The National Conference on Prostate Cancer 2005, Exploring New Pathways: Sharing the Journey took place in Washington, DC on June 16-19 and proved successful. First, the attendance was nearly 800 people, many walked in for registration. Conference Moderator, Charles “Snuffy” Myers, MD told the crowd during his wrap-up session that the attendance meant that from a financial standpoint the conference nearly broke even for his sponsoring Foundation for Cancer Research and Education (FCRE).

Second, the thirty plus presentations, the outstanding range of talent and the range information was all a bit overwhelming to try to summarize. However, it was three and a half days filled with fellowship, hope and inspiration. Feedback during and after the conference was positive.

This was not a Conference in which highly technical papers presenting fresh research results were given. Rather, it was a Conference in which highly respected presenters, mostly MDs and research PhDs, presented summaries and reviews of the current status of knowledge in a widely diverse set of subjects. These ranged from robotic surgery for radical prostatectomies, to biomarkers useful in diagnosis that are largely ignored by many of our local medical communities.

Prostate cancer research has exploded in the past ten years, so it is almost impossible for any professional to keep up, let alone laypersons who must struggle with the jargon and biochemical concepts. Most of the presenters did an excellent job of structuring their lectures so the majority of the audience could understand and follow them.

For those of you who were not able to attend, the entire conference was videotaped and will be available on CD. For those looking for details and access to the presentations it can be found at the FCRE webpage at <www.cancer-foundation.org>.

A special Thank you goes out to all those who assisted in making this conference a success and to all those who were able to attend. As so many of us agreed, there is much work to do in the days and months ahead, this conference helped bring us together, get us informed and get us motivated.
US TOO PUBLICATIONS

In addition to the HotSheet, Us TOO offers a FREE e-mail based service called NEWS You Can Use sponsored by Sanofi-Aventis, providing updates on the latest prostate cancer related news. To subscribe or link to the archives, simply visit the Us TOO website www.ustoo.org.

Items contained in Us TOO publications are obtained from various news sources and edited for inclusion. Where available, a point-of-contact is provided.

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COMPANIONS & FAMILY MEMBERS SHARE INSIGHTS AT NATIONAL CONFERENCE

The recent National Conference on Prostate Cancer in Washington DC featured a wealth of information, support and hope. Some presentations were clinical in nature while others spoke directly from the heart. The Us TOO Companions & Families panel was a fine example of the latter, featuring six partners of prostate cancer patients, including the panel moderator, Shirley Grey.

While each panelist brought with them a unique perspective and set of circumstances, common themes were heard from them all:

- Prostate Cancer is a disease that impacts the entire family, not just the patient.
- Self care is important for caregivers, though not always practiced.
- Prostate cancer, while extremely difficult, is an opportunity to grow, learn and evaluate life.

Panelists from the Us TOO partners' presentation, "You Matter Too! Affirming, Empowering and Supporting PCa Caregivers," Left to Right: Panel moderator: Shirley Grey, Panelists Mary Dolan, Kevin, put things in perspective when she said, “If we can drive ninety minutes for crab cakes, honey, we can certainly drive two hours for a second opinion.”

Special thanks to all our panelists and their partners for their presence and valuable insights at the National Conference on Prostate Cancer: Jo Ann & Jerry Hardy, Anne & Frank Brusca, Doris and Kenneth Howard, Bill Margolis and Ed Fisher, Mary & Kevin Dolan and our moderator, Shirley and Herb Grey.

Four of the panel members are featured in The Circles of Love Collection, the recently released book which is part of the Circles of Love Companions & Families Care Kit. Available individually or in the care kit at <www.ustoo.org>.

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US TOO SURVEY ON ADVANCED PROSTATE CANCER

Us TOO is conducting a survey this summer to learn more about patient and caregiver experiences with advanced prostate cancer. This survey will help us raise awareness, address critical needs for advanced prostate cancer patients and help us understand the need for more in-depth tools and resources for the US TOO Chapter Network volunteers.

