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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)

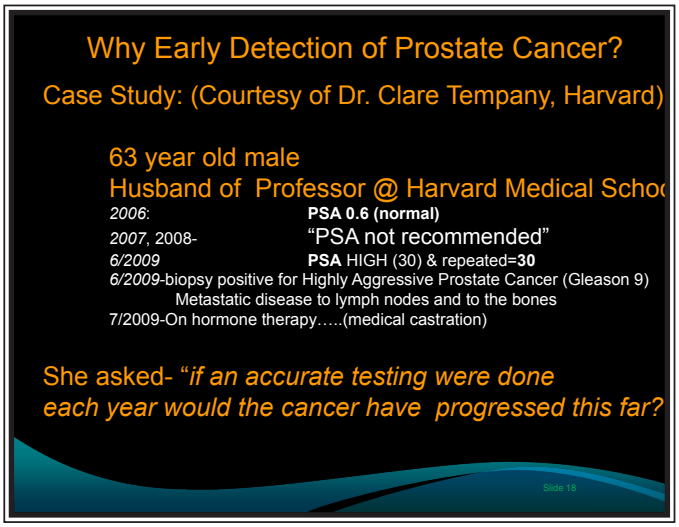

Figure 1

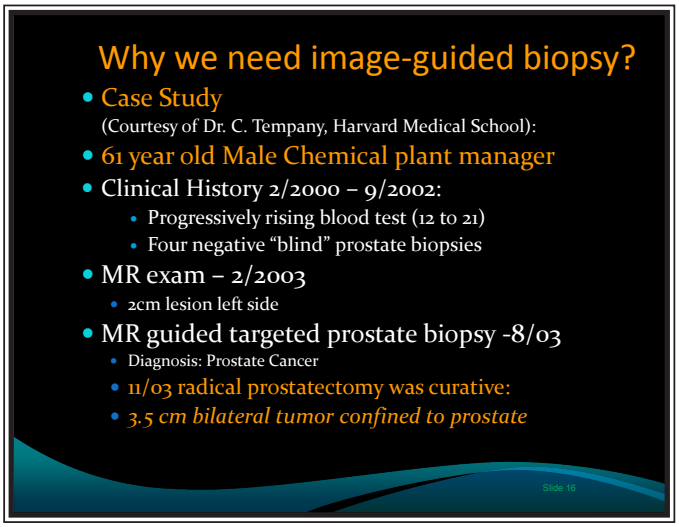

Figure 2

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)**.

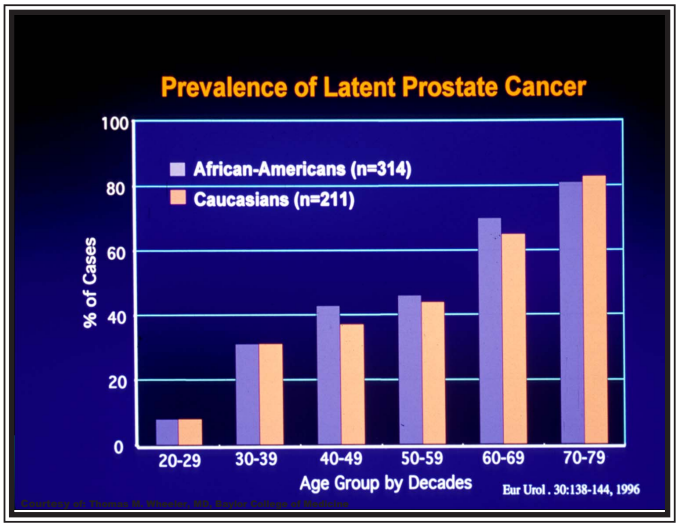

Figure 3

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)**.

