PROSTATE CANCER: NEW QUESTIONS ABOUT SCREENING AND TREATMENT

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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PROSTATE CANCER: NEW QUESTIONS ABOUT SCREENING AND TREATMENT

THURSDAY, MARCH 4, 2010

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

The committee met, pursuant to notice, at 12:10 p.m., in room 2157, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the committee) presiding.

Present: Representatives Towns, Maloney, Cummings, Watson, Connolly, Issa, and Cao.

Staff present: Linda Good, deputy chief clerk; Velginy Hernandez, press assistant; Carla Hultberg, chief clerk; Mike McCarthy, deputy staff director; Ophelia Rivas, assistant clerk; Julie Rones and David Rotman, counsels; Jenny Rosenberg, director of communications; Christopher Sanders, professional staff member; Leneal Scott, IT specialist; Shrita Sterlin, deputy director of communications; Ron Stroman, staff director; Gerri Willis, special assistant; Adam Fromm, minority chief clerk and Member liaison; and Ashley Callen and Jonathan Skladany, minority counsels.

Chairman TOWNS. The committee will come to order.

Good morning and thank you all for being here.

Prostate cancer is the second most common type of cancer found in American men, the first being skin cancer. It is also among the leading cause of cancer death in men, second only to lung cancer. One man in six will get prostate cancer in his lifetime, and 1 man in 35 will die from it.

The good news is that the death rate for prostate cancer is declining. The bad news is that we still don't know what causes it. We still don't know why African-American men are more likely to get it, and we still don't know why it seems to be most prevalent in North America and Europe.

But most importantly for today, there is still controversy over whether men should be screened for prostate cancer and there are still questions about how it should be treated. We are hoping to shed some light on these questions today.

Before we begin, I would like to acknowledge the important role my colleague, Rep. Elijah Cummings from Maryland, has had in requesting this hearing and helping to ensure that these issues get the attention they deserve, and I would like to give him a special thanks for that as well.

I also want to welcome to our hearing today Mr. Lou Gossett, a Brooklyn, NY native. Mr. Gossett is very well known for his work in the film industry, and has been widely recognized as one of the

great actors of our time. What is not well known is that he has been diagnosed with prostate cancer. Mr. Gossett has agreed to testify today to help bring attention to the issue. I want to thank you for that as well.

We also have Mrs. Betty Gallo, widow of our former colleague, Congressman Dean Gallo, who I served with, who died from prostate cancer. And we have with us also, Mr. Thomas Farrington, a 10-year prostate cancer survivor who has done a lot of work in this area as well.

There is a high degree of public awareness of the need for regular screening for certain kinds of cancers, notably breast cancer, prostate cancer, and colon cancer.

However, this widespread belief is now being debated. A few months ago, the New York Times reported that some scientists had concluded that the benefits of detecting many cancers, especially breast and prostate cancer, have been overstated, and that regular screening might do as much harm as good.

This has caused widespread confusion, which we hope to help clear up today. To help us do that, we have assembled some of the leading medical experts in the country to discuss the latest thinking on screening and treatment for prostate cancer.

I look forward to your testimony today because this is a very, very important issue.

Again, I thank my colleague, Elijah Cummings, for making certain that we move forward with this discussion.

[The prepared statement of Chairman Edolphus Towns follows:]

Opening Statement of
Chairman Edolphus Towns

House Committee on Oversight and Government Reform

March 4, 2010

"Prostate Cancer: New Questions About Screening and Treatment"

Good morning and thank you all for being here.

Prostate cancer is the second most common type of cancer found in American men, the first being skin cancer. It is also among the leading cause of cancer death in men, second only to lung cancer. One man in six will get prostate cancer in his lifetime. And one man in 35 will die from it.

The good news is that the death rate for prostate cancer is declining. The bad news is that we still don't know what causes it. We still don't know why African-American men are more likely to get it. And we still don't know why it seems to be most prevalent in North America and Europe.

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Before we begin, I would like to aknowledge the important role my colleague, Rep. Elijah Cummings, has had in requesting these hearings and helping to ensure that these issues get the attention they deserve.

I also want to welcome to our hearing today Mr. Lou Gossett. Mr. Gossett is very well known for his work in the film industry, and has been widely recognized as one of the great actors of our time. What is not well known, is that he has been diagnosed with prostate cancer. Mr. Gossett has agreed to testify today to help bring attention to the issue.

We also have Mrs. Betty Gallo, widow of our former colleague, Congressman Dean Gallo, who died from prostate cancer. And we have with us also, Mr. Thomas Farrington, a ten-year prostate cancer survivor who will tell us about his experience.

There is a high degree of public awareness of the need for regular screening for certain kinds of cancers, notably breast cancer, prostate cancer, and colon cancer.

However, this widespread belief is now being debated. A few months ago, the New York Times reported that some scientists had concluded that the benefits of detecting many cancers, especially breast and prostate, have been overstated, and that regular screening might do as much harm as good.

This has caused widespread confusion, which we hope to help clear up today. To help us do that, we have assembled some of the leading medical experts in the country to discuss the latest thinking on screening and treatment for prostate cancer.

I look forward to their testimony on this very important issue.

Thank you.

Chairman TOWNS. Now I yield to the gentleman from California for his opening statement, Congressman Issa.

Mr. ISSA. Thank you, Mr. Chairman. Thank you for holding this important hearing today. I would like to echo your comments about our colleague, Mr. Cummings. Last year he approached me to ask for us to work together on a bipartisan basis on this legislation. I accepted and I again thank him for his leadership.

As the chairman said, prostate cancer affects 2 million American men living here every day, including one of our witnesses. More importantly, when there is confusion as to what to do about it, even after decades of improvement in survivability, as there is with prostate cancer and also breast cancer, it is very clear Congress has a role to hold these types of hearings and fact-finding to reach, if at all possible, either a consensus on an outcome or a consensus on direction. I hope today is a beginning of that process so that we can provide guidance to the administration and to the health care industry about what the message should be.

We are not health care professionals here at the top of the dais; we do not intend to become that. What we do intend is to try to help make the message clear and understandable to 306 million Americans, slightly less than half of whom are men, but all of whom are concerned with the effects that will happen to themselves or loved ones and the possibility of preventing it or early detection leading to a cure.

With that, Mr. Chairman, I look forward to our witnesses and yield back.

[The prepared statement of Hon. Darrell E. Issa follows:]

EDOLPHUS TOWNS, NEW YORK
CHAIRMAN

DARRELL E. ISSA, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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Statement of Rep. Darrell Issa, Ranking Member

"Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Thank you, Mr. Chairman, for holding today's hearing to consider new questions about the screening and treatment of prostate cancer. In the last Congress, it was a privilege to work with you and Mr. Cummings on a bill that supported the development of new technologies for the detection and treatment of prostate cancer, a disease that affects more than two million men living in America today. Because Congress has made a priority of research programs that are working to discover new treatments – and perhaps a cure – for all types of cancer, more then $890 million has been appropriated to the Congressionally Directed Medical Research Programs since 1997.

There are three commitments, Mr. Chairman, that should guide our discussion of this important issue.

First, the American people should know that Congress is committed to supporting the work of front-line medical researchers seeking more accurate diagnostic tools and more innovative treatment technologies. We are also committed to encouraging every American to receive regular medical exams, without which the chance of early detection and successful treatment is seriously reduced.

Second, Mr. Chairman, the American people should know that Congress will not cut corners as we continue to look for ways to reform our health care system. Last year, we saw what happened when news got out that a task force commissioned by the Department of Health and Human Services was using mathematical risk models to justify a change in the age and frequency at which women should get mammograms. Decisions about when to get screened, and how frequently to get screened, are decisions that are best left to patients and their doctors – not panels of bureaucrats tinkering with algorithms at HHS.

Finally, the American people should always have the assurance that their medical care and treatment will be guided by patient safety principles and not by a need for doctors to protect themselves from out-of-control malpractice litigation. The cost of health care in America is skyrocketing, Mr. Chairman, and a large part of the growing cost is directly tied to the costs of defensive medicine and malpractice insurance that gets passed along to patients. As millions of Americans deal with prostate cancer – and other forms of cancer – they should be confident that their doctors are targeting their treatment, and not exposing them to unnecessary, expensive, and inconclusive tests.

I look forward to hearing from today's witnesses, Mr. Chairman, who have faced prostate cancer, spent their professional lives searching for a cure, and worked tirelessly to raise awareness.

Thank you, and I yield back.

Chairman TOWNS. Thank you very much.

Now I yield to the gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank you and the ranking member for scheduling the hearing. I realize we have witnesses that have been waiting for a while, so, Mr. Chairman, I will submit my written statement. But, again, thank you so very much for addressing this very crucial issue.

Chairman TOWNS. Without objection, so ordered.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Hearing Statement
Representative Elijah E. Cummings, (D-MD7)
Committee on Oversight and Government Reform
U.S. House of Representatives
111th Congress

Hearing on "Prostate Cancer: New Questions About Screening and Treatment"

Thursday, March 4, 2010

Chairman Towns,

I appreciate your leadership on prostate cancer issues and thank you for granting my request for today's hearing to examine prostate cancer screening and treatment options.

Many of us in Congress, and indeed throughout the country, have either personally been affected by the disease, or had a loved one suffer from it. For me, it was my father.

Each year, thousands of families in the United States are impacted by prostate cancer—which is the second most common cancer in men – striking 1 in every 6. It is also the second leading cause of cancer-related death in men.

In 2009, studies reported that over 190,000 men were diagnosed with prostate cancer and more than 27,000 died from the disease.

Of course, prostate cancer strikes men from all ethnicities. However, African American men are 60% more likely to be stricken with the disease and have a 100% higher mortality rate than Caucasians.

Despite these tragic statistics, there are no reliable, accurate, diagnostic tools for the detection and treatment of prostate cancer.

In fact, the current diagnostic tests are arcane and inconclusive, leaving men with:

- debilitating side effects;
- uncertainty of treatment;
- a false sense of security; or
- a sense of panic

all of which have devastating consequences.

Mr. Chairman, it is with an eye towards developing more effective and efficient diagnostic and treatment tools that I welcome our expert witnesses this morning and look forward to hearing their opinions. Specifically, I extend a heartfelt welcome to:

- Dr. Theodore DeWeese who is a professor and Oncologist in Chief at Johns Hopkins Hospital, located in my congressional district and hometown of Baltimore, Maryland;

- Mr. Thomas Farrington, prostate cancer survivor and President of the Prostate Health Education Network; and

- Dr. Fay Shtern, President and CEO of the AdMeTech Foundation.

Dr. Shtern worked with me on H.Res. 353 that passed during the 110th Congress, which recognized the need for developing innovative advanced imaging technologies for

prostate cancer detection and treatment. She also helped with the PRIME Act that was reintroduced this morning that provides federal funding for detection and treatment of prostate cancer, and also creates a national campaign to increase awareness about prostate cancer screening.

All of you have provided invaluable guidance that has allowed me to gain a better understanding of where we stand today on prostate cancer education, detection and treatment.

In closing, Mr. Chairman, last year the National Cancer Institute found that men who received the PSA or the DRE lived the same amount of time as those who did not.

The same study also determined that 15% of men with normal blood test levels may still have prostate cancer and 88% of men who undergo a biopsy end up not having prostate cancer at all.

Studies such as this and a report by the *Journal of the American Medical Association* led the American Cancer Society (ACS) to announce last year that the benefits of prostate cancer screenings have been overstated, and the ACS reaffirmed yesterday that men should discuss the risks and benefits of screening for prostate cancer with their doctor prior to being tested.

While I agree that patients should make informed decisions, I am worried that many men will not bother to have the initial discussion with their physician because of the **"new"** perception that screening will not make a difference in their overall health.

We saw a similarly threatening phenomenon unfold last November when the U.S. Preventive Services Task Force announced that women in their 40s should stop routinely having annual mammograms and older women should cut back to one scheduled exam every other year.

This controversial repost caused mass confusion and grave concern that women would no longer get the tests they need for their optimal health.

I am concerned that insurance companies may change how they cover these procedures but I am mostly concerned that people will no longer make their health a priority.

We only have one vessel and we must take all of the necessary steps to keep it in working order.

I look forward to hearing from our witnesses on ways to better inform the public about screening and learning what is being done to ensure that we are developing diagnostic tools that can detect aggressive and non-aggressive prostate cancer.

At a time when all of us are being more responsible with our money, we can and must do better to ensure that we are developing the best treatment options, as these unnecessary

surgeries and biopsies add a large cost to our health care system and take a toll on our lives.

Mr. Chairman, thank you for calling today's hearing and with that I yield back my time.

Chairman TOWNS. Will the witnesses stand? We always swear our witnesses in, so if you would stand and raise your right hands.

[Witnesses sworn.]

Chairman TOWNS. You may be seated.

Let the record reflect that the witnesses all answered in the affirmative.

Dr. DeWeese, we will start with you first.

STATEMENTS OF THEODORE L. DEWEESE, M.D., CHAIRMAN, SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER, JOHNS HOPKINS UNIVERSITY HOSPITAL; THOMAS A. FARRINGTON, PRESIDENT, PROSTATE HEALTH EDUCATION NETWORK, INC., PROSTATE CANCER SURVIVOR; LOUIS GOSSETT, JR., AWARD WINNING ACTOR AND PROSTATE CANCER VICTIM; AND BETTY GALLO, WOMEN AGAINST PROSTATE CANCER, WIDOW OF REPRESENTATIVE DEAN A. GALLO

STATEMENT OF THEODORE L. DEWEESE, M.D.

Dr. DEWEESE. Chairman Towns, Ranking Member Issa, and honorable members of the committee, good afternoon and thank you for the opportunity to testify at today's hearing. Let me also say thank you, Mr. Chairman, for accommodating my schedule. I do need to get back to Baltimore to see, actually, my prostate cancer patients this afternoon, so I do appreciate this opportunity.

I do care deeply about my patients with prostate cancer, and I am committed to doing what I can to improve their health and life.

By way of background, I am a professor and chairman of the Department of Radiation Oncology at the Johns Hopkins University, and I am also professor of urology and oncology. For more than 15 years I have dedicated my life to the treatment of men with prostate cancer and have treated over 2,000 men diagnosed with this disease. I also have directed a laboratory at Johns Hopkins over the same period of time and am intimately involved in research to develop new tests to diagnose prostate cancer and therapies to effectively treat the disease.

I have published more than 150 scientific articles, abstracts in these areas, and I believe these experiences provide me a unique perspective on the problem of prostate cancer and the need for improvements in imaging AND genetic analyses to enhance prostate cancer care. So, my goal today is to provide a brief background on the gaps in screening and treatment approaches, and explain why more robust research funding is needed in order to help our present and future patients.

Major advances supported by Federal funding have been made in the past 25 years to improve the care of patients with prostate cancer. The development of the PSA blood test has been one of the most important advances and serves as the primary means of screening men for the disease. The problem is that the PSA is not cancer-specific, it is only prostate-specific, such that changes in the PSA can occur for both cancerous and non-cancerous reasons, such as an infection. Moreover, the PSA typically does not indicate exactly how aggressive the cancer will be in any individual patient. This particular problem has produced great confusion for physicians and for patients alike.

And while advances in our understanding of how to properly use the PSA test have been made, significant changes in the PSA level typically results in a biopsy of the prostate to determine if cancer is present. This is problem one. Some men do not need to be biopsied because they really do not have cancer, only an abnormal PSA. However, we cannot tell which patients have cancer from those who do not. And for those patients with cancer, we cannot tell which have the aggressive type that can be deadly.

While the PSA test allows us to find some cancers earlier than we might without using the test, we find many cancers that would never have been a problem for the patient and do not need treatment of any sort. Put another way, prostate cancer comes in two general types. One is analogous to a domesticated kitten and the other to a dangerous lion. But right now we cannot easily tell them apart.

Now, this is not to say our present screening and biopsy methods are useless. No. In fact, many men have had their cancer detected early enough to receive care that was lifesaving. But this has been at a cost of finding many more men with cancer that never needed treatment. This approach is problematic because it exposes many men to unnecessary risk of treatment-related side effects. That is to say, we must find a way to ignore the kittens and focus our treatment on those deadly lions.

At present, a biopsy of the prostate is the only definitive way to determine if the patient has prostate cancer, and needles are placed through the rectum into the prostate to obtain that tissue. This is the second problem. Biopsies of the prostate are done in a blinded fashion. Unlike virtually any other organ we biopsy for cancer, we do not have effective imaging to guide the biopsy needles to suspicious areas of the prostate. We cannot see the cancer. Thus, it is very possible that needles placed into the prostate might miss the cancer cells. Even if the needles hit cancer cells in one area, the needles might miss a more aggressive cancer elsewhere in the prostate, which then goes undiagnosed and thus the appropriate management for the aggressive cancer cannot be used.

These facts demonstrate that our present approach can result in the over-diagnosis and over-treatment for many patients, the under-diagnosis in some men, resulting in less optimal therapy because an aggressive prostate cancer was not biopsied, while some patients are left undiagnosed because the biopsy completely missed the cancer. Finally, our ability to accurately determine which prostate cancers in which patients are likely to be lethal is limited.

Taken together, a strong case can be made that significantly improved prostate cancer imaging and genetic markers are needed. Such imaging would allow us to avoid blindly biopsying the prostate. Instead, these images would be used to help guide the placement of biopsy needles to the suspicious sites. In addition, advanced imaging and analyses of blood and urine may allow us to actually determine if a patient has the type of prostate cancer that will never cause harm, avoiding treatment for such men, while allowing us to direct more aggressive treatment to those that will benefit by it.

So despite these concerns, I am quite optimistic about the opportunities for our present prostate cancer imaging and genomic anal-

ysis that they will afford. The positive steps forward that I believe policy planners could consider include an increase in NIH research funding to support prostate cancer imaging, genetic and biomarker research, and clinical trial development by at least 100 percent in these areas of the next 2 fiscal years; support the creation of an NIH request for proposal that would specifically encourage study of imaging, biomarkers, and genetic analysis from patients that are in large patient networks so that the uniform analyses of these techniques could occur; and, last, to urge the NIH to make these initiatives a priority and request a public report on progress by 2011 involves outside experts.

So, in closing, I will say I have had the great privilege of caring for thousands of men with prostate cancer, including several distinguished Members of Congress. It has been a blessing for me, frankly, to see that most of these men are alive and doing well. However, not all of my patients have been so fortunate, and I wonder how much better their lives might have been if I would have had better imaging and diagnostic tools to take care of them. Thus, on their behalf, I am compelled to ask you to support legislation that increases research funding for prostate cancer screening, imaging, genetic analysis, and therapy; and I thank you all for your attention and for your consideration.

Mr. Chairman, thank you.

[The prepared statement of Dr. DeWeese follows:]

Statement of
Theodore L. DeWeese, M.D.
Professor of Radiation Oncology, Oncology and Urology
Chairman, Department of Radiation Oncology and Molecular Radiation Sciences
Johns Hopkins University School of Medicine
Radiation Oncologist-in-Chief
Johns Hopkins Hospital and Health System
Before the Committee on Oversight and Government Reform
March 4, 2010

Chairman Towns, Ranking member Issa, and honorable members of the committee, it is my pleasure to testify at today's hearing regarding prostate cancer screening and the efforts to improve the health of men with prostate cancer. By way of background, I am Professor and Chair of the Department of Radiation Oncology and Molecular Radiation Sciences at The Johns Hopkins University School of Medicine (URL: http://www.radonc.jhmi.edu/), and I am also a Professor of Urology and Oncology. For more than 15 years, I have dedicated my life to the treatment of men with prostate cancer and have treated over 2000 men diagnosed with this disease. I have also directed a laboratory over this same period of time that investigates how prostate cancer responds to radiation therapy and chemotherapy. I am intimately involved in research to develop new tests to diagnose prostate cancer and therapies to effectively treat the disease. I believe these experiences provide me a unique perspective on the problem of prostate cancer and the need for improvements in imaging and genetic analyses to enhance prostate cancer screening, diagnosis, and treatment. My goal today is to provide a background on the gaps in screening and treatment approaches, explain why more robust research funding is needed, and suggest policies that may help protect prostate cancer patients as we progress forward.

As you all know, major advances have been made in the past 25 years to reduce the suffering and death caused by prostate cancer. Since the mid-1970s when federal support was initiated, the death rate from prostate cancer in the United States has been reduced by about 30%. Despite that impressive figure, we can do even more to fight this disease. Among the most important advances in the screening for prostate cancer was the development of the prostate specific antigen (PSA) blood test. This blood test, typically combined with a digital rectal examination of the prostate, has served as the primary means of screening men for prostate cancer. The problem is that the PSA test is not cancer specific, it is only prostate specific. As such, not only can prostate cancer result in suspicious changes in PSA, but so can benign growth of normal prostate tissue and other non-cancerous conditions like infection. Moreover, the PSA typically does not indicate exactly how aggressive the cancer will be in any individual patient. This problem has produced great confusion for physicians and patients alike.

While it may sound odd, it is now generally accepted that many prostate cancers will never progress to cause harm to the patient or result in death from the disease. While refinements in our understanding of how to properly use the PSA test have certainly been made, significant

changes in the PSA level typically result in a biopsy of the prostate to determine if cancer is present in the organ. This is problem one—some men do not need to be biopsied because they really do not have cancer, only an abnormal PSA. However, we cannot tell which patients have cancer from those that do not. In addition, while the PSA test allows us to find some cancers earlier than we might without using the test (sometimes termed "lead time"), we find many prostate cancers that would never have been diagnosed in the patient's lifetime without screening, would never have been a problem for the patient, and do not need treatment of any sort (sometimes termed "over diagnosis" and "over treatment").

Even when diagnosed, we presently do not have adequate genetic markers to definitively determine which cancers are potentially lethal and, thus, demand treatment. This is not to say that our present screening and biopsy methods are useless. In fact, many men have had their cancer detected early enough to receive care that was life saving but this has been at the cost of finding many more men with cancer that never needed treatment. It is estimated that for every man that benefits from prostate cancer treatment, about 30-50 men who do not need treatment still receive it. Obviously, this approach is problematic in that it exposes many patients to the unnecessary risk of treatment-related side effects, and these treatments are associated with real economic cost.

Once a patient receives the news of an abnormal PSA test, the anxiety and fear associated with a potential cancer diagnosis begins. As noted earlier, the only definitive way to determine if the patient has prostate cancer is a biopsy of the prostate. This biopsy is done by inserting a biopsy device into the rectum which then guides needles into different areas of the prostate. Typically, 12 separate needles are placed through the rectum into the prostate in order to "sample" the organ. Hence, the second problem—the biopsies are done in a so-called "blinded fashion". That is, unlike virtually any other organ we biopsy for cancer, we do not have effective imaging that is or can be routinely used to guide the biopsy needles to suspicious areas in the prostate. We cannot see the cancer. Thus, it is very possible that biopsy needles placed into the prostate may miss cancer cells. Even if the needles hit cancer cells in one area, it may be that the needles miss a more aggressive cancer elsewhere in the prostate which then goes undiagnosed and, thus, the appropriate management for that more aggressive cancer is not employed. In fact, different therapies are used for different levels of prostate cancer aggressiveness. Many studies have been completed which document the benefit of more aggressive therapies, like high precision radiation therapy combined with hormonal therapy, which have resulted in improvements in survival for men with more aggressive prostate cancer.

As you can imagine, as more men are diagnosed with prostate cancer, the choice of the best treatment for a specific patient becomes critical. Currently, there are four options for prostate cancer patients with localized disease: prostatectomy (surgical removal of the prostate), external beam radiation therapy, brachytherapy (which is the insertion of radioactive seeds into the prostate), and watchful waiting. While these four options are generally equivalent for many men, there are specific reasons why a particular patient is a good candidate for one of these options rather than another. For example, a patient with a large prostate may not be a good candidate for brachytherapy; a patient with a history of bowel issues may not be a good

candidate for external beam radiation. In order to reduce the risk of overtreatment as well as to determine who should be treated and which treatment might be best for a given patient, more refined screening and genetic analyses applied to the problem are required.

I believe that because we do not have the type of the refined screening and genetic analyses that we need, strange treatment practices have emerged. Across the country, including in my community, new business arrangements are forming that produce strong incentives for one type of treatment (external beam radiation), while the use of other clinically appropriate, significantly less expensive treatments, such as radiation seed implants, or "watchful waiting," have declined or disappeared. I am concerned that the financial incentives are so great, that patients are not being given their full range of treatment options. I believe that high-quality, efficient patient care and informed patient choice supersedes financial benefit, and I hope this Committee will investigate and stop these perverse financial incentives.

These data make it easier to understand why and how our present prostate cancer screening and diagnostic strategy is not optimal and has actually resulted in treatment decisions that are not always in the patient's best interest. These facts demonstrate that our present approach can result in the over diagnosis and over treatment for many patients; under diagnosis in some men resulting in less optimal therapy because an aggressive prostate cancer was not biopsied; while some patients are left undiagnosed because the biopsy completely missed the cancer. Finally, our ability to accurately determine which prostate cancers in which patients are likely to be lethal is limited.

Taken together, a strong case can be made that significantly improved prostate cancer imaging and genetic markers are needed. With improved imaging, one would no longer have to biopsy the prostate blindly but instead, would have images to help guide the placement of biopsy needles to the most appropriate and suspicious sites. This would help to insure that all the cancer in the prostate is evaluated and that no lesion is missed. In addition, advanced imaging and genetic analysis of blood and urine may allow us to actually determine if a patient has the type of prostate cancer that will never cause harm and, thus, avoid a biopsy all together. Such optimized imaging and genetic analyses is also likely to allow us to determine which therapy would be most effective for a particular patient, avoiding unnecessary treatment for some men while directing more aggressive treatment to only those that will clearly benefit by it. Finally, it should be pointed out that most imaging and genetic analysis techniques that are contemplated are non- or minimally-invasive which tends to reduce the fear of the test and reduces the likelihood of complications.

It is my contention that our present prostate cancer imaging techniques are not adequate to meet the challenges we face and, thus, do not allow us to develop the robust genetic markers of aggressiveness that we need. Routine ultrasound imaging has not proven useful in identifying cancer in the prostate. CT scans have limited resolution and, thus, cannot be used for detecting cancers in the prostate. MRI scans with spectroscopic analysis are better and have improved our ability to detect some cancers in the prostate. Unfortunately, these scans also suffer from limited resolution and are not able to routinely detect the frequent, small

cancers with which most patients present. Standard PET and SPECT scans (which are similar in certain ways to PET scans) and their associated imaging agents have also proven to have limited utility in prostate cancer screening and diagnosis. Thus, a need exists for improved technology and academic institutions along with the government and private industry must play a role in creating these advances. It is fortunate that new imaging agents for PET scans, SPECT scans and MRI continue to be developed and show early promise. This also includes development of nanoparticles that preferentially target to areas of cancer and molecular-based imaging techniques that indicate cancer aggressiveness. While exciting, more support for development, testing and deployment of these and other approaches is necessary.

Despite these concerns, I am quite optimistic about the opportunities our present prostate cancer imaging situation affords. Studies using combinations of advanced imaging studies, performed on large networks of patients and employing uniform evaluation criteria could begin relatively soon, and I believe these studies would result in a much improved evaluation of our present imaging techniques. While such studies are laborious and relatively expensive, they are critical to moving closer to our goal. In addition, incorporation of novel, directed biopsy techniques (e.g. robotic) to obtain tissue for critical genetic analyses would more rapidly advance the evaluation and validation of these imaging studies over time and help in the development of tests to more accurately determine which cancers threaten the patient's life. It is critical that funding agencies demand and support genomic analysis of blood cells, normal prostate and prostate cancer tissue from all patients enrolled in these imaging studies in order to correlate genetic information with imaging data, which will in turn guide development of better imaging techniques, improved imaging agents and, ultimately, optimized biomarkers and treatment.

I remain devoted to my patients with cancer and continue to strive to develop better diagnostic and therapeutic techniques to help them. I fully support the notion that greater resources need to be directed toward the problem of prostate cancer screening, imaging and therapy. Positive steps forward that policy planners should consider include the following:

1) increase NIH research funding to support prostate cancer imaging, genetic and biomarker research and clinical trial development by at least 100% in these areas over the next two fiscal years
2) support the creation of an NIH request for proposal that would specifically encourage study of imaging, biomarkers and genetic analyses from patients in large patient networks so that uniform analysis of these techniques and genetic evaluation tools can be performed
3) urge the NIH to make these initiatives a priority and request a public report on progress by 2011 that involves outside experts in the analysis

Significant opportunities in each area exist. Federal research funding has already resulted in improved care for patients with prostate cancer and the 30% decline in the death rate from the disease is likely a result of both screening and better treatment. With enhanced research support for prostate cancer, I am confident further progress for our patients will be made.

Thank you all for your attention and consideration of my testimony.

Chairman TOWNS. Thank you very much, Dr. DeWeese.
Mr. Farrington, good to see you.

STATEMENT OF THOMAS A. FARRINGTON

Mr. FARRINGTON. Chairman Towns and members of the House Committee on Oversight and Government Reform, I am honored to appear before you today to address our Nation's prostate cancer crisis as a 10-year prostate cancer survivor and having witnessed the death of my father and both grandfathers from this killer disease.

Since my treatment for prostate cancer in 2000, I have worked nonstop to help educate others about this disease, including founding the Prostate Health Education Network in 2003, with a focus on African-American men who have the highest risk for being diagnosed with and dying from prostate cancer.

There is an urgent need for clarity in the fight against prostate cancer today. The high visibility debate sparked by the PLCO screening study released last year has caused public confusion, elevating the risk of men most vulnerable to the disease. This confusion comes at a time when we have witnessed a steady decline in the prostate cancer death rates over the past decade, which most attribute to earlier detection of the disease through PSA screening.

These are some of PHEN's positions, concerns, and recommendations for the committee: The PLCO study included approximately 10 percent of men at high risk for prostate cancer, which would be analogous to a study on lung cancer which includes only 10 percent of smokers. Because of this and other factors in the conduct of the study, we do not believe that the results should be the definitive basis for national policies on prostate cancer, but important data to be included with what is already known.

We strongly support early detection, and just as strongly disagree with any policies that would advocate men gamble with their prostates and their lives by not monitoring and knowing their prostate health through the use of the available tools. Today, those tools include screening via the PSA test and digital rectal examination.

The Federal budget for prostate cancer is inadequate to meet the education and awareness outreach needs, and the research needed for new detection and testing procedures that are mandatory to move us beyond today's confusion. We recommend that the budget be equivalent to that for breast cancer, a disease with comparable incident and death rates for women.

Lack of access to treatment and lack of equal treatment where there is access are critical factors in the higher African-American death rate that need to be addressed.

Expanded educational efforts for the public, and for doctors, should be undertaken to address the problem of over-treatment of prostate cancer.

Prostate cancer is a medical, political, and economic issue. We are concerned that the short-term political and economic factors not be allowed to overwhelm and minimize the pressing medical needs.

