Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

NOVEMBER 2010

US TOO BOARD WELCOMES 2 NEW MEMBERS

The Us TOO International Board of Directors welcomed two new members at their most recent meeting, held September 24-25 in Chicago IL: James L. Rieder and Dexter C. Rumsey, III.

James L. Rieder, a prostate cancer survivor, has 40 years` executive leadership experience in seven, diverse, for-profit, not-for-profit community and teaching hospitals, hospitals affiliated with large national systems, a vertically integrated multi-hospital system and a statewide non-profit foundation, in Ohio, Illinois, Virginia, Michigan, Tennessee, New Jersey and Connecticut. He has an MBA from Cornell University, Johnson School of Management, Ithaca, New York, with a concentration in Hospital and Health Services Administration, and a Bachelor of Science degree from University of Michigan in Ann Arbor, MI.

Rieder most recently served as the Executive Director of the Ohio Quality Cardiac Care Foundation in Columbus, OH, retiring in 2001. Mr. Rieder has strong experience in finance, marketing, human relations, strategic planning, negotiations, board relations, and State Legislative/Executive Branch lobbying and collaboration. He is an active professional and community leader, and lives with wife Mary in Powell, Ohio.

(Continued on page 2)

RISK FACTORS FOR PROSTATE CANCER DIFFER BETWEEN NATIVE AND FOREIGN BORN BLACK MEN

Significant differences in prostate cancer risk factors exist between black men born in the US and those born in African nations or the Caribbean who now live in the United States, according a study presented here at the Third American Association for Cancer Research Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved.

In a survey-based study of more than 3000 black men, researchers at the University of Florida, in Gainesville, found that black men born in the United States reported eating more red meat (46% of respondents) than those born in either African (29%) or Caribbean nations (26%; $P < .001$).

They also found that even though black men born in the United States are more likely to have health insurance (65.2%) than foreign-born (56.8%) and Caribbean black men (64.4%; $P = .014$), African-born men are the more likely to regularly discuss prostate cancer prevention with a doctor (41%) than American-born black men (50.1%; $P = .022$).

Of the 3040 respondents who identified their ethnicity, 2405 were native-born, 315 were African-born, and 320 were Caribbean-born.

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CABAZITAXEL OFFERS NEW APPROACH FOR PROSTATE CANCER

The newly approved chemotherapeutic agent cabazitaxel (Jevtana, Sanofi-Aventis) combined with prednisone extends survival by more than 2 months for men with advanced multidrug-resistant prostate cancer. The data from the international phase 3 TROPIC trial, which led to fast-track approval of the drug by the US FDA, were published in the 2 October 2010 issue of *The Lancet*. An accompanying editorial describes them as practice-changing. Preliminary results were presented earlier this year at the American Society of Clinical Oncology 2010 Annual Meeting.

Cabazitaxel is the first drug to show a survival benefit in patients whose disease has progressed after standard chemotherapy with docetaxel and for whom there are currently no approved treatment options, stated Principle investigator Johann de Bono, MD, from the Royal Marsden NHS Foundation and the Institute of Cancer Research in the United Kingdom.It was this survival benefit that led to FDA approval, de Bono emphasized.

Investigators compared overall survival in men with advanced castration-resistant prostate cancer (CRPC) that progressed on docetaxel), 378 randomized to cabazitaxel plus prednisone and 377 to mitoxantrone plus prednisone.

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NEW BOARD MEMBERS

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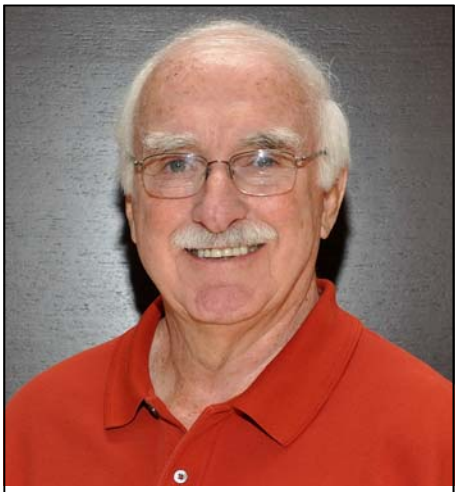
Dexter C. Rumsey, III, was diagnosed with prostate cancer in July 2007 and had a radical prostatectomy. After a recurrence in 2009, he has been managing the disease with radiation and hormone therapy.

