FROM THE DOCTOR: PHYSICIAN COMMENTARY ON SELECTED ARTICLES IN THIS MONTH’S HOT SHEET
By Gerald W. Chodak, MD

From the Editorial team: With every issue of the Us TOO HotSheet, we provide readers with a physician’s perspective on information and news releases published each month. Our goal is to provide patients and their families with a different, critical look at the latest information appearing about this disease, helping the reader understand the strengths and limitations of the information provided. Let us know if you like seeing this perspective.

Research, research and yet more research! With each new issue of the Hot Sheet, additional clinical trials are described for a subgroup of men with prostate cancer. Two new ones are described. The first one described here builds on the success of Taxotere and Prednisone by adding Bevacizumab or Thalidomide, two agents known to block blood vessel growth normally stimulated by cancers. This is one of many ongoing studies for men who are no longer controlled by hormone therapy.

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The preliminary results of this trial have been promising. "Of the 26 patients we've enrolled so far, only one patient has come off the trial for progression of disease," said Dr. Dalut. "The trial has been open for about a year, and the median survival of these patients with androgen-independent prostate cancer is about 15 months. That patients are still responding after a year is encouraging." 

Who Can Join This Trial
Researchers seek to enroll 33 to 60 patients aged 18 or over who have metastatic prostate cancer that has progressed despite hormone-suppressing therapy.

Study Site and Contact Information
The study is taking place at the NIH Clinical Center in Bethesda, Md. For more information, call the NCI Clinical Studies Support Center at 1-888-NCI-1937. The toll-free call is completely confidential.

To see the protocol summary and the list of eligibility criteria, go to http://cancer.gov/clinicaltrials/NCI-04-C-0257.

FROM THE EDITOR
The Us TOO HotSheet Editorial Team sincerely apologizes for the repeated text that appeared on page 2 of the July 2006 article “APPROVAL OF HR863 RECOMMENDS INCREASED FEDERAL COMMITMENT TO SUPPORT DEVELOPING INNOVATIVE IMAGING FOR PROSTATE CANCER.” We always appreciate your constructive comments and suggestions – they help make the newsletter stronger and more informational.

A second study described uses Sipulcel-T, which is designed to stimulate the immune response. In preliminary studies, both agents enhance the immune response and in preliminary studies, both appear to prolong survival. As discussed previously, men are strongly encouraged to participate in a well-designed study whenever possible; it offers new and potentially valuable therapies years before they are available to the general public. And, only by men participating can doctors figure out the best course of action when the disease begins to progress.

Perhaps the only limitation with the NCI study is the need to travel out of your home area. Nevertheless Us TOO members are encouraged to determine if they would be suitable candidates for this or other ongoing trials. Another treatment being highlighted in this issue is cryosurgery that is being encouraged for men with locally recurrent prostate cancer following radiation therapy. Despite the number of articles published using cryosurgery, considerable uncertainty surrounds the value of this therapy because no randomized, prospective comparison has ever been conducted to determine if men live longer when they undergo this procedure compared to other therapies that are available.

As with all uncontrolled studies, there is no way to draw any valid conclusions about the true efficacy of this therapy. Is there a downside, even if it doesn’t work? The answer is that side effects do occur so patients should be well informed about the risk and benefits and uncertainty before signing up. It certainly is an option to consider when a local recurrence is suspected following radiation therapy.

From the Editorial Team: Us TOO thanks Dr. Chodak for his insights and comments. As he stated this month in the HotSheet, several controversial topics are addressed and clearly more research is needed. In the meantime Us TOO will continue to provide the information that men and their families need to make informed decisions.

(Continued from page 1)
According to a recent report from the U.S. Center for Disease Control, women’s life expectancy rose from 79.7 to 79.8 years. White women have the highest life expectancy, 80.2 years; followed by black women (75.5 years); white men (75 years) and black men (68.6 years).

“Men simply need to be encouraged to go to the doctor and become more in tune with their own health. An Office of Men’s Health would be the ideal tool to make this happen,” said Betty Gallo, Director of Public Outreach for the Dean and Betty Gallo Prostate Center at the Cancer Institute of New Jersey. “If such a step can be taken at the federal level, the result would be a positive trickle down effect to state and local communities.”

“Illness and disease among men have significant impact on every facet of society,” said Jean Bonhomme, MD, MPH and Men’s Health Network Board Member. “Women and children are affected economically and emotionally by men’s unnecessary disability and premature death as well as by health care costs. An Office of Men’s Health has great potential for uplifting the health status of our nation as a whole.”

