VITAMIN E AND SELENIUM DO NOT PREVENT PROSTATE CANCER; USE OF THE SUPPLEMENTS STOPPED IN LARGE-SCALE STUDY

The SELECT (Selenium and Vitamin E Cancer Prevention Trial) prostate cancer prevention study is instructing its 35,000-plus participants to stop taking the 2 nutritional supplements because of an apparent lack of benefit and a possibility of harm.

“The Data and Safety Monitoring Committee made the decision to stop use of the supplements, not to stop the trial. We will follow participants for 3 more years to determine if there is any benefit or any harm,” said Larry Baker, MD, chairman of the Southwest Oncology Group, which coordinated the trial, and professor of medicine at University of Michigan Medical School in Ann Arbor, MI.

The Data and Safety Monitoring Committee said that “the data could not exclude a small chance that the study supplements might have effects later in the men’s lives.” However, the antioxidants selenium and vitamin E, taken alone or together for an average of 5 years, did not prevent prostate cancer, according to the committee.

AUA BEST PRACTICE STATEMENT RECOMMENDS CRYOSURGERY IN CERTAIN PROSTATE CANCER CASES

Men with clinically organ-confined prostate cancer of any grade with a negative metastatic evaluation can receive primary cryosurgery, according to a best practice statement issued by the American Urological Association (J Urol, Vol 180, pp. 1993-2004, 2008).

When the American Urological Association issued the “Guideline for the Management of Clinically Localized Prostate Cancer: 2007 Update” last year, insufficient data were available on the use of cryosurgery in men with the disease, according to a press release. Since then, a panel of experts convened to develop a best practice statement regarding cryosurgery as a primary treatment option.

Using medical databases, the panel reviewed available data and composed recommendations for treatment with cryosurgery. Included in the recommendations are procedure requirements for maximum efficacy in the following areas:

- Tissue freeze rate: the panel recommended rapid freezing;
- Temperature monitoring: the use of thermocouples was strongly advised;

(Continued on page 6)
GVAX Trial Terminated
(Continued from page 1)

therapy for prostate cancer. In view of the termination of both the VITAL-1 and VITAL-2 trials, the Company will place on hold the further development of GVAX immunotherapy for prostate cancer pending a review of the program with its collaborator, Takeda Pharmaceutical Co. Ltd.

As a result of these circumstances, Cell Genesys will reduce its staff of 290 by approximately 75 percent by year-end with further reductions anticipated in the first half of 2009. As of September 30, 2008, the Company had approximately $150 million in cash and currently estimates that the year-end cash will be approximately $128 million. Personnel-related restructuring charges of approximately $12.8 million are expected to be incurred in the fourth quarter of 2008.

“We are, needless to say, extremely disappointed with the outcome of the futility analysis for the VITAL-1 Phase 3 clinical trial, but remain committed to learning as much as we can about the potential role for immunotherapy in the treatment of cancer. On behalf of the Cell Genesys management team, I would like to express my deep gratitude to the courageous patients who participated in this study as well as our committed clinical trial investigators and their teams,” stated Stephen A. Sherwin, MD, chairman and chief executive officer of Cell Genesys. “At this time I would also like to extend my heartfelt thanks to the hardworking and dedicated employees of Cell Genesys to whom we must now sadly say goodbye. The significant changes in our business which we are implementing today are painful but necessary, and will enable us to consider the appropriate strategic alternatives for our company.”

Cell Genesys held a conference call on 16 October 2008 to discuss this announcement. The Company emphasized that GVAX® immunotherapy holds the potential to treat multiple types of cancer other than prostate cancer, including leukemia, pancreatic cancer and lung cancer. For more information, please visit the Company’s website at <www.cellgenesys.com>.

Cell Genesys, 16 October 2008

Rethinking Prostate Cancer in Older Men

Research suggests aggressive treatment is viable, even for patients in their late 70s

With increasing life expectancies, improved surgical tools, and better information on patient results, many older men diagnosed with early prostate cancer are taking a pass on the traditional advice to hold off on treatment for a period of time. So-called “watchful waiting” – closely monitoring the cancer’s progression – is still a viable option. But many experts now believe that aggressive treatment, even for older men, may be the better way to go.

A study published in the 4 February 2008 issue of the Journal of the American Medical Association helped shake up the conventional wisdom. The study involving some 44,000 men, found that the death risk for those who received prostate cancer treatment was nearly one-third lower than for men who received no treatment. That was true across all age categories, including ages 75 to 80.

