



PROSTATE CANCER HOT SHEET

Us Too! INTERNATIONAL **APRIL 2002**

DES CAN PREVENT ADVERSE BONE EFFECTS OF PCA THERAPY

<http://www.medscape.com/viewarticle/429392>

NEW YORK (Reuters Health) Mar 01 - The estrogenic agent diethylstilbestrol (DES) can provide an antiandrogenic effect in the treatment of prostate cancer without the rapid bone turnover associated with conventional androgen deprivation therapies, according to a report in the Feb. issue of *The Journal of Urology*

In their introduction the authors note that, currently, the most commonly employed androgen deprivation agents are luteinizing hormone releasing hormone (LHRH) agonists and non-steroidal antiandrogens. However, because their use has been tied to osteoporosis, interest in estrogen therapy, a much older treatment method, has been renewed.

Dr. Douglas Scherr and colleagues, from Cornell Medical Center in New York, evaluated bone turnover in 54 men with localized prostate cancer and in 24 men with benign prostatic hyperplasia (BPH). Of the men with cancer, 20 underwent radiation alone, 20 received 1-mg/day DES monotherapy, and 14 received DES in addition to an LHRH agonist or after undergoing orchiectomy. None of the men with BPH received hormonal therapy.

Urinary levels of collagen type I N-telopeptides, a marker for bone turnover, were determined at 3 separate monthly visits. Men who received DES had similar levels of N-telopeptide as men with BPH, and significantly lower levels than men who received androgen deprivation therapy without DES ($p < 0.05$).

Furthermore, mean testosterone levels
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PROLIFERATION OF DISCOUNT PLANS FURTHER MUDDLES PRESCRIPTION COSTS

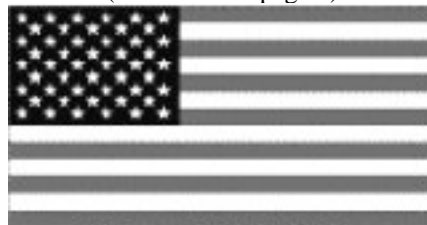
*Abstracted from: Washington Post
March 10, 2002*

Say you have high cholesterol and your doctor gives you a prescription for Lipitor, the widely advertised drug made by Pfizer Inc. Say you don't have a health insurance policy that covers prescription drugs. (You're not alone: Millions of Americans don't.) Say you walked into the CVS pharmacy on Dupont Circle one morning last week and asked for a month's supply of Lipitor (10-milligram tablets). The price to fill your prescription?

How about \$78.99? Or \$63.92. Or \$62.77. Or \$15. Same drug. Same day. Same store. But markedly different prices. The multiple prices for Lipitor and thousands of other medications are the result of a rapidly growing health-care phenomenon: the drug discount card.

The cards are a direct response to a host of things: the rising price of prescription drugs, the increasing amount of money Americans spend on medications, competition among pharmaceutical makers, the large number of people without coverage and threats by Congress to control drug manufacturers' prices.

There are hundreds of these cards on the
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**UNITED WE STAND
September 11, 2001**

HOW TO MAKE YOUR OPINION KNOWN ON PC SPES

As you undoubtedly are aware, on February 8th the California Department of Health Services (CDHS) recommended a recall of PC SPES.

The recall recommendation was based upon the discovery of what was identified as trace amounts of the chemical Warfarin, a synthetic blood thinner, in some samples tested. Since herbal supplements cannot contain prescription drugs, the CDHS had no recourse but to recommend a recall. BotanicLab ceased distribution of the product and has initiated a voluntary recall of PC SPES.

Since that time we have been contacted by many men struggling to survive prostate cancer who feel they have been helped by PC SPES and want to know what they can do to ensure availability of the product.