The office will be designed to monitor and coordinate efforts to improve the health and well being of men by streamlining government efforts on the federal and state levels in the areas of prevention, health education, outreach, and research. It will mirror the existing Office of Women’s Health, which was established in the early 1990s.

MHN is a non-profit educational organization comprised of physicians, researchers, public health workers, and individuals. It is committed to improving the health and wellness of men, boys, and their families through education campaigns, data collection, surveys, toll-free hotlines, and work with health care providers. With a network of chapters, affiliates, and health partners, MHN has a presence in every state and partners with both private and public entities to achieve these goals.

To learn more about the Men’s Health Network, call (202) 543-6461 x101 or go to <www.menshealthoffice.info>.

Men’s Health Network, 16 June 2006

If your prostate cancer was treated with radiation and your PSA is rising, it is important to find out why and what your options are.

A rise in PSA after any form of radiation (external beam, seeds, or combination external beam + seeds) can mean that your prostate cancer has come back (recurrence). A rising PSA may also be due to an irritation, infection or inflammation, or other benign (non-cancerous) condition. It is important to be evaluated by a physician as soon as possible. Only appropriate diagnostic tests can correctly identify the reason for a rising PSA. Diagnostic tests that can rule out cancer may include another PSA test, digital rectal exam, ultrasound imaging, and prostate biopsy. If cancer recurrence is diagnosed, additional tests (e.g. bone scan, tumor marker imaging, lymph node biopsy, CT/MRI scan) will help determine if the cancer has begun to spread beyond the prostate gland (metastasis).

If your cancer has recurred locally (the cancer is contained within the prostate capsule), you may be a candidate for salvage cryotherapy. Cryotherapy is a potentially curative treatment that destroys recurrent prostate cancer by freezing the remaining cell lines, regardless of the aggressiveness of the cancer. Cryotherapy is a minimally invasive procedure with few side effects and rapid recovery.

Cryotherapy is a minimally invasive procedure with few side effects and rapid recovery. Temperature sensors carefully monitor the process and precisely determine when target temperatures have been reached.

Thousands of men have chosen cryotherapy to treat their prostate cancer. Cryocare TCAP is an FDA cleared and Medicare covered treatment for men with primary prostate cancer and for prostate cancer that returns after any type of radiation treatment. Over 350 published studies help document the clinical value of cryotherapy as a treatment for prostate cancer. Many of these clinical studies document the effectiveness and safety of salvage cryotherapy for recurrent prostate cancer. One notable study reflects a range of disease-free rates from as high as 90% for low-risk radiation-recurrent prostate cancer to 69% for high-risk disease.¹

There are over 600 Cryocare TCAP physicians located nationwide. Many of these physicians specialize in treating recurrent prostate cancer. For more information about cryotherapy or for referrals to cryosurgeons in your area, please call (877) PCA-CRYO (877-722-2796) or visit <www.prostatecancer.com>. A patient advocate can also provide you with contact information for former salvage cryotherapy patients if you would like to talk with others about their cryotherapy experiences.

IMPORANT NOTE: If you had ANY form of radiation treatment for prostate cancer AND your PSA is rising, do not wait! Seek professional help as soon as possible. The earlier the problem is diagnosed, the more treatment options you have. ONLY a physician can determine why your PSA is rising, and what your options are.²


² This information is not intended to be used as medical advice, and is not intended as a substitute for medical advice.
PLACEBO-CONTROLLED PHASE III TRIAL OF IMMUNOLOGIC THERAPY WITH SIPULEUCEL-T (APC8015) IN PATIENTS WITH METASTATIC, ASYMPTOMATIC HORMONE REFRACTORY PROSTATE CANCER


**PURPOSE:** Sipuleucel-T (APC8015) is an investigational immunotherapy product designed to stimulate T-cell immunity against prostatic acid phosphatase. A phase III study was undertaken to evaluate the safety and efficacy of sipuleucel-T in a placebo-controlled study.

**PATIENTS AND METHODS:** A total of 127 patients with asymptomatic metastatic hormone refractory prostate cancer (HRPC) were randomly assigned in a 2:1 ratio to receive three infusions of sipuleucel-T (n = 82) or placebo (n = 45) every 2 weeks. On disease progression, placebo patients could receive APC8015F, a product made with frozen leukapheresis cells.

