Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

AUGUST 2010

MEDICARE TO REVIEW PROVENGE® COVERAGE

Medicare administrators say they will take a full year to review Dendreon Corporation's prostate cancer therapy Provenge and decide whether to cover the costly treatment.

Provenge, which costs $93,000 for a course of treatment, has been widely expected to bring Dendreon billions in revenue in the coming years. But sales will be slashed if Medicare decides not to cover the cost or offers only limited coverage. Medicare's Coverage and Analysis Group will propose a decision in about nine months and make a final ruling about a year from now. That decision will apply to all Medicare contractors.

The Food and Drug Administration approved Provenge in late April for patients who have prostate cancer that has spread and that has not responded to hormone-based treatment. Some Medicare insurance contractors already are paying for the therapy, but there is no national policy. Contractors can continue to cover Provenge during the agency's review, but must adhere to any final decision.

Medicare is evaluating whether or not it is reasonable and necessary to cover Provenge. Company studies have shown that taking Provenge added four months to the lives of men with advanced prostate cancer, about a month-and-a-half longer than that afforded by Sanofi-

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PROSTATE CANCER PATIENTS FACE YEARLONG RATIONING OF PROVENGE

Prostate cancer patients seeking Dendreon Corp.'s new tumor-fighting vaccine, Provenge, face delays of a year or more as hospital waiting lists dwarf the company's capacity to produce medicine.

Dendreon can only make enough Provenge to treat about 2 percent of eligible patients until manufacturing increases in mid-2011, said Chief Operating Officer Hans Bishop. The University of Texas MD Anderson Cancer Center and Duke University's Comprehensive Cancer Center are among 50 hospitals scrambling to decide who should get the drug.

Typically, cancer drugs are first approved for a narrow group of difficult-to-treat patients, and by the time they're widely released, there is sufficient supply. The last time a new cancer treatment faced similar shortages was in 1992, with Bristol-Myers Squibb Co.'s Taxol®.

"Until the capacity issues can be addressed, this will not be an effective agent," said Chris Logothetis, head of prostate cancer research at MD Anderson in Houston, in a telephone interview. "The waiting list – even as we are telling patients we're not starting a waiting list because we are inundated – is more than 50 patients. This is going to be a problem."

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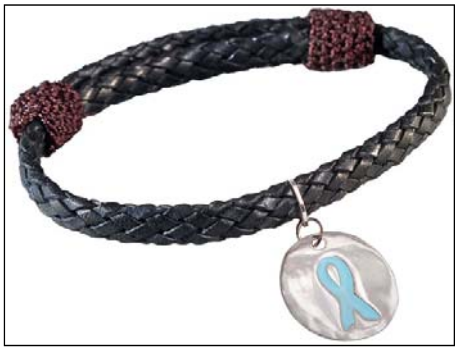
CATCHING UP WITH THE PINK: LEATHER WRISTBANDS HELP RAISE AWARENESS, PROSTATE CANCER FUNDS



Us TOO International Prostate Cancer Education and Support Network, the oldest and largest non-profit peer support organization dedicated to assisting men and their families battle a prostate cancer diagnosis, is proud to support the prostate cancer public awareness and fundraising "Conquer Prostate Cancer" wristband campaign created by fashion designer and cancer survivor Joseph Bruno.

The wristband is fashioned from genuine black leather braided so it can be adjusted to fit any size wrist and detailed with a non-tarnish silver-finish medallion marked with the blue ribbon symbolizing the fight against prostate cancer. All net proceeds of the $25 wristband are donated exclusively to Us

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PSA TEST DOES CUT PROSTATE CANCER DEATHS

Adding to the ongoing debate on the usefulness of the PSA blood test for prostate cancer, new research from Sweden finds that screening cuts lives lost to the disease by almost half. The argument over whether PSA screening saves men's lives or merely leads to overdiagnosis of very slow-growing cancers (with attendant worry and overtreatment) has bedeviled the medical world for years.