BotanicLab is currently exploring the possibility that the trace compound found in the PC SPES samples is actually naturally occurring coumarin, the compound which the prescription drug Warfarin is manufactured to mimic. According to statements from BotanicLab, coumarin is found in nature and is an incidental adjunct to the herbs in PC SPES (see the BotanicLab website www.botaniclab.com). Highly sensitive testing is required, and currently underway, before a

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PROSTATE CANCER NEWS YOU CAN USE

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FDA APPROVES NOVARTIS' ZOMETA FOR TREATMENT OF CANCER-RELATED BONE COMPLICATIONS

M2 Communications - February 26, 2002

Novartis AG has won expanded approval from the US Food and Drug Administration (FDA) for its Zometa cancer drug. The FDA panel found that Zometa is an effective treatment for patients with bone complications associated with several different types of cancer. Novartis' supplemental New Drug Application for Zometa included data from clinical trials involving more than 3,000 patients with multiple myeloma, breast cancer, prostate cancer, lung cancer and other solid tumors. The drug is already approved for the treatment of tumor-induced hypercalcemia, abnormally high levels of calcium in the blood. The drug has now been approved for the treatment of complications that arise when solid cancer tumours, such as prostate cancer, lung cancer and breast cancer, spread to the bone. The treatment must be carried out in conjunction with standard therapies.

LAPAROSCOPIC PELVIC LYMPHADENECTOMY JUSTIFIED IN SELECT PATIENTS WITH LOCALLY ADVANCED P Ca

FaxWatch Inc. - February 28, 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.

VARDENAFIL IMPROVES ERECTILE FUNCTION AFTER PROSTATE SURGERY, STUDY SHOWS

FaxWatch Inc. - February 26, 2002

In the first clinical study of its kind examining the use of drug therapy to improve erectile function in men who had undergone nerve-sparing radical prostatectomy, patients taking vardenafil reported statistically significant improvement in erectile function. Among men who had undergone bilateral nerve-sparing surgery, 71 percent of those taking vardenafil 20 mg experienced improved function. Approximately one-half of men who had erectile dysfunction associated with radical prostatectomy reported

successful penetration after being treated with vardenafil, according to the study. In addition, a four-fold increase in the ability to maintain an erection was observed in vardenafil-treated patients as compared with placebo. The data were presented in Birmingham, England, at the 17th Annual Congress of the European Association of Urology.

FDA GRANTS PRIORITY REVIEW STATUS TO BICALUTAMID

FaxWatch Inc. March 05, 2002

The Food and Drug Administration assigned priority review status to a 150-mg dose of AstraZeneca Plc's bicalutamide (Casodex) for the treatment of early stage non-metastatic prostate cancer. The supplemental New Drug Application was based on trials that demonstrated bicalutamide 150 mg reduced the risk of tumor progression by 50% as well as lowered the risk of bone metastase development by more than 30%. A 50-mg version of the drug is already available. Bicalutamide has already been approved in 12 other countries.

USING ULTRASOUND TO KILL PROSTATE CANCER CELLS

Medinews.com February 21, 2002

A phase I clinical trial is investigating the efficiency and safety of using high intensity focused ultrasound (HIFU) to destroy prostate cancer cells. In the minimally invasive procedure, doctors use 3-D ultrasound technology to locate cancerous cells. They then use HIFU to elevate tissue temperatures to 70-90° C in durations of up to four seconds, killing the cancer without damaging the tissue surrounding the prostate. The procedure can usually be completed within three hours, and the patient can go home after the anesthetic wears off. Candidates for the procedure are between 40 and 80 years of age, have confined prostate cancer, no bleeding disorder, and a prostate specific antigen (PSA) level of 10 or less. Patients who have failed previous external radiation for prostate cancer are also potential candidates notes Michael Koch, M.D., principal investigator of the trial and chairman of the department of urology at the Indiana University School of Medicine (Indianapolis, IN, USA), one of the two approved trial sites

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MODERATE DOSES OF SUNSHINE CAN HELP FIGHT CANCER

The Independent - London Feb 16, 2002

A modest amount of sunlight may protect against cancer, according to scientists who have found a link between sunshine and a substance produced naturally in the body which may lower the risk of developing tumours in later life. Michael Holick, Professor of Medicine at Boston University School of Medicine, has identified a critical enzyme involved in the production of vitamin D in the skin that appears to protect against colon, breast and prostate cancer. These findings may explain why the chances of dying of colon, breast and prostate cancer are greater for people living in colder, northern climates, who are less able to produce enough quantities of vitamin D because of a lack of year-round sunshine, he said.