As part of our activities during Prostate Cancer Awareness Month in September we will highlight Us TOO’s 15-year history and provide you with the findings of our survey. This survey is focused on late stage disease only. Often prostate cancer does not advance to this later stage, however experience tells us there have been relatively few resources to support men whose cancer is advanced. This survey will equip us to better speak about the day-to-day experiences, awareness, concerns and needs of men with late stage disease.

If you are hormone-refractory – that is hormone therapy is no longer working – (also known as hormone-insensitive, androgen-independent, or androgen-insensitive) and would like to participate in the survey, please go to the Us TOO website and click on the survey link.

Or, simply type <http://www.surveymonkey.com/s.asp?u=856011190791> into your web browser, and you will be automatically taken to the survey.

Thank you for supporting Us TOO and helping us reach prostate cancer patients across the world. We appreciate you taking the time to fill to this survey.

RUN, WALK ‘N ROLL FOR PROSTATE CANCER

In the Chicago area race plans are proceeding and support is growing. The Don Johnson Chapter of Us TOO and the Wellness Place have prepared the Save the Date card we thought the Greater Chicagoland readers might find of interest. The race is scheduled to take place in the Northwest suburbs at Busse Woods in Rolling Meadows. Russ Gould, an Us TOO International Board member and chapter leader, tells us that he is excited about the collaboration which is seen as a model that can lead to new program initiatives in the near future.

Tom Kirk, Us TOO President and CEO, speaks to the nearly 800 attendees at the National Conference on Prostate Cancer 2005. This conference, jointly hosted by Us TOO and the FCRE (Foundation for Cancer Research and Education), was the first of its kind to be held on the East Coast of America. Its origins are with the PCRI (Prostate Cancer Research Institute) in Los Angeles, CA, which helped to support the Conference.
**Exercise Improves Sexual Function After Prostate Cancer Radiotherapy**

Increased physical activity after external beam radiotherapy for prostate cancer results in better sexual functioning, according to a report in the May 2005 issue of Urology (Vol. 65, pp. 953-8).

Physical activity preserves the sexual functioning of older men, the authors point out, but whether physical activity influences sexual functioning after treatment for localized prostate cancer is unknown.

To investigate, Dr. Jason R. Dahn and colleagues from University of Miami examined possible associations among treatment procedure, physical activity, and sexual functioning in 111 men who were treated with radiotherapy for localized prostate cancer.

Overall, physical activity was independently related to sexual functioning, the authors report. The association was especially strong among men who received external beam radiotherapy, whereas physical activity did not significantly affect sexual functioning among men who received brachytherapy and combination treatment.

Sexual functioning was also negatively associated with participant age and medical comorbidity and positively associated with higher urinary and bowel functioning scores.

"The level of physical activity contributes independently to the explanation of variance in sexual functioning scores," the investigators conclude, "and physical activity and treatment procedure appeared to interact in such a way that both are required to appreciate fully the differential effect of physical activity on sexual functioning." 

"A randomized clinical trial assessing these relationships longitudinally in a larger sample," they add, "might provide very useful information.

*Reuters, 17 June 2005*

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**Common Virus Kills Cancer, Study Finds**

A common virus that is harmless to people can destroy cancerous cells in and might be developed into a new cancer therapy, U.S. researchers. The virus, called adeno-associated virus type 2, or AAV-2, infects an estimated 80% of the population.

"Our results suggest that adeno-associated virus type 2, which infects the majority of the population but has no known ill effects, kills multiple types of cancer cells yet has no effect on healthy cells," said Craig Meyers, a professor of microbiology and immunology at the Penn State College of Medicine in Pennsylvania.

"We believe that AAV-2 recognizes that the cancer cells are abnormal and destroys them. This suggests that AAV-2 has great potential to be developed as an anticancer agent," Meyers stated.

AAV-2 is a small virus that cannot replicate itself without the help of another virus. But with the help of a second virus, it kills cells.

For their study, Meyers and colleagues first infected a batch of human cells with HPV, some strains of which cause cervical cancer. They then infected these cells and normal cells with AAV-2. After six days, all the HPV-infected cells died. The same thing happened with cervical, breast, prostate and squamous cell tumor cells.