In addition to being an estate planner, estate tax attorney, and founding partner of law firm Rumsey & Bugg, he has served as president of two charitable organizations. His leadership experience includes membership on the board of directors for numerous professional and civic organizations.

After graduating from the University of North Carolina, Chapel Hill with a degree in Political Science, he served state -side and in Vietnam with the United States Marine Corps, attaining the rank of captain. While serving in Vietnam he was exposed to Agent Orange, proven to be a contributing factor in the development of prostate cancer.

In 1971 he earned his law degree from the University of Virginia School of Law. From 1978 to 1982 he a member and chairman of Board of Governors, Virginia State Bar Trusts and Estates Section, and received the Walker Award for Exemplary Service from the Virginia Bar Association in 2002.

Mr. Rumsey is an avid off-shore sailor and sailed across the Atlantic in the summer of 2004. He also enjoys hunting duck and quail. He resides in Irvington, Virginia, with his wife Bonnie. They have two children and five grandchildren.



James L. Rieder, New Director

Dexter C. Rumsey, III, New Director

PROTEIN ARRAY ACCURATE FOR PROSTATE CA

A panel of prostate cancer-derived autoantibodies distinguished cancer from benign prostatic hyperplasia and healthy tissue with greater than 90% accuracy, according to a preliminary report from the 2010 American Association for Cancer Research meeting.

The functional protein microarray had similar accuracy for detecting cancer (sensitivity) and for ruling it out when used to evaluate noncancerous tissue (specificity).

Prostate specific antigen (PSA) testing also has a sensitivity of about 90% but a specificity of less than 50%, John Anson, PhD, said at a press briefing during the American Association for Cancer Research International Conference on Molecular Diagnostics in Cancer Therapeutic Development.

"What that means is there are lots of potential false-positives," said Anson, of Oxford Gene Technology in the UK. "What that translates to in clinical practice is that a lot of men are going on for unnecessary diagnostic procedures, such as needle biopsies, and even radical prostatectomy, which perhaps are not required. Biomarker panels offer the potential to significantly improve detection of prostate cancer."

Interest in the diagnostic potential of protein microarrays has grown with the recognition that many disease states produce autoantibodies years before symptoms appear. Autoantibodies are

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ASTRAZENECA DRUG FAILS IN PROSTATE CANCER TRIAL

AstraZeneca's experimental prostate cancer pill zibotentan failed to improve survival in a late-stage clinical trial, dealing a fresh blow to the company's oncology pipeline. As a result, AstraZeneca plans no regulatory submissions for zibotentan at this time..

The failure of zibotentan to improve overall survival in the Phase III study follows similarly unsuccessful trials for two other AstraZeneca pills, Recentin® for colon cancer earlier this year and vandetanib in lung cancer in 2009. Vandetanib has since gone on to show benefits in thyroid cancer, a smaller potential market.

Zibotentan, a once-daily tablet, is being studied in more than 3,000 men with prostate cancer in a programme of clinical trials. Two other studies looking at the medicine in different settings are still ongoing.

Reuters(UK), 27 September 2010

NO PROSTATE CANCER INDICATION FOR SUNITINIB

A phase IIIa trial of the tyrosine kinase inhibitor Sutent® in patients with advanced castration-resistant prostate cancer (CRPC) was halted for lack of efficacy, Pfizer, the drug's manufacturer announced. The trial tested sunitinib in combination with prednisone in patients with disease progression while treated with docetaxel-based chemotherapy. Prednisone alone was the active control.

"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, CRPC," according to a press release from Pfizer.

Sunitinib, which targets intracellular signaling triggered by the vascular endothelial and platelet-derived growth factor receptors, is currently approved for gastrointestinal stromal tumors and for advanced/metastatic renal cell carcinoma. More indications for sunitinib have been sought, but so far have come up short.

A phase III trial of the drug as adjuvant therapy in patients with renal cell carcinoma is continuing, Pfizer said.

