



# PROSTATE CANCER *HOT SHEET*

**Us Too! INTERNATIONAL**

**MARCH 2002**

## **WANTED - A FEW GOOD MEN!**

The Department of Defense (DoD) has provided over \$300 million for prostate cancer research since 1997. Now the DoD has allocated \$85 million for 2002 for its Prostate Cancer Research Program (PCRP) and you can have a say in how these dollars are spent.



Cancer researchers in the United States and around the world will soon submit scientific research proposals to the DoD to compete for these funds. Scientists and clinicians with expertise in a variety of research fields will review each of these proposals and make recommendations for funding. Experience has shown that prostate cancer survivors can make a difference by participating in these reviews, working side-by-side with the scientific reviewers. Prostate cancer survivors serving as consumer reviewers have an equal vote in determining the relevance and relative merits of the submitted proposals. Preparation and work involved is substantial - but the results are rewarding.

The three-day peer review sessions will

be held during July in the metropolitan Washington, D.C., area. The DoD PCRP provides travel, accommodations, meals, and honoraria to each participant.

Forms are available at CDMRP web site: <http://cdmrp.army.mil/CWG/default.htm> look under "how to apply" on the left side..

If you are a prostate cancer survivor who is active in the battle against prostate cancer, contact Us Too! headquarters (e-mail [DoD@ustoo.org](mailto:DoD@ustoo.org)) to get detailed information and the nomination form.

Nomination forms, eligibility and selection criteria, roles and responsibilities can be obtained from the web site: <http://cdmrp.army.mil> (Click on "Consumer Involvement"). You can also obtain the necessary materials and information by telephoning the DoD offices in Maryland at 301-619-7076 or by accessing the web site noted above.

Deadline for nominations as consumer reviewers for the PCRP of the DoD is April 5, 2002.

Those seeking Us Too! nomination should have completed paperwork at Us Too! Headquarters before March 29th.

Those received on, or prior to, the deadline will be considered for Peer Reviews three day sessions in July, 2002.

## ***A FEW GOOD MEN CAN MAKE A DIFFERENCE!***



## ***SAFETY ALERT BOTANIC LABS***

### ***VOLUNTARILY RECALLS PC-SPES AND SPES***

***SAFETYALERTS / FEB 8, 2002***

The Food and Drug Administration (FDA) said that BotanicLab has recalled the dietary supplement / herbal products PC SPES and SPES capsules because they contain undeclared prescription drug ingredients that could cause serious health effects if not taken under medical supervision.

Laboratory analysis of the products by the California Department of Health Services found PC SPES contains warfarin and SPES contains alprazolam, which are available only by prescription and sold either by their generic names or the trade names, Coumadin and Xanax. PC SPES and SPES are respectively marketed "for prostate health" and strengthening the immune system. BotanicLab, the manufacturer of the products, has voluntarily recalled PC SPES and SPES nationwide.

The capsules were sold by mail, phone and Internet order as well as by stores and health care professionals. Consumers with unused capsules may return them to BotanicLab, which can be reached at 1-800-458-5854. Consumers with questions, comments or concerns may also contact California health investigators at 1-800-495-3232.

*See Story on Page 4*

**PROSTATE CANCER NEWS YOU CAN USE**

*Us Too!* publishes a FREE daily e-mail based news service which provides updates on the latest prostate cancer related news. To subscribe or link to the archives simply visit the *Us Too!* Website: [www.ustoo.org](http://www.ustoo.org)

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**IMAGING TOOL HELPS LOCATE SITES OF EARLY RECURRENT PROSTATE CANCER**  
*February 15, 2002*

A new multi-institutional study led by investigators at Duke University Medical Center indicates that a diagnostic scan may help localize recurrent prostate disease in men who have had surgical removal of the prostate and show early signs of recurrence. This diagnostic scan, called capromab pentetide immunoscintigraphy, trade name ProstaScint (trademark), is a monoclonal antibody scan that can detect recurrent disease if it is localized to the area of prior prostate surgery or has spread to other parts of the body. This knowledge can help doctors better decide which type of treatment would work best for each patient with recurrent prostate cancer. The study appears in the Feb. 15, 2002 issue of the journal *Cancer*.