Prostate cancer can be beaten, and it is also a disease that can end in tragedy which can oftentimes be prevented. My personal and family experiences illustrate this.

In 2000, I was treated for prostate cancer after detection through regular PSA testing. Every 6 months since my treatment I would get a PSA test, and in 2009 I had a disease recurrence. However, because of the early detection of this recurrence and my knowledge about treatment options, I am free of prostate cancer in 2010. I have been blessed with no side effects from any of my treatment because of early detection and knowledge. Ironically, because of today's confusion about screening, some survivors no longer believe they should be screened after treatment, a major step backward increasing the risk to those men who should be most on guard.

While battling my recurrence last year, I lost two additional members of my family to prostate cancer. One, my age, did not get annual PSA testing. The other, my uncle, because of his age, was told by his doctor that he would die of something else before prostate cancer. They both suffered horribly and needlessly. I also had another uncle diagnosed and treated successfully for the disease during this time. Unfortunately, my family situation is not unique, but represents the real and chaotic multi-generational prostate cancer devastation within high-risk families across our country today.

Black America is suffering a prostate cancer epidemic where men die at a rate two and a half times higher than for all other men. At what stage the disease is detected, and with what knowledge, determine whether we live or die, and, if we live, whether we have a good or poor quality of life. However, some of the policies now being advocated would accept this epidemic within Black America as collateral damage.

Chairman Towns and members of the committee, I sincerely thank you for addressing the prostate cancer crisis. We recommend that the policies and solution for this significant health issue have a primary focus on those most in need and implemented with a sense of urgency, an approach taken where most other diseases of this magnitude. This is an approach that we believe would better serve all men. With a publicly clear, well-focused war on prostate cancer and a high level of leadership and priority within the Federal Government, our Nation can save countless lives, dramatically reduce suffering, and overall impact of the disease.

Thank you.

[The prepared statement of Mr. Farrington follows:]

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Prostate Health Education Network, Inc.

HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
(Chairman, Ed Towns, D-NY)

Hearing on
"Prostate Cancer: New Questions About Screening and Treatment"
March 4, 2010

Written Testimony Of
Thomas A. Farrington, Prostate Cancer Survivor, and
President, Prostate Health Education Network, Inc.

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One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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PART I

House Committee on Oversight and Government Reform
(Chairman, Ed Towns, D-NY)

Hearing on
"Prostate Cancer: New Questions About Screening and Treatment"
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These are some of PHEN's positions, concerns and recommendations for the committee:

• The PLCO study included approximately 10% of men at high risk for prostate cancer which would be analogous to a study on lung cancer which includes only 10% of smokers. Because of this and other factors in the conduct of the study we do not believe that the results should be the definitive basis for national policies on prostate cancer but important data to be included with what is already known.

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One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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• Expanded educational efforts for the public, and for doctors, should be undertaken to address the problem of over-treatment of prostate cancer.

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One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

PHEN
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I sincerely thank the committee for the opportunity to provide this statement.

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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PART II

Written Testimony of
Thomas A. Farrington, Prostate Cancer Survivor, and
President, Prostate Health Education Network, Inc.

The Prostate Health Education Network, Inc., (PHEN) is a non-profit 501(c)3 organization. PHEN was founded in 2003 by Thomas A. Farrington, a prostate cancer survivor and author of the books, "Battling the Killer Within", and "Battling The Killer Within And Winning". PHEN is governed by a board of directors, and works with local advisory boards, partners and volunteers to assist with implementation of its programs and activities around the United States.

PHEN's primary mission is to increase prostate health education and awareness among African Americans. Saving lives through early detection and eliminating the African American prostate cancer disparity is PHEN's education and awareness goal. PHEN's mission also includes efforts to increase the overall support and resources to wage a war on prostate cancer that will eventually lead to a cure for the disease.

In 2005 PHEN organized and hosted the first ever "African American Prostate Cancer Disparity Summit." This historic event was held in collaboration with U. S. Senator John Kerry (MA) and U. S. Congressman Gregory Meeks (NY), and hosted in the Rayburn House Office Building. This summit is now an annual two day event which assembles members of congress, medical and research leaders, prostate cancer survivors and advocates to collectively address the prostate cancer epidemic. In 2009, for the second consecutive year, the summit was an official session of the United States Congressional Black Caucus' "Annual Legislative Conference." One day of the summit is now hosted in the Washington, DC Convention Center.

Why The African American Prostate Cancer Disparity? – This was a session held as part of the second annual summit in 2006. The presentations and findings are very pertinent to the hearing topic:

"Prostate Cancer: New Questions About Screening and Treatment"

Presenting as part of this session:

1. James L. Mohler, MD – Roswell Park Cancer Institute
2. Matthew Freedman, MD – Dana-Farber Cancer Institute
3. V. Diane Woods, Dr.P.H., M.S.N., R.N. – Loma Linda University
4. Timothy Gilligan, MD – Cleveland Clinic
5. Issac J. Powell, MD – Karmanos Cancer Institute
6. Mr. Yussif Dokurugu – Florida A&M University

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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Each of the presenters outlined key findings resulting from their research projects that were related to better understanding the key factors causing the African American prostate cancer disparity. Some of the findings included:

1. There is a lack of communication between doctors and black men about screening and early detection. More than half the doctors in one government funded study did not discuss early detection with their patients and more than half the patients did not know why they should be screened.
2. A prostate cancer risk locus has been identified through genetic research that appears to be a stronger effect at an earlier age for African American men.
3. Evidence suggests that prostate cancer incidence is higher in African men than African Americans
4. African American men are less likely to be screened for prostate cancer, be treated aggressively for localized disease, be followed for PSA relapse after treatment, receive androgen deprivation therapy for advanced disease.

Each of the presentations are available on PHEN 's website at http://prostatehealthed.org/page.php?id=66 in addition the presentations are available as part of PHEN Television at http://www.prostatehealthed.org/phen_tv_video.php?tv_id=3

In addition to these presentations other research has established that African American men are detected for prostate cancer at a later stage than white men. It has also been established that when black men and white men are diagnosed with the same conditions (stage and Gleason score) and receive the same treatment then the outcomes are the same.

The 2009 PHEN "African American Disparity Summit" addressed the subject:

Prostate Cancer Screening for African American Men
The Prostate cancer screening trial results released by the PLCO (Prostate, Lung, Colorectal and Ovarian) project team in March 2009 propelled this issue into the forefront of public visibility prompting debates on whether men should be regularly screened for prostate cancer. This session will presented an overview of the African American prostate cancer crisis, examined the screening debate issues as they relate to Addressing this crisis, and outlined a recommended set of early detection screening guidelines.

Session Moderator:
J. JACQUES CARTER, MD, MPH, Assistant Professor of Medicine, Harvard Medical School, PHEN Medical Advisor

Presentations:
The PLCO Prostate Cancer Screening Trial Results:
Christine D. Berg, MD - Chief, Early Detection Research Group, Division of Cancer Prevention, National Institutes of Health

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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The National Comprehensive Cancer Centers (NCCN)
Position on Screening and Recommended Guidelines:
Mark Kawachi, MD -Chair of the NCCN Guidelines for Prostate Early Detection and Associate Professor of Surgery, Urology and Urologic Oncology at City of Hope Comprehensive Cancer Center

The American Cancer Society Position on Screening
And Recommended Guidelines:
Durado D. Brooks, MD, MPH - Director of Prostate and Colorectal Cancers, American Cancer Society

The American Urological Association Position on
Screening and Recommended guidelines:
Willie Underwood, III, MD, MS, MPH - Roswell Park Cancer Institute

The Impact on Public Policies:
Mr. Scott Williams, VP - Men's Health Network

All of the presenters support early detection screening for prostate cancer for African American men. The presentations are available on PHEN's website at http://prostatehealthed.org/page.php?id=83 and they can be viewed on PHEN television at http://www.prostatehealthed.org/phen_tv_video.php?tv_id=26

PHEN's position and recommendation to the committee on the screening and treatment issues are that we use the knowledge that has been accumulated over the past years and increase the focus on the African American epidemic with the urgency and resources required to tackle a true epidemic which it is. This added urgency will surely accelerated new developments to aid in the overall prostate cancer crisis which will be available to assist all men. Efforts to minimize screening and early detection efforts because of the flawed PLCO study will be an acceptance of the African American epidemic. This would be a tragic direction in the fight against prostate cancer and one totally unacceptable to Black America.

Knowledge is the key prevention of prostate cancer deaths. PHEN has developed a national education and awareness initiative which is outlined here. Knowledge is an important part of treatment for prostate cancer. PHEN recommends that an audit assessment of the resources that are being allocated to prostate cancer education and awareness relative to the overall needs be made, again with a focus on the needs of the men most at risk and impacted by the disease.

PHEN's Rally Against Prostate Cancer - The PHEN "Rally Against Prostate Cancer" (RAP Cancer) initiative combines the outreach leadership efforts of prostate cancer survivors, cancer center partners, the communications reach of the internet, radio and television broadcasts for a broad and highly visible national movements to address the African America prostate cancer crisis. With an incidence rate 60% higher and a mortality rate 140% higher than for all other men

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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in the United States, black men are in desperate need of help in the struggle against prostate cancer. Dramatically increasing the knowledge, awareness and support among these men at highest risk are the objectives of RAP Cancer

RAP Cancer Activities

The PHEN Survivor Network: PHEN mobilizes prostate cancer survivors to work together and assume leadership roles in the fight against prostate cancer within their communities. PHEN empowers the survivor network members with online tools, materials, PHEN TV programs, and other resources which leverage their valuable volunteer efforts to reach men where they are; in their homes, at work, church, and other organizations.

PHEN Web Portal (www.prostatehealthed.org): The hub for communications and information for PHEN's online and local grassroots outreach efforts. The Web Portal highlights activities in the various focus cities providing news, information on screening locations and other important resources. The PHEN blog and online support community are hosted on this site.

PHENTV.com: Online television programs featuring national leaders, survivors, celebrities and medical specialists. These programs are produced by PHEN from presentations at its annual summit, meetings and guest interview discussions. PHENTV.com serves as an important online education and awareness resource for the public, and a tool to support the local outreach efforts of the PHEN survivor network members.

Community Television Outreach: PHENTV.com programs are broadcast on community television stations in cities nationwide. PHEN releases new programs monthly for regular broadcasts. These visible education and awareness programs allow PHEN to educate men and their families at home, as never before done.

Radio Broadcasts: Members of the US Congressional Black Caucus, and others, have recorded PHEN radio awareness messages which are broadcast on local radio stations across the country. These broadcasts reach their constituencies who are at high risk for prostate cancer. PHEN also broadcast special radio programs with members of its survivor network and medical specialists via its monthly radio program which broadcast in Boston on 106.1 FM and worldwide on the internet at www.TOUCHFM.org.

Student Outreach: PHEN recruits college students to use their computers as tools to view and discuss PHENTV.com programs with family members who are at risk, and possibly facing prostate cancer. This initiative will also inform and educate students about prostate health issues and related career opportunities that they can pursue.

On Father's Day 2009, PHEN implemented its inaugural "Father's Day Rally Against Prostate Cancer" in partnership with 33 churches in Massachusetts. This groundbreaking and highly successful effort is the model for a national rally on Father's Day 2010 where more than one thousand churches are expected to join in. The rally, which takes place within each church, will receive a high level of visibility through the media; radio, television, internet and print with a theme of ***"Joining Hands in Prayer to Save Lives."***

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2259 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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PART III

House Committee on Oversight and Government Reform

(Chairman: Ed Towns, D, NY)

Hearing on

"Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Joint Statement of

America's Prostate Cancer Organizations

comprising

Accelerate Progress

www.accelerateprogress.org

Malecare Prostate Cancer Support

www.malecare.com

Men's Health Network

www.menshealthnetwork.org

National Alliance of State Prostate Cancer Coalitions

www.naspcc.org

Prostate Cancer Foundation

www.prostatecancerfoundation.org

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.2444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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Prostate Cancer International

www.pcainternational.org

Prostate Conditions Education Council

www.prostateconditions.org

Prostate Health Education Network

www.prostatehealthed.org

Prostate Net

www.prostatenet.org

Us TOO International Prostate Cancer Education and Support Network

www.ustoo.org

Women Against Prostate Cancer

www.womenagainstprostatecancer.org

ZERO – The Project to End Prostate Cancer

www.zerocancer.org

Collectively, America's Prostate Cancer Organizations thanks the Committee on Oversight and Reform for holding this important hearing, and we appreciate the opportunity to submit joint testimony on the critical issues that affect the current status of the prevention, diagnosis, and treatment of prostate cancer, and research into all aspects of this disease.

America's Prostate Cancer Organizations is a collaborative group of independent not-for-profit organizations that seek to represent the best interests of men at risk for, diagnosed with, and treated for prostate cancer in America today. Our shared goal is that ***all*** such men should receive the most appropriate advice and care, and that we continue to limit the devastating impact of prostate cancer on men and their families.

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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America's Prostate Cancer Organizations counts among its collaborators:

- The largest network of prostate cancer patient support groups in the world

- The world's largest, independent, not-for-profit organization involved in raising money to support prostate cancer research

- Organizations that represent the interests of specific underserved and special interest groups, including African Americans and the gay community

Our fundamental objective in presenting this testimony is to offer the committee some guidance on current priorities -- as seen from the point of view of the men at risk for prostate cancer, patients with this disease, and the families of men who either have prostate cancer today or have passed away as a consequence of this disease.

Our testimony is brief and to the point, and demonstrates to the Committee the shared perspective of literally tens of thousands -- if not millions -- of men and their families across America.

We wish to make just five important observations, and we ask the Committee to consider these observations with great care:

- Prostate cancer is a complex and problematic disease that affects not only the male patient but also his wife or partner and other family members over many years. Nearly 200,000 men will be diagnosed with prostate cancer in the U.S. in 2010, and about 28,000 will die from this disease.

* The early detection and appropriate treatment of clinically significant and potentially lethal prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risk.

· Every man has the right to know whether he is at risk for potentially lethal prostate cancer.

· Experts disagree on the adequacy and usefulness of currently available tests to identify men at risk for potentially lethal prostate cancer early enough to offer curative therapy.

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

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· African-American men have one of the very highest rates of incidence and death from prostate cancer anywhere in the world.

· Physicians and their adult male patients should be encouraged to discuss the patients' personal risks for prostate cancer and the individual need for prostate cancer testing at each patient's annual physical exam.

· Men at higher levels of risk for prostate cancer (because of ethnicity, family history, and other factors) should be encouraged to undergo appropriate tests at a relatively early age.

- Until more accurate tests are available, all health care insurance plans should include coverage of regular testing for prostate cancer (including the prostate-specific antigen or PSA test and the digital rectal examination or DRE) – and its subsequent diagnosis.

- Additional funding is urgently needed to support research into better ways to identify and discriminate between very low risk ("indolent") and higher risk (clinically significant and potentially lethal) forms of prostate cancer at the time of diagnosis ***and*** into better forms of management for patients with or at risk for potentially lethal disease.

· Most specifically, we support a significant increase in funding for the Prostate Cancer Research Program (PCRP) of the Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense, which has been funded at $80 million each year since 2001.

- We continue to support the need for an Office of Men's Health (comparable to the highly successful Office of Woman's Health) within the Department of Health and Human Services (DHHS) that can represent the specific health interests of the male population of America.

In conclusion, we thank the Committee for its efforts and its leadership in many aspects of health care, and specifically for presenting this opportunity for the many issues affecting the prevention, diagnosis, and management of prostate cancer (and its clinical consequences) to be discussed in this public forum.

One Adams Place, 859 Willard Street, Suite 400 • Quincy, MA 02169 • Tel: 781.487.2239 • Fax: 781.487.7444
Website: www.ProstateHealthEd.org Email: thomas@ProstateHealthEd.org

Chairman TOWNS. Thank you very, very much.
Mr. Gossett.

STATEMENT OF LOUIS GOSSETT, JR.

Mr. GOSSETT. Yes, sir. Thank you for accepting me to be here. I am not a politician, so I am not going to speak at any first—I haven't prepared any speeches. I haven't done that in years, and I have spoken in front of a lot of executives in committee meetings in the Black Caucus and at universities across America. I think that, at this age, if I don't know it, I never will. I trust my heart and my experience, and I have been representing, hopefully. I thank you for accepting me here.

I went public with the fact that I have prostate cancer. I had a little cancer in my kidney and lost the kidney. The operation took 20 minutes and they said that the other kidney would increase its size, and it did; and a week later I was in the gym and everything was fine. But now, since I have gotten it again, I started to cancel some things in order to take care of the cancer instead of a lot of appointments, and the gossip began to hit; and gossip is the worst thing there is, it is worse than AIDS, sometimes. So in order to dispel all of the talks, I went public. I am a gentleman of service these days, and to serve all of the people who have prostate cancer who like to keep it a secret, I came out of the closet and said so, and hopefully it helped a great deal.

I got a great deal of emails and texts from gentlemen across the country thanking me for being courageous to come out of the public service and encourage them to take care of their doctors. A very ironic thing happened in some of them, because some of them around Louisiana, around California, around New York and different places went to find a doctor that they could afford, and could not find one. So there is a percentage of African-American men who do get it, and they also cannot afford to see a doctor.

My heart goes out to those particular men. I remember last time we had some kind of problem like this, when I was a child, you remember the polio epidemic. And what we did for the polio epidemic is we went to them with a kind of a—we took care of everybody in America, and there were no debates in Congress about whether it was pro or con. We took care of everybody in America.

Now, this year, this time, above all years, I believe that the playing field must be leveled. I think we are going in that direction anyway. So we must kind of take care of everyone in the equal American way. I am concerned that these facts that have been told to us in the other meetings are true, that we lose an African-American man or two every day to prostate cancer. I think it should be modernized. I think the mammograms have shown us that we can do the same thing with prostate if we give a little accent to that research so that my mind is fairly creative.

I have a book coming out next month and I plan—since I can't travel so much on planes—to take a train and a bus and promote Eracism, which is my foundation, to try and level the playing field for our next generation. If we do not plant negatives in the next generation, they will grow up free of certain prejudices that we might not know we have. So I think this generation is at the insight of making sure we don't add to the problem, but add to the

solution; of how we can be one Nation under God, indivisible, with liberty and justice for all.

There are some things that are very important to our children. Prostate cancer is one of those subjects. I can't imagine this great country being fought in our congresses pro and con, and eloquently, about the fact that there is somebody in this country who cannot afford to take care of their health. Of all countries in this world, I believe that we should be the one exemplary, that everyone in this country should be able to go to the doctor. I have a child who I took—when Jesse Jackson was running for President some 27, 25 years ago, and I found him homeless in St. Louis, and at that time we thought that every child in America should have free medicine, free education, free shelter, free food, free clothing, and free love; and I believe America is the foundation of that.

Once you have that, then your thoughts go to loftier things. I think every American should have that. If there are African-Americans—and I get these in emails—who can't afford to go to a doctor and they know they might have some prostate cancer, then they feel like step children. We have to get rid of our stepchildren and educate them to be three-dimensional responsible Americans, and have to give them the signals that they are as equal and as loved as everyone else.

The children of our stepchildren are gang-bangers, because they are planting a seed. They look at their fathers and see that they are not getting anything, and they say, well, I am going to go this way. So I am in those trenches trying to get these kids to be responsible, and my idea is to take this bus that our President is talking about, putting an incentive into the bus and the train systems, Amtrak, promote my book, my foundation, and subjects like this to tell them that they also are three-dimensional Americans and to roll their sleeves up and be prepared to be responsible; all the neighborhoods. And out of that will come a sensitive thought of going into clinics to advance the study of prostate cancer and other things so that we can realize in our minds that we are equal and we have access to being cured. I find myself special, but those who are not special will not get this treatment, unless we are more sensitive to their problem.

That is basically it. Today, the subject is prostate cancer; tomorrow, the subject will be something else. But we are losing people that should be responsible, and that makes this country better.

Chairman TOWNS. Thank you very much, Mr. Gossett.

Mrs. Gallo.

STATEMENT OF BETTY GALLO

Mrs. GALLO. I want to thank you, Chairman Towns and the committee, for holding this very important hearing. I appreciate the opportunity to speak to you today on a topic that has had a significant impact on my own life and on the lives of thousands of other men, women, and families.

One of the areas that I felt that we were lacking was the women and, according to a lot of the men, they feel that the women are much more verbalizing to talk about issues, so we have decided to create the Women Against Prostate Cancer, which I am co-founder of, and what our mission is is to unite the voices and provide sup-

port for the millions of women affected by prostate cancer; and today I am speaking on behalf of all women, widows, and caregivers, whose lives have ever been changed by prostate cancer.

As you mentioned, my husband, Congressman Dean Gallo, was diagnosed with prostate cancer in 1992. Unfortunately, he had a lot of pain in his back and when he went to the orthopedist they did a bone scan and he basically lit up like a Christmas tree; it was already into his bones. Normal PSA is normally 4 or less; his PSA was 882. Due to the fact that Dean was in Congress and was a little more familiar with what was going on as far as clinical trials, he did go to NIH and was enrolled in a clinical trial, and his PSA dropped from 882 in February 1992 to 3½ the following March. He, at that point, had done other treatment options and, fortunately, when he was first diagnosed, he was actually only supposed to live 3 to 6 months, and he survived 2½ years; and in that time he still remained in Congress working with his constituents, because he felt that is where his heart was.

There are some other stories. I have found that younger people, this woman, Jenny Taylor, and her husband were both physicians. Steve was 45. He had a PSA done. As a result, the PSA testing found that cancer had spread through 70 percent of his prostate. They couldn't remove the prostate because the cancer had spread, so Steve, through other means, is now in remission and the two of them are enjoying their time together. But, again, it is in remission for the time being, and how long that is one doesn't know.

There are a lot of stories I have heard out there about people going through this and now I am finding that there are younger men, it is not older men. It is not an older man's disease. Women truly have a big concern and it is being a caregiver to men that is so important, and there are so many issues that come along with prostate cancer that sometimes it can create a lot of havoc in marriages because people just don't understand how to deal with the side effects.

More support and education is one of the things that I think is needed for partners and caregivers and the entire family. We really haven't done a good job in that area. A lot of people have no clue what to expect after a prostatectomy or how to deal with issues, and this is one thing, in the 15 years I have been doing this, that I have found that we really need to be doing more in.

One of the areas I found that even in clinical trials we don't really have any outreach component for money to be able to use that to go out and talk to people about prostate cancer, to let the community understand what clinical trials are and how it can help them. Many people are afraid of being guinea pigs, and that is not what we want them to see. We want them to understand that we have something there that could really help.

Early detection and appropriate treatment of prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risks. Physicians of male patients should be encouraged to discuss the patient's personal risk for prostate cancer and the individual need for prostate cancer testing. Men at higher levels of risk for prostate cancer, including the African-American men and men with a family history, should be encouraged to undergo appropriate tests at a rel-

atively early age. Additional funding is needed to increase outreach and promotion of the clinical trials, which I discussed before.

The PSA is not a perfect test, but it is all we have right now. I have been, as a women, going for mammography, and through all of this I have found out that in this—where I have gone, 75 percent of the—not lumpectomies, but the—oh, I am sorry—they had done the biopsies were 75 percent benign. So you have the same issue in breast cancer as we do in the prostate, but at least with prostate cancer we, at this point, do have—this is the best we have. One of the issues that concerns me is like in New Jersey we have the Centers for Disease Control. We have prostate and breast and cervical cancer. They pay for detection and they pay for treatment. In prostate cancer they only pay for early detection. So, in other words, if they have prostate cancer, there is no way to treat them at this point. So it is almost a crazy kind of a way to do things, and this is something that really needs to be corrected in that respect.

Screening should be provided in any health reform legislation. In New Jersey we do pay for it, for a DRE and a PSA, because we find that it is very important for men to have it done and done with their insurance company. There is a lot of confusion today about prostate screening, and I think with the release of yesterday's prostate cancer screening guidelines from the American Cancer Society, there are now three sets of complex and differing screening guidelines, including those from the National Comprehensive Cancer Network and the American Urological Association. One clear set of guidelines is needed to make sure men know what steps to take and when in order to safeguard their health.

For the past 15 years, I have been involved in advocacy for prostate cancer. It has helped me through the grieving process and knowing how to be able to help other men and their families. As men and women in Congress, you are aware of what prostate cancer does to families and have experienced the loss of several colleagues to this disease. Increased education and awareness are the most critical issues.

Chairman Towns and members of the committee, I would like to thank you for addressing this crisis. More needs to be done to help the thousands of men and women and their families across the country who are suffering because of prostate cancer, and we need to allow them to have a better quality of life. Thank you.

[The prepared statement of Mrs. Gallo follows:]

FOR THE RECORD

House of Representatives
Committee on Oversight and Government Reform

Hearing on:
"Prostate Cancer: New Questions About Screening and Treatment"

10:00 a.m.
Rayburn 2154

Thursday, March 4, 2010

Statement Submitted for Consideration by the Committee

Betty Gallo
Co-Founder

Women Against Prostate Cancer
236 Massachusetts Avenue, NE
Suite 301
Washington, DC 20002
P: 202-580-5730

info@womenagainstprostatecancer.org
www.womenagainstprostatecancer.org

Committee on Oversight and Government Reform

Hearing on "Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Testimony of
Betty Gallo, Co-Founder, Women Against Prostate Cancer

I would like to thank Chairman Towns and the Committee for holding this important hearing. I appreciate the opportunity to submit testimony on a topic that has had a significant impact on my own life and on the lives of thousands of other men, women and families.

Women Against Prostate Cancer's mission is to unite the voices and provide support for the millions of women affected by prostate cancer. As health care leaders of the household, the role that women play in all phases of prostate cancer from preventive screenings to treatment and follow-up care is critical.

Our membership is made up of wives, partners, mothers, daughters, sisters, widows, caregivers, healthcare professionals and advocates who have been touched by prostate cancer.

My husband, former Congressman Dean Gallo, was diagnosed with prostate cancer in 1992. He went to the doctor for back pain, but what they discovered was prostate cancer that had already spread to his bones.

The PSA was not a widely used test at that time, and had he received this simple screening in time, he might still be here today. When his cancer was detected his PSA level was 882, much higher than the normal range of 1 to 4.

Given only a few months to live, Dean enrolled in several experimental therapies, some of which helped, but only for a short time.

Throughout his diagnosis and treatment Dean remained committed to serving the people that he faithfully represented and I am committed to follow in his footsteps and make sure more is done to end the suffering that thousands of men, women and families experience from this devastating disease.

In addition to my own experience, members of Women Against Prostate Cancer share their heartbreaking stories with me everyday and I would like to share just a couple with you now:

- When Gail Puffer's husband was diagnosed she "gathered information, organized lab work and office visit notes, and explored treatment options." She said, "The doctors loved that I have done some research. My familiarity with terms made us more conversant and better informed." Gail expresses some additional needs to help prostate cancer patients and families, "We also need to know more about what to expect when first diagnosed. If added to the treatment team, trained professionals, such as social workers, nurses or therapists, can help us get over some of the hurdles." She also shares that, "due to my husband's diagnosis my concerns are now very much with my sons who are at an increased risk for the disease," indicating her continued concern for better early detection methods.

- Sherrie Ellenburg of North Carolina shared that "In December 2003, the doctors concluded that Kenny's cancer was too advanced for surgery. At 42 years of age, his only treatment option was radiation with hormone therapy." "He did his part by encouraging his family and friends to have their yearly exams. His brother, Bryan, was his first success story when a year after Kenny's death he was diagnosed through early detection." Unfortunately Kenny

did not survive his disease, but Sherrie remains a very active advocate and expresses, "My biggest frustration throughout this ordeal was dealing with the finances. The financial struggles that we faced were so insurmountable at times I did not know how we would make it. We were thankful for every day we had together. However, instead of enjoying those last moments, we had to focus on how to provide the basics – food, electricity, and pay our mortgage – with no income. We applied for disability but were repeatedly denied. Finally, six months before his death he was approved. It was amazing to see how his quality of life improved! The struggle of treatment is a painful enough journey without the added financial pressures, such as we had to endure."

These are just a few of the stories I hear everyday that express the critical role that women play and how prostate cancer significantly impacts the entire family.

I would like to express the following concerns for the Committee to consider:

- More support and education is needed for partners, caregivers and the entire family when a man is diagnosed with prostate cancer. Women play a very important role in the screening, diagnosis, treatment and recovery phases of prostate cancer. With approximately 2 million men currently living with prostate cancer, there are countless partners, spouses and loved ones who are also suffering from the effects of this disease.

- Early detection and appropriate treatment of prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risk.

    - Physicians and male patients should be encouraged to discuss the patients' personal risks for prostate cancer and the individual need for prostate cancer testing.
    - Men at higher levels of risk for prostate cancer, including African American men and men with a family history, should be encouraged to undergo appropriate tests at a relatively early age.
    - Additional funding is needed to increase outreach and promotion of clinical trials. These trials provide crucial information to researchers and experts on better screening, detection and treatment options. NCI should provide grants to provide outreach for clinical trials.

- The PSA is not a perfect test, but it is all we have right now. Until more accurate tests are available, all health care insurance plans should include coverage for annual tests for prostate cancer (including the PSA test and the digital rectal examination) – and follow-up diagnostic testing when appropriate. And these screenings should be included in any health reform legislation. If the PSA had been available when Dean, he would not have died from advanced prostate cancer.

- Additional funding is urgently needed to support research into better ways to identify low risk versus higher risk forms of prostate cancer at the time of diagnosis. More specifically, an increase in funding for the Prostate Cancer Research Program (PCRP) of the Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense. Funding should be increased to $125 million from the current level of $80 million in order to continue and increase the important research that is being done.

- The creation of an Office of Men's Health (HR 2115), comparable to the highly successful Office of Women's Health, within the Department of Health and Human Services (HHS) is critical and can represent the specific health interests, like prostate cancer, of men and their families.

For the past 15 years I have been so involved in advocacy for prostate cancer. It has helped me through the grieving process and knowing I have been able to help other men, women and their families. As men and women in Congress, you are aware of what prostate cancer does to families and have experienced the loss of several colleagues to this disease. The most important issue is education.

In conclusion, I would like to thank the Committee for all of its work on this issue and allowing the opportunity for me to provide input into a discussion whose outcome will impact thousands of men, women and their families across the country.

I am attaching the statement from Women Against Prostate Cancer below as part of my testimony.

Chairman TOWNS. Thank you. Let me thank all of you for your testimony.

At this time I will yield to the ranking member for questions that he might have.

Mr. ISSA. Thank you, Mr. Chairman.

The next panel we are going to have will be physicians and specialists, researchers, but I think we were very fortunate that Dr. DeWeese was able to speak first, and in looking through his testimony and some of the things that he provided us in written material, an interesting fact came out, and one that I think, as survivors and, in fact, a victim of somebody who—I appreciate that he survived 2 years, but in many ways the loss is just as great, no matter how much time you had to say goodbye.