MedPage Today, 28 September 2010

US TOO SEEKING NOMINATIONS FOR 3RD ANNUAL EDWARD C. KAPS HOPE AWARD

Would you like to recognize someone who volunteers with your local Us TOO support group chapter that has made a difference in your life and in the lives of others battling prostate cancer? If so, please submit a letter of nomination to Us TOO by Friday, November 12, 2010.

The Edward C. Kaps Hope Award is given to *"An Outstanding Leader in an Us TOO Support Group Who Has Shown Unselfish, Dedicated Service to Prostate Cancer Survivors and their Families."* The award was created by and named for Ed Kaps, one of the organizing and founding Board Members of Us TOO International. He remains a Director Emeritus of Us TOO.

Who can be nominated? Any Us TOO International support group volunteer can be nominated. Nominees can include, but are not limited to, support group leaders, leaders of your spouse/companions group, special event volunteers, or any other volunteer whose leadership and commitment is vital to the success of your chapter. The size of your support group is not a criteria, the size of the heart of your nominee is!

How to make a nomination: Please send a letter of nomination, 500 words or less, indicating why your nominee should be considered. You will want to indicate the positive impact that this person has had on the life of your chapter, and how men and their families have benefited from their committed service. Also, please list the location and name of the Chapter that this individual represents.

Please email your letter or form to Terri Gibbons, Program Manager at terri@ustoo.org or mail to the Us TOO Charlotte NC Office**: Terri Gibbons, 105 N. Tanninger Road, Mount Holly, North Carolina, 28120.**

Letters of nomination must be received no later than November 12 and will be reviewed by the Us TOO Awards Committee. Awardees will be announced November 19 and invited to attend the Us TOO Annual Meeting in Chicago on Friday evening December 3, 2010 in Chicago.

Person(s) selected for the Edward C. Kaps Hope Award will receive:

- An Us TOO International Logo Watch
- Honorary Plaque
- Name engraved on our Hope Award plaque in the Us TOO home office and receive special recognition in an upcoming edition of our Hot Sheet.

Past awardees included: (2009) Russ Gould, Bill Stevens, Johnny Payne, Rex Zeiger, and in memoriam, Bill Boyd; (2008) Stan Rosenfeld, Ralph Valle, Shirley Grey, Chuck Maack, Bill Blair, and in memoriam, Jack Pais and Harry Pinchot.

We look forward to sharing the stories of the new nominees in upcoming issues of the *HotSheet*, the Us TOO webpage, the *Chapter News!* and in an email blast.

TEVA LAUNCHES PROSTATE CANCER PHASE III STUDY

Teva Pharmaceutical Industries Ltd. and OncoGenex Pharmaceuticals, Inc. reported the initiation of Synergy, a global Phase III trial evaluating custirsen as first line therapy for the treatment of castrate-resistant prostate cancer (CRPC).

Custirsen utilizes second-generation antisense technology, licensed from Isis Pharmaceuticals, to target and inhibit clusterin production, a protein involved in resistance of tumors to treatments. The clinical trial will be conducted in approximately 125 cancer centers and with designated recruitment of 800 men with metastatic CRPC progression and require first-line docetaxel/prednisone chemotherapy. Patients will be randomized to receive either docetaxel/prednisone plus custirsen or with docetaxel/prednisone alone. The main goal of the study is to see if overall survival is longer in patients receiving custirsen.

The co-principal investigator is Dr. Johann de Bono, who is affiliated with Institute of Cancer Research and The Royal Marsden Hospital, London.

The current study is the second of three planned. Custirsen has received Fast Track designation from the US FDA.

< www.globes-online.com>,

3 October 2010

COMPARATIVE EVALUATION OF RADIATION TREATMENTS FOR CLINICALLY LOCALIZED PROSTATE CANCER: A RECENT UPDATE BY MEDICARE

The Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS) requested a report from The Technology Assessment Program (TAP) at the Agency for Healthcare Research and Quality (AHRQ). The report is based on research conducted by the Tufts Evidence-Based Practice Center under contract to AHRQ.

The report included randomized controlled trials and non-randomized direct comparative studies of men with clinically localized disease that reported clinical outcomes for T1 or T2 disease. Single cohort studies, adjuvant, salvage, or post-prostatectomy RT studies, and studies evaluating androgen deprivation therapy were excluded.