CLUSTERIN LEVELS ENHANCED IN PROSTATE CANCER CELL FOLLOWING ANDROGEN WITHDRAWAL THERAPY
FaxWatch Inc. - February 18, 2002

Clusterin expression is significantly enhanced in prostate cancer cells following neoadjuvant hormone therapy (NHT), new research found. "Systemic administration of antisense clusterin oligonucleotides in prostate cancer xenograft models delays progression to [androgen independence] and enhances chemosensitivity," the investigators noted. . . . "These findings support clusterin as a valid therapeutic target in strategies employing novel multimodality therapy for advanced prostate cancer," the authors wrote. (July L, et al. Prostate 2002; 50:179-88.)

A TOMATO A DAY . . .

Nutrition Action Health Letter - March 01, 2002

When researchers fed one serving of pasta with tomato sauce every day for three weeks to 32 men who were scheduled for prostate surgery, levels of PSA (prostate-specific antigen) in the patients dropped by 20 percent. Since PSA is a measure of prostate cancer cell activity, lower levels mean a better prognosis. When their prostate tissues were later examined, the 32 tomato-sauce-eaters also had less DNA damage than the seven similar men who went sauce-less. Other studies suggest that

lycopene, a carotenoid and antioxidant, is the phytochemical in tomatoes that protects the prostate. (Lycopene is easier to absorb if the tomatoes are cooked.)

What to do: Although it's too early to say that tomato sauce can prevent or slow the growth of prostate cancer, men who have the disease should shoot for one serving a day. Healthy men should also consider eating tomato sauce more often. In other studies, men who ate tomato sauce two to four times a week had a lower risk of prostate cancer than men who ate it less often. Source: Journal of the National Cancer Institute 93: 1872, 2001

CONTRAST AGENT IMPROVES SOME ASPECTS OF VISUALIZING TUMOR VASCULARITY

NewsRx.com - February 28, 2002

Contrast-enhanced ultrasound can improve visualization of tumor vessels unseen in images where contrast agent is not used, but it is not necessarily able to depict actual patterns of vascular growth, Harvard Medical School researchers report. Irina Iordanescu and colleagues in the Departments of Radiology and Surgery at Harvard used a murine model of prostate cancer to examine the extent to which contrast-enhanced color Doppler ultrasound would correlate with histological evaluations when mice were treated with antiangiogenic gene therapy. The enhanced images improved on diagnostic indices in some areas, but failed to demonstrate any correlation with pathological findings in others.

STUDY REFUTES CLAIMS OF MORBIDITY FROM ASYMPTOMATIC PSA SCREENING
Health Media Ltd - March 07, 2002

Population-based PSA screening and prostate biopsy could be introduced without causing unnecessary physical or psychological morbidity, researchers have concluded. Their study revealed that healthy men screened for prostate cancer do not suffer any more psychological or physical stress on biopsy than symptomatic men. Lead author Mathias Winkler, urology registrar at the Lister Hospital, Stevenage, said the results were reassuring but PSA screening would only be justified if a large study found it improved mortality from prostate cancer. The NHS Cancer Plan promised a national screening programme when

screening and treatment techniques have "developed sufficiently". (Pulse 04/03/02; p.12)

HYPERMETHYLATION IMPAIRS FUNCTION OF PROSTATE HORMONE THERAPY
Health Media Ltd - March 07, 2002

