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◆ **AGENT ORANGE AND PROSTATE CANCER REVISITED** ◆

By
Ray Walsh

INTRODUCTION

Based on the Agent Orange Act of 1991, the Department of Veterans Affairs (VA) has determined that a positive association exists between exposure to herbicides and the subsequent development of adenocarcinoma of the prostate. Manifestation of prostate cancer in veterans who served in Vietnam between January 9, 1962 and May 5, 1975 is considered a service-related disability for which they should be compensated. A veteran qualifies no matter when this disease appears following a tour in Vietnam. The act also established the positive association with ten other health conditions. In a recent development, Navy and Coast Guard personnel who served aboard ships off the Vietnamese coast (so-called "Blue Water Navy") are seeking inclusion in the Agent Orange program; more about this later.

There is no time requirement when symptoms of the disease have to appear. Timeliness of the claim submission is of significant importance in determining the amount of compensation. A compensation application submitted immediately upon diagnosis of prostate cancer, prior to any treatment, could initially result in a 100 percent disability rating for at least six months.

Additionally, military retirees who receive a VA disability rating for Agent Orange related-prostate cancer may be eligible for compensation in the form of Combat Related Special Compensation (CRSC), or Concurrent Retirement and Disability Pay (CRDP) administered separately by the Military Services.

DISABILITY COMPENSATION FOR AGENT ORANGE-DERIVED PROSTATE CANCER

To receive disability compensation, a veteran must submit a Veteran's Application for Compensation or Pension (VA Form 21-526). If a veteran is receiving disability compensation for other conditions, a request for amended disability may be submitted in a letter application which documents the new disability. The claim is effective from the date of submission. When approved, payment of compensation begins the first day of the month following the submission date. The dollar value of compensation granted will be based on the disability rating awarded by the VA. There are no provisions for retroactive payments prior to the claim submission date.

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**◆ FROM THE EDITOR'S
DESK ◆**

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We learned that some Vietnam veterans now being diagnosed with prostate cancer are not fully aware that the herbicide Agent Orange was determined to be the presumed cause of prostate cancer and ten other diseases or medical conditions in men who served in Vietnam. Ray Walsh, our vice president, has extensive personal experience in dealing with the Veterans Administration and other agencies in establishing eligibility for Vietnam-related prostate cancer compensation. Fred Gersh, an US TOO Regional Director, provides information regarding the eligibility status of so-called "blue water navy" personnel for VA compensation. They share that information with us in this newsletter.



Our speaker at the November 1, 2006, quarterly meeting was Dr. Michael J. Manyak, The George Washington University Hospital and the Center for Prostate Disease Research at WRAMC. Dr. Manyak presented the latest developments in imaging technology affecting the diagnosis and treatment of prostate cancer. A summary of his presentation, "Advances in Imaging for Prostate Cancer," begins on page 14.



◆ PROGRAM FOR WEDNESDAY, FEBRUARY 7, 2007 ◆

Major Stephen A. Brassell, MC, is our speaker for February 7, 2007. He is Assistant Director of Clinical Research Programs and a Urologic Oncologist at the Center for Prostate Disease Research at WRAMC. His topic is "A Just Technology or Just Technology: Robotic versus Open Prostatectomy." Given the heightened interest in the Da Vinci Robotic System, Dr. Brassell's comparison of it with the traditional open prostatectomy should prove interesting. Join us at 7 PM on Wednesday, February 7, 2007, in Joel Auditorium. Plan now to attend and bring your spouse or a friend. They are always welcome.

recommendations for the individual reader. Consult with your physician before adopting any information contained herein for your personal health plan.

PROSTATE SPECIFIC ISSUES

As They Say, You're Never Too Old! There have been several recent recommendations to advance the age for a number of treatments that had been considered too risky for the elderly. The Mayo Clinic Cancer Center now has added radical prostatectomy to the list as a viable option for select octogenarian patients. This runs counter to the conventional practice of generally avoiding surgeries for individuals over 80 years old solely based on age. Lieber, et al., Mayo Clinic, say that increased life expectancy and generally higher levels of wellness, as well as safer forms of anesthesia and less-invasive surgical techniques, have made it possible for older adults to safely and effectively have surgeries traditionally not offered over a certain age. The researchers studied nineteen patients age 80 or older who underwent radical prostatectomy at Mayo Clinic from 1986 to 2003. The average patient age was 81; the average PSA was 10.2 ng/ml. Thirteen had pathological stage pT3 disease or a Gleason score of 7 or more. These were patients with very aggressive forms of prostate cancer. Of the 19 patients, 14 remained continent, none died within a year of surgery or from prostate cancer, and the 10-year survival rate was similar to that observed in healthy patients 60 to 79 years old undergoing a radical prostatectomy. Only three of the 19 died from any cause within 10 years of the surgery. The researchers concluded that aging is a highly individualized process, and treatment decisions should be made on a case-by-case basis; however, surgery can be offered to very healthy, active octogenarians with localized prostate cancer with satisfactory results. (Source: SeniorJournal.com. November 27, 2006)



Watchful Waiting - When is it Reasonable? Watchful waiting is an option for less aggressive prostate cancer, but doctors and patients are often reluctant to adopt it, fearing a lost opportunity for a cure. A recent Johns Hopkins study offers optimism about using watchful waiting for a select group of low-risk patients. All of the men in the Hopkins' study had Stage T1c cancer, a Gleason score of 6 or less, a PSA density of 0.15 or less, cancer present in no more than 2 cores, and no more than 50% of any core involved with cancer. Thirty-eight patients who delayed surgery for up to two years showed no greater risk of incurable cancer than 150 similar patients who had surgery immediately upon diagnosis. Age is another important consideration. Watchful waiting is discouraged for men younger than 65. The patient's own comfort level is another key factor. Many men, aware that they have a curable cancer, may find watchful waiting to be unbearable. Men who do select watchful waiting should be monitored with semiannual DREs, semiannual PSA testing, and annual prostate biopsies. If monitoring shows a change in PSA velocity, a Gleason score of 7, or more than 50% of one core, then other treatment options must be considered. The researchers continue to seek a group of biomarkers that will be able to predict disease progression while the disease is still curable. (Source: *Health after Fifty*, The Johns Hopkins Medical Letter; Vol 18, Issue 8, October 2006)



Watchful Waiting - A Second Opinion. A recent study published in the December 2006 issue of the Journal of the American Medical Association questions a wait-and-see approach to prostate cancer. The conventional wisdom is that many older men need not treat early prostate cancer because it tends to grow so slowly that they will die of some other health condition.