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**NONCLINICAL VARIABLES INFLUENCE PROSTATE CANCER MANAGEMENT**  
*February 14, 2002*

Researchers found that baseline disease-related function as well as various nonclinical variables are important determinants of treatment of clinically localized prostate cancer. Using data from the Prostate Cancer Outcomes Study, they evaluated 3,073 men with clinically localized disease (T1 or T2). The investigators examined the association of sociodemographic and clinical characteristics with 4 management options: radical prostatectomy, radiation therapy, hormonal therapy, and watchful waiting. "These results ... underscore the lack of consensus for care of this disease, probably attributable to the lack of definitive evidence of the efficacy of one approach versus another," the researchers commented. "Until such evidence can be obtained, we urge that men diagnosed with prostate cancer be informed of the potential risks and the potential benefits of all 4 main treatment options so that they might make an informed decision." (Harlan L, et al. *J Natl Cancer Inst* 2001;93:1864-71.)

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**COMPUGEN DISCOVERS NOVEL PROSTATE-SPECIFIC PROTEINS ENCODED BY THE PSA GENE**  
*February 13, 2002*

TEL AVIV, Israel — Compugen Ltd. announced the discovery of two novel prostate-specific proteins. These proteins

are encoded by alternative mRNA splice variants of the genes for prostate specific antigen (PSA) and its related protein, human kallikrein 2 (hK2). The novel transcripts were predicted using Compugen's proprietary LEADS computational biology platform and then verified in Compugen's molecular biology laboratory. These novel proteins may have important applications in developing additional diagnostic tools for prostate cancer and for understanding the pathobiology of the disease. The discovery is now published in *The Journal of Biological Chemistry* (David A. et al., electronic publication ahead of print). "Unfortunately, high serum levels of PSA are not a definitive indicator of prostate cancer and are also detected in cases of benign prostate hyperplasia," said Kineret Savitsky, Ph.D., Vice President Experimental Biology at Compugen and one of the authors of the paper. "The novel prostate-specific proteins that we discovered may provide additional tumor markers for the development of prostate cancer diagnostic tools aimed at enhancing the discrimination between patients with benign disease and prostate cancers."

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**PERCENT OF CANCER IN PROSTATE BIOPSY TISSUE PREDICTS DISEASE RECURRENCE**  
*February 11, 2002*

The percent of total biopsy tissue with cancer predicts the risk of biochemical recurrence and adverse pathological results, a study found. "Our data indicated that percent of prostate biopsy tissue with cancer was the strongest independent predictor of PSA failure after radical prostatectomy," the authors concluded. "Consideration should be given to reporting percent of total biopsy tissue with cancer in all prostate biopsy results." (Freedland S, et al. *J Urol* 2002;167:516-20).

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**CONVENTIONAL INCIDENCE RATES UNDERESTIMATE TRUE PREVALENCE OF PROSTATE CANCER**  
*February 11, 2002*

Correcting prostate cancer incidence rates for prevalent cancer increased the levels, more so among older age groups, according to an analysis of the National Cancer Institute's Surveillance Epidemiology and End Results (SEER)

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program. The results indicated that corrected prostate cancer incidence rates were higher in magnitude, particularly in older age groups and among black patients. "This study suggests that corrected prostate cancer incidence rates differ noticeably in magnitude from conventionally derived rates, more so in older age groups, among black men, and in recent years because of PSA screening," the authors wrote. "The American Cancer Society calculates annual estimates of new cancer cases for the United States by using conventional SEER-based cancer incidence rates. Hence, these national estimates of new cases will be underestimated for prostate cancer." (Merrill R and Morris M. Am J Epidemiol 2002;155:148-52).

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**PROSTATE SPECIFIC ANTIGEN EPIOTOPE RAISES HOPES FOR CANCER VACCINE**  
*February 06, 2002*

A group at the U.S. National Institutes of Health (NIH) has created an agonist epitope for prostate specific antigen, raising hopes that a vaccine for prostate cancer could soon be over the horizon. Key points reported in this study include:

- \* A novel agonist epitope for prostate-specific antigen (PSA), called PSA-3A, stimulates the immune system more than native antigen does
- \* T-cell activity and interferon-(gamma) production in response to treatment with PSA-3A in a series of laboratory and animal model experiments was high
- \* Because T cells stimulated by PSA-3A act against cells that express PSA, the epitope could be an important therapy for men with prostate cancer.

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**CHROMOGRANIN A ELEVATED IN PATIENTS WITH HIGH GRADE PROSTATE CANCER; CAN BE A SERUM MARKER WITH PSA**  
*February 05, 2002*

Serum chromogranin A tends to be higher in patients with high grade prostate cancer, and when combined with PSA can predict a poor prognosis after endocrine therapy, researchers revealed. "Chromogranin A is gaining acceptance as a serum marker of neuroendocrine tumors and the concentration is thought to be elevated in relation to neuroendocrine differentiation of prostate cancer," they wrote. "[W]e suggest that cases of prostate cancer

associated with low serum PSA and high serum chromogranin A, which would have more neuroendocrine cells with less androgen receptors, may show resistance to endocrine therapy and a poor prognosis," the authors wrote. (Isshiki S, et al. J Urol 2002;167:512-5.)

