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PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

March 2006

FROM THE DOCTOR: PHYSICIAN COMMENTARY ON SELECTED ARTICLES IN THIS MONTH'S *HOTSHEET*

By Gerald W. Chodak, MD

From the editorial team: Beginning with this issue of the Us TOO Hot-Sheet, we will provide readers with a physician's perspective on information and news releases published each month. Our goal is to provide patients and their families with a different, critical look at the latest information appearing about this disease, helping the reader understand the strengths and limitations of the information provided. Let us know if you like seeing this perspective.

This first commentary is provided by Dr. Gerald Chodak, MD. Dr. Chodak helped organize the first chapter of Us TOO in 1990, and continues to serve as a medical advisor to Us TOO International. He has published over 130 scientific articles on Prostate Disease and Prostate Cancer and has delivered more than 500 invited lectures in 18 countries. Dr. Chodak was a faculty member of the University of Chicago from 1981-99 when he formed the Midwest Prostate and Urology Health Center in Chicago. His current practice is limited to men with Prostate Cancer and Prostate Disease.

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MEDICARE COMPETITIVE ACQUISITION PROGRAM (CAP) UPDATE

Since physician enrollment for Medicare's Competitive Acquisition Program (CAP) begins April 3rd, this may be a good time to talk with your doctor to find out if he plans to participate and how it might affect access to your prescribed medications.

See below for an updated list of frequently asked questions about the program, plus some Patient Discussion Points to get the dialogue started with your physician.

CAP FAQs

1. What is the Competitive Acquisition Program?
This program will allow physicians to obtain Medicare Part B drugs, like LHRH agonists for prostate cancer, from vendors who will bill Medicare and collect coinsurance from you.
2. When does the program start?
Doctors can begin to enroll April 3, 2006. The program becomes operative July 1, 2006.
3. Is this program mandatory or optional?

This program is optional. Doctors can choose to enroll in CAP or may continue to obtain their drugs directly from manufacturers as they do now.

4. Why would my doctor enroll in this program?

CAP provides an alternative for doctors who do not wish to be in the business of drug acquisition.

5. If my doctor enrolls in CAP, who would collect my Medicare co-payment?

The vendor will bill and collect co-payments for the drug from you. You may also receive a bill from your physician for co-payments related to other Medicare services.

6. Who are these vendors?

These will be large wholesale drug distributors.

7. What happens if I do not pay my co-payment in a timely manner?

Vendors are given the author-

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FROM THE PHYSICIAN

(Continued from page 1)

Not a day seems to go by without some new report about the "benefits" of alternative and unconventional therapies. The American public increasingly is using these remedies. A recent study cited in this issue found that about one-third of men with prostate cancer use some form of alternative therapy. Often it seems that doctors are reluctant to recommend or even encourage the use of these unusual treatments. There are good reasons for that approach. Very few agents have been studied scientifically and without proper studies no valid conclusions can be made either about their true effectiveness or their side effects.

In this issue, the latest data on Omega-3 fatty acids found that there is no evidence it reduces the risk of prostate cancer. The third most popular herb used in the United States is Saw Palmetto. Primarily men with prostate symptoms and sometimes those with prostate cancer take it. However, in February, The New England Journal of Medicine published a well-controlled study that found it was no better than placebo in improving men's urinary symptoms. Why can't we simply give an unconventional agent to a group of men and see how they do? The problem is that in most clinical studies in which a placebo, or inactive drug is used approximately 20% of patients taking the inactive drug do get better. The "placebo effect" is real and it is the reason that doctors want to see the results of good clinical studies performed before encouraging their patients to embrace the latest new herb, supplement or even conventional drug therapy.

Although many men who take unconventional treatments recognize that a clear benefit may well be lacking, they also believe that there is little risk or danger. But that also may not be true. In fact, physicians are learning that some unconventional therapies can interact with prescription medications making them less effective or causing an increase in the side effects of FDA approved medications. Prostate cancer patients who took PC-SPEs may remember that it caused potentially life-threatening blood clots. Vitamin E, which is taken by many prostate cancer patients, increases the risk of serious bleeding and can cause death. If you choose to incorporate one or more over-the-counter untested products in your treatment plan make sure to inform your physician so that possible interactions can be assessed.