“We often think of prostate cancer as an indolent disease, and it is for many men, which is why observation is a very reasonable treatment option for patients with low and intermediate risk disease,” said the study’s lead author, Dr. Yu-Ning Wong, a medical oncologist at the Fox Chase Cancer Center in Philadelphia. “However, the life expectancy for a 70-year-old man is about 13 years, and patients who are otherwise healthy should recognize that if they live long enough, they may be at risk of developing complications from prostate cancer,” she added.

Observation or “watchful waiting” does not mean watching someone die. Many oncologists today prefer the term “active surveillance,” said Dr. Edouard J. Trabulsi, assistant professor in the department of urology at Jefferson Medical College and co-director of the Jefferson Prostate Diagnostic Center in Philadelphia, PA. It more diligently to monitors these patients, including the use of PSA blood tests, digital rectal exams and biopsies of the prostate to detect changes in the cancer.

Because prostate cancer is generally a
CELEBRATING PROSTATE CANCER AWARENESS EVENTS
Greater Chicago Prostate Cancer Run Walk ‘n Roll—October 19, 2008

Thanks to all the participants, sponsors, Mrs. Illinois, Jesse White Tumblers, volunteers and staff for a wonderful day!
When he was diagnosed with prostate cancer, California native James R. Jenner, 77, reached out to the Us TOO Prostate Cancer Education and Support Network for information and support, and the Berkeley area Us TOO Chapter. Now, the retired Alameda County Public Defender has named the Us TOO Prostate Cancer Support and Education Network as a beneficiary.

Jenner said that “What impressed me about Us TOO was all of the excellent, unbiased information provided as well as all of the support of the many chapter members. Us TOO has provided me and my peers with a wealth of knowledge and support. So, it seemed only natural that I should share some of my modest wealth with Us TOO.

“Accordingly, I have named Us TOO as beneficiary of a significant portion of one of my accounts. I chose this way of making a Planned Gift because it worked for me, but there are many other ways that one can make a Planned Gift as part of routine estate planning,” he said.

Jenner had been one of the original participants in the NIH sponsored Prostate Cancer Prevention Trial (PCPT) to determine whether finasteride (Proscar®) can prevent prostate cancer. The PCPT was stopped early in 2003 when it became clear that the drug did reduce incidence of the disease. In May, 2007, Jenner was diagnosed with Gleason Grade 9 prostate cancer. Not one to walk away from a challenge, he chose to undergo a radical prostatectomy in August, 2007. Currently, his PSA remains undetectable.

As a participant in the PCPT, Jenner became well aware of prostate cancer and various sources of information. So, when diagnosed with the disease, he quickly turned to the Us TOO Prostate Cancer Education and Support Network for more information and support, which he readily found at the Berkeley area Us TOO Chapter.

Jenner was raised in northern California and, in 1950, entered the University of California, Berkeley. He graduated from UC Berkeley, Boalt Hall School of Law and Advanced Law Studies at the University of Madrid. Prior to joining the Alameda County Public Defender’s office, Jenner was an interrogator in Russian and Spanish for the US Army, and was in private practice with the law firm of Marquard and Jackson.

From 1975 to 1980, he served as Chief Assistant Public Defender and then became Public Defender, a position he held until his retirement in 1989. Jenner has been described as a bearded, balding mountain climber, resembling a young Mahatma Gandhi. He was a brilliant, theatrical courtroom lawyer and handled many very high profile cases.

As he was starting his career in the Public Defender’s office, Jenner’s extracurricular activities included participation in the rugged 1975 Pike’s Peak Marathon. He has been actively involved in technical climbing, a risky and challenging sport using hands, feet, ropes, harnesses and other hardware to traverse difficult mountains. He even practiced this sport in the Himalaya Mountains, entering through Tibet on his way to Mount Everest.

Today, he is still in Berkeley where he lives with his wife, Mina. Jenner is still climbing, but in the milder form of scrambling over rocky terrain without the aid of various equipment. He and Mina recently took their VW van to remote areas of the mountains of central Nevada, where they climbed for three weeks, often spending three to four days without encountering anyone else – only nature.

“I would encourage anyone touched by prostate cancer to consider such a gift to Us TOO. There is great satisfaction in knowing that, long after you are gone, you will still be helping this great organization to continue on providing support and education for others dealing with prostate cancer,” he said.

PLANNED GIVING TO Us TOO INTERNATIONAL

On October 3, 2008, President Bush signed legislation (Public Law 110-343) that includes an extension of the IRA Charitable Rollover originally enacted as part of the Pension Protection Act of 2006. The extension is retroactive, applying to distributions made throughout both the 2008 and 2009 tax years. The extension will allow individuals 70½ and older to donate up to $100,000 from their IRAs to charities tax-free.