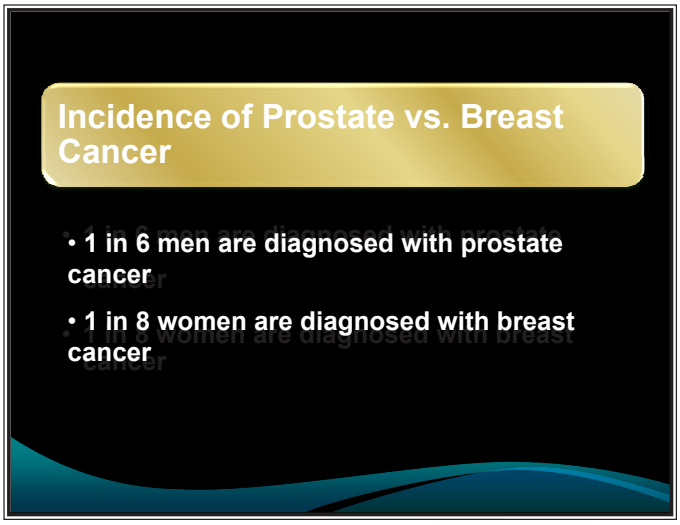

Figure 4

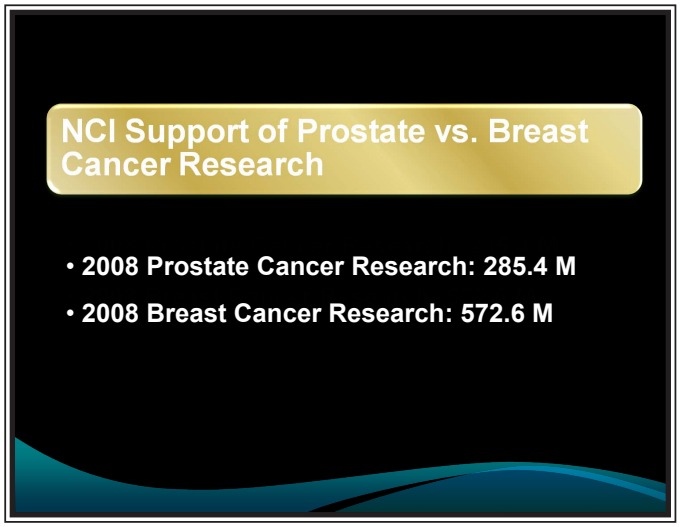

Figure 5

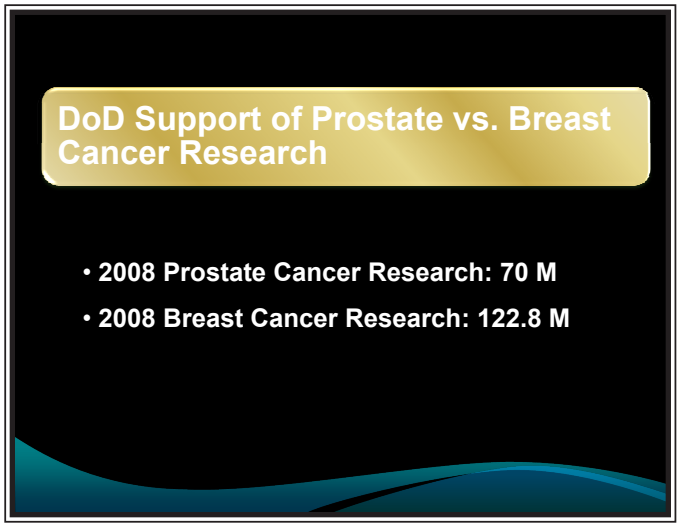

Figure 6

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 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

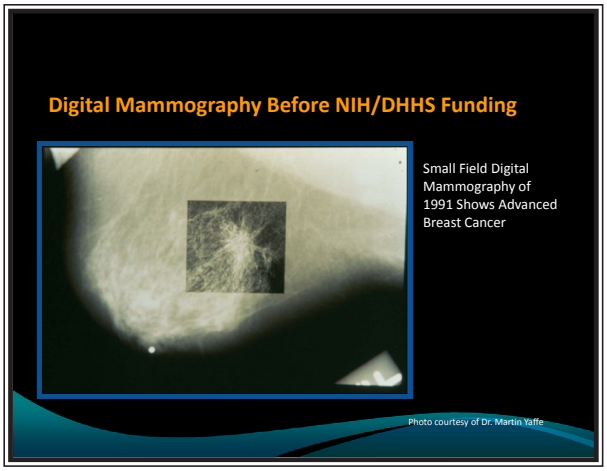

Figure 7

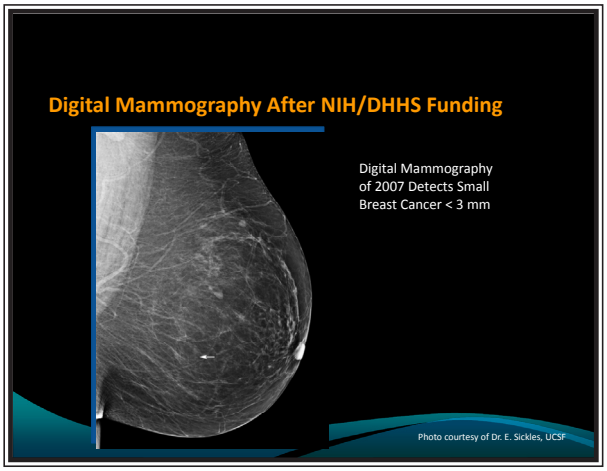

Figure 8

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

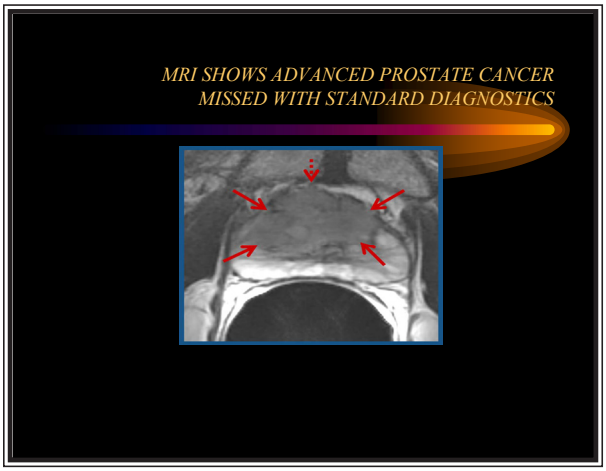

Figure 9 Courtesy of Dr. Hedvig Hricak, Memorial Sloan Kettering Cancer Center

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.

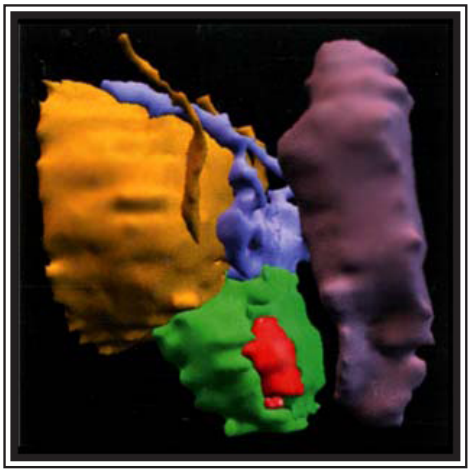

Figure 10 Courtesy of Surgical Planning Laboratory, Harvard Medical School

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