



Newsletter

Prostate Cancer 101, Inc.

<http://prostatecancer101.org>
November, 2014

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

Special Event Nov. 11 at 4:30 **Dr. Elizabeth Tapen**

A lot of us have sorely missed having our good doctor and friend nearby in the past few years, but we are delighted that she is now in Poughkeepsie at Professional Radiation Oncology Services at Mid-Hudson Regional Hospital, formerly known as St. Francis Hospital. Come help us welcome her back to the Hudson Valley.

She'll be speaking to us in the auditorium of Schadewald Hall at 4:30 pm about "Radiation Therapy in the Management of Prostate Cancer" and will be pleased to answer your questions at the end of her lecture. You will find

that Dr. Tapen is a forthright individual who inspires trust because she truly is trustworthy. Dr. Tapen puts her patient's needs above all else, an attribute we have admired over the years.

To fill you in on a bit of her background – she is a Jersey girl (Yay, Jersey!) who graduated from Rutgers University and Robert Wood Johnson Medical School.

She is a Board Certified Radiation Oncologist and did her residency at St. Mary's Hospital, San Francisco. Dr. Tapen worked in San Jose and Berkley at the cancer institutes there and has experience in brachythera-

py and HDR (temporary high dose radiation). Many of you may remember her as the Medical Director of the radiation department at Benedictine Hospital, where she helped quite a few of our members.

We are happy that she will be imparting some of her knowledge to us and even more delighted that she is back in the Hudson Valley to lend her expertise to those who need it most. Mark your calendars and come on Nov. 11.

Our usual First Tuesday meeting will be on Nov. 4, though we will be meeting downstairs as there is an Election Day dinner in the upper hall.

Vasectomy linked with aggressive prostate cancer risk

Last updated: 10 July 2014 at 3am PST

Contributions

Our thanks for your help so we can continue our outreach

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We need your donations! Without them we can not send you newsletters and continue to reach out to those men who need help.
We were there for you,
now pay it forward. We'll continue to do the rest of the work.

In the largest and most comprehensive study of its kind, researchers from Harvard School of Public Health in Boston, MA, find that vasectomy is associated with a small increased risk of prostate cancer, and a larger increased risk for advanced or lethal prostate cancer.

Prostate cancer is a major cause of cancer-related deaths in men in the US, where vasectomy is a common form of contraception, with around 15% of American men having the minor procedure, which blocks the tubes that carry sperm from the testicles to the penis.

The researchers report their findings in the Journal of Clinical Oncology, where they note that the link was still evident among men who had regular PSA tests, suggesting the link with increased risk of lethal cancer cannot be due to diagnostic bias.

Co-author Lorelei Mucci, associate professor of epidemiology at Harvard School of Public Health (HSPH), says:

"This study follows our initial publication on vasectomy and prostate cancer in 1993, with 19 additional years of follow-up and tenfold greater number of cases. The results support the hypothesis that vasectomy is associated

with an increased risk of advanced or lethal prostate cancer."

For the study, Prof. Mucci and colleagues analyzed data on 49,405 American men who were followed between 1986 and 2010 as participants of the Health Professionals Follow-up Study. The men were aged between 40 and 75 years at the start of the 24-year follow-up period.

In this study, 16 out of every 1,000 men developed lethal prostate cancer over 24 years of follow-up.

Over that time, 6,023 men were diagnosed with prostate cancer, including 811 who died of the disease. One in four of the participants reported having undergone a vasectomy.

When they analyzed the data, the team found a 10% overall increased risk of prostate cancer in those men who had a vasectomy.

However, further analysis found vasectomy was linked to a stronger increased risk of more aggressive forms of prostate cancer: a 19% higher risk for advanced cancer and a 20% higher risk of the lethal form.

And for a subgroup of men who were having regular PSA tests, the increased risk was 56%.

New Report: Past Drug Failures Help Create the War on Cancer's Next Successes

Washington, D.C. (October 7, 2014) — Today, the Pharmaceutical Research and Manufacturers of America (PhRMA) released a new report, "[Researching Cancer Medicines: Setbacks and Stepping Stones](#)," which highlights the number of investigational cancer medicines that did not succeed in clinical trials and how these so-called "failures" are a critical part of the drug development process.

