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Before

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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.

[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.