

In The

# Know

Confronting Prostate Cancer

FEBRUARY 2011

WHAT'S TRUE FOR YOUR BIKE IS TRUE FOR YOU

## LADIES & GENTLEMEN CHECK YOUR ENGINES



**HEALTH AWARENESS DAY-2011**  
**SATURDAY, FEB 12th-10am-2pm**  
**at BERGEN COUNTY HARLEY-DAVIDSON/BMW**  
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 US TOO PROSTATE CANCER EDUCATION & SUPPORT

\*Screenings of "Check Your Engines" is an equal trademark of The Prostate Net. The "Check Your Engines" Screenings are made possible by a grant from the New Jersey Department of Health and Senior Services, Office of Cancer Control and Prevention. The assistance of the Bergen County Cancer Center.

## Health Awareness Day 2011

by Virgil H. Simons

The President's Cancer Panel of the National Institutes of Health in 2001 clearly stated, "Lack of accurate cancer-related information that is readily available, understandable, clear and delivered in a sensitive and culturally acceptable manner is a major contributor to the inability of patients and the public to obtain the most appropriate cancer prevention, treatment and supportive care." One way to at least partially address this situation is to create successful outreach programs, which educate men in order for them to make informed decisions about their personal risk of the disease as well as other conditions affecting their health.

**Gentlemen Check Your Engines™** workshops, seminars, conferences and other events facilitate obtaining information on how best to manage men's prostate health and other medical options, and enhance communications between men and their healthcare providers using the Harley-Davidson dealerships as a network of trust. Additionally the on-site screening and educational programs provide better initial access to and participation in the health care system.

The basic concept behind this initiative is that men pay more attention to their cars, motorcycles and other toys than to their personal health. **Gentlemen Check Your Engines™** educational program focuses on utilizing a credible environment that is safe and comfortable, the Harley-Davidson dealership, and motivating men to come there for health information and screenings. The key innovative factors are found in the partnership with Harley-Davidson dealers, healthcare providers and public health agencies to promote men's health in a unique way.

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## In His Own Words



### What Happened When I Got My 'Engine' Checked

By Alan Bodner

In February, 2010, I attended a Men's Health Awareness Day, also known as "Gentlemen Check Your Engines," at the Bergen County, NJ Harley-Davidson store. When I stopped at a Prostate Cancer booth, the doctor asked me how old I was and if I'd ever had a PSA test. When I told him I was 63 and didn't know what a PSA test was, he told me it was a test for Prostate Cancer. He also said that 1 in 5 men get Prostate Cancer and, if I had it, my life could end in only 10 years. So I called my doctor to set up an appointment for a physical. He told me that my last visit was 7 years ago and asked why it took me so long to come in. I told him that I didn't feel sick! I also told him that I had learned about PSA tests and decided to come get a physical.

The first PSA blood test came back with a 6.4 reading. I was told that anything above 4.0 wasn't good, so my doctor asked me to come in for another PSA test. The second one came back again as a 6.4. Then I called Urology Specialty Care, where my daughter, Robyn, works as an RN. She arranged for me to meet with Dr. John Hajjar. He reviewed my PSA results and recommended a prostate biopsy that would show if there is cancer and how much. The biopsy took 10 samples and I had 3 "hot spots" [spots on the prostate positive for cancer]. Dr. Hajjar said radical prostate surgery would be the best option for me and that my recovery would be very good. He added that there was a downside--I wouldn't be able to have more children. I told him that having children at the age of 63 was not high on my list, but life was!

I was diagnosed at the end of May, 2010. I told the doctor I planned to go to Sturgis for the Motorcycle Rally with my friends in August. He said we should do the surgery as soon as possible, since it would take 8 weeks for me to recover. On August 4th, my 3 friends and I left on our bikes for Sturgis! My friends were great—they let me take all the time I needed at gas stops to use the bathroom. We had a great time. Thanks to the Men's Awareness Day and Dr. Hajjar, I can go there again someday. Next summer I'll be going on RT 66, the only highway to go on if you ride a motorcycle. This time I'll take a tire repair kit and a small compressor, but that is another story to tell.

To all men: do yourself a big favor—go for a PSA test even if you are only 45. Like all cancers, if they are found early, they can be treated. For men that are young and would like to have children, there are other types of treatments if you are diagnosed with Prostate Cancer. If you are unsure about a doctor's opinion on treatment, go to another doctor for a second opinion. In the end it's your life that you should be concerned with. Remember, your family would like to have you around for a long time.

