational new drug application filing with FDA and initiate proof-of-principle trials. Then NCI steps back out and the investigators are free to develop industry collaborations.

The next step is to actually carry out preliminary patient clinical trials to find out how best to apply the new intervention and whether it actually does appear to do something useful in patients. These studies are time consuming and personnel intensive and may require sophisticated tests. And it is increasingly difficult in today's medical care system to do such trials without grant funding. But it is challenging to get a conventional grant with little preliminary data and there can be frustrating and unsatisfactory delays.

For this reason, we developed the Prostate Cancer Quick Trials program, a process for rapid approval and funding of early trials of new agents. We feel we can increase the number of early clinical trials and the number of patients participating by two to threefold. If the Quick Trials approach works the way we anticipate it will, we want to make a similar mechanism available to researchers working in other cancers as well.

Then how do we speed up definitive testing of agents that do appear promising in these early trials? And how do we assure that patients all over the country have access to these?

NCI has begun a complete restructuring of the national system in which the best new approaches are compared with established treatments. These studies will be available not just for particular teams of doctors but to patients anywhere through any qualified oncologist. This new system is a complex one to set up and so it will be tried out in a limited number of diseases at first. Prostate cancer was selected as one of the two types of cancers in which to start.

It should be noted that all of these new initiatives are inherently open, competitive ones. They do not specify that the interventions be drugs. They could be dietary supplements or surgical procedures or new radiation techniques or gene therapies, whatever, and they may be intended for either treatment of established prostate cancers or for prevention. And they may arise within the conventional medical research community or from the alternative medical community, academia or industry.

In addition, the NCI is moving very quickly in important directions to develop CAM information and expand research opportunities for CAM investigators. These activities are broad in scope and include strengthening our relationship with the National Center for Complementary and Alternative Medicine [NCCAM], the careful evaluation of alternative therapies and the development of accurate CAM information for the public.

One collaborative goal is to develop centers for CAM research as well as specialized research centers to investigate the biological effects of botanicals, including those that are available as dietary supplements. Several studies of alternative approaches are already under way. NCI-sponsored projects recently have suggested that both vitamin E and selenium supplements may be capable of preventing prostate and other cancers. More investigation is needed, and NCI continues to support several studies addressing the effectiveness and the prevention of prostate cancer by lycopine and dietary soy as well as by vitamin E and selenium.

Now, everything I have described thus far has to do with applying interventions that build on what we have already discovered,

but the greatest potential for actually eliminating prostate cancer depends on dissecting and understanding biology of the disease, how it does its damage, what genetic and molecular abnormalities allow it to grow, spread, and for it to resist therapy. In fact, the real answer to many of the dilemmas in management of patients may be found only when we know enough about individual tumors to predict their behavior and access their vulnerabilities.

For example, we currently estimate which prostate cancers are most likely to recur by their appearance under a microscope, their stage, and the PSA level. But there is so much overlap that the decisionmaking for most patients is still terribly difficult. If we had better ways to classify whether an individual patient's tumor is one with a high malignant potential or one of the larger number that poses considerably less risk, then we could much more easily test early detection and screening technologies and we could provide the confidence to spare many men the long-term side effects of prostate surgery or radiation.

Mr. Chairman, if you would allow me to have 1 or 2 more minutes I would like to cover one other initiative. For these all important reasons, I would highlight these two other programs. The Cancer Gene Anatomy Project, which is CGAP, which has thus far discovered 146 genes that appear to be prostate specific and 400 genes that appear to be expressed differently between normal prostate tissue and prostate cancer.

This information and subsequent discoveries of CGAP will provide the raw material for undertaking the next initiative, the NCI Director's Challenge for Molecular Diagnostics. Its goal is to develop a tumor classification system that is firmly based on cell biology of cancers rather than on microscopic appearance. Prostate cancer is a particularly important area of application for this effort because its behavior is so variable from patient to patient.

Mr. Chairman, I appreciate the level of interest this committee has shown in prostate cancer. I hope my testimony demonstrates NCI's commitment to advancing our knowledge about prostate cancer as rapidly as possible. Our activities, and specifically Dr. Klausner's leadership efforts over the past year, have invigorated the prostate cancer research community. It is this essential partnership between NIH, other funders and that research community that will successfully accomplish the ambitious goals of this plan.

Dr. White and I will be pleased of course to answer any questions you may have.

[The prepared statement of Dr. Kaplan follows:]

For Release Upon Delivery

PROSTATE CANCER RESEARCH
at the NATIONAL CANCER INSTITUTE

Richard Kaplan, M.D.

Senior Investigator

National Cancer Institute

National Institutes of Health

Department of Health and Human Services

Before the House Government Reform Committee

September 23, 1999, 10:00 A.M.

Rayburn House Office Building

Introduction

Good morning, Congressman Burton and Members of the Committee. I am Richard Kaplan, M.D., of the National Cancer Institute (NCI). I am a Senior Investigator in the Cancer Therapy Evaluation Program and I coordinate NCI's extramural clinical research on prostate cancer treatment. I am accompanied today by Jeffrey White, M.D., Director of the NCI's Office of Cancer Complementary and Alternative Medicine.

I am pleased to appear before you today to describe NCI's prostate cancer research program and our growing interest in complementary and alternative approaches to prostate and other cancers. The Congress has asked NIH to make prostate cancer a top priority in allocating funding increases; to accelerate spending on prostate cancer; and to consult closely with the research community. Under Dr. Klausner's leadership, NCI has undertaken a vigorous effort to respond in all of these areas.

The nature and magnitude of the burden of prostate cancer has been tracked by NCI's surveillance program, and we estimate that about 180,000 men will be newly diagnosed with prostate cancer this year and about 37,000 will die. Prostate cancer exacts a particularly devastating toll on African American men; incidence rates are substantially higher among African Americans, and mortality rates in African American men remain more than twice as high as rates in white men.

This catalogue of statistics, while accurate, does little to convey the very real pain, fear, and uncertainty experienced by every man who is diagnosed with prostate cancer. Despite advances over the past decade, our treatments for prostate cancer are inadequate, the side effects of treatment are significant and often unacceptable, and troubling questions remain about the efficacy of early detection for the disease. Every day, too many men in the United States hear the life-changing words "You have prostate cancer." Every day, too many men are faced with the agonizing decisions of how best to treat their prostate cancer. And every day, too many men are dying too young of this disease. The limited knowledge about the causes of prostate cancer, how it may be prevented, and how to treat it successfully demand a broad, robust, and clearly articulated approach to research.

At NCI, prostate cancer research funding increased significantly from a 1998 level of $86.9 million to a current projection of $141.5 million in 1999. At the request of Congress, NIH developed a plan for a coordinated, trans-NIH prostate cancer research initiative outlined in *Planning for Prostate Cancer Research: Five Year Professional Judgment Estimates*. A copy of this 5-Year Plan has been provided to you. This report describes prostate cancer research opportunities across NIH from 1999 through 2003. Without regard for economic constraints or other competing priorities of the NIH or the Federal government, we estimate NCI could support $340 million, and NIH in total could support $420 million worth of targeted prostate cancer research by FY 2003.

Overview

The NCI is the lead NIH institute for prostate cancer research. Ongoing and future research initiatives have the potential to directly improve the length and quality of life of prostate cancer patients and survivors, as well as those at risk for the disease. Indeed, fully 70 percent of the research opportunities presented here are targeted at clinical or translational research that would have a direct impact on patients, survivors, and at-risk men.

The NCI has aggressively sought participation from non-government researchers, advocates, and patients in reviewing the prostate cancer research portfolio and charting a plan for a vigorous expansion of the prostate cancer research program. Over two years ago, we initiated a disease-specific planning process called a progress review group or PRG. The Prostate Cancer PRG involved scores of individuals from all over the country -- scientists, clinicians, and advocates--and challenged the prostate cancer research community and the NCI to review our current prostate cancer research portfolio, to develop a prioritized set of questions that needed to be answered and resources that needed to be developed or applied, and to provide a vision and chart a course for research and progress in prostate cancer. The PRG report was presented to the NCI last September and in the 12 months since then we have acted to implement a plan that we believe will fulfill the vision of progress articulated by the PRG. A copy of the report has been provided to you.

In all of our planning phases we have involved a variety of members of the prostate cancer communities including researchers, clinicians and advocates. To ensure that the professional and advocacy groups were fully represented, the PRG invited the input of 32 "stakeholder" groups that represented both professional societies and advocacy organizations and groups.

We have begun, in an aggressive way, to accelerate funding for prostate cancer.

- We have identified more than 20 initiatives through which high priority areas can be addressed and a special section of the NCI Web site serves to bring these to the attention of researchers and the public.
- We have further emphasized the importance of accelerating the pace of progress against prostate cancer by promising applicants that prostate cancer grant applications will have priority for so-called exception funding. That is, every effort will be made to fund worthy applications in the identified high-priority research areas even when peer-review assigned priority scores are not quite high enough to fit within conventional grant award paylines
- NCI has met with the representatives of the prostate cancer research community, the PRG, and the leadership of professional societies, such as the American Urological Association, in order to communicate these initiatives and to enlist the research community's support in responding to these opportunities.
- Extensive outreach and advertising will alert the larger research community to these opportunities to energize their participation in this prostate cancer research program.

Research Initiatives

The scientific opportunities we have identified fall into four major areas:

1) Clinical Science-- the near term direct testing of new interventions in patients or in those at risk for prostate cancer.
2) Translational Science -- moving ideas from the laboratory to the point of clinical testing, and determining how they should be applied and tested.
3) Risk, Burdens & Outcomes Science -- attempting to ask critical questions about cause, the unequal levels of cancer in different populations, outcomes and survivorship.
4) Basic research and discovery -- longer term investments in gaining insight into the development and biology of prostate cancer and the development of models for study.

Let me illustrate with a few examples of these new initiatives. In the area of clinical trials for patients with prostate cancer, we need to test new approaches and new agents aimed at a variety of clinical situations. We have established Prostate Cancer "Quick Trials," a new granting program to provide a rapid, streamlined funding mechanism for moving novel new ideas for therapeutic interventions into Phase I and II clinical trials for prostate cancer. This program has been set up in recognition of the urgent need for new types of interventions that are effective at different stages of prostate cancer, as well as the growing number of therapeutic ideas that are ready to be tested in patients.

In this type of project, where it is necessary to evaluate untested leads in the absence of preliminary data, conventional grant application and review procedures are not well suited. Quick Trials utilizes a process for rapid approval of early clinical trials. The NCI's goals are to increase the number of patients participating in early clinical trials by two to three-fold and to initiate 10-15 new trials per year through this accelerated mechanism. In addition, this year through NCI's Cancer Therapy Evaluation Program, we will initiate approximately 35 new Phase I/II trials in Prostate Cancer with agents directed against a number of particularly promising molecular targets and mechanisms. These targets include:

- angiogenesis and metastasis, the processes by which cancers induce new blood-vessel formation, invade these blood vessels, and spread throughout the body;
- growth factors and their receptors, which mediate growth signals to cancer cells; and
- tissue-specific genes expressed selectively in prostate or prostate cancer cells, thus allowing for the targeting of tumor-killing modalities to these cells.

We will test:

- Novel small molecule drugs
- Specific antibodies
- Vaccines
- Virus-based gene therapy
- Targeted radiation sensitizers

Compared to the current level of effort, this plan could more than double the

number of early clinical trials in prostate cancer in the first year, with another doubling projected in the next four years as per the full professional judgment estimate presented by Dr. Klausner last June.

This year, we will activate at least 5 new multi-center phase III clinical trials in prostate cancer that will attempt to optimize and test new hormonal and chemotherapeutic approaches for the most common clinical presentations of the disease, including:

- adjuvant therapy in the setting of primary surgical or radiation treatment;
- neo-adjuvant therapy, which has shown promising results in reducing the mortality from locally advanced prostate cancer;
- treatment after hormone therapy;
- treatment in the setting of rising PSA levels after definitive local therapy; and
- advanced disease, particularly directed at bony metastases.

With this initial ramp up in clinical trials, we project the ability to double the number again over the following four years.

