Prostate Cancer Support Association of New Mexico

LIFELINE

PCSA Quarterly Newsletter

January 2007 Volume 14, Issue 1

Issue Highlights

TIDBITS

Sip 5 cups of tea, stay germ free.

Non-tea drinkers who downed five-six cups of black tea for two weeks appeared better able to ward off illness, says a study in the Proceedings of the National Academy of Sciences. The tea and other varieties contain L-theanine, which breaks down into bacteria-fighting ethylamine in the liver.

New Law Allows Drug Importation
Drug Industry Daily,
5 October 2006

President Bush signed legislation on October 4, 2006 legalizing limited importation of prescription drugs from Canada, but a policy reversal by a federal agency could lead to even broader use of the practice.

Bush signed the fiscal 2007 Homeland Security Appropriations bill, which includes a provision prohibiting federal officials from stopping individuals from personally transporting prescription drugs across the Canadian border. The provision only applies to a "personal-use quantity," defined as less than a 90-day supply.

The move brought immediate criticism from the pharmaceutical industry. This new law is the "first step down a dark and dangerous road," leading to more counterfeit drugs entering the country, PhRMA Senior Vice President Ken Johnson said.

Meanwhile, the U.S. Customs and Border Protection (CBP) has gone a step further, deciding that it will no longer seize prescription drug shipments beginning Oct.9, the agency said in an Oct. 2 email. Instead the CBP will refer these shipments to the FDA for action, although it was not clear in the announcement what effect this would have on shipments.

The CBP reviewed its policy and determined a change was necessary, an agency spokeswoman said. Under the new policy, the CBP will only act if there is evidence that a drug is counterfeit. The agency will then send the product to the FDA for a final decision.

This represents broader importation than that allowed in the appropriations language. The bill only allows citizens to carry drugs with them across the border, while the CBP decision covers mailed shipments as well.

"This is a huge victory," Sen. Bill Nelson (D-Fla.) said in an Oct. 3 release. Nelson, who had been challenging the CBP seizure policy, said that more than 40,000 people have had their prescriptions seized since the agency first implemented this policy last November. "Senator Nelson believes the change in policy was due to the pressure exerted by the senator and the American public."

Basic errors made by doctors, including tests ordered too late, ended up harming patients, a study published in the Annals of Internal Medicine showed. Among 307 medical malpractice claims, 100 cases were failure to order appropriate diagnostic tests, and 81 were failure to follow up correctly. Nearly 60% of these cases resulted in serious harm and 30% resulted in death.

Coughing hard at the first sign of a heart attack could help save a patient's life by pushing blood through the body and to the brain, a Polish doctor said.

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CEO Joseph Nai

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In Memory of

Leo Bressan

With Deep Sympathy and Regret
We List These Names

PC SUPPORT GROUP MEETINGS

Support Meetings are usually held on the first and third Saturday of each month at 12:30 PM. We meet at the Bear Canyon Senior Center, located at 4645 Pitt NE (on Eubank go one block north from Montgomery - Right (East) on Lagrima De Oro - Left (North) on Pitt to Senior Center).

Please call ahead to verify time and dates.

PCSA *Lifeline*

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DISCLAIMERS

The PCSA of New Mexico gives medical information and support, not medical advice. Please contact your physician for all your

FIVE RECENT PUBLICATIONS ABOUT PCR Reviewed by Dr. Peter Lindberg

In a recent JAMA Journal Nov.15,2006, Ian Thompson along with many other PCa specialists (Edward Messing, David Crawford and other academic urologists) reported on a clinical trial of men who, after a radical prostatectomy, had a high risk of failure. Half of the 850 men received immediate radiation to the prostate bed. An equal number were just followed until signs of failure appeared. After 10 years, there is no difference in survival rate between the two groups. Of the men who received immediate radiation, 35% developed metastatic disease. The 43% who did not receive immediate radiation developed cancer spread or death - not a statistical difference. The study did show a longer time to PSA relapse, 10 versus 3 years, but no difference in chance of death. In the group who were observed until it became clear that surgery had failed, 63 required radiation. The side effects between the two groups were very significant; 3.3 % of rectal complications in the immediate radiation group versus 0% in the observed group, 17.8% versus 11.9% of urethral stricture, and 6.5% versus 2.8% of total incontinence or loss of urine control. I believe that the failure of the immediate radiation to improve survival is due the benefit of giving radiation when needed in the observation group. Also the equal survival rate is also due to the benefit of giving hormone therapy when surgery fails.