According to recently revised guidelines from the American Cancer Society, men at average risk for prostate cancer should discuss the PSA test with their doctor, starting at age 50. For men at high risk for disease – blacks and men who have a father, brother or son found to have prostate cancer at an early age (before 65) – that discussion should start at age 45. "Because prostate cancer grows slowly, those men without symptoms of prostate cancer who do not have a 10-year life expectancy should not be offered testing since they are not likely to benefit," the society notes on its Web site.

Ambivalence over the test hasn't been confined to the US. "In Europe, we have been reluctant to recommend that all men get PSA testing as we have felt that there has been a lack of knowledge," agreed lead researcher Dr. Jonas Hugosson, a professor of urology at the University of Goteborg. However, he believes that with the results of the new 14-year study, "it feels ethically difficult not at least to inform all men over the age of 50 about PSA and its possibilities. Personally, I would recommend my friends check their PSA," Hugosson added.

The report is published in the June 30 online edition of *The Lancet Oncology*.

For the still-ongoing study, Hugosson randomly assigned some 20,000 men to either PSA screening once every two years or no screening. The men were between 50 and 65 at the start of the study. Men whose PSA levels were above normal were offered more tests, such as a digital rectal exam and prostate biopsies. Over 14 years of follow-up, deaths from prostate cancer dropped by 44 percent among the screened men, compared with unscreened men, the researchers found. Overall, 44 of the men who had PSA testing died from prostate cancer, compared to 78 men who had not been screened.

Among screened men, 11.4 percent were diagnosed with prostate cancer, compared with 7.2 percent of unscreened men. Of the men in the screened group diagnosed with prostate cancer, nearly 79 percent were diagnosed because they took part in the study, the researchers noted. In addition, men in the screened group were more likely to have their cancer diagnosed while it was in an early stage. In the screened group, 46 men were diagnosed with advanced cancer, compared with 87 men in the unscreened group, Hugosson's team found.

"Our study has a longer follow-up than previous studies, but shows that in those men invited [to the study], the risk of dying is only half of that in the control group. In men younger than 60 at study entry, the effect was even more pronounced – only one-quarter of expected deaths occurred," Hugosson said. Moreover, the risk of over-diagnosis was less than previously thought, with just 12 men needed to be diagnosed to save one life. However, since PSA screening benefit require at least 10 years to be borne out, it still seems questionable to test PSA for men over 70, the researchers noted.

Dr. David E. Neal, a professor of surgical oncology at the University of Cambridge in the UK and author of an accompanying editorial, believes that, "PSA testing detects prostate cancer early in its natural history when it causes no symptoms. By doing so, it can save the lives of some men who would otherwise have died of the disease." Still, the PSA test remains "a blunt instrument," when it comes to determining the aggressiveness of a particular tumor, Neal said. "We need better tests that identify more accurately those men destined to develop problems in the future from this disease," he said.

According to Dr. Nelson Neal Stone, a professor of urology and radiation oncology at the Mount Sinai School of Medicine in New York, screening detects a lot of early cancers, which do not need to be treated. "Younger men benefit most from screening, because they have the greatest risk of dying," Stone said. "This study clearly supports PSA screening to prevent prostate cancer deaths."

Health Day News, 30 June 2010

LEATHER WRISTBANDS HELP RAISE AWARENESS, FUNDS

(Continued from page 1)

TOO International. To learn more, visit <www.prostatecancerwristband.com> or call 1-800-808-7866.

"For the most part, men don't want to think about prostate cancer, talk about it or go to a doctor. This 'head in the sand' mentality is certainly not macho and may be deadly," says Bruno. Hopefully, this wristband will help jumpstart a conversation for those guys who haven't been as mindful about their health as they should be," according to Bruno who designed the wristband to be worn by women as well as men.