We have initiated a new program creating a drug development process that enables investigators to advance novel molecules to clinical trials when they have not yet found a pharmaceutical or biotechnology industry partner with the necessary resources. We do this by giving academic investigators access, on a competitive basis, to NCI's preclinical drug development resources and expertise. Investigators who have molecules that hold promise for cancer treatment, but without access to the development resources required for initiation of clinical studies, are invited to submit applications twice a year. Those selected for support are assisted with necessary development steps to enable Investigational New Drug Application (IND) filing with the Food and Drug Administration and to begin initiation of proof-of-principle clinical trials. For FY 1999, our goal is the development of three to five new therapeutic agents, each relevant to prostate cancer. Projects already approved include development of a bioreductive compound with potential as a radio- and chemo-sensitizer, and a gene-therapy approach that will convert inactive pro-drugs into toxic agents within prostate cancer cells. Over five years, 15 new therapeutic agents for prostate cancer could potentially be developed if sufficient resources are available.

The NCI is moving very quickly in important directions to develop CAM information and expand research opportunities for CAM investigators. These activities are broad in scope and include strengthening our relationship with the National Center for Complementary and Alternative Medicine (NCCAM), the careful evaluation of CAM therapies, and the development of accurate CAM information for the public. One goal shared by the NCI, NCCAM, and other Institutes is to establish Centers for CAM Research that would provide the resources necessary for the rigorous scientific study of CAM approaches, as well as Specialized Research Centers to investigate the biological effects of botanicals, including those that are available as dietary supplements.

Several studies of CAM approaches are already underway. NCI - sponsored projects recently have suggested that both vitamin E and selenium supplements can safely prevent prostate and other cancers. More investigation is indicated and NCI continues to support several studies addressing effectiveness in the prevention of prostate cancer by lycopene and dietary soy, as well as vitamin E and selenium.

To enhance our collaboration with the CAM community toward bringing effective prevention strategies and therapies to cancer patients we worked with NCCAM to establish the federally-chartered Cancer Advisory Panel (CAP-CAM). The CAP-CAM meets 2 to 3 times a year and draws its 15 members from a broad range of experts from the conventional and CAM cancer research community. This group will review and evaluate summaries of evidence for CAM cancer approaches submitted by practitioners, make recommendations on whether and how these evaluations should be followed up, and be available to observe and provide advice about studies supported by the NCCAM and NCI, and about communication of the results of those studies. The panel affords CAM practitioners the opportunity to submit retrospective analyses of data from patients treated with a specific modality and to allow an expert panel of CAM and conventional scientists to assess possible therapeutic benefit. This is formally known as the Best Case Series (BCS). The CAPCAM held its first meeting on July 8-9, 1999, in Bethesda, MD. Panel members discussed the scope of their advisory role and assessed presentations of two Best Case Series. The CAPCAM's recommendations were: additional study of a specific dietary supplement as a treatment for non-small cell lung cancer, currently provided by the Connecticut Institute of Aging and Cancer; and further exploration of homeopathic cancer treatments, provided by the PB Homeopathic Research Foundation, Calcutta, India. We are enthusiastic that this group can work collaboratively in a new partnership between the conventional and CAM cancer research communities.

Direction of Future Efforts

A number of additional central questions about prostate cancer have been identified, as well as potential strategies to address them. These include:

1) Testing promising preventive agents, particularly in high risk individuals;
2) Developing new, predictive molecular diagnostics;
3) Validating current and new early detection markers;
4) The linkage of new imaging technology to directing therapy and assessing its effects without invasive procedures;
5) Epidemiologic studies to attempt to systematically identify correlates of the profound geographic and population differences in prostate cancer rates; and
6) Developing new animal models that faithfully reproduce human prostate cancer in order to better understand tumor development and spread, and to better test preventive and therapeutic interventions.

All of these opportunities build on a strong base of existing prostate cancer research including:

1. The Cancer Genome Anatomy Project (CGAP), the goals of which are to build an index of all genes that are expressed in tumors and support development of new technologies that will allow high throughput analysis of gene and protein expression as well as mutation detection. The tumor type with the highest representation in the early stages of the CGAP effort is prostate cancer. NCI has facilitated investigator collaborations of

interdisciplinary studies following the recent discovery of a susceptibility gene on chromosome 1. Leads from this effort may help to clarify genetic and gene-environment interactions responsible for black-white differences in risk.

2. NCI funded (in total or in part) 246 clinical trials in prostate cancer, including 80 Phase III studies and 37 Phase II studies. NCI clinical studies in prostate cancer have significant African-American participation. One NCI study shows that 14.7 percent of men enrolled onto NCI sponsored prostate cancer treatment trials are African American while 10.3 percent of Americans diagnosed with prostate cancer are African American.

3. NCI's ongoing Prostate Cancer Prevention Trial (PCPT) involves 18,000 healthy men over the age of 55 to determine if the drug finasteride can prevent prostate cancer.

4. NCI's ongoing Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO) is assessing the efficacy of prostate cancer screening. New PLCO sites are being added to enhance minority patient accrual. NCI also is co-sponsoring with the Veterans Administration the PIVOT trial in which "watchful waiting" is being compared in terms of outcome with surgical removal of the prostate. This trial is intended to determine whether conservative treatment of localized disease may be an acceptable alternative to surgery.

5. NCI staff analyzing the Surveillance and End Results (SEER) Program data have shown that there are tremendously differing patterns of care among black and white men with prostate cancer. Encouragingly, however, NCI staff and the Department of Defense have collaborated in a study of treatment data and shown that equal treatment yields equal outcome within disease stages. This finding suggests that NCI efforts to improve prevention, diagnosis, and treatment of this disease have the potential to benefit all patients equally.

6. NCI, along with the American Cancer Society and the Centers for Disease Control and Prevention sponsored a Leadership Conference on Prostate Cancer in the African-American Community in November of 1997. Developed in cooperation with the 100 Black Men of America, the Intercultural Cancer Council, the National Black Leadership on Cancer, and the National Prostate Cancer Coalition, the conference represented a significant step toward developing a strategy for the full participation of African Americans in prostate cancer research and control.

7. In addition, NCI recently conducted a large interview-based study of prostate cancer in African Americans and whites. Analysis of the results has not thus far revealed any specific factor that could explain the racial differences in risk. However, further studies are underway, including an extensive evaluation of the role of different components of the diet.

Public Understanding

Communicating with cancer patients, individuals at high risk for cancer, the general public, and the health care community is a central component of NCI's mission and mandate. For prostate cancer, the institute communicates information to all of those groups, as well as to the cancer research community.

Materials available from NCI, including print, video, and web products, range from basic information about the disease, information about research now ongoing to improve understanding and management of the disease, and information for men about early detection and treatment options.

One of the most recent communications initiatives is a partnership with the prostate cancer advocacy organization, US TOO, to develop a national communications initiative, called *Know Your Options*, to better inform men and their families about the disease. The initiative is based on an information package or kit that provides a solid base of information about prostate cancer to help US TOO chapters work with their hometown media. The media, in turn, use the information provided by US TOO with the NCI endorsement to keep their readers, listeners, and viewers informed about the disease. The kit includes the latest medical and scientific information available, as well as information about where US TOO chapter leaders can go for more information, advice, and help.

In addition, information specialists from the NCI-sponsored Cancer Information Service provide more than 60,000 people annually with information about prostate cancer, information about research on the disease, information about screening and treatment options, and information about coping with physical and psychological side effects of the disease and its treatment. The NCI web site provides information about prostate cancer clinical trials as well as information about treatment options for every stage of the disease.

NCI is currently working with the Centers for Disease Control and Prevention and with the Health Care Financing Administration to develop an educational video for men on issues they could face with regard to prostate cancer screening, diagnosis, and treatment. The video, intended to be relevant to a general male audience, will be developed to have special relevance to African-American men. The video will provide educational material on what men need to know about prostate cancer screening options, what they need to know about diagnostic follow-up if a screening test is positive, and what they need to know about treatment options if the diagnosis is positive.

NCI's basic print product about the disease, *What You Need to Know about Prostate Cancer*, is now available on the web as well. It provides information about prostate cancer; its symptoms, diagnosis, staging and treatment; clinical trials; side effects of treatment; nutrition and other support for prostate cancer patients; and what prostate cancer research holds for the future. A new publication from NCI, *Understanding Prostate Changes: A Health Guide for All Men*, will soon be available on the web too. It covers all aspects of prostate cancer in more depth than the basic booklet, but also describes non-cancerous prostate conditions. Another product in development, *called Prostate Cancer Treatment: Know Your Options*, will be published in print format soon and will also be available on the NCI web site.

NCI is communicating vigorously with the cancer research community. Earlier this year, NCI staff described all of the prostate cancer research initiatives that exist at the institute, and placed that information on its web site. The institute then promoted the availability of that information and issued an invitation for grant applications from the scientific community. The promotion of the information on the web site included the placement of advertisements in major scientific journals, the distribution of packets of information to the nation's cancer centers, and the distribution of information through direct mail to cancer investigators. Since the promotion began in late February, the web page listing prostate cancer grant opportunities has had thousands of hits from those seeking information about the grant opportunities.

Mr. Chairman, I appreciate the level of interest this Committee has shown in prostate cancer. I hope my testimony demonstrates NCI's commitment to advancing our knowledge about prostate cancer as rapidly as possible. Our activities, and specifically Dr. Klausner's leadership efforts, over the past year have invigorated the prostate cancer research community. It is this essential partnership between NIH, other funders and that research community that will successfully accomplish the ambitious goals of this plan. I would be pleased to answer any questions you may have.

National Cancer Institute Websites

To access electronic information about prostate cancer from NCI visit our web site at: http://www.nci.nih.gov

The National Institutes of Health Report, Planning for Prostate Cancer Research will be posted: http://www.nci.nih.gov/prostateplan.html

Prostate Cancer Initiatives is available at:
http://www.nci.nih.gov/prostate.html

The Prostate Cancer Progress Review Group Report is available at:
http://wwwosp.nci.nih.gov/planning/prg/default.htm

Mr. BURTON. Thank you, Dr. Kaplan. Dr. von Eschenbach.

Dr. VON ESCHENBACH. Good afternoon Mr. Chairman, members of the committee. I am honored to be here today representing the American Cancer Society as a national board member and would like to thank you and the committee for the opportunity to appear to testify on issues concerning our Nation's fight against prostate cancer.

In addition to my involvement in the American Cancer Society, I have been privileged to participate in this fight in a variety of other ways, serving as the chairman of the Prostate Cancer Multidisciplinary Research Program at the University of Texas M.D. Anderson Cancer Center. As well as being the chairman of the Integration Panel for Prostate Cancer in the congressionally directed research program at the Department of Defense, I am a medical and scientific advisory cochair of the National Prostate Cancer Coalition and a member of the Scientific Advisory Board of CAP-Cure. This involvement in prostate cancer has impressed upon me that this disease is a national tragedy.

Mr. Chairman, this morning you so eloquently described the burden of this disease by demonstrating those statistics. And we heard earlier today from Senator Dole and Congressman Cunningham and Mrs. Gallo the enormous pain and suffering that this disease inflicts on both patients and their families.

The Cancer Society recognizes that prostate cancer is a medical and scientific problem as well as a cultural and social problem and economic problem. And so we have chosen to really advocate a comprehensive three-pronged approach that recognizes the importance of contributing to and enhancing the funding of research so we can develop more effective strategies of prevention and therapy, to advocate for equal access to quality care throughout this entire country and to improve our education and promotion of early detection and treatment options.

Today I can only focus on one of those many important issues and I would like to then comment specifically upon the importance of enhancing our commitment to the research endeavor.

The American Cancer Society supports the strategic plan of the National Cancer Institute and the Department of Defense to promote and enhance our research effort in prostate cancer. This disease is an incredibly complex problem. There are important fundamental issues that need to be addressed if we are truly going to face and change those statistics that you pointed out to us this morning.

Why in one patient is this a latent disease while in another like Congressman Gallo it can be incredibly virulent and lethal in a short period of time? Why does it take such an enormous toll on African-Americans in this country? And why does the lethal form of prostate cancer that kills us preferentially metastasize to bone where it then becomes refractory to our standard treatments?

If we are going to make a difference, the only way to make that difference is by understanding these processes so we can then rationally develop appropriate, effective strategies to interrupt them.

It is true that you should take great pride in what you have already accomplished in supporting research throughout this country through your efforts, and that research is bearing fruit. The PSA

that you have heard about today from so many people that has altered and changed our ability to find this disease early in its course when it is potentially curable is a direct result of research. There are now new therapies that are being introduced in the clinic today, including at M.D. Anderson trials where we are now taking some of the genes that are defective in the more virulent forms of prostate cancer and, using an adeno virus as a carrier, we are able to reinfect those prostate cancer cells with the normal gene in an effort to prevent their lethal progression.

