



# Newsletter

## Prostate Cancer 101, Inc.

<http://prostatecancer101.org>  
**November, 2010**

The Prostate Cancer Information and Support Group of the Mid-Hudson

### Come Meet Dr. Elizabeth Tapen and George Sherouse, Medical Physicist On Tuesday, November 16 at 4:30 pm

Here is your opportunity to hear about the latest procedures available at Health Quest (Benedictine Hospital) and to ask those questions that you may have concerning radiation, what to do in case of recurrence and any other PCa related inquiries that are on your mind. Dr. Tapen has been kind enough to share her knowledge with us in times past and is looking forward to introducing you to her medical physicist, Dr. George Sherouse, who is no slouch in his own right.

If you want to learn more about Dr. Sherouse, go to the site <http://www.sherouse.gwsherouse.com/> and I think you will be as

impressed by who and what the man is, as I was. Anyone who has a quote from Chapter 9 of the “Tao Te Ching” right under his picture is telling you a great deal about himself....and it is good news. I can’t wait to meet him in person.

Many of you have consulted with and been treated by Dr. Tapen, who has earned the respect and admiration of your core leadership group. She is a doctor who puts her patient’s best chance of cure above all else. Not only does she “first do no harm, “but she does her best to be sure her patients get the best advice and counsel; the mark of a true doctor.

Some of the topics that may be covered are: Change in guidelines for very low risk patients, benefits of Radiation Therapy for locally advanced disease, outcome of combined modality for intermediate risk disease, IMRT types, Brachytherapy physics and where ever your questions take the good doctors after their presentation.

So, mark your calendars and come to the Hurley Reformed Church, Schadewald Hall on Tuesday, November 16 at 4:30. You don’t want to miss out on this lecture and in meeting these two fine people.

# Proving Innovation in Medicare

DAVID LEONHARDT, On Tuesday October 19, 2010, 10:54 pm EDT

The huge budget deficits that the country faces in coming decades are, above all, because of Medicare. The program will have to cover growing numbers of baby boomers while health costs are likely to keep going up.

It won't be possible to pay the bill by cutting other programs. They're not big enough. Making big cuts to everything but Medicare and Social Security — shrinking the military and other programs to their smallest share of the economy since World War II — might save \$200 billion a year by 2035. But by then, annual Medicare spending is projected to grow by more than \$1 trillion.

So any deficit strategy needs to focus on Medicare.

In the new issue of the journal *Health Affairs*, two doctors, both former Medicare officials, have laid out a plan to do so. It would give expensive new treatments three years to prove that they worked better than cheaper treatments, or their reimbursement rates would be cut to that of the cheaper treatments.

I understand that the idea will strike some people as — gasp — rationing. More modest ideas were shouted down during the debate

over health reform. But I'd urge anyone who does not like the doctors' plan to think a bit about how Medicare should be changed. The status quo isn't really an option.

We are now in a political campaign in which everyone seems to talk about cutting spending without offering many ideas for how to cut spending. When the campaign ends, all that talk won't balance the budget. Neither will cutting waste, fraud, abuse and foreign aid. Nor will ending the war in Afghanistan and the Bush tax cuts for the rich.

Policies like those can help shrink the deficit, yes. Raising taxes and tweaking Social Security can help even more. But you probably can't call yourself a fiscal conservative unless you are willing to support changes — that is, cuts — to Medicare.

- The treatment of prostate cancer offers a good example of the trouble with the current system. I devoted a column to prostate cancer last year, and the *Health Affairs* article — by Steven Pearson of Massachusetts General Hospital and Peter B. Bach of Memorial Sloan-Kettering Cancer Center — uses it as a case study, too.

The brief version is that the options for treating prostate cancer include three forms of radiation. One of them, three-dimensional radiation, costs Medicare about \$10,000. Another treatment, a targeted form of radiation known as I.M.R.T., came along a decade ago and initially cost about \$42,000. Lately, Medicare has also started covering a third, proton radiation therapy, for which it pays \$50,000.

No solid research has shown I.M.R.T. to be more effective at keeping people alive, with minimum side effects, than three-dimensional radiation. The backing for proton therapy is weaker yet. As Dr. Pearson says, "There is even less evidence on whether proton therapy is as good as other alternatives than there was for I.M.R.T. when it was the new kid on the block."