Increasingly, good clinical trials are being performed to determine if some of these agents can benefit patients. What about the GTP-0805, which is suggested, may improve the beneficial effects of lycopene? At this time, it is too early to tell. Unfortunately, what happens to a cell growing in a test tube may not correlate very well with what will happen to a patient. Another agent discussed here is resiniferatoxin, an extract from hot pepper that may lessen the pain caused by bony metastases. The bottom line is let's see what happens when good clinical trials are performed before prematurely embracing these agents.

Encouraging news is provided for men who undergo radical prostatectomy and may have to wait for up to one year to regain complete urinary control. A well-designed study at the University of Alabama assessed the impact of biofeedback training before surgery on the timing and rate of recovery of urinary control. Although questions remain about how to optimize this approach, the study did find patients had significantly better and earlier urinary control with this technique. The bottom line is that patients should ask their doctors about trying this approach.

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FROM THE PHYSICIAN*(Continued from page 2)*

Lastly, a few words about Tarvacin, a novel new agent under investigation. Most clinicians believe that whenever possible, patients should be encouraged to participate in a clinical trial. It is the only way progress can be made and ultimately is the key to improving survival for this and other diseases. Most drug studies are conducted at multiple sites throughout the United States, so that patients can locate convenient sites where they might be able to enroll. The sooner these trials are completed, the sooner new treatment options can become available.

ALTERNATIVE THERAPY COMMON IN PROSTATE CANCER

About one third of prostate cancer patients in the United States use some type of complementary or alternative medicine, according to a large national study published in the December issue of *Urology*. It's important for patients to tell their physician if they are using any type of alternative medicine, because these therapies could interact with other medicines, said Eric Elkin of the University of California-San Francisco, one of the study's authors.

However, up to one half of prostate cancer patients who take alternative therapies may not tell their doctors about it, he and his colleagues note in their report. "It's important that communication between the doctor and the patient to be there so that the doctor knows everything else the patient is taking," Elkin added.

Men using alternative medicine tended to have higher incomes, more education, and have more advanced cancer at diagnosis. They also were more likely to have other illnesses. The men who used alternative treatments targeted to prostate health were younger and less likely to be obese.

Reuters Health, 24 January 2006

CAP PROGRAM UPDATE*(Continued from page 1)*

- ity to withhold shipping drugs to your doctor if you are delinquent in paying your co-payments.
8. Will I realize any savings if my doctor participates in the CAP?
No. Vendors are not required to pass discounts on to patients. In fact, your co-payment may increase. If you agree to sign an Advanced Beneficiary Notice (ABN), the vendor may collect your existing co-payment plus the cost difference between your drug and the cheapest drug in the drug's class.
 9. Am I required to accept an ABN?
No. If you refuse to sign or verbally agree to an ABN, the vendor cannot charge you any additional amounts for your co-insurance.
 10. If my doctor joins this program, will all drugs and dosages be available in the CAP?
No. The vendor is not required to offer all drugs and dosages in the program. In fact, there are no four or six month LHRH products available. At this time, Lupron and Eligard are not included in the CAP.
 11. Will my doctor still be able to acquire Lupron and Eligard if he participates in the program?
Yes. Although these products are excluded from the program, your doctor can obtain them directly from the manufacturers just as he does today.
 12. If my doctor participates in the CAP and the vendor does not make available my drug or the dosage form that I require, do I have any other choice except to change drug, dosage and treatment plan?
Yes. Under a very narrow exception, your doctor may file a request to Medicare to "furnish as written." To qualify for this exception, your condition must demonstrate medical necessity to require your current therapy over what the vendor makes available to your doctor.
 13. Is my doctor required to notify me in advance of my next appointment that he is participating in this program?
No. According to the regulations, your doctor may give you a fact sheet about the program, but is not required to notify you in advance if he is participating and if your drug will be available.
 14. If my doctor is unhappy with the program, can he acquire my drugs directly from the manufacturer again?
Yes, but only after your doctor satisfies his contractual obligation with the vendor. For the first cycle of the CAP, this is a six-month obligation. In 2007, this will be a one-year requirement. Remember, at this time, your doctor can continue to acquire Lupron and Eligard as they do now regardless of their decision to participate in the program.