A.J. Stephenson, from Memorial Sloan Kettering in New York City, has published and recently presented at the June '06 American Society of Clinical Oncology meeting the results of Salvage Radiation for recurrent prostate cancer and the predictors of benefit of treatment. There were 868 patients who had a rising PSA above 0.2 and received radiation when it became clear the radical prostectomy had failed. At 5 years 38% of the treated patients were free of failure (PSA controlled). At 10 years only 19% were still failure-free. Predictors of radiation success include a PSA of below 1.0 when radiation started, a Gleason score of 7 or less, negative lymph nodes at time of surgery, and the presence of tumor at the surgical margins when the prostate was removed. A nomogram has been developed that can predict possibility of success of radiation.

Peeters and colleagues from the Netherlands reported in the Journal of Clinical Oncology a clinical trial of radiation therapy with patients receiving either 68 Gy or 78 Gy to the prostate. At 5 years 64% who got 78 Gy were free from failure, while in the lower dose group of 68 Gy only 54% were free from failure. More is better, especially in the higher risk groups. What is also striking is that at 5 years, 40 out of 669 patients had already died. In my practice, I have about 33 patients who were treated with the Bob Liebowitz hormone therapy of Lupron, Casodex and, Proscar for 13 months along with radiation and then lifetime Proscar. Only one man has died and all the rest remain with a stable PSA of less than 1.0. I have been doing this since 1998 but I do not think I have followed them for an average of 5 years.

An article in the American Journal of Hematology and Oncology asks the question, "Does age matter in selection of men with an early-stage PCa??" My urologic colleague in Los Alamos says I am crazy to recommend radiation therapy to a young man (under 55 or 60). I am certain most urologists here in New Mexico agree. At the Fox Chase Cancer Center in Philadelphia, Dr. Hanks and colleagues reviewed results in men younger than 55 who were treated with radiation for PCa between Nov. 1989 and Oct. 01. Results of treatment matched for disease severity were compared to men 60 to 70 and also 70+. With an average follow up of 40 months, about 90% of men in all age groups were free of PSA recurrence, ie. no sign of recurrent or persistant cancer. However this trial did not compare radiation to a radical prostatecomy. In a review done by Dr. Anthony D'Amico from Harvard, 7700 patients from 44 centers were matched and results of radiation to a radical prostatectomy were compared. Results were equal across all age groups over 60 years. For low and intermediate risk - excellent results, but a high rate of failure. If high intermediate or high risk patients and one had a single form of treatment, it was rarely adequate for a cure. Adding combined androgen blockade to radiation is proven to improve survival.

American Journal of Hematology/Oncology Sept 2006 discusses in an article from the Cleveland Clinic that the "PSA bounce", a rising PSA after brachytherapy. It can indicate treatment failure, but a PSA rise within the first two years after seed implant is very common. Up to 46% of men treated with seeds will have a bounce or rise. The Cleveland group recommends caution in starting any extra or new treatment in the first two years unless or until the PSA goes over the PSA value the patient had before the seeds were placed. PSA doubling time in the first two years is not helpful in deciding who has failed.

Iceland's Decode Genetics Inc.
Finds Prostate Cancer Risk Gene
By Reuters — May 8, 2006

Scientists at Iceland's Decode Genetics Inc. have identified a genetic variant that may account for about 8 percent of prostate cancers, marking a step forward in understanding the disease. Researchers at the biotech company and academic colleagues reported their findings in the online edition of Nature Genetics.

It is the first time that scientists have identified a major genetic risk factor for prostate cancer, the most common cancer in men within the general population.

One in five men of European ancestry with prostate cancer carry at least one copy of the variant, which confers an approximately 60 percent increased risk of the disease, the researchers said. The variant confers roughly the same increase in risk among African Americans, but it is twice as common.

"This discovery is important from a medical standpoint, because the only firmly established risk factors for the disease until now have been age, family history and ethnicity," said Decode Chief Executive Kari Stefansson. The variant appears to be associated with the development of more aggressive prostate tumors, so a diagnostic test for it may enable doctors to make more informed decisions about how closely they should monitor patients at high risk.

Decode, which specializes in using population studies to find the genetic basis of disease, plans to use the discovery to develop such a test.

AstraZeneca — Patient Assistance Program

Important information about increased access to medications for many patients without or with limited insurance coverage. As of November 2, AstraZeneca is announcing that they are increasing the income level for those who are eligible to participate in Out Patient Assistance Program. This is very exciting because individuals with incomes at 300% above the federal poverty index are now eligible for their medications at no cost. This means that a single person can earn up to $30,000/year and a family up to $60,000/year to qualify. The program changes go into effect on November 15, 2006.
For more information call 1-800-424-3727 or go to

Health Care Reform Proposals
Emerging in Other States
By Nandini Kuehn, PhD

Is Health Care going to be beyond the reach of most?
The Feds can't seem to put a Health Care Package together so a number of states are coming up with a product that they hope will work. The question is, what is New Mexico doing?