Late-stage prostate cancer is unresponsive to hormone therapy because the cells have shut down genes for the oestrogen receptors where the drugs act, in a process called hypermethylation. Dr Raj Dahiya and colleagues at the San Francisco Veterans Affairs Medical Center showed that normal prostate cells were free of methylation at oestrogen receptor genes and displayed plenty of oestrogen receptors. In comparison, cells from late-stage prostate cancer had hypermethylation on their oestrogen receptors and the cells displayed no oestrogen receptors. "This hypermethylation explains why we see inactivation of oestrogen receptors in prostate cancer and why hormone therapy no longer works in many cases," said Dr Dahiya. He explained that cells from an early-stage prostate cancer have some methylation, which leads to intermediate activity and the generation of relatively few oestrogen receptors. The team studied tissue taken from 38 prostate cancer patients. Based on their findings, the researchers are hopeful that they can find a way to reverse the methylation. "People are testing de-methylating agents in clinical trials for several other cancers," explained Dr Dahiya. "In prostate cancer, we could inject these drugs directly into the prostate and that might restore the lost effectiveness of hormonal therapy." Reference: Dahiya et al, Journal of the National Cancer Institute 2002;94:384-390

CANCER ANSWERS 'IN A DROP OF BLOOD'

World Entertainment News Network March 08, 2002

Cancer could one day be diagnosed just by testing a drop of a patient's blood or urine, scientists suggest. The simple test could even indicate what type of cancer a patient has, and whether it is treatable. The test, developed by Epigenomics of Berlin, distinguishes normal DNA from that of cancerous cells by detecting whether

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PCA NEWS YOU CAN USE

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particular genes have been switched on or off by the removal or addition of a DNA "tag" called methyl groups. In cancer cells, this methylation process can turn off protective tumour suppresser genes, while cancer-promoting genes called oncogenes become more active if methyl groups are stripped off. Epigenomics has designed "biochips" that can pick up changes in these genes to see if the DNA is methylated or not. They were also able to distinguish prostate cancers from harmless growths called benign prostate hyperplasia. They suggest that checks could be carried out on blood or other bodily fluids because fragments of DNA from cancerous cells are detectable in them. Source: New Scientist magazine

SLING SURGERY EFFECTIVE TREATMENT FOR MALE URINARY INCONTINENCE

FaxWatch Inc. - March 05, 2002

Minimally invasive male sling procedure "appears to be a safe, efficacious, and cost-effective surgical treatment for stress incontinence," preliminary data indicated. Dr. Craig Comiter of the University of Arizona Health Science Center and the Southern Arizona Veteran's Administration Healthcare Center assessed the outcomes of 21 men with incontinence who underwent the sling procedure. The mean follow-up period was 12 months. Sixteen patients (76%) were completely cured by the procedure, 3 (14%) reported substantial improvement, 1 (5%) reported the problem was somewhat improved, and the procedure failed in 1 patient (5%).

MORE THAN HALF OF CALIFORNIA MEN FAIL TO TAKE THEIR PROSTATE HEALTH SERIOUSLY, NEW SURVEY REVEALS

PR Newswire March 05, 2002

Do you know what your prostate does? Have you had your prostate checked lately? Talked to your doctor about what you need to do to keep your prostate healthy? Probably not if you're like many American men. In fact, more than half (52 percent) of men in California are not very or not at all concerned with their prostate health, compared with 46 percent of American men overall, according to a national survey released today by Food-

Nutrition Inc. and conducted by Harris Interactive(SM). But if men do not start making their prostate health a priority now, they could face potential health risks later. Nearly three million American men experience prostate concerns(1), often because they ignore the warning signs until it is too late. And, poor prostate function can lead to urinary tract concerns and other health issues. However, 26 percent of California men surveyed could not identify any of the signs associated with prostate concerns, compared with 22 percent nationally. Not only are men in the dark about which signs are linked to prostate health, they are not seeking information about the issue either. Only one-third of California men surveyed have talked to their doctor about their prostate health.

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

FaxWatch Inc. - February 28, 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 PCa Study Group.

NORTHWEST BIOTHERAPEUTICS' PHASE I/II PCA TREATMENT STABILIZES THE DISEASE IN 55% OF PATIENTS

DataMonitor Healthcare Newswire March 05, 2002

Of the 29 patients in the trial 10 of these patients with rising PSA values following hormone therapy did not have measurable metastatic disease at the time of treatment initiation. All 10 were stable at the conclusion of the trial as measured by radiographic criteria at weeks 23 and 28. ALSO: Northwest Biotherapeutics Presented New Phase I/II Clinical Data on promising late stage prostate cancer clinical evaluation of its dendritic cell-based immunotherapy, DCVax-Prostate. The data was presented at the invitation only, Fourth Walker's Cay Colloquium on

Cancer Vaccines and Immunology sponsored by the Albert B. Sabin Vaccine Institute.

