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August 2008

PINTS FOR PROSTATES DELIVER MEN’S HEALTH MESSAGE USING THE UNIVERSAL LANGUAGE OF BEER

Effort Enlists the Beer Industry to Urge Prostate Cancer Screening

Symptoms of prostate cancer rarely show before the disease has progressed, but a simple PSA blood test can serve as an early warning and save men’s lives. But how do you reach men in their late 30s and early 40s, when statistics show they often skip regular physicals and avoid doctor’s offices? “Pints for Prostates is an awareness campaign designed to reach men through the universal language of beer. We want to communicate with them in a friendly and non-threatening way about the need for regular PSA testing,” says Rick Lyke, a 47-year-old Charlotte, N.C., marketing executive and drinks journalist who was diagnosed with prostate cancer in February. “Early detection is the key to fighting prostate cancer and a PSA test and a physical exam are the best method to catch it early.”

“There are more than 230,000 cases of prostate cancer diagnosed in the U.S. each year, more than the number as new breast cancer cases in women. The problem is that prostate cancer does not get the same level of media attention as breast cancer and most men never discuss the subject with friends or family,” Lyke said. “Luckily I insisted on having a PSA test during a routine physical because a good friend is being treated for the disease. Time is precious when you are fighting prostate cancer. I received the gift of time from a friend. I felt like I had a responsibility to warn other men.”

After successful prostate surgery in April at Northwestern Memorial Hospital in Chicago by Dr. William Catalona, Lyke started to think about ways to reach as many men as possible with a message about prostate screening and PSA testing. That is when it occurred to him that one of the best ways to reach men is over a pint of beer.

Lyke started Pints for Prostates after talking to a couple of editors at magazine...

MRS. ILLINOIS 2008 SUPPORTS PROSTATE CANCER AWARENESS AND US TOO INTERNATIONAL

Michelle Beckwith, crowned Mrs. Illinois International on May 3, 2008, has selected as her personal platform and mission to be an awareness advocate for Us TOO International. “My father died from prostate cancer that could have been cured through early detection (as my melanoma was). Therefore, I am passionately committed to ensuring that others live full and healthy lives.”

Michelle states, “My goal is to encourage men to get preventative check ups, and after a cancer diagnosis and treatment, to “Commit2BFit.” For her efforts and passion for the cause, the Moline native received the Mrs. Illinois Spirit and Community Service Award.

As part of her official duties as Mrs. Illinois International over the next year, Michelle will be doing television and other media events, attend health fairs, and will be a spokesperson for the Quad Cities Marathon and the Greater Chicago Prostate Cancer Run Walk ‘n Roll events in September.

Us TOO extends great thanks and appreciation to Michelle for her support of prostate cancer patients, survivors, their families and those at risk, and...
PROSTATE CANCER PATIENT SUPPORT - CALL 1-800-80-US TOO, OR GO TO <WWW.USTOO.ORG>

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US TOO PROSTATE CANCER EDUCATION & SUPPORT HOT SHEET - AUGUST 2008 P. 2

PROSCAR® LOWERS PROSTATE CANCER RISK IN ALL MEN

Finasteride (Proscar®) reduces the risk of prostate cancer in all men, regardless of their risk level for the disease, new research shows. In the Prostate Cancer Prevention Trial, finasteride treatment cut the risk of prostate cancer by 25 percent. Whether this was because the drug prevented the cancer from forming or because it effectively treated early disease was unclear, Dr. Ian M. Thompson, from the University of Texas Health Science Center at San Antonio, and colleagues note.

The new findings, reported in the May 2008 issue of the journal Urology, suggest that the drug has both effects. In a re-analysis of data from the Prostate Cancer Prevention Trial, Thompson and co-researchers stratified 10,181 participants into five groups based on their prostate cancer risk, as determined using standard criteria. At study entry, the men were also grouped according to PSA (prostate-specific antigen) levels, a common blood test in which increased levels may suggest the presence of prostate cancer.