You have heard about a variety of new compounds and substances that are coming to us, such as the antiangiogenesis factors that stop the blood supply to these tumors and keep them from being able to spread and progress.

And so much is being accomplished but so much yet needs to be done, and frankly the funding to do it is inadequate. As I mentioned, I chair the Integration Panel at the Department of Defense. You have been generous in this Congress in fiscal year 1999 to allocate $50 million to that program for research, of which we had about $41 million to spend across a wide variety of needs, including the training of new investigators in the field, the development of programs in minority universities and colleges, and then we had about $20 million left over to fund novel new ideas in prostate cancer research as well as the development of young investigators.

We received in that program over 560 applications of which we had only sufficient money to fund 46, an 8 percent funding level. If we just look at those ideas that the peer review panels believed to be outstanding and excellent and scored about 2.0 in their priority scores, we were only able to fund one of three; two out of every three ideas had to be rejected, not because they were not excellent but because we did not have sufficient funds.

It is essential for us to change the face of this disease to understand it better, and then to translate that understanding into clinical trials, evaluating new and effective methods so that we can make them available to men and their families to achieve the scientific breakthroughs that you expect of us.

I have been privileged for over 25 years to walk this journey with prostate cancer patients and their families, and my own father died of this disease. I thank you and your committee for the concern and dedication that you are demonstrating in having these hearings. And this week, National Prostate Cancer Awareness Week, is a special time to remember the fathers and husbands and brothers who have been lost to this disease. The American Cancer Society and I, along with all the organizations I am privileged to be a part of, look forward to working with you in a partnership to change this journey of fear and suffering into a journey of hope. Thank you.

[The prepared statement of Dr. von Eschenbach follows:]

TESTIMONY OF
ANDREW VON ESCHENBACH, MD
NATIONAL BOARD MEMBER
AMERICAN CANCER SOCIETY

BEFORE THE
UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

"FIGHTING PROSTATE CANCER: ARE WE DOING ENOUGH?"

SEPTEMBER 23, 1999
10:00 AM

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Good Morning, Mr. Chairman and members of the Committee. I am Dr. Andrew von Eschenbach, Director of the Center for Genitourinary Cancer and the Prostate Cancer Research Program at the University of Texas M.D. Anderson Cancer Center. I am honored to be here today representing the American Cancer Society as a national board member and would like to thank you for the opportunity to appear before this Committee to testify on issues concerning our nation's fight against prostate cancer. In addition to my involvement in prostate cancer issues at the American Cancer Society, I am currently the Chairman of the Integration Panel for the Congressionally directed Department of Defense Prostate Program, Co-Chair of the Medical Scientific Advisory Committee of the National Prostate Cancer Coalition (NPCC), and a member of the Medical Scientific Advisory Committee of CAP-Cure. But today, my most important role is to bring you the message of the American Cancer Society.

The Society is the largest voluntary community-based health organization in the country. We're comprised of all walks of life -- including doctors, scientists, researchers, nurses, healthcare providers, and health educators. And perhaps most importantly, we're comprised of cancer survivors, and family of those who lost their battles. Men and women like you all, and the people in this room. Every single one of us has unfortunately been touched by cancer in some way, and every single one of us wants to stop its scourge. The American Cancer Society is two million men and women strong, and with our diverse backgrounds, we're uniquely qualified and positioned to help shape policy and respond to questions pertaining to cancer and how to help stop it. Because of our make-up, we are positioned to balance medical and scientific perspectives with the needs of cancer survivors, patients, and future cancer patients. To that end, I appreciate the opportunity to share with you and members of this Committee the American Cancer Society's strategies for conquering prostate cancer, as we know it today.

PROSTATE CANCER: STEPPED UP COMMITMENT IS NEEDED TO ADDRESS A NATIONAL KILLER

Mr. Chairman, you have asked me to testify about a national killer that takes the lives of more than 37,000 men annually. As you know, prostate cancer is the most prevalent malignant disease afflicting American men and their families. And while it's the second leading cause of cancer death in all men, far too little is known about the cause and behavior of prostate cancer. We do know that the disease is more than a medical and scientific curiosity. It is a national problem that has a severe impact on our society and the economy.

Everyday one hundred men die from this disease. It is a slow death—taking several years with progressive pain, distress and mounting medical costs. It is certain that

every man is at risk of developing prostate cancer, but it is uncertain in many cases what the optimal choice and timing of therapy should be.

Like many other forms of cancer, prostate cancer disproportionately impacts socioeconomically disadvantaged Americans and some racial minorities. African American men are at particularly high risk for this disease. In fact, African American men have the highest rate of prostate cancer in the world. Black men are also much more likely to be diagnosed with more advanced stage disease and are less likely to survive prostate cancer. Interestingly, Chinese men residing on mainland China have the lowest rates in the world, but Chinese men living in the United States have a rate 16 times higher than their counterparts.

Because of the prevalence and diverse behavior of prostate cancer, the American Cancer Society recommends a multiple pronged approach to tackling this deadly disease. The first is providing much-needed funding for research. The second is bridging the gap between what is known and what is practiced. The third is assuring better communication between health care providers, patients and their families regarding early detection and treatment.

I. RESEARCH--AN URGENT NEED TO EXTEND AND EXPAND OUR SCIENTIFIC KNOWLEDGE OF PROSTATE CANCER:

Cancer research is producing extraordinary breakthroughs – for example, recent studies have given us increased understanding of how prostate cancer progresses and have lead to new treatments and medicines that may lead to longer survival and improved quality of life for cancer patients. Research gives us hope for a cure and advancements in the treatment and management of the disease. It has given us the Prostate-Specific Antigen (PSA) test, which is by far the best screening test available for prostate cancer. Research has also shown us that diets high in fat increase the risk for more aggressive forms of prostate cancer. There is also recent evidence that smokers with prostate cancer have worse prognosis than nonsmokers diagnosed with the disease.

However, at this point, we do not yet have answers to many basic questions about prostate cancer. Can prostate cancer be prevented? Does screening save lives? Why does prostate cancer impact African American men disproportionately? Why does prostate cancer preferentially metastasize to the bone and become refractory to therapy leading to lethal disease? We can expect that new scientific knowledge will be forthcoming to answer many of the important research questions that remain outstanding only if the national investment in cancer research is increased significantly. Also, we must ensure that these research findings are broadly applied in real life for the prevention,

detection, and treatment of prostate cancer -- that all Americans whether they are rich or poor, insured or uninsured benefit from optimal care.

There are scientists who are ready and able to take on new projects that may answer these important questions-- but the funding just isn't there. The American Cancer Society is calling on Congress to increase investment in prostate cancer research by providing the necessary funding for research at the Department of Defense (DOD) and the National Cancer Institute (NCI). Specifically, the American Cancer Society urges Congress to provide $5 billion to the National Cancer Institute to continue efforts on their broad research agenda while ensuring that laboratory findings, cancer control interventions and services, and prevention efforts reach all Americans. The American Cancer Society also supports the Department of Defense Peer Reviewed Prostate Cancer Research Program. When Congress established this medical research program three years ago, it offered real leadership and hope to the millions of men and their families in this country whose lives have been touched - and in many cases devastated - by prostate cancer. Consequently, the American Cancer Society urges Congress to provide no less than $100 million for the DOD prostate cancer research program in Fiscal Year 2000 and commit to fully fund the program in no more than three years.

Both the DOD and the National Institutes of Health (NIH) have outlined strategic investment plans for their respective research programs. The American Cancer Society believes these business plans hold promise for rapid progress toward better treatments and ultimately a cure. But unless these programs are adequately funded, it's just a plan on a piece of paper and its promise will remain unrealized. The bottom line is that if we are to mount a serious attack on prostate cancer, researchers must have the tools and resources that they need. Effective strategies will result from this investment and will change the face and future of prostate cancer.

Clinical trials are a critical component of research. These trials are the only way we know if the treatment developed in the lab will be effective in treating patients. Treatment under a clinical trial may be the best and/or only option of treatment a patient has; and, clinical trials advance clinical knowledge on how to best prevent, detect and treat prostate cancer. However, the NIH has noted that enrollment in clinical trials is decreasing and some of that is attributable to the changes in our health care delivery system. Continuing to increase national funding for NIH and prostate cancer research -- while failing to take the essential steps to ensure adequate enrollment in the clinical trials that are necessary to study the benefits of various new strategies and therapies -- is not a wise national investment. One strategy to ensure greater participation in clinical trials is to assure that routine patient care costs are covered. It is crucial that all health plans, including Medicare, cover routine patient care costs associated with clinical trials so all individuals who wish to participate may do so. To that end, the American Cancer Society supports legislation, including HR1388: the Medicare Cancer Clinical Trials

Coverage Act, that will assure the coverage of routine patient care costs associated with clinical trials.

II. BRIDGING THE GAP BETWEEN WHAT IS KNOWN AND PRACTICED-

Mr. Chairman, the gap between what is known and can be known is smaller today thanks to our nation's ongoing commitment to research. Another challenge -- for the American Cancer Society, Congress, and others in the public and private sectors -- is to reduce the gap between what is known by the scientists and what is practiced by health professionals and experienced by patients. Cancer patients have unique health care needs. Policymakers need to ensure that cancer patients get quality health care every time they see their doctor, go to the hospital, or need medical services of any kind. Access to quality and timely cancer care is needed if we are to stem the tide of this disease.

Similarly, the Society continues to support legislation aimed at assuring coverage of prostate cancer screening for all men—risk and age appropriate. The Society also believes that information should be provided to patients regarding potential risks and benefits of intervention. The decision to be screened for prostate cancer should be made by men in consultation with their doctors. Men who decide with their doctors to be tested should not have their decision altered by financial considerations. To that end, the Society supports legislation, such as HR1285: The Cancer Screening Coverage Act of 1999. This legislation helps assure guaranteed access to important cancer screening tools used for early detection of multiple kinds of cancer, including prostate cancer. Additionally, the American Cancer Society appreciates efforts by Congress to include prostate cancer screening for Medicare beneficiaries. As you know, the prostate cancer screening benefit is expected to be available the beginning of 2000. The American Cancer Society hopes that the process of implementation is on track and that there will be no delay.

Unfortunately, if you are among the 43 million uninsured (16% of the population) in our nation, you are not assured quality, timely, cancer screenings and care. This number is likely to rise to 53 million within the next few years. Of additional concern is the problem of underinsurance. Millions more Americans have inadequate health insurance coverage -- a problem which can often adversely impact care seeking behavior and health outcomes. Prostate cancer affects these individuals as well. We can not overlook the importance of effective public health policies and strategies to ensure quality cancer care for all individuals. The American Cancer Society stands ready to work with you and your colleagues to develop an action plan and appropriate public policies to move our nation in a direction where cancer prevention, early detection, quality cancer care and survival are the norm -- not the exception—for all individuals.

III. ASSURING COMMUNICATION BETWEEN PATIENTS, FAMILY AND DOCTORS

Mr. Chairman, health and medical organizations have not yet come to consensus on the issue of screening for prostate cancer. Some groups believe that there is insufficient scientific evidence to determine whether prostate cancer screening saves lives or whether treatment is more effective than no treatment. Others, including the American Cancer Society, believe that men at high risk should be offered screening for prostate cancer because cancers may be found at an earlier stage when treatment is more likely to be effective. While we recommend that men at risk be offered screening tests, we also recognize that many men have undergone treatment for prostate cancer that has reduced their quality of life. We have concluded that the best approach is to provide men and their families with good information about the possible benefits of screening and the potential risks of treatment. Men should be offered the test, and they should decide in consultation with their physician whether to be screened or not. What we need to do is to create education programs that raise awareness about prostate cancer and get the right information out to those at highest risk.

Mr. Chairman, medical choices should always be made on an individual basis, requiring that physicians and their patients have access to the resources needed to make an informed decision about their treatment and care. The American Cancer Society is committed to improving public understanding of emerging science and will continue to work with its public and private partners to raise public awareness of key issues in the area of prostate cancer. Of considerable importance to all of us is the public availability of accurate, up-to-date information about prostate cancer therapies, including complementary and alternative methods.