CAP Patient Discussion Questions

1. Doctor, do you plan to participate in the CAP?
2. I am concerned that my current drug and dosage may not be available through the vendor that you choose. Is there a way that we can ensure that I can stay with my current treatment?
3. I understand that Lupron/Eligard are unavailable through the CAP at this time. Will you continue to obtain Lupron/Eligard directly from the manufacturer just as you do today?

LIFE BEGINS AGAIN AT 51

By Bob Chwedyk, Senior Staff Photographer, Daily Herald

Prostate cancer is to men, what breast cancer is to women, although not as well publicized. It's a nasty bit of business that will shake you to your very soul. I'm one of the lucky ones, my numbers were good. My PSA had just ticked over the magic 4.0 in March, and the biopsy in May revealed stage 1C on a scale of three, and a Gleason reading of 6 on a scale of 10, both meaning that it was moderate and still fairly early in the game for me. Another year and I might not be writing this.

My urologist/surgeon, Dr. Ramesh Khanna, was so skilled at breaking the news to my wife Kathy and me, that he never uttered the C-word, instead using handy euphemisms like tumor, growth, etc. He was also the only urologist in the Blue Cross Blue Shield BlueAdvantage network, and just happened to be the most experienced surgeon in the area, doing prostatectomies for nearly 30 years. I lucked out and felt I was in good hands. I had no reservations going the surgery route, having been told unanimously by a number of specialists that I was young, healthy, and strong, and it was the best alternative for me. Dr. Khanna meant it when he said, "we are going for a cure, not a treatment." Good. I'm 51 years old, and despite some lapses in lifestyle decisions through the years, I was truly hoping for a longer life expectancy than your average blues musician.

I drove Kathy and I to Provena St. Joseph's Hospital in Elgin at 7am Friday morning July 15th, wearing a Fender t-shirt and warm-up pants, knowing I would appreciate the loose fit when I returned home in three days. As I was being ushered into pre-op, this fairly innocu-

ous song currently being used for a car commercial, "Dust in the Wind," kept rolling around in my head, all of a sudden taking on a chillingly different meaning. The O-R nurses began to hover around me sticking I-V needles into my hands and hooking up the various tubes, all the while making pleasant small talk with me and among themselves. I realized this was strictly routine for them, and this relaxed manner gave me a certain calm. Suddenly, I was alone for a few moments, and it finally dawned on me, this is REALLY happening to ME. In a few moments I will be inert, and my life will be in the hands of some highly skilled strangers... who I hoped had a very good night's sleep.

The anesthesiologist introduced himself to me. Although I can't remember his name, he would be the one who would seamlessly bring me back to life in a little over three and a half hours. Dr. Khanna popped his head in briefly, but he wouldn't be taking the stage for a little while yet, not until I've been plied and prepped like a Thanks-

giving turkey ready to be carved. These people collectively saved my life, and except for Dr. Khanna, I never had the opportunity to thank them, because within minutes after a nurse suggested that she give me something to make me feel more comfortable, it was lights out. The three martini buzz turned into a full blown hay maker. The last thing I remember ironically, was talking to the anesthesiologist about my job as a Daily Herald photographer when I suddenly launched into the abyss.

Picture this. You point your remote control at your TV set. You press the on button, and suddenly the image jerks into sight on the screen. Only the image on the screen is not that of Desperate Housewives, or CSI Miami, it is the faces of your surgeon and anesthesiologist staring down at you assuring you that everything went well, the pathology looked clear, and that you are indeed alive. Three and a half hours of cancer surgery had just been reduced to

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Bob Chwedyk, prostate cancer survivor and inspiration for fellow employee donations, at the Daily Herald book sale and fundraiser for Us TOO International. Bob attends Us TOO meetings at Provena St. Joseph Hospital in Elgin, Illinois.