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**ADDITION OF ISOTRETINOIN TO HORMONAL THERAPY IN PATIENTS WITH ADVANCED HORMONE-SENSITIVE PROSTATE CANCER DOES NOT IMPAIR PSA DECLINE**  
*February 05, 2002*

In a study testing whether the addition of isotretinoin (13-cis retinoic acid) to hormone ablation therapy could alter the PSA response in patients with advanced hormone-sensitive prostate cancer, researchers found that PSA decline was not impaired and that the regimen was well tolerated. "[T]he results indicated that the coadministration of retinoids, whether during the first or second 12 weeks after the beginning of androgen ablation therapy, did not impair the steep nor the secondary plateau phase of PSA decline," the researchers concluded. (Ferrari A, et al. J Clin Oncol 2002;20:538-44.)

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**M. D. ANDERSON CANCER CENTER ORLANDO TO WIELD POWERFUL WEAPON FOR TUMORS**  
*February 04, 2002*

Doctors at M. D. Anderson Cancer Center Orlando unveiled an innovative and advanced cancer treatment called Novalis(R) Shaped Beam Surgery for brain, head, neck, spine, liver, lung and prostate tumors. M. D. Anderson — Orlando is among the first sites in the United States to offer this advanced radiosurgery technology. Novalis Shaped Beam Surgery is the non-invasive delivery of a precise dose of high-energy radiation to shrink or control the growth of a tumor by killing tumor cells or interfering with their ability to grow. Using precise and detailed computer-generated images as well as a highly accurate patient positioning system, the Novalis treatment exactly mirrors the shape and size of a patient's tumor. Each beam of radiation conforms to the tumor's exact dimensions, specifically targeting and, unlike conventional beam radiation, treating diseased tissue while leaving surrounding healthy tissue unharmed.

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**NATIONAL MEETING OF HEALTHCARE EXPERTS TAKES AIM AT SUBSTANDARD CARE FOR MINORITIES AND UNDERSERVED POPULATIONS**

*February 07, 2002*

The United States could significantly reduce the incidence of cancer in the years ahead without any further research breakthroughs — if all available information about cancer prevention, detection, early treatment, intervention and education were put to use now, cancer researchers and minority health officials meeting in Washington said. Speaking at the Intercultural Cancer Council's (ICC) 8th Biennial Symposium on Minorities, the Medically Underserved, & Cancer, cancer control experts told the conference attendees that just making use of the information that now exists will significantly improve the survival of all Americans who are poor, lack health insurance, or otherwise have inadequate access to quality cancer treatment.

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**CONFERENCE DISCUSSES DISEASE CURES**  
*February 02, 2002*

Richard Lutz, director of the Center of the for Deep Sea Ecology at the Institute of Marine and Coastal Sciences at Rutgers University, is studying deep-sea organisms and analyzing the toxicity of the organisms' extractions to find out if the extracts kill cancer cells. He said the findings have been particularly helpful in regard to the study of prostate cancer. Lutz said many types of creatures — such as a type of tubeworm that grows up to about 6 feet — survive in hydrothermal vents along the bottom of the deep ocean floor. Upon its discovery, the tubeworm was placed in a new phylum. "We've essentially got an organism with no mouth, no gut, no anus ... just hydrogen sulfide diffusing across it," Lutz said. Conference presenters indicate that neutragenomics will lead to new compounds to treat and prevent cancer and other human diseases.

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**PERSONALIZED VACCINES MAY TEACH CELLS TO HUNT CANCER**  
*The Virginian-Pilot / Norfolk, VA*  
*January 30, 2002*

A new generation of cancer vaccines being tested adds an interesting twist - individualized therapy, custom-tailored to

(continued on page 5)

## TWO HERBAL SUPPLEMENTS RECALLED AMID RISING REGULATORY CONCERNS: PC-SPES IS A POPULAR TREATMENT FOR PCA THAT HAS SHOWN PROMISE IN TESTING

By RAY HERNDON  
LA Times Staff Writer  
February 9, 2002

The manufacturer of a promising and widely used herbal treatment for prostate cancer told consumers Friday to stop taking the product after California authorities determined it was contaminated with potentially harmful prescription drugs.

State health officials asked BotanicLab Inc. of Brea to recall PC SPES, the prostate cancer treatment, and another supplement, SPES, after finding they contained elements of the anxiety drug Xanax and the blood-thinning drug Coumadin. Both drugs are supposed to be taken under the supervision of a physician.