The American Cancer Society realizes that there are many definitions for the terms "alternative" and "complementary" methods and makes the following distinction between these categories. "Alternative" methods are defined as unproven or disproved methods, rather than evidence-based or proven methods to prevent, diagnose, and treat cancer. "Complementary" methods are defined as supportive methods used to complement evidence-based treatment. Complementary methods do not replace mainstream cancer treatment and are not promoted to cure disease. Rather, they may control symptoms and improve well being and quality of life. This distinction separates the two methods based on how they are promoted and used.

The Society is sensitive to the growing public interest (in particular, from those living with cancer) in information about alternative and complementary methods. The Society acknowledges that more research is needed regarding the safety and effectiveness of many of these methods. The Society advocates the development of peer-reviewed scientific evidence of the safety and efficacy of these methods. It is the belief of the

American Cancer Society that all cancer interventions must withstand the scrutiny of peer-reviewed scientific evaluation before they can be recommended for the prevention, diagnosis, or treatment of cancer.

The Society recognizes the need to balance access to alternative and complementary methods while protecting patients against methods that might be harmful to them. The Society supports patient access, but strongly encourages more oversight and accountability by governmental, public, and private entities to protect the public from harm as they seek methods to complement mainstream cancer care. Harmful drug interactions may occur and must be recognized. Unnecessary delays and interruptions in standard methods are detrimental to the success of cancer treatment.

The Society supports the right of individuals with cancer to decide what treatment is best for them. But we encourage people to discuss all treatments they may be considering with their physician and other health care providers. We also encourage people with cancer to consider using methods that have been proven effective or those that are currently under study in clinical trials. We also encourage health care professionals to ask their patients about their use of alternative and complementary methods. Health care professionals should listen and know how to communicate with their patients. Open, trusting, non-critical dialogue is essential in this important area.

CONCLUSION-

Mr. Chairman, as someone who has had the privilege to walk the journey with prostate cancer patients and their families for more than 25 years and whose own father died of this disease, I want to thank you and your Committee for the concern and dedication you have demonstrated for eradicating this disease. This week, National Prostate Cancer Awareness Week, is a special time to remember the fathers, husbands, and brothers who have been lost to this disease. But after this week has passed, we must remember that every single day for the rest of the year that approximately 400 men will learn they have the disease and 100 men will die as a result of prostate cancer. As horrific as those numbers are, they don't begin to tell the story of the journey of anxiety, suffering, fear, and humiliation that they unfortunately will likely face every day for the rest of their lives. The American Cancer Society and I, along with all of the organizations I am privileged to be a part of, look forward to working with you in partnership to change that journey of fear and suffering into a journey of hope.

I will be happy to answer any questions.

Mr. BURTON. Thank you, Doctor. Dr. Thompson.

Dr. THOMPSON. Good afternoon, Mr. Chairman, members of the committee. My name is Ian Thompson. I am a urologic oncologist from San Antonio. I am a professor of urology at the University of Texas Health Science Center, director of the Prostate Cancer Program at the San Antonio Cancer Institute, and consultant in urology to the Surgeon General of the United States Army. I would like to express my sincere appreciation for the opportunity to participate in this important hearing.

With the successful aging of the U.S. population, prostate cancer has become an increasingly important public health threat. This disease will assume increasing importance as its frequency is directly related to a man's age. With the continued improvement in life expectancy in the United States, prostate cancer will become an even more significant disease.

Traditionally, we have focused on two methods of addressing the disease. The first was an effort to improve our treatment of prostate cancer which as of this morning you heard it can spread to the bone and can be associated with significant pain, decreased appetite, and a major reduction in the quality of life. While much knowledge has been attained through cancer clinical trials, rarely can this stage of the disease be cured.

With the advent of prostate specific antigen [PSA], testing in the 1980's, the focus moved to early detection and treatment. Over the subsequent decade we have witnessed a fall in prostate cancer deaths. The degree to which this fall is due to PSA testing is yet undetermined, but it is an extremely important and promising development. Nevertheless, the cost and side effects of such treatment can be significant.

The science of cancer prevention is one of the youngest fields of oncology. Nevertheless, important advances have been witnessed in the past 10 to 15 years with many of these advances heralding a new age in our approach to prostate cancer. I often tell my colleagues and my residents and my peers that I personally believe the next decade will be the decade of prevention in oncology, and I am very optimistic that much will be accomplished in the very near future.

We are currently witnessing a confluence of many discoveries that when paired with the considerable interest by your committee and by the National Cancer Institute and other funding agencies, can be expected to provide patients and clinicians with practical, proven methods to reduce a man's risk of developing prostate cancer.

On the basic science front we are understanding much better those individual steps that cause a normal prostate cell to divide, invade the prostate, and then spread. Each of these steps involves many processes and each offers a target of opportunity to prevent development or spread of the disease.

Through observational studies we have also identified a number of new agents and approaches that deserve investigation, many of which offer tremendous promise to reduce the risk that a man will develop prostate cancer.

We know, for example, that male hormones play a major role in the development of the prostate and ultimately of enlargement of

the prostate and prostate cancer. With the development of the first five-alpha reductase inhibitor medication called finasteride that reduces the hormonal stimulation of the prostate, the National Cancer Institute in collaboration with the Southwest Oncology Group developed the Intergroup Prostate Cancer Prevention Trial to determine if this agent can prevent the development of prostate cancer.

The response of men in this country to this trial was overwhelming and indeed 18,881 men ultimately enrolled in this study and this study reached its enrollment goals exactly 3 years to the date of its inception directly on schedule. We were actually overwhelmed with the response. My understanding is that the Cancer Information Center of the National Cancer Institute received its largest volume of phone calls the day after we had a press conference here in Washington to announce this trial. I oftentimes say that men voted with their feet. They thought that they would never participate in a prevention trial. These were healthy men without evidence of prostate cancer and we were overwhelmed by the interest.

We expect the results of this study to be available in the next several years. Efforts at prostate cancer prevention, however, have not stopped there. I am aware of many trials assessing the effects of multiple novel agents on prostate cancer development. We in San Antonio are currently conducting a study of alpha tocopherol, which is vitamin E, a very promising chemo-preventive agent in men at high risk of developing prostate cancer.

A second micronutrient, selenium, an agent which may, like vitamin E, function as an antioxidant is also being studied in a number of trials. In response to the evidence of the potential effectiveness of these agents the Southwest Oncology Group and the Department of Veterans Affairs have collaborated to develop the neat intergroup prevention trial called SELECT, the Selenium and Vitamin E Chemoprevention Trial, a study proposed to study 32,400 men and we hope if it is funded it will begin next summer. I am very optimistic that for many of my generation and certainly for those of my son's generation—and I have to reflect back, my grandfather passed away from prostate cancer as well, and so I have a personal interest in this as well—that we will have clear evidence that the risk of prostate cancer can be reduced.

We are currently approaching this challenge on many fronts: In the molecular biology laboratories of the United States, through epidemiologic studies, using cancer models and most importantly through well-designed prospective clinical trials. It is only through these trials that we will be able to assure men with confidence that our recommendations are scientifically valid. The contributions of the Cooperative Clinical Trials Groups and the National Cancer Institute have been enormous, as has this interest by this committee, and your collaboration sets the stage for the discoveries over the next decade.

Again, Mr. Chairman, members of the committee, it has been a distinct honor to have been here, and I thank you for your interest.

Mr. BURTON. Thank you very much, Dr. Thompson.

[The prepared statement of Dr. Thompson follows:]

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Medical School
Department of Surgery

Good morning Mr. Chairman, Congressman Waxman, ladies and gentlemen. My name is Ian Thompson, M.D. and I am The Consultant in Urology to the United States Army Surgeon General as well as Professor of Urology at the University of Texas Health Sciences Center at San Antonio. I would like to express my thanks for the opportunity to participate today in this important hearing.

With the successful aging of the U.S. population, prostate cancer has become an increasingly-important public health threat. The disease will assume increasing importance as its frequency is directly related to a man's age. With the continued improvement in life expectancy in the U.S., prostate cancer will become an even more significant disease.

Traditionally, we have focused upon two methods of attacking the disease. The first was an effort to improve our treatment of prostate cancer which had spread to the bone and was associated with pain, decreased appetite, and a major reduction in quality of life. While much knowledge has been attained through cancer clinical trials, rarely can this stage of cancer be cured.

With the advent of Prostate Specific Antigen (PSA) blood testing in the 1980's, the focus moved to early detection and treatment. Over the subsequent decade, we have witnessed a fall in prostate cancer deaths – the degree to which this fall is due to PSA testing is yet undetermined but it is an extremely promising development. Nevertheless, the cost and side effects of such treatment can be significant.

The science of cancer prevention is one of the youngest fields of oncology. Nevertheless, important advances have been witnessed in the past 10-15 years, with many of these advances heralding a new era in our approach to prostate cancer. I often tell my colleagues that the next decade will be the decade of prevention. I am very optimistic that much will be accomplished in the near future.

We are currently witnessing a confluence of many discoveries that, when paired with the considerable interest at the National Cancer Institute and other funding agencies, can be expected to provide patients and clinicians with practical, proven methods to reduce a mans risk of developing prostate cancer. On the basic science front, we are understanding much better the steps that cause a normal prostate cell to divide, invade the prostate, and spread. Each of these steps involves many processes and each offers a target of opportunity to prevent development or spread of the disease.

Through observational studies, we have identified a number of new agents and approaches that deserve investigation, many of which offer tremendous promise to reduce the risk of prostate cancer. We know that male hormones play a major role in the development of the prostate and of prostate cancer. With the development of the first five-alpha reductase inhibitor – finasteride – that reduces the hormonal stimulation of the prostate, the National Cancer Institute in collaboration with the Southwest Oncology Group developed the Intergroup Prostate Cancer Prevention Trial to determine if this agent can prevent the development of prostate cancer. The response of men around the U.S. was overwhelming with 18,881 men ultimately enrolling in the study that reached its enrollment goals on schedule, exactly three years to the day of its inception. We expect the results of this study to be available in the next several years.

Efforts at prostate cancer prevention have not stopped there. I am aware of many trials assessing the effects of multiple novel agents on prostate cancer development. We are currently conducting a study of alpha tocopherol – Vitamin E – a very promising chemopreventive agent – in men at high risk of developing prostate cancer. A second micronutrient – selenium – an agent that may, like Vitamin E, function as an antioxidant, is also being studied in a number of trials. In response to the evidence of the potential effectiveness of these agents, the Southwest Oncology Group and the Department of Veterans Affairs have collaborated to develop the next Intergroup prevention trial – SELECT – the SELenium and vitamin E Chemoprevention Trial, a trial proposed to study 32,400 men.

I am very optimistic that for men of my generation and certainly for those of my son's generation, we will have clear evidence that the risk of prostate cancer can be reduced. We are currently approaching this challenge on many fronts – in the molecular biology laboratories of the U.S., through epidemiologic studies, using cancer models, and, most importantly, through well-designed, prospective clinical trials. It is only through these trials that we will be able to assure men with confidence that our recommendations are scientifically valid. The contributions of the Cooperative Clinical Trials Groups and the National Cancer Institute have been enormous and their collaboration sets the stage for these discoveries over the next decade.

Again, Mr. Chairman, Congressman Waxman, I would like to express my appreciation for your invitation and the opportunity to address this Committee. Thank you.

Mr. BURTON. Dr. Kail, you indicated that one-third of 1 percent of the total NIH budget is used for alternative therapies; is that correct?

Dr. KAIL. That was the figure that was passed out at the NCCAM meeting that recently was held when they looked at just what funding characteristics they had had. Other interesting things there was about this much basic science funding and this much clinical outcome funding, which I thought was quite appropriate.

The thing I found most interesting about the funding pattern was that many of the institutions that put forth proposals at least, at the NCCAM meeting, were conventional institutions. I mean Harvard for instance had 10 or 12 proposals put forth. Many of these institutions have no CAM providers in their proposals and they were not being done at CAM institutions. With the paucity of knowledge in the conventional community about alternative therapies, I find that we are having the same research organizations as apply for conventional grants turn right around and go for funding under alternative medicine.

It is very clear that the alternative medicine research community is not equipped to compete for funds even under NCCAM guidelines. We have to go out and recruit these individuals, mostly because the best research—the best treatment of cancer patients does not occur in the research institution itself, does not even occur in medical schools. It occurs by alternative medicine doctors practicing on their own in the field and most of these people are getting good outcomes but not even tracking them.