Treatment with finasteride reduced the risk of prostate cancer for all five risk groups, including men with the lowest and those with the highest risk for prostate cancer. Finasteride treatment also lowered the risk of prostate cancer regardless of the PSA level. However, the researchers found that the benefits of the drug decreased slightly as PSA levels rose.

Although this study began with the objective of evaluating the prevention versus treatment hypothesis, “the results speak to the clinical use of finasteride for reducing a man’s risk of a prostate cancer diagnosis,” the investigators conclude.

Thompson stresses that “all men undergoing PSA screening should be informed of the potential for finasteride to reduce their risk of prostate cancer.”

Reuters Health, 12 Jun 2008

RADIATION MAY HELP AFTER PROSTATE CANCER SETBACK

Men whose prostate cancer recurs after they have undergone surgical removal of the prostate may benefit from early radiation therapy, according to study findings reported in the June 18, 2008 issue of the Journal of the American Medical Association.

“Our study provides the first evidence that salvage radiotherapy can improve survival,” Dr. Bruce Trock commented to Reuters Health. Trock, at Johns Hopkins School of Medicine in Baltimore, and colleagues analyzed the outcomes of 635 men who underwent radical prostate surgery between 1982 and 2004 and subsequently relapsed.

While 397 men were not given any salvage treatment, 160 received radiotherapy, and 78 received hormone therapy plus radiation therapy. The mortality rates from prostate cancer in those three groups at 6 years after the recurrence of cancer were 22 percent, 11 percent, and 12 percent.

The survival advantage was confined to patients treated within 2 years of recurrence.

MRS. ILLINOIS

(Continued from page 1)

Michelle Beckwith, Mrs. Illinois International 2008, with husband, Dr. Chris Beckwith.

Photo by Sean McCabe

Michelle Beckwith, Mrs. Illinois International 2008, with husband, Dr. Chris Beckwith.

Photo by Sean McCabe

Michelle Beckwith, Mrs. Illinois International 2008, with husband, Dr. Chris Beckwith.

Photo by Sean McCabe
GPC BIOTECH ANNOUNCES
INITIATION OF NCI-
SPONSORED PHASE 2 TRIAL
OF SATRAPLATIN IN
PATIENTS WITH
METASTATIC HORMONE-
REFRACTORY PROSTATE
CANCER PREVIOUSLY
TRATED WITH DOCETAXEL

Study seeks to determine if presence of certain gene impacts patient outcome

GPC Biotech AG announced the initiation of a Phase 2 study evaluating satraplatin in combination with the steroid, prednisone, in patients with metastatic hormone-refractory prostate cancer (HRPC) who previously have been treated with docetaxel (Taxotere®). The study is being sponsored by the U.S. National Cancer Institute (NCI), and the principal investigator is William L. Dahut, MD, Chief, Genitourinary Research Section, Medical Oncology Branch, Center for Cancer Research, NCI.

The trial is a single-arm study with a planned enrollment of 66 patients with metastatic HRPC who have been previously treated with docetaxel therapy and with no more than one other previous cytotoxic chemotherapy regimen. The primary objective of the trial is to determine if the presence of certain variants of the gene, ERCC1, affects progression-free survival in this patient population. ERCC1 is involved in DNA damage repair. Satraplatin, like other platinum agents, has been shown to work via targeting the DNA in tumor cells.

“The results of this trial may provide important information in determining which hormone-refractory prostate cancer patients are more likely to benefit from treatment with satraplatin,” said Martine George, MD, Senior Vice President, Drug Development and Chief Medical Officer at GPC Biotech. “We are pleased to be working with the NCI to conduct this potentially ground-breaking study.”

BUSINESS WIRE, 24 June 2008

PINTS FOR PROSTATES (Continued from page 1)

zines where he writes. The idea was well received and he contacted Us TOO International Prostate Cancer Education and Support Network, a not-for-profit group founded and governed by prostate cancer survivors that works to support, educate and advocate for men with prostate cancer.

“The idea of reaching mean about health issues through beer sounded a little strange at first, but it makes perfect sense,” said Thomas Kirk, President and CEO of Us TOO International. “Our mission and program goal is to educate and empower men and their family members so men and their loved ones can take an active role in their health care. One in six men is at risk of developing prostate cancer during their life time and early detection through the monitoring of PSA levels is critical to getting the disease under control. Pints for Prostates will help us reach more men at a time when a growing number of men are at risk.”