"One of the most compelling findings is that AAV-2 appears to have no pathologic effects on healthy cells," Meyers said. "So many cancer therapies are as poisonous to healthy cells as they are to cancer cells. A therapy that is able to distinguish between healthy and cancer cells could be less difficult to endure for those with cancer."

AAV-2 is being studied as a means to carry disease-correcting genes into the body. Gene therapy researchers favor it because it does not seem to cause disease or immune system reaction on its own.

*Reuters, 21 June 2005*

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**Abbott to Give Cancer Drug to Some Patients**

Abbott Laboratories announced it received U.S. regulatory approval to make its experimental prostate cancer drug Xinlay available this summer to certain patients even though it is not yet approved.

The U.S. Food and Drug Administration has given Abbott permission to make Xinlay available in the U.S. to men with late-stage prostate cancer who do not respond to hormone therapy under a program known as expanded access.

Xinlay is an oral, once-a-day, non-chemotherapy cancer agent. It belongs to a class of compounds known as selective endothelin-A receptor antagonists, a protein thought to be involved in the spread of cancer cells.

An Abbott spokeswoman said the company will distribute information about the drug to investigators in its clinical trials and to patient advocate groups. Abbott will be required to report safety information to the FDA.

"We believe that today's news is a signal that the FDA considers Xinlay to be safe and effective enough to be used on patients," Bank of America Securities analyst Glenn Novarro said in a research note. "This gives us more confidence that the drug will receive approval by year-end."

He believes about 200 prostate cancer patients will receive treatment under the program.

If approved in late 2005, Novarro expects Xinlay sales to reach $300 million in 2006 and ultimately reach $1.5-2.0 billion annually.

An FDA advisory hearing on Xinlay is set for September. The current application is for patients whose cancer has spread to the bone and who have failed to respond to standard treatments.

Clinical trials for use of the drug earlier in the disease are underway.

*Reuters, 23 June 2005*
Purpose: To prospectively assess health-related quality of life (HRQOL) during the first year after treatment with prostate brachytherapy (PB) alone for T1c-2a prostate cancer.

Materials and Methods: Ninety-eight patients from 24 institutions were eligible and properly entered on this study. All patients were treated with PB alone using I-125 (Oncura Model 6711). The prescription dose was 145 Gy. Three separate health-related quality of life questionnaires (HRQOL) (Functional Assessment of Cancer Therapy-Prostate [FACT-P], Sexual Adjustment Questionnaire [SAQ], and International Prostate Symptom Score [IPSS]) were self-administered before and after PB (baseline; 3, 6, 9, and 12 months after PB). The standard error of the mean (SEM) was used to analyze changes in HRQOL scores over time. Patients who improved greater than the SEM were categorized as improved; patients that declined greater than the SEM were categorized as declined; patients were otherwise categorized as stable. All changes are measured using the pretreatment HRQOL score as baseline.

Results: The percentage of men who reported the ability to have an erection decreased from 73% at baseline (65% unassisted, 8% assisted) to 57% at 1 year (36% unassisted, 21% assisted). The rate of urinary incontinence increased to 14% at 6 months but had decreased to 1% at the 12-month follow-up. At 1 year after PB, 80% of men reported decreased sexual functioning according to SAQ scores. More than 60% of men reported decreased urinary function at 12 months compared with baseline.

Conclusions: This article represents the first prospective, multi-institutional study of HRQOL in men treated with PB and demonstrates that patients undergoing PB have a very high overall HRQOL. The rate of incontinence by 1 year after PB is low, but many patients continue to have obstructive symptoms at 1 year. Although 78% of 1-year respondents state that they can achieve an erection with or without assistance, almost 50% report a decrease in sexual function.

**Evolution of Chemotherapy Options for Hormone-Refractory Prostate Cancer: Emerging Role for Platinum Compounds**

Chemotherapy is gaining an increasing role in the treatment of hormone-refractory prostate cancer. Trials in the mid-1990s indicated that systemic therapy with steroids and mitoxantrone provided some benefits (pain reduction and improvements in quality of life). Recent studies with the chemotherapy drug docetaxel (Taxotere), in hormone-refractory prostate cancer reported survival benefits with chemotherapy in hormone-refractory prostate cancer, for the first time. Currently, docetaxel (Taxotere) is considered first-line treatment for hormone refractory prostate cancer and there is no approved treatment available if docetaxel fails. Promising data from additional drugs are beginning to accumulate from clinical trials in hormone-refractory prostate cancer.