Health Awareness Day 2011...

*continued from page 1*

An important tangent to the basic core promotional effort has been the involvement of a women's initiative to encourage greater male participation in the educational and health screening activities. The experience from 2010's event in New Jersey, done in conjunction with the "St. Valentine's Day" promotion period, served to increase the numbers of men participating in the health event through the use of incentive items suitable for the women in their lives. As a result, we have expanded our focus to include women's health as part of the overall mission.

The Prostate Net® piloted this initiative in February 2008 as part of the Bergen County Cancer Coalition and in partnership with the local Harley-Davidson dealership. The program continued into 2009 with a return to the Bergen County dealership as well as into Chicago and Atlanta. Participation increased to 2,861 men, as well as a surveyed increase in participation satisfaction with the event and a desire for continued efforts of its kind. In 2010 the program expanded further and we saw our first documented case wherein the educational effort resulted in the diagnosis of, several previously undiscovered cases, prostate cancer.

Additionally one of our World Wide Prostate Cancer Coalition partner organizations, the Prostate Cancer Foundation of Australia, tested the concept in two major communities in Australia with comparable success in education and on-going involvement with their prostate cancer support organizations.

The experience gained from the execution of this program over the past three years and in multiple markets has shown that information coming from a trusted source has a very significant impact on increasing awareness and education among men as well as motivating them to utilize the access to care afforded by the program.

#### EDITORS NOTE:

The 2011 Global Gentlemen Check Your Engines™ Day will be held Saturday, February 12th

The New Jersey program will take place from

10:00 a.m. to 2:00 p.m. at

the Bergen County, NJ, Harley-Davidson/BMW at

124 Essex Street-Rochelle Park.

For more information, call (201) 843-6930.

**LADIES &  
 GENTLEMEN  
 CHECK YOUR ENGINES**

## Prostate Cancer & the PSA Debate

By John Andrews

Prostate cancer is the most common cancer and the second leading cause of cancer-related deaths in American men. Although the use of the prostate-specific antigen (PSA) test for prostate cancer screening since the 1990s has led to increased early diagnoses, the most recent studies are in conflict about the risks and benefits of routine prostate cancer screening.

On September 11, 2010, The Prostate Net and The Robert H. Lurie Cancer Center in conjunction with the Prostate SPORE, a consortium of Northwestern University, University of Chicago and North Shore University Health System presented their Inaugural Prostate Cancer Forum. This dual track educational initiative for patients/spouses, Advocates and Healthcare professionals convened a world-class faculty of medical professionals to present and discuss the most contemporary treatment options and issues surrounding prostate cancer, including PSA screening.

The initial symposium topic; PSA Testing: Is There An Answer? was introduced by Virgil Simons, Founder and President of The Prostate Net and continued with presentations by two well-known, leading prostate cancer experts, William Catalona, MD, Professor, Northwestern University, Feinberg School of Medicine, Department of Urology and Otis Brawley, MD, Chief Medical and Scientific Officer Executive Vice President American Cancer Society, and Professor of Hematology, Medical Oncology, Medicine and Epidemiology Emory University.

A point-counter-point discussion by Dr. Catalona and Dr. Brawley followed and has been captured for review on The Prostate Net's Symposium Portal: <http://prostatenet.com/page/>

You are encouraged to read the articles here, visit the site and investigate and decide for yourself the value of routine PSA screening.

## Prostate Cancer Screening

By Brian Stone, MD

This is a year of controversy in health care. The economic crisis and the aggressive move towards healthcare reform have further stimulated cost cutting measures by Medicare and private insurance carriers. Reimbursements for cancer early detection are being heavily scrutinized.

The AUA believes that the wide spread use of PSA screening has led to the earlier diagnosis of prostate cancer and improved short term outcomes after diagnosis. However, this belief has not been supported by randomized trials. The current position by many opponents of screening, that prostate cancer early detection is not warranted is fueled by those lobbying for "healthcare cost containment" and not necessarily for the preservation of male lives. This is especially true in high risk populations such as men of African descent and those with a strong family history of prostate cancer.

By the end of our discussion I am certain that you will be convinced that early detection is warranted in high risk populations, especially African American men when offered in an informed manner.

### FACTS:

Prostate cancer remains the most frequently diagnosed cancer in men. An estimated 192,280 new cases are expected to be diagnosed in 2009 along with 27,360 deaths from this disease. There is a significant disparity in the incidence and mortality of prostate cancer between men of African descent and the rest of the American population (specifically African American and Jamaican men).