The intervention of interest was RT used as a first line treatment of prostate cancer. The treatments included various forms of external beam RT (intensity-modulated RT, conformal RT, stereotactic body RT including CyberKnife®, and proton beam), and brachytherapy (permanent seed implantation and high dose rate temporary brachytherapy).

The treatments reviewed also included combination RT approaches, such as external beam RT with brachytherapy boost. Outcomes of interest included overall and prostate cancer-specific survival, metastatic and/or clinical progression free survival, freedom from biochemical (PSA) failure, quality of life, bowel and urinary toxicities, and sexual dysfunction.

From the included studies, the report extracted information on patient samples, RT characteristics (e.g., type of RT (proton vs. photon), source of RT (linear accelerator, Cobalt-60, internally planted radioactive seeds), dose, number of fractions, and manufacturer of device), treatment planning algorithm, outcomes (clinical and biochemical), adverse events, and study design.

AHRQ used a 3-grade (A, B, C) rating system to rate the quality of each individual study. They also used a 3-category rating system (high, moderate, insufficient) to assess the overall strength of evidence for the outcomes reported in each of the comparisons.

According to the AHRQ report, definitive benefits of RT compared to no treatment or no initial treatment for localized prostate cancer could not be determined because available data were insufficient. Data on comparative effectiveness between different forms of RT (BT, EBRT, SBRT) are also inconclusive whether one form of RT is superior to another form in terms of overall or disease-specific survival.

Studies suggest that higher EBRT dose results in increased rates of long-term biochemical control than lower EBRT dose. EBRT administered as a standard fractionation or moderate hypofractionation does not appear to differ with respect to biochemical control and late genitourinary and gastrointestinal toxicities. Available data suggest that BT might be associated with an increase in genitourinary toxicity compared with EBRT. BT appears to be largely comparable to EBRT in the rates of gastrointestinal toxicity. However, more and better quality studies are needed to either confirm or refute these suggested findings.

The report includes 8 appendices having in-depth comparisons between the various RT modalities, 13 data tables and 5 graphic figures. Overall, the report reviewed 74 peer-reviewed references.

The full report can be accessed at the CMS website: <www.cms.gov/coveragegeninfo/downloads/id69ta.pdf>.

PROTEIN ARRAY FOR PROSTATE CANCER *(Continued from page 2)*

easily detected in blood samples, which entail minimal invasiveness.

The technology employed by Anson and colleagues allows assessment of autoantibodies that bind simultaneously to more than 1,000 microarrayed proteins selected because of their association with disease. Advanced data analysis techniques are used to sort proteins according to their association with disease states and their ability to discriminate between disease and normal states.

For the prostate cancer test, researchers began with a microarray of 925 proteins, which they used to evaluate blood samples from 73 patients with prostate cancer, 37 healthy individuals, and 23 men with BPH. Repeated testing pared the 925 proteins down to arrays of 15 or fewer proteins. With further refinement, the panel eventually could separate cancer from benign conditions with greater than 90% sensitivity and specificity.

"Biomarker panels may offer better performance than single markers, such as PSA," said Anson. "Early disease detection by means of autoantibodies could increase cure rates for a variety of diseases. Patient acceptability should be good because collection of blood samples is a relatively noninvasive process."

Investigators have expanded evaluation of the test in a follow-up study involving more than 1,800 specimens, including men with prostate cancer, as well as a 1,200-person control group that includes healthy men and those with BPH and other interfering conditions.

Diagnostics based on biomarker panels have potential application in other diseases. Prototype tests have generated promising results in preliminary studies related to systemic lupus erythematosus and non-small cell lung cancer.

MedPage Today, 30 September 2010

POM WONDERFUL CHARGED WITH SELLING 'SNAKE OIL'

Despite being rich in antioxidants, pomegranate juice is probably not an effective treatment for heart disease and other serious health conditions. At least according to a Federal Trade Commission (FTC) lawsuit filed in September 2010 against POM Wonderful LLC, which makes POM Wonderful 100% Pomegranate Juice and POMx supplements, among other products made from the fruit.

In response, POM Wonderful issued a statement, which appears separately in the first panel of page 5.