Photo by Bill Zars

DAILY HERALD EMPLOYEES CONTRIBUTE TO US TOO

Daily Herald and Reflejos employees contributed a total of \$4,015.36 to Us TOO International while enjoying some bargain holiday shopping. Based in Downers Grove, IL, this organization provides support, education and advocacy for men diagnosed with prostate cancer. Three-quarters of the funds came from a sale of books and other items that companies sent throughout the year to the Editorial Department, generally Features. The remainder of the money was raised by the Employee Activities Committee with a silent auction. Most of the items sold in the auction were donated by employees.

While many people work on both arms of the sale, Lisa Miner heads up the Features Department part of the effort, which includes storing books and other items all year. For this work over several years, Lisa received the 2005 Robert Y. Paddock Sr. Community Service Award.

Us TOO was selected as the 2005 recipient of the funds in honor of Bob Chwedyk, staff photographer, who had successful surgery this year for prostate cancer. Bob urges male employees and loved ones of employees to have regular PSA blood tests and exams so that cancer can be detected early, as his was. Us TOO recommends that tests start at age 40 for African-American men and those with a family history of prostate cancer. Studies show there might be relationships with other cancers in the family, especially breast and colon. All men should have tests and exams beginning at age 45. For more information visit <www.ustoo.org>.

Reprinted with permission from the Daily Herald employee newsletter, December 2005

LIFE BEGINS AGAIN AT 51

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what seemed like five minutes, and I couldn't have been more grateful. As I was wheeled into recovery, I felt for the first time something radically different. In-between the narced-up grogginess of the fading anesthesia, and warm fuzzy blanket of sister morphine, was the burning sensation that seared through the five inch incision that was now in my abdomen. Doubled over in a fetal position, I could hear the clanging of appliances as the surgery personnel put the O-R back in order. An hour in recovery was another five minutes of suspended time.

Finally, the floor nurse came to get me, and began wheeling me to my private room on the fourth floor. As the nurse swung me into position in the hallway I could here my wife's chirpy little voice from inside the room say, "Hey, he's mine, he goes in here!" There, Kathy and her sister Jane, who had traveled five hours that morning from Indiana just to be with us, welcomed me back among the living. As I slowly came to, I held Kathy's hand and kissed it, not unlike kissing the ground after a long rough journey.

My life will forever be defined as before and after surgery. Six months later I don't dare say out loud that I'm a cancer survivor just yet, even though I feel confident that I am. My PSA is undetectable, and it appears that they have gotten it all. I wear my Lance Armstrong yellow wristband and blue Us TOO wristband, not because they're cool, but to remind me of what I've been through, and how far I've come. I seem to have been spared for now, and yet feel almost guilty that others have suffered a lot more than I have, and were not as lucky as me. I think about that every day, and feel blessed to be alive.

HOT PEPPER CHEMICAL MAY TREAT SEVERE BONE PAIN

New treatment aim is to ease pain

The dog hopped on three legs, pain from bone cancer so bad that he wouldn't let his afflicted fourth paw touch the floor. His owner was bracing for euthanasia when scientists offered a novel experiment: They injected a fiery sap from a Moroccan plant into Scooter's spinal column - and the dog frolicked on all fours again for several months.

The dramatic effect in dogs has researchers from the National Institutes of Health preparing to test the chemical in people whose pain from advanced cancer is unrelied by even the strongest narcotics. The first human study could begin by next year, at the NIH's Bethesda Maryland hospital.

Why would a substance that feels like it's burning a hole in your tongue - yes, one researcher tasted it - relieve pain, too? This fiery chemical, called resiniferatoxin or RTX, can poison certain nerve cells that control a type of heat-related, inflammatory pain, apparently eliminating one of the body's pain-sensing systems. Yet it doesn't seem to harm other nerves that sense, say, the sharp pain from stepping on a tack.

Optimistic, the NIH is hunting a pharmaceutical company to take over developing the experimental drug. That may be a challenge: This would be a small market. Still, the Food and Drug Administration already has designated RTX a potential orphan drug, easing research requirements.