Several screening trials are currently underway attempting to provide the much needed data but they have severe under representation of high risk populations making their conclusions useless for men of color. There was never comparable scrutiny for mammography and breast cancer early detection, why????

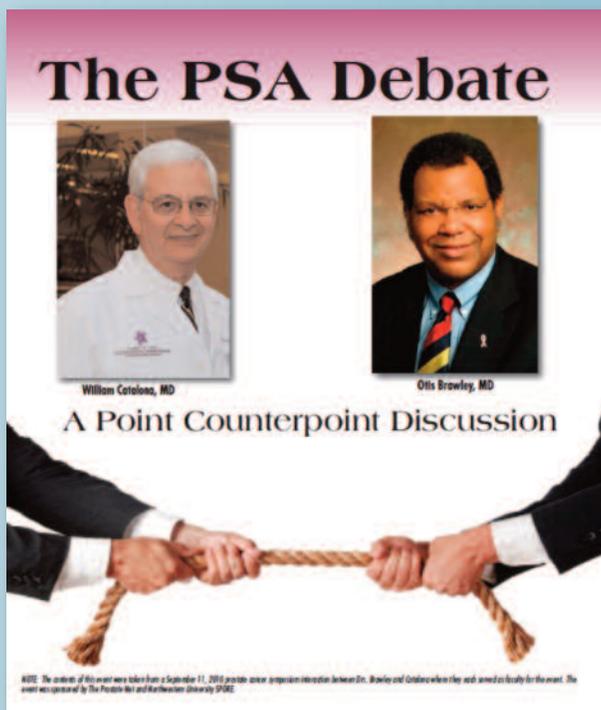
### QUEBEC TRIAL (LABRIE ET AL)

This trial enrolled 46,486 men aged 45 -80 years which were randomly assigned to screening and no screening in 1988. The 11 year follow up showed a 62% reduction in prostate-specific mortality among the screened men (P = .005).

Study Drawback: There are concerns over the design of this trial leaving this the least robust data set addressing PSA screening. No data on men of African descent.



Brian Stone, MD



## Prostate Cancer Playbook

by Diane Johnson



Marcelo Balboa

When I spoke to Marcelo Balboa, he was eagerly anticipating soccer's World Cup in South Africa last year. He knows about World Cups—he played in three of them in the 1990's and became the U.S. team's captain. He is also in the National Soccer Hall of Fame. Since he retired in 2003, he has expanded his role from footballer to reporter, announcer, analyst, adviser and coach.

Now he's added another role: advocate and spokesman for "TEAM UP AGAINST PROSTATE CANCER". In partnership with the Prostate Conditions Education

Council (PCEC) and the pharmaceutical company Sanofi-Aventis, U.S., Mr. Balboa is coaching men from a new playbook. This one is about protecting their prostate. The TEAM UP AGAINST PROSTATE CANCER Playbook includes information on the prostate, how to recognize the signs of prostate cancer, and, if diagnosed, how to "draft an all-star team for treatment." This playbook is free and available at [www.prostateconditions.org](http://www.prostateconditions.org) (click on "Programs and Events" to find the 'Team Up Against Prostate Cancer' page), in both English and Spanish. (If no computer access, phone calls can be made to 866-4PROST8 (866-477-6788). All calls will be handled privately and anonymously.)

While researching his family background, Mr. Balboa was surprised to find out that his grandfather had been diagnosed with prostate cancer. "I had never thought about it," he said. "My grandfather had surgery and was cured. He actually died later from something else," he said. "That threw a red flag up for me." So Mr. Balboa got checked last year at the age of 41. "I was born in the United States and my mom and dad are Hispanic," he continued. "In the Hispanic community, talking about prostate cancer or rectal exams is a big faux pas. Even here, American men are almost embarrassed about it," he said. "We need to get over it." He emphasizes that the exam is a "private thing." "I didn't announce to the world that I had my exam," he said. "And if you have the exam it doesn't mean you are less macho," he added. "It's something that could save your life."

Mr. Balboa has met and talked with many survivors during this campaign--those who were diagnosed early and treated and those who have more advanced disease. "It is very humbling to hear their stories," he said. He is determined to spread the message so men can take charge of their health and get checked. He encourages men over 50, or those who have a family history, to get checked. "[The prostate] is a part of our body that no one wants to talk about and it is something that could kill you," he said. He described his prostate exam as a "20 second procedure that could save my life." "I'll take that," he said, "so I can be around another 30 years for my kids and see my grandkids." "There is nothing to be embarrassed about," he added. "Don't die because of your pride."