On February 8th, the company posted a letter on its Web site asking consumers and distributors to return all unused PC SPES pills in their original containers for a refund. The letter did not mention SPES.

Meanwhile, the U.S. Food and Drug Administration announced it was launching an investigation based on California authorities' findings.

PC SPES, taken by at least 10,000 American men, is one of the few herbal supplements to demonstrate substantial therapeutic effects. Studies on its positive effects have been published in respected medical journals and demand for the compound, whose effectiveness is still being studied, has grown dramatically.

The contamination underscores ongoing concern about the lack of regulation for supplements—particularly of manufacturing standards.

PC SPES appears to reduce the growth of prostate tumors. SPES is marketed as a supplement that can help boost the

immune system. But little is known about the compounds they contain and how they work. The PC SPES ingredients are reishi, Baikal skullcap, rhabdosis, dyer's woad, mum, saw palmetto, San-Qui ginseng and Chinese licorice.

The state Department of Health Services announced Friday that its investigators, in tests of product samples at a Sacramento laboratory, had found warfarin in PC SPES, and alprazolam in SPES. Warfarin is marketed under the trade name Coumadin and alprazolam under the trade name Xanax.

Independently, researchers at UC San Francisco's medical school confirmed to The Times that they had tested four different lots of PC SPES and found that all contained yet a third contaminant, diethylstilbestrol, or DES, a hormone that was once used to prevent miscarriages but later was banned when it was shown to cause birth defects in children and blood clots and other side effects among men.

### 1994 Law Limited FDA's Authority

PC SPES, which had shown success in treating men whose prostate cancer did not respond to conventional therapies, had been undergoing clinical trial at UC San Francisco.

But Ray Wilson, a scientist with the state health department, said the trial was abruptly halted recently by Dr. Eric J. Small, who was heading the study, because of concerns about DES contamination.

The recall comes as concern is mounting among medical experts nationally over the lack of regulation of herbal supplements. Herbal remedies are classified as food supplements and, unlike prescription drugs, are not subject to regulation by the U.S. Food and Drug Administration.

The FDA once had authority to regulate dietary supplements and in 1989 did act swiftly to recall one such substance—L-tryptophan—which was ultimately linked to 37 deaths. But under a 1994 law, the supplement manufacturers were made responsible for ensuring the safety of a product and the accuracy of the labeling.

Federal officials can still intervene in the case of fraudulent marketing claims. And the FDA is required under the 1994 law to issue "good manufacturing practices" guidelines for the makers of supplements, although it has yet to do so.

On February 8th, FDA officials warned consumers that the supplements PC SPES and SPES may pose serious health risks and are under investigation by the agency.

"In this case, the agency's warning is due to the finding of the California state government that the ingredients in [the supplements] posed serious health risks," FDA spokesman Jason Brodsky said. "We certainly are supportive of the company's decision to recall the products."

Brodsky declined to comment on the nature or scope of the FDA investigation, citing agency policy.

FDA officials said they are unaware of any consumer complaints of adverse reactions to the supplements. However, Brodsky cited a recent report in the New England Journal of Medicine about a serious reaction to PC SPES.

### D.A. Fielded Complaints of PC SPES Side Effects

BotanicLab has not been shy about marketing PC SPES, but the company has avoided media scrutiny and typically has refused requests by the media to speak to its scientists.

Although the state health department and FDA Web sites said both PC SPES and SPES were being recalled, the recall notice posted on BotanicLab's Web site made no mention of the SPES recall.

No one at BotanicLab, a privately held company founded by patent-holder Sophie Chen, could be reached for comment before deadline.

In a letter to customers, president John Chen said the company believes "further testing [of PC SPES] is necessary to confirm the material at issue is warfarin." The letter said that the company was nonetheless recalling the product to be prudent.

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## RECENT TRENDS IN MORTALITY RATES FOR FOUR MAJOR CANCERS, BY SEX AND RACE/ETHNICITY UNITED STATES 1990 - 1998

Reported by: P Gargiullo, PhD, PA Wingo, PhD, RJ Coates, PhD, and TD Thompson  
*Div of Cancer Prevention and Control,  
National Center for Chronic Disease  
Prevention and Health Promotion, CDC*

January 27, 2002 - In 1998, 53% of all cancer-related deaths in the U.S. were associated with four sites: lung/bronchus, colon/rectum, prostate, and female breast. Rates remained high for blacks, have not decreased equally among all populations, and have increased in certain instances. Continuing research and prevention efforts are needed to reach high-risk and underserved populations and understand reasons for differences in cancer mortality among racial/ethnic populations.