FDA APPROVES LEUPROLIDE PROSTATE CANCER THERAPY

FaxWatch Inc. March 08, 2002

Atrix Laboratories Inc. received approval from the Food and Drug Administration to market leuprolide (Eligard) 7.5 mg for the treatment of advanced prostate cancer. Eligard, which was formerly known as Leuprogel One-month Depot, will be marketed in the United States by Sanofi-Synthelabo Inc. The drug is injected subcutaneously and releases its active ingredient during a 1-month period. In September, Atrix submitted a New Drug Application for a 3-month formulation of leuprolide and anticipates filing for approval of a 4-month version of the drug in the first half of this year.

'MIRACLE' MUSSEL CANCER CURE A DUD - RESEARCH STOPS

The Evening Post - March 09, 2002

Trials of a supposed "miracle cure" for cancer found in New Zealand green-lipped mussels, which caused near hysteria in the country in 1999, have been stopped.

ALP FLARE POST-ORCHIECTOMY COULD IDENTIFY PATIENTS MOST LIKELY TO BENEFIT FROM EARLY CHEMOTHERAPY

FaxWatch Inc. March 08, 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. "A flare in ALP activity [post-orchietomy] has been shown to be of negative prognostic value for progression-free survival in patients with prostate cancer," the researchers wrote. (Pelger R, et al. Prostate 2002;50:119-24.)

MEN WITH FAMILY HISTORY OF PROSTATE CANCER MORE LIKELY TO HAVE PCA AT YOUNGER AGE

FaxWatch Inc. - March 07, 2002

Men with a father affected by prostate cancer are more likely to have a diagnosis of prostate cancer at an earlier age,

according to new research. Using a self-administered questionnaire that assessed age at diagnosis, ethnicity, family history of prostate cancer and first indication of potential prostate cancer, researchers analyzed 952 men with prostate cancer. The study showed that men with a family history of prostate cancer received a diagnosis of prostate cancer at an earlier average age than those who didn't have a family history.

CERTAIN HRQOL DOMAINS MAY BE LESS FAVORABLE WITH PROSTATE BRACHYTHERAPY THAN EXTERNAL-BEAM RADIATION, RADICAL PROSTATECTOMY

FaxWatch Inc. - March 08, 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." "HRQOL concerns are pivotal in choosing prostate cancer therapy," investigators wrote. "However, concurrent HRQOL comparison between brachytherapy, external radiation, radical prostatectomy, and controls is hitherto lacking."

CHROMOGRANIN A ELEVATED IN PATIENTS WITH HIGH GRADE PROSTATE CANCER; CAN BE A SERUM MARKER WITH PSA

FaxWatch Inc. March 12, 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.)

CRYOSURGERY GAINS PROMINENCE AMID GROWING CONCERNS REGARDING 30 PERCENT FAILURE RATE OF RADIATION PATIENTS-TREATMENT HIGHLIGHTED IN PEER-REVIEWED JOURNAL ARTICLES

PR Newswire - March 11, 2002

Endocare Inc., a developer of innovative diagnostic and treatment tools for cancer and other diseases, announced today that recent peer-reviewed articles written by four of the world's leading urologists demonstrate that the number of recurrent cancer patients is expected to increase because of the increasing utilization of radiation therapy, especially brachytherapy. "Radiation Therapy in Prostate Cancer: Risk Factors and Methods of Detection" in Reviews in Urology by Dr. Michael K. Brawer of Seattle's Northwest Prostate Institute

KARO BIO RECEIVES AWARD FOR PROSTATE CANCER RESEARCH

M2 Communications March 12, 2002

Karo Bio AB has received a three-year award from the U.S. Army for research into prostate cancer. The grant will be used by Karo Bio USA Inc. Karo Bio's US-based unit, to define the relationship of androgen receptor function to prostate cancer. Karo Bio believes the research will be important both for its drug discovery program and for regulatory agencies involved in the fields of prostate cancer therapy and prevention.