Prostate Cancer Screening

continued from page 3

### THE TYROL STUDY

This study involved [12] different projects. The PSA screening study enrolled 21,079 men in Tyrol, Austria in 1993 and study published in 1999. These data suggest that PSA-based screening with low PSA cut-off values increase the detection rate of clinically significant, organ confined and potentially curable prostate cancer.

**STUDY DRAWBACK:** Follow up period not long enough and there were no men of African descent in the study.

### EUROPEAN RANDOMIZED STUDY OF SCREENING FOR PROSTATE CANCER (ERSPC)

This study evaluated the effects of screening on advancing the time of diagnosis (i.e., lead time) and detecting cancers that would not have been diagnosed in the absence of screening (i.e., over detection). Investigators identified 182,000 men 50 to 74 years of age from seven European countries in the early 1990's (enrollment dates in each country varied). These men were randomized in to screening vs. control group. The screening group received a PSA test every 4 years and the men in the control group "supposedly" did not receive a PSA test at all. The 162,243 men included in this analysis were 55 to 69 years of age. This study concluded that while prostate cancer deaths were reduced by 20%, over detection of incidental prostate cancers is a consequence of screening.

**STUDY DRAWBACK:** Follow-up period not long enough to assess true mortality impact and no data of men of African descent.

### PLCO CANCER SCREENING TRIAL

The prostate, lung, colorectal and ovarian cancer study is a large-scale clinical trial to determine whether certain screening tests reduce the mortality from these cancers. This study enrolled 154,942 men and women between the ages of 55 and 74. Men entering the prostate cancer component of the study were randomized into either the cancer screening arm or to continue their normal health care routine. Men in the screening arm received PSA blood testing and a DRE upon entry.

The PLCO data six rounds of annual screening led to the diagnosis of 22% more prostate cancers by 7 years after the start of screening and 17% more prostate cancers by 10 years from the start of screening. The difference in the number of prostate cancer deaths between the two study groups was not statistically different.

**STUDY DRAWBACK:** Follow-up period not long enough and no analysis of data in AA men available.

### SCREENING GUIDELINES:

#### US PREVENTATIVE SERVICES TASK FORCE

In 2008, the USPSTF concluded that there was insufficient data to support / recommend PSA screening in men 75 years of age or older.

#### American College of Preventive Medicine

They concluded in February 2008 that there is not enough evidence to recommend routine population screening for prostate cancer using DRE and PSA testing.



## New Office Of Indian Men's Health

### An Excellent Beginning

by Diane Johnson

The Patient Protection and Affordable Care Act was signed into law in March of 2010. There are many worthy initiatives contained in this massive bill, one of which will hopefully start a trend.

One of those initiatives, the Indian Health Care Improvement Act, includes the creation of an Office of Indian Men's Health, an adjunct to the existing Office of Indian Women's Health. American Indian and Alaskan Native men will now have access to information on disease prevention and detection, tailored specifically to men. The initiative also focuses on health problems disproportionately endemic in this same group of men: diabetes, depression, obesity and prostate cancer. Emphasizing awareness and prevention is the cornerstone of the program. "Cultural forces and the often stoic nature of men in our community frequently results in the ignoring of symptoms and a reluctance to seek medical care until treatable conditions are in their end stages," said Daniel Molina, MD, Assistant Medical Director of the Oklahoma City Indian Clinic. Michael Trujillo, MD, MPH the American Cancer Society's Great West Division Board Director, agrees saying, "This critical initiative gives men—often the guideposts in the community—the ability to set a powerful example about the importance of being proactive about health."

The trend I mentioned at the beginning of this article? Jimmy Boyd, Executive Director of the Men's Health Network ([www.menshealthnetwork.org](http://www.menshealthnetwork.org)), a national non-profit organization dedicated to men and their families, says he hope this will be "the first such office." It has long been the wish of men's advocacy groups that an Office of Men's Health be created in this country. Scott Williams, V.P., also with Men's Health Network, said, "We look forward to the day when there will be an Office of Men's Health at each of the federal agencies addressing the health of American families."

It's time to tell the men in this country how much we value them by making their good health a national priority.