Women are generally more proactive about heath issues. I envision the band being worn by family and friends whose lives are touched by survivors or in memory of those who didn't. So we wanted to include them in this awareness campaign," adds Bruno. "Most everyone's life has been touched by someone with prostate cancer. They can help create awareness and support a worthy organization by wearing the wristband for their husband, dad, brother, grandfather, uncle, partner, or friend who have the disease."

According to Thomas N. Kirk, Us TOO president and CEO, "Grassroots awareness and peer-to-peer support and education are major efforts of our organization. We're committed to educating and empowering men to take better care of their health.

Our non-profit organization was founded 20 years ago by five men who experienced a need for helpful information and support so they could make informed decisions about how to address their prostate cancer," says Kirk.

Leading Life-Threatening Disease for Men

Although prostate cancer is projected to kill more than 32,000 men in the United States this year, it is not always recognized as a serious health issue. According to estimates based on new National Cancer Institute data, more than 217,000 new prostate cancer cases will be diagnosed this year – exceeding the number of new breast cancer cases predicted.

The new NCI numbers represent a 17 percent jump in deaths and a more than 13 percent rise in diagnosed cases this year as compared to 2009, which marks the greatest percentage increase since the mid-1990s.

Despite these unsettling statistics, if detected early, prostate cancer is often treatable. But because the disease is generally asymptomatic until late in its course, too many men remain unaware of the risk and unaware of the resources Us TOO provides to those diagnosed,

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CABAZITAXEL NEW CHEMO APPROVED FOR ADVANCED PROSTATE CANCER

Cabazitaxel (Jevtana®, Sanofi-Aventis) has been approved in the US for second-line use in advanced hormone-refractory prostate cancer in men who have already been treated with docetaxel.

Cabazitaxel is the first chemotherapy to have shown a survival benefit in this setting since docetaxel. It was described as "clearly a major advance in secondary chemotherapy for advanced prostate cancer" by Nicholas J. Vogelzang, MD, from US Oncology in Woodlands, Texas, at the recent American Society of Clinical Oncology 2010 Annual Meeting, as reported by Medscape Oncology.

The drug was approved ahead of schedule by the FDA after reviewed under the agency's priority review program, an expedited 6-month review for drugs that offer an advance in treatment or provide a treatment where none exists. Under this program, a decision was expected before 30 September 2010; in fact, it was made in 11 weeks.

"Patients have few therapeutic options in this disease setting," said Richard Pazdur, MD, director of the Office of Oncology Drug Products at the FDA.

"This is truly a significant announcement for the prostate cancer community, addressing an unmet medical need," noted lead investigator Oliver Sartor, MD, Plitz Professor of Cancer Research at Tulane Medical School in New Orleans, Louisiana, in a statement. Dr Sartor was the lead investigator in the drug's pivotal trial, known as TROPIC.

Survival Benefit in TROPIC Trial

The approval was based on data from the single company-sponsored phase 3 TROPIC clinical trial, conducted in 755 patients. All patients had advanced hormone-refractory prostate cancer and all had previously been treated with docetaxel. They were randomized to receive either cabazitaxel or mitoxantrone, both in combination with prednisone.

The median overall survival was 15.1 months with cabazitaxel and 12.7 months with mitoxantrone (hazard ratio, 0.72; 95% confidence interval, 0.61 - 0.84; P < .0001).

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

"Why I would NOT get excited about vitamin D supplements in large doses! And, for all you "vitamin D cures all research ignoring advocates" please refrain from throwing lycopene filled tomatoes at my head!"

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

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. This piece contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Bottom Line: There is now a new randomized trial to demonstrate that when you take large and ridiculous doses of vitamin D supplements they can potentially increase your risk of falls and bone fractures.

Do you have any idea how many letters I get from vitamin D advocates that basically say that I am an idiot! Of course I know I am an idiot (tell me something my friends don't tell me), but my track record in the area of diet and dietary supplement predictions either makes me a lucky idiot or a smart idiot!