One of his facts that concerns me is he says that for every man who benefits from prostate cancer treatment, 30 to 50 effectively have no benefit. It begs the question that I would ask all of you, both as survivors and the widow of one. We put in about $300 million from NIH, another $80 million from DOD, and some smatherings of others into various forms of research, and you did say we should do more, but is this not a disease that effectively, until we aim better, a great deal of our treatment is, by definition, a complete loss; if you have 30 to 1 in treatment, that there is a real risk that people are going through pain and suffering?

Even when they say I am a survivor, the question is are you a survivor of somebody who had cancer, but cancer that wouldn't have killed them versus Mrs. Gallo's husband Dean, who the cancer clearly would; it was aggressive, it spread. Differentiating those, coming up with a much more targeted approach both in lifestyle decisions—because it is one of the challenges we have. We apparently don't know what makes us more likely than European or African or other people of our same DNA mix but in other countries, but, more importantly, the fact that we can't measure or predict.

So no group could be more demonstrative of the people who would most likely disagree about cutting treatment, but I would like you to look at these dollars, the Federal dollars. Where would you have us put more dollars if we only had a very limited amount? Would we put in $300, $400, $500 million more into trying to get these better tests first?

Mr. GOSSETT. May I?

Mr. ISSA. Of course. It is a leading question knowing that everyone would like to answer.

Mr. GOSSETT. Well, I think the way I have been educated—and I am one of the lucky ones, and those of us who have survived are one of the lucky ones in finding the cancer in the prostate to those who have doctors who have access to the best is still like winning the lottery. Whereas, on the other side, the women, they have mammograms, they have sophisticated things that have made their science much more successful. I see more heroines in that. We need to catch up to them. And in order to do that I think we need to concentrate our dollars or your dollars, to those particular specialists who know how to sophisticate and find an equal to the mammogram to the prostate sufferer, because the ones who fail because of our inadequacy of really pinpointing what it is is hit and miss,

and I think we have the ability and the knowledge to really be better than that and save some lives.

Mr. ISSA. Mrs. Gallo, would you concur with that?

Mrs. GALLO. Well, honestly, in the beginning, when this all happened with Dean, the first thing I wanted to do was scratch everyone's eyes out that didn't have the PSA because I lost a wonderful man and it has really been difficult to really understand why. And, again, when we talk about breast cancer, they have all sorts of testing; you start with a mammography, then you go to another mammography if there is a problem, then there is an ultrasound, there is an ultrasound biopsy. The hard part with prostate is you can't see the prostate, so everything is kind of a guessing game. I think even if they say it takes 10 years for prostate cancer to really get to the point of where you are going to see it, sometimes even doing a baseline at, say, an earlier age might be the way to go. You know, at least you can keep track of it that way.

I agree we need to put more money into getting a better testing for prostate cancer and nothing is going to be 100 percent, and it is the same thing, I think, in a lot of cancers. But at the moment I feel it is something we have and it at least has saved some people's lives. I think no matter what cancer, there are going to be people who are going to die from cancer because maybe they didn't need treatment and others are going to live, and I just think that, unfortunately, I think because we have always thought of prostate cancer as an older man's disease, we didn't really look at now how it is really affecting the younger population.

So I agree we need to put more money in to be able to find a better way to detect it, but also I personally feel that what we have is better than nothing at this point.

Mr. ISSA. Mr. Farrington.

Mr. FARRINGTON. Yes. Mr. Issa, I think there is an abundant amount of data that exists that shows that what we do now does save lives. I think if you look at the decline in deaths since the PSA was widely used, we have seen over 30 percent decline in death rates. I mean, that is real. That is not theory, that is real.

Mr. ISSA. Sure, but Dr. DeWeese and I think the second panel, they spend a lot of time basically saying it is like the Hubble telescope. You know, it does give you a picture of the stars, unfortunately, it is insufficiently clear to be meaningful to have only those people who have a treatable disease, or at least close to only those people, versus having 30 times as many people go through extensive treatment as receive benefit.

I am not disagreeing. I think universally the early detection and improving early detection we think is important. But then that secondary—and I think Mrs. Gallo said it very well—are the tools today for prostate as good as they are for breast cancer once you think you might have something. The answer is no. I think if we were doing radical mastectomies, as we did in the 1950's, on everyone who had a lump, practically, we would be horrified at the results. But that is what we used to do in breast cancer. We have come a long way.

I guess the question as a survivor is if I only have—if the Japanese will only loan us and the Chinese will only loan us another $1 billion this year for something related to prostate cancer, where

would you put those dollars first if you were seeing the testimony we are seeing, such as Dr. DeWeese's. And I ask you because you are the hardest people to make the decision that you would put it into research or you would put it into better detection or better differentiation versus treatment.

Mr. Gossett, you said it fairly well. There are so many people who don't have access, but it takes tens of billions of dollars to incrementally improve the access to the under-served, and it is one of our challenges here, and one of the things that I have worked on with the chairman here, is prioritizing at least some dollars to the area that could, in the long run, cause 30 out of 31 people not to suffer needlessly and those 1 to get the treatment early.

Mr. FARRINGTON. Sure. You asked for two areas. Let me respond, sir. One, in terms of research, I think we do have to better focus much about research. I think we know that there are some genetic factors related to prostate cancer risk, and I think there needs to be more research in the area of genetics and biomarkers, detection of procedures. I would put money there.

The other area is in education and awareness. A lot of men really do not understand their risk level for prostate cancer, and when they are diagnosed with prostate cancer they do not understand their options and they don't know whether they should be treated or not treated. I agree that every man should not be treated for prostate cancer that is diagnosed with the disease, but today people are not educated on those factors, so they will, many times, move quickly to treatment when they should not be treated.

So I would look at education awareness and research into genetics and biomarkers. And we talked about imaging today. So I think those are critical areas.

Mr. ISSA. Thank you. I appreciate it.

Thank you, Mr. Chairman. I yield back.

Mr. CUMMINGS [presiding]. Thank you very much.

First of all, I want to thank you all for your testimony. I think we are constantly addressing the issue, as we are doing it in the health care debate that we are now having in the Congress, exactly how do we take the resources that we have and spend them most effectively and efficiently. And then there comes a time when you are trying to figure that out and you say what is a life worth? In other words, do you make a decision not to go forward in a direction which might yield a, as sure as it can be, diagnosis or do you say we don't have enough money and let people suffer and die? And that is a question that I think the Congress wrestles with right now, and I fall on the side of life.

But I was just wondering, when you hear all of this, Mr. Farrington, I guess your family history caused you to take extra precautions, is that right? I mean, in other words, it seems like when you see a history like that—my father, by the way, had prostate cancer, and I have many friends. I was in the bank about a year ago and I was amazed, just standing there, one person comes up, he is talking about he just got out of the hospital, and then two or three more show up. Come to find out there were seven of us standing around, and out of the seven of us four had gone through prostate cancer. Of course, we were all around the same age level.

But I was just wondering what advice are you giving men? What are you saying to them?

Mr. FARRINGTON. Well, No. 1, my family history should have put me on alert, but, very frankly, my doctor never had a conversation with me about prostate cancer, which is one of the real problems with some of the guidelines that are dependent upon that discussion between doctor and patient. A lot of doctors do not have that discussion and they do not have it with Black men at an early enough age to make a difference. I did not have that discussion with my doctor, which required me, when I was diagnosed, to leave Boston to get a specialized treatment.

What I am advising men to do is to know their prostate health. And the only way that you can know your prostate health today is through PSA testing and your digital rectal exam. Once you know your prostate health, if you find that you have cancer, then to understand your options. And those options may be to treat; they may not be to treat. We have talked men with PHEN out of being treated for prostate cancer and told them that they are better off through active surveillance.

So I think those are the things that need to be done, but it does require some action on the part of the patient. You cannot stand back and gamble with your prostate. You cannot stand back and not be knowledgeable, because that is the highest risk of death. That happened in my family last year. So those are the things that we are trying to foster, a higher level of understanding and education. That saves lives.

I would also just like to add one other point to Mr. Issa's question about where we would direct research. I failed to point out that one of the key areas is in research to be able to distinguish between cancer that will kill and cancer that will not kill. I think that is a major question that we have today relative to research.

Mr. CUMMINGS. Thank you, sir.

Mrs. Gallo, in my discussions with a number of groups that address the issue of cancer in general, they say—and you alluded to this in your testimony—that when it comes to breast cancer, I think a lot of the attention that has been given to breast cancer is because there has been a very aggressive effort on the part of women, and research has shown that women are more likely to go to a doctor than men. So with all of the campaigns for breast cancer, I think it has helped to elevate it to a level that NIH and others have to pay attention to it.

How do you see us raising this issue to the level of breast cancer, when one out of every six families in the United States is affected by this? I was just wondering.

Mrs. GALLO. To be honest with you, Congressman, I know a lot of it is the fact that we haven't taken the ability to really get out there. As they say, "the squeaky wheel gets what it is looking for." And in my 15 years of working with men, it is very difficult for them. Some of them don't believe they can make a difference, and I have explained to them I have been out there fighting this battle for 15 years. Sometimes it is difficult being a woman, but we really need to bring it to the forefront, and I think part of the problem with prostate cancer is we don't work directly with the researchers like we should, where the breast cancer coalitions do.

We are lacking in a lot of areas and I hate to say that sometimes it is egos, it is, you know, whatever, but the bottom line is, as a woman, you bring the passion to the disease and you explain it to them, and that is why a lot of men that are prostate survivors have said to me and other women that they feel we are the ones that are going to make it happen, and that is why we started the Women Against Prostate Cancer, because we felt we, as women, women that have lost their husbands or their survivors or whatever, are planning to come down to the Hill, talk to the Congress and tell them the importance of losing our husbands or the possibility of it happening.

There are just so many issues with prostate cancer that goes beyond just what we are talking about here that affects the family that, again, as Mr. Farrington had said, the education is so important; we just don't have it. We don't have the education like we need to, and this is one thing I felt that I really wanted to hone in on, you know, letting people know about what prostate cancer is, where they can go if they have prostate cancer. Like he said, you don't have to have it taken out, because the first thing men want to do is get rid of it, and that is not always the best thing to do for those people.

So I feel that really the education is really important and we need to help the Congress to really be behind us and, of course, here are men sitting here that could have prostate cancer at one point, and it is you that myself, as a woman, are advocating for, such as these gentlemen here or any other men in my life. So I am here because I care. I am here because my husband died of prostate cancer.

I don't have prostate cancer, but it has been very upsetting to me to know that you could lose a man over this disease, and when it goes to the bones like it did to Dean, it is the most horribly excruciating pain that I cannot explain to you. He was working in Congress when he had the pain, and he had a brace on from a hip replacement, and he would walk over to the Capitol in excruciating pain. There was nothing we could do to make it better for him. So that is a concern I have, that we want to make sure they don't get to that point.

But I just want to give you another note here. Prostate screening, just so you know, is not included in the provided health care reform and legislation, and the problem it would do, it would wipe out the prostate cancer screening available to over 30 million men in 37 States. So that is one thing I think, when we go into the health care bill, I think needs to be looked at, that we don't overlook the prostate screenings and the importance of doing that. Like Mr. Farrington said, if you really look at the numbers, since prostate cancer has been used as a tool, you have seen the death rate go down and the incident rate go up, because even though more people are getting diagnosed, there is not as many people dying from it. So that is a good thing.

So, again, I think we really need the Congress behind us to really be there and say we need to put more money into outreach, we need to put more money into finding a better tool to diagnose prostate cancer and just be able to do the best we can, because I don't want to see our men lost to this disease.

Mr. CUMMINGS. Thank you very much.

Mr. Cao.

Mr. CAO. Thank you very much.

My first question is to Mr. Gossett. First of all, when I was a teenager, I was a very big fan of yours. One of the movies that I watch and still remember was Iron Eagle, whether or not you remember it.

Mr. GOSSETT. I remember Iron Eagle.

Mr. CAO. That was one of my favorite movies during my teens. But I represent the city of New Orleans, which is comprised of 60 percent African-Americans, and obviously prostate cancer disproportionately affects African-American males. My question to you, knowing what you know now, what advice would you give to my constituents as to, one, how to prevent prostate cancer and, two, what would they do, if they were to have it, to fight prostate cancer, since you are a survivor?

Mr. GOSSETT. Well, some comics are saying that prostate cancer to the African-American man because of the way they have to be examined is a sure-fire way of them keeping it and dying with it. The examination——

Mr. CAO. I am sorry, can you turn on the——

Mr. GOSSETT. It is on. The examination of prostate cancer, especially in places like Louisiana, Detroit, places of the macho African-American man turns him off because you know what you have to do in order to examine the prostate. It really literally makes him put it aside, put it in the back of his head and forget about it. As a result, more deaths happen because he does not want to go through the experience. You understand the experience I am talking about?

Mr. CAO. Right.

Mr. GOSSETT. With the rubber glove. That is exactly the reason why most African-American men do not go to that. They need to get to that examination; they need to put it aside and go for it. I had a little bit of that, but it is over because I really know how important that is.

Now, once you know you have it, then they talk about—and this is what I get from emails and faxes—a diaper, incontinence. So that is a world that the African-American macho man does not want. So, in his mind he takes it, he puts it in a drawer, and the next thing you know, it is incurable. We need to educate them. We have to do deeper research to show them that it is a little bit more pleasant, it is more like a mammogram to get them off that high horse. There is a fear, as you know, especially in Louisiana, of not being able to make love to your woman again. And I am speaking of these in real terms.

That is why the African-American man, I think, has more incidences of prostate cancer than someone else, because he doesn't want to hear about it. He doesn't want to hear about not being able to make love, wearing diapers, and having incontinence. Those are real things, especially if he is poor. That is the last place he can express himself. So he takes it and puts it in his back pocket until it is a problem.

Mr. CAO. Mr. Farrington, do you believe that we have done enough to inform the African-American community, the African-

American male, of the dangers of prostate cancer and the preventive measures in connection with prostate cancer?

Mr. FARRINGTON. Absolutely not. I don't think we have done enough to inform the high-risk community——

Mr. CAO. And what would you recommend that we should do?

Mr. FARRINGTON [continuing]. That is African-American men, men with a family history and some Vietnam veterans, inform them about the risk and that the prevention to death is knowledge. I am not sure there is a prevention to the disease itself, but certainly the prevention of death is knowledge and early detection.

As I outlined in my testimony, I am a strong advocate of education. That is the reason I founded the Prostate Health Education Network, and what we are doing is that we are outreaching across the country through a number of means to the public. We are outreaching through television, through online, and we created a survivor network of African-American men that can work on the ground in their community to talk with other men. As Mr. Gossett pointed out, there is a fear about the disease.

But if a prostate cancer survivor can touch another man and talk with him about the experience and say I am here and I have survived and I am whole, and you can do the same, but you have to begin the process of knowing your prostate. Those are some of the things that we are doing.

I just was speaking with Mr. Gossett. We are starting this year a nationwide Father's Day rally in churches across the country. We did that in Massachusetts last year and at Mr. Gossett's church in Los Angeles. It just so happened the first book that I wrote, it was unveiled in his church in Los Angeles. So we are going to work together on some of these things for a higher level of public education.

Mr. CAO. And my last question is to Mrs. Gallo. What would be your recommendations to women? How can they encourage their husbands to I guess to be more open to the procedure of prostate cancer detection? How can you encourage husbands to take those preventive measures in order to not suffer this disease?

Mrs. GALLO. Well, nagging is always the first good thing they can do, until they are blue in the face and had enough of listening to you. Sometimes, it is making the doctor appointment for them. And the other part of it is saying, "look, honey, I want you around for a while, and this is a disease that is out there that we ought to make sure you don't end up with." And I think that women nowadays, even the younger women, are really learning more about prostate cancer and the need to get their husbands there.

And I know that there are a lot of women that have basically dragged their husbands to the doctors. I mean, some may be a little bit more nice about it, but that is why, again, we talk about education. My feeling is educating the women to go back and get their husbands, because most of the time the women are the ones that drag the husbands to the doctors or are a little persistent about it.

I think also, I say, look, the women go through exams every year. Look at what we go through. Yours is nothing compared to what we have to do. And, again, it is the importance of saving your life. I will give you a for instance. At one point Dean said to me, "well, if it doesn't work, shoot me, OK?" Well, when it came to prostate

cancer and his possibility of dying, that whole thing went out the window, because the concern was he wanted to live. So I think people have to understand, and I don't think that we have educated men and women enough to understand the importance of getting early detection and being able to treat it at an earlier stage.

You know, 10, 12 years ago, or 15 years ago, before Dean died, there wasn't much out there, and I have seen such a difference even in this 15 year time that there are different ways to be able to help through a lot of the times with the side effects and what not. But people have to understand, and if they don't tell them, then they are more upset when they find out, after the fact, that nobody talked to them about it. So I think we almost have to be kind of real now; we can't just beat around the bush. And I am talking about what Mr. Gossett was talking about, the side effects. We don't want to talk about them, but it has to be talked about because when people go through it and find out these side effects exist, then it creates another problem.

So I think it is more or less just getting women to really—if they really care about their husbands, they are going to get them there one way or the other.

Mr. CAO. Thank you very much.

Thank you, and I yield back.

Mr. CUMMINGS. Thank you very much.

We are going to—first of all, thank you all very much for your testimony. We are going to adjourn now for about a half an hour; we have three votes. This panel is dismissed, and then we will come back and hear the second panel. But your testimony has been very, very helpful. Thank you very, very much.

We will be back in about a half an hour.

Mr. CONNOLLY. Mr. Chairman, just a unanimous consent. I would ask unanimous consent that my full statement be entered into the record.

Mr. CUMMINGS. Without objection.

Mr. CONNOLLY. Thank you.

[The prepared statement of Hon. Gerald E. Connolly follows:]

Opening Statement of Congressman Gerald E. Connolly

Committee on Oversight and Government Reform

"Prostate Cancer: New Questions About Screening and Treatment"

March 4th, 2009

Chairman Towns, thank you for holding this hearing to provide our constituents with information about prostate cancer. Recent recommendations from the American Cancer Society and the United States Preventive Services Task Force have provoked confusion and controversy about cancer screenings, so I appreciate the opportunity to provide some clarity about the benefits and limitations of cancer screenings. In short, we know that prostate cancer screenings serve an important role catching cancer in its early stages, but that screenings frequently are unable to distinguish between dangerous and innocuous tumors. Breast cancer screenings have similar benefits and limitations.

Unfortunately, some have attempted to politicize the findings of these non-political, scientific entities. Republicans Sue Myrick and Dave Camp suggested that the Preventive Services Task Force breast cancer screening recommendations would somehow lead to health care rationing, which was an unusual suggestion given that the panel's members were appointed by Republicans.

Not surprisingly, the same individuals who voted against the Recovery Act failed to note that we have made historic investments in cancer research. As the written testimony of William Dahut, with the National Institutes of Health, notes, the Recovery Act dedicated $53 million to prostate cancer research over Fiscal Years 2010 and 2011. President Obama's budget proposal includes a $19 million funding increase for prostate cancer.

These proposals are important because doctors frequently do not have enough information to distinguish between more and less aggressive forms of prostate cancer. As Otis Brawley of the American Cancer Society noted in his prepared testimony, "One of the greatest problems is that we do not yet have a test that distinguishes the kind of disease that needs treatment from the kind of disease that will never kill."

Mr. Brawley also emphasizes the importance of "improving access to quality care" in order to reduce disparities of care resulting from unequal access. This requires a more comprehensive approach than increases to research funding, an approach that would resemble the health care reform legislation that the House of Representatives has already passed.

In summary, this hearing reminds us of how connected many health policies are. We are providing the immediate service of disseminating information to our constituents, but must continue to make progress funding research and, most critically, reforming our health care system so that our constituents have access to the best available cancer information and treatment, as recommended by the American Cancer Society itself.

Mr. CUMMINGS. Thank you very much.

[Recess.]

Chairman TOWNS [presiding]. The meeting will come to order.

If you would stand. We swear all of our witnesses in. If you would stand and raise your right hands.

[Witnesses sworn.]

Chairman TOWNS. Let the record reflect that all the witnesses answered in the affirmative.

Why don't we just go right down the line, starting with you, Dr. Dahut, and just come right down the line?

Thank you all for being here.

STATEMENTS OF WILLIAM L. DAHUT, M.D., CLINICAL DIRECTOR, NATIONAL CANCER INSTITUTE, NATIONAL INSTITUTES OF HEALTH; OTIS W. BRAWLEY, M.D., CHIEF MEDICAL OFFICER, AMERICAN CANCER SOCIETY; CAROLYN J.M. BEST, PH.D., PROGRAM MANAGER, PROSTATE CANCER RESEARCH PROGRAM, U.S. ARMY MEDICAL RESEARCH AND MATERIAL COMMAND, CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAM; DR. STEVEN G. KAMINSKY, PH.D., VICE PRESIDENT FOR RESEARCH AND DIRECTOR OF RESEARCH ADMINISTRATION, UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES CENTER FOR PROSTATE DISEASE RESEARCH; FAINA SHTERN, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, ADMETECH FOUNDATION; AND JAMES L. MOHLER, M.D., CHAIRMAN, DEPARTMENT OF UROLOGICAL ONCOLOGY, ROSWELL PARK CANCER INSTITUTE

STATEMENT OF WILLIAM L. DAHUT, M.D.

Dr. DAHUT. Thank you, Mr. Chairman, for giving me the opportunity today to speak. I also wish to thank you for accommodating my schedule, allowing me to leave early today.

My name is Dr. Bill Dahut, and I am the Clinical Director of the National Cancer Institute. Our particular research focuses on the development of novel therapeutic strategies for the treatment of prostate cancer.

Prostate cancer is the second highest cause of cancer deaths for men in the United States. The good news is the overall death rates from prostate cancer are on the decline. Most think this improvement is due to a combination of improved treatments and possibly earlier detection. However, it is important to remember that there is not just one prostate cancer. Some patients respond to treatment and live out normal life spans, while other lives are cut short by aggressive disease. The clinical course of the disease reflects the interplay between the biology of the tumor, the genetics of the patient, factors in the environment, and available treatments.

There is a huge challenge in the field right now. We are struggling to differentiate lethal or deadly prostate cancer from non-lethal prostate cancer, a form of the disease unlikely to ever cause symptoms or lead to death. Another unfortunate reality is that the burden of prostate cancer is disproportionately borne by African-American men, who have a 60 percent higher incidence of prostate cancer as compared to white men and are twice as likely to die from the disease.

Many men will die with prostate cancer, but not from prostate cancer, or never have any cancer-related symptoms. Since all treatments have side effects, with some being quite significant, the potential for over-treatment is a real problem in this disease. Nevertheless, nearly 20,000 men die yearly from this disease, while many others have cancer-related pain. Thus, the single biggest challenge to researchers is to identify a means to distinguish lethal from non-lethal prostate cancer. Without this information, we are likely to under-treat or over-treat our patients.

Even within these broad categories, prostate tumors may have very different characteristics, which may ultimately guide treatment decisions. Not all prostate tumors are like other prostate tumors, and they do not respond to therapy in the same ways. In fact, the biology of a given prostate tumor may turn out to be much more like a breast tumor than like another prostate tumor. NCI is moving aggressively toward the goal of distinguishing lethal from non-lethal prostate cancers by researching biomarkers, genetics and molecular characterization, nanotechnology, and imaging techniques that may help to differentiate the aggressive prostate cancers from the less threatening ones.

While the use of Prostate Specific Antigen [PSA], has led to the earlier detection of prostate cancer, some patients with elevated PSA values are found not to have prostate cancer when biopsied. Furthermore, there is no safe PSA value, and even patients with very low PSA values have a surprisingly high risk of prostate cancer. We are actively searching for other biomarkers, substances that may be found in tumor tissue or released from a tumor into the blood or other body fluids such as urine that would distinguish between cancerous and benign conditions, and between slow growing cancers and fast growing potentially lethal cancers. The identification of such biomarkers is a high priority in order to provide safe and effective large population screening.

The NCI Clinical Cancer Team is studying new therapeutic approaches to prostate cancer through various clinical trials. For example, an NCI-developed prostate cancer vaccine has shown significant benefit in a Phase II study at the NIH and should be moving into larger clinical trials soon. NCI has also participated in the research and development of a drug known as Bevacizumab, which is a drug developed to target blood vessel growth. The results of a very large clinical trial using this agent in men with advanced prostate cancer will likely be available in 2 to 3 months.

We are continuing to press forward in our efforts to develop the knowledge that will allow us to treat prostate cancer based on specific molecular characteristics of the tumors that tell us about the way the genes and proteins interact. In order for this to be successful, we need to understand the relevant targeting of the tumor and develop potent drugs effective against this target. Although this targeted approach has been successful for infectious diseases for nearly a century; unfortunately, therapy for metastatic prostate cancer has all remained trial and error—that is, the drugs are not targeted or personalized for an individual specific type of prostate cancer. We are aggressively pursuing research to enable us to personalize cancer therapies.

We are optimistic that through the specific genetic abnormalities in an individual patient's prostate tumor, that we will be able not only to identify the aggressive forms of the disease, but also to develop specific treatments appropriate for the patient's cancer, ultimately reducing death and suffering from prostate cancer.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Dahut follows:]

Testimony
Before the
Committee on Oversight and Government Reform
United States House of Representatives

Prostate Cancer Research at the National Institutes of Health

Statement of
William Dahut, M.D.
Clinical Director, NCI
Chief, GU/GYN Clinical Research Section
Medical Oncology Branch
National Cancer Institute
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
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Thursday, March 4, 2010

Thank you for the opportunity to speak to you today. I am Dr. Bill Dahut, Clinical Director of the National Cancer Institute (NCI) and Chief of the GU/GYN Clinical Research Section within the Medical Oncology Branch at the NCI within the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The National Cancer Institute is dedicated to the understanding, diagnosis, treatment, and prevention of cancer. Our research portfolio in prostate cancer seeks to increase our understanding of the disease and to improve outcomes for men with prostate cancer, and includes research on screening and imaging, treatment, and health disparities. My particular research focuses on the development of novel therapeutic strategies for the treatment of prostate cancer.

Prostate cancer is the second highest cause of cancer deaths for men in the United States, second only to lung cancer. American men have a 1 in 6 chance of being diagnosed with prostate cancer within their lifetime, and the incidence increases markedly as men age. The good news is that overall death rates from prostate cancer are on the decline. This improvement is thought likely to be from a combination of earlier detection and improvements in treatment. The bad news is that we are still struggling to differentiate lethal prostate cancer from non-lethal prostate cancer, which is the most significant factor in deciding how to treat the disease. Another unfortunate reality is that the burden of prostate cancer is disproportionately borne by African American men, who have a 60% higher incidence of prostate cancer as compared to white men, and are twice as likely to die from their disease.

It is important to understand that prostate cancer is not like most other cancers. Most prostate cancers grow very slowly and never cause problems. But a few grow quickly and spread through the body. The single biggest challenge for researchers is to identify lethal from non-lethal disease and to determine the best way to approach treatment. There are three standard treatments for early prostate cancer: surgery, radiation, and "active surveillance." It is difficult to determine which treatment option is most appropriate for a particular patient. Research has shown that, in general, younger men with larger tumors live longer if they opt for surgery as opposed to observation. However, it is likely that there are men with indolent (i.e., not aggressive) disease, in whom surgery not only would be unnecessary, but also could potentially produce debilitating side effects. To determine the best choice for a man with early prostate cancer, we need to better understand the characteristics of his tumor. For instance, if a physician knew that a particular tumor was life-threatening, then an aggressive treatment approach could be selected, but if the tumor was indolent, then possibly no treatment would be needed. NCI is moving vigorously toward this goal by researching genetic analyses, molecular characterization, and imaging techniques that will help to differentiate the aggressive prostate cancers from the less bothersome ones.

Prostate cancer remains a high research priority for the NIH. In Fiscal Year (FY) 2009, NIH devoted approximately $310 million towards prostate cancer research, and an additional $47 million was devoted to prostate cancer research from funds provided under the American Recovery and Reinvestment Act of 2009 (ARRA). For FY 2010, $319 million in funding is expected, with an additional $26 million in funding under ARRA. And the President's budget request for FY 2011 includes an estimated $329 million.

With these funds, NIH is supporting researchers nationwide studying ways to better detect prostate cancer and to determine which prostate cancers will be aggressive.

For example, a recent NCI-funded study found that screening with the prostate-specific antigen (PSA) blood test, while capable of detecting the presence of prostate cancer, was not effective in reducing mortality. There are some concerns that results from this trial were confounded when men who did not receive PSA screening as part of the trial checked their PSA values independently, but despite this concern, it appears that the impact of PSA on overall mortality is likely to be small. Notably, PSA alone does not differentiate which men have those aggressive forms of prostate cancer that are likely to lead to pain and suffering from cancer. Another challenge for screening is the poor specificity, or high rate of false negatives, of the current screening approaches (PSA testing and digital rectal exam). This means that important treatment decisions require confirmatory evidence from prostate tissue biopsies. However, traditional biopsy procedures do not always successfully identify and obtain sample malignant tissue, which may lead to significant under-diagnosis of potentially lethal cancers. Researchers are trying to address this problem by developing novel image-guided prostate biopsy approaches. NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB) is currently funding a study at Johns Hopkins University that is developing a novel MRI-compatible robot that will substantially decrease the "false negative" rate and increase the accuracy for standard prostate cancer biopsy procedures.

NCI is actively searching for other biomarkers -- substances that may be found in tumor tissue or released from a tumor into the blood or other body fluids such as urine -- that

will distinguish between cancerous and benign conditions, and between slow-growing cancers and fast-growing, potentially lethal cancers. The identification of such biomarkers is a high priority in order to provide safe and effective large population screening.

Nanotechnology is providing new opportunities for prostate cancer treatment. NCI's Alliance for Nanotechnology, a program that brings together science and technology and applies them to cancer research, has yielded exciting findings for prostate cancer. In late 2009, a team at Northwestern University used gold nanoparticle probes to recognize and detect PSA at very low levels - 300 times more sensitive than commercially available PSA tests. This new assay could be used to monitor PSA in post-surgery patients and pinpoint optimal timing to target further treatment. Other NCI research has shown how to target nanoparticles to detect and destroy prostate tumors, ensuring that only the cancer cells get the chemotherapy drug. This represents a great opportunity to maximize anti-tumor impact while minimizing toxicities associated with chemotherapy.

Imaging studies can also be important tools in helping to determine which prostate cancers are aggressive and which are slow growing, as well as in developing minimally invasive treatments. Specialized imaging can help monitor men who elect active surveillance, and improved imaging techniques may allow more accurate characterization of disease and more sophisticated methods of monitoring response to therapy. Better imaging capabilities would allow us to plan the most appropriate treatments for a specific patient, including focal, prostate-sparing therapies, and to gauge success or failure of a therapy more quickly. There are many different imaging tools available, but currently

there is no clear consensus within the field about the best ways to integrate imaging into clinical management. NCI is working toward bringing imaging experts together to standardize an approach to apply imaging measurements to clinical outcomes.