Death rates for prostate cancer were more than twice as high for blacks than for whites. Rates were lowest among Asian-Pacific Islanders [APIs]. Death rates decreased for men of each race/ethnicity except American Indians/Alaska Native [AI/ANs]. Death rate declines for whites (2.8% per year) and APIs (3.4% per year) were approximately twice the decreases for blacks, Hispanics, and AI/ANs.

Findings indicate that death rates have declined for lung and bronchus, colorectal, prostate, and female breast cancers among most racial/ethnic populations; however, death rates remained high for certain cancers among blacks and are generally increasing among AI/ANs. Trends in cancer death rates might reflect changes in cancer risk behaviors, new screening modalities, and the development and use of new and more effective treatments.

Prostate cancer is second to lung cancer as a cause of cancer-related death among men. The report indicates that the gradual decreases in death rates for all the reported races/ethnicities during the study period might reflect aggressive treatment of advanced cancer and use of serum prostate-specific antigen (PSA) testing. However, long-term effectiveness of PSA screening and early-stage treatment in reducing mortality remains unconfirmed.

## BOOK REVIEW

Review by: Bill Marvel  
The Dallas Morning News

### 'Angels Prostate Fall'

by Marshall Terry  
Southern Methodist University Press (\$19.95)

Cancer is not ordinarily a funny subject. But there is something ruefully humorous about cancer of the prostate: It messes up body functions that are, in themselves, rich sources of comedy. And it's an old guys' disease (I write this as one old guy reviewing a book by another old guy). With any luck at all, old guys have learned to chuckle at life's dirty tricks, even its potentially lethal dirty tricks.

Also, prostate cancer is one of the most survivable forms of the disease. And what is funnier than a close brush with Mr. Death that leaves one, if just barely, still standing? Think of slapstick comedy.

The painful humor here starts right in with the awful pun in the title. The story is simple: Stanley Morris, a distinguished professor of English, is diagnosed with prostate cancer, and watches, bewildered, as his world begins to slip away. (The novelist is, himself, a distinguished professor of English - former department chair and provost at Southern Methodist University.)

"Every man gets cancer of the prostate sooner or later," his doctor cheerfully informs him. Apparently so. As he goes about setting his affairs in order, Professor Morris discovers there is a regular Brotherhood of the Prostate out there, its members eager to share the gruesome details of catheters and erectile dysfunction.

And not just cancer: He goes to donate blood and the attendant drops dead of a stroke. Everywhere around him, folks suddenly start falling like autumn leaves. A close friend commits suicide. His brother loses a foot to diabetes. The university president struggles with a fluttery heart.

Change is in the wind, the kind of change that threatens to come along and sweep clean after him. As the professor prepares

for surgery, he learns one of his favorite students is about to drop out. The new dean is a feisty, politically correct woman. And the university trustees have brought in a motivational guru, one of those latter-day snake-oil salesmen who roam the land seeking to reprioritize, restructure, and reengineer, getting us all to embrace goals before we've even achieved the old ones.

Small wonder, as he flits in and out of the post-operative twilight zone, memories flickering like an old movie, the professor encounters the ghost of his friend the recent suicide, accompanied by Jesus, who turns out to be pleasant but noncommunicative.

The book is really about crossing that line that all of us must if we hope to become grown-ups. On one side, we think we will never die. On the other, we're never quite sure we're going to live another day. It also reminds us, to paraphrase an old joke, that there is a vast difference between fallen angels and those that have merely lost their balance.

On one side, we think we will never die. On the other, we're never quite sure we're going to live another day.

## PCA NEWS YOU CAN USE

(continued from P. 3)

each patient. These vaccines incorporate a patient's own blood cells and, in some cases, unique proteins secreted by their tumors. Scientists hope the vaccines - designed for treatment, not prevention - will train the immune system's infection-fighting white cells to recognize and destroy cancer. During vaccine therapy, doctors draw blood and isolate dendritic cells, a type of white blood cell that mobilizes T-cells to fight foreign invaders. The blood is sent to Seattle-based Dendreon Corp., which manufactures the vaccine. Scientists then combine the dendritic cells with a genetically altered protein, said David Urdal, company president. Normally, the protein is only manufactured by the prostate. In men whose prostates have been removed, the only source for that protein is the patient's cancer, which may have hidden tumor cells elsewhere in the body, Urdal said. Dendreon scientists alter that protein to make it fit - like a lock and key - to

(continued on page 6)

**PCA NEWS YOU CAN USE**

(continued from P. 5)

immune-system cells. When the patient's blood is infused back into his body, the dendritic cells carry that protein with them, Urdal said. The dendritic cells act like generals, giving orders to germ-fighters called killer T-cells, which are sent on a search-and-destroy mission for cancer. These special forces now know how to spot the cancer. They just look for the protein. Vaccine therapy causes relatively mild side effects, such as fevers or chills, compared with radiation and chemotherapy, which can lead to nausea, vomiting and hair loss. But physicians caution that vaccines, for all their potential, have never lived up to their promise. All the vaccines being tested today are considered experimental. None are being marketed commercially. Dendreon is just one of many companies working on vaccines. Others include Therion Biologics of Massachusetts and New York-based Antigenics. Doctors today are testing more than a dozen vaccines against prostate cancer alone.