But Medicare today doesn't pay for good outcomes. It pays for any treatment that it deems reasonable and effective.

Obviously, the medical industry — drug makers, device makers, hospitals and, depending how they're paid, doctors — has an

incentive to promote the most lucrative treatment. So too many people end up persuading themselves that the most lucrative one is the best one.

As a result, I.M.R.T. has supplanted three-dimensional radiation as the standard. Urologists have spent millions of dollars buying I.M.R.T. machines, which then become profit centers for their practices, as Stephanie Saul of The New York Times reported. Most recently, proton therapy has been making inroads.

Similar stories exist throughout medicine. Genentech has not shown that its expensive vision-loss drug is better than a cheaper alternative, but taxpayers still pay the bill. Implantable cardiac defibrillators have become increasingly intricate and expensive, without evidence that the more intricate versions are better at restarting a stopped heart.

Then there are drug-coated cardiac stents. They cost much more than the uncoated kind and were gaining market share — until evidence suggested that the coated stents sometimes harmed patients.

In many of these cases, you can argue (and companies do) that the more expensive treatment

will prove the better one once all the evidence is in. And sometimes it will. But sometimes it won't. In the meantime, life-and-death decisions are too often made based not on the best reading of the evidence, but on the best profit margin.

The plan from Dr. Bach and Dr. Pearson would try to change this.

It is from far the most radical out there. The full costs of treatments would be covered for three years, which would still give companies an incentive to innovate.

After three years, absent evidence that a treatment was better, Medicare would pay no more than it paid for equally effective treatments. Only \$10,000 of the bill for proton therapy, for instance, would be covered. The blank checks would not go on forever. New treatments would bring a windfall only if they improved health.

“To me, this is the way you make the market work,” says Karen Davis, president of the Commonwealth Fund, a health research group. Recently, private insurance companies, including Aetna and Cigna, have

begun experimenting with similar policies, notes Mark McClellan, the former head of Medicare.

Of course, any such Medicare system would have some downsides. Dana Goldman, a University of Southern California economist who likes the general idea, says he thinks five years may be a better window than three. That would allow more time for research into a treatment's effect on different subgroups. Even so, Mr. Goldman adds, no window could ever guarantee answers to every question.

The point is that all systems have their downsides. If we spend large sums on treatments that don't make us healthier, as we are now, we waste resources that could have been used productively. Instead of going toward health insurance premiums, the money could have lifted our salaries. Or it could have paid for medical research and treatments that would have improved health.

Unfortunately, today's political debate doesn't seem to have room for downsides. It conjures a world of free lunches — unlimited Medicare, vague spending cuts, low taxes and balanced budgets.

It's a nice world, until it isn't.

*Source: New York Times*

# FDA Approves PROVENGE® for the Treatment of Men with Advanced Prostate Cancer

Posted by jacquie strax

SEATTLE, April 29, 2010 – Dendreon Corporation (Nasdaq: DNDN) today announced that the U.S. Food and Drug Administration (FDA) has approved PROVENGE(R) (sipuleucel-T), an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone-refractory) prostate cancer (CRPC). PROVENGE is designed to induce an immune response against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers, and is the first in a new therapeutic class known as autologous cellular immunotherapies.

The FDA approval of PROVENGE is a testament to the courage of the patients and researchers who participated in our studies and is the culmination of nearly 15 years of research and development by our dedicated employees,” said Mitchell H. Gold, M.D., president and chief executive officer of Dendreon. “The approval of PROVENGE is a significant step towards realizing our mission of transforming the lives of patients with cancer, and it also marks Dendreon’s transformation into a commercial enterprise, ready to support the

successful launch of the first personalized treatment for cancer.”

Dendreon intends to make PROVENGE available through approximately 50 centers, all of which were approved PROVENGE clinical trial sites, and expects to increase capacity over the next year. The increased capacity will be a result of the anticipated licensure of its expanded New Jersey, Atlanta, Georgia and Orange County, Calif. facilities in mid-2011.