NCI research efforts in prostate cancer imaging are geared towards developing an accurate method for identifying prostate cancer and directing treatments to the tumor under image guidance, detecting recurrent disease, and monitoring tumor that has spread outside the prostate. Part of our research effort focuses on creating image-guided procedures that fuse magnetic resonance imaging (MRI) data with Ultrasound in order to guide interventions based on the imaging findings. Additional goals are to better understand the biology of low-grade prostate cancer and how to differentiate aggressive tumors using imaging. We are also investigating imaging agents that could monitor the effects of treatments for more advanced disease. Ultimately, we seek to develop targeted therapies for prostate cancer that will be more effective for the specific individual's prostate tumor with fewer side effects. Progress in prostate cancer imaging is already beginning to translate into better treatment selection and accurate imaging-guided therapies, including focal ablation and customized surgery and radiation. It his hoped that these advances in imaging will improve detection, treatment, and clinical outcomes for prostate cancer.

NCI broadly supports the development of new technologies that will help us not only diagnose prostate cancer earlier, but also determine more specific information about the characteristics of individual tumors to enable more effective treatments. In addition to cancer imaging methods and nanotechnology, NCI is also studying genetic factors at play

in prostate cancer as well as proteomics, which is the study of the structure and function of proteins, to develop methods to identify cancers at an earlier stage.

Genomics and proteomics are playing an important role in NCI's research efforts for all cancers. Data from the pilot phase of The Cancer Genome Atlas (TCGA), a genomic sequencing and analysis program being conducted jointly with NIH's National Human Genome Research Institute, has generated remarkable insights into glioblastoma and ovarian cancer. The data suggest that initiating a whole genome sequencing project for prostate cancer would likely provide us with the genomic information necessary to discriminate between low risk and high risk prostate cancer. NIH has just expanded TCGA to include prostate cancer in the 20 new cancers to be studied in the next phase of TCGA. This should yield a wealth of important data on the genomics of prostate cancer.

It is clear that prostate cancer is a complex and diverse entity, and combining the knowledge of genomic, proteomic, imaging and clinical behavior into the evolving field of "systems biology" will lead to a better understanding of the origins of prostate cancer and its cure. The NCI Clinical Center team is studying new therapeutic approaches to prostate cancer through various clinical trials. An NCI-developed prostate cancer vaccine has shown significant benefit in a Phase II study at the NIH and will be moving into larger clinical trials soon. NCI has also participated in the research and development of a prostate cancer vaccine called Provenge that is currently undergoing FDA review for approval.

NCI funds investigators across the country to develop and test new therapeutic research strategies for prostate cancer. As part of an NCI-wide program aimed at identifying new opportunities in prostate cancer research, the NCI has expanded the prostate cancer Specialized Program of Research Excellence (SPORE) program from 2 funded prostate SPOREs in 1992 to 10 SPOREs in 2009 with a total budget of over $19 million. This program has developed new scientific approaches in early detection, diagnosis, treatment, and prognosis of human prostate cancer. The SPOREs in prostate cancer have evolved into a collaborative network, with experts across the country conducting their inter-SPORE scientific studies for the clinical evaluation of biomarkers, early phase clinical trials of anti-prostate cancer agents, and the development of inter-institutional systems to accelerate prostate cancer research.

In addition to the SPOREs, NCI's extramural research portfolio includes the 65 NCI-designated Cancer Centers, centers that are characterized by scientific excellence and the capability to integrate a diversity of research approaches to focus on the problem of cancer. They play a vital role in advancing towards our goal of reducing morbidity and mortality from all cancers.

The NCI has also heavily invested in its Clinical Trials Cooperative Groups and Community Clinical Oncology Program (CCOP). Both of these programs conduct clinical trials designed to study new cancer treatments, explore methods of cancer prevention and early detection, and study quality-of-life issues and rehabilitation during and after treatment. NCI's Cooperative Groups provide access to prostate cancer clinical trials in every state though an extensive network of cooperative groups and community based study sites. The CCOP program brings clinical trial expertise to the community

level and ensures broad access to clinical trials across populations and geographic areas. The program supports groups of community hospitals and physicians funded by a peer-reviewed cooperative agreement to participate in NCI-sponsored cancer treatment, prevention, and control clinical trials. A subgroup of the CCOPs, the Minority-Based-CCOPs (MB-CCOPs), were established to connect academic centers with community physicians in underserved and minority communities. Forty percent of new cancer patients in Minority-Based CCOPs are from minority populations. This is particularly important in studying diseases such as prostate cancer that has a higher incidence and mortality in African-American men as compared to other racial groups.

Through these innovative programs, NCI is providing access to state-of-the-art approaches to early detection and treatment of prostate and other cancers to people in the communities in which they live.

In light of the fact that prostate cancer occurs and causes death more frequently in African-American men than other racial groups, health disparities is a particularly important area of prostate research. We have learned that complex and interrelated factors contribute to the observed disparities in cancer incidence and death among racial, ethnic, and underserved groups. The most obvious factors are associated with a lack of health care coverage and low socioeconomic status (SES). SES factors, such as a person's income, education level, occupation, access to health insurance, and living conditions, are associated with the risk of developing and surviving cancer. Behavioral risk factors, such as tobacco use, obesity, and excessive alcohol intake, are influenced by SES, and people with low SES are also less likely to follow cancer screening recommendations. Research also shows that individuals from medically underserved

populations are more likely to be diagnosed with late-stage diseases that might have been treated more effectively or cured if diagnosed earlier.

The higher incidence of prostate cancer in African American/Black men compared with men from other racial/ethnic groups prompted the hypothesis that genetic factors might account, in part, for the observed differences. Recent findings from NCI's Cancer Genetic Markers of Susceptibility (CGEMS) program (http://cgems.cancer.gov) and other investigations support this hypothesis. Researchers have identified changes—called variants—in human DNA that are associated with the risk of developing prostate cancer. Different combinations of these variants have been found in men from different racial/ethnic backgrounds, and each combination is associated with higher or lower risk for prostate cancer. Nearly all of the variants associated with an increased risk of developing prostate cancer were found most often in African American/Black men, and certain combinations of these variants were associated with a five-fold increased risk of prostate cancer in men of this racial/ethnic group.

NCI's Center to Reduce Cancer Health Disparities (CRCHD), headed by Dr. Sanya Springfield, is central to the NCI's efforts to reduce the unequal burden of cancer in our society and to train the next generation of competitive researchers in cancer and cancer health disparities research. CRCHD initiates, integrates, and engages in collaborative research studies with other NCI divisions and with other NIH Institutes and Centers to promote research and training in cancer health disparities research and to identify new and innovative scientific opportunities to improve cancer outcomes in communities experiencing an excess burden of cancer.

An important component of CRCHD's efforts to address this challenge is through the Continuing Umbrella of Research Experiences (CURE), which is a comprehensive training and career development program that seeks to increase the number of competitive cancer researchers who are currently conducting research in cancer health disparities. Since the inception of CURE in 1997, approximately 16% of the pre-doctoral trainees and 10% of the junior investigators that were supported have conducted research in the area of prostate cancer.

CRCHD supports a broad portfolio of prostate cancer research that includes a study of a preventive vaccine for prostate cancer that stimulates the immune system to attack tumor cells. This is an important research area because an effective prostate cancer vaccine would protect against disease and decrease doctor visits and the need for extensive follow up, factors that are important for the African American community that has less access to care and lower utilization of health care resources overall. CRCHD is also examining ways to increase education and awareness about prostate cancer in the African American and Hispanic communities through new types of media and community programs. For example, funded programs include a Spanish language radio talk show about prostate cancer, training for African American barbers to educate clients about prostate cancer, and the use of church settings to provide screening and prevention information to specific communities.

NIH continues to partner with academic researchers, community-based physicians, and the advocacy community to advance prostate cancer research. In April of this year, NCI will hold the first collaborative meeting with the Prostate Cancer Foundation to gather the nation's leading investigators in the treatment sciences of metastatic prostate cancer. This

group will explore and define cutting-edge approaches to the scientific treatment of advanced prostate cancer patients. We expect to reconvene this group on a yearly basis to exchange data and explore new frontiers in prostate cancer research.

We are optimistic that through the application of new technologies and innovative approaches to detecting, assessing, and treating prostate cancer, we will be able to better understand of this disease and thus, more effectively identify and treat the aggressive forms of this disease, thereby reducing death and suffering from prostate cancer.

Thank you for the opportunity to testify.

Chairman TOWNS. Thank you very much, Dr. Dahut.
Dr. Brawley.

STATEMENT OF OTIS W. BRAWLEY, M.D.

Dr. BRAWLEY. Thank you, Mr. Chairman. Good afternoon. Mr. Chairman and distinguished members, I am Otis Brawley, a practicing oncologist. I am the chief medical officer of the American Cancer Society, and I am also a professor of hematology, oncology medicine and epidemiology at Emory University. On behalf of the American Cancer Society and the millions of cancer patients and survivors, thank you for holding this hearing and for your continued leadership in the fight against cancer.

As you know, the Society, yesterday, released updated guidelines on prostate cancer screening. We customarily undertake such reviews when new evidence or other information emerges. In the case of prostate cancer screening, results from two randomized trials of screening were reported in early 2009. The finding of these studies, combined with other advances in knowledge related to prostate cancer screening prompted this review.

The review recommended no major changes in our position with respect to prostate cancer screening. The Society continues to recommend asymptomatic men who have at least a 10-year life expectancy should discuss with their doctor the uncertainties, the possible benefits, and the known risks of screening for prostate cancer before deciding whether to be tested. There are uncertainties, there are known proven risks, and there are, at this time, possible benefits. We also provide additional guidance about testing for African-American men and those at high risk.

The bottom line is men need to have the substantive discussion with their doctors in order to make meaningful decisions about which preventive services and early detection tests are the best choice for them.

Other organizations in the United States, Canada, Europe, and Australia that issue prostate cancer screening guidelines, have also issued statements calling for this informed shared decisionmaking, realizing that prostate cancer screening has not yet proven to save lives.

I want to make sure my testimony is very clear about the Society's position on prostate cancer screening, as it has sometimes been misunderstood or mischaracterized. The Society is not against testing for early prostate cancer detection if a man has been given the true facts about what we know and what we don't know about the uncertainties of prostate cancer screening; what we do know about the proven harms and the possible benefits of screening. The Society, along with many other health and medical organizations, as well, are against screening when the doctor-patient conversation to describe the benefits and harms does not take place in a meaningful way. We are only against prostate cancer screening when there is no informed decisionmaking.

As an oncologist, I have counseled and treated hundreds of prostate cancer patients in my career. I have observed firsthand the traumatic impact this disease has on men and their families. I firmly understand the emotion involved when someone says their life has been saved by a PSA test. But in every instance we need

to better explain the limitations of the test and make sure we don't overstate the benefits.

There is legitimate argument based on the scientific evidence as to whether prostate cancer screening saves lives. Clear evidence has emerged from several trials indicating that prostate cancer screening leads to unnecessary treatment. For example, many men who do not have prostate cancer will screen positive and require an unnecessary biopsy for diagnosis. In addition, even if this biopsy finds cancer, many prostate cancers grow so slowly that they may not actually pose a threat to the patient's life or his continued quality of life. This is an important point because treatment of prostate cancer is associated with symptoms and side effects that can interfere significantly with quality of life, such as impotence and incontinence. The key problem is that we don't have, and we have yet to discover, definitive tests that tell us the cancers that kill and require treatment versus the cancers that don't kill and need to be watched.

One can reasonably ask how did we get into this quandary of not knowing whether prostate cancer screening saves lives? Truth is the promotion of the PSA test has delayed our medical progress, because we have come to rely on what is really an imperfect test instead of doing the clinical trials to evaluate PSA and actually defining the scientific questions and actually going out to answer those scientific questions. The plain fact is the PSA test is not good enough. We need to invest in developing something that is better. We also need to invest in a way to determine the deadly tumors versus the tumors which are not threatening life.

In closing, increased funding for NIH and the National Cancer Institute would do much to enhance current discovery efforts and also enable us to design better tests and better treatments for prostate cancer. Thank you, sir.

[The prepared statement of Dr. Brawley follows:]

Statement by
Otis W. Brawley, MD
Chief Medical Officer
American Cancer Society

Before

House Committee on Oversight and Government Reform
United States House of Representatives

Thursday, March 4th, 2010, 10:00 a.m.
2154 Rayburn House Office Building

Good morning, Mr. Chairman, Mr. Ranking Member, and distinguished members of the Committee. Thank you for the opportunity to testify today about prostate cancer. I am Dr. Otis Brawley, Chief Medical Officer of the American Cancer Society (the Society). On behalf of the Society and millions of cancer patients and survivors in America today, thank you for holding this hearing and for your continued leadership in the fight against cancer.

Introduction

Among US men, prostate cancer is the most commonly diagnosed cancer and the second-leading cancer killer. This year alone, over 192,000 men will be diagnosed with prostate cancer and approximately 27,000 men will die from the disease.[1]

Like many other forms of cancer, prostate cancer disproportionately affects the medically underserved and certain racial minorities. African Americans have one of the highest rates of prostate cancer in the world. African American men are also much more likely to be diagnosed with more advanced stage disease and are more likely to die of the disease.

[1] American Cancer Society. Cancer Facts and Figures 2009.

Despite the significant health burden we know that prostate cancer poses, many uncertainties remain about this disease. In my testimony, I will address briefly the Society's screening guidelines for prostate cancer and key aspects of the scientific basis behind them. I will also explain the Society's views and priorities for tackling the disease – namely, the need to (1) increase research investment to develop more effective prevention, screening, diagnostic, and treatment tools; and (2) address disparities in prostate cancer health outcomes, by improving access to quality care and bridging the gap between what is known about quality care and what is practiced.

American Cancer Society Guidelines on Prostate Cancer

The Society released updated guidelines on prostate cancer screening just this week. We customarily undertake such reviews of our existing guidelines when new evidence or other information emerges indicating that updates or changes to our recommendations may be necessary. The accumulation of new knowledge relevant to prostate cancer screening, as well as the publication of results from two randomized controlled trials of screening reported in early 2009, triggered the recent review of the Society's prostate recommendations.

A group of experts in medicine, outcomes and epidemiology as well as some patients reviewed these data and recommended that the Society clarify and include additional information in its updated prostate guidelines. There are no major changes in our position on prostate cancer screening.

The Society recommends that asymptomatic men who have at least a ten-year life expectancy have an opportunity to make an informed decision with their health care provider about whether or not to be screened for prostate cancer, after receiving information about the uncertainties, known risks, and potential benefits associated with prostate cancer screening. This decision process should begin at age 50 for white men, and age 45 for black men. We also provide guidance about testing for men with a family history.

Men at higher risk because a first degree relative (father or brother) was diagnosed with prostate cancer before age 65 should receive this information beginning at age 45. Men at appreciably

higher risk (multiple family members diagnosed with prostate cancer before age 65) should receive this information beginning at age 40. Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources.

Our guidelines make clear that significant uncertainties still exist about the effectiveness of prostate cancer screening and it should not occur without an informed decision making process.

Men need access to credible, understandable health information that allows them to make meaningful decisions with their healthcare professionals about which preventive services and early detection tests are the best choice for them. Unfortunately, recent data show that the sort of informed and shared decision making that the Society and other organizations recommend is not taking place. There are several reasons for this:

1. Many doctors are not fully versed on the scientific evidence and therefore do not have all the information they need to initiate a discussion about screening risks and benefits with their patients.

2. Done right, these types of discussions are not brief. But our current delivery model for health care in the primary care setting allows very little time and provides few incentives for conducting meaningful conversations about the broad range of recommended preventive health services.

3. Men often are not getting complete information regarding the benefits and harms of prostate cancer screening when they talk to their doctor. The data show that when these discussions do take place, they often over-emphasize the benefits and under-emphasize the harms.

I want to make sure my testimony is very clear about the Society's position on prostate screening, as it has sometimes been misunderstood or mischaracterized: The Society is not against testing for early prostate cancer detection if a man has been given the facts about what we know and don't know about the uncertainties, harms, and potential benefits of screening. We and many other health and medical organizations are against screening when that conversation between patient and physician about risks and benefits has not taken place in a meaningful way.

Men who are concerned about prostate cancer can very reasonably choose to get screened and those who are less worried may reasonably choose not to.

As an oncologist, I have counseled and treated hundreds of prostate cancer patients in my career. I have observed firsthand the heartbreak this disease has on men and their families. I understand the emotion involved when someone says they were saved by a PSA test. But in every instance, we need to strive to better explain the limitations of the test and of our knowledge about prostate cancer. Many men with an elevated PSA will not have prostate cancer. Many men with prostate cancer will have a normal PSA. Among men with prostate cancer, most prostate cancers grow so slowly that they are not a threat to the patient's life.

One of the greatest problems is that we do not yet have a test that distinguishes the kind of disease that needs treatment from the kind of disease that will never kill, but needs to be watched. This is a particularly important point, because treatment for prostate cancer is associated with severe side effects that can interfere significantly with quality of life. Simply put, prostate cancer screening requires a greater research investment to expand and enhance our early detection and diagnostic arsenal. The PSA test is not good enough. Given the burden of prostate cancer, men in our country deserve better tools to detect the disease, determine if it is the kind that is deadly and needs treatment, and treat it effectively while preserving the man's quality of life.

One can reasonably ask, how did we get into this quandary of not knowing whether screening saves lives? Ironically, the promotion of prostate cancer screening has delayed our ability to address the uncertainties and slowed our medical progress because men have relied on the PSA test instead of enrolling in clinical studies that could improve existing tools. We began promoting and using this test before it had been adequately evaluated. We need to make up for time lost by investing in this research now and ensuring promising findings are properly evaluated.

Increase the Investment in Prostate Cancer Research

Researchers are making notable progress in every area of prostate cancer prevention, early detection, treatment and care, with innovative prostate cancer studies are programs like:

- NCI's prostate Specialized Programs of Research Excellence (SPOREs), which is important for finding new screening tests, diagnostics and treatments.
- The NCI Clinical Trials Program has provided tremendous insight into the treatment of this disease at all stages. For example, the clinical trials group recently showed that docetaxel can prolong survival in metastatic disease. The groups have tried several times over the past three decades to compare the effectiveness of radiation therapy to radical prostatectomy in low stage disease without success due to a lack of patients volunteering.
- The more than 18,000 person Prostate Cancer Prevention Trial demonstrated that finasteride treatment can decrease risk of prostate cancer by 25%. It is also the only study to adequately evaluate how good our current screening tests are at finding prostate cancer. It found that seven years of annual screening of the several thousand men on the placebo arm missed as many cancers as are found.
- The Selenium and Vitamin E Cancer Prevention Trial (SELECT), a 24,000 person NCI sponsored trial, showed that neither selenium nor vitamin E prevented cancer and prolonged high doses of these drugs were associated with harms. These findings make clear the importance of making recommendations based on evidence that remain faithful to and guided by the scientific method.

Despite these advances, scientists have not yet discovered strategies to:

- Completely prevent prostate cancer;
- Develop a good screening test for prostate cancer;

- Reliably distinguish between aggressive life threatening and non-aggressive non life threatening disease;
- Halt its deadly progression in more aggressive forms of the disease;
- Identify the precise reasons behind the drastic differences in incidence and mortality between men of African heritage in the western hemisphere.

Increased research funding for NIH and the National Cancer Institute (NCI), with increased emphasis on addressing these challenges, would do much to enhance current discovery efforts and also enable design and implementation of the next generation of collaborative studies to make further advances against prostate cancer.

Decreasing Disparities and Improving Quality of Care for Prostate Cancer Patients

High prostate cancer mortality in minority populations, especially Black men, has long been documented. African American men have one of the highest incidence rates of prostate cancer in the world – they get the disease about 60 percent more often than white American men. And they are twice as likely as white men to die from it. We still cannot answer the question why African American men are so disproportionately burdened by prostate cancer. Limited research has identified some biological reasons for the differences, but for the most part, these findings are inconclusive.

Studies in the U.S. Department of Defense have been especially helpful in suggesting that inherent biology is not the major factor in the disparity. These studies have suggested that racial differences in body mass index, energy balance, and diet are contributing causes to the disparity. Today many experts believe that differences in diet, education and income as well as access to health insurance and medical care are more important than inherent biological explanations for the higher death rates among African-Americans. It's been documented, for example, that African-American men are less likely to receive aggressive treatment for clearly life threatening disease compared to white men with similar disease. Differential treatment patterns by race/ethnicity may result from socioeconomic status, the health systems in which men are

treated, and physician and patient factors, including communication and variations in understanding about treatment options.

Several studies have also found higher levels of medical mistrust among African American men with prostate cancer, particularly among those who delayed seeking care after experiencing symptoms of the disease. Disparities in receipt of curative treatment among African Americans and Hispanic patients may contribute to disparate mortality rates. Several studies suggest that equal treatment yields equal outcomes among equal patients. But there is not equal treatment. To make real gains in addressing health disparities, we need a significant investment in both research and effective policies and strategies that ensure quality cancer care for all Americans.

Improving Access to Care

Cancer in general remains one of the most costly medical conditions in the United States. A 2006 national survey of cancer patients and their families conducted by the Kaiser Family Foundation found that one in five cancer patients with insurance used all or most of their savings when dealing with the financial cost of cancer.[2] The situation is even worse among the uninsured. The same survey found that nearly half of uninsured cancer patients used all or most of their savings as a result of their cancer.[4]

We also know that lack of health insurance can be deadly. A recent study by the Society found that uninsured cancer patients are more likely to be diagnosed at a later stage of diagnosis and have a lower survival rate than patients who are privately insured.[3] The study revealed consistent associations between insurance status and stage at diagnosis across multiple cancer sites. Far too many cancer patients are being diagnosed too late, when treatment is more difficult, more expensive, and less likely to save lives.

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[2] *USA Today*, the Kaiser Family Foundation, the Harvard School of Public Health. National survey of households affected by cancer, August 1 – September 14, 2006.

[3] Halpern MT, Ward EM, Pavluck AL, Schrag NM, Bian J, Chen AY. Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: a retrospective analysis. Lancet Oncol. 2008;9(3):222-31

No one should have to choose between saving their life and their life savings. But the current health care system puts many Americans in that terrible predicament. That is why the Society and ACS CAN have undertaken a broad, joint initiative to promote access to the full continuum of evidence-based, quality health care necessary to optimize health and well-being for all Americans. Looking through the cancer lens, the Society and ACS CAN are advocating for health system reforms that promote prevention and wellness and ensure quality of life throughout disease-directed treatment and continuing into survivorship and for the rest of life. We believe that a health system that works well for cancer patients and survivors and those at risk for cancer will also work well for all Americans who may one day be faced with a serious medical condition.

Continued progress in the fight against cancer requires timely access to medical care that gives all cancer patients an equal opportunity to battle this disease. To help accomplish this, health care reform must happen now. The cost of waiting to take action, both financially and in suffering and lives lost every year, is just too high.

Conclusion

As someone who has dedicated a large part of my career addressing issues related to prostate cancer, I want to thank you and your Committee for your dedication to the goal of eradicating this disease. On behalf of the American Cancer Society, I am honored to be part of this very important hearing, and look forward to working with you to change the course of cancer.

Thank you and I welcome any questions.

Chairman TOWNS. Thank you very much, Dr. Brawley.
Dr. Best.

STATEMENT OF CAROLYN J.M. BEST, PH.D.

Ms. BEST. Chairman Towns and distinguished members of the committee, thank you for this opportunity to convey the important efforts being supported by Congress through the Department of Defense Prostate Cancer Research Program [PCRP]. My name is Dr. Carolyn Best, and I am currently program manager for the PCRP, which has received over $1 billion in funding since the beginning of the program in fiscal year 1997. Here with me today is Captain Melissa Kaime, my supervisor and the Director of the Congressionally Directed Medical Research Programs, under which the PCRP is 1 of the largest of 19 programs.

The PCRP is the second largest nationwide funder of prostate cancer research after the NIH. The program's vision is nothing less than to conquer prostate cancer, which translates into our mission to fund research that will eliminate all death and suffering from this disease. We fund highly innovative science to stimulate major advancements in research and clinical care. All PCRP funds are openly competed; we contract with hundreds of leading prostate cancer scientists, clinicians, and survivors to select research proposals that are both of the highest scientific merit and that best fit the objectives of the program.

With the $1 billion in funding this program has received during its existence, it has provided nearly 2,200 grants to support prostate cancer research in almost every State and the District of Columbia. Our grantees are studying better approaches for prostate cancer prevention, screening, imaging, diagnosis, treatments, and treatment decisionmaking; identifying aggressive disease and discovering the underlying environmental and genetic factors that contribute to prostate cancer.

Our grantees are also striving to answer the most critical questions in prostate cancer research and clinical care, which several of the witnesses have brought up today. Does prostate cancer screening lead to more harm than good? And, if true, how can this be corrected? Which men with prostate cancer need to be treated and which do not? How can we develop more effective treatments for preventing or curing the advanced forms of the disease that are responsible for prostate cancer death?

So to briefly highlight just two of our grants, since fiscal year 2005, the PCRP, together with the Prostate Cancer Foundation, has supported the Prostate Cancer Clinical Trials Consortium, which has brought together 13 major cancer centers across the Nation to conduct faster, more precise, and more cost-effective clinical testing of new treatments. In under 4 years, the Consortium has conducted more than 60 early phase studies investigating over 30 different drugs, and has moved five potential therapies into the final phases of testing before the new drugs can be approved.

Another key research effort is the Prostate Cancer Project [PCaP]. PCaP is a major collaboration, among institutions in Louisiana, North Carolina, and New York, that seeks to identify the factors that contribute to the highly disproportionate impact of prostate cancer on African-American men, as others have noted,

who are more than twice as likely to suffer and die from prostate cancer than Caucasian men. Over 2,000 men have participated in this landmark study, which may finally help us understand and address the factors that cause health disparity.

The effectiveness of the PCRP relies on a strong partnership between the U.S. Government and prostate cancer survivors, scientists, and clinicians. These groups work closely together to determine the program priorities, adapting them every year to ensure that we are continually addressing the most important needs. For example, for fiscal year 2010, the program is focused on two major challenges: first, to develop effective treatments for advanced prostate cancer so that fewer men will be lost from their families and society due to this disease; and, second, to distinguish lethal from non-lethal disease so that a great deal fewer men diagnosed with prostate cancer will undergo treatment that is actually unnecessary, yet causes them intense personal suffering and has an immense financial impact on our health care system.

To conclude, the PCRP provides direct and undiluted support for prostate cancer research, funding innovative, gap-filling projects and researchers that might not otherwise be supported in the battle against this disease.

So I thank you once again for your interest in hearing about this program and Captain Kaime and I look forward to any questions.

[The prepared statement of Ms. Best follows:]

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FINAL

STATEMENT BY

CAROLYN J.M. BEST, PhD
PROGRAM MANAGER OF THE PROSTATE CANCER RESEARCH PROGRAM
OF THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS OF
THE UNITED STATES ARMY MEDICAL AND MATERIEL COMMAND

ACCOMPANIED BY
CAPTAIN E. MELISSA KAIME, MD
DIRECTOR OF THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH
PROGRAMS

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

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COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

Chairman Towns and distinguished members of the Committee on Oversight and Government Reform, thank you for providing this opportunity to convey the important efforts being supported by Congress through the Department of Defense Prostate Cancer Research Program. My name is Carolyn Best, and I am the Program Manager for the Prostate Cancer Research Program, also known as the PCRP, which has received over $1 billion in funding for prostate cancer research since the program's inception in Fiscal Year 1997 (FY97). I am a former prostate cancer researcher and have been managing the PCRP since 2007. Here with me today is Captain Melissa Kaime, my supervisor and the Director of the Congressionally Directed Medical Research Programs, or CDMRP, under which the PCRP is one of the largest of nineteen programs. Captain Kaime is a hematology and oncology physician and currently sees cancer patients at Bethesda Naval Hospital, in addition to her responsibilities directing our organization. CDMRP is a research funding organization under the auspices of the United States Army Medical Research and Materiel Command, with Major General James K. Gilman as our Commanding General.

The PCRP, which I am representing today, is the second-largest nation-wide funder of prostate cancer research, after the National Institutes of Health. The estimated funding for prostate cancer research in 2009 is approximately $72 million for the PCRP and $300 million for the National Institutes of Health (NIH) (exact funding will be known at the completion of award negotiations). One important distinction, however, is that PCRP funds are used exclusively for prostate cancer research, while the NIH funding supports research that includes prostate cancer but may not be exclusively focused on it. Another significant source of funding for prostate cancer research is the

philanthropically-supported Prostate Cancer Foundation, which distributed approximately $10 million in funding in 2009.

The vision of the PCRP is nothing less than to conquer prostate cancer; this translates into our mission to fund research that will eliminate all death and suffering from this disease. We seek to fund highly innovative science that will result in major advancements in prostate cancer prevention, detection, diagnosis, and treatment. All PCRP funds available for research are openly competed to identify the most scientifically meritorious projects with high potential for significant impact on the field of prostate cancer research and/or patient care. The PCRP does not itself conduct research. To select proposals for funding, we contract with hundreds of scientists, clinicians, and disease survivors each year to evaluate the merit of each proposal. Our Integration Panel, composed of 16 nationally and world renowned leaders in prostate cancer research and leaders of the prostate cancer survivor community, identifies and recommends for funding the most meritorious proposals that best fit the objectives of the program. The Integration Panel also recommends the award mechanisms that the program will use each year. These award mechanisms are designed to address specific needs in prostate cancer research while still motivating the scientific community to propose research questions that the program may not have specifically posed. For example, we have one award mechanism designed to bring exciting new drugs to clinical testing through academic avenues rather than solely through efforts by the pharmaceutical industry. Another mechanism is focused on bringing practicing prostate cancer physicians, who have a better understanding of patients and clinical needs, into

research so that fresh research ideas from the laboratory can be matched with the most critical patient needs.

Funding for the PCRP has ranged from $38 million in FY97 to $100 million in FY01. Since FY06, funding has remained at $80 million each year. With these appropriations, the PCRP funds approximately 200 competitive research awards, or grants, per year to prostate cancer researchers in almost every state and the District of Columbia. After the FY09 awards are negotiated, the program will have provided nearly 2,200 grants to support prostate cancer research directed at eliminating this disease. These grants were selected from over 10,000 research proposals received over our 14-year history.

PCRP grants support a wide range of research areas critical to achieving our vision. We have numerous investigators studying better approaches for prostate cancer screening and early detection, imaging, diagnosis, treatments and treatment decision-making, identifying aggressive disease, and discovering the underlying environmental and genetic factors that contribute to prostate cancer. This includes the causes of prostate cancer health disparity, which are the reasons why African American men suffer and die from prostate cancer at twice the rate of Caucasian men. There are many critical yet unanswered questions in prostate cancer research and clinical care: Which men with prostate cancer need to be treated and which do not? Does prostate cancer screening lead to more harm than good and, if true, how can this be corrected? How can we develop more effective treatments for preventing or curing the advanced forms of the disease that are responsible for prostate cancer death? Our grantees are

striving to answer these and other important questions, which will improve our understanding of the disease and advance our efforts to eliminate its consequences.