Wong, et al., Fox Chase Cancer Center, analyzed data from a Medicare database for about 44,300 men, ages 65 to 80, diagnosed with early prostate cancer. They compared the death rate of those who selected watchful waiting with those who selected radical prostatectomy or radiation therapy within six months of diagnosis. Those who were treated had about a 30 percent lower risk of death during the twelve years of follow-up. Even the oldest men, those between 75 and 80, were 27 percent less likely to die from the disease. Some commentators were skeptical of the study, questioning the study design. Some doctors feel that the cancer is being over-treated, especially in older men, subjecting them to therapies that leave many of them with significant side effects affecting their quality of life. The researchers acknowledge the comments, but cite increased longevity and advances in treatment techniques that minimize some side effects as reasons why aggressive treatment should not be determined solely by the patient's age. The patient's overall health and life expectancy are more important factors in the treatment option decision. (Source: *The Washington Post*, Section A, page 3, Wednesday, December 13, 2006)



Long-term Outcomes Among Localized Prostate Cancer Survivors: Surgery Side Effects More Stable. A study in the *Journal of Clinical Oncology* looked at the long-term side effects of various treatments for early-stage prostate cancer. Researchers at the University of Michigan reported that although patients treated with radiation saw their initial side effects get better with time, they were likely to see new side effects appear as much as 6 years later. Side effects of surgical treatment were not found to change much over that period. Radical prostatectomy can lead to urinary incontinence and impotence. This improves in some men. But in an earlier study, the same researchers found that about 2.5 years after surgery, nearly 20% of men still had some problem with incontinence and close to 70% were impotent. In the same earlier study, the authors found that men who received external beam radiation also had a high rate of impotence 2.5 years after treatment, but few problems with incontinence. About 15% had rectal irritation from the radiation. Men treated with radioactive seed implants had different urinary problems. About one-fourth had irritation and trouble urinating but incontinence was not a problem. Three-fourths were impotent. The same men from the original study were asked about their symptoms about 6 years after their treatment. The new results were compared with the earlier findings. Men who had surgery reported no change in their symptoms from the time of the first survey. But men who got external radiation or seed implants did see changes in their symptoms. Urinary irritation (pain, burning, bleeding, or frequency) improved in the seed implant patients, and the rectal problems lessened in the external beam radiation patients. But both groups experienced more urinary incontinence, particularly the seed implant patients. Also, in both groups of radiation-treated men, an additional 10% of men had become impotent. When all the side effects were combined, surgically treated men had the best bowel function and even the best sexual function after 6 years, though by only a slight margin. The seed implanted men had the worst outcomes for sexual function and incontinence. The study concluded that men who undergo surgery for prostate cancer can be fairly certain that after about 2.5 years, the side effects from the surgery won't change much. This is not the case for men who are treated with either radioactive seed implants or external beam radiation. After about 6 years, they may see improvement in rectal or urinary irritation from the radiation. But sexual performance will likely decrease and incontinence may develop. (Source: *Journal of Clinical Oncology* (Vol. 23, No. 12: 2772-2780) via American Cancer Society News)

Another Quality of Life Comparison. Men with prostate cancer treated with radical prostatectomy have, in general, the highest scores on health-related quality of life measurements 10 years after treatment, while men who underwent hormone therapy generally have the lowest quality of life scores. Those findings come from a population-based study of men in the Eindhoven Cancer Registry in The Netherlands. The researchers administered a health Survey and a quality of life cancer questionnaire to 964 men diagnosed with prostate cancer between 1994 and 1998. Mean follow-up time was 10 years. General Health Perceptions scores were worse but Mental Health scores were better for cancer survivors compared with age-matched normative controls. Quality of life scores were similar between cancer survivors and controls. However, when analyzed by type of treatment received for prostate cancer, the team found that the long-term quality of life can vary significantly as a function of the type of primary treatment. Men who underwent radical prostatectomy had the highest physical health-related quality of life scores and men who received hormone therapy had the lowest scores. Men who underwent radiotherapy or watchful waiting fell between these two groups. (Source: *Cancer* 2006;107:2186-2196 via Reuters Health, December 1, 2006)



Rapidly Rising PSA Signals More Aggressive Prostate Cancer. Prostate cancer is more likely to be life-threatening if the man's PSA level rose rapidly during the years before he was diagnosed, according to a new study that may help change how PSA tests are used. The finding could help doctors diagnose aggressive cancers earlier, when they might be easier to fight. Perhaps more important, it suggests a more in-depth evaluation of the common blood tests could better predict who needs aggressive treatment and who has a slower-growing tumor that may be OK to monitor instead. The study does not prove that decisions based on so-called PSA velocity can really save lives. But the researchers contend that the findings suggest that men should consider getting a baseline PSA test around age 40, instead of the more usual 50, to use as a comparison for future changes. Commentators note that biopsying men with low PSA would worsen another problem, over-diagnosis. Many specialists say too many men today are undergoing side-effect prone treatment for tumors too small and slow-growing to ever threaten their lives. Still, growing numbers of doctors are using the method already to help decide when to order a biopsy factor in determining prognosis. Another commentator said the re-search is another step on the road to more sophisticated prostate cancer screening and treatment. (Source: *Associated Press*, November 1, 2006)