STUDY FOUND NO ASSOCIATION OF PERCENT FREE PSA WITH OUTCOME AFTER RADICAL PROSTATECTOMY

FaxWatch Inc. March 12, 2002

"Percent free PSA is not an independent predictor of organ confinement or PSA recurrence in unscreened patients with localized prostate cancer treated with radical prostatectomy," new research found. "[T]he predictive accuracy of statistical models using clinical stage, pretreatment PSA, and biopsy Gleason sum were not improved by adding percent free PSA," the authors wrote. "This observation questions the usefulness of percent free PSA beyond its role in the detection of prostate cancer." (Graefen M, et al. J Urol 2002;167:1306-9.)

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

FaxWatch Inc. March 12, 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.)

MEN WITH CLINICAL STAGE T1c PROSTATE CANCER HAVE SIMILAR OUTCOMES REGARDLESS OF RACE

FaxWatch Inc. March 12, 2002

Black and white men with clinical stage T1c prostate cancer undergoing radical prostatectomy (RP) have similar clinical and pathologic findings, a study found. "These results suggest that early-detection programs using serum PSA testing for prostate cancer in black men potentially can result in improvements in prostate cancer outcomes in the high-risk group," the authors wrote. (Eastham J, et al. Prostate 2002;50:236-40.) The authors said race should not be used as a factor in recommending treatment for clinical localized prostate cancer. "Patients with similar clinical staging parameters will fair equally well with radical prostatectomy regardless of race," lead author Dr. James Eastham of the Memorial Sloan-Kettering Cancer Center Told FaxWatch.

ASPIRIN LINKED TO PCA DROP

United Press Int'l - March 13, 2002

A Mayo Clinic study suggests that regular use of aspirin, ibuprofen and other nonsteroidal anti-inflammatory drugs (NSAIDs) may help protect against prostate cancer. The study found that men age 60 and older who used NSAIDs daily reduced their risk of prostate cancer by as

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PCA NEWS YOU CAN USE

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much as 60 percent. The study also suggested that the beneficial effect may increase with age. The findings are published in the March issue of Mayo Clinic Proceedings. The 1,362 Caucasian men were followed for an average of five and one-half years. Of the 569 men who reported using NSAIDs daily, 23 developed prostate cancer, compared with 68 of 793 men in the same study who did not use NSAIDs daily and developed the disease. "These numbers mean the proportion of men who used NSAIDs daily and developed prostate cancer was about one-half that of men who did not use NSAIDs daily — four percent compared to nine percent," says Dr. Rosebud Roberts, a Mayo Clinic epidemiologist. "Men should follow their doctor's advice on this, because there are also negative side effects of NSAIDs that

need to be considered and monitored in people who take them on a daily basis."

CAUTION NEEDED IN HERBAL MEDICINE

*The Record, Bergen County, NJ -
March 14, 2002*

To many physicians, the most alarming thing about the rise of alternative medicine is their own ignorance. They are ignorant about the treatments or herbs their patients use because most patients don't tell them. And they're often ignorant about what those treatments and supplements do as well as potential interactions and side effects when patients do tell them. The consequences can be dangerous: Garlic, ginkgo, and vitamin E exaggerate the effects of anticoagulants. St. John's wort inactivates the protease inhibitors used to treat AIDS. Ginkgo, St. John's wort, and kava can make anesthetics last longer. Be sure to inform your physician about any vitamins and supplements you are taking.

VOICE YOUR OPINION ON PC SPES

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complete understanding of the true nature of this compound is known.

Patients who rely on PC SPES want it to be available now - but there are obstacles to overcome.

The current CDHS action could hold up distribution of PC SPES until the agency is satisfied that the product contains absolutely nothing that could be considered to have a potentially harmful effect on anyone taking the product.

The CDHS position also invites legal actions that could keep this product hostage in the courts for a long time...and possibly keep PC SPES from survivors indefinitely – or even permanently.

In either case, it is the PC SPES users and those who are counting on this product as their last hope, who stand to lose.