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**FDA ADVISORY COMMITTEE  
RECOMMENDS APPROVAL OF NOVARTIS  
DRUG ZOMETA(R) (ZOLEDRONIC ACID  
FOR INJECTION) FOR THE TREATMENT OF  
CANCER-RELATED BONE  
COMPLICATIONS  
January 31, 2002**

The Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA) has recommended approval of ZOMETA(R) (zoledronic acid for injection) for the treatment of bone complications (metastases) associated with a broad range of tumor types. These include prostate cancer, lung cancer, and other tumor types for which no intravenous bisphosphonate therapy is currently approved for treatment, as well as breast cancer and the osteolytic lesions associated with multiple myeloma. ZOMETA offers patients and clinicians treatment with a convenient 15-minute infusion time. In the prostate cancer trial, ZOMETA demonstrated efficacy when compared to placebo in the treatment of bone metastases. Over the 15-month evaluation period of this trial, a lower proportion of patients receiving ZOMETA experienced a skeletal related

event (SRE), such as radiation to bone, pathological fractures, and spinal cord compression compared to those receiving placebo. Additionally, patients on ZOMETA had a delay in the onset of the first SRE compared to placebo. The results of the prostate cancer trial mark the first time any bisphosphonate has demonstrated efficacy in treating SREs. U.S. FDA approval of ZOMETA for these indications would mark the first time a bisphosphonate would be available to this patient population. More than 250,000 patients worldwide suffer from bone complications from metastatic prostate cancer.

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**CLEVELAND CLINIC HOSTS FIRST  
WORLD SUMMIT ON RADICAL  
PROSTATECTOMY  
January 30, 2002**

Experts from across the country will meet at The Cleveland Clinic March 13-15 for an in-depth review of radical prostatectomy. Proceedings from the First World Summit On Radical Prostatectomy will be shared via teleconferencing with physicians in Europe and Asia. The summit is being coordinated the Minimally Invasive Surgery Center at The Cleveland Clinic and the Section of Laparoscopic and Minimally Invasive Surgery in The Cleveland Clinic Urological Institute. Patrick C. Walsh, M.D., Urologist-In-Chief at the James Buchanan Brady Urological Institute at Johns Hopkins School of Medicine, will serve as program chairman. A prestigious 17-member faculty will present a comprehensive evaluation of all available techniques of radical prostatectomy. Radical prostatectomy, or surgical removal of the prostate gland, is the treatment of choice for many men coping with prostate cancer. More than 200 surgeons are expected to attend the summit, with more than 600 surgeons in Italy, Korea, India, Japan and England participating via teleconference.

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**ULTRASOUND TESTED AS PCA THERAPY  
January 30, 2002**

Ultrasound technology, long known to expectant parents and used in the monitoring of fetal conditions, is making new waves at the Indiana University School of Medicine for its value in fighting

prostate cancer. A Phase I clinical trial at the IU School of Medicine investigates the efficiency and safety of using high intensity focused ultrasound (HIFU) for prostate cancer. The minimally invasive procedure combines the latest in 3-D technology to plot the location of cancerous cells and then fires ultra-focused sound waves to destroy them. The IU School of Medicine one of two trial sites in the nation approved by the Food and Drug Administration late last year, the other being Case Western Reserve University in Cleveland, Ohio. For more information about enrolling in HIFU trial, call 317-630-6044.

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**INITIAL CLINICAL STUDY SHOWS SAFETY  
January 30, 2002**

A new phase I clinical trial of a prostate cancer vaccine developed at Duke University Medical Center has shown that the vaccine made from the patient's own dendritic cells causes no adverse side effects. More importantly, the trials indicate that the vaccine is able to boost the patient's immune system to fight cancer. The results of this trial in 13 patients are published in the February 2002 issue of the Journal of Clinical Investigations. "This is the first study that has data on the safety and immunological efficacy of this type of cancer vaccine," said Dr. Johannes Vieweg, an associate professor of urology and assistant professor of immunology at Duke University Medical Center and senior investigator in the study. "And while this work was done in prostate cancer patients, we believe this method may prove to work in most cancers, not just prostate cancer."