Regardless, after decades of working in the supplement business full-time you need to be aware of the "jump on the bandwagon" pattern of behavior I have witnessed! "Shark cartilage cures cancer!" actually did nothing. "Beta-carotene supplements cure cancer!" They actually increased the risk of cancer in smokers. "Selenium and vitamin E cure cancer!" Actually, high-doses of vitamin E increased the risk of internal bleeding and probably increases your risk of prostate cancer, and selenium did nothing but probably increases the risk of type 2 diabetes and skin cancer recurrence! "Exotic juice antioxidant drinks from all parts of the world cure cancer?!" Actually some of these expensive juices have so many calories I am convinced they increase the obesity rate, ultimately increasing your risk of ____ (fill in the blank – I may get in trouble if I say any of these words).

This brings me to vitamin D! "Vitamin D cures cancer!" Well, do you know when one of the most potent forms of vitamin D (prescription high-dose calcitriol) was combined recently in a phase 3 trial with Taxotere® chemotherapy it actually reduced survival! Now, it could be that vitamin D has a benefit against cancer (we know it helps the bones and muscles in moderation), but we need to be careful and learn from history, and the freakin' (is that a word?) research that has already been done. Several studies have suggested that high blood levels of vitamin D may increase the aggressiveness of prostate cancer. And, now a recently published, well-designed randomized trial found that very high blood levels of vitamin D in older women was associated with an increased risk of falls and fractures compared to placebo, but especially in the 3 months after supplementation when blood levels were way beyond 40 ng/mL (100 nmol/L).

This is why I continue to urge you not to take more than ~1,000 IU of vitamin D3 per day unless your blood test tells you that your number is very low (below 20 ng/mL). And, if your blood test is 50 or 60 or even 70 ng/mL it is really time to cut back until we get more research. Better to be safe than really, really sorry!

Have a nice summer folks and do not forget your SPF of 100, and broad spectrum sunscreen next time you go out and face one of our biggest known carcinogen – oops I am sorry I meant to say "sun" or "ultraviolet A and B radiation." Man, am I a party pooper (that is definitely a real word) or what?!

Reference:

Sanders KM, Stuart AL, Williamson EJ, et al. *JAMA* 303: 1815-22, 2010.

PROVENGE COVERAGE

(Continued from page 1)

Aventis SA's Taxotere®, the only chemotherapy approved for men in this situation. Doctors hope for even greater benefit if they give the drug earlier in the course of the disease.

The Coverage and Analysis Group is a team of medical officers, managers and analysts. A technical panel and a coverage advisory committee also will take part in the review. The group will be considering whether it makes sense to cover a costly drug that has a relatively narrow approval. But if it decides to cover Provenge treatment for patients with less advanced cancer, that could help sales.

Medicare will also deal with a deceptively simple question: what is Provenge? Is it a traditional drug, a biologic drug, or something else? The answer could affect the amount that Medicare will cover because different types of drugs are covered at different rates.

Provenge is designed to train a patient's immune system to attack tumors. It is different from traditional drugs and even biotech drugs because it is made by mixing blood cells from the individual patient with a protein found on cancer cells and an immune system-boosting substance.

Side effects of Provenge are relatively mild, such as chills, fatigue, fever, and headache. By comparison, side effects of chemotherapy typically include hair loss, nausea, anemia and diarrhea.

About 192,000 new cases of prostate cancer were diagnosed in 2009, and 27,000 men died of the disease, according to the FDA. Prostate cancer most often affects older men.

June 30th marked the beginning of a 30-day public comment period on coverage. After the comment period ends, the agency will take about nine months to create a proposal. The public will then have 30 days to comment on the proposal, and Medicare will publish a final decision within 60 days of the end of that comment period. The decision goes into effect as soon as it is published.

To comment, go to <www.cms.gov/mcd/m_nca.asp?id=247>.