The CDHS action effectively places the treatment options for some men living with prostate cancer in limbo. If you care about access to PC SPES, you must speak out now.

The Food and Drug Administration (FDA), the federal agency responsible for oversight of drugs in the United States, has taken no action against PC SPES. Only the CDHS has recommended any action - which prompted the voluntary recall by BotanicLab.

The CDHS and FDA must be made aware of the extreme seriousness of the current situation and the frustration many survivors feel about their inability to obtain PC SPES.

PC SPES users and their families are the only people who can help CDHS understand the serious, unintended consequences of its recommendation. It is possible for the government to meet its responsibility to protect the public without doing irreparable harm to

PC SPES LAWSUIT FILED
CLASS ACTION STATUS BEING SOUGHT

In addition to the regulatory investigations, BotanicLab now faces two lawsuits that could obtain class action status. The lawsuits were filed in Los Angeles Superior Court – Central District on February 7, 2002.

If the court rules that the lawsuit can proceed with class action status, additional members of that class will be solicited to join the lawsuit. The required number to gain class action status is not known. This decision will be made by the Judge in charge of the case.

It is important that you understand the repercussions to you and your fellow survivors by joining this class action lawsuit. If enough members join the class, the class will be certified.

BotanicLab is a very small company. If faced with the potentially large legal fees required to defend itself in such a case the company could conceivably be unable to continue in business and could be forced into bankruptcy. As a result, PC SPES would cease to exist and would be forever unavailable.

If the company is financially able to defend itself against the case and for whatever reason loses, PC SPES would no longer be available to you or future patients - regardless of your need or desire to make an informed decision to use the product.

If you or a man you know depends on PC SPES, joining this class action lawsuit may not be in your best interest. At best defending against a lawsuit would likely make PC SPES unavailable throughout the litigation, and could result in it becoming permanently withdrawn from production.

In order to preserve the PC SPES treatment option for you, your fellow men living with prostate cancer and future men in need we urge you to seriously consider the consequences of these lawsuits before joining any class action lawsuit.

The decision is yours.

thousands of prostate cancer patients who have come to rely on this product.

Your fundamental right to have *informed access* to life-sustaining treatment is the *only* issue. Many men living with prostate cancer have told us that their life and the lives of others depend on continuing to make this product available. If you feel this way you need to act so as not to allow anyone to take that right away from you.

Write a letter of testimony and send it today.

Your letter should:

- Be accurate, honest, personal, and reasonably detailed.
- Speak passionately and describe your true feelings about PC SPES.
- Give your history in words that non-medical people can understand.
- Include treatments you have tried and your reasons for turning to PC SPES.
- State clearly what you believe PC SPES has done for *you*.
- And, if you believe this, make it *very* clear that nothing but PC SPES is likely to hold your cancer in check at this point in your treatment history.

In order for it to be considered, your letter must be signed with your name and address (and telephone number and e-mail as appropriate) printed below your signature.

A list of CDHS staff and other public officials who will be interested in what you have to say is provided below. There is also a sample statement you can use as a guide when writing your letter(s).

If you want continued access to PC SPES, you need to get involved and make your opinion known today.

Sincerely

Us Too! INTERNATIONAL
Board of Directors

Sample Letter

Dear _____ ;

I am writing to make you aware of the unintended but most serious consequences of the California Department of Health Services warning about PC SPES.

Many men have for years kept their prostate cancer in check *primarily* through the use of PC SPES. Many of us have exhausted all other possible treatments and now have no other option for treatment. Without this product, we face an unchecked progression of our cancer and ultimate death.

For many others with a rising PSA, who are not presently on PC SPES, we should ensure that the hope this product may offer as a future treatment option is not taken away and that PC SPES remains available to them when needed. Furthermore, this action affects men throughout the USA, not just in California.

The consequences of having no access to PC SPES greatly overshadows any possible risk posed by low amounts of Warfarin.

Please recommend that the California Department of Health Services immediately issue a formal recognition, that, at the very least, *for those men currently using PC SPES* the supply must remain uninterrupted, so long as its users are *informed* of the risk of adulteration and who choose to continue its use *at their own risk*.