To make gifts of life insurance, securities, retirement plan assets and bequests to Us TOO International, contact Pam Barrett, Director of Development, by phone at (630) 795-1002 or e-mail pam@ustoo.org.

Military and Federal Employees: please remember Us TOO in your Combined Federal Campaign contribution.

Us TOO CFC# 11614
Bottom Line: The party is officially over! High-dose (400 IU or more per day) vitamin E supplements do not prevent or treat prostate cancer, and may actually do very, very bad things to you! (PS: My new book is now available by calling toll free (877) 722-2264 or going to <www.Amazon.com> and it explains all this stuff and of course this is a shameless plug).

Just 10 years ago, vitamin E supplements in high-doses were all the rage and excitement and sales were through the roof!!! There was also an article and it explains all this stuff and of course this is a shameless plug).

However, this poor doctor received a lot of hate mail from folks that did not like what I was saying about high-dose vitamin E supplements. You see, not only were high-dose vitamin E supplements not heart healthy, but they may have actually caused harm, so let’s forward this time machine to late 2008!

Vitamin E supplements at 400 IU per day are part of the 114 million dollar SELECT prevention trial, which is the largest prevention trial of prostate cancer in the world! However, the participants were told to stop taking the supplements because vitamin E did not reduce prostate cancer risk, and there was a suggestion that it may increase the risk of prostate cancer.

In addition, in the past few days the largest trial of healthy men in the world taking 400 IU per day of vitamin E found that it not only did not reduce the risk of heart disease, but may have significantly increased the risk of internal bleeding!!! OUCH!!!

Finally, the largest trial of cancer patients taking 400 IU of vitamin E during radiation treatment found that it reduced the efficacy of this conventional treatment and may have increased the risk of dying from cancer!!!

Vitamin E in high-doses is simply a complete and total mess! I WANT YOU TO KEEP SOMETHING IN MIND PLEASE! IT ONLY TAKES ABOUT 15 to 30 IU OF VITAMIN E PER DAY TO NORMALIZE YOUR BLOOD LEVEL OF VITAMIN E!

This you can get from a cheap multivitamin and some healthy foods like plant-based cooking oils (safflower…) and all sorts of nuts like almonds!

Now, in the next issue I will tell you why high-dose selenium supplements (200 mcg or more per day) are a waste of money as much as high-dose vitamin E! OUCH AGAIN! (Oh and by the way, if Michigan beats Ohio State this year in football, I will donate 100 dollars to Us TOO and buy beer for the entire staff at Us TOO and for myself!)

SELECT Trial Stopped (Continued from page 1)

“We went back to the biologists, and they said 8 months was sufficient to see benefit,” Dr. Baker explained. The data from SELECT also show 2 trends that were of concern but not statistically significant: in men taking only vitamin E, there were slightly more cases of prostate cancer; and, in men taking only selenium, there were slightly more cases of diabetes. Both findings could be due to chance.

Dr. Baker said that results to date speak for themselves, and that SELECT is a much larger trial than previous trials that suggested benefit. “This is the definitive study and anyone who argues that is ignoring the facts.”

Medscape, 29 October 2008

SELECT Prevention Trial: The largest prevention trial of prostate cancer in the world! However, the participants were told to stop taking the supplements because vitamin E did not reduce prostate cancer risk, and there was a suggestion that it may increase the risk of prostate cancer.

In addition, in the past few days the largest trial of healthy men in the world taking 400 IU per day of vitamin E found that it not only did not reduce the risk of heart disease, but may have significantly increased the risk of internal bleeding!!! OUCH!!!

Finally, the largest trial of cancer patients taking 400 IU of vitamin E during radiation treatment found that it reduced the efficacy of this conventional treatment and may have increased the risk of dying from cancer!!!

Vitamin E in high-doses is simply a complete and total mess! I WANT YOU TO KEEP SOMETHING IN MIND PLEASE! IT ONLY TAKES ABOUT 15 to 30 IU OF VITAMIN E PER DAY TO NORMALIZE YOUR BLOOD LEVEL OF VITAMIN E!

This you can get from a cheap multivitamin and some healthy foods like plant-based cooking oils (safflower…) and all sorts of nuts like almonds!

Now, in the next issue I will tell you why high-dose selenium supplements (200 mcg or more per day) are a waste of money as much as high-dose vitamin E! OUCH AGAIN! (Oh and by the way, if Michigan beats Ohio State this year in football, I will donate 100 dollars to Us TOO and buy beer for the entire staff at Us TOO and for myself!)