Associated Press, 2 July 2010

ASK DOCTOR SNUFFY MYERS

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Of the supplements that you recommend for your patients, is there one that you believe is the most critical?

This is a great question. My first choice would be to have you measure your vitamin D blood level and take enough vitamin D to reverse any deficiency. When the interest in vitamin D started to increase, I went ahead and began measuring serum vitamin D in 91 sequential new patients. Just under one half of these men were deficient enough to start losing bone. Many were actually profoundly deficient.

My first reason for choosing vitamin D is that deficiency is common and ideal blood levels are well defined. For this reason, adding vitamin D is safe and overdosing easy to avoid. The second issue is that the literature linking vitamin D to the development and progression of prostate cancer. Men with vitamin D deficiency are more likely to develop prostate cancer. After surgery or radiation therapy, the rate of PSA increase slows when vitamin D deficiency is corrected. Even in men dying of prostate cancer, bone pain appears to be lessened if vitamin D deficiency is reversed.

The third issue is that vitamin D appears to improve many aspects of health. Its role in bone health is well established and bone loss is a serious problem in men with prostate cancer. This is so even before hormonal therapy starts. A recent randomized controlled trial in postmenopausal women showed vitamin D supplementation caused a large drop in cancer risk over a five-year period. Breast and colon cancers were among those affected. Vitamin D deficiency has also been associated with an increased risk of heart disease, diabetes and hypertension.

Vitamin D may also play an important role in immunity. Before the era of modern drug therapy, treatment of tuberculosis involved special emphasis on sun exposure. We now know proteins the body uses to kill bacteria, the defensins and cathelicidin, are stimulated by vitamin D. Cathelicidin may well explain why sun exposure was part of the traditional treatment for tuberculosis before modern drugs became available.

So, vitamin D is my first choice because deficiency is common, safe and effective blood levels are well defined, it plays a major role in prostate cancer biology and it appears to have other important health benefits.

SEEKING PATIENTS FOR NEW STUDY TO IMPROVE PREDICTION OF PROSTATE BIOPSY RESULTS

Dr. Catalona is conducting a new study to improve the accuracy of PSA testing in predicting prostate biopsy results.

Men who, at any time in the past, have had a negative prostate biopsy and men of African-American and Hispanic background who have had either a negative or positive biopsy are invited to participate in this study.

Participation involves a simple, single test that can be done at no cost in the comfort of your home.

The new study is seeking to improve the accuracy of PSA testing in predicting prostate biopsy results by combining PSA testing with a DNA test that checks for certain variations in DNA that are associated with prostate cancer.

Doctors may then be able to combine the DNA test with traditional PSA testing to better predict whether a biopsy is prudent or not. Participation involves signing a consent form, a short phone call, swabbing the inside of the cheek with a device similar to a tongue depressor, filling out a questionnaire, and mailing back the materials (pre-paid).

Men interested in finding out more about participating in the study can contact a research coordinator at:
(312) 695-4426, (312) 695-1406, or
(312) 695-4511.

This study is being conducted through the Department of Urology of Northwestern University in Chicago (Study Number: STU00027808).

PROVENGE SHORTAGE

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It takes about a month to prepare each custom-made course of doses, Dendreon's Bishop said. The company plans to make enough to accommodate 2,000 patients in the first year, falling short of the 100,000 patients with advanced tumors who may be eligible to receive it.

The shortages stem from Dendreon's uncertainty about whether the U.S. Food and Drug Administration would approve the drug. The agency had previously denied approval, asking for more testing. Dendreon couldn't develop manufacturing facilities and seek clearance of the plants until the regulators reached a decision, Bishop said in a telephone interview. Dendreon is producing the initial doses in a single New Jersey plant. The facility will reach full capacity in early 2011, quadrupling the available vaccine, Bishop said. By the end of next year, the plant will be joined by facilities in Atlanta and Los Angeles.