The FTC said POM Wonderful violated trade laws by making "false and unsubstantiated claims" that its products will prevent or treat heart disease, prostate cancer, and erectile dysfunction. "Contrary to POM Wonderful's advertising, the available scientific informa-

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'SNAKE OIL'

(Continued from page 4)

tion does not prove that POM Juice or POMx effectively treats or prevents these illnesses" said David Vladeck, director of the FTC's Bureau of Consumer Protection.

The FTC wants to make any future claims about the health benefits of pomegranate juice subject to verification by the Food and Drug Administration, according to the agency's complaint.

Matt Tupper, POM Wonderful's president, was named in the FTC complaint, along with fellow executives Stewart Resnick and Lynda Resnick. The agency also charged a POM Wonderful affiliate, Roll International, in the lawsuit.

CNN Money, 27 September 2010

US TOO SEEKS BOARD MEMBER APPLICATIONS

Us TOO is still seeking nominations to fill two remaining seats on the Us TOO International Board of Directors. The Board Membership Committee, chaired by Carl Frankel, will review and evaluate nominees and submit recommendations to the full Board for approval throughout the remainder of this year, as well as at its December 2010 Board meeting.

The Us TOO Board is made up of 15 seats, one third of which are up for reelection annually. Two Board members who will be ending their terms of service this December 2010 are Greg Bielawski and Carl Frankel, Esq.

Selection criteria include items such as the candidate's relationship to Us TOO's purpose, its membership criteria ("…any man diagnosed with prostate cancer, a member of such a man's family or significant other, or any person involved in or interested in support or treatment of any such patients…"), familiarity with an Us TOO chapter, ability to think globally, skills or experience deemed beneficial to the work of Us TOO and commitment to Us TOO's purpose and mission.

Letters of nomination with a vita or resume can be sent now to Thomas Kirk, President/CEO, Us TOO International, 5003 Fairview Avenue, Downers Grove, IL 60515 or send via E-mail to <tom@ustoo.org>.

CABAZITAXEL

(Continued from page 1)

The primary end point was overall survival. Median survival was 2.4 months longer with cabazitaxel (15.1 vs. 12.7 months) yielding a 0.70 hazard ratio for death in favor of cabazitaxel ($P < 0.0001$). Median progression-free survival was twice as long with cabazitaxel (2.8 vs. 1.4 months) as was time to progression (8.8 vs. 5.4 months; $P < 0.0001$). PSA response rates were 39.2% with cabazitaxel and 17.8% with mitoxantrone ($P = 0.0002$).

However, cabazitaxel caused more adverse events. Grade 3 or higher neutropenia occurred in 82% of cabazitaxel patients and in 58% of mitoxantrone patients. Grade 3 or higher diarrhea rates were 6% and less than 1%, respectively. Febrile neutropenia occurred in 28 cabazitaxel patients and in 5 mitoxantrone patients. Dr. de Bono advised clinicians treating docetaxel-resistant CRPC with cabazitaxel to "monitor for neutropenia in course 1, and dose-reduce to 20 mg/m^2 if grade 4 neutropenia lasting longer than 5 days is seen.

The authors conclude "cabazitaxel is the first treatment to prolong survival for metastatic multidrug-resistant prostate cancer in the post-docetaxel setting. . . . On the basis of these results, cabazitaxel will become a standard of care for treatment of prostate cancer in this setting."

In an accompanying editorial, Tanya Dorff, MD, and David Quinn, MD, PhD, from the University of Southern California, Los Angeles, write: "The key result – a 2.4-month improvement for cabazitaxel over mitoxantrone – changes our practice. Cabazitaxel provides an added line of therapy for patients with CRPC," they explain.

However, the editorialists caution about the adverse effects encountered with the new drug including allergic-type reactions during infusion requiring prophylaxis, an increased treatment-related mortality (4.9%), perhaps because of substantial neutropenia and diarrhea. In this context, they recommend contingency plans to manage diarrhea and febrile neutropenia , with access to antibiotics and other supportive measures.

Medscape Medical News, 6 October 2010

POM TO FTC: "STOP PERSECUTING POMEGRANATES!"

In response to the FTC, POM Wonderful issued the following statement:

"POM Wonderful fundamentally disagrees with the FTC and believes that the commission's allegations against POM are completely unwarranted.