US TOO PROSTATE CANCER EDUCATION & SUPPORT HOT SHEET - DECEMBER 2008
Sometimes it may seem that the more information we gather, the more confusing this disease becomes. Many studies in the news seem to result in conflicting conclusions and recommendations. One case in point relates to the article on "Rethinking Prostate Cancer in Older Men" which suggests that aggressive treatment of early prostate cancer in older men resulted in better survival compared to conservative therapy. This important conclusion warrants very careful scrutiny. Unfortunately, as the authors acknowledge, THIS IS NOT A PROSPECTIVE RANDOMIZED STUDY and for that reason the results may or may not be correct. The only randomized study to date found something different, that there was almost no benefit to surgery over conservative management for men older than 65.

Another problem with the results from the study cited in this issue is that the pathology reports for the surgery group were based on the operative report compared to the biopsy for the men undergoing watchful waiting. Studies have repeatedly demonstrated that the Gleason score is commonly higher when the prostatectomy is used rather than the biopsy. This means that men with bad cancers found at surgery in this study were not included in this analysis whereas they were still counted in the watchful waiting group.

This is yet another example of the hazards of non-randomized studies. The bottom line is older men should understand that the benefits of aggressive therapy may be very small and each individual will have to weigh that against the side effects of therapy.

Another example of the need for careful prospective studies, something that is emphasized repeatedly in this column, is the findings from the study on Vitamin E and Selenium. Some preliminary studies had suggested and many doctors have promoted these two agents as a way to prevent prostate cancer. Given the controversy, the National Institutes of Health sponsored a large prospective trial to find out if the preliminary findings were correct. There are many advocates who thought it unnecessary to do such a study arguing that the answer was already in. But in fact, that turned out not to be the case. Not only did the combination of the two vitamins fail to lower the detection rate, it actually was slightly but not significantly higher. Furthermore, side effects were uncovered demonstrating that taking vitamins and/or supplements is not without harm and for that reason it should never be advocated without having good science to support it.

In last month's HotSheet, the need for a randomized study to assess the value of screening for prostate cancer was again questioned by Dr. Catalona who challenged the recommendations recently made by the US Public Task Force. The organization stated that men over 75 should not be screened because the benefits outweighed the harms and no good scientific study has demonstrated a real benefit.

Unfortunately, all the statistical information cited in the article by Dr. Catalona is circumstantial and does not prove anything. Although they could mean screening is worthwhile, they also could simply be observations that are being interpreted incorrectly. We must resist the temptation to make premature conclusions that sound reasonable but which may result in doing more harm than good. We are all awaiting anxiously the findings from the ongoing screening trials that should provide the necessary information to answer this critical question.

But until those results become available, everyone should understand that screening is an individual decision to be made after understanding the potential for benefit and the potential for harm. And the lesson to learn from the vitamin study is that despite having preliminary evidence supporting an intervention, when tested properly, we may find that our initial assumptions were incorrect.

The article about the protein IGF-1 could be another example where caution is needed regarding interpretation. A recent report from England found that having higher levels of this protein was associated with a higher risk of prostate cancer. Does this mean that the answer is no, not at all. This observational study does raise some interesting questions but this report and none to date so far proves cause and effect. This also was not a prospective study and the control group was not routinely screened for the disease. Even if they were, without performing biopsies to prove that cancer was absent, these data have uncertain validity. Because the findings were consistent with other uncontrolled reports, there would appear to be enough evidence to justify performing a proper study. Until that time, we cannot justify telling patients to have their IGF-1 level measured to tell them if they are at increased risk for this disease.

CRYOSURGERY
(Continued from page 1)

- Nadir temperature: —40 degrees Celsius is the lowest temperature at which active cells can survive;
- Thaw rate: cancer is proven to be improved with slow thawing; and
- Freeze cycles: the panel recommended a double-freeze thaw cycle.

Though the panel supports the use of primary cryosurgery in certain cases, they wrote that patients at high risk may require multimodal therapy. The use of cryosurgery in clinical T3 disease is undetermined because of limited data on patient outcomes.

The statement includes, when selecting patients eligible for cryosurgery, gland volume, lymph node dissection and comorbidities should be considered. Due to the protection of the urethra during cryosurgery, the panel recognized the unlikelihood of achieving a completely undetectable PSA level following surgery. The panel also recommended follow-up biopsies.