From **Health Action New Mexico News-Summer 2006**, Nandini Kuehn gives us some insight into what some states are up to.

Facing growing numbers of uninsured and high rates of uncompensated care at hospitals whose emergency rooms bear the brunt of providing care for the uninsured, many states have talked for years about how to address these problems. Eight states have conducted a number of studies, but concrete action has been slow.

More recently, however, mandated health care access reforms have suddenly emerged as a major force in restructuring state health care systems.
.
The Massachusetts Plan
First the state established a target of either subsidizing an expanded low-income group or providing affordable health insurance for all state residents. The state wants all residents to sign up for coverage by July of 2007. Although there are many critics of the plan. Moreover, this agreement was achieved in a bipartisan process that has put every other state on alert.

This proposal is a blend of incremental reform, i.e., augmented Medicaid to cover households earning up to 300% of the Federal Poverty Level (FPL), and employer mandated "pay or play". In addition, the state has proposed the development of a "Connector" who would negotiate "affordable" health insurance premiums that everyone not covered by an employee health plan will be mandated to purchase health insurance. Those who choose not to purchase a health plan (either through their employer or through the Connector) will have a penalty assessed on their taxes. Employers who choose not to offer plans will be assessed a per-employee penalty.

Why did Massachusetts move at this time? First, it was in danger of losing a Medicaid waiver of almost $400 million unless it acted to expand health coverage.

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Digested from

New Molecular Tests Can Predict the Return of Prostate Cancer

Prostate Cancer Communication
Vol 22 No. 2 Sept 2006

Jason M. Alter, Ph.D.
Aureon Laboratories, Inc.

Earlier this year Aureon Laboratories released Prostate Px™, the first in a series of tests that predict prostate cancer recurrence. The test stratifies patients into high or low-risk categories for the likelihood of experiencing a return of their prostate cancer after they have had their prostate surgically removed (prostatectomy).

Approximately 15-40% of patients who have had their prostate removed will develop a serum PSA or biochemical recurrence (BCR). Moreover, a man with prostate cancer who has had a PSA recurrence can still develop a metastasis some eight years post PSA/BCR suggesting that identifying this group of patients early in their treatment program is critical to their overall survival.

An accurate prognosis is important because the majority of tumors are indolent and require minimal intervention while a subset are more aggressive and early intervention may be valuable.

The Prostate Px test has two endpoints for cancer recurrence:

- PSA Recurrence Px Score describes the likelihood of the patient developing a PSA recurrence within five years of having their prostate removed.

- Disease Progression Px Score describes the likelihood of the patient developing Disease Progression defined as bone/soft tissue metastasis and/or androgen independent rise in PSA within five years of having their prostate removed.

Compared to existing methods, Prostate Px provides a very accurate prediction of PSA recurrence with a sensitivity of 96%. In addition, Prostate Px can predict disease progression and does so with a sensitivity of 89%.

Prostate Px benefits patients and physicians at a number of decision points after surgery. The predictive test can:

- Provide a probability of whether a patient, after a prostatectomy, will have a PSA recurrence within five years.
- Predict whether a patient, after a prostatectomy, will have disease progression within five years.
- Avoid possible side effects associated with therapy (e.g. androgen deprivation therapy) for asymptomatic low-risk patients.
- Identify patients with high-risk of clinical failure who may benefit from increased surveillance or early assisted therapy.
- Help relieve anxiety and allow patients, their families and their physicians to decide upon the best treatment regimen moving foward.
- Assist in patient selection for new therapies as part of randomized clinical trials.

The basis for the predictive power of Prostate Px is its unique breakthrough technology. Aureon's System Pathology platform combines histological, molecular and clinical information to predict cancer recurrence.

After prostatectomy, the physician orders Prostate Px and a small section of the prostate tissue sample is collected from the pathology department at the hospital where surgery was performed and sent to Aureon's specialized laboratory. Aureon's approach integrates:

- Histology (tissue): Prostate Px analyzes the cells and other structures in a prostate cancer tissue sample. This results in the generation of specific (quantitative) features for inclusion in the mathematical model.
- Molecular markers: Prostate Px selectively measures specific proteins in prostate tissue samples in order to obtain a unique molecular picture of the patient's prostate cancer.
- Clinical data: Prostate Px takes into account important clinical information such as the Gleason score and the pathology results from the patient's surgery.