### The National Comprehensive Cancer Network Guidelines

They recommend baseline risk assessment with DRE and PSA at age 40. Men with a baseline PSA of <0.6 ng/ml can wait until age 45 for additional prostate cancer screening, but men with a PSA >0.6 ng/ml should proceed with follow-up screening.

### American Urological Association Guidelines

The AUA recommends that the PSA blood test be offered to well informed men aged 40 years or older who have a life expectancy of at least 10 years. The AUA recognizes that the use of PSA in the detection of prostate cancer is very controversial; however, they believe that when the test is offered and interpreted appropriately, the PSA blood test may provide essential information for the diagnosis, pre-treatment staging or risk assessment and post-treatment monitoring of prostate cancer.

### R. Frank Jones Urological Society Guidelines

The RFJUS represents the interests of the nations African American urologists (and patients) and established guidelines that were published in 1998 that recommended that all high risk males began annual PSA testing and DRE at the age of 40. We are currently a recognized society within the AUA and have embraced its current guidelines.

### American Cancer Society Guidelines

The ACS does not support routine testing for prostate cancer at this time. However, they do believe that health professionals should "discuss" the potential risks and benefits of prostate cancer early detection testing with men before any testing is initiated. This discussion should include an "offer" of testing with PSA blood testing and the DRE annually starting at the age of 50 in men with an "average" risk of prostate cancer and a life expectancy of 10-years. This discussion should take place at the age of 45 in high risk populations.

**Editor's Note: The Prostate Net® supports the importance of PSA testing for all men in order to, at minimum, establish a baseline level of prostate health, from which informed decision making can be made.**

The   
Prostate  
Net

[www.theprostatenet.org](http://www.theprostatenet.org)

Email: [support@prostatenet.org](mailto:support@prostatenet.org)

Phone: 1.888.477.6763



## 2011 Innovative Minds in Prostate Cancer Today (IMPACT) Conference

By Theresa Miller, PhD

The second Innovative Minds in Prostate Cancer Today (IMPACT) conference will be held in March 9-12, 2011 in Orlando, Florida. The conference is sponsored by the Department of Defense (DOD) Prostate Cancer Research Program (PCRP). The purpose of the IMPACT meeting is to highlight the progress in prostate cancer research that has been supported by the PCRP. Since its inception in 1997, the PCRP has funded research targeted toward conquering prostate cancer at universities, hospitals, nonprofit and for-profit institutions, private industry, and state and federal agencies. Recognizing that the war against cancer must be fought on multiple fronts, the DOD PCRP has developed a multidisciplinary research portfolio that encompasses the spectrum of basic to clinical research aimed at preventing, detecting, and treating prostate cancer, and improving the quality of life for men with prostate cancer and their families. The involvement of prostate cancer survivors, or consumer advocates, in the PCRP brings a sense of urgency to the research and ensures that the research is relevant to the understanding and eventual elimination of suffering and death from prostate cancer. The partnership of scientists and prostate cancer survivors with the PCRP is designed to push the boundaries of prostate cancer research rather than to duplicate more traditional research. The meeting will serve as a forum for the prostate cancer community to discuss critical issues in prostate cancer and explore new avenues of research.

The IMPACT meeting will provide a broad overview of the field of prostate cancer research while highlighting the important contributions that PCRP-funded investigators have made. It will showcase the strong collaboration between the research community and prostate cancer survivors and advocates that has made the PCRP so successful. It also will provide networking opportunities for the prostate cancer community to share ideas and identify promising, innovative avenues in prostate cancer research targeted at the most critical issues.

All PCRP awardees for fiscal years 2006-2008 (FY06-FY08) will be invited to submit abstracts, as well as selected awardees from the FY97-05 and FY09 PCRP portfolios. Prostate cancer advocacy groups will be invited to submit abstracts highlighting projects or programs having an impact on prostate cancer research, advocacy, education, and/or survivorship. In addition, undergraduate students participating in the PCRP-funded Summer Training Programs will be asked to submit abstracts. Abstracts will be showcased in approximately 15 plenary and symposium sessions and 30 poster sessions. Morning "Meet the Experts" sessions will allow open dialogue about current concepts in screening, quality of life, and treatment options for prostate cancer. In addition to the PCRP awardees, distinguished scientists, clinicians, and prostate cancer research advocates will be present as invited speakers at IMPACT.