There are currently no approved chemotherapy drugs for the second line treatment of hormone-refractory prostate cancer (HRPC). In a preliminary randomized trial conducted in Europe, the combination of satraplatin and prednisone had superior activity compared to prednisone alone, for the treatment of HRPC patients who had not previously been treated with chemotherapy. Satraplatin is a member of the platinum-based class of chemotherapy drugs. Platinum-based drugs have been clinically proven to be one of the most effective classes of anticancer therapies. Unlike the currently marketed platinum-based drugs, satraplatin can be given orally (by mouth). Satraplatin is also the only platinum-based drug that has demonstrated efficacy against hormone-refractory prostate cancer in a randomized trial.

Currently enrolling, the SPARC (Satraplatin and Prednisone Against Refractory Cancer) Phase III clinical trial is designed to compare the combination of the investigational oral cytotoxic drug, satraplatin, and prednisone, versus prednisone alone as second line chemotherapy in patients with hormone-refractory prostate cancer. The SPARC trial is intended for patients who have hormone-refractory prostate cancer and whose disease has progressed after treatment with one chemotherapy regimen. Two-thirds of the patients will receive satraplatin plus prednisone and one-third of the patients will receive prednisone alone.

For more information about the ongoing trial, including key inclusion and exclusion criteria, please visit www.sparctrial.com or contact Faith E. Nathan, M.D., at phone 609-524-1048 or e-mail sparct-us@gpc-biotech.com.
MEDICARE COMPETITIVE ACQUISITION PROGRAM: PATIENT IMPACT ISSUES

As you may have heard, US TOO is concerned about the Medicare Competitive Acquisition Program (CAP) and recently our Advocacy Committee prepared and sent input on draft Federal Regulations. We want to raise your awareness on this issue because this program may limit access to life saving medications and create undue financial burdens for patients. It is our understanding that CAP has the potential to interfere with the doctor/patient relationship and we think it may add unnecessary stress during the critical period when treatment decisions are made.

The Medicare Modernization Act passed by Congress in 2003 calls for the Centers for Medicare and Medicaid Services (CMS) to develop the CAP as an alternative system for doctors to obtain their physician administered part B drugs. Recently, on July 6, 2005, CMS published the Final Rule for the CAP, which enables the agency to move forward with the program’s implementation.

Effective January 1, 2006, this program will allow doctors to obtain their Medicare Part B reimbursed drugs from competitively selected vendors. These vendors will supply the drugs, bill Medicare and collect the co-insurance from patients. The objective of this program is to deliver savings to CMS while giving physicians an alternative to the buy-and-bill drug acquisition system.

In order to ensure the continued availability of your current treatment, it is important to begin a dialogue with your doctor about his intent to participate in the CAP. To assist with this process, US TOO plans to publish “CAP Frequently Asked Questions” on our website and provide discussion points to aid you in your conversations with your doctor.

We will also feature a more detailed description of the CAP in the September issue of the HotSheet. For now, here are some key issues about the program.

- Medicare vendors can encourage doctors to change cancer treatments based on cost rather than patient choice.
- Of those prostate cancer therapies that will be included in the CAP, vendors are not required to provide every dose and formulation.
- Lucky some products like Lupron and testosterone are not included in this program and will continue to be available without restriction.
- Medicare vendors have the authority to withhold shipment of drugs for those patients who are delinquent in paying their co-insurance.
- Patients could be pursued by large corporate entities for their co-payments.
- Patients do not realize any savings under this program, and their co-payments may increase.
- Doctors are not required to disclose their CAP participation prior to the patient’s appointment.
- All of these factors interfere with the nature of the doctor/patient relationship and are points of concern to Us TOO that we felt you need to know.