They have an inherent fear of dealing with research organizations, especially allopathic ones, because they are concerned that they may not have control of the research and the outcomes may not be the same as they could achieve. This is a real problem about getting alternatives really looked at under this microscope. We have to get them access to it.

Mr. BURTON. Dr. Chen, you were talking about this new combination of vitamins and other things that was put into what did you call it, PC SPES?

Dr. CHEN. Yes, a combination of plant extracts.

Mr. BURTON. And you said that there were some side effects. What kind of side effects were you talking about?

Dr. CHEN. The side effect has not been officially established but based on the observation include the decrease in libido.

Mr. BURTON. Decreasing libido?

Dr. CHEN. Yes, and some breast tenderness.

Mr. BURTON. Some breast tenderness? And that is a combination of how many different kinds of vitamins? Selenium, vitamin E. What else? Green tea.

Dr. CHEN. Well, there are eight different herbs. Seven of them are Chinese herbs and one American herb. The herbs belong to the common use.

Mr. BURTON. I think I take all of those things and I haven't had any of those side effects yet, but I don't take them in one pill.

Let me just ask those of you who are from the National Institutes of Health and National Cancer Institute, why is it that we don't put more money into alternative research? One-third of 1 per-

cent seems like such an insignificant amount, especially when there is a growing percentage of Americans and if you don't believe it, all you have to do is go to the health food stores. They are voting with their feet and their dollars. They believe that there are some preventive qualities in some of these things that they are buying at health food stores and from going to these alternative physicians.

Why is it that the NIH and National Cancer Institute are not allocating more money for research in those areas? Can somebody answer that for me? One-third of 1 percent of the total budget doesn't seem like very much to me.

I think the answer is not so much why they are not putting so much money in as much as why are investigators not applying more effectively to get that money. Most of the money that is spent is spent in response to applications that come in from independent investigators who say, here is an experiment that I want to do, and it gets peer reviewed; and as we all know, we don't get to fund as many as review well, but we fund as many as we can. But a lot of the money goes to whatever research applications come in that are very well done.

If they don't come in, the money doesn't go in that direction so much.

Mr. BURTON. You heard Dr. Kail talk about one of the problems that he had with it.

Dr. KAPLAN. I did. Can I respond to that? Because I think he was describing a glass that was half empty, but I would say, in a sense, that is a glass that is half full. I actually find it encouraging that conventional practitioners and institutions are, in fact, willing to take up this level of research, that there is not some wall between the types of agents involved or the types of research.

There has been an unfamiliarity, but it looks like there are efforts afoot to break down that unfamiliarity, and those researchers do have the track records of knowing how to get patients to respond and participate. I think that is going to be a tremendous asset to evaluation of these techniques.

Mr. BURTON. Do you have a comment?

Dr. VON ESCHENBACH. Thank you, Mr. Chairman.

I cannot speak for the National Cancer Institute, actually, but with regard to the Department of Defense program in prostate cancer, I will be happy to provide specific detail later. I don't have it, but I do know that in that research effort, we did fund and have received important applications in looking at the role of diet and dietary supplements, such as the ones that were mentioned today.

So much interest is being developed in the scientific community in looking at these opportunities. Even at an institution such as M.D. Anderson, which is a very large, complex academic cancer center, we have a substantial investment in what would be described as complementary and alternative medicine, including research that is being developed in the role of spirituality, stress reduction. We have the availability of tai chi and yoga, the availability of acupuncture.

So I think the point to be made is that there is an explosive interest in what we would consider to be first-line academic, scientific institutions, to look into this area, but to look into it in a critically

important way so we can then apply it to patients in a rational fashion.

Mr. BURTON. Mr. Turner, do you have some questions?

Mr. TURNER. You know, it is always, I think, confusing for most men when they hear all these stories and come across articles about dietary supplements and vitamins and herbs that were perhaps helpful in preventing prostate cancer, and it would be interesting—in fact, I guess I might ask Dr. Thompson or Dr. von Eschenbach. If we were to do a survey of the established medical community at the Health Science Center in San Antonio or down at M.D. Anderson, what would we find the urologists and oncologists taking, more likely than not, as a dietary supplement? Because that would probably indicate where at least the medical community thinks there might be the most hope for some effective prevention by way of dietary supplement. What would we find?

This is kind of a talk you might have over coffee with your colleagues, but what would you find them doing?

Dr. THOMPSON. I will answer perhaps for San Antonio, and perhaps Andy can answer for Houston.

We have actually looked at not just members of the medical community, but our patients as well, and we find as many as 45 percent to 50 percent in an average urologic practice are taking some form of dietary supplements, micronutrients and so forth.

I recently addressed about 400 men who are participants in the prevention trial in San Antonio, and when I asked how many were taking vitamin E, which I suspect is second maybe only to a baby aspirin that frequently they are taking at that age, probably one-third to one-half of those men raised their hands. I suspect that our medical colleagues are probably doing that as well.

The difficulty with it, though, is that we suspect that it may have that effect. Heretofore we know that populations who take betacarotene have a lower cancer risk, but then when the National Cancer Institute collaborated with the Finnish and did the study where you take the supplement itself to try to reduce lung cancer risk, it actually increased it. So we have that suspicion that it may work, but actually it takes the clinical trial to move that forward.

I suspect vitamin E and perhaps aspirin is the answer to your question. But, unfortunately, we are kind of—we have no autopilot, we are not sure exactly where we are going until we actually do that clinical trial.

Dr. KAPLAN. Congressman, I would echo those comments. It is extremely important for us to engage our patients in this regard, so that we know what they are doing and how that might or might not interact or complement what we are doing with regard to therapy and treatment, because sometimes they may be taking things that could actually be harmful with regard to the kind of treatments that we are applying.

We provide to patients dietary survey. We provide to them dietary consultation and recommendations regarding low fat and the use of supplemental vitamins. For me, personally, just on a personal note, when I remember, I take my vitamin E and selenium every morning.

Mr. TURNER. Dr. Thompson, you mentioned the study that is involving 18,000 men and then you mentioned one that will involve

30,000 or something. I am not sure I understand exactly what those two studies are designed to do.

Dr. THOMPSON. It is an excellent question, Congressman.

The prostate cancer prevention trial is the first large-scale, randomized trial to address whether an agent can actually reduce prostate cancer. It began in 1993, and it was designed to enroll 18,000 men, actually we overaccrued because of the interest, we had almost 19,000 men who participated. Each one of these men, if you look at a map of the United States, there are dots for each individual's home of record.

The map of the United States is covered with those dots. There are 220 centers around the United States, ranging from cancer centers to a community oncologist's private practice. Those men are taking either the drug itself, which reduces the hormonal stimulation of the prostate, or a placebo tablet, to see whether it will actually reduce their risk of prostate cancer.

The study will begin its end-of-study biopsies of the prostate, as you heard earlier today, in January 2001. It takes a long time to complete those studies because prostate cancer grows and develops so slowly. But we hope by 2004, maybe a little earlier, maybe a little later, we will have the results of the first trial. It is, if you will, the male analog to the tamoxifen trial for breast cancer, one of the first study results.

We feel the data for selenium and vitamin E are so compelling, we are not stopping there. We are planning to begin the next trial to look at vitamin E and selenium to see whether they can reduce the risk in a larger group of men, again men without prostate cancer, absolutely healthy men. We hope to begin that trial next summer. Because we are going to be looking at two agents, it requires even more men and it will be somewhere around 32,000 to address the question.

In 1993—it seems like ages ago that we began—but we are just on the doorstep of our first results of that trial. We feel very, very encouraged by the interest coming from Washington and from the National Cancer Institute in supporting these prevention trials.

Mr. TURNER. Thank you, Mr. Chairman.

Mr. BURTON. Dr. Kail.

Dr. KAIL. I would like to respond to that a little bit.

Here again, is a single or double agent trial that has gone on for years and years and years in a large population until you look at again, alternative medicine uses multiagents. I realize it is difficult to study that, but we cannot use the same old tired methodologies to look at the same stuff. Single-agent, double-blind, crossover trial methodology does not work for alternative medicine, period, end of discussion.

I would like to ask these gentleman if any alternative medical providers are on their staffs or were consulted in protocol or consulted to look at how the care is delivered. I think these are key, key questions that have to be answered by the research community, and we have to get to some new methodology.

This level of trial and taking this long to get to answers is not serving anyone. Too many people are dying. What is wrong with instituting a whole protocol of alternative medicine during this watchful-waiting period and look at outcomes in a group that get

a whole protocol designed in alternative medicine doctors' institutions and see what is the outcome there?

If we go agent by agent in this design, we are going to take a long time to get to answers and it will cost us a lot in morbidity and mortality.

Mr. BURTON. Do any of these organizations within NIH or the National Institute have anybody on their boards that practice alternative medicine?

Dr. KAPLAN. Oh, yes. Certainly the NCI Office of Complementary Alternative Medicine does have people on its board. But I think that is not exactly the answer to the question of the studies that Dr. Thompson was describing. Those are, as Dr. Kail points out, not packages of a series of complementary treatments all together; they are in fact——

Mr. BURTON. Very specific.

Dr. KAPLAN [continuing]. Concentrating on specific agents. They don't perhaps require for that kind of study exactly what you are describing, perhaps. But I absolutely agree, for what you are describing, we need to develop the correct methodology and probably need the advice of your entire community to develop it, because I don't know how we would come up with it otherwise.

Mr. BURTON. Let me tell you a problem. This is on a different subject, but I think it bears on the point that is being made here. Do you know what chelation therapy is?

Dr. KAPLAN. Yes.

Mr. BURTON. Some people think it is bogus, others think it really does help with coronary problems and heart disease and so forth.

We sent 564 case histories from various chelation physicians around the country, these are doctors who use chelation as an adjunct to their practices, international heart-lung, and we found that they said there was not sufficient information in these reports that we sent in, and they wrote back and asked for more information. They couldn't make an evaluation based upon what was sent in. So we are writing a letter back to all those physicians asking for at least 100 of these cases to go into great detail. It is going to take them a lot of time and effort to give us these details.

But it seems as though there was a doctor over there, one of the people that makes the decisions, that said they were not going to move on—they said they wouldn't do a clinical trial because they just didn't think they had enough information.

Now, we have people all across this country, myself included, that are using chelation therapy, and it seems to me, like I said a while ago, with people voting with their feet and their pocketbooks, and more and more people are trying this all the time, some with some extraordinary results—I have talked with a number of people who have had extraordinary results—people told they should have open heart surgery or heart transplant, they didn't do that, they went to chelation instead, and they had some tests done that showed their arteries were actually opening up to a degree and the chest pain, the angina they had, was going away.

Why is it that the alternative therapy money, one-third of 1 percent, why is it they are not using more money in that area to look at these alternative therapies and maybe use different approaches

to finding out whether or not they are effective, instead of the same approaches they have always used, with the double-blind studies?

I think that Dr. Kail makes a good point, that while we are going through these studies that take 3, 4, 5, 6, 7 years, people are dying, and if there are alternative therapies that physicians—and the one that is giving me chelation therapy has an advanced education in medicine, so he didn't come off the assembly line of doctors, he is a pretty sharp fellow—it just seems to me we ought to let the alternative therapy have a little bit more money for research and let them see what they can come up with, as well as the conventional approach which is these double-blind studies that take 3, 4, 5, 6 years. I just don't understand it.

We had a boy here who was dying of, I think it was leukemia, and his parents wanted to have him go to a doctor that tried an unconventional approach dealing with that. He had been judged terminally ill; there was nothing more that could be done for him. He was being prevented to get treatment even though the parents wanted that, and there appeared to be some hope from previous patients that had been down there, because they said there hadn't been enough research.

Well, this kid is going to die. Why should we prevent that parent from looking at that, especially when there is some record that there has been some success, although not a huge amount?

I just don't understand the rationale, because people are dying from these various problems, prostate cancer and others; and it looks like, to me, that there ought to be some more attention paid to alternative therapies as adjunct to conventional therapies that could be researched thoroughly through the alternative therapy budget. And there is not enough money there to do it, and one-third of 1 percent just does not cut it.