Bone Mineral Density in Men Receiving Anti-Androgen Therapy. Zoledronic acid treatment can increase bone mineral density (BMD) in men with prostate cancer receiving androgen deprivation therapy (ADT), according to a report in the September issue of *The Journal of Urology*. Ryan, et al., colleagues evaluated the effects of zoledronic acid intravenously every 3 months on BMD and bone turnover markers in 120 men with prostate cancer without bone metastases in whom ADT was begun within the previous 12 months. Compared with patients receiving placebo, men receiving zoledronic acid experienced mean BMD increases of 3.6% yearly in the femoral neck, 3.8% in the total hip, and 6.7% in the lumbar spine. Bone turnover

markers decreased significantly in patients receiving zoledronic acid, but increased in patients receiving placebo. Adverse event rates were similar in the treatment and placebo groups, although men taking zoledronic acid reported nausea significantly more often. The researchers concluded that it is important to screen and monitor androgen-deprived prostate cancer patients for osteoporosis; intervention with a bisphosphonate such as zoledronic acid can be very efficacious in reversing bone loss in these men. The study does not recommend automatic treatment with zoledronic acid, but reserves it for patients with documented osteoporosis, or baseline osteopenia at the start of androgen deprivation. Studies of the long-term effects of zoledronic acid on BMD and the optimal duration of bisphosphonate administration are needed. (Source: *J Urol* 2006; 176:972-978, via Reuters Health Information, October 12, 2006)



Value of the Ultrasensitive PSA Test. Ultrasensitive measurements of prostate-specific antigen (PSA) do not enhance the assessment of prostate cancer recurrence after radical prostatectomy, and may even add to patient stress, according to a report in the September *BJU International*. Taylor, et al., University of Connecticut Health Center, investigated the utility of using ultrasensitive PSA assays (USPSA) in detecting prostate cancer recurrence after radical prostatectomy in 225 men and say that refinements in PSA testing have been of little clinical value and may add to patient stress. Although the mean USPSA remained relatively constant for men with no recurrence and increased over time for men with recurrence, the confidence intervals overlapped significantly between the groups. More than 40% of men with no recurrence had an undetectable PSA level outside the range of the ultrasensitive PSA assay during follow-up, compared with only 14% of the men with recurrence. Significant fluctuations within the ultrasensitive PSA range precluded calculation of PSA doubling times and velocities. The researchers conclude that ultrasensitive PSA levels currently are of no added value in postsurgical patients. If the ultrasensitive PSA is used, this fact should be emphasized to alleviate potential patient concern. They note that patients tend to remember their PSA values, and if they are told it should be undetectable after surgery, it might add more stress for them to be advised about USPSA results given levels that would have otherwise been reported as 'undetectable' with standard assays. (Source: *BJU International* 2006; 98:540-543 via Reuters Health, September 28, 2006)



Tadalafil May Be Helpful for Erectile Dysfunction After Radiation. Treatment with tadalafil (Cialis) for men with erectile dysfunction after radiotherapy for prostatic carcinoma was effective and well tolerated, according to the results of a study reported in the October issue of the *International Journal of Radiation Oncology, Biology and Physics*. Incrocci, et al., the Erasmus MC-Daniel den Hoed Cancer Center in Rotterdam, note that erectile dysfunction after three-dimensional conformal external-beam radiotherapy (3DCRT) for prostatic carcinoma occurs in as many as 64% of those patients. The study sought to determine the efficacy of the oral drug tadalafil in patients with erectile dysfunction after radiotherapy for prostatic carcinoma. Sixty patients (average age 69 years) who had completed 3DCRT at least 12 months before the study were enrolled in a double-blind, placebo-controlled, cross-over study lasting 12 weeks. Patients received 20 mg of tadalafil or placebo for 6 weeks, taken on demand at their discretion (at least once a week and no more than once daily), with no restrictions regarding the consumption of alcohol or food. At 6 weeks, patients crossed over to the other treatment.

Outcome measures included responses on the Sexual Encounter Profile (SEP) and the International Index of Erectile Function (IIEF) questionnaires, as well as adverse effects. With tadalafil, but not with placebo, there was a significant increase in mean scores from baseline for almost all questions of the IIEF questionnaire. Improvement of erectile function was reported with tadalafil by 67% of the patients compared with 20% of those receiving placebo. Successful intercourse was reported by 48% of those in the tadalafil group versus 9% in the placebo group. Adverse effects were mild or moderate. As a result, the researchers concluded that tadalafil is an effective treatment for erectile dysfunction after 3DCRT for prostatic carcinoma with successful intercourse reported in almost 50% of the patients; and it is well tolerated. The simplicity of delivery, its efficacy, and tolerability make tadalafil a good treatment option for patients with ED after radiotherapy for prostatic carcinoma, who are not using nitrates. Lilly Icos provided drugs and placebo and an unrestricted grant to cover patients' visits and administration costs. (Source: *Int J Radiat Oncol Biol Phys.* 2006; 66:439-44 via Medscape Medical News, October 5, 2006)



OK, Bartender, Make It a Double! Alcohol consumption is not associated with the overall incidence of prostate cancer, according to findings published in the September issue of the International Journal of Cancer. And aggressive prostate cancers and mortality may be decreased in men who consume alcohol. Giles, et al., the University of Melbourne, Australia, analyzed data on 16,872 men followed from 1994 to 2003. The participants ranged in age from 27 to 70 years and questionnaires were used to obtain detailed information on alcohol consumption. A total of 732 prostate cancers occurred, including 132 aggressive cases, and 53 deaths from prostate cancer were documented. Overall, no association was observed between alcohol intake and prostate cancer incidence. Also, the pattern of drinking and type of alcohol were not significantly linked with prostate cancer incidence. Compared to abstainers, men who consumed 1 to 19 g/day of alcohol had a slightly reduced risk of aggressive prostate cancers. Prostate cancer mortality was also reduced in this group. Questions remain concerning the effect on aggressive and non-aggressive tumors and the pattern and type of alcohol consumed. If it can be confirmed that moderate alcohol consumption protects against aggressive and fatal prostate cancer, it would have a "major impact," the researchers say because "there are no established modifiable risk factors for this common type of cancer." (Source: *Int J Cancer* 2006; 119:1501-1504 via Reuters Health Information, October 2, 2006)



University of Florida Proton Therapy Institute Officially Opens. The University of Florida (UF) officially opened a new center for proton cancer therapy in conjunction with UF College of Medicine and the UF Shands Cancer Center. The University of Florida Proton Therapy Institute is only the fifth center for proton therapy to be built in the United States. The facility houses a huge device used to treat cancer by targeting protons narrowly on the tumor itself, sparing healthy surrounding tissue. The University of Texas' M.D. Anderson Cancer Center opened a proton therapy treatment facility in July of this year. Loma Linda University Medical Center in California opened the world's first hospital-based treatment facility in 1990, and Indiana University and Massachusetts General Hospital in Boston also have such centers. Source: *AWARE*, National Prostate Cancer Coalition, October 17, 2006)