Details can be seen at:

<https://cdmrcures.org/ocs/index.php/impact/impact11/index>

## Millennium And Takeda Announce Advancement Of Prostate Cancer Program

**CAMBRIDGE, Mass., and Osaka, Japan, November 4, 2010** – Millennium: The Takeda Oncology Company with its parent company Takeda Pharmaceutical Company Limited (TSE:4502) today announced the initiation of a Phase III clinical trial for TAK-700 in the U.S. in patients with advanced prostate cancer. TAK-700 is a selective, oral, non-steroidal androgen synthesis inhibitor that in preclinical studies has been shown to selectively bind to and inhibit the enzyme 17,20 lyase in both the testes and adrenal glands.

This randomized, double-blind, multi-center, global Phase III study will examine TAK-700 with prednisone compared to placebo with prednisone in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC) and has primary endpoints of Overall Survival (OS) and Progression Free Survival (PFS).

"Our hope is that this trial will demonstrate strong levels of efficacy that address the unmet medical needs in advanced prostate cancer," said Nancy Simonian, M.D., Chief Medical Officer, Millennium. "The progress of TAK-700 into Phase III study further demonstrates commitment of Millennium and Takeda to advancing the treatment of prostate cancer.

Millennium and Takeda anticipate to open enrollment of a second Phase III clinical trial of TAK-700 later this year. This second study will compare TAK-700 plus prednisone versus placebo plus prednisone in patients with mCRPC that have progressed during or following docetaxel-based therapy.

### About TAK-700

TAK-700, discovered by Takeda Pharmaceutical Company Limited, is an oral, non-steroidal androgen synthesis inhibitor that selectively inhibits the 17,20 lyase enzyme. This enzyme, which is present in both the testes and adrenal glands, is central to the production of steroidal androgens. Synthesis of androgens outside the testes contributes to disease progression in castration-resistant prostate cancer (CRPC). Therefore, TAK-700 is a good candidate for development as a therapeutic agent in this disease setting.

**For details on the clinical trials, criteria and study locations, please visit:**

<http://clinicaltrials.gov/ct2/show/NCT01193244>

## In the *Face of Pain*<sup>®</sup> Launches New Resource Guide for People with Pain and Advocates

Pain sufferers and pain care advocates struggling to address the many challenges associated with persistent pain can now find extra help and guidance from the In the *Face of Pain*<sup>®</sup> Resource Guide. This one-stop pain management resource provides a compilation of tips and hands-on tools to help people assess pain and manage their treatment. New to this year's Guide is the addition of several Spanish-language resources. Features of the Guide include:

- Pain assessment tools such as pain intensity scales, daily pain logs and diaries;
- Suggestions for treatment plans that empower patients to communicate with their healthcare;
- Tips on how to stay healthy through proper nutrition, physical activity, stress management and sleep;
- Tools for caregivers assisting people living in pain;
- Special considerations for seniors; and
- Resources to address financial concerns

"It is important while on our pain journeys we become empowered and get the support and help we need," said Paul Gileno, president and founder of the Connecticut Pain Foundation. "The resource guide is an invaluable resource and much needed tool in all of our lives."

To download or order a free copy of the In the *Face of Pain*<sup>®</sup> Resource Guide for People in Pain, visit: <http://www.IntheFaceofPain.com>

According to the National Centers for Health Statistics, an estimated 53 million Americans suffer from persistent pain every year. Pain can interfere with the routine activities that make life rich and fulfilling, things like working, driving, shopping, or even hugging your child or grandchild.

"This Resource Guide puts patients and caregivers in the driver's seat by providing them with the tools they need to effectively communicate with their healthcare team about pain symptoms and treatment," said Pamela Bennett, RN, BSN, executive director of Healthcare Alliance Development at Purdue. "We are grateful to our many partners for allowing us to share their resources and for taking an active role in advocating for those living in pain."

In the *Face of Pain*<sup>®</sup> is an interactive website, offered by Purdue Pharma L.P., which aims to empower healthcare professionals, people with pain, caregivers or concerned individuals to create tailored advocacy plans and provide information on many types of pain-related issues.

## Pfizer Discontinues Phase 3 Trial Of Sutent<sup>®</sup> In Advanced Castration-Resistant Prostate Cancer

Pfizer Inc. announced the discontinuation of the SUN 1120 Phase 3 trial evaluating Sutent<sup>®</sup> (sunitinib malate) in combination with prednisone for men with advanced castration-resistant prostate cancer (CRPC) that had progressed despite treatment with a docetaxel-based chemotherapy regimen. During a scheduled interim analysis, an independent Data Monitoring Committee (DMC) found that the combination of sunitinib with prednisone was unlikely to improve overall survival when compared to prednisone alone. No new or unexpected safety issues were identified. The full data set from this trial is being analyzed and will be presented at an upcoming medical meeting.