Beginning in the next six to eight weeks, MD Anderson will be allotted enough Provenge to treat two new patients a month, each of whom will receive three doses, Logothetis said. Duke's cancer center in Durham, NC, looked to the example of organ transplants to come up with its plan for dealing with the Provenge shortage, said Jeffrey Peppercorn, an ethics expert and breast cancer specialist who helped craft Duke's guidelines. It convened a group of medical specialists to outline criteria for choosing who will receive the drug, he said.

"We know more about this product than anyone," Bishop said. "We realized that much of the challenge was in an area that we had strong expertise. If you think about the commercial infrastructure that a product like Provenge requires, it's actually very manageable for a company our size."

Health insurers Aetna Inc. and Humana Inc. have said they will cover Provenge, and other plans are expected to follow, according to Dendreon. Patients may need to seek outside assistance to cover the 20 percent co-pay some plans charge.

For questions, contact a Dendreon ON Call specialist at (877) 336-3736 or visit <www.provenge.com/>.

Bloomberg News, 28 Jun 2010

STATINS REDUCE PSA SPIKES AFTER SURGERY

Among men who underwent radical prostatectomy (RP), biochemical recurrence (BCR) – a spike in PSA over a critical threshold – was less likely in men on statin therapy, a retrospective study showed. The relative risk of BCR was 30% lower in statin users after adjusting for several clinical and pathological factors (HR 0.70, 95% CI 0.50 to 0.97), Stephen Freedland, MD, MPH, of Duke University Medical Center in Durham, NC, and colleagues reported online in the journal *Cancer*.

"Our findings require confirmation in other settings and in particular to determine whether statins are associated with a reduction in metastases and/or prostate cancer-specific and overall mortality," Freedland and his colleagues wrote. But, "if confirmed in other studies, a randomized controlled trial of statins among men undergoing RP may be warranted," they wrote, noting that 35% of men will have BCR within a decade of having their prostate removed.

Laboratory studies have shown that statins may combat cancer through several cholesterol-mediated and non-cholesterol-mediated mechanisms, including the inhibition of inflammation, angiogenesis, cell proliferation, migration, adhesion and invasion, as well as the promotion of apoptosis selective for tumor cells, according to the researchers. Studies exploring whether statins lower risk of prostate cancer, however, have yielded conflicting results.

Freedland and colleagues evaluated the relationship between statin use and BCR – defined as a single PSA value higher than 0.2 ng/mL, two concentrations at that threshold, or secondary treatment for detectable postoperative PSA. Using the Shared Equal Access Regional Cancer Hospital database, they retrospectively analyzed data from 1,319 men treated from 1988 to 2008 at four VA Medical Centers and received a RP.

Overall, 18% of the men were taking statins at the time of surgery; these men were older and had higher body mass index (BMIs) and Gleason scores compared with non-users. BCR occurred in nearly a quarter (23%) of the men overall

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US TOO SEEKS APPLICATIONS FOR BOARD OF DIRECTORS

Us TOO is seeking nominations to the Us TOO International Board of Directors. In addition to the two seats that will become vacant beginning January 1, 2011, there are also seats currently available now.

The Board Membership Committee, chaired by Carl Frankel, Esq., 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 International Board of Directors is made up of 15 seats, one third of which are up for re-election annually. Two Board members who will be ending their terms of service this December 2010 are Greg Bielawski and Carl Frankel, Esq.

Retiring Board Secretary Carl Frankel exclaims, "What a wonderful experience and opportunity it has been to serve on the Board of Us TOO, International! For Directors, the "dividend" is the knowledge that we have contributed meaningfully and in our own individual way to the goal of providing support, education and a voice to prostate cancer patients and their families. It is how we fight back against the disease that has invaded all our lives."