PSA Screening for Elderly Men. Most guidelines do not recommend PSA screening for elderly men who have limited life expectancies because the known harms outweigh potential benefits; however, there are no large-scale studies of actual PSA screening practices for elderly men. Walter, et al., University of California, San Francisco, studied 598,642 male veterans aged 70 and older who were seen at 104 Veterans Administration facilities during 2002 and 2003. The veterans had no history of prostate cancer, elevated PSA, or prostate cancer symptoms. They were stratified into three groups ranging from best health to worst health. The researchers then determined PSA testing done from VA data and Medicare claims. They found that 56 percent of the resulting sample had a PSA test performed. PSA screening rates decreased with advancing age, but within each 5-year age group, the percentage of men who underwent a PSA test did not decrease significantly with worsening health. Of men aged 85 years and older, 34 percent had a PSA test, as did 36 percent of men in the worse health. Analyses revealed that marital status, region of the country, and other non-clinical factors had a greater effect on the extent of PSA screening than did health status. In fact, some subgroups of men in the worst health had screening rates greater than 60 percent. The researchers concluded that PSA screening for elderly men with limited life expectancy is not beneficial, and more attention should be paid to prognosis before making screening decisions for these elderly men. So why are all these elderly men being tested? One commentator says public health policy does not support PSA testing for elderly men with limited life expectancy, but doctors order the test anyway because of patients' exaggerated fear of prostate cancer mortality and their overestimation of treatment efficacy. He says that doctors also order PSA tests because the reward for treatment can be significant, and the penalty for failing to diagnose can be severe. He notes that this dilemma is quite common in our health system, and it requires urgent attention. (Source: *JAMA*.2006; 296:2336-2342, 2371-2373, via Medscape Medical News, November 14, 2006)



Androgen Deprivation and Risk of Diabetes and Cardiovascular Disease. A recent study indicates that men receiving androgen deprivation therapy have a higher risk for diabetes and cardiovascular disease. Keating, et al., Harvard Medical School, say that current use of GnRH agonists significantly increased the risk for diabetes, coronary heart disease, myocardial infarction, and sudden cardiac death in elderly men (mean age, 74.3), compared to men not receiving that therapy. Orchiectomy was also associated with diabetes risk, but not cardiovascular disease. The researchers recommend that patients with metastatic prostate cancer or aggressive, locally advanced non-metastatic cancers who are likely to benefit from GnRH agonists therapy be made aware of these risks, permitting them to work on risk reduction factors. For men with less-advanced disease, care should be taken to weigh potential benefits against these potential risks when making decisions about hormonal therapy for prostate cancer. (Source: *J Clin Oncol*2006; 24:4448-4456 via Reuters Health Information, September 29, 2006)



Long-Term Hormone Therapy with Radiation Therapy Reduces Metastases in Prostate Cancer. Horowitz, et al., Fox Chase Cancer Center, conclude that prostate cancer patients with locally advanced disease reduce the risk of disease progression by taking long-term androgen deprivation therapy. The researchers followed 1,554 patients with locally advanced prostate cancer. All the patients received four months of hormone therapy before and during radiation

therapy. After radiation therapy, the patients were randomized into two groups; one group received an additional 24 months of hormone therapy and the other did not. After ten years, the group receiving additional hormonal therapy did significantly better in several categories, although overall survival rates differed only slightly. The researchers say their study establishes that the standard of care for locally advanced, non-metastatic prostate cancer is two years of hormone therapy. (Source: Doctor's Guide Dispatch, November 9, 2006, via *AWARE*, National Prostate Cancer Coalition, November 14, 2006)



THE WRAMC Us TOO NEWSLETTER IS ALSO AVAILABLE ON THE WEBSITE OF THE CENTER FOR PROSTATE DISEASE RESEARCH AT WWW.CPDR.ORG. GO TO WWW.CPDR.ORG/PATIENT/NEWSLETTER.HTML.

(Agent Orange – Continued from page 1)

EVALUATION PROCESS

Upon receipt of a claim, a VA case worker reviews the documentation for completeness, and schedules the veteran for a medical evaluation by a VA physician. The purpose of this examination is to confirm the state of the veteran's prostate cancer on the date of the claim.

Following receipt of the physician's evaluation, the case worker will complete evaluation of the claim. When diagnosed with prostate cancer (included under VA Code 7528, a "malignant neoplasm of the genitourinary system") and prior to any treatment, a disability rating of 100 percent applies. Following the cessation of surgery, radiation, chemotherapy or other therapeutic procedure, the rating of 100 percent continues until a mandatory VA follow-up examination is performed.

DISABILITY FOLLOW-UP EXAMINATION

During the follow-up examination, the VA physician will determine the state of the veteran's prostate cancer through interview, evaluation of any new documentation, and the results of a PSA blood test and digital rectal examination (DRE). At that time, if the PSA is undetectable, it is assumed that the treatment was successful. The physician will then rule that the veteran does not have prostate cancer. If no prostate cancer is detected, the 100 percent rating will be withdrawn. If the PSA is detectable and it is determined that the treatment was not successful or that the cancer has returned, the veteran would continue to be eligible for a 100 percent disability rating. In the case of prostate cancer, the disability rating is either 100 percent or 0 percent.

If there has been no local reoccurrence or metastasis, the disability rating is based on rating the treatment residuals (side effects). The VA physician should inquire about any treatment side effects, such as incontinence or impotence, affecting the veteran. Depending on the extent of side effects, an appropriate disability rating will be assigned. For example, incontinence can be rated as high as 60 percent.

SELECTED COMPENSATION AMOUNTS

The dollar amount payable for each rating is defined in a VA Compensation Rate Table. In 2006, a veteran with 100 percent disability rating and a dependent spouse was entitled to \$2,528.00 monthly. A 60 percent disability rating resulted in a payment \$954.00 to a veteran with a spouse.