In order for it to be considered, your letter must be signed with your name and address (and telephone number and e-mail as appropriate) printed below your signature.

Your Elected Officials

The names, addresses, fax and e-mail addresses of your elected officials are all available on the Us Too! website by simply entering your zipcode:

<http://www.ustoo.org/advocacy.html>

Send your statement to:

- **Senator Robert Dole**
c/o Verner, Lipfert, Bernhard, McPherson and Hand
901 15th Street, N.W.
Washington, DC 20005-2301
Phone: 202-371-6007
Fax: 202-371-6262
<http://www.bobdole.org/contact.html>
- **Mr. James Waddell**
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- **Glen Lawrence**
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- **Representative Dan Burton**
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- **Janet Woodcock, M.D.,**
Director
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PRESCRIPTION DRUG CARDS

(continued from P. 1)

market, none of them regulated. Many are designed for the uninsured, or those whose health plan doesn't include prescription coverage. Some target Medicare patients. Some cards have monthly fees. Some have age or income restrictions. Some require only name, address and credit card number. Not all cards cover all drugs. Not all pharmacies accept all cards. And the cards only rarely deliver the "up to 65 percent" or greater savings that some advertise.

Many of the biggest discounts are available only for certain medications at certain pharmacies in certain cities on certain days. And because prices can change every day, patients rarely have the information they need to decide, up front, whether a card is worth the trouble — or, in some cases, the monthly fee. What's more, some discount-card companies are charging fees to provide savings that other cards are offering free. While some drug discount cards are available to all, most target elderly and disabled Medicare recipients who don't have insurance for prescription drugs.

Enter the drug cards offered by retailers such as CVS, associations such as AARP, insurers such as Trigon and start-ups such as Pinnacle Choice of Fairfield, N.J. And now a new breed has entered the discount-card business: the pharmaceutical

manufacturers themselves. Novartis and GlaxoSmithKline were first with cards, issued free, each giving lower-income Medicare participants discounts on medications manufactured by that company. Pfizer rolled out a card March 1, and Eli Lilly & Co. announcing a program that will begin April 1.

If the word on the consumer side is bewilderment, the word on the drugmaker side is competition. Discount cards issued by drug companies are a by-product of the situation manufacturers find themselves in today: Companies are fighting for market share, competing head to head with drugs that address the same complaints. Drug manufacturers are willing to sell their pills at one price to those on fixed incomes and at another to young, relatively healthy workers with prescription plans. Some pharmacists already lament that they're spending more time sorting out discounts and less time discussing medications — and their side effects — with customers.

Last summer, President Bush proposed a temporary fix — drug discount cards overseen by the government and operated by pharmacy benefit managers (PBMs) such as AdvancePCS. PBMs make money by negotiating rebates and discounts with pharmaceutical companies and by managing drug benefit and discount-card programs for themselves and others. The Bush plan drew a sharp rebuke from drugstore trade groups, in part

because PBMs steer customers to their own Internet and mail-order pharmacies.

On Capitol Hill, lawmakers are debating how to ease the burden of low-income Medicare patients. There's even talk in Congress about reining in the prices pharmaceutical companies charge. That's a chilling prospect to drugmakers. And patient advocates say that this, more than competition, is the major reason the four manufacturers rolled out their no-fee discount cards for low-income people.

While the debate continues, the ritual of Americans bringing discount cards to pharmacy counters will continue.

DES & BONE EFFECT

(continued from P. 1)

were 387 ng/dL in the BPH group and 340 ng/dL in the radiation group, but only 24 ng/dL in the men receiving DES alone and 11 ng/dL in those receiving DES with LHRH/orchiectomy.

The current findings indicate that "rapid bone turnover and resorption can be prevented with 1-mg DES alone or in conjunction with other modes of androgen deprivation," the investigators conclude, and they recommend DES monotherapy for men who need long-term antiandrogen therapy. "Osteoporosis is an unnecessary and potentially costly sequelae of androgen deprivation therapy that need not continue," they stated
SOURCE: J Urol 2002;167:535-538.

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