I am for getting more money for conventional research, and I believe my colleagues on both sides are, as well. But while we are willing to get more money for conventional treatment and studies for cancer, why not let the other people who are generally looked upon with disdain and disfavor by a lot of people in the medical community, why not let them have their shot at the egg, too, because there are some positive results.

Does anybody have an answer to that? You are with NIH.

Dr. KAPLAN. I do actually have some thoughts about that. Could I have Dr. White also address some of your points?

Mr. BURTON. Sure.

Dr. WHITE. Thank you. I am Dr. Jeffrey White from the National Cancer Institute.

Mr. BURTON. You have been before us before.

Dr. WHITE. Yes, once before.

I can address the issue about case reports as sources of evidence. We do actually have at the National Cancer Institute a best-case program, best-case series program, that does allow actually for the review of case report information and internal review within the NCI.

What I am talking about then is the alternative medicine practitioner who is treating cancer patients with an alternative approach, who has records of improvements of those patients and can send those records to my office and have—what I do is review them

for completeness, in much the same way apparently NIH did with your records. If it is not complete, we go back and forth with correspondence about what does need to be added to it to make it complete.

Then we present them actually to the panel of experts of both cancer and alternative medical backgrounds. Actually, Dr. Kail is on that panel. This is done in collaboration with the National Center for Complementary and Alternative Medicine. So we have recognized that case report information is the type of information that comes out of complementary and alternative medicine practices generally, rather than clinical trials, and we are trying to make use of that information to make research decisions.

Mr. BURTON. That is commendable.

I want to yield again to my colleague in a second.

That is commendable, but why is it that there isn't a bigger percentage appropriated or allocated by NIH for these alternative studies and therapies? I just don't understand it. One-third of 1 percent is such a small amount, especially when the American people are clamoring for it. You know that. I know you know that, because if you don't believe it, look at the tremendous amount of money that is being spent for alternative therapies and vitamins and minerals and all kinds of things—shark cartilage. You know what I am talking about.

It seems to me that, as a defense mechanism if nothing else, NIH would say, hey, we need to get these Congressmen and these Senators off our back. Let's put a little bit more money into alternative therapies so we can shut them up and find out if this stuff really works.

I mean, that is such a small percentage. Can you give me an answer on that?

Dr. WHITE. Part of it is, I don't know what the actual percentage is, because the definition of complementary and alternative medicine is actually a very difficult one to make; and a lot of things we have talked about today, certain specific vitamins or minerals as single compounds, some people would not consider them to be alternative.

Really, you can debate it. But certainly support group research is an important element that I think might have been touched upon a little bit, but some people may not consider that to be complementary and alternative medicine.

I think there are issues so that if you wanted to look at all the nutritional-type work that is done as cancer prevention and as adjunctive therapy, or all of the behavioral research done, I think those numbers would be much larger. So a lot of it does break down to what the real definition is.

But I do think we are growing our research portfolio, and I think we have established linkages with the National Center to address some the specific things, like the concerns of Dr. Kail about naturopathic schools or other alternative practitioner schools not vying well in the funding. There are programs that are in development to get them in collaboration with experienced research programs to help buildup their research departments. So I think we are making inroads there.

Mr. BURTON. Did you have some more questions?

Mr. TURNER. I don't, Mr. Chairman.

Mr. BURTON. Dr. Kail, did you have something else to say too? Let me go to Dr. Geffen first and then we will come back to you real quick.

Dr. GEFFEN. I just wanted to make one point that—actually two points, very briefly.

First of all, I want to speak again from the perspective of a treating oncologist in the community, but also as somebody who spent many years in academic medicine, has been very involved in scientific research, has had NCI grants. I am very familiar with the process. There is no question that I am a firm believer and advocate for research of anything that has potential.

I also want to once again remind my colleagues and all of us that we are talking about—our language again is about treating prostate cancer. But we are not really treating prostate cancer. We are treating men, human beings, who happen to have prostate cancer.

I honestly feel that this is as fundamental a paradigm shift that we need to make as the paradigm shift of embracing alternative and complementary therapies might appear.

Do you understand what I am saying?

This is the problem. We can spend years and years studying this chemotherapy drug or this herb or that herb, and I can tell you as a physician, it is absurd. I have patients coming with bushel baskets full, shopping bags full of vitamins and herbs and supplements, or men with prostate cancer who were given all of the standard treatments; they are neurotic, frightened, they are afraid, they are not sleeping.

I am spending thousands of dollars a year performing studies that are being demanded. Their marriages are in shambles, and I think that it is time that we make an equal commitment to addressing this component of cancer, which is really, I tell you, this is where the rubber hits the road in the community. This is really where the real action is, taking care of real people. It is not in how many micrograms of selenium to take. It is absurd.

I feel strongly about it because I spent years answering the phone calls in the middle of the night from these people, and I say—I want to be clear; I love science, and I love alternative and complementary therapies, and I will always advocate for doing everything that we can think of to pursue this area of research. But really it is time to say, wait a minute, we are not treating cancer, we are treating human beings, and explore how we need to reorganize ourselves in this entirely new framework. That is really the challenge before us.

One last thing I want to say also. You know, it is amazing to me, and this is part of this discussion in terms of where do we really want to put our resources. As strong an advocate for scientific research as I am, I think we need funding to learn how to take care of people. I think it is unconscionable that as a physician, I could spend easily $20,000, $30,000, $40,000 with the full blessing of Medicare to prolong the life of a 89-year-old man with prostate cancer by 6 or 9 months with every therapy and MRI scans and bone scans and strontium and growth factors and Neupogen shots at $125 a pop for weeks or months at a time.

But there is no funding for therapists for these people, for massage therapy, there is no funding for end-of-life discussions. I mean, it is crazy. But this is the reality of taking care of people in the community, and I think I can't sit here and not say that.

Don't you think it is kind of crazy?

I can get the full blessing of Medicare to do this, as long as I follow the documentation guidelines. It is painful.

Mr. BURTON. I am sure it does make sense to everybody here, and perhaps Congressman Turner and I and others can talk to our colleagues on the appropriate Appropriations Committees—I think Congressman Porter is one of them—to take a look at maybe revising how we approach something like that. It is going to take a real education process I think, because I had never really thought about it before until you mentioned it.

You just don't think about those things. You think about, how do you take care of the guy that is sick. You don't think about quality of life and how close they are to the end of the road, which we are all going to be facing.

Dr. Kail.

Dr. KAIL. Well, just, first of all, I wanted to acknowledge the National Cancer Institute at the NIH and the CAPCAM advisory panel. I think they are taking the lead within NIH in bringing the alternative medicine into the NIH. I think the best-case series is the best mechanism I have seen so far to go identify the alternative practitioner in the field and get him started.

But CAPCAM is not a funding agency. It does not grant funds. All it does is recommend strategies so that they can do better competition in the research pool.

What I am saying is, that is not quite good enough. We are going to have to go out and do something else that is not going to take multiyears get these people involved. Why can't you put an advisor in every part of the NIH and have them put an alternative spin, if you will, on every study that comes through, or some direction toward the director of the panels?

I don't know what the answer is. I think the National Cancer Institute is taking a big step forward and doing the best-case series. I applaud them for doing that. I am out personally recruiting people in my field to apply for that best-case series, but that does not imply funding. All the funding that has come through for alternative medicine research has been mandated by this body, by the Congress, and I think that is where the answer is. The Congress has to mandate the funds. Then the NIH will spend the funds.

Thank you.

Mr. BURTON. Well, as a first step, maybe we can talk to some of the heads of the various agencies at NIH and see about trying to get some input from the alternative therapy physicians in some way, because I think that is probably a good idea, to at least have that input.

Did you have a comment, Dr. Geffen? I have a series of questions, and I will let you guys get out of here, for the record.

Dr. KAPLAN. I just wanted to follow up on points that both Dr. Kail and yourself have made regarding the design of studies and whether it is necessary to do randomized control trials and so forth.

Randomized control trials are not something that just the alternative community objects to; every scientist wants to see things move faster than randomized trials can allow. I should say, by the way, that most of them are not placebo controlled. But, anyway—if we didn't have those, however, there is no question that we would think, for instance, as I would have said a few years ago, that betacarotene is probably a good thing and everybody should take more of it. It turns out to be a bad thing. If we didn't have a randomized controlled trial, we would still be doing radical mastectomies, which we did for 100 years, when everybody thought it was better than limited mastectomies. The randomized clinical trials answered that.

We have got to constantly question our own assessments. I have been wrong, like everybody else, many, many more times than I have been right about what seemed to be working with the drugs I have worked on myself. We always have to look at that carefully.

Now, I can easily imagine a situation, however, in which a number of alternative approaches could be piggybacked onto lots of studies. There could be trials of conventional therapy with or without another alternative approach added to it. It doesn't mean you would have to have twice as many patients or separate studies. You can actually use a sort of piggybacking technique and still get that high-quality scientific evidence without having to say we are going to go one way or another.

Mr. BURTON. That may be one approach to doing it.

It just seems to me that, and I am not a physician, I have a son who is a physician, who believes everything that the FDA says, so he and I have arguments from time to time, not that I don't think the FDA does a good job, you understand, but we do have differences. But it seems to me, and I think to a lot of my colleagues, because we have talked about this numerous times at the committee hearing and on the floor, that while the conventional approach to checking everything out, the double-blind studies and all that, is very important, and that is probably where the vast majority of the funding ought to go, it seems to me the alternative therapy approach ought to have at least an adequate amount of funds so they can try it from their viewpoint as well. There is more than one way to skin a cat. You have heard that before. It seems to me whether it is piggybacking on or letting them have funds to try another way, and then looking at the results over a 10 or 5-year period, it seems it makes sense, especially when we are talking about the huge quantities of money which the Congress is putting out, which still isn't adequate, but nevertheless we are spending a lot of money, $3 billion at NCI.

Let me go through a series of questions, and if Mr. Turner has any, interrupt at any time.

Dr. Geffen, Senator Dole talked about Medicare coverage being important for access to adequate care. Do you offer treatments at your center, conventional and complementary, that would help a patient but that you cannot get reimbursement for through Medicare?

Dr. GEFFEN. Yes, many. It is a big problem. As I was saying earlier, I think that this is something that we are going to really have to grapple with, because until we have—and I will just say my own

personal belief is the most effective answers are probably going to come from molecular biology. They are probably not going to come from randomized trials of compounds, no matter how toxic or natural they may be. I think the real advances are going to come from molecular biology, but that is going to take time. In the meantime, we have to take care of people, human beings, who are suffering. We have to use everything that is available.

Mr. BURTON. Let me interrupt. Could you do me a favor? Could you in a one page send us a list of things that you think ought to be looked at seriously in Medicare adjustments, adjustments to Medicare that would help people? If you could get us that, we can sit down and talk to the relevant leaders in the Congress and see if that can't be incorporated into the long-range planning for Medicare.

Dr. GEFFEN. Terrific.

Mr. BURTON. Just get that to us. Rather than telling me, let me have it in writing so Beth and I can get it to the proper people. What do you say to a patient who wants to try an alternative therapy?

Dr. GEFFEN. What do I say personally?

Mr. BURTON. Yes.

Dr. GEFFEN. Well, I try, first of all, to do a comprehensive medical evaluation and try to make an assessment as to whether or not there is a conventional therapy that we can reliably predict what it is likely to do. My own personal bias is I don't really embrace alternative therapies as cancer treatment. I can be, as open-minded as I have been and as far as I have traveled in this world to study and learn and try to see what is effective, I have not been convinced that there is any alternative therapy for cancer that is as or any more effective than conventional therapies are on a reliable, consistent basis. So I typically don't offer alternative therapies, unless I have a patient who really has a cancer for which there is no meaningful conventional therapy.

Mr. BURTON. So if they have been judged by conventional medicine to be in a hopeless situation, you would talk about something?

Dr. GEFFEN. Exactly. But there is some gray zone between what is alternative and what is complementary, and complementary medicine includes things that I consider to be therapies that can be used very elegantly in conjunction with conventional therapy. That is really where our primary focus is, is trying to explore a whole universe of phenomenally wonderful things that are not in conflict with conventional therapies.

Mr. BURTON. Dr. Kail, how do you co-manage patients with allopathic physicians?

Dr. KAIL. That is a great question. This speaks to where everybody has spoken here. Again, allopathic physicians, as Dr. Geffen said, they will try any allopathic or conventional agent that will work and, at the exhaustion of those, will send a patient or allow their patient or recommend their patient seek alternatives. Unfortunately, that is the worst case scenario for the success of the alternative therapy.