Disability ratings of 20 percent (\$218), 40 percent (\$539), or 60 percent (\$954) could be assigned for incontinence resulting from treatment. Erectile dysfunction resulting from treatment could be rated as 20 percent disabling. The rating is based on a combination of penile deformity (if any) and the loss of erectile function. In addition to the disability compensation, a veteran whose prostate is removed or rendered useless by radiation would be entitled to a Special Monthly Compensation (SMC) for anatomical loss of a creative organ (the prostate). The SMC paid in 2006 was \$87.00 per month for life.

GETTING APPLICATION ASSISTANCE

The individual states have Departments of Veterans Affairs that provide guidance and assistance regarding eligibility and the application process. For example, The Department of Veterans Affairs in Virginia may be contacted at (703) 630-2811. In addition, numerous national veterans' service organizations provide VA disability application services to veterans and their families free of charge through their National Service Officers (NSOs). Veterans need not be members of these organizations to take advantage of this free service. As part of their activities, NSOs assist veterans in preparing VA Form 21-526 for submission and, if necessary, act as the veteran's advocate during disability compensation hearings with the VA. Contact information for these service organizations is provided below.

OTHER USEFUL INTERNET ADDRESSES

For those with access to the Internet, the Department of Veterans Affairs web site (www.va.gov) provides wealth of information, including details on Agent Orange-related compensation. The Veteran's Application for Compensation or Pension (VA Form 21-526) may be downloaded from the site. Internet access for the full text of Title 38 (Pensions, Bonuses, and Veterans' Relief) is available at www.access.gpo.gov/nara under the Code of Federal Regulations.

MILITARY RETIRED PAY AND VA COMPENSATION

Acceptance of tax-free VA disability payments results in a corresponding reduction in taxable military retired pay. If the VA disability is higher than the retired pay, the higher payment is received. A veteran retired from military service needs to become familiar with the Concurrent

Retirement and Disability Payments (CRDP) and the Combat Related Special Compensation (CRSC) programs managed by the Military Services. These programs are discussed next.

CONCURRENT RETIREMENT AND DISABILITY PAYMENTS (CRDP)

Following many years of lobbying by veteran-related organizations, public law now allows a veteran to receive payment of both military retired pay and VA compensation. The Concurrent Retirement and Disability Payments (CRDP) program provides a 10-year phase-out of the offset to military retired pay due to receipt of VA disability compensation. The criteria and provisions related to CRDP are controlled by the Military Departments, not the VA. Payment of CRDP is made automatically to retirees who meet CRDP qualification criteria.

COMBAT RELATED SPECIAL COMPENSATION (CRSC)

Combat Related Special Compensation (CRSC) pays added benefits to selected retirees who receive VA disability compensation for combat-related disabilities and have 20 years of military service. Prostate cancer (and side effects resulting from its treatment) attributed to service in Vietnam is a combat-related disability. A retiree may not receive both CRDP and CRSC.

Information on CRSC is available at the following Service and DoD web sites:

Army: <http://www.crsc.army.mil/>

Navy & Marine Corps: <http://www.hq.navy.mil/ncpb/CRSCB/combatrelated.htm>

Air Force: <http://www.afpc.randolph.af.mil/disability/CRSC/CRSCnew.htm>

DOD: <http://www.defenselink.mil/prhome/mppcrsc.html>

Veterans' Service Organizations Providing Assistance with VA Claims Applications

American Legion: 1-800-433-3318

Armed Forces Services Corporation: 1-888-237-2872

Disabled American Veterans: 1-877-426-2838

Paralyzed Veterans of America: 1-800-426-2838

Veterans of Foreign Wars of the United States: 1-800-VFW-1988

Vietnam Veterans of America: 1-800-882-1316 or 202-530-9180

“BLUE WATER” NAVY/COAST GUARD VIETNAM VETERANS AND AGENT ORANGE

**by
Fred Gersh**

On August 16, 2006, the US Court of Appeals for Veterans Claims (CAVC) handed down a benchmark decision extending the presumption of service connection for diseases related to

Agent Orange exposure to Vietnam veterans who served on vessels that sailed in the waters off of the Republic of Vietnam, even though they did not set foot on shore. The VA had denied presumptive Agent Orange-related service connection to these "blue water" veterans, arguing that the law extends the presumption only if the veteran actually set foot in Vietnam. The Court determined that the VA's interpretation of the law was in error, and that a veteran who served in the "blue water" Navy/Coast Guard is entitled to the presumptions of exposure to Agent Orange and service connection if he or she suffers from one of the recognized presumptively service-connected diseases. The list of diseases includes prostate cancer, chloracne, Type II diabetes, chronic lymphocytic leukemia, multiple myeloma, respiratory cancers, and soft-tissue sarcomas. These "blue water" sailors generally were awarded the Vietnam Service Medal (VSM); award of the Vietnam Service Medal is recognized by the VA as appropriate evidence of service in Vietnam.

The court concluded that because the statute does not specifically limit the application of the presumption of service connection for herbicide exposure to those who actually set foot on Vietnamese soil, the statute does not clearly preclude the application of the presumption to service members who served aboard a ship in close proximity to Vietnam. The court held that the distinctions between "brown water" and "blue water" and those on shore or afloat did not make sense with an airborne agent.

The dispute is still unresolved because the court decision faces an appeal from the VA. In the meantime, the VA has set aside compensation applications from "blue water" veterans until appeals and legal reviews are complete. Advocates for "blue water navy" eligibility for Agent Orange-related compensation urge sea-service veterans to file disability claims with the VA now if they are suffering any symptoms of diseases associated with exposure to Agent Orange. They should not await the outcome of the appeal process.

A final decision is not expected until mid-2007, and could be extended beyond that time frame. Interested persons may follow developments at www.va.gov or www.bluewaternavy.org.

(Editor's note: Ray Walsh, the author of the basic article, will accept comments and questions from readers who may be eligible for compensation for Agent Orange-related prostate cancer. He may be contacted at (703) 425-1474 or at raywalsh34@erols.com.) Fred Gersh is available to respond to readers' inquiries about "blue water" navy eligibility. He may be reached at (703) 768-6001 or fmgersh@cox.net.)