“The approval of PROVENGE, the first autologous cellular immunotherapy, represents a significant scientific and clinical advancement for the treatment of prostate cancer,” said Philip Kantoff, M.D., Director of the Lank Center for Genitourinary Oncology, Chief of the Division of Solid Tumor Oncology, and Chief Clinical Research Officer at Dana-Farber Cancer Institute, Professor of Medicine at Harvard Medical School. “Cancer immunotherapies that use the patient’s own immune system will likely create an entirely new treatment paradigm for patients with cancer.”

Clinical Trial Results Supporting FDA Approval

Three Phase 3 studies involving 737 patients were submitted to FDA to support licensure. The pivotal study was the Phase 3 IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment) trial (D9902B), a 512-patient, multi-center, randomized, double blind, placebo-controlled study that evaluated men with asymptomatic or minimally symptomatic, metastatic CRPC. PROVENGE extended median survival beyond two-years, demonstrating a median improvement of 4.1 months compared to the control group (25.8 months versus 21.7 months). Overall, PROVENGE reduced the risk of death by 22.5 percent compared to the control group (HR=0.775). Results from the similarly designed Study D9901 in asymptomatic metastatic CRPC also demonstrated a survival advantage of similar clinical magnitude as the IMPACT study.

“The approval of PROVENGE represents a sig-

nificant advancement in the care of men with advanced prostate cancer. PROVENGE offers a new choice in the front line treatment for these men who – until today – had few appealing treatment options,” said David Penson, M.D., Professor of Urologic Surgery at Vanderbilt University Medical Center.

### PROVENGE Safety

PROVENGE is intended solely for autologous use and is not routinely tested for transmissible infectious diseases.

The safety evaluation of PROVENGE was based on 601 prostate cancer patients in four randomized clinical trials who underwent at least one leukapheresis procedure. The most common adverse events (incidence greater-than or equal to 15%) are chills, fatigue, fever, back pain, nausea, joint ache, and headache. Serious adverse events reported in the PROVENGE group include acute infusion reactions (occurring within 1 day of infusion) and cerebrovascular events. In controlled clinical trials, severe (Grade 3) acute infusion reactions were reported in 3.5% of patients in the PROVENGE group. Reactions included chills, fever, fatigue, asthenia, dyspnea, hypoxia, bronchospasm, dizziness, headache, hypertension, muscle ache, nausea, and vomiting. No Grade 4 or 5 acute infusion reactions were reported in patients in the PROVENGE group.

To fulfill a post marketing requirement and as a part of the company’s ongoing commitment to patients, Dendreon will conduct a registry of approximately 1500 patients to further evaluate a small potential safety signal of cerebrovascular events. In four randomized clinical trials of PROVENGE in prostate cancer patients, cerebrovascular events were observed in 3.5% of patients in the PROVENGE arm compared with 2.6% of patients in the control arm.

### About PROVENGE and Patient Resources

PROVENGE (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic, castrate resistant (hormone-refractory) prostate cancer. PROVENGE represents the first product in a new therapeutic class known as autologous cellular immunotherapies.

Dendreon will donate funds to an independent non-profit organization that will provide financial assistance to patients who cannot afford the co-payments associated with their prostate cancer medicines. In addition, Dendreon’s dedicated call center case managers will proactively help match patients

with foundations to support their financial assistance needs.

For more information, please visit <http://www.provenge.com/>.

*Source: psa-rising.com*

## Important Notice to Members

We try to keep our lists and files up to date, but we need your help to do so. If you have had additional treatment for prostate cancer or recurrence, please let us know which doctor you went to for such treatment so we can add that data to our membership list next to your name. If you no longer wish to have your name on the membership list distributed to newly diagnosed men so they can talk to you in person, then let me know that too. While we are at it, if you have moved or have a new email address, please let me know so that I can keep you informed of important notices, such as flu shots, special programs and the like.