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**ALP FLARE POST-ORCHIECTOMY COULD  
IDENTIFY PATIENTS MOST LIKELY TO  
BENEFIT FROM EARLY CHEMOTHERAPY  
January 29, 2002**

New data suggest that measuring serum alkaline phosphatase (ALP) activity within 4 weeks of castration could indicate which prostate cancer patients undergoing androgen ablation would benefit from additional early chemotherapy. Results showed that while there was no difference in overall survival and progression-free survival between the 2 groups, patients additionally treated with EMP who had a greater than 50% increase in ALP after

orchiectomy had better progression-free survival. (Pelger R, et al. Prostate 2002;50:119-24.)

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**RELATIONSHIP BETWEEN LIFESTYLE AND PROSTATE CANCER SUBJECT OF NEW STUDY: RESEARCHERS HOPE TO ENROLL HIGHLY DIVERSE STUDY POPULATION**

*January 29, 2002*

Kaiser Permanente California is enrolling volunteers for a long-range study to examine family history and lifestyle factors that may cause or prevent prostate cancer and other illnesses. Beginning in January, Kaiser Permanente is writing, in English, Spanish and Chinese, to more than 500,000 of its members to invite them to participate in the California Men's Health (CMH) Study. From the respondents, researchers are hoping to enroll a highly diverse group of 100,000 participants, which will make the CMH Study the largest survey of men's health ever undertaken in the State. For more information:

[www.kaiserpermanente.org/california](http://www.kaiserpermanente.org/california)

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**CERTAIN HEALTH-RELATED QUALITY OF LIFE DOMAINS MAY BE LESS FAVORABLE WITH PROSTATE BRACHYTHERAPY THAN EXTERNAL-BEAM RADIATION, RADICAL PROSTATECTOMY**

*January 29, 2002*

In comparing patients' health-related quality of life (HRQOL) after common contemporary therapies for localized prostate cancer, researchers found that brachytherapy may not be as free from long-term morbidity "as often suggested and broadly advertised." Bothersome sexual dysfunction was reported in each of the therapy groups as compared with the controls. While radical prostatectomy was associated with adverse urinary HRQOL and external-beam radiation was associated with adverse bowel HRQOL, brachytherapy was associated with both, as well as, adverse sexual HRQOL (PAs compared with external-beam radiation and radical prostatectomy, brachytherapy had more HRQOL outcomes that were less favorable 1-year post-treatment. The researchers also reported that sexual and hormonal HRQOL was better in progression-free subjects than in subjects with increasing PSA (P<.0001). "These findings provide a basis for counseling patients in regard to long-term HRQOL

expectations after primary prostate cancer therapy and demonstrate that urinary irritative and hormonal concerns are significant elements of localized prostate cancer HRQOL," the authors concluded. (Wei J, et al. J Clin Oncol 2002;20:557-66.)

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**NEW PCA GENE MUTATION FOUND**

*January 21, 2002*

An international study has identified a gene mutation found in men at high risk of prostate cancer. Although the mutation was discovered in only a small number of cases, researchers suspect that it may play a role in the early stages of the disease. They also say that although this gene mutation doesn't answer all of the questions about prostate cancer, it provides another piece of the puzzle about how the disease develops. It is the second time in a year that researchers have connected a gene mutation to prostate cancer. An expert familiar with the findings says the discovery could someday give doctors the tools to screen for men at increased risk of the disease, and may point to new avenues in drug development. The research appears in the February issue of the journal Nature Genetics. Last year, Utah researchers, also reporting in Nature Genetics, said they had discovered another gene mutation tied to prostate cancer. That, too, was implicated in only a tiny number of cases, the researchers said, but at the time they suspected there could be as many as five or six genes responsible for the disease.

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**FIVE-YEAR FOLLOW-UP SHOWS PROGRESSION-FREE SURVIVAL NOT IMPROVED WITH NEOADJUVANT ANDROGEN DEPRIVATION BEFORE RADICAL PROSTATECTOMY**