"This planned interim analysis helped us determine that the combination of sunitinib with prednisone would not ultimately improve the overall survival of men with advanced stage, castration-resistant prostate cancer," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs, Pfizer Oncology Business Unit. "There is a great need for better therapies for prostate cancer and we are committed to working with basic scientists and clinical researchers to identify more effective treatments for this disease."

Sunitinib is currently approved for both gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate, and advanced/metastatic renal cell carcinoma (RCC), based on efficacy and safety data from large, randomized Phase 3 clinical trials. Sutent has played a significant role in advancing the treatment landscape and remains a standard of care in its approved indications. To date, more than 91,000 patients have been treated with sunitinib worldwide.

Pfizer is evaluating the potential role of sunitinib for the adjuvant treatment of renal cell carcinoma in a Phase 3 trial. Healthcare professionals, and others, who are interested in learning more about Pfizer Oncology clinical trials that are open for enrollment can visit [www.PfizerOncology.com/clinicaltrials](http://www.PfizerOncology.com/clinicaltrials).



## New Prostate Cancer Pain Clinical Trial: The Saturn Study

by Diane Johnson

Inclinx, Inc., a global clinical trial solutions provider ([www.inclinx.com](http://www.inclinx.com)), recently announced a drug study that is seeking volunteers who have advanced prostate cancer. The Prostate Cancer Saturn Research Study will “test the safety and ability of the experimental drug [custirsen] to enhance the effects of chemotherapy to further reduce pain from advanced prostate cancer.”

### HYPOTHESIS

Men who are living with *advanced prostate cancer* (prostate cancer that has become resistant to hormone therapy and might have spread to other parts of the body) can experience several symptoms, especially pain. Narcotics or radiation treatments are often given to control this kind of pain, but some men experience significant side effects. This study tests custirsen, in combination with docetaxel, to see if it offers patients a better option “in the management of prostate cancer and associated pain.”

### PRE-QUALIFICATION

Information about the details of the study will be provided to potential volunteers, who must meet specific eligibility criteria, including having received previous docetaxel-based chemotherapy. All volunteers must also sign an *informed consent form* and then be screened with “baseline pain evaluations”.

### STUDY DETAILS

This is a Phase III trial that is *randomized*--men who qualify for the study will be randomly assigned to one of two groups: those treated with docetaxel and custirsen or docetaxel and a *placebo* drug. The study is also *double-blind* (neither the patient nor their doctor will know which treatment group they are in). Participants may also receive prednisone.

### CONTACT INFORMATION

To find out if you might qualify or to get more information, please contact:

1-877-888-3762 or [www.TheProstateCancerSaturnStudy.com](http://www.TheProstateCancerSaturnStudy.com)

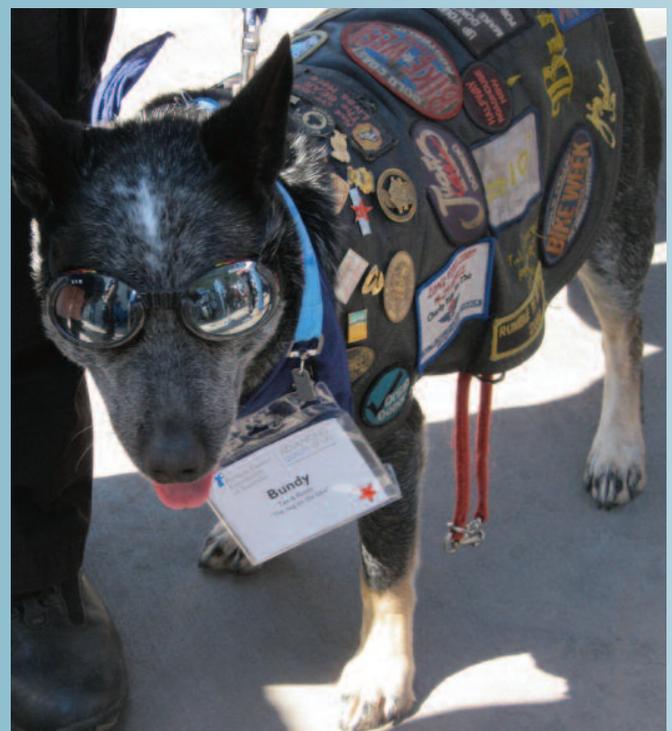
## Casting the Prostate Net

The disparity in regards to men’s health is one of the most important issues facing the health care industry today. Addressing the **Prostate Cancer Foundation of Australia’s National Conference**, Virgil Simons, Founder of The Prostate Net®, cited a number of influences responsible for this disparity, and spoke about how PCFA and local support groups can help address this chasm in the health care system.