The panel found documentation of long-term complications that included fistula formation, incontinence, erectile dysfunction and urethral sloughing. The panel labeled the use of subtotal prostate cryosurgery as undetermined. They recommended further data be collected for future analysis.
**Celebrating Prostate Cancer Awareness Events**

**Pints for Prostates**

Us TOO and *Pints for Prostates* booth at the World Beer Festival in Durham, NC on October 4, 2008. L to R: Rick Lyke, Pints creator, Tom Kirk, Us TOO President & CEO, and volunteers Susan Bavisotto, daughter of Joan and Phil Harris, from the Us TOO Prostate Cancer Support Group of Wake County.

(Left) Chris Ferrell won the Dogfish Head pub sign raffle prize at the World Beer Festival in Durham as part of the Pints for Prostates campaign.

Pints for Prostates was at the Texas beer festivals Flying Saucer hosted in Austin on Oct. 4th and Fort Worth on Oct. 11th. Mike Jones (far right) and friends pictured above manned the Us TOO table.

**Sneakers@Work Day—Friday, September 19, 2008**

(Left) U.S. Trust Bank of America Private Wealth Management participated in Sneakers@Work Day in honor of Pat’s husband, Tim Crouse, who has been has been battling metastatic prostate cancer since 2003.

(Right) Fran’s Boys sporting sneakers AND shorts for the event!
OLD C An CA PATIENTS
(Continued from page 2)
slow-growing cancer, some men may never need treatment. And for many older men without symptoms, watchful waiting has been recommended, because it was believed they would die from other causes before their cancer advanced. But as men’s life expectancy creeps higher and new robotic techniques improve the precision of surgery, the decision is becoming more complicated.

“Patients should understand the risks and benefits of all treatment options – radiation, surgery and observation,” Wong noted. “If they choose observation, they should be committed to careful follow-up with their physicians.”

Oncologists may have better information regarding the benefits and risks of active surveillance compared with treatment, by late next year. The National Cancer Institute and the Department of Veterans Affairs are co-sponsoring a study, called the Prostate Cancer Intervention Versus Observation Trial, to compare surgery and expectant management on patient survival and overall quality of life.

HealthDay News, 17 October 2008

NEW RISK FACTOR FOR PROSTATE CANCER

The greater the levels of a protein called Insulin-like Growth Factor-1 (IGF-1), the greater the risk of prostate cancer, an Oxford University-led study has found.

An international team of researchers funded by Cancer Research UK, analyzed data from 12 previous independent studies on the relationship between blood concentrations of suspected prostate cancer risk factors, and subsequent onset of the disease. Previously, some but not all studies had suggested a link between IGF-1 levels and increased risk of developing the disease. IGF-1 levels are affected by lifestyle factors such as diet, so the study could help tailor the advice given to men at high risk of developing prostate cancer.

“There is a need to identify risk factors for prostate cancer, especially those which can be targeted by therapy and/or lifestyle changes,” says lead author Dr. Andrew Roddam of the University of Oxford. “Now we know this factor is associated with the disease we can start to examine how diet and lifestyle factors can affect its levels and whether changes could reduce a man’s risk.”

More than 34,000 men in the UK are diagnosed with prostate cancer each year and around 10,000 die from it. The disease is the second most common cause of cancer death in UK men after lung cancer.

The scientists looked at the data collected from blood samples of 3,700 men with prostate cancer and 5,200 men without the disease. The research found that men with higher levels of IGF-1 were more likely to go on to develop prostate cancer than those with lower levels of the protein. Results were published in the October 2008 issue of the Annals of Internal Medicine (Vol. 149, pp. 461-71, 2008).

“While there are established risk factors associated with prostate cancer of age, family and ethnicity, there are no clear data on modifiable risk factors,” says Dr. Lesley Walker, Cancer Research UK’s director of cancer information.

“It is important to point out that there is no evidence to suggest that measurement of IGF-1 levels could be used to develop new prostate screening methods,” adds Dr. Roddam. “Other studies have shown that existing methods of detecting prostate cancer are not improved by also measuring IGF levels.”

ScienceDaily, 14 October 2008

US TOO INTERNATIONAL
OUR MISSION
Communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.

US TOO INTERNATIONAL
Tax Deductible Donation
Name: ____________________________ Company: ____________________________
Address: ____________________________________________________________________
City: _____________________________ State: ______ ZIP: _______________
Phone: (       ) ____________ Fax: (       ) _____________ e-mail: _________________________
Please accept my enclosed tax-deductible donation to Us TOO a not-for-profit 501(c)(3) organization.
Amount: ____ $25   ____ $50   ____ $75   ____ $100   Other: $ _______ Check # ____________
VISA/MasterCard # ____________________________ Expiration Date: _____ / _____
Signature ________________________________________________________________________

US TOO INTERNATIONAL, Inc., 5003 Fairview Ave., Downers Grove, IL 60515