Pomegranates are food – highly nutritious produce, designed by nature itself. Because POM products may in fact offer the promise of better health, we believe it is important to share the research results as they become available. This is especially true since our products do not carry the risks associated with pharmaceutical drugs. It's a shame that the government is unable to understand this fundamental distinction, and instead is wasting taxpayer resources to persecute the pomegranate.

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CATCHING UP WITH THE PINK: LEATHER WRISTBANDS HELP RAISE AWARENESS, FUNDS FOR US TOO

- Braided black leather adjusts to any wrist size
- Non-tarnish silver-finish medallion
- Net proceeds donated exclusively to Us TOO International

For more information, go to <www.prostatecancerwristband.com> or call 800-808-7866

"Conquer Prostate Cancer" Wristband $25

DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

"I'm still on strike! We need more signatures on the CMS petition!"

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

Bottom Line: Dr. Moyad is still on strike to raise attention to the national grass roots petition on Medicare reimbursement for FDA approved cancer drugs.

Do you want the determination of who might or might not get a cancer drug be decided by Medicare???? There is nothing I or any doctor can say in our columns that is as big as this....

So far, Us TOO has now received 1,244 signatures from individuals in 26 states. Great job! But can we hit 5,000 signatures from this great network of survivors and family members – to present at the CMS meeting on 17 November 2010?!?!

Sign on today! Please take a look at this petition at <www.ustoo.org> OR at your local Us TOO support group chapter meeting and sign it like Dr. Moyad did if you believe in this cause.

Petition to National Medicare (CMS): Cover FDA Approved Cancer Treatments!

"We the undersigned call on CMS Administrator Donald Berwick MD to stop potentially limiting access to FDA approved cancer treatments, such as Provenge, for men fighting advanced prostate cancer. Instead we want Dr. Berwick to demonstrate his commitment to patients, their families, and health care professionals by providing his full support for appropriate unrestricted access and coverage by Medicare."

Mail signed and completed petition pages by November 5th to:

Tom Kirk, President & CEO, Us TOO International, 5003 Fairview Ave., Downers Grove, IL 60515.

Questions? Contact Tom Kirk at tom@ustoo.org or call (630) 795-1002.

Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet.* It is our desire to enrich the content of the *HotSheet* to empower the reader. The columns by Drs. Chodak, Moyad and Myers contain the opinions and thoughts of its author and is not necessarily those of Us TOO International.

ABOUT THIS CMS MEETING

In his column, Dr. Moyad mentions that all collected petition signatures will be presented at a CMS meeting on Nov 17, 2010. The meeting will be conducted by the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) of the Centers for Medicare & Medicaid Services (CMS). Discussion will focus on the currently available evidence regarding the clinical benefits and harms of on-label and off-label use of Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (aka Provenge), and if it is adequate for the Committee to advise that the treatment costs be covered by Medicare. This meeting is open to the public and will also be broadcast via a Webinar. You must register for the Webinar portion of the meeting by 5 pm EST, Wed, Nov 10, 2010. Go to <www.ustoo.org> to find the specific registration link.

POM TO FTC

(Continued from page 5)

We do not make claims that our products act as drugs. What we do, rather, is communicate, through advertising, the promising science relating to pomegranates. Consumers and their health providers have a right to know about this research and its results.

We stand behind the vast body of scientific research documenting the healthy properties of Wonderful variety pomegranates. For more than a decade, we have provided over $34 million to support scientific research on pomegranates, working with top researchers, including a Nobel Laureate, at leading universities around the globe. To date, more than 55 studies on POM products, including 19 clinical trials, have been published in peer reviewed journals. The results have been encouraging and many additional studies are in progress.

POM believes very strongly in its first amendment rights to communicate the promising results of our extensive scientific research program on pomegranates. We believe the FTC is violating POM's constitutional rights to share useful and important information with the public, and therefore we have initiated a separate lawsuit to preserve these rights."

POM Wonderful , 27 September 2010

ASK DOCTOR SNUFFY MYERS

What effect does coffee consumption or caffeine have on prostate cancer?

As long as I have been in medicine, it seems that folks keep trying to find something wrong with coffee or caffeine. Instead of problems, research keeps finding benefits. Talk about the law of unintended consequences!