And finally, your donations help us pay for ads in newspapers, copy information for newly diagnosed packets and even print the newsletter, which is not inexpensive to do. So if you can find it in your heart and pocket-book to help, we’d be most grateful. And if you’d like to help in hands on fashion, we’d welcome you with open arms. Diane Sutkowski  
[dsutkowski@hvc.rr.com](mailto:dsutkowski@hvc.rr.com)

# Dendreon Sets Provenge Price at \$93,000, Says Only 2,000 People Will Get it in First Year

[Luke Timmerman 4/29/10](#)

Dendreon's groundbreaking new immune-booster for prostate cancer helps men live longer, and it will not be cheap. The Seattle-based biotech company (NASDAQ: [DNDN](#)) said it is planning to charge \$93,000 per patient for the new drug.

The product, sipuleucel-T (Provenge) will cost \$31,000 per infusion, and patients will get three infusions over a one-month period, [chief operating officer Hans Bishop](#) said today on a conference call with analysts. That price is far higher than [the \\$62,000 average estimate](#) that Wall Street analysts had been expecting. [Dendreon](#) stock surged more than 25 percent to over \$50 after the company disclosed the price today. *[Updated with stock price.]*

The company [made history](#)

[early today](#) when the FDA cleared sipuleucel-T (Provenge) for men with prostate cancer that has spread through the body and no longer responds to standard hormone-deprivation treatment. The drug showed in a pivotal clinical trial that patients lived a median time of 25.8 months on Provenge, compared with 21.7 months if they got a placebo. Dendreon's pricing equation assumes that people are willing to pay about \$23,000 per extra month of life, which is comparable to other cancer drugs for terminal groups of patients, Bishop said today.

Dendreon also is benchmarking its overall cost of treatment not just against competitors' prices, but how much supportive care and hospital expenses other treatments require because they force patients to endure more side effects, Bishop said. Sanofi-Aventis's docetaxel (Taxotere), for example, costs about \$60,000 per patient when you factor in the

cost of extra supportive care, and Dendreon's drug has been shown to help people live longer.

"Our price compares favorably to other cancer drugs," Bishop said.

Pricing is obviously a touchy issue. Set the price too low, and Dendreon might not recoup enough of the \$1 billion that has been invested in the company over the past 15 years, and it could create major shortages over the next year. Set the price too high, and it runs the risk of upsetting insurers and alienating its allies in the patient advocacy community.

Dendreon isn't equipped yet to meet all the demand it anticipates for the drug. Only about 2,000 patients will be able to get Provenge in the first 12 months that it is

available, while the company relies on a single factory in New Jersey that's operating at one-fourth of full capacity. By the middle of 2011, Dendreon hopes to have two more factories in southern California and Georgia, as well as the New Jersey plant, operating at full tilt. That should enable the company to sell about \$1.2 to \$2.5 billion worth of Provenge per year, CEO Mitchell Gold said.

Dealing with scarcity has been a big issue for Dendreon. It consulted doctors, patients, and medical societies for advice on what to do. In the early days, it will only allow 50 medical centers in the U.S. to fill orders for Provenge, and they are all places that have experience with the product in clinical trials.

The company isn't going to establish a waiting list—it will allow doctors to decide which patients should get the drug first. Dendreon is going to donate some undisclosed amounts of money to a non-profit foundation which will help patients make their co-payments if they can't afford the drug, the

company said.

It will be interesting to see if insurers balk at the price, or create lots of red tape to make it hard on doctors who prescribe it. Dendreon has had some preliminary conversations with private insurers, and plans to meet with officials at the Centers for Medicare and Medicaid Services next week, Bishop said.

Since prostate cancer generally afflicts older men, about three-fourths of the patients are expected to be eligible for Medicare, Bishop said.

*Luke Timmerman is the National Biotech Editor of Xconomy, and the Editor of Xconomy Seattle. You can e-mail him at [ltimmerman@xconomy.com](mailto:ltimmerman@xconomy.com), or follow him at [twitter.com/ldtimmerman](https://twitter.com/ldtimmerman).*

Source: [www.psa-rising.com](http://www.psa-rising.com)

## **Thank you all for your Contributions**

**Eric Deyo  
Joseph & Florence  
Hoffman  
Sidney Sperber  
Edward Surowitz  
Edward Weber**

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## Prostate Cancer Treatment Progress: Death Rate Declines 45% by Mark Huffman

ConsumerAffairs.com | 10.07.2010  
While prostate cancer remains a serious health concern for men over 60, the disease is becoming less threatening. American men with prostate cancer were 45 percent less likely to die from the disease in 2006 than they were in 1999, according to the U.S. Agency for Healthcare Research and Quality.