Creative development and design for the advertising materials and logo for Pints for Prostates was donated by Eric Mower and Associates, a marketing communication agency with offices in Buffalo, Rochester, Syracuse and Albany, NY; Charlotte, NC; Atlanta, GA and Sarasota, FL. Lyke is senior partner with the firm and heads up the agency’s southeast public relations operation. Work is now underway to reach out to breweries, brewpubs and on-premise retailers to get their support in a cooperative effort among industry partners. The aim is to raise funds for Us TOO’s outreach efforts and to spark a grassroots effort to reach men that might be missed through traditional health education programs.

“One of our goals is to get brewers to print a PSA testing message on the back of beer coasters they use to promote their brands in restaurants and taverns around the country,” Lyke said. “Men can tell you about their favorite IPA (India Pale Ale), but few know about their PSA. We need to help educate them about getting the simple blood test that measures PSA because it can save their lives.”

Us TOO Board Chairman, prostate cancer warrior and support group leader Jim Kiefert says, “Early diagnosis is essential. When I was 50-years-old a PSA test was the first step in my successful battle with prostate cancer. We envision Pints for Prostates will help reach millions of men with the PSA testing message. It is anticipated that many of Us TOO’s 325 local chapters will get involved with special events held country-wide as part of the effort.”

For more information on the program please visit <www.ustoo/pints>.

Rick Lyke
**Doc Moyad’s What Works & What is Worthless Column also known as “No Bogus Science” Column**

“Saturated Fat may increase my risk of cancer returning after surgery, radiation or another treatment for localized prostate cancer?!”

Mark A. Moyad, MD, MPH
University of Michigan Medical Center, Department of Urology

**Support Dr. Moyad and his team at the 2008 Greater Chicago Prostate Cancer Run Walk ‘n Roll event, Sept 14 at <www.ChicagoProstateWalk.org>**

**Bottom Line:**
Reducing (not eliminating) your saturated fat intake is simply another way to reduce the amount of total calories you get in one day. Getting some saturated fat in your diet is okay, especially when it comes from healthy nuts, oils, and seeds!

Saturated fat is also known as “hydrogenated fat” and for years “experts” have been telling the public to reduce saturated fat intake to reduce the risk of heart disease. I have also said that what is heart healthy is usually prostate healthy.

So, is it possible that lowering your saturated fat intake could reduce the risk of your prostate cancer returning after surgery, radiation or another treatment for localized prostate cancer? YES (this is where most writers now use the words “but more research is needed” to cover their politically correct butts; however, I am not going to do that because in this issue I want to honor George Carlin—one of my favorite politically incorrect heroes)!

Researchers at one of the largest and best cancer centers in the world (MD Anderson) looked at almost 400 men that had localized treatment for prostate cancer (surgery), and they also had some information on their overall diets. Men getting a high saturated fat intake had two times the risk of cancer recurrence compared to the men getting a low saturated fat intake. Also, obese men with higher saturated fat intakes had the highest risk of their cancer coming back!

Just so you know, the men that were considered to be in the low saturated fat group were men that received approximately 10% or less of their calories from saturated fat, and this is similar to the heart healthy recommendation given to the public from the American Heart Association (AHA)!

In other words, if you were already following a heart healthy diet, it seems to be the same one that helped prostate cancer patients! This is awesome news dudes and dudettes (I was not at Woodstock but I thought I would still sound hip and groovy)! Also, the men with the lower saturated fat intake also consumed about 200 less calories per day overall compared to the men with the high saturated fat intake.

So, it is possible that eating less overall calories is the real answer here. Think about milk for a second and this should make sense. Skim milk has no saturated fat and has 80 calories, whereas 1%, 2% and whole milk all have increasing amounts of saturated fat and more and more calories.

Finally, do not be fooled that saturated fat is all bad for you, because even in this study, men consumed saturated fat since it is hard to avoid because it is found in all sorts of healthy foods, but in very low amounts. In fact, getting a little saturated fat from heart healthy cooking oils like olive oil or safflower oil may even slightly increase your good cholesterol (HDL).