NEW TREATMENT OPTIONS FOR ADVANCED, HORMONE REFRACTORY PROSTATE CANCER

Last month, the National Cancer Institute (NCI) announced a new Phase II trial for hormone-refractory prostate cancer has opened for patient enrollment. The new trial will evaluate the efficacy of the anti-angiogenesis drug, Bevacizumab (trade name Avastin®) in conjunction with standard chemotherapy plus thalidomide, a drug which also possesses anti-angiogenic effects.

Bevacizumab is a monoclonal antibody that works by attaching to and blocking the activity of vascular endothelial growth factor (VEGF). This drug is approved for use against metastatic colorectal cancer, and is currently being studied for the treatment of a variety of different cancers.

The highlights of the new NCI study “Protocol 04-C-0257 Phase II Trial of Docetaxel, Thalidomide, Prednisone and Bevacizumab” are summarized below:

Eligibility:

- Metastatic androgen independent prostate cancer
- Progressive disease either on x-rays/scans or evidenced by a rising PSA
- No prior chemotherapy for metastatic disease
- Controlled hypertension (systolic blood pressure < 170, diastolic blood pressure < 100)
- No coumadin, heparin or heparinoids

Treatment Plan:

- 21 day cycles during which patients receive:
  - Day 1 docetaxel
  - Day 1 bevacizumab
  - Daily thalidomide
  - Daily prednisone
- Patients will be placed on prophylactic anticoagulation
- Patients will be seen monthly at the NCI

Keeping physicians informed and updated about clinical trials is a top priority of the NCI. Physicians interested in referring patients are asked to contact NCI’s Nurse Practitioner, Kathy Fedenko, MS, CRNP, by phone (301) 451-1407, by FAX (301) 594-4712 or by e-mail <fedenkok@mail.nih.gov>.
US TOO FEATURED RESOURCES
To order or find, visit www.ustoo.org

1) NEW! The Circles of Love Care Kit – $24.99 includes S+H
Our new care kit is an excellent resource collection for friends and loved ones of those facing the battle against prostate cancer. Our care kit includes:
   - The Circles of Love Collection: Stories of Companions and Families Facing Prostate Cancer: This new book, an Us TOO original publication, is a compilation of interviews with friends and loved ones of prostate cancer patients. These supportive and inspirational stories are meant to help others who are facing similar challenges. Also available separately for $17.00 includes S+H.
   - Circles of Love Music CD: This original collection of upbeat and inspirational songs was written to celebrate the love and support between the patient and his companions and family members. Contributing artists include Soozie Tyrell of the E Street Band, Alan Glass (who has written hits for Aretha Franklin, Earth, Wind and Fire, Kenny G and others), Jerry Peters (who has written for Luther Vandross and others), country artist Deborah Allen, and folk artist Kat Eggleston. 12 songs including pop, R&B, soul, country, folk and dance. Also available separately for $15.00 includes S+H.
   - Intimacy with Impotence: The couples guide to better sex after prostate disease: This book, authored by Ralph and Barbara Alterowitz, is written for couples who have survived prostate cancer and whose normal sexual function has been disrupted. The authors bring a unique and personal perspective to the topics as they too live this experience. 220 pages.
   - What You Need to Know about Prostate Cancer: from NIH and NCI
   - “Life after Cancer Treatment” Resource and Referral Guide: excerpt from NCI

2) NEW! Prostate Cancer Car Magnets “Know Your PSA” – $5.00 – includes S+H

3) STRIVE Initiative Wristbands – $1.00 each plus S+H

4) HotSheet Subscriptions – $35 for 12 issues
   HotSheets are distributed FREE at all Us TOO Support Group Chapter meetings, and on www.ustoo.org. But what if you are unable to regularly attend chapter meetings, or don’t have access to the Internet? Don’t miss an issue—we can deliver it right to your home or office!