The federal agency found that the rate at which American men died from prostate cancer declined from 23.5 deaths to 13 deaths per 100,000 males during the period.

The analysis also shows that following changes:

Compared with white men, black men were still more than twice as likely to die from prostate cancer in 2006 just as they were in 1999 -- 69 to 50.5 deaths and 29 deaths to 22 deaths per 100,000 males during the period.

The rate for Hispanics and Asian-American Pacific Islanders declined from 23 to 18 and from 17

to 14, respectively, per 100,000 males.

Men age 65 and older were 20 percent less likely to succumb to prostate cancer in 2006 compared with 1999. Their rate plummeted from 205 deaths to 164 deaths per 100,000 males.

While AHRQ didn't give a reason for the decline in deaths, it's likely that early detection was a major contributor. In current clinical practice, men with elevated levels of Prostate Specific Antigen (PSA) are considered at risk of having prostate cancer.

PSA is a substance produced by the prostate gland and, when increased amounts are found in the blood, patients are typically referred for diagnostic biopsies to confirm the presence of prostate cancer. A regular PSA test can give doctors a head start on treatment.

### Predictor

A recent study published in the British Medical Journal found

that a man's PSA level measured at age 60 could predict his lifetime risk of dying of prostate cancer.

Dr. Hans Lilja, of Memorial Sloan-Kettering Cancer Center in New York, and colleagues studied data from 1,167 Swedish men 60 years of age who provided blood samples in 1981 and were followed up to age 85. Only a minority of men age 60 with PSA levels higher than 2 ng/mL experienced fatal prostate cancer, but those men comprised 90 percent of the prostate cancer deaths.

Men with a PSA level of 2 or higher at age 60 have 17 times and 26 times increased odds of metastasis and death from prostate cancer, respectively, than men with PSA levels of 0.65-0.99, according to the study.

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Source: ZERO-The Project to End Prostate Cancer



# PSA Test Reduces Risk of Spread if Prostate Cancer Strikes Study found screening showed benefit, despite debate about its usefulness

by Alan Mozes | Bloomberg Businessweek | 10.25.2010

(HealthDay News) Having a prostate-specific antigen (PSA) test to screen for prostate cancer reduces the risk that if cancer develops it will spread to other parts of the body, new research indicates.

The finding adds to the ongoing debate on whether PSA screenings actually improve survival rates or, by contrast, lead to unnecessary treatment.

"Our study shows that routine screening not only improves the patient's quality of life by stopping metastatic disease, but it also decreases the burden of care for this advanced disease that must be provided by the health-care system," study author Chandana Reddy, a senior biostatistician at the Cleveland Clinic in Ohio, said in a news release from the American Society for Radiation Oncology.

"This demonstrates that the

PSA test is extremely valuable in catching the disease earlier and allowing men to live more productive lives after treatment," Reddy said.

Reddy and his colleagues are to report their findings Monday at the American Society for Radiation Oncology annual meeting, in San Diego.

PSA tests are blood tests that have been available and widely used since 1993. They measure levels of the prostate-specific antigen protein produced by the prostate; high levels are thought to be an indication of prostate cancer.

However, critics have cautioned that some patients diagnosed with early prostate cancer are subjected to aggressive treatments -- and their unwelcome side effects, such as incontinence and erectile dysfunction -- for a disease that is

often slow-moving and of no real consequence to survival if left untreated among older patients who are likely to die of other, unrelated causes.

The researchers pointed out that prostate cancer is not curable when it is caught late and has spread (or metastasized) to other parts of the body. They suggested that assessing to what degree a PSA diagnosis might reduce the risk of metastasis could be the best way to determine the value of the test.

To that end, Reddy and his team analyzed data on more than 1,700 prostate cancer patients who between 1986 and 1996 had been treated with either radiation therapy or surgery to take out their prostate gland and the surrounding tissue.

Noting that in the first half of the study period, PSA tests were

not yet available, the authors compared the spread of the disease over the course of 10 years among those who had been diagnosed with a PSA test and those who had not.