Frankel continues, "The last few years have been especially challenging, but Us TOO has responded well, and we look forward to our 20th anniversary celebration in just a few months. As for the future, I see opportunities to provide new and improved services to what promises to be a growing patient base and, importantly, to secure the necessary resources to fund those services.

Though I enjoyed and profited emotionally from my two terms on the Board, I do envy the successor Directors who will share in this upcoming adventure" added Frankel.

Greg Bielawski will also end his term of service this December. He has served as Board Treasurer, and Co-Chair of the Annual SEA Blue Prostate Cancer Walk & Run event in Chicago, IL.

Greg comments: "Us TOO International is celebrating its 20th birthday this year. Over the last 7 years as a board member, I am proud to have been part of the maturing and growth of Us TOO from primarily a prostate cancer education and support organization into that of a leader in the prostate cancer advocacy world whose perspective is sought out and respected. If you wish to see Us TOO become even more influential in the next decade, and have the passion and desire to help that happen, please consider applying to join the Board of Directors."

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 e-mail <tom@ustoo.org>.

NUCLEAR REGULATORY COMMISSION (NRC) HOLDS MEETING ON A PROPOSED RULE ON MEDICAL EVENTS DEFINITIONS FOR PERMANENT IMPLANT BRACHYTHERAPY

On 8 July 2010, Us TOO International was invited to attend a Nuclear Regulatory Commission (NRC) public meeting for discussion of possible revisions to regulations regarding the reporting by physicians of events during brachytherapy (radioactive seed treatment) for prostate cancer. Us TOO Board member David Houchens, PhD attended the event in Washington DC.

The draft regulations would require doctors to report any changes that were 20% higher or lower in regards to the number of seeds or radioactive dose and the placement of those seeds. Discussion was presented by several physicians who said that this would place a burden on them since the majority of doctors evaluate the patient very carefully during the surgical procedure and if additional tumor is found or extracapsular extension or involvement of the seminal vesicles is determined then changes are made in the treatment plan. These changes frequently are beyond 20% of the original plan.

Us TOO stated that it is important for experienced doctors to use their clinical judgment to best treat the patient. The NRC commissioners will review and evaluate the input from the meeting prior to final approval or disapproval of the document.

THE PROSTATE NET REGIONAL SYMPOSIUM SERIES 2010 DATES / SITES

28 August	Jacksonville, FL
11 September	Chicago, IL
2 October	New York, NY

Register and see agendas at <http://prostatenet.com/Symposium.html>.

DOCTOR CHODAK'S BOTTOM LINE

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.* Our desire is to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Is the cup half empty or half full? That may be one question that follows the success of the latest randomized screening study from Sweden. It showed that at the end of 14 years, the death rate from prostate cancer occurred in 9 out of every 1000 men who were not screened compared to only 5 of 1000 men who had a PSA every two years. Although this is a 44% drop in cancer deaths, it only helped 4 men out of every 1000 who were tested. The reasons the glass is only half full are that 12 men had to be treated to prevent each cancer death, and even more importantly, the overall survival was exactly the same in both groups at the end of 14 years. In other words, screening did prevent cancer deaths but it did not help men live longer. This last point was omitted from the article in the *HotSheet* but it is very important because it means the overall benefit is less certain.

The Bottom Line

PSA screening every two years helps a small proportion of the population avoid dying from prostate cancer. But as has been said before, it results in considerable over treatment and it does not appear to prolong overall survival, at least in the first 14 years. Each man should make a personal decision whether the benefit is worth the risk.

A major ethical problem exists for patients with progressive metastatic prostate cancer who are suitable candidates for Provenge, the new immunotherapy recently approved by the FDA. For now, the treatment will be only available to a small percentage of these men due to production limitations. This will cause considerable frustration among patients and difficulty for doctors who must decide who to treat. In addition, Medicare has decided to conduct a one-year review to determine if it should be covered. A negative decision would cause significant angst among patients because it would be difficult to personally cover the expense.