So, do not avoid saturated fat, but just get it from healthier foods like oils, seeds, and nuts for example (1 serving of healthy almonds and pistachios have only 1 to 1.5 grams of saturated fat). And, if you simply must break your routine and get some fast food, well that is fine and dandy, but also try and order the low calorie foods from the menu. Remember, LESS = MORE (except when it comes to love or love making, where more = more…now that was a politically correct way of ending my column)!

**Reference**
International Journal of Cancer 122: 2581-2585, 2008

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**High Fat Diet May Abet Prostate Cancer Progression**

Diets high in saturated fat may increase the risk of prostate cancer progression, researchers from the University of Texas M. D. Anderson Cancer Center in Houston report.

In a follow up study of men who had their cancerous prostates removed, researchers found that men who consumed higher amounts of saturated fat - mostly from steaks, burgers, cheese, ice cream, salad dressings, and mayonnaise -- were nearly two times more likely to experience disease progression after surgery than men with lower saturated fat intake. “Diet before surgery, especially saturated fat, may modulate patient outcome after surgery,” Dr. Sara S. Strom, who was involved in the study, told Reuters Health.

Strom and colleagues also found significantly shorter “disease-free” survival times among obese men who ate high amounts of saturated fat compared with non-obese men consuming diets low in saturated fat. These results expand upon the team’s previous finding linking obesity with prostate cancer progression “and suggest that saturated fat intake plays a role in prostate cancer progression,” the researchers note in the June 1, 2008 International Journal of Cancer (epub ahead of print).

Strom’s group used standard food questionnaires to assess the saturated fat intake of 390 men during the year before surgery for localized or “organ-confined” prostate cancer. The researchers also assessed the men’s medical and family history for other risk factors for disease progression. The men, all Caucasian, were about 60 years old on average and consumed between 600 and 5,000 calories daily. Overall, 293 men averaged 10 percent of their daily energy from saturated fat (low intake) while 97 men averaged 14 percent (high intake). Obese men with a high saturated fat intake had the shortest survival time free of prostate cancer (19 months), while non-obese men with low intake survived the longest time free of the disease (46 months). Non-obese men

(Continued on page 8)
SOME NEW CANCER DRUGS’ RISKS EXCEED THEIR EFFICACY

Mark Thornton’s May 29th commentary “Grassley’s War on Cancer Patients” does not accurately describe the substance of Sen. Charles Grassley’s request to the Government Accountability Office to “launch an inquiry into whether the FDA behaved appropriately in granting the ‘accelerated approval’ of Avastin, a drug for treating women with metastatic breast cancer.” Moreover, the issues surrounding the regulatory approval of prescription drugs where proof of efficacy is based on “surrogate endpoints” are far more complex than Mr. Thornton describes.

First, Sen. Grassley’s request was related to the FDA’s approval of drugs based on surrogate efficacy in general and was not specifically limited to Avastin and other oncology products. Second, the use of surrogate outcomes for regulatory drug approval is, in my opinion, often problematic. Surrogate efficacy endpoints do not necessarily translate into favorable outcomes such as improved survival, reduced complications and improved quality of life. Moreover, there are few established surrogate safety endpoints; as a result, the regulatory goal of balancing benefit and harm cannot be adequately met.

Take the case of Avandia (rosiglitazone). Its FDA approval in 2000 was based on the reduction of hemoglobin A1C, a surrogate measure of glycemic control in diabetic patients. The available safety data, especially concerning long-term use, was grossly inadequate at the time of approval. Eight years later there is no scientific evidence that Avandia’s surrogate effect translates into a health benefit. But there is now evidence that it may double the risk of heart failure, fractures (in women), increase the risk of heart attacks by 40%-50% and, in rare cases, cause blindness. The fact that it’s evident that risks of Avandia exceed its efficacy in lowering what is only a lab value would, in my opinion, more than justify Sen. Grassley’s desire to have this regulatory failure explained.