By combining these sources of information and by applying advanced computer technology and mathematics, Prostate Px is able to provide patients a more thorough picture of their individual risk for recurrent disease.

Prostate Px is just the first in a new generation of predictive tests from Aureon that combines the power of advanced mathematics with biology and clinical practice.

Drugs Used to Treat BPH May Also Prevent Prostate Cancer

By
Diane Johnson
Condensed from "In The Know"
July 2006 Issue

New evidence shows that doxazosin and terazosin (alpha-blockers), currently being used for the treatment of BPH (Benign Prostatic Hyperplasia) and hypertension, may also decrease the risk of developing prostate cancer. In addition, they may prevent the progression to advanced prostate disease if the PSA begins to rise after initial treatment.

The study was conducted at the University of Kentucky Medical Center by a research team led by Natasha Kyprianou, MD, PhD, Professor of Urologic Surgery and Director of Urologic Research at the Markey Cancer Center. Doxazosin (brand name: Cardura) and terazosin (brand name: Hytrin) are widely used for the treatment of the various obstructive symptoms of BPH (enlarged prostate, difficult or painful urination, etc.). They work by relaxing the muscles of the bladder and prostate. Growing evidence suggests that these drugs have additional effects such as targeting prostate growth by inducing cell death (apoptosis) and reducing tissue vascularity (angiogenesis) in both the benign and the malignant prostate.

The researchers analyzed the medical records of over 27,000 male patients from the Lexington Veterans Administration Medical Center in Kentucky who were treated with these blockers for either hypertension or BPH between 1998 and 2002. These data were then linked with prostate cancer diagnoses found in the Kentucky Cancer Registry, a National Cancer Institute's central cancer registry. Dr. Kyprianou and her colleagues found that men who took the blockers had a 40% lower risk of developing prostate cancer than men who did not receive those drugs.

Longer term, prospective, randomized trials are needed to test doxazosin and terazosin before they can be recommended for use as prostate cancer chemopreventive agents. "I recognize that this initial retrospective study has certain limitations," says Dr. Kyprianou.

High Dose Testosterone Replacement Therapy (TRT) and Prostate Cancer (CaP) Part 1

Robert L. Leibowitz, M.D.
Compassionate Oncology Medical Group
From PAACT Vol. 22 #2 Sept 2006

A number of men have come into the office asking me about this new idea of increasing the testosterone levels. Read what Dr. Leibowitz has to say and then check out his website. He is a much better source than I.

In 1941, Huggins and Hodges reported that removing the testicles in men with metastatic prostate cancer resulted in a remission for more than 80% of them. Unfortunately remissions only lasted an average of about 18 months.

Since removing testosterone (T) initially controlled metastatic CaP, it is most logical to assume that giving T to a man with CaP would be like pouring gasoline on a fire. This is what 99.9% + of all doctors believe. The package inserts for all TRT products state that "testosterone is contra-indicated for all men with CaP." This implies that T will markedly stimulate CaP cells to grow, spread and hasten death.

Because of space limitations in this PAACT edition, readers are urged to log onto our website www.compassionateoncology.org where you will find the complete text I have written on Testosterone Replacement Therapy along with the medical references that support my beliefs, insights and opinions. This paper and all of my papers may be downloaded at no charge from our website, under Publications. I urge everyone to please read the full text on TRT before trying to determine if you could ever consider TRT.

I cannot overemphasize that this paper should not be brought to your doctor along with a request for a testosterone prescription. Testosterone is contraindicated in men with prostate cancer. It has caused the death of some patients (fortunately, no one in my practice), permanent paralysis, increased bone pain, and new metastases. I do not recommend use of T for anyone with prostate cancer.

Be Happy, Be Well, Live Long and Prosper,

Dr. BOB

(continued from page 4)

Second, their uninsured population is significantly lower than New Mexico's and therefore easier to accommodate. Finally, they had a substantial "uncompensated care" pool which will be used to offer the subsidies.

There is an assumption that "affordable" health care with comprehensive coverage can be provided for those above 300% FPL even though no actual examples are provided. At current premium levels, a family with two children and a total income of $60,000 will have to pay $11,000/ year for coverage if their employer does not provide coverage. That translates to around $916 each month for that family. The plan allows them to do this with pre-tax dollars-an obvious advantage-but there is some skepticism that most families will be able to afford this without substantial governmental subsidies. Critics also fear that any low-premium plans will not have comprehensive benefits or will have high co-pays.