5) “What You Need To Know For Better Bone Health” – FREE Us TOO brochure

6) 100 Questions & Answers About Prostate Cancer – $14.95 includes S+H
   By Pamela Ellsworth, MD, John Heaney, MD, Cliff Gill

7) Prostate Cancer Resource Kit – $18.95 includes S+H
   Included in this handy boxed kit:
   - A Primer on Prostate Cancer - by Dr. Stephen Strum and Donna Pogliano
   - Know Your Options – from Us TOO and the National Cancer Institute (NCI)
   - Prostate Cancer Treatment Guidelines for Patients – from National Comprehensive Cancer Network (NCCN)
   - and the American Cancer Society
   - What You Should Know About Prostate Cancer - from Prostate Cancer Research Institute (PCRI)
   - Prostate Cancer Resource Guide - from the American Foundation for Urologic Disease (AFUD)
   - Us TOO / Phoenix 5 CD-ROM - developed by Robert Young

8) Understanding Prostate Cancer: A Patient's Resource Kit – $7.50 includes S+H
   Included in this handy boxed kit:
   - Humanizing Prostate Cancer: A Physician-Patient Perspective by Roger E. Schultz, MD (Physician), and Alex W. Oliver (Patient)
   - Living With Prostate Cancer – booklet
   - Know Your Options – from Us TOO and the National Cancer Institute (NCI)
   - Living With Advanced Prostate Cancer video - patient testimonials on Viadur


10) Us TOO Prostate Cancer NEWS You Can Use – FREE e-News

Proceeds from all items benefit Us TOO’s FREE programs, support services and educational materials for prostate cancer patients and their families.
LAWMAKERS URGING PROSTATE CANCER SCREENING

If it seems members of Congress are diagnosed with prostate cancer more than most American males, anti-cancer activists say there's a logical reason. They're tested more.

Several congressional prostate cancer survivors, led by Georgia Sen. Saxby Chambliss, are uniting Wednesday to encourage men to get screened often for the disease, which is deadly but treatable if detected early enough.

Chambliss, a Republican, learned he had prostate cancer last summer as part of an annual physical given to members of Congress. He has since had a surgical procedure, and the disease is in remission.

"We're on the road to winning our battle," Chambliss said. "I want to make sure I communicate my story to men all across Georgia and all across the country. It just proves if you have cancer and find out early about it, you can be cured."

Chambliss has plenty of colleagues to help him spread the message. Fellow prostate cancer survivors in the Senate include both Alabama's Republican senators, Richard Shelby and Jeff Sessions, Idaho Republican Mike Crapo and South Dakota Democrat Tim Johnson. Congressmen who were diagnosed with it include Jim Marshall, D-GA., and Duke Cunningham, R-CA.

"I think for years that people died of cancer, and it probably came from prostate cancer but people didn't know what it was," Shelby said. "Now you can save people's lives." Shelby and most of the others will participate in the awareness event Wednesday outside the Capitol. Also expected to attend are two activists from the baseball world, former Los Angeles Dodgers manager Tommy Lasorda and former New York Mets third baseman Robin Ventura.

Jamie Bearse, spokesman for the National Prostate Cancer Coalition, said about 48 percent of men over 50 haven't been screened. That's troubling considering one out of six men get the disease in their lifetimes, and only a third survive five years if it isn't detected early.

Sessions said screening is an easy procedure. "They draw blood, may check your cholesterol and PSA at the same time," Sessions said. "If that comes back positive, they can do a biopsy that will confirm the PSA."

Washington Post, 14 June 2005

CELL GENESYS INITIATES SECOND PHASE III TRIAL OF GVAX

Cell Genesys has initiated a second multicenter Phase III clinical trial of its GVAX vaccine for prostate cancer in patients with metastatic hormone-refractory prostate cancer.

This second Phase III trial, referred to as VITAL-2, is the other key component of the company's product registration strategy that builds on promising findings from two previously reported Phase II trials of the vaccine in over 100 patients with advanced prostate cancer.

The trial will compare GVAX plus Taxotere (docetaxel) chemotherapy to Taxotere plus prednisone with respect to survival benefit. The study is expected to enroll approximately 600 prostate cancer patients at approximately 100 medical centers throughout North America and Europe.

In May 2005, Cell Genesys received a special protocol assessment from the FDA for the trial, which provided FDA confirmation that the trial design would adequately support a product registration application.

FDA News, 6 July 2005