Over the 10-year period, metastatic disease took hold among 13 percent of all the patients. However, the researchers found that regardless of whether patients were categorized as having high-, medium-, or low-risk disease, those who had been diagnosed as a result of a PSA screening were significantly less likely than those who weren't to have seen their cancer spread during the decade following their original treatment.

It should be noted that studies presented at scientific meetings do not face the same peer-review scrutiny as those published in reputable journals.

Dr. Lionel L. Banez, an assistant professor of urologic surgery at Duke University Medical Center, said that the current study leans toward the relative benefits of prostate cancer screening.

"There is compelling evidence that PSA testing saves lives, especially when performed in an optimized strategy," he said. "For example, getting an initial PSA measurement at age 40 to properly assess baseline prostate cancer risk has been proven to be quite beneficial."

Nevertheless, Banez acknowledged that doctors need to interpret test results judiciously.

"The challenge," he stressed, "lies in ensuring that the risks for over-diagnosis and over-treatment, as well as potential decline in quality of life, are minimized or avoided."

Copyright HealthDay News  
2010

*Source: ZERO-The Project to End Prostate Cancer*

## **Male-Pattern Baldness and BPH: What's the Connection?**

According to Spanish researchers, screenings for urinary symptoms in men with androgenetic alopecia (AGA, more commonly known as male-pattern baldness) could help with earlier identification of those who could benefit from treatment to prevent benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS). Their rationale: Men with male-pattern baldness have higher than normal levels of 5-alpha-reductase, the chemical that converts the male hormone testosterone into dihydrotestosterone, the active form of male hormone within the prostate.

Male-pattern baldness, which accounts for almost all hair loss in men, results from a genetic malfunction that causes hair follicles to become more susceptible and shrink in the presence of dihydrotestosterone.

Over time, the affected hair fol-

icles stop producing hair. The chemical 5-alpha-reductase also plays a key role in the development of BPH. When testosterone is converted to the more potent dihydrotestosterone by 5-alpha-reductase, it can cause the prostate to enlarge, eventually leading to BPH and LUTS.

Prostatic enlargement that causes lower urinary complaints is often treated with finasteride (Proscar), a 5-mg dose taken daily which blocks 5-alpha-reductase and very slowly starts to shrink the prostate. Men with complaints of male pattern baldness are also treated with finasteride (Propecia), but in a 1-mg dose that effectively lowers dihydrotestosterone levels in the scalp by as much as 60% when taken daily, helping to stop hair loss in more than 85% of the men who use the drug.

With the link between male pattern baldness and BPH noted, the

Spanish researchers wanted to know if the balding men also had signs of BPH, even though they may not have noticed symptoms. So they enrolled 30 men with early-onset male pattern baldness and compared several variables with a control group of men who had full heads of hair.

What they found through ultrasound examinations was that the balding men had prostates that were 34% larger than those of the men with full heads of hair; that their urine flow was 32% less; their prostate symptom scores significantly higher, and PSA scores also higher. All of these factors led the researchers to conclude that the balding men had early-stage BPH -- and they didn't know it.

This study suggests that patients with male-pattern baldness should talk with their doctors about any urinary symptoms

they may be experiencing so they can take preventive measures.

Posted in Enlarged Prostate on November 3, 2010

*Source: Johns Hopkins Health Alert*

**“Believe and you shall be right, for you will persevere. Doubt and you shall be right again, for you will fail!”**

**Submitted by Ralph Walters**

**“You live only once—but if you work it right, once is enough.”**

**Joe E. Lewis**

**“People in your life are like pillars in your porch. Sometimes they hold you up, and sometimes they lean on you. Sometimes it’s enough to know they are just standing by.”**

**Merle Shain**

Prostate Cancer 101, Inc.  
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**1<sup>st</sup>**

**Tuesday**

**3<sup>rd</sup>**

**Tuesday**

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Meetings are held the First Thursday of the month at the Central Hudson Auditorium on South Road in Poughkeepsie, starting at 6:30 p.m. Various doctors and speakers are on the agenda and one on one help is available after the meeting.

**Contact**

Paul Totta 845 297-7992  
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**If you need or want to help:  
PCa 101 Seminar  
*First Tuesday of every month***

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