Each of the research grants we fund is subjected to an active management process through which the PCRP is kept apprised of all progress, outcomes, accomplishments, and publications that communicate the research results to the full scientific and clinical communities so that discoveries can be used to help patients as quickly as possible.

I would like to briefly highlight just two of our grants for you to illustrate the impact that Congress is having on conquering prostate cancer through the PCRP. Since FY05, the PCRP has supported the development of the Prostate Cancer Clinical Trials Consortium, which has brought together vast scientific and clinical expertise and unique institutional resources from 13 major cancer centers across the nation to work together to design and execute faster, more precise, and more cost-effective clinical testing of new treatments. In less than four years, the Consortium has conducted more than 60 early-phase studies investigating over 30 different drugs. Over 1,700 patients have been recruited to participate in these studies, and these efforts have recently moved five potential therapies into the final phases of clinical testing before use of the new drugs can be approved. The Clinical Trials Consortium is poised to make a major impact on the lives of prostate cancer patients by ensuring the selection of the most promising drug candidates and executing their testing in the fastest and most productive fashion possible. Importantly, the Consortium also represents key leveraging of federal and private funding, as the Prostate Cancer Foundation has also contributed significant funding of its own to this effort.

Another example of a key research effort is the Prostate Cancer Project, or PCaP, which the PCRP has funded since FY02. The PCaP seeks to delineate the factors that contribute to the high incidences and disproportionate rates of prostate cancer deaths in African American versus Caucasian men. The PCaP is a collaboration among three leading institutions in Louisiana, North Carolina, and New York and, despite losing ground due to hurricane Katrina in 2005, has this year completed accrual of over 2,000 men with newly diagnosed prostate cancer. This landmark study may finally help us understand and address the factors that cause health disparity, including 1) access to and interaction with the health care system, 2) diet and genetics, and 3) race-dependent prostate cancer characteristics. Several more of our awards and their research awards are described in our program booklet, which we have provided for your reference.

The effectiveness of the PCRP relies on the strong partnership it fosters between the U.S. government, disease survivors, and prostate cancer scientists and clinicians. Disease survivors, who have become experts in what it means to cope with this disease, serve alongside scientific and clinical prostate cancer experts. These individuals work together to determine the priorities of the program, adapting them every year to ensure that we are continually addressing the most important needs in prostate cancer research that will move us closer to eliminating death and suffering. For example, for FY10, the program will present to the research community two overarching challenges: 1) to develop effective treatments for advanced prostate cancer so that fewer men will be lost from their families and society due to this disease and 2) to distinguish lethal from non-lethal disease so that a great deal fewer men who are

diagnosed with prostate cancer will undergo treatment that is actually unnecessary, yet causes them intense personal suffering and has a tremendous financial impact on our health care system.

In conclusion, the DOD Prostate Cancer Research Program, with the support of Congress, provides direct and undiluted support for prostate cancer research, funds both innovative, gap-filling projects and also scientists that would not otherwise be supported in the battle against this disease. I thank you once again for your interest in hearing about this program, and its efforts towards conquering prostate cancer.

Chairman TOWNS. Thank you very much, Dr. Best.
Dr. Kaminsky.

STATEMENT OF DR. STEVEN G. KAMINSKY, PH.D.

Mr. KAMINSKY. Chairman Towns, thank you very much for the opportunity to address you. The Uniform Services University is your university, and I am here to talk about one of the programs that Congress actually set up at the University, the Center for Prostate Disease Research. It was the insight of Congress that actually put this program on the map within the military, and I think that the thing that is most important about what it put on the map is the fact that within the military health care system we have equal access to health care, and with this particular Center, which is set up in three different aspects—a clinical research center, a basic science research center, and a data base and tissue repository—the Center has actually made enormous inroads into understanding the disease in an equal access medical care system. The Center was the first to actually demonstrate that African-American males in this system actually needed to be screened earlier and more often with the testing that is available today.

The challenge for the Center is everything that Dr. Brawley talked about, and that is how do we really come up with better screening tools, and that is really what the Center is all about from the standpoint of trying to really look at the aggressive forms of the disease and how to actually get there quicker, faster, and better. Today we are working on new genetic tools to try to do that and actually have some products that are hopefully going to make transitions.

But one of the key pieces of this Center is actually its data base, which is following over 28,000 patients in a longitudinal study with over 102,000 tissue and blood samples, so that we can actually look at and analyze the disease across time.

So to keep us flowing, I am going to hold my comments there and hopefully questions at the end about this particular Center and about essentially Congress's wisdom in setting up a center like this at the University within the military treatment facility really allows us to do things that maybe some others can't because of the kind of health care system that the military has.

Again, thanks for the opportunity to talk.

[The prepared statement of Mr. Kaminsky follows:]

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STATEMENT BY

STEVEN G. KAMINSKY, PH.D.
VICE PRESIDENT OF RESEARCH
UNIFORMED SERVICES UNIVERSITY FOR THE HEALTH SCIENCES

COMMITTEE OF OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

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Chairman Towns and distinguished members of the Committee, thank you for the opportunity to discuss some of the programs at the Uniformed Services University of the Health Sciences (USUHS) and, in particular, the Center for Prostate Disease Research (CPDR). I am here representing Dr. Charles Rice, President of the University. Today I will outline three congressionally directed programs at USU, two well established programs and the newest center that Congress has established.

The Center for Prostate Disease Research was established to meet the demands for a better understanding of prostate disease in the military. The CPDR has three components: 1) a clinical research program; 2) a basic science research program; and 3) a tissue repository with an associated database. The Clinical Research Program is located Walter Reed Army Medical Center. It offers military beneficiaries the opportunity to participate in clinical trials for the prevention and treatment of prostate disease. As the committee is aware, prostate cancer is the most common non-skin cancer in America, affecting 1 in 6 men. In 2009, it has been estimated that more than 186,000 men were diagnosed with prostate cancer, and more than 28,000 men will die from this disease in the next year. Today approximately 2 million American men are currently living with prostate cancer.

The goal of CPDR's clinical research program is to combine prostate screening, data collection, clinical diagnosis, education and counseling, and prostate disease clinical trial research in an efficient, personal, patient oriented center. This unique approach to the diagnosis and treatment of prostate cancer and other prostate-related diseases has resulted in significant clinical breakthroughs in these areas. In concert with the basic science research program, the clinical research program's clinicians and researchers have achieved a number of scientific discoveries through extensive patient observation and data analysis.

The Basic Science Research Program of CPDR is a multi-disciplinary research endeavor and represents integration of collaborative efforts of basic science and clinical science researchers. Its mission is to discover and define prostate cancer specific gene alterations for improving diagnosis, prognosis and treatment. To date, this group of researchers has identified new tools for the diagnosis of prostate disease and possible genes for targeted therapy.

The third component of CPDR is the Biorepository and National Database. This component was set up to support translational studies at CPDR, and it complements the efforts of other investigators in the field, by providing human biologic specimens unique to prostate cancer with the mission to collect, process and bank well characterized prostate tissue and blood-related biological samples, and to provide these specimens, linked to clinical and pathological data, for translational prostate cancer research projects within and outside the CPDR. In addition, they are developing and providing cell-based experimental model systems to support translational research by complementing the tissue-based experimental systems derived from human prostate specimens.

Since its inception, the CPDR has published over 300 peer review articles, filed 24 patents, licensed 4 technologies from the existing patents, and trained 24 residents, 29 fellows, 40 medical students and a handful of doctoral students. They have discovered the most common prostate cancer gene alteration, improved our understanding of male hormone receptor defects in prostate cancer, and developed a cancer-associated gene panel to aid in the diagnosis and targeted therapy. It is important to note that the CPDR was the first to report a higher serum PSA in African American patients in the equal-access military healthcare system which led to the current recommendation of age and race-adjusted PSA screening.

A second program I would like to highlight for the committee is the USUHS **Center for the Study of Traumatic Stress.** The Center for the Study of Traumatic Stress (CSTS) is one of the university's first congressionally directed centers. Today it is a highly regarded center that addresses a wide scope of trauma exposure including the consequences of combat, terrorism, natural and human-made disasters, and public health threats. A unique aspect and contribution of the center is the bridging of military and disaster psychiatry and the integration of disaster mental health and public health. In applying the principles and practices for dealing with individuals and groups exposed to extreme environments (in the military), the CSTS has generated and disseminated its subject matter expertise to inform disaster preparedness, response and recovery principles and practices across a wide range of traumatic events and populations.

Today the center is uniquely positioned to respond to DoD mission relevant activities and issues, as well as to educate regional and national stakeholders in government, industry, healthcare, public health, and academia on mitigating the effects of disaster and trauma in the civilian community to foster human continuity and community and national resilience. The CSTS develops and carries out research programs to extend our knowledge of the medical and psychiatric consequences of war, deployment, trauma, disaster and terrorism, including weapons of mass destruction. In addition, CSTS educates and trains health care providers, leaders, individuals and public and private agencies on how to prevent, mitigate and respond to the negative consequences of war, deployment, traumatic events, disasters, and terrorism.

The center published a book entitled "Individual and Community Responses to Trauma and Disaster." This book and the CSTS's work on the effects of trauma on first responders helped shape the landscape of disaster and trauma research, education and consultation. In response to the events of 9/11, CSTS was instrumental in educating leadership at the federal, state and local level about individual and community responses to terrorism. The center expanded its research to encompass workplace preparedness for terrorism and disaster, and provided consultation to the U.S. Senate, the U.S. House of Representatives, the U.S. Department of State, the U.S. Department of Transportation, a number of Fortune 100 corporations, and numerous government leaders.

Recently the CSTS was awarded an NIH/Army sponsored grant to study suicide in the military. This is the largest study of suicide anywhere, in any population and it has the potential to include as many as 400,000 people. The research began in July 2009 and is a

direct response to the Army's request to NIMH to enlist the most promising scientific approaches for addressing the rising suicide rate among soldiers. During the next five years, the Army, NIMH and the four research institutions under CSTS guidance will examine mental health, psychological resilience, suicide risk, suicide-related behaviors, intervention strategies and suicide deaths in the Army. This consortium brings together interdisciplinary research teams that are internationally known for their expertise in research on military health, health and behavior surveys, epidemiology and suicide – including genetic and neurobiological factors involved in suicidal behavior.

This study will not only identify risk and protective factors, but how those factors fit together to cause a person to lose hope. The study's findings will be applicable across all services, as well as the civilian community. Researchers are currently gathering archival data sets from the Army from the past five years to be analyzed for risk and protective factors. The findings gathered during the study will help determine the nature of the Army's suicide prevention and intervention efforts and identify who is at risk very rapidly. As new data is collected and new programs are implemented, investigators will continue to update and refine their recommendations.

Finally the CSTS has a robust Child and Family Program that has expanded the Center's reach and expertise on the effects of trauma on families and children from war, natural disaster, terrorism and bioterrorism. This program generates and disseminates knowledge related to military childhood experiences, develops effective public education materials, and expands and studies effective intervention strategies to advance the health and mental health of military children and family. This CSTS program has led Department of Defense activities in the study of U.S. Army family violence and child maltreatment and child abuse in particular. The CSTS continues to be at the forefront of understanding the contribution of military community and family stress to theses measured changes in child maltreatment.

The last USUHS Center that we would like to highlight for the committee is the newest center that Congress has asked the University to establish. This is the **Center for Neuroscience and Regenerative Medicine**. The Center for Neuroscience and Regenerative Medicine (CNRM) was established to address the current needs of the medical community to better diagnose and intervene for the prevention of the long term consequences resulting from traumatic brain injury (TBI), particularly in the context experienced by service members in Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF). The Congressional language establishing the CNRM specifically stated to study combat casualties cared for at Walter Reed Army Medical Center and the National Naval Medical Center using neuroimaging technology at the National Institutes of Health Clinical Center. CNRM is working to ensure the development of a set of mutually reinforcing programs among collaborating DoD facilities and the National Institutes of Health focused on the diagnosis and treatment of uniformed personnel with traumatic brain injury.

TBI, especially as a consequence of blast explosions, has come to the forefront as a "signature injury" among the U.S. Armed Forces serving in OIF and OEF. Members of

the Armed Forces are increasingly experiencing neurologic impairments caused by primary, as well as repeated, blast exposure without a direct blow to the head or outward sign of significant injury. Further, the incidence of post traumatic stress disorder (PTSD) has become an important factor in the diagnosis and treatment of TBI in these service members where psychological trauma is occurring in tandem with TBI. Despite the advancements in body armor and battlefield medicine, soldiers continue to be critically wounded and face the possibility of TBI.

To respond to Congress the CNRM is bringing together the expertise of clinicians and scientists across disciplines to catalyze innovative approaches to TBI research with an emphasis on aspects of high relevance to the military populations. The CNRM has broadly involved and considered all avenues to improve TBI recovery and developed these approaches into six integrated Programs to interact as the CNRM. The CNRM seeks to capitalize on its unique opportunity to develop a set of mutually reinforcing programs among collaborating DoD facilities and the NIH to focus on the needs for diagnosis and treatment of soldiers.

In conclusion, we would like to thank the Committee and Congress for their support. The leadership at USUHS believes that these three examples of Congressionally directed programs illustrates how USUHS can be used to quickly address health care issues important to both military medicine and public health.

Chairman TOWNS. Thank you very much, Dr. Kaminsky.
Dr. Shtern.

STATEMENT OF FAINA SHTERN, M.D.

Dr. SHTERN. Chairman Towns, thank you for the opportunity to testify today and for your continued support of the AdMeTech Foundation's work. There are many members of this committee who are supporting our work.

As you know, there is no family, no community in this country that is not impacted by prostate cancer. When my father's prostate cancer was missed at the leading national hospital, a very powerful point was brought home. In spite of the magnitude of prostate cancer epidemic, men do not have accurate diagnostics for early detection, which is critical to cure cancer and to save lives. Indeed, as reflected in the new guidelines by the American Cancer Society, there is no confidence in the current diagnostic tools for screening and early detection. An American man dies every 19 minutes, even though prostate cancer can be cured when diagnosed early.

Mr. Dana Jennings, an editor for the New York Times, echoed sentiments of millions of people when he said prostate cancer and its treatment breed anger and confusion among the men who have it and those who love them. Mr. Jennings, age 49, was diagnosed with advanced and aggressive prostate cancer only recently. He underwent surgery, followed by radiation and hormonal treatment, with the latter being essentially, in plain speak, medical castration. According to a recent VA study, men aged 50 and younger have had a sevenfold increase in the incidence of prostate cancer since 1986, when PSA was invented. These stories—my father's story, Mr. Jennings' story—reflect our prostate cancer crisis.

Many other speakers pointed out the first aspect of the prostate cancer crisis, the sheer magnitude of the epidemic. Two million American men live with prostate cancer and many more millions face a threat of prostate cancer each year. African-American men, as was pointed out repeatedly, are disproportionately affected. Unfortunately, for all these millions of men, there is another aspect of prostate cancer crisis: current diagnostic tools are unreliable and, as has been pointed out, cause a staggering extent of unnecessary biopsy, unnecessary treatment, and failed patient care, which in turn reduce quality of life in millions of men, and at billions of dollars in health care cost. I have shared with the committee in my written testimony my estimate that there is over $5 billion each year wasted in health care costs.

AdMeTech Foundation's mission is to end our prostate cancer crisis by developing accurate imaging tools for early detection and minimally invasive treatment. I would like to issue a disclaimer. Imaging will not play a significant role in mass screening and prevention, but imaging will be critical for early detection and minimally invasive treatment, and here is why.

Slide No. 1, please.

[Slide shown.]

Dr. SHTERN. On the left of the slide you can see film-based digital mammography in 1991, when I was head of diagnostic imaging at the National Cancer Institute. At that time, with small field of view digital mammography, we were lucky to see a larger breast

cancer. On the right you can see digital mammography full field done today. There is a striking difference in the quality. It renders entire breast cancer tissue transparent and we can see a tiny breast cancer. Precise imaging has made it possible to guide needle biopsies to detect breast cancer very early and to save lives and, just as importantly, to replace radical and deforming surgery with image-guided minimally invasive lumpectomies.

While prostate cancer is even more common than breast cancer, national screening lags far behind and men do not have accurate imaging akin to life-saving mammograms. With congressional support and Federal investment, we can create similar opportunities for men.

Slide No. 2, please.

[Slide shown.]

Dr. SHTERN. On the left you see data from Memorial Sloan Kettering in New York. It shows advanced prostate cancer missed this early imaginable current diagnostic, including blind biopsy. There are reports from all over the world that show that MRI-guided biopsy can detect at least 59 to 60 percent of prostate cancer that was missed by blind biopsies at least twice. There are growing reports, I am happy to report, that imaging technologies, molecular imaging, MRI, can determine what is aggressive and what needs to be treated, and what is not aggressive, non-lethal that cannot be treated. This report creates great hope for the future of prostate cancer care, and yet they are extremely preliminary. Further extensive research is needed.

On the right hand side you see a three-dimensional MRI that shows small and early prostate cancer rendered in red. When we have this kind of three-dimensional data, we can administer image-guided minimally invasive treatment to eradicate cancer, while sparing normal tissue to avoid complications. This procedure can be performed in outpatient screening with minimal costs, complications, and discomfort to patients.

And that is how we will end prostate cancer crisis, with advanced imaging. What we need to succeed is a Manhattan Project for prostate cancer diagnostics, if you will, in order to save lives, improve quality of life in millions of men, and save billions of dollars.

I just was told that Representative Cummings, a member of this committee, just introduced "the PRIME Act," H.R. 4756, that calls for a national investment of $500 million over 5 years in medical imaging. It is only 10 percent of the annual waste in health care costs. This act also calls for an increased $100 million for improved in vitro diagnostics over 5 years. It is only 2 percent of annual waste. The success of the PRIME Act at the end of the 5-years we will have accurate imaging technologies for improved early detection and treatment and reliable in vitro testing for improved mass screening and prevention.

I hope that this committee will empower and support NIH and DOD in making research in prostate cancer diagnostics, including imaging, a much higher priority than it has been. Passage of the PRIME Act, introduced by Congressman Cummings and Senator Boxer earlier in 2009, will be an important step in that direction.

Thank you for your leadership.

[The prepared statement of Dr. Shtern follows:]

STATEMENT OF DR. FAINA SHTERN
CHIEF EXECUTIVE OFFICER AND PRESIDENT
ADMETECH FOUNDATION

HEARING ON "PROSTATE CANCER: NEW QUESTIONS ABOUT SCREENING AND TREATMENT"

HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
MARCH 4, 2010

Chairman Towns, Ranking Minority Member Issa, and Members of the Committee, thank you for the opportunity to participate in this historic hearing dedicated to prostate cancer. I am particularly grateful to recognize so many supporters of AdMeTech Foundation's work on this Committee, including not only the Chairman and Ranking Member, but also Representatives Cummings, Burton, Watson, and Norton, among others.

This hearing is directly related to the mission of the AdMeTech Foundation to end prostate cancer crisis. To accomplish this mission, AdMeTech provides leadership in the establishment and successful implementation of ground-breaking programs in research and education in order to facilitate development of accurate diagnostic tools for early detection and minimally-invasive treatment of prostate cancer. (See Figure 1,2)

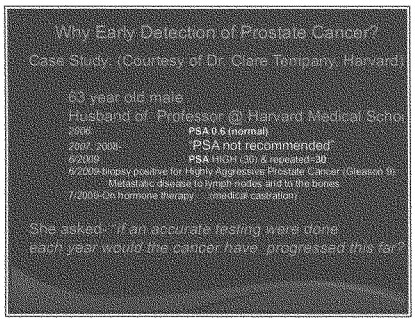


Figure 1

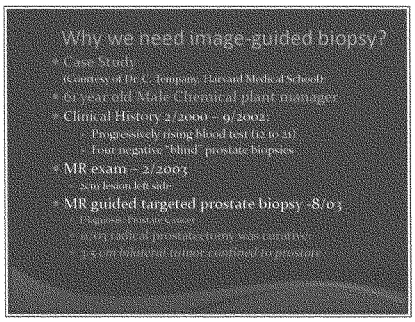


Figure 2

AdMeTech's primary focus is to develop advanced imaging technologies to guide early detection, biopsy and treatment. I would like to start with a disclaimer. Imaging technologies will not play significant role in mass screening or prevention of prostate cancer; this would be accomplished through investment in research to advance in vitro diagnostics, such as blood or urinary testing for specific biomarkers. However, advanced imaging will improve early detection and end blind biopsies and blind treatment, which currently cause prostate cancer crisis.

Four reasons why we believe this country faces prostate cancer crisis:
1) The magnitude of prostate cancer epidemic;
2) Blind diagnosis and treatment:
3) Patient Care Crisis; and
4) Socio-economic problem.

PROSTATE CANCER CRISIS: KEY STATISTICS

PROSTATE CANCER EPIDEMIC

Prostate cancer is the most common cancer in the United States and the second most lethal cancer in men. There is no family in this country that has not been touched by this disease, including my own:

- Prostate cancer crisis strikes 1 in 6 men. It is particularly common and lethal among African American men, who are 60% more likely to be stricken and more than 2.5 times more likely to die.
- Two million American men are currently living with prostate cancer.
- Since 1986, per recent study of the researchers from Department of Veterans' Affairs, incidence of prostate cancer had risen dramatically in younger men[1], including:
  - Seven fold increase in men aged 50 and younger;
  - Three fold increase in men aged 50 to 59.
  - Two fold increase in men aged 60 to 69
- A man is diagnosed with prostate cancer every 2.5 minutes.
- A man dies every 19 minutes, even though prostate cancer can be cured when detected early.
- Since 1996, scientific studies demonstrated high prevalence of latent prostate cancer among younger men who died of unrelated causes, including about 35% in men in their 30s, about 40% in men in their 40s and 50s, over 60% in men in their 60s and 80% in men in their 70s and older **(Figure 3)**.

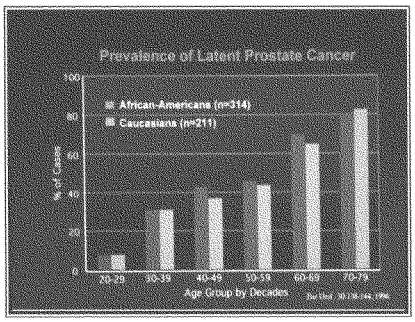


Figure 3

PROSTATE CANCER IS UNRECOGNIZED AS A NATIONAL PRIORITY: CURRENT DIAGNOSTIC TOOLS ARE UNRELIABLE

The magnitude of the prostate cancer epidemic brings into a sharp focus that today, men do not have accurate diagnostic tools for screening, early detection and treatment.

While prostate cancer is more common than breast cancer, which strikes 1 in 8 women, national investment is lagging behind, and men do not have life-saving tools, such as mammography **(Figures 4,5,6 below)**.

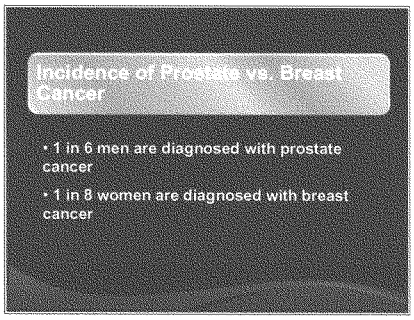


Figure 4

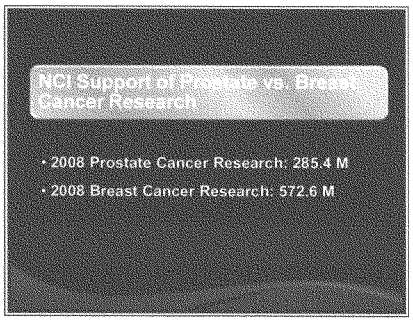


Figure 5

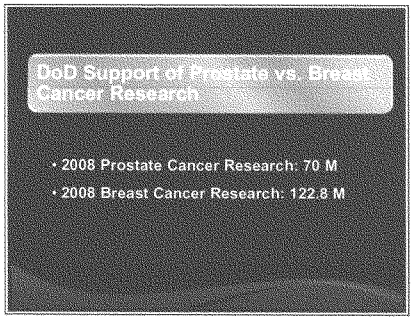


Figure 6

Indeed, emerging scientific evidence has shown uncertain benefits of PSA and digital rectal exam (DRE), in saving lives, and clearly demonstrated their harm due to overdiagnosis, causing unnecessary biopsies and treatment and related complications: [2,3]

- PSA causes false reassurances and false alarms:[3]
  - When PSA is normal, 15% of men still have cancer.
  - When PSA is abnormal, only 12% of men have prostate cancer and 88% of men undergo unnecessary biopsies.
- Biopsies are blind and random:
  - Miss at least 20% of cancer;[4]
  - Underestimate the spread, or stage of cancer in at least 20-30% of men;[4]
  - In many men, current diagnostics are insufficient to distinguish aggressive prostate cancer, which requires treatment, from the non-aggressive disease, which only requires careful monitoring.[4,5]

PROSTATE CANCER CRISIS:
DIRECT CONSEQUENCE OF UNRELIABLE DIAGNOSTICS AND BLIND PATIENT CARE

KEY FACTS:

- Underdiagnosis leads to:
  - Missed and/or under-estimated cancer and lost lives;[4]
  - Treatment failures and progression of cancer in as many as 1 in 2 men.[6]

- Overdiagnosis causes:
  - Unnecessary biopsies in as many as 88% of men, or over 1 million each year at a cost of $2 billion annually to national health care;[3]
  - Unnecessary treatment in as many as 54% of men with early disease.[5]

- Human and societal impact is dire:
  - Millions of men experience reduced quality of life due to treatment complications, such as incontinence and impotence;[7]
  - Billions of dollars are added to health care costs.[8]

The lack of reliable diagnostic tools, including imaging technologies, causes prostate cancer to become both a patient care crisis and socio-economic problem. Over-diagnosis and over-treatment are widespread. In 2009 alone, while estimated 192,280 men were newly diagnosed, over 1.5 million men experienced prostate biopsies. This data is in alignment with the previously published data of the large-scale NCI-sponsored clinical trial.[2] The staggering extent of unnecessary treatment is a direct consequence of the inability of the current diagnostics to distinguish aggressive prostate cancer which has to be treated from indolent, more harmless disease which is not likely to progress and should not be treated. A clinical study in over 76,000 men demonstrated that as many as 54% of men[5] who are diagnosed with early prostate cancer undergo unnecessary treatment, which causes life-altering complications, such as impotence and incontinence, to men and billions of dollars in health care costs. The authors of the study concluded the following: "Efforts to reduce overtreatment should be a clinical and public health priority."
Under-diagnosis has dire consequences. In 2009 alone, it is estimated that 27,360 men died, even though prostate cancer is most often curable when detected early. Without imaging, biopsies are performed blindly and randomly, and consequently, miss at least 20% of prostate cancer and under-estimate the spread and the aggressiveness of prostate cancer in at least 20-30% of men.

Recent preliminary data indicate that novel, advanced, high-precision MRI can discriminate aggressive from indolent prostate cancer.[9] While this data creates hope for the role of imaging in avoiding unnecessary procedures, larger-scale, definitive clinical research is needed to study the value and cost-effectiveness of MRI in prostate cancer care.

Recent preliminary data demonstrated that when prostate cancer biopsies were guided by high-precision, experimental MRI, they accurately detected 59% of clinically significant prostate cancer missed by at least two consecutive blind biopsies.[10] Similar case histories have been reported by other leading academic institutions, including but not limited, to National Cancer Institute, Brigham and Womens Hospital of Harvard Medical School, Memorial Sloan Kettering Cancer Center. Under-diagnosis of prostate cancer leads to treatment failures in over 70,000 men per year – about half of all men who undergo treatment experience related recurrence and progression of their disease, and ultimately, advanced prostate cancer.

Unnecessary or failed, blind treatment has left millions of men in this country with reduced quality of life and added billions of dollars to health care costs.

IMAGING TECHNOLOGIES: SOLUTION TO PROSTATE CANCER CRISIS

Prostate cancer crisis is a direct consequence of blind patient care. As it has been pointed out by Dr. Shahin Tabatabei,clinical urologist from Harvard Medical School, "If you cannot see, you cannot treat". This was echoed by Dr. Patrick Walsh, a pioneer of radical surgery for prostate cancer at Johns Hopkins Medical School: "The most critical pieces of information...are the precise location and extent of cancer within the prostate. I can't think of anything more important. Right now, there is no proven method... we need that desperately.... We do not want to treat patients, based on unreliable information. "

MODEL: BREAST CANCER IMAGING BEFORE AND AFTER GOVERNMENT SUPPORT

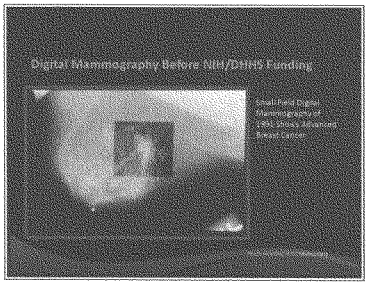


Figure 7

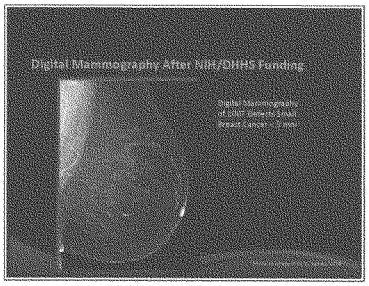


Figure 8

Figure 7 shows the state-of-the-art digital mammography in 1991, before NCI/DHHS funding, when more than 40% of women aged 50 and younger had film-based, non-diagnostic mammography, which was not transparent for x-ray imaging. At that time, we had only small field of view digital mammography, which created a small window into the breast tissue and showed a large breast cancer. **Figure 8** shows digital mammography in 2007, after NCI/DHHS funding. We can see that the entire breast tissue is transparent, and it is possible to see a small 3 mm lesion (arrow). With this precision of imaging, it has become possible to: 1) To replace surgical biopsies with image-guided, minimally-invasive, stereotactic, precision needle biopsies, which do not cause pain or deformities and cost about 40% compared to surgical procedures; and 2) To replace radical surgery with image-guided, minimally-invasive lumpectomies. What made it possible to advance breast cancer imaging from 1991 to the current care? Congressional leadership and government investment in advanced imaging, which was followed by private investment. Unfortunately, national investment in prostate cancer imaging over the same period of time has lagged behind, and today, we have only emerging promise of experimental imaging tools. With Congressional leadership and government investment, we will be able to create similar options for men.

CONSENSUS STATEMENT

AdMeTech convened a Consensus Conference in 2009, which brought together over 40 leaders of medicine, government, industry, and advocacy and concluded the following:

"We firmly believe that more accurate imaging technology would lead to better patient care, including guidance for diagnosis, biopsy and minimally-invasive therapy. Real and important improvements in prostate cancer care are at hand if we are resolved to increase the national investment in prostate diagnostics."