Mr. BURTON. Too late in most cases.

Dr. KAIL. Well, the person's recuperative abilities have already been spent by the rather extreme measures they have.

Most alternative practitioners would suggest you need to start the alternative therapies early on, as early as you can find. They are not bailout therapies. They will not succeed if someone is totally compromised. I don't care how good they are. Although there are some case reports of that happening, the chance is very little.

The best case scenario, it is best to start with a person who has an inkling that they might have some increased risk and aggressively attack that risk, and then alternatives become very viable in actually reducing or stopping the cancer process. But they haven't been studied.

There are plenty of docs that I could tell you about that have clinical results but haven't been studied. So my approach is usually I start treating a patient and then they go see an oncologist. I always recommend that they do. As a matter of fact, I hesitate to treat patients if they don't see an oncologist.

Usually in that scenario, when they are already doing what they are, and then going for conventional care, they get better results, meaning I report from the oncologist, which usually doesn't matter, they don't care if I am using alternatives, as long as I can assure them that it is not going to adversely affect their therapy, which I usually can.

Mr. BURTON. You are talking about using it in conjunction with?

Dr. KAIL. Absolutely. In that scenario, I think we do very well. My feedback from the oncologists has been that my patients tolerate conventional treatments better, they get better outcomes, and have a better quality of life. That is the feedback I get from my patients.

Mr. BURTON. Does the general public have access to naturopathic physicians?

Dr. KAIL. The other States——

Mr. BURTON. But they are not reimbursed under Medicare or other insurance programs regularly?

Dr. KAIL. There are none, in no cases. There are two States that enjoy mandates, Connecticut and Alaska. Other States, in Arizona we do get insurance reimbursement by choice. There is no mandate, but we have three or four, Cigna, Intergroup and some other health plans, because their consumers wanted them, have put us on as providers.

That is a very good situation, because now I have to communicate with their primaries, we have to write consultation reports, we have an exchange of ideas. Sometimes that person says I don't understand this, I don't want to know about it, go get another primary. Sometimes they start to interact with me and then they get to understand what I do and I get to understand what they do a little bit better and the benefit is to the patient. The patient ends up doing better and having two doctors that are very happy to talk with each other.

Mr. BURTON. Dr. Chen, is the NIH funding any studies on your invention, your scientific research?

Dr. CHEN. No, Mr. Chairman. As a matter of fact, I wrote an application for NIH funding and it was rejected. Some of my funding comes from private research foundations such as CapCURE.

Mr. BURTON. That is Milken's foundation?

Dr. CHEN. Yes.

Mr. BURTON. But you were turned down?

Dr. CHEN. I was rejected several times.

Mr. BURTON. Are you aware of any government funding on Chinese botanicals and prostate cancer prevention?

Dr. CHEN. Not that I know of.

Mr. BURTON. Do any of you know if there is any funding by NIH for any of that research? Nobody knows?

Dr. CHEN. There is only a so-called alternative medicine category, and just like Dr. Kail said, any application in alternative medicine usually goes to famous hospitals, Harvard, Stanford, M.D. Anderson, their research groups get it.

Dr. THOMPSON. Mr. Chairman, from the physician's data query, which is NCI sponsored, there is a phase three randomized study of the effect of a diet low in fat, high in soy, fruits, vegetables, green tea, vitamin E and fiber on PSA levels in patients with prostate cancer. It is NCI sponsored and it looks like it is being conducted at Memorial Sloan Kettering Cancer Center.

Mr. BURTON. But that sounds like that may be the exception, rather than the rule. Well, anyhow——

Dr. CHEN. The problem is, each time you talk about a mixture, it is also a question. According to conventional strategy, anything has to be single agents. If you talk about more than two, it is a no-no.

Mr. BURTON. That is what I was talking about. I think Dr. Kaplan touched on it when we were talking about piggybacking on a study. Maybe you could in some way put something like that in the study, in a small percentage of it, and it might give you some very telling results. Does NIH ever do that or have they ever done that? You suggested it. Maybe it is a great suggestion. But have they done that?

Dr. KAPLAN. Normally the kinds of studies in these large studies that are done——

Mr. BURTON. Straight double blind.

Dr. KAPLAN. No, it is normally from investigators proposing that these are the arms that should be in the study, this versus that. If we can in our advising them, if we can come up with some other suggestions and say there is something else viable and we think at the time are strong enough, would you consider that, then they may in fact be willing to add those substances to those studies. But it is not normally something where we will direct them what they should specifically study. The investigators themselves have to become convinced that the data warrant that.

Mr. BURTON. I understand. But, you know, the one who gives the money plays the tune to which people dance. I think you get the message there. It seems to me that if there is a suggested study and there is something that is very close to or uses some of the same substances that you are doing the study, it seems they could be piggy-backed on by suggestion of the people at NIH.

Dr. KAPLAN. They could. The difficulty I have with suggesting it outright is making the case for it, is the fact we have heard just in this room today of many, many approaches that could be useful, and I think we all hope that they are all going to be useful, but we also all know that not every one of them is. Somehow we have to decide if we are going to say here is a study of 5,000 men, let's

add such-and-such to 2,500 and not to the other 2,500, which is that going to be right now.

Mr. BURTON. I understand. And that being the case, it seems to me there ought to be more funds allocated for alternative therapy research so that they can at least follow the line of thinking that they are talking about. One-third of 1 percent sounds like a very small amount.

Anyhow, I think you understand what we are talking about and I hope you will carry this message back. We will have more hearings on this in the future and discuss it further.

Dr. Kaplan, what specific complementary and alternative treatments are under consideration for research on prostate cancer right now?

Dr. KAPLAN. I don't think I can answer that comprehensively, aside from, for instance, the study that was just read to you.

Mr. BURTON. That wasn't for prostate cancer.

Dr. KAPLAN. Yes, that was for prostate cancer.

Mr. BURTON. The one you were talking about a minute ago, that was for prostate cancer?

Dr. KAPLAN. Yes. There are a handful of others on a scale that have already come in and are being funded, but there are certainly, I think, many investigators out there in both the alternative community and the conventional community who are looking at a lot of possibilities and thinking about this. I think particularly the prostate cancer quick trials program may bring several more really promising applications to us, because I think there are fewer hurdles for people to overcome to get funding that way.

Mr. BURTON. Dr. von Eschenbach, in your experience, what complementary therapies may be helpful for prostate cancer patients?

Dr. VON ESCHENBACH. Well, as I mentioned earlier, one of the things we do promote is a diet low in fat and an exercise program. We have also been beginning to investigate in a complementary fashion the role of stress reduction.

Mr. BURTON. But that is something we need here in Congress, I will tell you. If you have any ideas, aside from some of these pills they give us, I would appreciate knowing about it.

Dr. Thompson, you are also a colonel in the Medical Corps. Does the prostate cancer care differ at all for active duty military than those who are not on active duty?

Dr. THOMPSON. I don't believe so, Mr. Chairman. We have actually looked at prostate cancer outcomes in DOD health care beneficiaries, and there have been about three or four studies in the United States that have looked at outcomes. Some have suggested that ethnicity plays a role in survival. For example, if you are African American, you have lower survivals. We found in health care beneficiaries at the Department of Defense ethnicity did not affect survival, such that if you look at the same stage of the disease African Americans and Caucasians have the same survival.

Some of that may have to do with health seeking behavior and the fact that if you are in the military after the age of 40 you have a regular physical examination, and we think that plays a little bit to the differences we see in the Department of Defense beneficiary population.

Mr. BURTON. I just have a couple more questions. Are there new screening devices and tests in development over there?

Dr. THOMPSON. In the Department of Defense?

Mr. BURTON. Yes.

Dr. THOMPSON. Actually there are any number of new opportunities. In fact, there are a number of imaging studies that are being looked at, the ability of PET scans and some new methods of using MRI. There are new bio markers being looked at.

At this time, truly the most reassuring thing is that although it has been around for 15 to 20 years, prostate-specific antigen remains a superb screening tool, perhaps better than virtually any other type of screening tool. You are able to tweak it a little bit by looking at fractions of the PSA, the PSA that is bound to plasma proteins, and to perhaps improve your detection abilities in younger men and perhaps to reduce the number of biopsies that are required in older men.

Mr. BURTON. Dr. White, you get the last question from me. Can you tell me about the homeopathy cancer projects?

Dr. WHITE. Yes. This is one project, actually there were two projects that were reported, both from the same group. One of them was withdrawn and the other one is going forward.

This is a best case series of homeopathic preparations for the treatment of cancer that was presented by a group from Calcutta, India, and they presented 12 cases of cancer that they felt had been benefited by their approach. It was presented to the CAPCAM, the Cancer Advisory Panel for Complimentary and Alternative Medicine in July, and on the basis of review by the panel, they recommended we do some prospective observational research in the clinic in Calcutta, which basically would be to track new patients that come through the clinic, specifically lung cancer patients, be sure that they have good pathology that could be confirmed, and good radiologic followup, and just look at outcomes.

So we are in the process of trying to put together basically a research contract mechanism that will allow us to get a clinical researcher to go to the clinic there in Calcutta and actually start taking statistics about patients that come in following these patients getting the CAT scans reviewed.

So I hope to give a summary of where we are in the December 13th meeting of the CAPCAM.

Mr. BURTON. If you could let us know about it, we would appreciate that.

I want to thank all of you for your patience. It has been a very interesting hearing. I think we have learned a lot, and hopefully we will be able to get some results down the road from what we have learned.

Mr. Turner, do you have any other questions?

Mr. TURNER. No, thank you, Mr. Chairman.

Mr. BURTON. Thank you very much. We stand adjourned.

[Whereupon, at 2 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

Urology Times®

The Leading Newsmagazine for Urologists

Vol 27, No 8 • August 1999

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Practice Management

Complementary medicine growing by leaps and bounds

PC-SPES, other supplements for prostate disease show gains in popularity, credibility

Norman Bauman
UT CONTRIBUTING EDITOR

Dallas—After years of rejection and skepticism, physicians are finally beginning to accept complementary and alternative medicine—if the evidence is there.

William R. Fair, MD, who used complementary medical techniques during his own bout with colon cancer, addressed the subject head on during a plenary session

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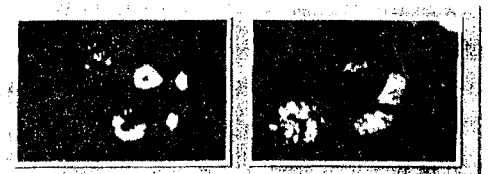

PC-3 prostate adenocarcinoma cells grown for 48 hours in the presence (left) or absence (right) of PC-SPES. Apoptotic cells (indicated by arrows) characterized by highly condensed chromatin and nuclear fragmentation are present in the culture treated with PC-SPES. (Photos courtesy of Sophie Chen, MD)

Complementary Medicine

Inside, see related articles on complementary medicine, including use of antioxidants and a low-fat diet (page 16), issues of safety (page 18), and soy protein's effect on PSA (page 20).

Research, reorganization head AUA's agenda

As the new president of AUA, Lloyd H. Harrison, [redacted] exposed to the scientific method and ulti-

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at the AUA meeting here. Dr. Fair, director of the Beatheim Prostate Diagnostic Center, Memorial Sloan-Kettering Cancer Center, New York, gave examples of controversial therapies that are showing promise in rigorous scientific studies, including PC-SPES, vitamin E, selenium, and low-fat diets for prostate cancer, and saw palmetto for BPH.

Dr. Fair

"My introduction to complementary and alternative medicine was by necessity," said Dr. Fair, referring to his fight against cancer. "What I gleaned from this, with surprise, was how much science really exists in the field. While it's true that there are a lot of unknowns and a lot of things that need more exploration, that's also true of allopathic medicine. An estimated 15% of what we do is really evidence-based."

Dr. Fair prefers to call it "complementary medicine" rather than "alternative medicine." He believes the term "alternative" implies something other than standard medicine, whereas "complementary" suggests using these therapies in addition to traditional medicine. Diet, supplementation, exercise, and stress reduction "really should be part of standard medicine," he said.

Urologists must keep up

"The growth of complementary and alternative medicine is real," said Dr. Fair. "It's being driven by patients, and we have to keep up with it. The demand is growing, and if we're not aware, the parade will pass us by. In 1997, there were more patient visits to providers of alternative and complementary medicine than there were to primary care physicians in the U.S."