THE AGENT ORANGE REGISTRY

INTRODUCTION

The Agent Orange Registry program is separate from the disability compensation program described above. The Department of Veterans Affairs Agent Orange Registry was established in 1978 as a registry of Vietnam veterans who were worried that they may have been exposed to chemical herbicides that might be causing a variety of ill effects. It offers extensive medical examinations. The Agent Orange Registry is a computerized index of these examinations. The VA later expanded this program for veterans who served in Korea in 1968 or 1969. The VA

further expanded the registry to include those veterans who during military service were exposed to Agent Orange or other herbicides during testing, transporting, or spraying of these herbicides for military purposes.

WHAT A PARTICIPATING VETERAN CAN EXPECT

Each veteran participating in this voluntary program, offered at all VA medical centers, receives a series of basic laboratory tests; a chest x-ray; and urinalysis. Attention is paid to the detection of chloracne, porphyria cutanea tarda, Type 2 diabetes, soft tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease, respiratory cancers, multiple myeloma, chronic lymphocytic leukemia, prostate cancer, and peripheral neuropathy. Evidence is also sought concerning these symptoms or conditions: altered sex drive; congenital deformities (birth defects, including spina bifida) among children; repeated infections; nervous system disorders; sterility; and difficulties in carrying pregnancies to term.

HOW A VETERAN BENEFITS FROM THE AGENT ORANGE REGISTRY EXAMINATION

The examination provides the participating veteran a complete health evaluation and information about the possible relationship between herbicide exposure and subsequent health problems. After the examination, the veteran has a face-to-face discussion with a physician and receives a summary report of the examination. Registry participants are automatically added to the mailing list for the *Agent Orange Review*, a periodic newsletter with information about Agent Orange developments.

ELIGIBILITY

Any veteran, male or female, who had military service in the Republic of Vietnam between 1962 and 1975, and expresses a concern relating to exposure to herbicides, may participate in the Registry. A veteran who did not serve in Vietnam is not eligible for the Agent Orange Registry examination unless he or she (1) served in Korea in 1968 or 1969, or (2) was exposed to Agent Orange or other herbicides while on active duty military service during testing, transporting, or spraying of these herbicides for military purposes. The spouses and children of veterans are not eligible for this examination.

OTHER CONSIDERATIONS

A. Veterans interested in the Agent Orange Registry examination should request one at the nearest VA medical center. The Registry program is separate from the disability compensation program.

B. The following health conditions are presumptively recognized for service connection as having been associated with exposure to herbicides used in Vietnam. Vietnam veterans with one or more of these conditions do not have to show that their conditions are related to their military service; the VA presumes that their condition is service-connected. (1) Chloracne; (2) Non-

Hodgkin's lymphoma; (3) Soft tissue sarcoma; (4) Hodgkin's disease; (5) Porphyria cutanea tarda; (6) Multiple myeloma; (7) Respiratory cancers, including cancers of the lung, larynx, trachea, and bronchus; (8) Prostate cancer; (9) Acute and subacute transient peripheral neuropathy; (10) Type 2 diabetes; (11) Chronic lymphocytic leukemia.

◆ SNEAKERS @ WORK ◆

A NATIONWIDE AWARENESS CAMPAIGN FOR PROSTATE CANCER

Have you noticed the disparity in public awareness between prostate cancer and breast cancer? It jumps out at you, doesn't it? Whether it's federal funding for research, sympathetic full page ads in major newspapers and magazines, celebrity spokespersons, participation in research fundraising events such as 5K runs, walks, and other promotions, breast cancer elicits much greater support than all the other cancer-related diseases combined.

This disparity in disease awareness is not going to change unless the prostate cancer community makes it happen. Us TOO International and the American Prostate Cancer Initiative (APCI) aim to do just that by establishing a national awareness day on June 15, 2007.

SNEAKERS@WORK
JUNE 15, 2007
THE DAY FOR PROSTATE AWARENESS & ACTION
A WORKPLACE AWARENESS AND GIVING PROGRAM

Sneakers@Work is a nationwide workplace-based fundraising and awareness raising event just prior to Father's Day. The goal is the creation of a permanent awareness campaign as widespread and recognized as similar events associated with breast cancer. This is how it works. Organizations of all types allow their employees to wear sneakers to work on June 15. In turn, employees make a voluntary donation of \$5.00 to receive a pair of blue sneaker laces to wear that day. All proceeds go directly to Us TOO and APCI, both non-profit organizations, to support prostate cancer awareness, patient education, and advocacy and research programs. Doctors' offices, church groups, service clubs, and social groups can also be enlisted to participate.

Interested? For more information, visit the Us TOO web site at www.ustoo.org/sneakers@work, or contact Dan Reed at 800-808-7866 or dan@ustoo.org.

◆ SEARCHING FOR PROSTATE CARCINOMA: THE EVOLUTION OF IMAGING ◆

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(A summary of a presentation to the WRAMC Us TOO on November 1, 2006)

INTRODUCTION

Thank you for inviting me to speak this evening. The topic of imaging in dealing with prostate cancer is a very exciting one. I have been involved with both biotechnology and cancer research, especially prostate cancer, for a long time, and I am pleased to talk about some of the advances in imaging that will improve the diagnosis and treatment of prostate cancer. I need not tell the men in the audience how important it is to determine the extent of the disease upon diagnosis so that appropriate therapy can be selected. Frankly, we currently are limited in our ability to do just that, but the good news is that we are on the brink of an explosion in imaging technology that will help solve the problem. A major factor that limits us today, not just in cancer but also in chronic diseases, is our ability to detect disease early, treat it appropriately, and monitor it after therapy. So it is clear that advances in imaging technology hold much promise for the clinician and the patient. That is what I'll be speaking about tonight.

IDENTIFYING THE CLINICAL NEED

No doubt you are familiar with the holy triad of prostate cancer diagnosis in a clinical setting. It includes the digital rectal examination of the prostate gland, the blood test known as the PSA, and the ultrasound-guided biopsy for detection of the disease. But you should also be aware of the fact that

some of their parameters are not very useful in many cases. We really need more help in the diagnostic and therapy selection processes.