Third, Mr. Thornton cites FDA requirements that sponsors conduct post-marketing studies to confirm that surrogate endpoints do indeed reflect clinical benefit. Describing them as the most stringent post-marketing requirements in history, he neglects the fact that sponsors overwhelmingly fail to meet these commitments and suffer no consequences for their failure. The latest update in the Federal Register reports there were 1,259 such unmet sponsor commitments! Based on the above, accelerated approval based on surrogate efficacy should only be granted for new drugs for conditions without acceptable treatment alternatives.

Sen. Grassley’s request to GAO makes good sense from a public health perspective.

Curt D. Furberg, MD, PhD
Winston-Salem, NC
Wall Street Journal, 9 June 2008

FDA CAUTIONS CONSUMERS AGAINST CANCER “CURES”

Consumers should beware of products sold on the Internet that claim to cure cancer. US health officials said on Tuesday, threatening penalties against more than two dozen companies selling creams, tea and pills as treatments for the disease. The US Food and Drug Administration said a variety of Web sites sell such products, which can harm patients with potentially risky ingredients or by keeping them from seeking proven therapies.

“FDA is very concerned consumers will purchase these products on the Internet and use them instead of products that have been proven safe and effective,” said Michael Levy, head of the FDA’s Division of New Drugs and Labeling Compliance. Levy and other officials said their warning letters targeted roughly 125 products that claim to treat, cure or prevent cancer. The FDA has not received any reports from consumers who have fallen ill taking them, officials said, but called on the companies to stop making promises.

They could not say how many such products have been sold. Some included various ingredients such as bloodroot, shark cartilage, coral calcium and various mushrooms, according to the agency. Representatives for the American Herbal Products Association said such ingredients are not harmful but that manufacturers of products that include them are not allowed by law to make medical claims.

“These companies are making drug claims and it is simply illegal to market an unapproved new drug,” said Michael McGuffin, president of the association which represents a variety of herbal product makers.

“FDA expects prompt and complete corrective action,” said David Elder, director of the FDA’s Office of Enforcement. “Firms that don’t heed the warnings that we’ve delivered and other firms marketing similar unapproved products may face further regulatory action.”

The agency listed the companies targeted by the letters on its website at: <http://www.fda.gov/cder/news/fakecancercures.htm>.

Reuters Health, 17 June 2008

2008 US TOO ONLINE AUCTION HITS NEW HEIGHTS

The Us TOO Online Auction closed on June 30th with fabulous results, raising just under $7,000 for Us TOO programs and services, and an unmeasurable level of prostate cancer awareness. Of the 80 items in the auction catalog, 42 were bid on and sold. Many thanks go out to all of our item donors and winning bidders who helped make the 3rd annual online event the most successful to date. The majority of the items that sold were in fact donated by individuals, chapters or companies compared to last year where most of the items were bought on consignment — this increased the level of funds raised substantially.

The Us TOO staff is looking forward to better results in 2009 as the Online Auction continues to grow since its inception three years ago. We still need your help because the best thing you can do is donate popular, quality items to greatly increase the Auction revenue potential. If you have an item you think we can use next year, please contact Dan Reed at 1-800-808-7866 or dan@ustoo.org.

Reuters Health, 17 June 2008
A few months ago, I introduced a new educational website for men with prostate cancer. I am happy to report that it has been further modified into an even easier format and can be located at <www.ProstateVideos.com>. This month’s HotSheet provides some very useful new information about prostate cancer. Another update about the prostate cancer prevention trial now suggests that all men may benefit from using finasteride, regardless of their risk. Earlier reports suggested that while there were fewer cancers, those that did develop were more likely to be aggressive.

One problem with the study is that the impact of the drug on survival is as yet unknown. So for now, all we can say is that taking the drug may result in a lower chance of diagnosis but whether patients will live longer remains unknown. However, for those men without prostate cancer, these findings probably warrant a conversation with their doctor.

Diet is another factor often in news about prostate cancer and other diseases. A report from M.D. Anderson Cancer Center suggested that a high fat diet in the year before surgery might result in worse outcomes. Although interesting, the results are not definitive because of the study design. Mainly, it is unclear if this is a cause-effect relationship, but perhaps other studies will be forthcoming.