Dr. Fair was citing a recent study by David Eisenberg, MD, of Beth Israel Deaconess Medical Center, Boston, and colleagues (*JAMA* 1998; 280:1569-75). According to the study, 46% of the American population uses alternative medicine, but less than 40% of those individuals have told their physicians.

However, one skeptic challenged those numbers. Stephen Barrett, MD, a retired psychiatrist who operates the Quackwatch web site (*www.quackwatch.com*), charged that Dr. Eisenberg "classified things as alternative that are part of standard practice so he could pump up his numbers." For example, Dr. Eisenberg's study included relaxation techniques—"which have been part of standard psychological practice for years," said Dr. Barrett—along with massage and self-help groups.

Dr. Barrett was a reviewer for two other articles in the *JAMA* issue in which Dr. Eisenberg's study appeared. The issue was devoted mainly to discussions of alternative and complementary medicine.

The *Wall Street Journal* estimated the annual market for complementary and alternative medicine at $50 billion, said Dr. Fair. Dr. Eisenberg, meanwhile, estimated 1997 out-of-pocket expenditures for such therapies to be $27 to $34 billion, or about equal to the $29 billion in out-of-pocket expenditures on physician services.

The AUA showed "presence and foresight of leadership" by establishing a committee on complementary and alternative medicine, the first specialty society to do so, Dr. Fair said.

Dr. Fair focused on PC-SPES, a popular combination of herbs from traditional Chinese medicine consisting of chrysanthemum, isatis, licorice, *Ganoderma lucidum*, *Panax pseudo-ginseng*, *Rabdosia rubescens*, saw palmetto, and scutellaria (skullcap). Ginseng and licorice are known to exhibit phytoestrogenic activity, he noted.

Just another estrogen?

PC-SPES was damned with faint praise in the *New England Journal of Medicine* (1998; 339:785-91, 839-41), which reported estrogenic activity, lowering of serum testosterone to the castrate level in two of six men, and drops in PSA in men with prostate cancer. Side effects were breast tenderness, loss of libido, and superficial venous thrombosis in one patient.

On the other hand, PC-SPES inhibits hormone-resistant prostate cancer cells, noted Dr. Fair, including the metastatic MAT-LyLu tumor in vitro in rats and the hormone-insensitive PC-3 and DU-145 lines. In addition, it increases apoptosis, downregulates bcl-2 (which renders cells apoptosis-resistant), and upregulates bax (which enhances apoptosis).

> *"The growth of complementary and alternative medicine is real. It's being driven by patients, and we have to keep up with it."*
>
> WILLIAM R. FAIR, MD

Clinical studies also suggest PC-SPES activity against hormone-refractory prostate cancer. For instance, Eric J. Small, MD, co-director of the urologic oncology program, University of California, San Francisco, reported phase II study results at a recent meeting of the American Society for Clinical Oncology. PC-SPES produced a >50% PSA decline in all 27 hormone-naive patients studied, and undetectable PSA in 15 of the 27 (56%). It also produced a >50% PSA decline in 19 of 34 (56%) hormone-resistant patients.

Some drugs, like finasteride, can reduce PSA without affecting the progress of prostate cancer, but Dr. Small believes he can eliminate that problem. "Half of 16 evaluable patients with hormone-sensitive disease showed a decrease in cancer with ultrasound," Dr. Small told *Urology Times*. "Also, two of 12 patients with evaluable bone scans have shown improvement. In some patients, the pain got much better. PC-SPES also shows in vitro activity, so we believe it's probably real."

Dr. Small's trial was funded by the Association for the Cure of Cancer of the Prostate (CaPCURE).

In a German study being submitted for publication, 15 of 16 patients with hormone-refractory prostate cancer had a decrease in PSA of 60% from an initial mean of 108 ng/mL after 3 months on PC-SPES, said Dr. Fair. They responded with decreases in pain and narcotic intake, and increases in overall quality of life (*Br J Urol* 1999; in press).

"We tend to dismiss things as hocus-pocus because they don't fit in with our traditional training," said Dr. Fair. "I think we have to keep an open mind about this whole issue." **UT**

House Government Affairs Committee

Hearings on
"Fighting Prostate Cancer: Are We Doing Enough?"

September 23, 1999

Statement of Tracie Snitker
Director, Government Relations
Men's Health Network
P.O. Box 75972
Washington, DC 20013

[Submitted for the record]

MHN The Men's Health Network – An informational and educational organization recognizing men's health as a specific social concern.
www.menshealthnetwork.org

Government Reform Committee

"Fighting Prostate Cancer: Are We Doing Enough?"
September 23, 1999

Statement of Tracie Snitker, Director, Government Relations
Men's Health Network

Some basic prostate cancer facts:

- Prostate cancer accounts for 15% of all diagnosed cancers, but receives only 5% of federal cancer research funds.
- Prostate cancer is the most widely diagnosed non-skin cancer in America.
- Almost 40,000 men will die from prostate cancer this year.
- African-American men are more likely to contract prostate cancer and twice as likely to die from the disease.
- Prostate cancer is treatable if the disease is caught in the early stages.

We would like to thank the Committee for holding these very important hearings and we welcome the opportunity to submit testimony on this critical health issue. As a founding member of the National Prostate Cancer Coalition, the Men's Health Network has actively promoted prostate cancer awareness while seeking an increase in prostate cancer research. Our activities have included the establishment of a toll free number (888-MEN-2-MEN) to disseminate information on prostate cancer and other men's health issues, creation of prostate cancer awareness weeks in Texas and Florida, the establishment of a state prostate cancer task force, promotion of public service announcements on radio and television, and working with a state health department to create a prostate cancer brochure for the African-American community.

Our testimony examines these action areas:

- Research funding
- Research focus
- Awareness
- Early Detection
- Physician education
- Importance that family plays in detection and treatment

Research Funding:

Research plays a critical role in controlling or curing any disease. Historically, prostate cancer research has been underfunded compared to other cancers and diseases with similar mortality rates. Among cancers, prostate cancer accounts for 15% of all diagnosed cancers, but receives only 5% of federal cancer research funds. According to information provided by the American Foundation for Urologic Disease, NIH research funding per patient is $2,400 per diagnosed case from breast cancer and only $600 per diagnosed case for prostate cancer.[1] AIDS, with a much lower mortality, receives $31,000 of NIH research funding per diagnosed case to only $600 for prostate cancer.[2]

We believe that it is critical that the research level for breast cancer and AIDS be maintained so that a cure can be found for those devastating diseases. However, it is just as critical that funding for prostate cancer research be increased dramatically to reflect the crisis nature of the disease. To that end, we recommend that:

- The investment strategy developed by the Department of Defense (DOD) be fully funded. DOD estimates that it needs a funding level of $200 million to successfully pursue its research goals.
- The prostate cancer research program at NIH be doubled over the next three years.

Research focus:

The NPCC developed a uniquely productive method of approaching decisions about research goals, establishing diverse workgroups to develop and recommend research objectives. These workgroups consisted of researchers, urologists, activists, spouses, and health association executives. The results have been research recommendations that consider the needs of each element of the prostate cancer community. We feel that government decision makers should follow a similar pattern, therefore we suggest:

- Requiring that NIH, DOD, VA-HUD, and other entities that perform or fund prostate cancer research consult with grassroots organizations that have expertise in the area of prostate cancer when developing prostate cancer research strategies.

[1] "Comparisons of Prostate Cancer, Breast Cancer, and AIDS. American Foundation for Urological Disease, 1999.
[2] Ibid.

Awareness:

Awareness is the key to early diagnosis and treatment of prostate cancer. Prostate cancer awareness should include expansion of programs in the minority community, the development of awareness partnerships with businesses, and the development of campaigns that encourage families to be active partners in the detection and treatment of prostate cancer. Unfortunately, government support for prostate cancer awareness programs is almost nonexistent. We recommend:

- Prostate cancer awareness programs should be funded at levels comparable to those for breast cancer and AIDS.
- Grassroots organizations that have expertise in the area of prostate cancer and special knowledge about the affected population should be consulted when designing awareness programs.

Early Detection (promotion of screening)

Prostate cancer detected early can usually be cured. While awareness plays an important role in the early detection of prostate cancer, MHN feels that the most effective method is yearly screening beginning at an appropriate age, depending on the person's ethnic background and family medical history. We recommend:

- That government promote yearly screening for prostate cancer using the most modern methods available (presently the PSA and DRE).

Physician Education:

Prostate cancer appears to be one of the few areas of medicine where outdated theories and practices continue to endanger patient health. Failure to adequately keep physicians informed of new developments in prostate cancer diagnosis and treatment can lead to unnecessary patient mortality.

Bob Watson, then General Manager of the New York Yankees, testifying before the Senate Select Committee on Aging, spoke of his experiences when he requested a PSA test. He was 47 years old and in what we know to be a high risk category.

Apparently, his physician was not aware that African-American men over 40 are considered at high risk.

> *As part of the exam, I asked the doctor to give me a PSA (prostate specific antigen) test in addition to the DRE (digital-rectal exam). Several scouts I knew had been diagnosed with prostate cancer the year before and they had urged me to ask for the test.*
>
> *The doctor said "No. No. You're too young to do that. We don't start giving the PSA blood test until you're fifty or so; we'll just do the digital-rectal exam."*
>
> *I insisted. "No," I said. "Do the PSA."*
>
> *Well, the results came back at 5.8, which alarmed our team urologist, who ordered more tests and a biopsy. Out of six core biopsies, one of the biopsies came back positive. It was a particularly aggressive form of cancer.*
>
> Bob Watson, Vice-President and General Manager of the New York Yankees, Senate Select Committee on Aging, September 23, 1997

We hear this story repeated time after time, patients having to insist that they be given a PSA or DRE when they have reached the age that screening is considered prudent.

Many physicians are unaware of the level at which a PSA reading indicates that more tests should be conducted. We now know that a PSA reading of 4.0 is considered borderline high, but many physicians still believe any reading under 10 is normal.

At a NPCC conference on research and education, we found physicians who had virtually no prostate training in medical school, other than to learn where the prostate was located and what function it served. They learned nothing about prostate cancer, warning signs, treatment options, or at-risk groups.

Because of these and other disturbing reports, we recommend the following:

- Increase the level of prostate educational material that licensed physicians and other health care professionals receive.

- Require that medical schools expand their prostate curriculum to include diagnosis of prostate abnormalities, treatment options, and information about high risk populations.

Importance that family plays in detection and treatment:

For many reasons, men are notoriously reluctant to seek regular check-ups, even to seek medical advice when an abnormality arises. They leave medical decisions to their wives, mothers, and sisters. Often, it is a wife or other loved one who sets a doctor's appointment, forces him to go, explores treatment options, and saves his life as a result.

Len Dawson, pro football Hall of Fame, is a good example. Testifying before the Senate Select Committee on Aging, he commented on his wife's insistence that he receive a complete prostate exam:

> *In the Spring of 1991, I had a complete physical, came home and told my wife Linda that I was in top shape. A few months later she asked if I had a prostate examination during that physical, because she had just seen Senator Bob Dole on television talking about the importance of the use of both the PSA blood test and the digital rectal examination or DRE for the detection of prostate cancer. My physical had included a DRE but not the PSA blood test.*
>
> *The following day Linda read an article regarding free prostate cancer screening to occur later that month. Linda was adamant that I have the test and called and made an appointment for met to have both the DRE and PSA tests.*
>
> *During my visit on the 19th, my doctor found my PSA to be regular. It was during my DRE exam that he thought he found something. Further testing showed that I had early stage prostate cancer. Fortunately, the cancer was caught in its earliest and most treatable stages. My prostate was removed five years ago and I'm doing fine.*
>
> Len Dawson, NFL Hall of Fame Quarterback, Senate Select Committee on Aging, September 23, 1997

We recommend the following:

- Develop public awareness campaigns designed to inform wives, mothers, and other family members about the dangers and risk factors for prostate cancer.
- Develop awareness campaigns in coordination with businesses, government employees, churches and other civic entities.
- Encourage businesses and government employers to give men (and women) mandatory time off to seek regular medical check-ups.

Again, we thank the Committee for its leadership in the area of health care, and for presenting this opportunity for diverse prostate cancer issues to be discussed in a public forum.

###