**RESULTS:** Of the 127 patients, 115 patients had progressive disease at the time of data analysis, and all patients were followed for survival for 36 months. The median for time to disease progression (TTP) for sipuleucel-T was 11.7 weeks compared with 10.0 weeks for placebo (P = .052, log-rank; hazard ratio [HR], 1.45; 95%CI, 0.99 to 2.11). Median survival was 25.9 months for sipuleucel-T and 21.4 months for placebo (P = .01, log-rank; HR, 1.70; 95%CI, 1.13 to 2.56). Treatment remained a strong independent predictor of overall survival after adjusting for prognostic factors using a Cox multivariable regression model (P = .002, Wald test; HR, 2.12; 95%CI, 1.31 to 3.44). The median ratio of T-cell stimulation at 8 weeks to pretreatment was eight-fold higher in sipuleucel-T-treated patients (16.9 v 1.99; P < .001). Sipuleucel-T was well tolerated.

**CONCLUSION:** While the improvement in the primary end point TTP did not achieve statistical significance, this study suggests that sipuleucel-T may provide a survival advantage to asymptomatic HRPC patients. Supportive studies are underway.

<http://highwire.stanford.edu/cgi/medline/pmid;16809734>
Okay, Doc Moyad cut to the chase and what is the skinny on that magic pill for weight loss?! Acomplia® (rimonabant) made by Sanofi-Aventis is a 20 mg a day pill that was just approved in Europe in the past few weeks. However, the FDA wants to review some more data before they approve it in the United States.

What I like about this drug compared to other drugs and supplements is that it seems to be heart healthy unlike many of the other past weight loss pills. It can significantly increase your HDL or “good cholesterol”, and it may even help some individuals quit smoking. It works by blocking some of the same receptors in the brain that are stimulated by marijuana to give you the munchies.

Personally, I do not know anything about marijuana except for that one night in college on my twenty-first birthday, but like Clinton I did not inhale (at least this is what I told my parents). These receptors that are blocked by Acomplia® are known as the “cannabinoid-1” receptors. In other words, it can suppress appetite and may even increase metabolism.

This drug also has the ability to reduce triglyceride and insulin levels, which need to be reduced in many prostate cancer patients. Nausea was the most common side effect with this drug that occurred at almost twice the rate as that observed in the placebo group (11.2% versus 5.8%).

Regardless, keep watching the newspapers and talk to your doctor because in 2006 no other weight-loss drug has a chance of being approved by the FDA. In the meantime, increasing your consumption of fiber and regular aerobic exercise are still effective ways to reduce weight. In addition, lifting weights and increasing your muscle mass is another cheap way to increase your metabolic rate and reduce your overall weight.

In the next issue we will talk about more fun stuff, so stay cool and think thin thoughts.

Note: To contact Dr. Moyad, please call (734) 936-6804. He can also now be e-mailed at WJR.com (an ABC radio station). Feel free to email him frequently here because he wants to suck up to this radio station in order to maintain his high profile status on the airwaves.

**PREDICTORS OF MORTALITY AFTER PROSTATE-SPECIFIC ANTIGEN FAILURE**

D’Amico AV., Kantoff P, Loffredo M, Renshaw AA, Loffredo B, Chen M-H

*Int J Radiation Oncol-Biol Phys 65: 656-60, 2006*

**Purpose:** We identified factors associated with the length of survival after prostate-specific antigen (PSA) failure.

**Methods and Materials:** The study cohort comprised 81 of 206 men enrolled on a randomized trial evaluating external-beam radiation therapy (RT) with or without androgen suppression therapy (AST) and who experienced PSA failure. Salvage AST was administered at a PSA level of ~ 10 ng/mL as per protocol. Cox regression was used to determine factors associated with length of survival after PSA failure.

**Results:** A PSA DT (doubling time) <6 months ($p = 0.04$) and age at the time of PSA failure ($p = 0.009$) were significantly associated with length of survival. By 5 years, 35% and 65% of all-cause mortality was from prostate cancer in men whose age at PSA failure was 75 or higher vs. <75, respectively. Across all ages, 0%, 4%, as compared with 63% of men, were estimated to die of prostate cancer within 5 years after PSA failure if their PSA DT was >12, 6–12, or <6 months, respectively.

**Conclusions:** Advanced age and a PSA DT <6 months at the time of PSA failure are associated with a significantly shorter survival.

**THERAPEUTIC DUAL VIRAL VECTOR VACCINE PLUS GM-CSF DOES NOT IMPROVE PROGRESSION-FREE SURVIVAL IN PHASE II RANDOMIZED TRIAL IN HORMONE-REFRACTORY PROSTATE CANCER PATIENTS**

In a randomized, double-blind, controlled phase II trial, the administration of a dual-vector prostate cancer vaccine, PROSTVAC-VF, combined with granulocyte-macrophage colony-stimulating factor (GM-CSF), has demonstrated no improvement in progression-free survival compared with placebo in patients with hormone-refractory prostate cancer, according to data presented at the 42nd Annual Meeting of the American Society for Clinical Oncology in Atlanta, Georgia.1

The vaccines PROSTVAC-V, engineered from a vaccinia virus, and PROSTVAC-F, engineered from a fowlpox virus, are recombinant viral vectors that encode prostate-specific antigen gene variants designed for optimal antigen presentation.