Regardless of industry interest, if RTX works in people like it seems to in dogs, "we'll go the distance ... and make it a medicine," pledges Iadarola.

Associated Press, 16 January 2006

BIOFEEDBACK CAN REDUCE POST- PROSTATECTOMY INCONTINENCE

Preoperative biofeedback training reduces the duration and severity of urinary incontinence after radical prostatectomy (RP) for prostate cancer, according to a report in the January 2006 issue of *The Journal of Urology* (Vol. 175, pp. 196-201). Behavioral training has been shown to decrease incontinence that persists following prostate surgery, the authors explain, suggesting that interventions before surgery might also be effective.

Dr. Kathryn L. Burgio and colleagues from the University of Alabama at Birmingham evaluated the effectiveness of preoperative biofeedback assisted behavioral training to hasten the recovery of urinary control, decrease the severity of postoperative incontinence, and improve the quality of life in the 6 months following RP.

The intervention consisted of one session of biofeedback assisted behavioral training, in which men learned pelvic floor muscle control and received instructions in daily pelvic floor muscle exercise. A rectal probe measured and provided rapid visual feedback of rectal pressure and external anal sphincter contraction.

Of the 51 men in the intervention group, 70% reported that they were still doing the exercises they learned preoperatively at the 6-month follow-up. Median time to continence in the biofeedback training group was 3.5 months, the authors report, but fewer than 50% of the 51 men in the control group achieved continence by the 6-month follow-up. At 6 months, men in the intervention group reported a mean of 72.6 days with no leakage, compared with 54.2 days reported by men in the control group.

Severe or continual leakage was still present in nearly 20% of controls at the 6-month mark, the re-

searchers note, compared to 5.9% of those in the intervention group. Men who had received biofeedback training were also less likely to report ongoing symptoms of stress incontinence.

"Several important questions remain to be answered," Dr. Tomas L. Griebing from University of Kansas, Kansas City, writes in a related editorial. "What is the optimal timing for the implementation of pubic floor exercises in men undergoing RP? How can this therapy be best incorporated into routine practice? Additional research on this topic will help clarify these issues.

Reuters Health, 5 January 2006

FISH OIL WON'T FIGHT CANCER

But finding doesn't mean omega-3 fatty acids aren't heart-healthy, experts add

They may be great for the heart, but the omega-3 fatty acids found in fish and fish oil supplements do nothing to prevent cancer, a major analysis finds. A new review of more than 38 studies on the subject finds no evidence that diets rich in fish fight any kind of malignancy.

Omega-3 fatty acids "definitely have health benefits, but they are not a panacea. Preventing cancer is not one of the things omega-3 fatty acids do," said lead researcher Dr. Catherine MacLean, a natural scientist at Rand Health and a rheumatologist at the Greater Los Angeles VA Healthcare System.

The study, supported by the U.S. Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health, appears in the Jan. 25th issue of the *Journal of the American Medical Association*.

An earlier meta-analysis, also funded by AHRQ, found that diets rich in omega-3 fatty acids did have a beneficial effect on cardiovascular health. But evidence of any protection against cancer has been more elusive.

"There was a plausible mechanism," MacLean said. "Omega-3s are integral to some of the inflammatory pathways that are also common to cancer, so the idea was that if you had more omega-3s maybe that would dampen this inflammatory process." But proof for the theory was scanty.

"I think there were a lot of high hopes, but very little evidence," said AHRQ director Dr. Carolyn Clancy. While some research -- mostly animal studies -- suggested omega-3s might have an anti-cancer effect, other studies found no such link. "So the office at the NIH that deals with dietary supplements asked AHRQ to do a very rigorous review of the studies that had been done," Clancy explained.

In the study, MacLean's group analyzed data from studies conducted over the past 40 years.

The vast majority showed no effect of even high-dose omega-3 fatty acids on the incidence of a wide range of cancers, including breast, colon, lung and prostate malignancies, the researchers found.

Colleen Doyle, director of nutrition and physical activity at the American Cancer Society (ACS), said the finding was "not surprising," since the evidence had always been slim that the nutrient might fight cancer.