Employer penalties are extremely low and provide no incentive to take the plan seriously. In fact, there is no obvious language targeting employers who may choose to stop providing health insurance because the penalty is actually much lower than the cost of premiums.

Employees who cannot afford the $916/month tab and choose not to purchase coverage will face tax penalties. While the details of how much are being worked out, one estimate suggests around $1000/year. If this were the case, the penalty should be significantly lower than the cost of premiums, and individuals could choose to pay the annual tax penalty rather than the higher monthly premium cost.

No analysis of costs has been undertaken in Massachusetts and the plan's long-term feasibility will unfold as it is implemented (California just completed an analysis that claims it could cost their state 6 to 9 billion dollars to implement the Massachusetts plan). Conversely, there are no measures in the plan to control costs, eliminate administrative waste, reduce duplication, or reward good practices.

Two other states, Wisconsin and Vermont, are moving in a similar direction with recently passed legislation. The **Wisconsin Health Care Partnership Plan** is more along the pay or play model with a significant twist-all employer insurance would buy into a single negotiating pool modeled on the state's workers compensation plan; self employed and others could buy in at cost. The biggest advantage of this plan is that it seeks to eliminate plan duplication, creates substantial negotiating power and could reduce costs.

The **Vermont Catamount Plan** is more complex than Massachusetts' because it does seek to introduce several systemic improvements. For example, it will target cost-control in premiums and in quality of care for those with chronic diseases. It uses a blend of increased Medicaid-type coverage and a state-wide integrated health care delivery system to target quality and focus on reductions in the growth of premiums. The new health insurance would be offered through private insurance plans. All employers will be required to contribute toward health insurance premiums, and a tobacco tax is also proposed to help pay for additional costs. The goal is that 96% of all Vermonters who want health insurance will get it within five years.

The Governor of **Michigan** publicly announced in April her intention to bring universal health care to all residents by providing coverage for the 1.1 million uninsured in that state within the next five years. No legislation has yet been passed. Michigan UHCAN has been very active for many years, and has created alliances not only among advocacy groups but also among the business, medical and hospital communities to move in this direction.

Recently, Mayor Gavin Newsom of **San Francisco** announced a cooperative plan to provide health care to any adult resident, regardless of immigration or employement status. San Francisco already provides universal health coverage to all children. The Health Access Plan would provide preventative and catastrophic health care. The city estimates the plan would cost $200 million a year. The plan still needs to be approved by the city's Board of Supervisors and would cover the 82,000 uninsured.

(continued from page 5)

Aureon is in the final stages of development of **Prostate Px ™+**, a new predictive test for prostate cancer that will use biopsy tissue, at the time of diagnosis, and Aureon's system pathology platform to assess disease severity.

Prostate Px™ + will enable the assessment of disease severity at the time of diagnosis, thus more information will be available to the patient and their physician prior to the selection or implementation of any therapies.

PCSA *Lifeline* Newsletter
January 2007
Prostate Cancer Support Association
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RETURN
SERVICE
REQUESTED

Chairman's Corner

The year 2006 has been a great year for our Association. As an organization, we have been invited to participate in a number of state-wide Health Fairs, along with our Outreach Presentations both at the Fairs and to men's groups, locally and across the state. In doing this, we have achieved another of our Outreach goals - participation in the Native American community. The Socorro Support Group continues as a viable effort and was instrumental in the local hospital expanding it's laboratory capability to include PSA testing. Our Outreach Chairman, Tom Davis, has provided the necessary help and materials to the Farmington cancer support group to include assistance and information to men with prostate cancer. Tom and Board member, Marian Bruce, are also working with the medical communities on the east side of the state to develop support resources.

Our organization is the benefactor of a very generous bequest from the estate of Al Gillespie, for which we are most appreciative.

We are happy to announce that Kristie Gray has joined us as our office secretary. She will be working with a completely newcomputer system. A much needed office update.

Jan Marfyak is our newest Board member. He comes to us from Pennsylvania where he was founder and co-chairman of the Pennsylvania Prostate Cancer Coalition. In addition, he is both a founder of and Vice President of the National Alliance of State Prostate Cancer Coalitions. Jan is retired from the Federal Govedrnment's Department of Energy and resides in Rio Rancho with his family.

The National Alliance of State Prostate Cancer Coalitions (NASPCC) draws together some 27 states which currently have state coalitions. The organiztion is helping develop coalitions in states that do not currently have a presence. They are providing a turnkey seminar for new coalitions to build upon. You can visit the Alliance's website at: www.naspcc.com.