The study, presented by Philip W. Kantoff, MD, from the Dana-Farber Cancer Institute in Boston, Massachusetts, included 125 patients randomized 2:1 to receive either the dual-vector vaccine plus GM-CSF or control (empty vec-
A CIRCLE OF LOVE REACHES SOUTH AFRICA

The Circles of Love Companion and Family Support Program and materials were originally conceived in 2004. Even in its infancy, the advisory panel who helped create the program, mainly comprised of companions of prostate cancer patients, knew from first hand experience there was a far-reaching need. Exactly how far the program would reach is only now becoming clear. A seed was planted that took hold around the world.

In May, we received a delightful letter from a gentleman in Pretoria, South Africa. He read an article about the program in the HotSheet called Circles of Love Alive in Chicago. He is associated with a monthly prostate cancer support group in Pretoria, South Africa, that meets regularly to hear from doctors, dieticians and spiritual leaders. The average attendance is about twenty, including some wives who accompany their spouses. As he read about the Circles of Love, he realized this program was exactly what they were lacking.

The materials were promptly shipped to Pretoria and a joyful email arrived in swift response. "I regret that I, indeed ‘we’ (my wife and I), did not have this when I was operated on 7 years ago! However, who knows what we can achieve for those who are under the knife, or whatever treatment they are going to receive, in the future. I’m sure there will be less uncertainty for them.

A few weeks later, yet another email arrived, "I have been steadily working through The Circles of Love and all I can say is that I am amazed at what the whole parcel contains. As I read, I think, ‘Ah but what about ...’ and then I find the answer – truly wonderful.”

They are eager to translate the materials into Afrikaans, which is one of the 13/14 official languages that is used particularly in Pretoria.

His most recent correspondence concluded, "I think the whole idea, and the information given, is out of this world!!!"

Circles of Love Care Kit was released in June 2005. The Circles of Love Discussion Guide was distributed to all chapters in early February. The Circles of Love Care Kit and all its individual components are available for purchase by calling the Us TOO offices at 800-808-7866. For additional information about The Circles of Love Program, please contact Elizabeth at 320-980-8437 or Elizabeth@ustoo.org.

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VA CONTACTING VETERANS WHO RECEIVED PROSTATE BIOPSIES

Some veterans who received prostate biopsies in medical facilities of the Department of Veterans Affairs (VA) in 11 states, The District of Columbia and Puerto Rico may have been treated with improperly disinfected instruments, VA officials announced.

Although the VA has not received any reports of patients being harmed, the Department is notifying all veterans who were treated by the equipment in question, called "a prostate biopsy transducer." The VA is also offering follow-on testing to determine if these veterans were exposed to any other ailments.

"The safety of our patients is of paramount concern," said Dr. Jonathan B. Berlin, VA's Under Secretary for Health. "VA's patient safety program detected this problem. Whenever there's a problem, we believe in notifying our patients and taking remedial steps immediately."

Although VA inspectors found that the equipment used for the prostate biopsies was being cleaned and disinfected after each procedure, some equipment was not being scrubbed by a brush after each use, resulting in the remote possibility of infection. Improperly scrubbed equipment carries a small risk of exposing patients to Hepatitis B, Hepatitis C and the Human Immunodeficiency Virus (HIV).

The VA is notifying patients who received biopsies with the equipment in question at the following facilities:

District of Columbia
Ohio: Cincinnati
Indiana: Indianapolis

Iowa: Iowa City
Ohio: Columbus

Maine: Togus
Indiana: Fort Rucker

Minnesota: Minneapolis
Indiana: Indianapolis

Montana: Fort Harrison, Miles City
Ohio: Cleveland

Nevada: Las Vegas
Tennessee: Memphis, Murfreesboro, Nashville

New York: Buffalo, Canandaigua
Wisconsin: Milwaukee

Patients treated by the improperly scrubbed equipment will be notified and will be offered tests. The Department is working with the Food and Drug Administration (FDA), the manufacturer and the Centers for Disease Control and Prevention (CDC).

FIRST US TOO ONLINE AUCTION A SUCCESS!