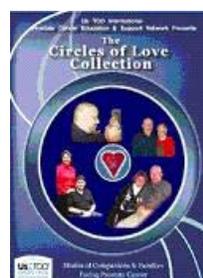
Doyle said healthy diets can discourage cancer by keeping obesity at bay. "Being overweight, especially, increases circulating hormones such as estrogen and insulin that we know are associated with cancer cells and tumor growth," she explained. MacLean agreed, adding that fish-rich diets are proven to fight heart disease.

"The results of this study need to be taken in the context of the body of literature on omega-3 fatty acids," she said. "Eating fish, as opposed to a hamburger with cheese and bacon, would be a great idea, in general," Clancy added. "And it is not going to hurt you."

HealthDay News, 24 January 2006

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Circles of Love Music CD – \$15.00 includes S+H. Also available as part of the **Circles of Love Care Kit** (see below).

The Circles of Love Care Kit – \$24.99 includes S+H

Our new care kit is an excellent resource collection for friends and loved ones of those facing the battle against prostate cancer. Our care kit features:

- **The Circles of Love Collection: Stories of Companions and Families Facing Prostate Cancer**
- **Circles of Love Music CD**
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**DRUG CANDIDATE
'COULD BOOST
LYCOPENE EFFECT
IN FOODS'**

Addition of a phosphorylated variant of gamma-tocopherol to lycopene-rich foods like tomato sauce might boost the carotenoid's anti-cancer activity.

Australia's Phosphagenics developed GTP-0805 using its phosphorylation technology base to enhance the bioavailability of drugs and improve absorption through the gastrointestinal tract or skin. Not only have laboratory tests found that the compound induced a greater than 90 per cent reduction in breast and prostate cancer cells, but the company says it also demonstrated a synergistic anti-cancer affect on prostate cancer cells when combined with the antioxidant carotenoid lycopene.

The compound, which claims to destroy diseased cells while not affecting normal ones by primarily acting as a signaling molecule and modulator of cancer pathways, is presently a drug candidate. Phosphagenics has announced the start of animal studies on the compound – an early stage along the road towards regulatory approval. For

GTP-0805 to be used as a food ingredient in Europe it would need to be granted novel food status. In the US, it would need GRAS (generally recognized as safe) status.

The proposed animal studies will assess the anti-cancer properties of GTP-0805 both alone and in combination with lycopene or with an anti-cancer drug, it being common practice to use combination therapy in the treatment of cancer. Phosphagenics' earlier data, carried out by the Malaysian Palm Oil Board, suggested that GTP-0805 could enhance the absorption and intracellular uptake of cancer drugs, potentially minimizing both the doses required and the adverse effects of cytotoxic drug therapies.

"The early-stage in vitro investigations of GTP-0805 demonstrate the potential of the compound in the treatment of cancer," said Dr Esra Ogru, executive director of research and development at Phosphagenics. "We are particularly delighted with our initial test results because they suggest GTP-0805 has a unique action that selectively inhibits and destroys cancer cells while leaving healthy cells undamaged."

*NUTRA Ingredients.com
25 January 2006*

**SECOND DEFENSE
DEPARTMENT GRANT
AWARDED FOR
TARVACIN™ STUDIES**

Peregrine Pharmaceuticals, Inc. announced in January 2006 that the U.S. Department of Defense (DOD) has awarded a grant totaling \$585,000 to its collaborators at the University of Texas Southwestern Medical Center at Dallas to conduct preclinical studies of Tarvacin™ Anti-Cancer as a potential treatment for prostate cancer. Tarvacin Anti-Cancer, Peregrine's lead vascular targeting antibody, is currently in a Phase I clinical trial for advanced refractory solid tumors.

In the new prostate cancer studies, UT Southwestern researchers will use models of prostate cancer to optimize therapy, including dose, dosage frequency and how to best achieve synergistic therapeutic effects with chemotherapy. They will assess the efficacy of Tarvacin Anti-Cancer against primary tumors and also examine its impact upon bone metastases. The results of these studies are expected to help guide the design of human prostate cancer studies for Tarvacin Anti-Cancer in the future.

PR Newswire, 18 January 2006

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