EMERGING SCIENTIFIC DATA

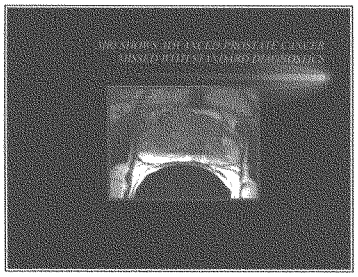


Figure 9 Courtesy of Dr. Hedvig Hricak, Memorial Sloan Kettering Cancer Center

VISION FOR THE FUTURE:

Three-dimensional MRI **(Figure 10)** detects early, small cancer (red) in the prostate (green) before it spreads to the surrounding organs. Advanced MRI can now make it possible to provide precisely targeted, minimally-invasive guidance for biopsy and removal of cancer, while sparing normal tissues to avoid complications. Image-guided, minimally-invasive biopsy and treatment can be performed in outpatient clinics, with reduced patient discomfort, complications, and costs.

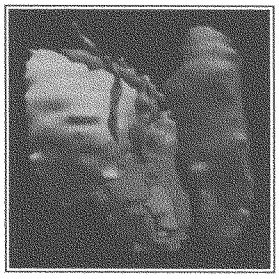


Figure 10 Courtesy of Surgical Planning Laboratory, Harvard Medical School

EXPECTED IMPACT OF IMAGING TECHNOLOGIES ON PROSTATE CANCER CARE

In the same way that mammography transformed breast cancer care, advanced prostate cancer imaging will:

- Save lives;
- Improve early diagnosis, which is critical for cure;
- Enable the least invasive and the most effective care;
- Decrease treatment complications and discomfort;
- Eliminate unnecessary procedures;
- Improve quality of life in millions of men;
- Reduce health care costs by at least $5 billion annually (see attachment).

SUMMARY

Prostate cancer imaging is not likely to play a significant role in screening or prevention, which is expected to be achieved through research investment in the development of more specific molecular biomarkers, which can be detected by in vitro, blood and urinary testing.. However, imaging is expected to end blind prostate cancer care and to create the future of image-guided biopsy and early detection, which is critical for cure and saved lives. Further, advanced imaging – by showing location, extent and aggressiveness of prostate cancer - will make it possible to achieve that holy grail of clinical care: patient-tailored, minimally-invasive treatment, which can be performed in outpatient clinics, with drastically reduced discomfort, complications and costs.

Given the potential improvements in men's health, as well as the substantial cost savings with improved diagnostic tools I have described, I hope that this Committee and others in Congress will recognize the full extent of prostate cancer crisis and the possibility to end end this crisis through increased national investment in research to advance prostate diagnostics, including imaging and in vitro testing. I hope that this Committee will empower and support the National Institutes of Health and the Department of Defense in making prostate cancer research in general and prostate diagnostics research specifically, including imaging and in vitro testing for improved biomarkers a much higher priority than it has been. I am hopeful that by holding this hearing, you will have helped in this regard, just as when Congress empowered NIH and DoD to increase funding of breast cancer research in the early 1990's, when the Executive Branch responded and we see that womens; lives and quality of life are saved with current-day mammography and image-guided, minimally-invasive treatment. We are grateful for the Congressional leadership that resulted in this hearing and brought all the key stakeholders in one room, because with the support of this committee and government investment, together, we will be able to create similar options for men. I want to thank this Committee and other witnesses who took time out of their busy schedule for their commitment to advance prostate cancer care.

[1] H. Gilbert Welch, Peter C. Albertsen. Journal of the National Cancer Institute 2009; 101(19): 1325-1329

[2] Andriole GL, et al. New England Journal of Medicine 2009; 360(13): 1310-1319.

[3] Andriole GL, et al. Journal of the National Cancer Institute 2005; 97 (6): 433-438.

[4] Robert KA, et al. Journal of Urology 2002; 167(6): 2435-2439.

[5] Miller DC, et al. Journal of the National Cancer Institute 2006; 98: 1134-1141.

[6] AdMeTech's Public Conference, September 2007.

[7] Stanford JL, et al. Journal of the American Medical Association, January 19, 2000.

[8] AdMeTech's Brain Trust, April 2007.

[9] Thomas Hambrock, et al. Annual Meeting of the European College of Radiology, March 2010.

[10] Thomas Hambrock, et al. Journal of Urology 2010; 183(2): 520-528. February 2010.

COST SAVINGS FOR NATIONAL HEALTH CARE

ADVANCED IMAGING TECHNOLOGIES WILL SAVE AN ESTIMATED $5.04 BILLION PER YEAR

1) Unnecessary Biopsies: $1.44 Billion

Currently, the yield of prostate cancer with blind biopsies is 12% per NCI study. In practical terms, if we had 240,000 new cases diagnosed in 2006 (mostly due to abnormal PSA), it means that about 2 Million biopsies were performed. The costs of all biopsies would be $4 Billion.

Assumption #1: Imaging procedures will increase cancer yield to even as low yield as 25%. Then we would have decreased the number of biopsies to 960,000 per year, with the related costs of $1,920,000. Thus, the cost savings would be $2.08 Billion.

Assumption #2: Every man with abnormal PSA (2 million, as above) will have imaging screening procedure, with estimated cost of at least $200 per optical and/or ultrasound imaging. The additional cost to health care will be 400 Million.

Assumption #3: Each man diagnosed with prostate cancer on biopsy will have diagnostic MRI (for staging and aggressiveness assessment), with est. cost of $1000 per procedure. The additional cost to health care will be $240 Million.

Net Estimated Saving to Health Care: $2.08 Billion ($400 Million for imaging screening plus $240 Million for imaging diagnostics) = $1.44 Billion

2) Unnecessary Treatment: $1.6 Billion

Assumption #1: Conservatively estimated, 25% of men with prostate cancer currently undergoing radical surgery or radiation would benefit from active surveillance, and the unnecessary treatment results in health care costs of $2 Billion (25% of the annual costs of $8 Billion).

Assumption #2: The cost of treatment is at least $20,000. Current available data: The costs of radical surgery is about $20,000-$30,000 national average; and the cost of standard radiation treatment is $20,000, while the cost of IMRT is about $40,000 – 50,000.

Assumption #3: Each man who will undergo active surveillance instead of treatment will have MRI procedure per year for 4 years (in addition to the original diagnostic procedure counted above). At $1000 per procedure, this will bring the additional cost of MRI to $4,000 per patient, or 20% of the lowest costs of treatment, or $400 Million (compared to est. $2 Billion, as above).

Net Estimated Cost Savings: $2 Billion - 400 Million = $1.6 Billion

3) Transition from Current Methods of Treatment to Minimally-Invasive Procedures: $2 Billion

Assumption #1: The cost of minimally-invasive procedures is 50% of the current treatment (the worst case scenario). Per published data, the cost of minimally-invasive procedures is estimated at about 25% to 50% of standard radiation and radical surgery.

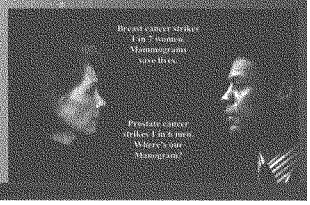
Assumption #2: With earlier diagnosis and improved localization with imaging, we will replace at least 50% of current standard treatment with minimally-invasive procedures.

Net Estimated Cost Savings: $2 Billion **(compared to the current $8 Billion per year)**

4) Total Estimated Annual Savings to Health Care: $5.04 Billion per year

AdMeTech Foundation

Ending the Era of Blind Cancer Care and Creating the Future of Image-Guided, Minimally-Invasive Diagnosis & Treatment



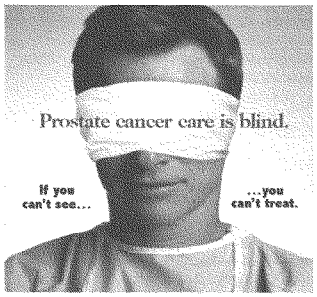
AdMeTech's Mission

AdMeTech Foundation develops strategic partnerships with academia, advocacy, industry, and government to facilitate development and implementation of accurate, affordable, accessible diagnostic tools for improved early detection and treatment of prostate cancer. Specific objectives include:

- Development and implementation of effective strategy for technological innovation and related research
- Education of medical community and general public.

Prostate Cancer Epidemic

- 1 in 6 men is stricken compared to 1 in 7 women stricken with breast cancer
- African American men are even more likely to be stricken by and die, with
  - 60% higher incidence;
  - Over 100% higher mortality;
- A new case is diagnosed every 2.5 minutes (or over 230,000 new cases every year).



AdMeTech's Challenge

Men do not have diagnostic tools, similar to life-saving mammograms for women, to guide early detection, biopsy and treatment.

While the state-of-the-art diagnostics, such as blood test PSA and biopsy have made it possible to detect prostate cancer earlier, there is no scientific evidence to support their impact on saving lives and cost-effectiveness of patient care:

- PSA causes false reassurances and false alarms:
  - When PSA is normal, 15% of men still have cancer
  - When PSA is abnormal, only 12% of men have prostate cancer.
- Biopsies are blind and random:
  - Miss at least 20% of cancer
  - Underestimate cancer aggressiveness in at least 20-30% of men.
- In many men, diagnostic information is insufficient to distinguish:
  - virulent prostate cancer which requires treatment; from
  - Non-aggressive disease which requires only careful monitoring.

Patient Care Crisis

Each year, the numbers are staggering:

- Over 27,000 men die (a man dies every 18 minutes)
- Over 1 million men have unnecessary and traumatic biopsies due to false alarms:
  - Costing over $2 billion to health care
- Over 70,000 men (or about 50%) experience failure of treatment
- Blind treatment leaves up to 50% of men incontinent and impotent
- Many men have unnecessary treatment:
  - At least 10% of men have unnecessary surgery
  - At least 44% of men have unnecessary radiation treatment.
- Current treatment costs approximately $8 billion per year.

Advanced imaging will improve diagnosis, eliminate unnecessary procedures and enable minimally-invasive treatment. Health care savings could be more than $5 billion annually.

Imaging is the Solution:

Advanced diagnostic technologies will make a direct and profound impact on quality of care, quality of life, and health care costs, including:

- Saving men's lives
- Identifying men requiring preventive measures
- Improving early detection, and staging, of cancer which is critical for cure
- Eliminating unnecessary treatment -with all the related complications and costs - by recognizing non-aggressive prostate cancer
- Enhancing patient monitoring before, during, and after treatment
- Avoiding unnecessary biopsies
- Enabling least invasive and most effective treatment:
  - To be performed in outpatient clinics
  - With minimal complications, discomfort and expense
- Reducing health care costs by at least $5 billion per year.

Emerging Scientific Evidence: A Glimpse of the Future

Preliminary research results in leading academic institutions indicate that MRI and other novel imaging technologies can detect prostate cancer missed with standard diagnostic tools, including biopsy (see Figure 1, Courtesy of Dr. Hedvig Hricak , Memorial Sloan Kettering Cancer Center).

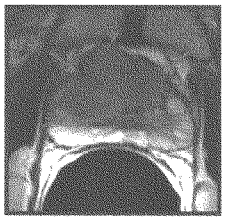


Figure 1:
MRI shows a large cancer (solid red arrows) with significant expansion outside of the prostate (dashed red arrow). In this 68 year old patient, biopsy was negative

AdMeTech's Research Program Produces Quick Results

Telemedicine and Advanced Technologies Research Center of the Department of Defense supports AdMeTech's research program which expedites development of novel imaging technologies. Examples of the funded projects include:

1) Development of the first-generation medical robotics dedicated to prostate cancer biopsy and treatment at Johns Hopkins University – within one year of funding;
2) Fundamental discovery of novel molecular pathways for imaging, which would enable early detection, assessment of aggressiveness, and prediction of response to treatment earlier than was previously possible at Dana Farber Cancer Institute– within 6 months of funding;
3) Development of new generation, prostate-dedicated optical technologies for detection of prostate cancer and guidance of biopsy at Boston University– within one year of funding;
4) Discovery of new molecular imaging agents at the Massachusetts General Hospital and Johns Hopkins University – within one year of funding.

AdMeTech's Educational Campaign

AdmeTech convenes public conferences and other educational events, where leaders of the medical, industrial, philanthropic, federal, US Congress, consumer, media and entertainment communities review the state- and create the future vision for prostate cancer care. These events offer a crucial opportunity to stimulate new ideas, develop high-impact scientific projects, and shape research strategy. An important component of this educational effort is to discuss with leadership of US Congress innovative pathways to expedite the transfer of promising technologies from laboratories to patients.

U.S. Congress Supports AdMeTech's Initiatives

AdMeTech has been successfully working with members of the US Congress to develop legislative initiatives calling upon the federal government to put forth the resources necessary to advance prostate diagnostics, including:

- U.S. Senate S. 1734 The PRIME (Prostate Research Imaging & Men's Education) Act; and
- U.S. House Resolution 353.

AdMeTech's Appeal

In the current cost-sensitive health care environment, many promising innovative technologies do not find support from traditional funding entities. such as clinical facilities, industry and government. Federal and private support permits AdMeTech and its partners to expedite development and testing of novel imaging technologies in order:

- To arm physicians with diagnostic technologies for men similar to those women currently have in the fight against breast cancer; and
- To end the era of blind prostate cancer care, and create the future of image-guided, minimally-invasive, and precisely-targeted diagnosis and treatment.

CONSENSUS CONFERENCE ON PROSTATE IMAGING

JANUARY 12–13, 2009
POOKS HILL MARRIOTT, BETHESTA, MD

Organized by the AdMeTech Foundation in cooperation with the National Institute of Health, National Cancer Institute, and National Institute of Biomedical Imaging and Bioengineering

Imaging Technologies: Solution to Prostate Cancer Crisis

"We firmly believe that more accurate imaging technology would lead to better patient care, including guidance for diagnosis, biopsy and minimally-invasive therapy. Real and important improvements in prostate cancer care are at hand if we are resolved to increase national investment in prostate diagnostics".

(Please See Faculty List – Attached)

CONSENSUS CONFERENCE ON PROSTATE IMAGING

JANUARY 12–13, 2009
POOKS HILL MARRIOTT, BETHESTA, MD

ROSTER OF PARTICIANTS

Chair:
Dr. Faina Shtern, MD, President, AdMeTech Foundation

Onikepe Adegbola, MD, PhD, Deputy Director, U.S. Medical Affairs Diagnostic Imaging, Bayer Healthcare Pharmaceuticals

Jelle O. Barentsz, MD, PhD, Professor of Radiology, Radboud University, Netherlands

James D. Brooks, MD, Associate Professor, Department of Urology, Stanford University

Melvin Clouse, MD, Deaconess Professor of Radiology, Harvard Medical School, Emeritus Chairman of Radiology, Beth Israel Deaconess Medical Center

Francois Cornud, MD, Clinique de l Alma, Paris France

Angelo De Marzo, MD, PhD, Associate Professor of Pathology and Oncology, The Sydney Kimmel Comprehensive Cancer Center, Johns Hopkins

Theodore L. DeWeese, MD, Professor and Chair, Department of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University
Lloyd D. Estkowski, Development Manager (Body MR), GE Healthcare

Jens Fehre, Vice President for R&D Urology, Siemens AG Healthcare
Harry T. Friel, MS, Senior Clinical Scientist, Philips Healthcare

Wesley Gilson, PhD, Research Scientist, Siemens Corporate Research, Inc.

Joseph Habovick, Product Manager, MEDRAD

Ethan Halpern, MD Professor of Radiology and Urology, Director, Jefferson Prostate Diagnostic Center, Thomas Jefferson University

Thomas Hambrock, MD, Researcher in Prostate MRI, Department of Radiology, Radboud University, Netherlands

Arend Heerschap, MD, PhD, Professor of MR Sciences, Department of Radiology, Radboud University, Netherlands

Stijn Heijmink, MD,Department of Radiology, Radboud University, Netherlands

Robert Honigberg, MD, Chief Medical Officer, GE Healthcare

Hedvig Hricak, MD, PhD, Chairman, Department of Radiology, Carrol and Milton Petrie Chair, Memorial Sloan Kettering Cancer Center

Henkjan Huisman Ph.D, MSEE, Assistant Professor of Radiology, US and CAD Specialist, Radboud University, Netherlands

Michael Jacobs, PhD, V. Associate Professor, Department of Radiology and Oncology, Johns Hopkins University School of Medicine

James J. Kiefert, EdD, Chairman of the Board of Directors, Us Too International

Tom Kirk, President/CEO, Us Too International

Jochen Kruecker, PhD, Principal Scientist, Philips Research

Martin Leach, PhD, Professor, Section Chairman, Institute of Cancer Research, Royal Marsden Hospital, United Kingdom

Andrew Lee, MD, MPH, Associate Professor of Radiation Oncology, Department of Radiology, MD Anderson Cancer Center

Shawn E Lupold, PhD, Assistant Professor of Urology, Johns Hopkins University School of Medicine

Cynthia Menard, MD, Assistant Professor, University Health Network, Princess Margaret Hospital, Toronto, Canada

Ms. Theresa Morrow, Director, Marketing and External Relations, Men's Health Network

Naira Muradyan, PhD, Lead Senior Research Scientist, iCAD, Inc.

Rick Ortega, Director of Marketing, MR Programs, iCAD Corporation

Aytekin Oto, MD, Associate Professor, Chief of Body MRI, University of Chicago

Anwar Padhani, MD, Consultant Radiologist, Paul Strickland Scanner Centre, Head of MRI and Imaging Research, Mount Vernon Cancer Centre, London, United Kingdom

Yuxi Pang, PhD, MR Clinical Scientist, Philips Healthcare, National Cancer Institute, Molecular Imaging Program

Alan Pollack, MD, PhD, Chair and Sylvester Professor, Department of Radiation Oncology, Associate Director, Community Professional Relations Sylvester Comprehensive Cancer Center, University of Miami Miller School of Medicine

Martin G. Pomper, MD, PhD, Professor, Johns Hopkins University

Jan Sabisch, Product Manager, Invivo Corp

Tom Scheenen, MSc, PhD, MR Scientist, Department of Radiology, Radboud University Nijmegen Medical Center, Netherlands

Mitchell Schnall, MD, PhD, Professor of Radiology, Associate Chair of Research, Department of Radiology, Hospital of the University of Pennsylvania

Rajeev Sehgal, Director, Patient Care Products, MEDRAD, Inc.

Clare M.C. Tempany, MD, Professor of Radiology, Harvard Medical School
Ferenc Jolez Chair of Radiology Research, Department of Radiology, Brigham and Womens Hospital

Heinrich von Busch, PhD, Director of Prostate Cancer Care Cycle, Philips Healthcare

Richard L. Wahl, MD, Professor of Nuclear Medicine, Director of Nuclear Medicine/PET Facility, Johns Hopkins Medical Institutions

Thomas M. Wheeler, MD, Professor and Chairman Department of Pathology, Professor of Urology, Baylor College of Medicine

Brian Wilson, BSc, PhD, Professor of Medical Biophysics, Head, Devision of Bioimaging, Ontario Cancer Institute, University of Toronto, Canada

Chairman TOWNS. Thank you so much for your testimony.
Dr. Mohler.

STATEMENT OF JAMES L. MOHLER, M.D.

Dr. MOHLER. My name is Jim Mohler, and I am the Chair of the Department of Urology at Roswell Park Cancer Institute in Buffalo, NY. Roswell Park discovered the PSA that has been taking a beating here today. Also, I chair the National Comprehensive Cancer Network [NCCN] Prostate Cancer Treatment Panel. The NCCN consists of 21 of the 40 NCI-designated comprehensive cancer centers. Finally, I am the principal investigator for PCaP, the North Carolina-Louisiana Prostate Cancer Project that Dr. Best mentioned earlier, which is the largest population-based study of prostate cancer ever undertaken, and half of our patients in that study are African-Americans.

I would like to discuss just four points that warrant our attention, and then make three recommendations.

The first point is that prior to the development of PSA only 4 percent of men diagnosed with prostate cancer could be cured. Most men were diagnosed with prostate cancer, like Congressman Gallo, when it had spread to their bones and caused pain. The standard treatment was androgen deprivation therapy and mean survival was 3 years. Now, less than 10 percent of men are diagnosed with incurable prostate cancer and 5 years survival after treatment is essentially 100 percent. However, the age-adjusted incidence of prostate cancer has increased 30 percent since 1994 to produce this 36 percent reduction in deaths. Now, if we had achieved a 36 percent reduction in mortality in any other solid cancer in America, there would be cause for jubilation.

So why is there so much controversy about PSA? Well, that controversy stems from my second point, and that is a term that hasn't been discussed here yet, autopsy prostate cancer, also called non-lethal prostate cancer earlier. The problem is that the incidence of prostate cancer, if one autopsied the prostate, is approximately the age of the man. In other words, 20 percent of 20-year-olds already have prostate cancer in their prostate, and 80 percent of 80-year-olds already have prostate cancer. So prostate biopsies will find about half of these autopsy cancers. Because PSA, as has been mentioned here today, can be elevated for many reasons, many men may undergo prostate biopsy and have an "autopsy type" prostate cancer found. This cancer poses no threat to their life expectancy.

The New England Journal of Medicine published back-to-back papers in their March 26, 2009, issue that has reignited this controversy about early detection of prostate cancer, which has been increased by the ACS guideline change issued yesterday. The American study shows no apparent benefit from PSA early detection, although many men were ineligible for the study because they probably had already had their potentially fatal prostate cancers diagnosed and treated, and the majority of the men in the arm of the study that was not subjected to screening annually received PSAs anyway from their personal physicians. Finally, the followup of this study is so short that any benefit from PSA early detection would not yet be apparent.

The European study shows a benefit to early detection using PSA, which is actually surprising to me because its followup also is short, and the PSA screening frequency was only once every 4 years. The press has focused upon the fact that 1,400 men needed to be screened and 49 men needed to be treated in order to prevent one death from prostate cancer in the European study. Over-treatment of prostate cancer would not be an issue if the treatment had no side effects and was free.

And this brings me to point three, over-treatment of prostate cancer. The NCCN guidelines have already responded by changing their guidelines last month to focus on more careful detection of aggressive prostate cancer in younger men, while urging a more conservative approach to early detection of prostate cancer in older men. The NCCN 2010 Guidelines also recommend active surveillance of men who have been found to have low risk prostate cancer when life expectancy is less than 10 years.

In addition, the NCCN has created a new prostate cancer risk category, very low risk prostate cancer. Active surveillance is the only recommended treatment in this group of men when life expectancy is less than 20 years. So let me emphasize that here is a cancer treatment guideline panel recommending active surveillance instead of treatment. These changes allow appropriate aggressive treatment of men who are at high risk of death from prostate cancer while avoiding over-treatment of men at low risk of prostate cancer death.

My last point is how PSA and treatment can actually perform better than it does today. African-American men and men with a family history of prostate cancer, especially in their brother or father, represent a group of men that we all agree are at higher risk of death from prostate cancer. PSA and treatment will perform better if efforts at early detection of prostate cancer are focused on these higher risk groups.

So, this leads me to my three recommendations. The first hasn't been made by anyone yet. We need a blood or urine test that can be combined with PSA to indicate who doesn't need a biopsy. This is critically important because then men with autopsy type prostate cancer can be spared biopsy and the anxiety attached to the diagnosis of an autopsy prostate cancer.

I agree with the other panelists that, once diagnosed with prostate cancer and tissue is available, we need better imaging or a tissue-based biomarker of life-threatening prostate cancer. Currently, PSA, extent of disease, and Gleason grade of cancer, correlate with prostate cancer aggressiveness in groups of men, but not in individual patients. More funds must be spent to develop biomarkers of aggressive prostate cancer, and I believe that these markers may come through more careful study of the prostate cancers found in African-Americans.

Until we succeed in these two areas, the NCCN guidelines should be used to guide the diagnosis and treatment of prostate cancer to assure that we continue to reduce the mortality from prostate cancer, while not subjecting men to the consequences of over-treatment.

I thank the committee for their wisdom in addressing these very complex issues posed by prostate cancer.

[The prepared statement of Dr. Mohler follows:]

Opening Statement to the House Committee on Oversight and Government Reform

March 4, 2010

James L. Mohler, MD

My name is James L. Mohler. I am Chair of the Department of Urology at Roswell Park Cancer Institute. Roswell Park Cancer Institute discovered prostate-specific antigen (PSA). The PSA test became available in the late 1980's and has revolutionized our ability to diagnose prostate cancer and monitor the effects of treatment. I am Chair of the National Comprehensive Cancer Center Network (NCCN) Prostate Cancer Treatment Panel and a Member of the NCCN Prostate Cancer Early Detection Panel. The NCCN consists of 21 member institutions that seek to improve early detection and treatment of the common cancers through education and guidelines. Each of the 21 member institutions is 1 of the 40 NCI designated Comprehensive Cancer Centers (excellence in education, treatment, and research). The NCCN Prostate Cancer Guidelines were developed in 1995 and are updated annually. Finally, I am the principal investigator for the North Carolina-Louisiana Prostate Cancer Project (PCaP), which is funded by the Department of Defense Prostate Cancer Research Program with a total award that has now reached $15.2 million. PCaP is the largest population-based study of prostate cancer ever undertaken. The study has enrolled 2,264 men; about ½ are African Americans and ½ are Caucasian Americans. The goal of PCaP is to provide insight into the reasons for racial disparity in prostate cancer. African-American men are 1½ times more likely to be diagnosed with prostate cancer and, when diagnosed with prostate cancer, they are more than twice as likely to die from it than Caucasian Americans. PCaP seeks to determine the relative importance of 3 potential contributors to the racial disparity in prostate cancer: racial differences in interaction with the American healthcare system, racial differences in the patient himself, and racial differences in the tumor itself.

I will discuss 4 points that warrant our attention and then make 3 recommendations.

Point 1: PSA for Early Detection of Prostate Cancer

Prior to the development of PSA, only 4% of men diagnosed with prostate cancer could be cured. Most men were diagnosed with prostate cancer when it had spread to their bones and caused pain. The standard treatment was androgen deprivation therapy and mean survival was 3 years. The development of the PSA test has changed the demographics of newly diagnosed prostate cancer patients completely. Less than 10% of men are diagnosed with incurable prostate cancer and 5 year survival after treatment is essentially 100%. However, the age-adjusted incidence of prostate cancer has increased 30% since 1994 to produce a 36% reduction in deaths. If we had achieved a 36% reduction in mortality in any other solid cancer in America, there would be cause for jubilation. So why is there is so much controversy about PSA? The controversy stems from my second point.

Point 2: Autopsy Prostate Cancer

The incidence of prostate cancer if one autopsied the prostate is approximately the age of the man. In other words, 20% of 20 year olds already have cancer in their prostate and 80% of 80 year olds have prostate cancer. Prostate biopsies will find about ½ of these autopsy cancers. Thus, 40% of 80 year olds and 10% of 20 year olds will be found to have prostate cancer if their prostates are biopsied. Because PSA can be elevated for many reasons, many men who undergo prostate biopsy may have an autopsy-type prostate cancer diagnosed rather than one that poses a threat to their life expectancy. The New England Journal of Medicine published back to back papers in their March 26, 2009 issue that has reignited the controversy about early detection of prostate cancer. The American study shows no

apparent benefit from PSA early detection although many men were ineligible for the study because they already had their potentially fatal prostate cancers diagnosed and treated and the majority of the men in the arm of the study that was not subjected to screening annually received PSAs anyway. Finally, the follow-up of this study is so short that any benefit from PSA early detection would not yet be apparent. The European study shows a benefit to early detection using PSA, which is actually surprising because its follow-up also is short and PSA was used for screening only once every 4 years. The press has focused upon the fact that 1,410 men needed to be screened and 49 men needed to be treated in order to prevent 1 death from prostate cancer in the European study. Overtreatment of prostate cancer would not be an issue if the treatment was free of side effects and expense.

Point 3: Overtreatment of Prostate Cancer

Indiscriminate use of PSA and aggressive diagnosis and treatment of prostate cancer is unlikely to impact significantly the survival of American men and may adversely affect the quality of life of American men. The NCCN has responded by changing the 2010 Guidelines to focus on a more careful detection of aggressive prostate cancer in younger men while urging a more conservative approach to early detection of prostate cancer in older men; NCCN recommends that attempts to find prostate cancer cease when a man's life expectancy falls to <10 years. The NCCN 2010 Guidelines also recommend active surveillance of men who were found to have low risk prostate cancer when life expectancy is <10 years. In addition, the NCCN has created a new prostate cancer risk category, very low risk prostate cancer; active surveillance is the only recommended treatment in this group of men when life expectancy is <20 years. These changes allow appropriate aggressive treatment of men who are at high risk of death from prostate cancer while avoiding overtreatment of men at low risk of prostate cancer death.

Point 4: How can PSA and Treatment Perform Better

African-American men and men with a family history of prostate cancer, especially in their brother or father, represent a group of men who are at higher risk of death from prostate cancer. PSA and treatment will both perform better if efforts at early detection of prostate cancer are focused in these higher risk groups. I believe that careful study of the prostate cancer of African Americans holds the key to understanding the aggressive type of prostate cancer.

Recommendations

1. Develop blood (or urine) tests that can be combined with PSA to indicate who doesn't need a prostate biopsy so that men with autopsy-type prostate cancer can be spared biopsy and the anxiety attached to a diagnosis of prostate cancer.
2. Once diagnosed with prostate cancer and tissue is available, we need a tissue-based biomarker of life-threatening prostate cancer. Currently, PSA, extent of disease, and Gleason grade of cancer correlate with prostate cancer aggressiveness in groups of men, but not individual patients. More funds must be spent to develop biomarkers of aggressive prostate cancer and I believe that may come through more careful study of the prostate cancers found in African Americans.
3. Until we succeed in these 2 areas, guidelines should be used to guide the diagnosis and treatment of prostate cancer to assure that we continue to reduce the mortality from prostate cancer while not subjecting men to the consequences of overtreatment of prostate cancer.

I thank the committee for their wisdom in addressing the complex issues posed by prostate cancer.

Chairman TOWNS. Thank you very much.

Let me thank all of you for your testimony. The way I generally start out, is to ask the witnesses are there any statements that you have heard that you would like to sort of clarify and give your input to them, be it from the first panel or from this panel. And the reason I do that is because I was at the airport 1 day and a person said to me, "I did not agree with anything that person said, and you didn't allow me to respond." I don't want to be guilty of not allowing you to respond. So that is the first question.

Yes, Dr. Brawley.

Dr. BRAWLEY. Yes, if I may, sir. In the first panel I heard that the mortality has gone down, so it must be because of screening. I think it is important to realize that if you go to various countries in Europe which, as a policy, have said not to adopt screening because it hasn't been proven to save lives, mortality has been going down in those countries as well. So it is hard for me to attribute all of the decline in mortality in the United States to screening when there are several other countries—Britain, France, so forth—that have a decline in mortality without having screening.