The Bottom Line

Until the supply problem is resolved, physicians will need to develop some type of guideline for selecting patients to receive Provenge. General health and life expectancy are two considerations that could be used, but often they are not so easy to determine. We can only hope this problem will be short-lived. This issue of the *HotSheet* has another article suggesting the men who take a statin drug for their cholesterol have a reduced risk of getting recurrent prostate cancer. This and every other similar study has been uncontrolled, which means none of them prove whether the drug is truly beneficial. The FDA does not recognize PSA as a valid outcome for prostate cancer studies and there could be other reasons why the PSA was affected besides taking the statin. Only a prospective, randomized trial can determine the real effect and there may not be sufficient financial incentives for a drug company to sponsor it.

The Bottom Line

Since many uncontrolled studies suggest that a statin may be helpful in prostate cancer, we can only hope that the government considers funding a study to find out if these drugs are beneficial.

SNEAKERS@WORK DAY

Friday, 17 September 2010

Honor your colleagues who are battling or have survived prostate cancer. Raise awareness where you work. Learn more and register at <www.ustoo.org/sneakers@work>.

WRISTBANDS

(Continued from page 3)

according to Kirk.

This year, Us TOO celebrates 20 years of providing patient education and peer-to-peer support services for prostate cancer patients and their families around the world, yet we still often hear "I wish I had known about your organization six months ago when my husband was diagnosed." Kirk stated.

"We don't want to be a best-kept secret," Kirk added. From the time we were founded to today, the Us TOO name reflects our realization that breast cancer organizations are ahead of us in awareness, services and fundraising efforts, and are especially successful in their pink ribbon marketing and messaging campaigns. The men who we serve say: don't forget about the needs of prostate cancer patients; don't forget about us, too!"

"With Joseph's Conquer Prostate Cancer wristband and outreach campaign to kick off Prostate Cancer Awareness Month this September, Us TOO encourages efforts to raise awareness and increase support for men afflicted with the disease," Kirk said, "and to just let people know we are here if they need us."

CABAZITAXEL APPROVED

(Continued from page 3)

The manufacturer, Sanofi-Aventis, noted in a press release that the most common adverse reactions (grades 1 to 4), seen in 10% or more of patients, were neutropenia, anemia, leucopenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysguesia, cough, arthralgia, and alopecia.

The most common adverse events leading to discontinuation of the drug were neutropenia and renal failure. In the cabazitaxel group, 18% of patients discontinued because of adverse events, as opposed to 8% of whom discontinued from the mitoxantrone group.

Concern about the toxicity of the drug was raised recently by Ian Tannock, MD, PhD, from the University of Toronto in Ontario. In a recent interview with Medscape Oncology, he said that "by far the most worrying toxicity is residual neuropathy," although he noted that many patients will have experienced fatigue and neuropathy while on docetaxel.

Medscape Medical News, 18 June 2010

STATINS REDUCE PSA

(Continued from page 6)

– 16% of statin users and 25% of non-users. After adjustment for several clinical and pathological factors, statin use was associated with a reduced BCR risk.

The association was only significant for men taking a dose equivalent to simvastatin (Zocor®) 20 mg (HR 0.57, P=0.05) and higher. The relationship was not modified by duration of statin use before surgery, preoperative risk, race, age, or whether cancer was organ-confined at RP, but it was significantly modified by BMI (P=0.001). "This finding may be spurious, as only 22 men in [the higher] BMI category used statins," the researchers cautioned.

They said the study was limited by unmeasured factors such as diet, physical activity, and smoking, lack of statistical power regarding mortality and by the lack of information on whether non-users starting taking statins after RP.

Reference:

Hamilton R, *Cancer* 116: 3389-98, 2010

MedPage Today, 28 June 2010

US TOO INTERNATIONAL: OUR MISSION

Be the leading prostate cancer organization helping men and their families make informed decisions about prostate cancer detection and treatment through support, education and advocacy.

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