So, my review of the literature shows that habitual coffee consumption is associated with a drop in overall risk of death and a reduction in many common diseases including Parkinson's and many cancers. Now, it is important to know that coffee is more than caffeine: freshly brewed coffee is rich in many of the same polyphenols found in tea. It also has a range of other chemicals thought be beneficial, including caffeic acid. As far as cancer risk is concerned, habitual coffee consumption appears to reduce the risk of liver, kidney, colon and premenopausal breast cancer. On the other hand, there appears to be no association at all between coffee consumption and cancers of the ovary, pancreas and prostate.

As with anything in life, coffee in excess is not completely free of risk. Atrial fibrillation is one of the most common heart problems. One major problem with atrial fibrillation is that it can cause blood clots to form in the heart and when these blood clots migrate, they can block arterial blood flow, causing strokes and other problems. As a result, chronic atrial fibrillation is managed by anticoagulation with warfarin, with the resulting risk of bleeding and bone loss. Atrial fibrillation is often triggered by stress, too much alcohol and too much coffee. Excess coffee, especially late in the day, can cause insomnia.

(Continued on page 8)

DOCTOR CHODAK'S BOTTOM LINE

Anyone enjoying their pomegranate juice is likely to be upset by the government's warning to POM Wonderful. Their ads suggested that studies had shown it was good for men with prostate cancer. Here are the facts about what is known.

- Pomegranate juice slows the growth of prostate cancer cells growing in a plastic dish.
- Mice given prostate cancer had slower growth of the tumor if they were taking pomegranate juice.
- Pomegranate juice slowed the rate of PSA rise in men with a biochemical failure after local treatment.

The Bottom Line: Although encouraging, none of these results prove that pomegranate juice is worthwhile in men with prostate cancer. According to the Dietary Supplement Health and Education Act of 1994, dietary supplements cannot make false claims about the effect and they must state, "It is not intended to diagnose, treat, cure, or prevent any disease." This prevents any company from misrepresenting the results from studies it helps finance. Although everyone is hopeful that dietary products and supplements can help fight prostate cancer, the truth is they must be properly studied before any claims can be made. This is not the only company selling supplements that oversteps the boundary for proper advertising, which means men should view any such ads with caution.

Although the value of supplements remains uncertain, important progress has been made with conventional medications for men with metastatic disease. One of them is Jevtana, which was recently approved by the FDA for men getting worse despite receiving Taxotere. Clinical studies showed that it significantly improved survival although more men getting Jevtana died from complications compared to the control group. Even though this is likely to frighten many men, the fact is that medications that would have helped reduce the risk of dying from an infection could not be given. Now, all men getting Jevtana are advised to get these medications, which should lower the risk.

The Bottom Line: Despite the potential for serious side effects, this is yet another advance for men with progressive metastatic disease and it should be discussed as one of the options.

Other new developments for progressive disease also are actively being studied. One of them called custirsen is a protein that inhibits the formation of clusterin, which normally helps cancer cells grow better. Custirsen is being combined with Taxotere and prednisone to see if it does a better job than these two drugs given alone. Now, not only do men with advanced disease have the option of getting Taxotere, Provenge, or Jevtana, but other drugs such as custirsen, abiraterone and MDV3100 may become available.

The Bottom Line: It seems that research in prostate cancer has been accelerating with new options now available and more on the horizon. If they all gain approval, doctors will face an interesting challenge; what is the best sequence for using all these options?

These ongoing studies of new drug therapies are in sharp contrast to studies of non-drug treatments. In two very disturbing reports, the authors found that the benefits of radiation compared to watchful waiting or no initial treatment could not be determined after reviewing all articles published in medical journals. They also could not find proof that one form of radiation was superior to another and not one comparative study was published for proton beam therapy.