Second, Dr. Mohler talked about—my good friend, Dr. Mohler, by the way; we have worked together on a number of things—talked about 5-year survival. When I am teaching epidemiology and teaching screening, we don't use 5-year survival as a good use of outcome. It is not an evaluation of outcome, especially in prostate cancer, where many of the people you pick up with screening would have never died; they had those autopsy style prostate cancers. They actually artificially push your 5-year survival rate up.

And this is best seen, by the way, in the old studies of lung cancer, lung cancer screening with chest x-ray. By the way, we have been here before. Lung cancer screening was advocated in the United States from 1960 to about 1975. The Otis Brawleys of the 1960's said "let's do a study." Many people said "no, it finds disease earlier, it increases 5-year survival rates." When those studies were done—my favorite is the Mayo Clinic study—the death rate on the screened arm of the Mayo Clinic randomized chest x-ray study was 3.2 per 1,000 per year on the screened arm and 2.8 per 1,000 per year on the unscreened arm. Keep in mind survival was increased on the screened arm, but risk of death was increased as well.

So when we teach in epidemiology and we are doing screening, we don't look at 5-year survival rates, we look at decrease in mortality rates. That is what we want to find.

Chairman TOWNS. Thank you very much.

Anyone else? Yes, Dr. Mohler.

Dr. MOHLER. I cannot let misstatements by Otis go unaddressed.

Chairman TOWNS. Are you guys really friends?

Dr. MOHLER. Yes. I always like to say that two people can be looking at a horse, and if one is standing at the head and the other is standing at the tail, they describe something that looks very different. Many aspects of this debate are about where are you standing. Now, the decrease in mortality in Great Britain, which has been argued for to counteract the 36 percent decline in age-adjusted prostate cancer mortality in America, has been thoroughly investigated. Great Britain changed the way that their national registry recorded deaths at autopsy, and when this was accounted

for the decline in prostate cancer mortality in Great Britain basically went away.

I think our country is unique in having had objective evidence of a decline in prostate cancer mortality. This occurs at the same time that the worldwide incidence of prostate cancer is increasing 1.1 percent per year. The reasons for this are unknown. The best evidence suggests that this may be from westernization of the diets. But we do not know much more than we do know about prostate cancer. So Otis very appropriately is challenging the 5-year 100 percent survival being inadequate to say that treatment is effective. We know that as we follow those men longer, many of them are going to recur, but this is the data that is reported by the American Cancer Society and why I conform to the 5-year number.

Chairman TOWNS. Yes, Dr. Shtern.

Dr. SHTERN. Thank you. There was a statement made at the previous panel that only 25 percent of women undergoing biopsy have breast cancer. What I would like to refocus, if you look at the number of breast cancer and prostate cancer is close. Let's say it is around 2,000 per year. The average yield, percentage of men who have cancer and undergoing biopsy, according to the largest trial NCI supported that we have, is 12 percent. So if we look from that and we know from actual numbers that 1 million women undergo biopsy every year; however, 2 million or close to 2 million men undergo biopsy every year, it means that if we had an imaging tool that will eliminate, that will be compatible to mammography and will eliminate 1 million biopsies right there and then, there is a possibility to save over $2 billion. Thank you.

Chairman TOWNS. Thank you very much.

Let me now go to you, Dr. Brawley. Now, I understand, of course, that you are perhaps an expert on cancer screening, and I respect that and really appreciate that you are here and your work over the years, but before I get to that focus, I want to ask your opinion on any correlation between education and mother's diet and why African-Americans are significantly more disproportionately impacted by the lethal form of prostate cancer. I lost a brother to it.

Dr. BRAWLEY. Yes, sir. Thank you. We have been working long and hard for probably now 30 years to try to finally start addressing the question why do Blacks have a higher rate around 1980. And, by the way, it is Blacks in the western hemisphere for sure; Blacks in Brazil and Jamaica have a higher rate, as do Blacks in Canada. I don't know about Blacks in Africa because there is no good registry there, and the National Cancer Institute of the United States actually tried to establish a registry to try to figure it out and just couldn't.

What data that we do have indicates that a large number of the Black prostate cancer problem can be due to diet, it can be due to differences in diet over time, differences in body mass index. There are some studies that have been done primarily in animals that indicate that animals that are fed a high fat diet when they are pregnant, their children will have a differing sensitivity in terms of estrogen and androgen receptors when the children are born. So there are some people who have speculated that it is the socioeconomic status of the fetus and of the mother, and the diet of the

mother when in utero that actually affects risk of both prostate and breast cancer 40, 50, 60 years after birth.

For example, many people talk about the breast cancer problem in Black women with triple negatives. If you go to Scotland, one of the best studies on breast cancer in Black women has been done in Scotland, where they have no Black women. They figured out that women in Scotland who have a lifelong history of poverty—and you can't look at socioeconomic status at the time of diagnosis; you have to look at socioeconomic status over the entire lifetime, beginning in utero. Women who were born and have a lifetime of poverty have breast cancers that are more likely to be triple negative, more likely to present at an earlier age, just as Black women in the United States. So socioeconomic status, diet, a number of other environmental factors actually can change the genetics of a breast cancer. Estrogen receptor negative breast cancer, that is a genetic difference, but white women in Scotland who are poor tend to have more of it than white woman in Scotland who are not poor.

Chairman TOWNS. Dr. Mohler.

Dr. MOHLER. So the North Carolina-Louisiana prostate cancer study is seeking to look at many of these dietary and lifestyle differences that may be contributing. I think it is very important to recognize that there is fundamental differences between the African-American prostate and the Caucasian American prostate, and Dr. Brawley is exactly correct that we don't know where these come from.

But one of the fundamental questions that PCaP will address is whether the African-American prostate seems to have a revved up androgen access. The circulating androgens are the same between the two races, but the African-American prostate, for unknown reasons, has more of the protein that testosterone binds to to turn on growth than does the Caucasian American prostate. That level of protein is 21 percent higher in the benign prostate, and then once African-American men develop prostate cancer, their cancers have 81 percent more of this protein. It is completely unclear why that is and whether this is a consequence of diet and lifestyle, has something to do with genetic environmental interaction, but much of PCaP is devoted to figuring out whether this is actually true in a large number of men from a population-based series.

I still think that most of the racial differences in prostate cancer mortality stem from socioeconomic disadvantage and not race, per se. In fact, when we look at our treatment results in North Carolina and Louisiana, once you correct for socioeconomic status, race is no longer a factor in treatment received or outcome of that treatment.

Chairman TOWNS. So you are also saying education plays a part?

Dr. MOHLER. I think that is the greatest contributor to the racial disparity right now, yes.

Dr. BRAWLEY. Sir, we have—Dr. Mohler and I completely agree on that. And, by the way, some of the best early studies to look at Black-White differences on this very issue actually came from the Intramural Department of Defense Prostate Cancer Program that Dr. Kaminsky represents.

Chairman TOWNS. Thank you very much.

I now yield to the ranking member.

Mr. ISSA. Thank you, Mr. Chairman. I think it is not good to find out that to be poor in America can kill you, but it sounds like, once again, that would be the short way of expressing what you have found. We are having a lively debate on health care and I think it is pretty safe to say, on either side of the dais here, that we are concerned that there are two Americas relative to health care.

But, Dr. Brawley, I am particularly interested in a couple of the things that you have attacked, because you could tell by the earlier panel—I tend to want to figure out how to fix the Hubble telescope in the sense that we have put a lot of money into this project and it doesn't appear—if 30 out of 31 people that get treated would be just as well off not being treated—that we have yet focused on the right answer, which means we don't have the real visibility we need.

Earlier, actually, it was in Dr. Dahut's—but he has left—statement, but I think you are probably very capable of answering this. When we talk about prostate cancer, are we really talking about flu—I am using the term broadly—flu of the prostate versus H1N1 of the prostate and some other group of various things? We are using a broad-brushed statement when in fact it is cancer in the prostate, not prostate cancer.

Dr. BRAWLEY. What we are talking about is actually prostate cancer that become malignant and start growing.

Mr. ISSA. But they are malignant due to different forms of cancer in the sense that they react differently, they are differently treated. And if you could isolate, if you will, various strains and treat them appropriately, you could have better results?

Dr. BRAWLEY. Yes, that I would agree with, but the cancer itself originates from cells in the prostate. And there are a variety of different, more aggressive, less aggressive—one of our problems actually is that Vera Cao, in 1848, described what prostate cancer was, and he described it using autopsy specimens. And now, even though we have moved into a molecular age 168 years later, we are still using his light microscope definition of cancer, and that is why we really desperately need molecular tests are actually where I think it will come from, where we can say, Mr. Smith, you have prostate cancer, but it needs to be watched; Mr. Jones, you have prostate cancer and we need to treat it aggressively, because if we don't treat it aggressively it is going to bother you.

Mr. ISSA. Now, the American Cancer Society has put out figures on both breast cancer and prostate cancer, and they are relatively interesting in the sense of their similarity. Breast cancer, 192,370 cases of invasive breast cancer; 192,280 new cases of prostate cancer. I noticed a word missing there. The death today, after all the good work that we earlier talked about, from breast cancer, 40,170; from prostate cancer, 27,000.

To understand the statistics and balance it here for us lay people, if I understand correctly, the 192,000 prostate cases, if you took out the ones that were likely not to kill you—that is hindsight, but if you took those out, you are probably not talking about 192,000, you are not even talking about 19,000; you are talking about probably 10,000 cases, new cases. Then you say, well, wait a second, how do I end up with 27,000 deaths from 10,000 cases. So I want to understand what that figure really is.

Dr. BRAWLEY. When Dr. DeWeese talks about 30 to 50 people treated for every one life saved, that is among people who are screened detected. OK? The European study——

Mr. ISSA. Screened and found to have cancer.

Dr. BRAWLEY. That is right. The European study—remember, screening is going to find disease that we would not have found if there had not been any screening. Indeed, a man in the United States who chooses to be screened doubles his risk of being diagnosed with prostate cancer from about 1 in 10 to 1 in 5, from 10 percent to 20 percent.

Mr. ISSA. You mean if you don't look, you don't find; but if you look, you find.

Dr. BRAWLEY. That is right. That is exactly right. Now, by the way, on the other hand, if we take the European study, which showed that 20 percent relative risk in decrease in death with a soft P value, so we are not 100 percent sure of that finding, that is 3 percent lifetime risk of death going down to 2.4 percent lifetime risk of death. So the answer to your question is the 30 to 50 to 1 is in a screened detected population.

Mr. ISSA. Right. But I wanted to see how it boiled down to when you get to the 192,000 versus the 192,000 for these two types of cancers, and more people die of breast cancer, a cancer that we can look at with mammography, we have a better feel for being able to see it, feel it, and eliminate it, but you have a higher number, to me that begs the question of when we use the number 192,000 in prostate cancer, are we basically saying here is a cancer we are not very good at actually curing, but we are also not very good at putting a number up there that are really the number that kill you? Does this include a number that people would live 20 more years?

Dr. BRAWLEY. Oh, yes.

Mr. ISSA. So the 192 versus 192, 192,000 that says invasive breast cancer, these are going to kill women; and the 192 of prostate not so much.

Dr. BRAWLEY. That is right. Many are not going to kill. But if you will bear with me, the big difference between——

Mr. ISSA. I don't want to interrupt you excessively, but I just would like to know, after the fact, if you could, if you could re-estimate that 192,000 to give me your best guess of invasive prostate cancer so that we can look at the cases versus death, because they make them look like breast cancer is less successful in treatment and more likely to kill women, when in fact it looks like there are less cases, but we don't do so good with prostate cancer.

Dr. BRAWLEY. That is actually the reason why I like to look at mortality rates, rather than absolute numbers. What I was going to say is we have nine randomized trials in breast cancer that consistently show that mammography screening decreases the mortality rate. Nine. Two of those nine happen to focus on women in their forties, by the way.

We have four randomized trials in prostate cancer that have ever been attempted. One actually was with digital rectal exam and not PSA. Three of those four trials actually show a slight increased risk of mortality in the screened arm versus the unscreened arm; one

of them, the European study, shows that 20 percent decrease in mortality.

So the reason why there is uncertainty why there is uncertainty is we have three studies that say that this screening stuff could be like lung cancer screening back in the 1960's, and we have one study that says no, it does save lives.

Mr. ISSA. Let me just concentrate on two last quick questions. One is the Europeans, regardless of whether they lower mortality because of what they do or not, they spend less, is that correct? They basically decided, whether it was because of the cost or because they didn't see a benefit, they have decided to prescribe less action both in testing and in treatment.

Dr. BRAWLEY. Yes, sir, and that relates directly to the health care debate that is going on right now. There is an American tendency that if you have a technology that you think works, go out and do it. I can name 12 things over the last century—you mentioned the Halstead mastectomy earlier. Remember, we did that for 75 years because Dr. Halstead said it was a good thing, and we criticized all the people who wanted to do an evaluation of it for more than 75 years. Finally, we get around to doing an evaluation of it and we find out that a lumpectomy and radiation is equal to the Halstead mastectomy. We did the wrong thing for 75 years.

This came out—PSA came out in the late 1980's and we started pushing it, started encouraging people to get it rather than doing an adequate evaluation. The Europeans actually decided to do an adequate evaluation. The contamination rate on the European study is so low—that is, the number of guys in control who did not get the PSA, because you can't get a PSA over there unless you are in a study to see if it works.

Mr. ISSA. OK, I realize—begging the indulgence, very quickly, Mr. Chairman.

Dr. Shtern, because you are someone who is talking about an alternative, anyone who is talking about where we should invest in research for alternatives, including Dr. Mohler, if you are talking about a Next Generation PSA that wouldn't be such a shotgun approach to actually diagnosing specific cases of invasive cancer.

Dr. Shtern.

Dr. SHTERN. Thank you very much. I would like to refute just a couple of numbers. I think the numbers you cited need to be put in a slightly different perspective with some slightly different statistics that frame prostate cancer as a patient care crisis, in spite of the numbers you just cited, which was absolutely accurate.

If we look at the number of men who fail on prostate cancer treatment every year, it is 70,000 men. What that means in practical terms, about 50 percent of men undergoing prostate cancer treatment fail and prostate cancer progresses and becomes life-threatening. This is 70,000 men.

If you look at another number, in August 2006, there was a study in over 76,000 men published by the University of Michigan, and it demonstrated at the necessary treatment, and it demonstrated that up to 54 percent of men with early localized prostate cancer have unnecessary treatment. That is why it is with billions of dollars in health care cost in procedures alone. We never could get access to hospitalization costs and related data.

The bottom line is that you have essentially one and a half men undergoing treatment failing on treatment on one side; on the other hand, you have roughly one in two men who have failed treatment, and where we failed, we do not have accurate diagnostic information either by a marker for mass screening or imaging to create patient tailor appropriate treatment. That is why investment, as Dr. DeWeese pointed out, in diagnostic information is that critical.

Mr. ISSA. Thank you, Mr. Chairman. I think the day after we eulogized Jack Murtha, it tells all of us that we don't want to have procedures unless they are going to yield the right result, because procedures can lead to other loss of life and loss of qualify of life. So I thank the chairman and yield back.

Chairman TOWNS. I thank the gentleman.

I now yield to the gentlewoman from California, Congresswoman Diane Watson.

Ms. WATSON. Thank you, all panelists, for being here and for your testimony. I would like to address Dr. Brawley.

You have argued that prostate screening began to be implemented before adequate studies were conducted, and that such studies are still needed. In the meantime, who should be screened? When should they be screened? Should Black men be first, and then—at one age and then white men at another? And how should screening be utilized in the treatment?

And you might have given us some answers before I came in.

Dr. BRAWLEY. No, no, no. Good important questions. I think right now the most important thing is to tell men the truth, because a lot of what I am hearing on advertisements and other places, sometimes from hospitals that make money off of treating prostate cancer, sometimes from prostate cancer survivor groups who want to do the right thing, prostate cancer survivor groups that are frequently supported by industry that makes these tests, I will say, frequently, but not always.

I think people need to know the right information, which is we don't know if this test saves lives. There are some very smart people who think that it does. I actually think it saves lives. I think it saves lives, but I know we have to treat a large number of people in order to save each life. Some men may want to take the option of getting screened, and we should support those men. Some men, knowing this, may want to not get screened, and we should support and not criticize those men for that decision. And I really do believe we need to get into informed decisionmaking.

The American Cancer Society has favored informed decisionmaking since 1997 is just people would read what we said and then say the ACS says men should get screened. The ACS says men should be informed and make a decision is what we wanted people to say, so that is why we changed our guideline. Our guideline as of yesterday is, within the physician-patient relationship—none of this free screening is done to generate income by hospitals. Within the physician-patient relationship, the physician and the patient should have a conversation, talk about the uncertainties, the known risks, and the possible benefits, and make a decision as to what is right for the patient. That is what we need to be doing.

Ms. WATSON. You know, years ago, when I was in the Senate in California chairing the Health and Human Services Committee, I also was very involved in a statewide organization looking at Black women with breast cancer. A few months ago the question—not the question, but the directive was out that women are to wait later, until they are 40, before they do the screenings.

I am talking about breast cancer in this instance. The women that were part of our study and was directed at UCLA under Dr. Love, by the time a year or two passed, all of them were dead. So I was struck that there is something in the DNA among African-Americans that causes cancer at an earlier age, and I am recognizing that because I carry the bill for the first screenings on prostate cancer among Black males.

I think you might have answered this. You said it has to be an individual thing, but I do see African-Americans more prone toward prostate and breast cancer than other groups. What will we have to do and how much time will it take us to come up with some decisions on just when?

Dr. BRAWLEY. Unfortunately, we lost a lot of time because we started advocating the screening in the early 1990's. Indeed, how we lose time is saying everybody should get screened dissuaded men from going in the studies to figure out if screening worked. And things like the American study that just reported was 5 years late because of slow accrual. Why would you go into this study when all these advertisements are saying everybody should get screened; screening saves lives? OK? That is how we slowed down.

Now, once we have people to understand that this is a huge problem, it is probably going to be 10 or 15 years before we can get a good answer, and it is through supportive things like Dr. Mohler's study, it is through support of many of the wonderful things that have gone on in the Department of Defense studies and the NCI, and it takes doctors who are practicing medicine to realize this was a problem. This over-diagnosis thing was "pooh-poohed" by a number of physicians in practice in the early 1990's when those of us in academia were saying that it is a problem. Now we have numerous studies.

The Prostate Prevention Trial is my favorite. It is the only study that ever biopsied men who had normal PSAs. It showed that PSA screening for men in their sixties over 7 years can diagnose 13 percent with prostate cancer. It also showed that PSA misses just as many prostate cancers as it found, and of that 26 percent of men in their sixties who were diagnosed with prostate cancer, we know only 3 percent are going to die, 3 out of the 26. OK? So that is an indication of this over-treatment thing.

There was actually a vote in the integration committee for the Department of Defense—these are survivors and doctors—earlier in this decade that said that more money for the Defense Department ought to go toward seeing how to get men screened and take that money away from studies of the biologic behavior of prostate cancer. So we are letting our emotions—I am very emotional about this because I want men to get the right thing, and I know that I am hearing that men are not getting the right information.

Chairman TOWNS. The gentlewoman's time has expired.

I now yield 5 minutes to the gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

Dr. Brawley, let me ask you this, and any of our other panelists. You know, the problem is that I think it was Lou Gossett said it a little bit earlier when he was talking about—he was talking about African-American men, but he could have applied this to men, period—are squeamish about the prostate and the exams. So I am trying to figure out—so they already are not likely to go in for the exam. Don't want to talk about it. So how do you make the jump—with all this new information that just came out yesterday, it gives men an excuse not to do it. I am telling you. And men look for excuses not to do this. They already don't want to do it, but they really don't want to do it. They say, see, told you it is not going to do any good anyway. I can hear them now. So, I mean, how do we deal with that? Then the question also for them becomes, well, even if I go in, it sounds like there is confusion. You follow me?

Dr. BRAWLEY. There is confusion, sir.

Mr. CUMMINGS. So what is the best argument to a man who is looking at you right now to go and try to address this issue?

Dr. BRAWLEY. Well, I can tell you the argument to address the issue. I can't tell you the argument why a man should be screened, because I actually think that our guideline yesterday—and the experts came together and said if a man doesn't want to be screened, we should support that man in that decision.

Mr. CUMMINGS. OK.

Dr. BRAWLEY. OK. But I do think that we should be talking about prostate cancer. A big problem in the Black community is a number of men who don't have prostate cancer, but have benign prosthetic hyperplasia, difficulty urinating, and are suffering from that and won't go get it treated or get it assessed. I do think we need to talk about these things openly. And I will also tell you, growing up and becoming a screening expert, growing up from the inner city of Detroit, where all my relatives were afraid that people weren't telling them the truth, I grew up to find out that my relatives were pretty wise, because on this issue there are a lot of things out there that are not truthful, that is misleading.

We do not know if prostate cancer screening saves lives. Some of us think it does, but I hear routinely that prostate cancer screening saves lives. I hear routinely that any man who doesn't get screened is a fool. Yet—I had nothing to do, by the way, with the ACS guideline; I am a staff person. These were volunteers; these were doctors, epidemiologists, outcomes people, and some patients who met over a period of a year looking at all the literature that we have, and they came up with—and, indeed, they came up with the same thing that they came up with in 2001—there are huge uncertainties here. People need to know there are huge uncertainties and then make a decision about what is right for them.

Mr. CUMMINGS. OK. Dr. Shtern, and then I will go to you, Dr. Mohler.

Dr. Shtern, the imaging, does it appear that the imaging—Dr. DeWeese, a little bit earlier, testified that there is the radical type of prostate cancer and then he said there is more like a, I don't

know, dormant? I don't know whether that is the right word. But is it the belief that this imaging will be able to detect which one it is?

Nice and loud, please.

Dr. SHTERN. Not only did we always believe that with appropriate research funding it would be possible to develop imaging tools that will be able to differentiate dormant from aggressive prostate cancer, but there is current emerging scientific information that points us in that direction. Specifically, at the University of California in San Francisco, data were produced that magnetic resonance spectroscopy may help to differentiate aggressive from non-aggressive prostate cancer.

Only in a few days, on March 10th, there would be a study published by my co-leader of AdMeTech finding international prostate MRI working from Dr. Berenson in Holland, and he will be presenting data, pilot studies in 51 men where novel MRI technology, diffusion-weighted imaging was able to discriminate aggressive from non-aggressive prostate cancer. Now, these are pilot studies. Further extensive research is needed in order to have definitive answers. That is why investment in imaging research is critical.

Thank you.

Mr. CUMMINGS. I see my time is up, Mr. Chairman. I think Dr. Mohler wanted to say something, but I know we are running out of time.

Chairman TOWNS. Yes, Dr. Mohler, if you could be brief.

Dr. MOHLER. I just wanted to reiterate that I think you have heard a message here that we need, in addition to a way to detect prostate cancer, we need a way to separate autopsy from the lethal prostate cancer.

Mr. CUMMINGS. Right.

Dr. MOHLER. That is a common theme. The problem right now is that men have to decide what to do now; they cannot wait for Dr. Brawley's 15-year studies from now. What happens in the 15 years since the American and European screening studies were designed is medicine advances, and then the results 15 to 20 years into the future become obsolete. So men are being faced with this difficult problem of what to do now, and the NCCN guidelines emphasize aggressively finding prostate cancer in young men, because the young man who you can detect prostate cancer, he is going to live so long that he is going to die from it. You need to relax as men get older, because they will suffer the increasing incidence of the autopsy type cancer that you don't want to go aggressively find. So PSA and treatment are being justifiably criticized right now because there has been overzealous use of both PSA for early detection and treatment. We need more science to separate this autopsy cancer from the lethal cancer, and then we wouldn't have to be having so many of these discussions.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Chairman TOWNS. Thank you very much.

Let me indicate that we will leave the record open for 5 additional days for additional comments and information.

Let me just thank all of you for your testimony today. I tell you, it points out that we still have a long way to go, but we appreciate your work and what you are doing, and we look forward to working

with you as we move forward. I think this is a very important hearing when you look at the statistics and what is really going on. So let me thank you again.

At this time, the hearing is adjourned.

[Whereupon, at 3:09 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

FOR THE RECORD

Addendum to the testimony of:

Betty Gallo

Consisting of the following statements:

America's Prostate Cancer Organizations

Men's Health Network

MaleCare

Committee on Oversight and Government Reform

Full Committee Hearing on:

"Prostate Cancer: New Questions about Screening and Treatment"

Thursday, March 4, 2010

10:00 a.m.

Room 2154, Rayburn House Office Building

House Committee on Oversight and Government Reform

(Chairman: Ed Towns, D, NY)

Hearing on

"Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Joint Statement of

America's Prostate Cancer Organizations

comprising

Malecare Prostate Cancer Support
www.malecare.com

Men's Health Network
www.menshealthnetwork.org

National Alliance of State Prostate Cancer Coalitions
www.naspcc.org

Prostate Cancer Foundation
www.pcf.org

Prostate Cancer International
www.pcainternational.org

Prostate Conditions Education Council
www.prostateconditions.org

Prostate Health Education Network
www.prostatehealthed.org

The Prostate Net
www.theprostatenet.org

Us TOO International Prostate Cancer Education and Support Network
www.ustoo.org

Women Against Prostate Cancer
www.womenagainstprostatecancer.org

ZERO – The Project to End Prostate Cancer
www.zerocancer.org

With Support From:

RetireSafe
www.retiresafe.org

Veterans Health Council
www.veteranshealth.org

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House Committee on Oversight and Government Reform

Hearing on

"Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Joint Statement of

America's Prostate Cancer Organizations

Collectively, America's Prostate Cancer Organizations thanks the Committee on Oversight and Reform for holding this important hearing, and we appreciate the opportunity to submit joint testimony on the critical issues that affect the current status of the prevention, diagnosis, and treatment of prostate cancer, and research into all aspects of this disease.

America's Prostate Cancer Organizations is a collaborative group of independent not-for-profit organizations that seek to represent the best interests of men at risk for, diagnosed with, and treated for prostate cancer in America today. Our shared goal is that ***all*** such men should receive the most appropriate advice and care, and that we continue to limit the devastating impact of prostate cancer on men and their families.

America's Prostate Cancer Organizations counts among its collaborators:

- The largest network of prostate cancer patient support groups in the world
- The world's largest, independent, not-for-profit organization involved in raising money to support prostate cancer research
- Organizations that represent the interests of specific underserved and special interest groups, including African Americans and the gay community

Our fundamental objective in presenting this testimony is to offer the committee some guidance on current priorities -- as seen from the point of view of the men at risk for prostate cancer, patients with this disease, and the families of men who either have prostate cancer today or have passed away as a consequence of this disease.

Our testimony is brief and to the point, and demonstrates to the Committee the shared perspective of literally tens of thousands -- if not millions -- of men and their families across America.

We wish to make just five important observations, and we ask the Committee to consider these observations with great care:

- Prostate cancer is a complex and problematic disease that affects not only the male patient but also his wife or partner and other family members over many years. Nearly 200,000 men will be diagnosed with prostate cancer in the U.S. in 2010, and about 28,000 will die from this disease.

- The early detection and appropriate treatment of clinically significant and potentially lethal prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risk.
    - Every man has the right to know whether he is at risk for potentially lethal prostate cancer.
    - Experts disagree on the adequacy and usefulness of currently available tests to identify men at risk for potentially lethal prostate cancer early enough to offer curative therapy.
    - African-American men have one of the very highest rates of incidence and death from prostate cancer anywhere in the world.
    - Physicians and their adult male patients should be encouraged to discuss the patients' personal risks for prostate cancer and the individual need for prostate cancer testing at each patient's annual physical exam.
    - Men at higher levels of risk for prostate cancer (because of ethnicity, family history, and other factors) should be encouraged to undergo appropriate tests at a relatively early age.
- Until more accurate tests are available, all health care insurance plans should include coverage of regular testing for prostate cancer (including the prostate-specific antigen or PSA test and the digital rectal examination or DRE) – and its subsequent diagnosis.
- Additional funding is urgently needed to support research into better ways to identify and discriminate between very low risk ("indolent") and higher risk (clinically significant and potentially lethal) forms of prostate cancer at the time of diagnosis ***and*** into better forms of management for patients with or at risk for potentially lethal disease.
    - Most specifically, we support a significant increase in funding for the Prostate Cancer Research Program (PCRP) of the Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense, which has been funded at $80 million each year since 2001.
- We continue to support the need for an Office of Men's Health (comparable to the highly successful Office of Woman's Health) within the Department of Health and Human Services (DHHS) that can represent the specific health interests of the male population of America.

In conclusion, we thank the Committee for its efforts and its leadership in many aspects of health care, and specifically for presenting this opportunity for the many issues affecting the prevention, diagnosis, and management of prostate cancer (and its clinical consequences) to be discussed in this public forum.

FOR THE RECORD

Committee on Oversight and Government Reform

Full Committee Hearing on:

"Prostate Cancer: New Questions about Screening and Treatment"

Thursday, March 4, 2010

10:00 a.m.

Room 2154, Rayburn House Office Building

Statement Submitted for Consideration by the Committee

Scott T. Williams

Men's Health Network
P.O. Box 75972
Washington, D.C. 20013

202-543-MHN-1
info@menshealthnetwork.org
www.menshealthnetwork.org

Committee on Oversight and Government Reform

Hearing on "Prostate Cancer: New Questions about Screening and Treatment"

March 4, 2010

Statement of Men's Health Network (MHN)

On behalf of Men's Health Network we applaud the Committee's decision to hold hearings on this critical health issue.

We also support the joint statement from America's Prostate Cancer Organizations which was submitted to this committee. MHN's additional recommendations are found on page 4 of this statement. Supportive materials begin on page 6.

Impact on Women and Families:

Prostate cancer does not affect men in isolation. Spouses, significant others, and children are too often emotionally, financially, and physically strained, and the diagnosis reaches beyond the family to impact friendships, employers, churches, and communities.

Prostate Cancer Incidence

Prostate cancer is the number one cancer in men and the second leading cause of cancer deaths among men. 37 states currently require private insurers to cover testing for prostate cancer, reflecting the public's concern about this issue. As this disease continues to strike one in six American men, it is important that patients and physicians engage in a meaningful conversation about prostate cancer, an individual's risk of getting the disease, and the value of early detection and prevention.

Screening/Detection/Treatment

Because of regular screening, including Prostate Specific Antigen (PSA) tests, prostate cancer death rates have fallen significantly. Prostate Specific Antigen (PSA) and the Digital Rectal Exam (DRE) are currently the most effective tools healthcare providers and patients have to detect a disease that kills over 27,000 men a year in the US.

Prostate cancer screening is particularly important for those segments of the population and individuals who are identifiable as high risk, including African American men and men who have a family history of prostate cancer.

Recognizing that prostate cancer can be treated successfully if caught early, the American Urological Association currently recommends that men consider a "baseline" prostate cancer test at age 40.

In addition to the approximately 200,000 men who are diagnosed with prostate cancer each year, we must remember that the disease can have a devastating effect on entire communities.