Of course, we do have some useful clinical tools, e.g., PSA doubling time that measures the velocity of disease progression. But PSA doubling time doesn't tell you either the location or the extent of the disease - two important matters that we need to know. Then there are clinical nomograms, such as the Partin tables, that help to predict risk under certain circumstances. The several available nomograms have similar characteristics and similar limitations. They are very robust regarding the prostate and the seminal vesicles, but the problem is that they are not so robust for evaluating lymph node disease. The sampling for lymph node disease covers only a very small area, so we are often left with an underestimation of the number of lymph nodes that may contain prostate cancer. What else do we have available to look for disease? Well, you certainly know about CT scans and MRIs. You should be aware that these have limited sensitivity to detect prostate cancer. In fact, CT scans are about 4% sensitive for finding prostate cancer and MRIs are about 15% sensitive, inadequate by anyone's standards. Some people are trying to shoe-horn PET scanning into the evaluation of prostate cancer. PET scanning certainly is useful for some cancers, but not for prostate cancer because the tiny particles (analogs) that it uses require a rapid metabolic rate. Prostate cancer usually doesn't have that rapid metabolic rate. Improvements in PET scanning are on the horizon, but right now

PET scanning is not useful for prostate cancer diagnosis. The occasion when PET scanning does detect prostate cancer is the exception rather than the rule.

SURGICAL SAMPLING OF LYMPH NODES

So we are left with surgical sampling to help determine whether or not there is metastatic disease in the lymph nodes. It is well established that cancers spread in different directions. Yet, the conventional wisdom has been that prostate cancer marches in an orderly fashion through the pelvis, then onward to the rest of the body. Well, I am going to show you data that suggest that isn't what happens with prostate cancer, and that's the reason why we miss disease. Keep in mind that we are talking about the standard lymph node dissection, which is a very tiny amount of tissue. There have been at least three publications in the last few years demonstrating that if you extend the lymph node dissection very slightly, you see a significant increase in the number of patients who have positive lymph nodes. And this still doesn't even approach the entire area where the disease can spread to the lymph nodes.

Nowadays prostate cancer patients are stratified into high risk, intermediate risk, and low risk categories based on PSA values, Gleason scores, and other data points. Relying on nomograms, we are taught that in the low-risk category we should expect 2-3% of patients with lymph node positivity. Yet, this one study found 11% of low-risk patients with lymph node positivity. No doubt about it, we are missing lymph node disease. Other related research on colorectal cancer unexpectedly showed that prostate cancer progression to lymph nodes is underestimated. The bottom line is that many diagnosed and treated men still have cancer that is

progressing because we are missing cancer that actually is in those lymph nodes.

THE PROSTASCINT SCAN

Now let's talk about the Prostate-specific membrane antigen (PSMA) scan. A Prostate-specific membrane antigen (PSMA) scan is like a bone scan in a way. It's a radioactive particle, but it's attached to an antibody. An antibody is a very specific protein that recognizes another particular protein in the body called an antigen, e.g., a prostate-specific antigen or PSA. The scan reveals areas where that prostate-specific antigen is present in the patient. So if you see an increased signal that is a strong suggestion that something is going on. Take a look at this Prostate-specific membrane antigen (PSMA) scan. Here in the pelvic area you can see some activity, but you are not sure what is occurring. Now look at the corresponding MRI scan. There is nothing that would be declared metastatic disease according to the criteria that radiologists use. But when you superimpose the Prostate-specific membrane antigen (PSMA) and the MRI (called a fused Prostate-specific membrane antigen (PSMA) scan), you see the tiny areas of lymph nodes deep in the pelvis and next to the rectum light up. This is precisely the area where we are told prostate cancer doesn't reach until it is at an advanced stage. So again this demonstrates those lymph nodes deep in the pelvis can be positive for prostate cancer. I'll be talking more about this later.

RADIOIMMUNOSCINTIGRAPHY

Now let me return to my discussion about the explosion of imaging technology. There are some very exciting developments on the horizon. What is even more interesting is the combination of these imaging technologies, so-called sensor fusion. What makes this possible are the astounding advances in computer technology. When I hear talk about quantum computers with a billion times more computing power, I can't quite get my arms around those numbers! But what it means is that we can process in

real time a tremendous amount of signal from the tissue when it is perturbed with different types of energy, be it light, ultrasound, high frequency waves, or thermal energy. My own experience and my discussions with such organizations as AOL and NASA convince me that we will reap immense benefits from dramatic developments in imaging technology in our lifetime.

Tonight I am going to focus on radioimmunoscintigraphy. It's a long, fancy name; radio – immuno – scintigraphy. Radio - something radioactive; immuno – refers to an antibody or protein that recognizes something else; and scintigraphy – refers to imaging. It is based on the fact that prostate cancer has a very interesting molecule or antigen that's known as Prostate Specific Membrane Antigen (PSMA). Here is a schematic representation of it on the left side of this slide. PSMA is expressed in prostate cancer, and it is up-regulated in high grade cancer, in androgen insensitive cancers in patients failing hormonal therapy, and in patients with metastatic deposits. The PSA you are familiar with becomes variable in this expression as the tumor progresses. It isn't proportionate necessarily to the amount of tumor that is there; we see that all the time. On the other hand, PSMA is definitely proportionate and is consistently up-regulated in all these cases. Remember, PSMA is completely different than PSA; I don't want you to be confused about that. As yet, we cannot accurately measure PSMA in the blood to reflect this situation. But it is interesting that PSMA may be expressed in the new blood vessels that accompany tumor growth. That is not so common with prostate cancer, but other types of tumors spread by obtaining their blood and nutrient supply from these newly forming blood vessels. So PSMA may be a wider marker and a better imaging agent for disease beyond just prostate cancer.

Some observers have said that Proscint can't work because it would only recognize dead cells. Well, that is simply not the case. We have data to show that there is invitro ("in the Petri dish") recognition with both live and dead cells by the antibody. Furthermore, we also have at least three studies that show a high correlation of the imaging results to the pathological results, i.e., confirmation by surgical removal of tissue to compare under the microscope to the available imaging scans. When I use the term "tissue confirmation," that is what I mean.

Years ago when I first started working in this area, some investigators did get variable images. This led to varying opinions as to the value of the process. The problem was the limitations imposed by the existing imaging technology. The scan could not detect the particle. The particle was there; we could see it in the pathology results, but the cameras couldn't pick it up. In the last five years there have been dramatic improvements in camera technology; they have much better resolution and much better image processing. Then along came the fusion studies – the imposition of the anatomic scan on the functional scan that I described earlier. This showed the activity of a protein compared to where it appears localized in the body. There was recognition that imaging technology was an important tool in the localization of the disease.