Thanks to all bidders, item donors and sponsors for making the first-ever Us TOO International Online Auction so successful! A total of 51 items were sold, raising more than $15,000. Proceeds are for the Us TOO Founders’ Fund, which will be used to create and expand Us TOO services earmarked for prostate cancer patients and their families.

The auction — held online using a software service called cMarket — was open and accepted bids for three weeks, ending on the day after Father’s Day. The auction opened with a catalog of 34 times for potential bidders. The website software allowed people to contribute items to the auction. By the time the auction closed, 52 new items were donated by generous individuals, Us TOO chapters, businesses and corporate supporters, for a total of 86 items for bidding consideration.

Special thanks to our TRUE BLUE auction sponsor Valera Pharmaceuticals and our BLUE RIBBON sponsor Endocare.

SHOW YOUR TRUE BLUE COLORS
During September for Prostate Cancer Awareness Month and Prostate Cancer Awareness Week, September 17-23, 2006

1. Wear and display the BLUE RIBBON
Show your support for prostate cancer patients and survivors. Let's make the blue ribbon as visible as the pink one! The blue ribbon universally signifies research and patient support efforts for Prostate Cancer. Visit the Us TOO Store at www.ustoo.org to obtain wristbands, hats, car magnets and more.

2. Focus on Self Health
Get tested—schedule an appointment for a PSA blood test and DRE. Eat healthy. Look at new ways to improve your diet. Stay informed on new advances in treatment options and erectile dysfunction and incontinence solutions.

3. Volunteer
Start an Us TOO support group chapter to serve your own community, or help with a fundraising event for Us TOO.

4. Honor a survivor or the memory of a loved one
Consider making a Tribute or Memorial to Us TOO in honor of a friend or family member fighting prostate cancer now, or remember a loved one who has passed away.

Please accept our sincerest thanks for all you have done over the years to support Us TOO International Prostate Cancer Education & Support Network and all those men and their families who have been touched by prostate cancer.

- Baseball Hats – Navy or white, $16.00 ea
- Prostate Cancer Car Magnets “Know Your PSA” – $5.00 ea
- Blue Us TOO Awareness Wristbands – $1.00 ea
- Plus many more patient resource materials...

To order, visit www.ustoo.org or call 1-800-808-7866

Proceeds from all items sold benefit Us TOO’s FREE programs, support services and educational materials for prostate cancer patients and their families.
Enrollment was restricted to patients with metastatic adenocarcinoma of the prostate whose Gleason scores at the time of initial diagnosis were \( \leq 7 \). No prior chemotherapy was allowed and patients had to be refractory to hormone therapy with rising prostate-specific antigen levels (> 5 ng/mL) despite castrate testosterone levels.

Since previous clinical trials indicate the use of therapeutic vaccines for the treatment of prostate cancer can be safe and effective, Dr. Kantoff concludes that these study results may warrant further testing of this particular vaccine regimen to assess overall survival trends.

Reference

Clinical Care Options Oncology
3 June 2006

The Cancer Quality Alliance, headed by the American Society of Clinical Oncology (ASCO) and the National Coalition for Cancer Survivorship, met June 14, 2006. The Alliance is a forum for diverse stakeholders in the cancer community whose mission is to improve the quality of care provided to people with cancer. At the meeting, members divided work into three areas:

**Blueprint Work Group:** Tasked with developing a blueprint for what quality cancer care could be, the work group will use the Institute of Medicine (IOM) Aims of safety, effectiveness, patient-centeredness, timeliness, efficiency and equity as a framework to develop scenarios to illustrate "ideal" cancer care through the trajectory of care.

**Measures Work Group:** In order to promote the use of a comprehensive set of quality cancer care measures; the work group is identifying current measures and gaps in care, using the same six IOM Aims as a framework.

**Implementation Work Group:** This group is working on fostering broad dissemination and use of cancer quality measures and tools for improvement. The work group recognizes the importance of stage information and will develop a policy statement on collection and use of G-codes from the 2006 oncology demonstration project.

The Alliance members also reviewed the chemotherapy treatment summary and care plan, which is being developed and pilot-tested by ASCO. Its purpose is to help other treating clinicians and be shared with patients, especially those transitioning from active cancer treatment to post-care surveillance.

For more information on the Quality Cancer Alliance, contact ASCO’s Quality Division by phone at (703) 519-2905 or via E-mail at <cancerqualitycare@asco.org>.

**FACTOID**

**PSA and DRE testing:** From an Us TOO survey conducted in May 2006

Ninety-eight percent of men over 50 years of age felt that it was important to get tested for prostate cancer, however only 2/3 were tested and of those tested, more than half report skipping annual testing.