Diet may play another important role in diagnosing prostate cancer. Detecting prostate cancer may require more caution in obese men since their PSA levels, on average are lower than normal weight men. This finding may affect whether men are advised to have a biopsy. The problem, of course is we now know that no PSA level guarantees the absence of cancer, but this also means another factor should be considered when deciding which patient to biopsy. Whether they should have a screening PSA at all is still a question that has not yet been answered.

Often in this column, caution has been raised about unconventional therapies that appear in the news. This caution is now further supported by a report from the FDA that issued a warning to 23 companies falsely advertising about the efficacy of their products promoted in magazines and on the Internet.

While patients frequently hear about someone doing well on one of these products, the facts are that there is no scientific proof these agents do anything beneficial and companies cannot portray them as treatment for cancer or anything else. Furthermore, there is little information about whether they are harmful or will cause other medications to have more side effects. So let the buyer beware and patients would do well to be more careful about using a supplement heralded as a cancer therapy until properly studied.

Another concern appropriately raised about FDA approval of drugs based on surrogate end points rather than survival. This illustrates the importance of truly proving that a drug is beneficial by improving survival and reducing mortality rather than just lowering a blood test. There are many researchers who would like to use changes in PSA as proof that a treatment for prostate cancer is beneficial. However, as (Continued on page 8)

Novartis Pharmaceuticals Corporation celebrated Sneakers At Work Day 2008 a bit early this year and held their event on June 11. Employees at their three corporate campuses in New Jersey, Suffern and Emeryville, CA participated and raised just over $5,000. Novartis generously provided a matching gift, so their total contribution will be about $10,000 toward program beneficiaries Us TOO International, Dean and Betty Gallo Prostate Cancer Center and the American Prostate Cancer Initiative. Us TOO awareness and educational materials were also distributed.
**ABNORMAL P53 BOOSTS PROSTATE CANCER RECURRENCE**

Prostate cancer is more likely to recur in men with abnormal p53 protein expression compared with their counterparts without this abnormality, according to researchers.

“Men whose prostate cancers lack the normal function of the p53 gene -- ‘the guardian of the genome,’” lead investigator Dr. Anthony V. D’Amico told Reuters Health, “have a higher chance of recurrence following combined radiation and hormonal therapy.”

Dr. D’Amico of Brigham and Women’s Hospital, Boston and colleagues came to this conclusion after studying data from 113 men with prostate cancer who were

(Continued on page 8)
ABNORMAL p53
(Continued from page 7)

seen with Avandia, the morbidity increased over time and yet the improvement in the blood test measured did not lead to better survival. This is particularly relevant for men with advanced prostate cancer as another drug goes through testing. For men suffering recurrent prostate cancer after Taxotere there is no clear best course of action. However, patients should now be aware of a new clinical study using Satraplatin for men failing the other chemotherapy. Interestingly, the investigators are looking at whether a marker can distinguish responders from non-responders. This is worth considering for a patient facing tumor recurrence.

What about adjuvant treatment following radical prostatectomy for a man whose PSA is rising? An interesting but not well-controlled study suggests that men with the fastest growing tumors did better if they received radiation within two years of the surgery. Unfortunately, this study is not proof that the treatment made the difference and it conflicts with another prospective study that found a benefit only after a very long follow-up period.

POST-OP RADIATION
(Continued from page 2)

relapse and those whose PSA level was rising rapidly. Men whose PSA was rising more slowly “had a better prognosis already -- their survival at 10 years was 75 percent without any salvage treatment -- so adding salvage radiation didn’t improve their survival much,” Trock explained. Summing up, he said, “Our results suggest salvage radiation may be appropriate for those men with rapidly growing tumors who previously may not have been considered for such therapy.”

HIGH FAT DIET
(Continued from page 4)

with high intake and obese men with low intake had “disease-free” survival of 29 and 42 months, respectively, the researchers report. Additional investigations looking at associations between post-surgery dietary changes and disease progression would be worthwhile, Strom suggests.

Reuters Health, 2 July 2008