The Bottom Line: To borrow the famous line "Houston, I think we have a problem", this disparity between approval requirements for drugs compared to non-drug treatments is absolutely crazy. Why shouldn't they be the same? Don't doctors have an ethical obligation to prove that every treatment they use definitely improves men's survival or quality of life beforehand? Although they would be costly to do, expense does not keep drug studies from being done, which routinely cost several hundred million dollars to complete. The reason why the studies are not done is mostly about business. Why do a time-consuming study when the government's rules permit reimbursement for non-drug therapies without proof they actually work? Had similar requirements existed years ago, we would know by now which therapies improve survival and which ones do not. Perhaps the testing requirement for drugs should be removed but then we would worry about how many men would be harmed or get an ineffective treatment. Ultimately, patients may have to raise their voices and demand that the rules for approving treatments are consistent so they can finally find out which treatments truly help them.

Although some new treatments are moving along through the testing process, many do not. Sunitinib combined with prednisone in men failing chemotherapy did not improve survival. Zibotentan also failed to show a benefit in men with advanced disease but is still undergoing testing for other stages.

The Bottom Line: These studies reinforce that drugs useful for one type of cancer do not necessarily work in other cancers. Although testing new drugs is both expensive and time consuming, it is critical to find out which ones are helpful.

Please remember to include

Us TOO International

in your Holiday giving plans.

Thank you!

You've probably seen all the NFL players in pink gear the past few years in October for Breast Cancer Awareness Month. We support PCF's petition to urge the NFL to wear light blue for Prostate Cancer Awareness. Take a few seconds to sign the petition to show that the prostate cancer community wants to see the NFL step up for the cause of prostate cancer: <http://apps.facebook.com/causes/petitions/552>. THANK YOU!

US FDA APPLICATION FOR PROGENSA® PCA3 FILED

Gen-Probe announced that the Company has submitted a Premarket Approval Application (PMA) to the US FDA for its PROGENSA® PCA3 assay, a new molecular test that may help determine the need for repeat biopsies in men suspected of having prostate cancer.

Gen-Probe is seeking FDA approval to use the PROGENSA PCA3 assay to test urine samples from men who previously have had a negative prostate biopsy. In support of this objective, the Company conducted a prospective, multicenter clinical study of the assay that enrolled 507 men from August 2009 to May 2010. Gen-Probe intends to present the results of the study at a future medical meeting.

"Based on the results of our US clinical study, data from numerous peer-reviewed publications, and our European commercial experience, we believe the PROGENSA PCA3 assay can help determine the need for repeat prostate biopsies, thereby improving patient care," said Carl Hull, Gen-Probe's president and chief executive officer.

A meeting of the Medical Devices Advisory Committee's Immunology Panel is required to support PMA approval.

Medical News Today, 22 September 2010

NATIVE AND FOREIGN BORN BLACK MEN *(Continued from page 1)*

Folakemi Odedina, PhD, professor of pharmaceutical outcomes and policy at the Univ. of Florida, who led the study, said findings refute a common belief of physicians that 'black is black.' "What we are finding is that risk factors are different. When you pool all those people, then you are confusing [risk profiles]."

Research on differences among native- and foreign-born black men, she said, is necessary, especially in light of the healthy immigrant effect, which proposes that when immigrants arrive in the US, they are healthier than their counterparts already in the US. Studies have focused on this effect in Asians and Hispanics, but not in blacks, she said.

Levi Garraway, MD, PhD, assistant professor in the Department of Medicine at Harvard Medical School in Boston, MA, who moderated the session, said the study might be the beginning of more awareness of a new meaningful level of understanding about cancer risk.

"This is one of those things where it's the beginning of looking at this," he said. "I hadn't personally thought about that level of complexity."

"In terms of the actual data that [Dr. Odedina] presented, it's not totally clear that... there's something obvious to do differently," Dr. Garraway said. "I think it's more that the levels of awareness of the risk for prostate cancer and how aggressive the patient will be in talking to the physician may vary, and that these different regions may influence that to a certain degree."

"What the findings do is give you a sense of whether the point of intervention falls within the physician's office or falls somewhere else in the community," Dr. Garraway said. "The limiting point of intervention might be even before they arrive into the healthcare system."

Reference

Third American Association for Cancer Research Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, Abstract PR-2; Presented 1 October 2010.

Medscape Medical News, 4 October 2010

ASK DR. MYERS

(Continued from page 6)

So, my final take is that coffee is something to be enjoyed in moderation and in that fashion it will be generally good for your health. It joins tea and chocolate as health-giving foods that make you feel good while being good for you.

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