“What we see happening here is a confluence of things,” said Mr Simons. “Lack of various national emphasis on individual health care; the method of compensation for the medical establishment; and the lack of prioritization of men’s health. We see that more and more people today are becoming disparate, in terms of information access, and access to care.”

Mr. Simons and The Prostate Net work alongside PCFA through the World Wide Prostate Cancer Coalition. This relationship, combined with his observation of the support group delegates attending the conference, lead him to believe that Australia is on the verge of a great leap forward in terms of addressing this disparity. The concept of promoting health awareness and funding for cancer research in partnership with local motorcycle clubs is one that has proven successful in the U.S. with **The Prostate Net’s Gentlemen Check Your Engines** promotion.

- MBN News Gold Coast (AU)



## Patient Advocate Foundation Announces Additional Support for Co-Pay Relief Program Serving Prostate Cancer Patients

The Patient Advocate Foundation (PAF) is a national non-profit organization that seeks to safeguard patients through effective mediation assuring access to care, maintenance of employment and preservation of their financial stability relative to their diagnosis of life threatening or debilitating diseases. PAF is pleased to announce that it has received a substantial contribution which will provide additional funding support for prostate cancer patients through its Co-Pay Relief Program (CPR).

PAF's Co-Pay Relief Program currently provides direct financial support for pharmaceutical co-payments to insured patients, including Medicare Part D beneficiaries, in 20 disease categories, who financially and medically qualify. Since the program's inception in April 2004, CPR has provided assistance to over 36,000 patients nationwide, raised federal poverty level (FPL) guidelines to 500%, and created a 24-hour provider application portal.

- The program offers personal service to all patients, caregivers or providers through the use of live CPR call counselors; personally guiding the applicant through the enrollment process. Contact us toll-free at 1-866-512-3861 to initiate an application for assistance.
- For those who prefer a web based process, the program also accepts new applications electronically through a dedicated, secure web-based patient portal, available 24 hours, at [www.copays.org](http://www.copays.org).
- Additionally the program offers a secure, web-based application portal, available 24 hours, designed specifically for providers and/or pharmacy allowing them to enroll on behalf of their patients via the Internet, minimizing enrollment time as well as offering real-time information on the availability of assistance in each disease category. It requires them to register prior to open enrollment. Contact the CPR program toll-free at **1-866-512-3861** for information on how to register.

PAF is committed to improving the quality of life of patients facing medical and financial hardship through our professional case management and Co-Pay Relief services at no cost to the patient.

## FDA Approves New Purdue Pharma Patch For Chronic Pain

by Diane Johnson

In July of 2010, Purdue Pharma, headquartered in Stamford, CT, announced their Butrans™ Transdermal System CIII has been approved by the Food and Drug Administration. Butrans is a skin patch containing the opioid buprenorphine that "delivers a continuous release of medication for seven days." It is intended for "the management of moderate to severe chronic pain in patients requiring a continuous... analgesic for an extended period of time."

As with other opioids, the drug is not appropriate for all patients and there is a concern that this drug might be abused. To give physicians guidance, Purdue has provided detailed instructions about who should, and who shouldn't, receive this drug, as well as healthcare provider training and safe use guidelines (otherwise known as REMS (Risk Evaluation and Mitigation Strategy)). The patch comes in 5, 10, and 20 mcg/hour doses and is designed to be worn for seven days. John H. Stewart, President and CEO of Purdue Pharma L.P. said, "We are very pleased with the FDA approval of Butrans and believe it will be a valuable pain management option for healthcare professionals and patients." Butrans is expected to be available in the U.S. in early 2011.

Complete prescribing information, including the label's boxed warning, precautions, and contraindications, is available at [www.purduepharma.com/PI/prescription/ButransPI.pdf](http://www.purduepharma.com/PI/prescription/ButransPI.pdf).

For medical questions, Purdue's Medical Services Department can be reached at

1-888-726-7535, prompt #1.