The detection and treatment of prostate cancer is a variable process, involving a number of important factors and requiring knowledge and understanding by both men and their healthcare providers. Important research progress is being made in developing better, more specific diagnostic tools for prostate cancer. However, until we have them at our disposal, we need to bring clarity to the debate, and continue utilizing the tests and tools we have while informing patients and their families about the benefits of screening and the risks involved with various treatments.

Prostate cancer testing has been supported by a resolution of the Democratic National Committee in September 2009 and by President Obama in a town hall meeting and again in a Weekly Address on August 15, 2009 (see appendix below). President Obama said that he would "require insurance companies to cover routine checkups and preventive care" so that "diseases like breast cancer and prostate cancer" can be detected early.

Patient Navigation / Education / Informed Treatment Decisions

Patient navigation and education are key elements in helping patients with their fight against prostate and other cancers. Even well-educated patients with access to resources often have difficulty understanding the labyrinth of medical care and treatment options in the face of prostate cancer. Patient navigators are essential to helping patients make informed decisions and understand the options for treatment, and possible outcomes.

Patient navigation has also been shown to be effective in reducing disparities, as well as mortality rates.

We acknowledge the key role that oncology nurses and nurse navigators, physician assistants, nurse practitioners, and many others play in the health and well-being of men and their families.

Healthcare Reform / USPSTF

We are concerned that the health care needs of males, and the prostate cancer community, are not adequately addressed in healthcare reform legislation currently being considered. Men's health and well-being has a crucial financial and social impact within American families and communities. This impact is highlighted by an Administration on Aging study which found that more than half the elderly widows living in poverty were not poor before the death of their husbands.[1]

According to the United States Census Bureau, the ratio of men to women in the early retirement years (age group 65-69) reduces to 85 men per 100 women.[2] The growing disparity in this statistic suggests that among other factors, the declining health of men increases the risk of women entering retirement age as widows.

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[1] Meeting the Needs of Older Women: A Diverse and Growing Population, The Many Faces of Aging, U.S. Administration on Aging. June 20, 2001

[2] Premature Death Among Men = Poverty for Aging Women, found at www.menshealthnetwork.org/library/retireratio.pdf

We also understand that health disparities exist and that Healthy People 2010 made one of its core issues the elimination of gender disparities, a goal largely unrealized over the past 10 years. Across all racial and ethnic categories, American men live less healthy lives and die younger than American women. Engaging men in health care has enormous benefits for women, children, and society.

Recent changes in national guidelines and standards for mammography screenings from the United States Preventive Services Task Force (USPSTF) have caused a flurry of discussion around the role of the Task Force. Men's Health Network has monitored their recommendations closely for many years and is concerned that the USPSTF does not recommend prostate cancer testing even while the use of the DRE and PSA continues to save lives.

We are also concerned that the recommendations of the USPSTF will override the prostate cancer testing benefit required of insurance companies in 37 states (and currently available to millions of men across the country), the life-saving benefits offered to those entering Medicare, the wishes of the Democratic National Committee, and the promises made by the President of the United States, Barack Obama.

We are concerned that the failure to recognize the benefits of early detection of prostate cancer (and breast cancer) will result in the unnecessary suffering of cancer victims and their families.

Recommendations:

In addition to the concerns expressed in the joint statement submitted by America's Prostate Cancer Organizations, we offer the following suggestions:

- *Health Reform Legislation*. A comprehensive preventive health care screening package for men that mirrors the preventive health screening package for women that was added to the Senate health reform bill is a top priority.

- *Office of Men's Health*. We support HR 2115, bipartisan legislation which would establish an Office of Men's Health within the Department of Health and Human Services for the purpose of improving the health of men and their families. This Office will mirror the existing Office of Women's Health, established in the early 1990s, which has improved the quality of life for women nationwide.

  The Office of Men's Health will be designed to monitor and coordinate efforts to improve the health and well-being of men by streamlining government efforts on the federal and state levels in the areas of prevention, health education, outreach, and research. The office would conduct and support programs and activities to improve the state of men's health in the United States. It would provide for consultation among offices and agencies of HHS for the purpose of coordinating public awareness, education, and screening programs and activities relating to men's health.

- *Least Costly Alternative (LCA)*. We urge Congress to demand that the Centers for Medicaid & Medicare Services (CMS) rescind the Least Costly Alternative policy for prostate cancer drug therapies to ensure patients have equitable access to vital drug

treatments. This policy drives healthcare providers to make treatment decisions based on cost, rather than clinical factors.

LCA unfairly singles out prostate cancer patients, disproportionately affects low-income patients, and does not apply to other conditions. LCA policies for prostate cancer drugs are inappropriate because they substitute Medicare's determination that certain drugs are interchangeable for the physician's professional judgment that one drug may be more efficacious or have fewer side effects for a particular patient. LCA is not provided for in statute, Furthermore, the District of Columbia Appellate Court has ruled that this is not based in law, and CMS does not have statutory authority to continue the least costly alternative policy. Therefore, we call on Congress to abolish this unfair and unjust rule that disenfranchises prostate cancer patients

- *Research*. We have some of the brightest minds in this country working on research and development of breakthrough therapies, tests, and treatments for prostate cancer, but they are drastically underfunded. We need to find better ways to support these efforts, while continuing to keep our focus on improving the lives of patients and their families. We are close to significantly moving the needle in the prevention, treatment, and management of prostate cancer for men and their families. As a nation we should be committing resources and expertise toward ensuring the continuation of these exciting new developments.

- *Treatments Options / Innovation*. Cutting edge research and development and novel innovative discoveries will lead to new treatment options for advanced stage disease as well as opportunities for prevention and earlier detection of prostate cancer. We should *Fast Track* new therapies through FDA to facilitate the development and expedite the review of drugs and treatments that will help improve the lives of victims of prostate cancer.

  The utmost should be done to support public education campaigns to inform men and their families of new treatment options, tests, and risk reduction and/or prevention therapies for prostate cancer when they become available.

Appendix

State requirements on insurance providers:

Currently 37 jurisdictions require that insurance companies operating in those states provide coverage for prostate cancer tests. A July 17, 2009 letter to this Committee on this issue, signed by the majority of prostate cancer advocacy organizations, is attached. (Arkansas became the 37th earlier this year, joining the 35 states and the District of Columbia mentioned in the accompanying letter to the Committee.)

A total of 50 jurisdictions, 49 states and the District of Columbia, require the same benefit for breast cancer screening (mammograms), Utah being the exception.

Role of the USPSTF:

Secretary Sebelius stated in her November 18, 2009 comments on the new breast cancer screening recommendations:

> "The U.S. Preventive Task Force is an outside independent panel of doctors and scientists who make recommendations. They do not set federal policy and they don't determine what services are covered by the federal government."

But, under the health care bill passed by the House of Representatives and the bill passed by the Senate, the USPSTF will do exactly that: determine which services are covered by a public plan offered by federal government while setting minimum standards for private insurance policies – thereby effectively overriding the prostate cancer test wishes of 37 state legislatures.

This language from HR 3962 as passed by the House of Representatives on November 16, 2009:

> Sec. 222. Essential Benefits Package Defined.
> (a) In General- In this division, the term `essential benefits package' means health benefits coverage, consistent with standards adopted under section 224, to ensure the provision of quality health care and financial security, that--
> . . .
> (8) **Preventive services, including those services recommended with a grade of A or B by the Task Force on Clinical Preventive Services** and those vaccines recommended for use by the Director of the Centers for Disease Control and Prevention.
> . . .
> (1) **No Cost-Sharing For Preventive Services** - There shall be no cost-sharing under the essential benefits package for--
> (A) **preventive items and services recommended with a grade of A or B by the Task Force on Clinical Preventive Services** and those vaccines recommended for use by the Director of the Centers for Disease Control and Prevention; or. . . .

The "Task Force on Clinical Preventative Services" will consist of the members of the USPSTF and others, and the current recommendations of the USPSTF will be the initial recommendations of the "Task Force on Clinical Preventative Services":

> `Subtitle G--General Provisions
> `SEC. 3171. Definitions.
> `In this title:
> . . . . . .
> (b) Transition Provisions Applicable to Task Forces-
> (1) Functions, Personnel, Assets, Liabilities, And Administrative Actions- All functions, personnel, assets, and liabilities of, and administrative actions applicable to, the Preventive Services Task Force convened under section 915(a) of the Public Health Service Act and the Task Force on Community Preventive Services (as such section and Task Forces were in existence on the day before the date of the enactment of this Act) shall be transferred to the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively, established under sections 3131 and 3132 of the Public Health Service Act, as added by subsection (a).
> (2) **Recommendations- All recommendations of the Preventive Services Task Force** and the Task Force on Community Preventive Services, **as in existence on the day before the date of the enactment of this Act, shall be considered to be recommendations of the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively**, established under sections 3131 and 3132 of the Public Health Service Act, as added by subsection (a).
> (3) Members Already Serving-
> (A) **Initial Members**- The Secretary of Health and Human Services may select those **individuals already serving on the Preventive Services Task Force** and the Task Force on Community Preventive Services, as in existence on the day before the date of the enactment of this Act, **to be among the first members appointed to the Task Force on Clinical Preventive Services** and the Task Force on Community Preventive Services, respectively, under sections 3131 and 3132 of the Public Health Service Act, as added by subsection (a).

President Obama addresses the need for early detection of breast and prostate cancer:

The availability of tests, while not perfect, which can identify cancer in an early stage is certainly responsible for the increased detection of early stage, treatable prostate cancer and breast cancer, and the dramatic reduction in deaths from those cancers over the past two decades.

Those tests should be made available so that we might continue to identify cancers while they are treatable, thereby saving the lives of mothers, fathers, brothers, sisters, husbands, wives, and other loved ones.

President Obama promised as much in his weekly address of August 15, 2009:

> "Finally, we'll require insurance companies to **cover routine checkups and preventive care**...because there's no reason we shouldn't be saving lives and dollars by catching diseases like **breast cancer and prostate cancer** on the front end."

This followed a similar statement he made at the Town Hall meeting in Portsmouth, New Hampshire on August 11, 2009

The Democratic National Committee calls for prostate cancer screening and tests:

The President's commitment was reinforced by the Democratic National Committee at the DNC Annual Meeting in Austin held over September 10-12, 2009 in a resolution which concluded:

> Therefore Be It Resolved, that the Democratic National Committee urges action to promote prostate cancer screening and testing

That resolution in support of prostate cancer testing is attached to this statement.

The "Welcome to Medicare" physical provides for prostate cancer screening tests:

As to Medicare, Congress has provided an excellent prostate cancer screening benefit, available to any man aged 50 and above who is enrolled in the program:

> Title 42--The Public Health And Welfare - Chapter 7--Social Security
> Sec. 1395x. Definitions
> . . . . .
> (oo) **Prostate cancer screening tests**
> (1) The term ``prostate cancer screening test'' means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer **to a man over 50 years of age** who has not had such a test during the preceding year.
> (2) The procedures described in this paragraph are as follows:
> **(A)** A digital rectal examination.
> **(B)** A prostate-specific antigen blood test.
> **(C)** For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.
> . . . . .
> (ww) Initial preventive physical examination
> (1) The term ``**initial preventive physical examination**'' means physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2), but does not include clinical laboratory tests.
> **(2) The screening and other preventive services described in this paragraph include the following:**
> . . . . .
> **(D) Prostate cancer screening tests as defined in subsection (oo) of this section.**

Democratic National Committee

September 10-12, 2009

Resolution Urging Action to Promote
Prostate Cancer Screening and Testing

WHEREAS, one in every six men in the United States will be diagnosed with prostate cancer; and,

WHEREAS, nearly 30,000 men in the United States will die of prostate cancer this year; and,

WHEREAS, nearly 200,000 men in the United States will be diagnosed with prostate cancer this tear; and,

WHEREAS, prostate cancer is the second most common cancer in American men; and,

WHEREAS, Senator Chris Dodd was recently diagnosed with prostate cancer and received timely treatment because of early detection; and,

WHEREAS, the American Urology Association recommends prostate cancer screenings such as PSAs and other diagnostic tools as part of a detection and treatment protocol;

THEREFORE BE IT RESOLVED, that the Democratic National Committee urges action to promote prostate cancer screening and testing

July 17, 2009

The Honorable Henry Waxman
Chairman
Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Joe Barton
Ranking Member
Energy and Commerce
2322-B Rayburn House Office Building
Washington, DC 20515

Dear Representatives,

The undersigned organizations commend Congress and the Administration for seeking ways to extend health benefits to all Americans, and to make prevention the cornerstone of that effort. However, we are concerned that the health care needs of males, and the prostate cancer community, are not adequately addressed in the legislation currently being considered. We are also concerned that these bills appear to preempt state benefit laws that now require private insurers to provide a number of critical services, including tests for prostate cancer, the number one cancer in men.

Men's health and well-being has a crucial financial and social impact within American families and communities. This impact is highlighted by an Administration on Aging study which found that more than half the elderly widows living in poverty were not poor before the death of their husbands.[3] We also understand that health disparities exist and that Healthy People 2010 made one of its core issues the elimination of gender disparities.

Across all racial and ethnic categories, American men live less healthy lives and die younger than American women. Engaging men in health care has enormous benefits for women, children, and society.

Specifically, we encourage language within the final health reform legislation that will address these concerns:

- Current state mandates on health insurance coverage must be honored. The Essential Benefits Package as presently written (in the House bill) will offer only those preventive services actively recommended by the US Preventive Services Task Force (USPSTF). However, the USPSTF does not recommend many services now required by many different states. As just one example, at least 36 states require private insurers to cover testing for prostate cancer. The 2006 Census estimates found over 35 million men between the ages of 40 and 64 in those 36 states. Those 35 million men now have coverage for prostate cancer testing if they have health insurance. They will not be covered under the Essential Benefits Package unless state mandates are honored, and would therefore lose their right to understand their potential for risk of the most prevalent form of cancer in men
- The Senate and House bills each establish means whereby government will determine how best to proceed with prevention and wellness activities in both the private and public sectors. In making these determinations, advice will be sought by the heads of various agencies, including the Office on Women's Health.

  This highlights the need for an Office on Men's Health to advise, recommend and direct wellness and prevention efforts for men and boys.

[3] Meeting the Needs of Older Women: A Diverse and Growing Population, The Many Faces of Aging, U.S. Administration on Aging. June 20, 2001

Signed:

Accelerate Progress
Malecare
Men's Health Network
National Alliance of State Prostate Cancer Coalitions
Out With Cancer – The LGBT Cancer Project
Prostate Cancer International
Prostate Cancer Foundation
Prostate Conditions Education Council
Prostate Health Education Network
The Prostate Net
Us Too International
Women Against Prostate Cancer
Zero – The Project to End Prostate Cancer

State Organizations:
Alaska - Alaska Prostate Cancer Coalition
Arkansas - Arkansas Prostate Cancer Foundation
California - California Prostate Cancer Coalition
Colorado – PCEC Colorado Coalition
Connecticut - Prostate Cancer Education Forum of Connecticut
Georgia - Georgia Prostate Cancer Coalition
Hawaii - Hawaii Prostate Cancer Coalition
Kansas - Kansas Prostate Cancer Coalition
Kentucky - Kentucky Prostate Cancer Coalition
Maine - Maine Coalition to Fight Prostate Cancer
Maryland - Maryland Prostate Cancer Coalition
Michigan - Prostate Cancer Coalition of Michigan
Nevada - Nevada Prostate Cancer Task Force
New Hampshire - New Hampshire Prostate Cancer Coalition
New Jersey - Prostate Cancer Coalition of New Jersey
New York - New York State Prostate Cancer Coalition
North Carolina - Prostate Cancer Coalition of North Carolina
Pennsylvania - Pennsylvania Prostate Cancer Coalition
Pennsylvania - Obediah Cole Foundation for Prostate Cancer
Texas - Texas Prostate Cancer Coalition
Virginia - Virginia Prostate Cancer Coalition
West Virginia - Dan Blue Prostate Cancer Foundation

For the Record

To: The House Committee on Oversight and Government Reform

Re: Hearing on "Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

We wish to thank the Committee for allowing us to present four important issues, on behalf of the thousands of men, their loved ones and their families, whom Malecare serves.

Founded in 1998, Malecare is our country's first and leading Gay men's cancer survivor support group and advocacy national nonprofit organization. All who work for Malecare are volunteers. Malecare publishes the worlds' largest multi-lingual prostate cancer focused website, malecare.org and several online support groups. Malecare is noteworthy for facilitating the largest grass roots prostate cancer survivor advocacy effort in over ten years. The Petition to make Prostate Cancer a National Priority currently has over 16,300 signatures of Americans who ask this Committee to increase federal funding for prostate cancer research.

Malecare has four unique programs, focused on men diagnosed in their thirties and forties, African American men, Gay men and men diagnosed with advanced disease, relevant to the Committee's discussion on prostate cancer screening and treatment.

Malecare's "Prostate Cancer under 50" is our country's only psycho-social support program for men diagnosed in their thirties and forties. We've seen approximately 700 men benefit from our program, with more men enrolling every day. From our experience, we can suggest that men diagnosed in their thirties and forties are more likely to die than men diagnosed later in later years. We ask the Committee to support promotion of prostate cancer information to all men from age 35 and up, during medical consultations.

Our New Dad program teaches patenting skills young African American experiencing their first child. Integrated in our parenting skills workshops and website is the need for early vigilance around health care. Mixed messages about screening and access to healthcare diminish our capacity to help young African American men find reason to ask about prostate cancer during personal medical consultations. We ask the Committee to support promotion of prostate cancer awareness in our African American community.

Malecare is our country's only national nonprofit focused on psycho-social support for men with advanced and terminal stage prostate cancer. Advanced prostate cancer is not curable. Approximately 27,000 American men died from prostate cancer in 2009 and comparable numbers will continue to die, every year, until there is a durable, morbidity free treatment or cure.

End stage treatments present debilitating morbidity and degrees of hope measured in days, weeks and months. Often, men learn of drugs and treatment protocols that might help, but are not yet available as they wait for outcomes of clinical trials and FDA approval. We ask the Committee to work with the FDA to create a mechanism for early and compassionate access to investigational or yet to be approved drugs and treatment protocols.

Current debate seems to have shifted focus towards those who live with their disease rather than those men who die from their disease. We need to refocus our consideration of prostate cancer towards helping those most likely to die from prostate cancer. We ask the Committee to support increased funding and promotion for research into end stage treatment.

Approximately 10% of all American men diagnosed with prostate cancer are men who have sex with men. Malecare is our country's only cancer survivor support and advocacy national nonprofit focused on gay and bisexual men, and transgender women. Prostate cancer presents unique and only recently understood psycho-social challenges for gay men. Unfortunately, we are still in the dark about the disparities of prostate cancer incidence and outcomes of homosexual and heterosexual men.

Approximately 800, 000 men in the United States are HIV positive, and innovative therapies have dramatically improved survival. Prostate cancer is a common malignancy in HIV-positive men. With improved therapies for HIV and increasing survival, the importance for screening and treating prostate cancer is increasing.

In a 2004 paper, Dr. Crum and her colleagues concluded that HIV-positive men aged 60-70 years had a higher rate of cancer diagnosis compared to an age-matched US general population rate. Dr. Hessol and her colleagues recently found that a cohort of HIV positive men in San Francisco had a significantly higher incidence of prostate cancer than the general population. In New York City, at the February 11, 2009 Gay Men and Prostate Cancer forum sponsored by the American Cancer Society, 50% of the audience self disclosed that they were both HIV positive and diagnosed with prostate cancer.

Many HIV positive men are receiving testosterone replacement and are not adequately being screened. If HIV truly does represent a risk for prostate cancer, then more rigorous screening may be necessary among men who have sex with men as a whole, and especially in those on testosterone replacement therapy. We ask the Committee that all funding for prostate cancer research include stipulations that men who have sex with men be identified and considered as a unique and significant cohort.

We thank the Committee for its leadership and for providing the opportunity to present four critical issues in prostate cancer regarding men diagnosed in their thirties and forties, African American men, Gay men and men presenting with late stage disease.

Presented by

Darryl Mitteldorf, LCSW

Executive Director

Malecare

125 Second Avenue

New York NY 10003

212 673 4920

darryl@malecare.com

FOR THE RECORD

House of Representatives
Committee on Oversight and Government Reform

Hearing on:
"Prostate Cancer: New Questions About Screening and Treatment"

10:00 a.m.
Rayburn 2154

Thursday, March 4, 2010

Statement Submitted for Consideration by the Committee

Women Against Prostate Cancer
236 Massachusetts Avenue, NE
Suite 301
Washington, DC 20002
P: 202-580-5730
tmorrow@womenagainstprostatecancer.org
www.womenagainstprostatecancer.org

Committee on Oversight and Government Reform

Hearing on "Prostate Cancer: New Questions About Screening and Treatment"

March 4, 2010

Testimony of
Women Against Prostate Cancer

Women Against Prostate Cancer (WAPC) would like to thank Chairman Towns and the Committee for holding this important hearing. We appreciate the opportunity to submit testimony on a topic that has a significant impact on our constituents and thousands of other men, women and families.

The mission of Women Against Prostate Cancer is to unite the voices and provide support for the millions of women affected by prostate cancer. As health care leaders of the household, the role that women play in all phases of prostate cancer from preventive screenings to treatment and follow-up care is critical.

Our membership is made up of wives, partners, mothers, daughters, sisters, widows, caregivers, healthcare professionals and advocates who have been touched by prostate cancer. Below we have shared stories from a few of our members that express the essential role that women play in the lives of the men they love when diagnosed with prostate cancer:

- Betty Gallo of NJ: When Betty's husband, former Congressman Dean Gallo, was diagnosed with prostate cancer in 1992, the PSA, so widely used today for diagnosing prostate cancer, was not utilized. "Dean went to the doctor for back pain," Betty shares, "But by then it was too late. The cancer had already spread to his bones." Unfortunately Dean did not survive his battle, but Betty continues on as a dedicated advocate who wants to make sure no man or woman has to experience the frustration and lack of resources that they had.

- Kathy Meade of Virginia: "Together we fought an aggressive and valiant fight against his cancer, working as a team to understand his disease and treatment options, and face difficult choices. He knew he was the ultimate decision maker, but he deferred to me for information, analysis and common sense."

- Gail Puffer of Connecticut: When her husband was diagnosed she "gathered information, organized lab work and office visit notes, and explored treatment options." She said, "The doctors loved that I have done some research. My familiarity with terms made us more conversant and better informed." Gail expresses some additional needs to help prostate cancer patients and families, "We also need to know more about what to expect when first diagnosed. If added to the treatment team, trained professionals, such as social workers, nurses or therapists, can help us get over some of the hurdles." She also shares, "due to my husband's diagnosis my concerns are now very much with my sons who are at an increased risk for the disease," indicating her continued concern for better early detection methods.

- Sherrie Ellenburg of North Carolina: "In December 2003, the doctors concluded that Kenny's cancer was too advanced for surgery. At 42 years of age, his only treatment option was radiation with hormone therapy." "He did his part by encouraging his family and friends to have their yearly exams. His brother, Bryan, was his first success story when a year after Kenny's death he was diagnosed through early detection." Unfortunately Kenny did not survive his disease, but Sherrie remains a very active advocate and expresses, "My biggest frustration throughout this ordeal was dealing with the finances. The financial struggles that we faced were so insurmountable at times I did not know how we would

make it. We were thankful for every day we had together. However, instead of enjoying those last moments, we had to focus on how to provide the basics – food, electricity, and pay our mortgage – with no income. We applied for disability but were repeatedly denied. Finally, six months before his death he was approved. It was amazing to see how his quality of life improved! The struggle of treatment is a painful enough journey without the added financial pressures, such as we had to endure."

These are just a few of the stories we hear everyday that express the critical role that women play and how prostate cancer significantly impacts the entire family.

In addition to our testimony outlined below, we fully support the group testimony submitted by America's Prostate Cancer Organizations. As a collaborative partner in the group we share the goal that all such men should receive the most appropriate advice and care, and that we continue to limit the devastating impact of prostate cancer on men and their families.

We wish to express the following concerns for the Committee to consider:

- Prostate cancer is a complex and problematic disease that affects not only the male patient but can also be devastating to his wife or partner and other family members over many years. Nearly 200,000 men will be diagnosed with prostate cancer in 2010, and about 28,000 will die from this disease. With Approximately 2 million men currently living with prostate cancer, there are countless partners, spouses and loved ones who are also suffering from the effects of this disease. In addition, we are concerned about the reported increase in the percentage of younger men (35 – 60 years old) being diagnosed with metastatic prostate cancer which has lead to increased strain and stress placed on families with young children who in many cases will grow up without a father.

- More support and education is needed for partners, caregivers and the entire family when a man is diagnosed with prostate cancer. Women play a very important role in the screening, diagnosis, treatment and recovery phases of prostate cancer.

    - As health care leaders of the household, women often provide the extra encouragement and reminders that men need to make an appointment with a physician for regular check-ups, prostate exams or when symptoms appear.
    - Women often attend doctor's appointments with their loved ones to provide support, ask questions and take notes.
    - If diagnosed with prostate cancer, there may be several treatment options and partners and spouses often play an important role in researching the options and helping their loved one decide which option is best for them.

- The early detection and appropriate treatment of clinically significant and potentially lethal prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risk.

    - African-American men have one of the very highest rates of incidence and death from prostate cancer anywhere in the world. The increased rates in this community have a significant impact on the spouses and families of those with the disease.
    - Every man has the right to know whether he is at risk for potentially lethal prostate cancer.
    - Experts disagree on the adequacy and usefulness of PSA and DRE testing to identify men at risk for potentially lethal prostate cancer.
    - Physicians and their adult male patients should be encouraged to discuss the patients' personal risks for prostate cancer and the individual need for prostate cancer testing at each patient's annual physical exam.

  - Men at higher levels of risk for prostate cancer (because of ethnicity, family history, and other factors) should be encouraged to undergo appropriate tests at a relatively early age.
  - Additional funding is needed to increase outreach and promotion of clinical trials. These trials provide crucial information to researchers and experts on better screening, detection and treatment options. NCI should provide grants to provide outreach for clinical trials.

- Until more accurate tests are available, all health care insurance plans should include coverage for annual tests for prostate cancer (including the prostate-specific antigen or PSA test and the digital rectal examination or DRE) – and follow-up diagnostic testing when appropriate. The PSA is not a perfect test, but it is all we have right now.

- Additional funding is urgently needed to support research into better ways to identify and discriminate between very low risk ("indolent") and higher risk (clinically significant and potentially lethal) forms of prostate cancer at the time of diagnosis and into better forms of management for patients with or at risk for potentially lethal disease.

  - Most specifically, we support a significant increase in funding for the Prostate Cancer Research Program (PCRP) of the Congressionally Directed Medical Research Program (CDMRP) at the Department of Defense, which has been funded at $80 million each year since 2001. We would like to see this funding increased to $125 million per year in order to continue and increase the important research that is being done.

- We continue to support the need for an Office of Men's Health (HR 2115), comparable to the highly successful Office of Women's Health, within the Department of Health and Human Services (HHS) that can represent the specific health interests of men and their families.

In conclusion, we would like to thank the Committee for all of its work on this issue and allowing the opportunity for patient organizations like ours to provide input into a discussion whose outcome will impact thousands of men, women and their families across the country.

NCI Statement for the Record
For the Committee on Oversight and Government Reform Hearing
"Prostate Cancer: New Questions About Screening and Treatment."

Prostate cancer is a complex spectrum of diseases ranging from indolent to life threatening. However, current methods do not predict the aggressiveness of prostate cancer with reliability. This challenge is a subject of much NCI funded research on prostate cancer. It is important that research focus on developing and testing biomarkers (e.g., serum, urine, tissue, etc.) and imaging that can provide insight into tumor aggressiveness.

It is critical that the NCI research portfolio be broadly distributed and not directed at just one area - each method has potential advantages and disadvantages. Methods that predict cancer the best should be the first methods used, and the choice of what methods to use should be data-driven. At this point, there is no reason to favor imaging over other biomarkers for the prediction of tumor aggressiveness.

TESTIMONY FOR THE RECORD
AMERICAN UROLOGICAL ASSOCIAITION

House Committee on Oversight and Government Reform
Prostate Cancer: New Questions About Screening and Treatment
March 4, 2010

There has been a great deal of debate about prostate-specific antigen (PSA) testing, commonly used for detection of prostate cancer. Urology is the medical specialty that diagnoses and treats prostate cancer, and the American Urological Association (AUA), which represents more than 16,000 urologists and urologic health professionals worldwide, speaks on behalf of the profession.

On March 4, 2010, the House Committee on Oversight and Government Reform held a hearing entitled *Prostate Cancer: New Questions about Screening and Treatment.* While the AUA did not participate in the hearing, we do wish to submit testimony.

Recently, the frequency and validity of PSA testing has been questioned, and during this discussion, the AUA's position on PSA testing been misinterpreted. To be clear, the AUA stands in support of appropriate prostate cancer testing. However, the AUA does not advocate universal annual PSA testing for all men, nor does it support routine biopsy. Research has shown that a PSA above a certain level at age 40 is a stronger predictor of prostate cancer risk than family history or race, which are commonly viewed as leading risk factors. The AUA recommends that men ages 40 and older talk to their doctors about prostate health and the pros and cons of establishing a baseline PSA score. Establishing a baseline PSA at age 40 empowers patients and doctors to make informed decisions about future testing. The AUA also clearly states that follow-up should be determined based on a patient's individual risk and discussions with his doctor.

We feel that the recent debate is inappropriately focused on the PSA test itself, when we should be focusing on how test results are being interpreted and impacting treatment decisions. The 2009 *AUA Best Practice Statement on Prostate-specific Antigen* presents a balanced assessment of the test's strengths and weaknesses and provides comprehensive guidance on how to appropriately interpret test results based on a patient's individual risk factors.

Early detection of prostate cancer is of the utmost importance. However, current early detection strategies need to be refined and validation improved. Additionally, the AUA affirms that we should better direct our country's limited resources to our most critical needs. With this idea in mind, the American Urological Association Foundation's Research Council will soon be releasing the National Urology Research Agenda (NURA). The NURA identified the ability to distinguish between aggressive and indolent prostate cancer to be of the highest priority. Currently, there is no adequate test to determine whether one's prostate cancer will progress, requiring treatment. The NURA would focus research on biomarkers and the evaluation and development of additional clinical tools to identify aggressive cancers. Not only would significant efficiencies and cost savings be naturally achieved, but the delivery of high-quality patient care would be greatly improved.

Congressionally Directed Medical Research Programs (CDMRP)
Department of Defense Prostate Cancer Research Program
Army Medical Research and Materiel Command

Hearing Follow up Statement for the Record
For the House Committee on Oversight and Government Reform Hearing
"Prostate Cancer: New Questions About Screening and Treatment".

CDMRP is providing the following link to its publication for reference by the Committee and the public: http://cdmrp.army.mil/pubs/pips/pcpip.pdf

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