Another important factor is the availability of outcomes data. Critics had cited the lack of outcomes data for the latest imaging technology. If the imaging identified metastatic disease, did the patient later die from the disease as might reasonably be expected? Was the prognosis correct? That's an important factor. We now have a lot of outcomes data validating the use of the Proscint scan in the clinical setting. In fact, the images have gotten so good that we

can now begin to think about adjusting the therapy for prostate cancer. Not every patient has the disease throughout his prostate. But an article of urologic faith was that prostate cancer was certainly multifocal and diffuse. You usually found it later. Now we are finding men presenting much earlier, at a younger age with lower PSAs, and smaller volume disease. Well, there is a subset of those patients that clearly have focal disease. Could we perhaps treat only part of the prostate? Obviously, surgeons can't surgically remove only a portion of the prostate, so radical prostatectomy is out. But what about radiation therapy or cryotherapy? Could these therapies be used to radiate or freeze a portion of the prostate in such a way as to preserve other functions that no patient wants impaired, yet still treat the prostate cancer? The fact of the matter is we can't select those patients all that well yet. But the quality of these images is such that we are starting to consider the possibility. I wanted to share this development with you because it is very interesting, and you are likely not aware of it. There is no doubt about it; you are going to see an evolution in the traditional therapies for prostate cancer.

CLINICAL OUTCOMES

(Editor's Note: Dr. Manyak proceeded to show a series of slides that demonstrated the clinical outcomes of radioimmunoscintigraphy in the location of suspected prostate cancer metastases. The highlights are summarized here.)

- The fusion of the Prostate-specific membrane antigen (PSMA) with other imaging techniques allows you to see signal activity exactly in relationship to the anatomical structures. This has doubled localization accuracy.
- Three studies show a high correlation of the imaging results to the pathological results, i.e., confirmation by surgical

removal of tissue to compare under the microscope to the available imaging scans.

- Patients who have over-expression of PSMA in the prostate gland have a poorer prognosis. They have twice the incidence of PSA recurrence and a faster time to that recurrence.
- There are two distinct patterns to prostate cancer lymph node metastasis. In the continuous pattern we see signal activity in the pelvis, then spreading up into the area of the mid-abdomen. The second pattern may be called a skip pattern because there is little or no signal activity in the pelvis, just a mid-abdomen signal. Prostate-specific death rates are ten times higher in patients whose imagings show the skip pattern.
- Radiation oncologists find that the fused scan is an effective tool in selecting patients likely to benefit from external beam radiation therapy. The fused scan also helps define the radiotherapy field more accurately, reducing the risk of toxicity. The scan is also helpful in planning brachytherapy because it facilitates the accurate placement of the seeds, and therefore, the efficacy of the procedure.

- Patients who failed radiation as their primary therapy may be candidates for salvage cryotherapy. The fused Prostate-specific membrane antigen (PSMA) scan effectively identifies patients likely to benefit from cryotherapy.

THE FUTURE USE OF PSMA

Let's talk about that for a bit. PSMA holds additional promise for monitoring patients after therapies such as androgen blockade, chemotherapy, and focal treatments. Enhanced image-guided therapy for localized focal treatments and isolated metastasis offers other opportunities. It is early in the evaluation of this imaging technology for other cancers. Nevertheless,

PSMA may be a vascular marker for other malignancies that have been shown to express PSMA (e.g., renal, breast, colon, lung, and bladder cancers).

It is extremely interesting that the antibody in Proscint can be attached to a luciferin particle which is another type of radiation particle. It has some imaging characteristics which are known as gamma rays. But it also produces beta rays that kill cells. So you can both image and treat at the same time. This protocol is starting at Sloan Kettering very soon.

It is also interesting to note that PSMA is being used in at least three different vaccine strategies for prostate cancer. This is a very technical matter, but suffice to say that PSMA is a very important component for some of these strategies. Finally, a study is underway in Philadelphia to combine immunoscintigraphy with the fluorocarbon microbubble, a contrast agent for ultrasound. The fluorocarbon microbubble is very tiny, but it can be seen well in ultrasound. The hope is that some prostate cancers with tiny vessels will show up with the higher density of this ultrasound contrast agent.

Where does this all come together? Well, let's look at some very interesting technology that will soon be here at Walter Reed. This slide shows a surgeon wearing a Personal 3D Monitor, head-mounted display similar to the fighter pilot head bonnet display technology. It gives the surgeon performing a laparoscopic prostatectomy a 3-dimensional view of the tissues. The displays also can be attached to the Da Vinci robotic machine so that the surgical assistant sees exactly what the surgeon at the console is seeing. The Personal 3D Monitor provides the surgeon with a wide field of vision, a voice-activated call-up of secondary or archived images, and a picture-within-a-picture capability for various kinds of imaging technology. For example, the

surgeon simultaneously can see archived images and real time images and he has the ability to combine them even as he is operating. In another example of imaging utility, the Cleveland Clinic is incorporating imaging technology into something called augmented reality. It gives the surgeon a road map to seek and to find tumors. It's going to be extremely interesting. Imaging technology is starting to come together in ways I've been talking about for five years. But it's here now and it holds great promise for the patient.

CONCLUSION

In conclusion, I trust you recognize the value of the advances in imaging technology now that you've seen the images and the supporting data. There are consistent results from multiple institutions that validate the data. Both newly diagnosed patients and patients with recurrent disease now have a higher assurance that their conditions are accurately diagnosed so that the appropriate therapy may be chosen. And that's what it's all about! Thank you for your attention. I enjoyed being with you this evening.

◆ WRAMC US TOO COUNSELORS ◆ (AS OF January 26, 2007)
(These persons are willing to share their experiences with you. Feel free to call them.)

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◆ SPEAKER ◆

**MAJOR STEPHEN A. BRASSELL, MC
Center for Prostate Disease Research
Walter Reed Army Medical Center**

◆ TOPIC ◆

**“A Just Technology or Just Technology: Robotic versus Open
Prostatectomy”**