*January 21, 2002*

Researchers suggested that induction androgen deprivation before radical prostatectomy is not indicated "[u]ntil studies document improvement in biochemical or clinical recurrence with longer periods of treatment." They reached this conclusion after long-term monitoring of patients who had participated in the Lupron Depot Neoadjuvant Prostate Cancer Study Group. "In the initial report of [this study],

patients who received 3 months of androgen deprivation had a significant decrease in the positive margin rate," the authors wrote. To investigate the long-term outcome the researchers followed the subjects for 5 years. The participants had clinical stage T2b prostate cancer and had been randomized to receive either radical prostatectomy only (n4) or 3 months of neoadjuvant androgen deprivation followed by radical prostatectomy (n8). The neoadjuvant androgen deprivation therapy consisted of 3 months of combined androgen blockade with 7.5 mg leuprolide injections monthly and 250 mg flutamide 3 times daily. During a 5-year follow-up, the subjects were tested every 6 months for serum PSA levels. A PSA level >0.4 ng/mL defined biochemical recurrence. Results comparing the 2 groups exhibited no significant difference in the biochemical recurrence rate at 5 years. "[C]urrently, there is no evidence to indicate that neoadjuvant androgen deprivation before radical prostatectomy improves progression-free survival in patients with stages cT1-T2 prostate cancer who undergo radical prostatectomy," the investigators concluded. (Soloway M, et al. J Urol 2002;167:112-6.)

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**LAPAROSCOPIC PELVIC LYMPHADENECTOMY JUSTIFIED IN SELECT PATIENTS WITH LOCALLY ADVANCED PROSTATE CANCER**

*January 21, 2002*

In a study assessing the role of laparoscopic lymph node sampling in patients with locally advanced prostate cancer before radical radiotherapy, researchers concluded that laparoscopic lymph nodes can be sampled safely by urologists with experience in laparoscopic surgery. "There is little information on the role of pelvic lymphadenectomy for patients with suspected locally advanced prostate cancer before radical conformal radiotherapy," the authors noted. To address this issue, they prospectively evaluated 50 prostate cancer patients with presumed locally advanced disease (mean age, 65 yrs). "[P]elvic lymphadenectomy is justified in selected patients with locally advanced prostate cancer to choose the most appropriate treatment and to avoid unnecessary radiotherapy," the

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## PCa NEWS YOU CAN USE

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researchers concluded. (Parking J, et al. BJU Intl 2002;89:14-7.) In the context of clinical trials, an editorialist supports the use of laparoscopic lymphadenectomy as a “relatively noninvasive method of obtaining information on lymph node status.” However, in the clinical management of patients undergoing radiotherapy for locally advanced prostate cancer, “the case has yet to be made for the general introduction of pelvic lymphadenectomy.” (Kirk D, et al. BJU Intl 2002;89:17-8.)

### PC-SPES RECALL

(continued from P. 4)

“As we implement a new quality control process, further shipments of PC SPES may not be immediately available,” the letter said.

Wilson, the state health department scientist, said state investigators visited BotanicLabs’ Brea facility after receiving a report from a Southern California district attorney who had been fielding complaints of adverse effects from constituents who had taken PC SPES.

He said the reactions reported were consistent with those experienced by men

who have been exposed to an estrogen product—swollen breasts, tender nipples, erectile dysfunction and lower sex drive.

Lea Brooks, a spokeswoman for the state health department, said officials there keep tabs on Web sites and chat rooms where dietary supplements are discussed. Officials became aware of persistent reports of DES contamination through consumers who had ordered laboratory tests and reported the results on the Internet.

“We went looking for DES in PC SPES, and we didn’t find it,” he said, explaining that the state’s tests may not have been sufficiently sensitive to detect the small quantities—3% or less—that UCSF detected.

#### Study Discovered Taint—and Benefit

The discovery of Xanax in SPES came by accident. Wilson said the department did not originally intend to test SPES but took samples along with PC SPES to the lab. Xanax was detected when the product was given a conventional test for prescription drugs.

The state also detected warfarin, or Coumadin, in PC SPES. Although BotanicLab officials suggested that the warfarin may have been naturally present in some of the herbs it uses, Wilson said state scientists were confident that it was a synthetic version of the drug.

The state health department and the manufacturer recommended that users of the supplements immediately halt their use. However, medical experts said this could lead to complications for the users of SPES, since drugs like Xanax are somewhat addictive and abruptly ending their use could result in withdrawal symptoms if usage had been heavy and prolonged. Because dietary supplements are generally not taken under the supervision of a doctor, doses and duration of use are often not carefully controlled.

A research assistant for UCSF researcher Small confirmed Friday that letters had recently been sent to study participants advising them that small amounts of DES had been discovered in the pills they were being given.

“Because of ongoing concerns about the contents of PC SPES, we recently decided to test each of the lots provided to us for the study by BotanicLab. We tested samples from all four lots used in the study. The laboratory tests revealed that each of the lots tested had small amounts of DES present,” the letter states.

The letter did have some good news for the cancer patients enrolled in the study: Preliminary data suggest that 45% of patients treated initially with PC SPES have had a 50% or greater reduction in their prostate-specific antigen levels, considered a marker for prostate cancer.

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