The report illustrates the immense challenges in bringing new medicines to patients with cancer, and explores the factors that contributed to both the approvals of new treatments and those that "failed" between 1998 and 2014. The report focuses on three cancers that are particularly difficult to treat: melanoma, lung cancer and brain cancer.

- 96 potential treatments for melanoma did not make it through clinical trials, but paved the way for 7 approved medicines, a nearly 14:1 ratio of "failures" to "successes."
- Ten medicines have been approved to treat lung cancer, whereas 167 other potential treatments did not make it through clinical trials.

Only 3 new medicines have been approved to treat brain cancer, while another 75 investigational medicines were unsuccessful in the development process.

There was no significant link between vasectomy and risk of low-grade cancer.

Concerns have been raised before in connection with this type of study, that the links could be a result of bias, but the researchers say their analyses took into account diverse information that meant they could rule out potential biases. For example, one bias could be that men who have vasectomies are more likely to seek medical care, or undergo more PSA tests. They also ruled out bias due to the possibility of sexually transmitted infections.

It should be noted that the researchers are not suggesting in this study that simply undergoing regular PSA screening can raise the risk of prostate cancer. There could be other explanations for why the men having regular PSA screening showed the strongest raised risk for prostate cancer. For instance, if an initial screening is positive, then regular screening is recommended. Relative risk does not mean absolute risk

Another point to note is that these numbers refer to relative risk - that is the extent to which the underlying or absolute risk of developing the disease is affected. So, for example, if a person's risk of getting a disease is 10%, then a relative risk of 10% means the absolute risk is only 10% of 10%, or 11%.

In this study, 16 out of every

1,000 men developed lethal prostate cancer over 24 years of follow-up. Thus, the result that vasectomy was linked to a 20% raised risk of lethal prostate cancer, is relative to that 16 out of 1,000.

Therefore, as the researchers point out, although the 20% was found to be statistically significant (that is unlikely due to chance), its effect is a relatively small increase in the absolute risk of developing prostate cancer.

"The decision to opt for a vasectomy as a form of birth control is a highly personal one and a man should discuss the risks and benefits with his physician," says co-author Kathryn Wilson, a research associate in HSPH's Department of Epidemiology.

Funds from the National Cancer Institute and the National Institutes of Health helped finance the study.

Meanwhile, Medical News Today reported how a study led by the University of Adelaide in Australia found that a test based on semen may be more accurate at diagnosing prostate cancer. The researchers found that testing semen samples for small molecules called microRNAs was "surprisingly accurate" at indicating which men had prostate cancer and how severe it was.

Written by Catharine Paddock PhD

Copyright: Medical News Today
Source: <http://www.medicalnewstoday.com/articles/279410.php>

New Guidelines for Treating Advanced Prostate Cancer

Recommendations are for men whose tumors have grown resistant to hormonal therapies.

By E.J. Mundell
HealthDay Reporter

September 8, 2014
(HealthDay News) -- Men newly diagnosed with prostate cancer often turn first to testosterone-depleting therapies, since male hormones help prostate tumors grow.

But, those therapies almost always fail over time as the tumor develops resistance, according to oncologists.

Now, experts are issuing updated guidelines to help patients in this situation decide what to do next.

The guidelines, issued jointly by the American Society of Clinical Oncology (ASCO) and Cancer Care Ontario (CCO) in Canada, highlight recent advances in treating this more advanced form of prostate cancer.

"We have seen unprecedented progress against advanced prostate cancer recently, with six new treatments approved in the last couple of years,"

Despite these challenges, America's biopharmaceutical companies continue to invest in research to develop new treatments. According to a new [report](#) by PhRMA, there are 771 cancer medicines and vaccines either in clinical trials or awaiting review by the U.S. Food and Drug Administration (FDA). Of these medicines, more than 50 are for the treatment of melanoma, 98 for lung cancer and 47 for brain cancer.

"While it may sound counterintuitive, research setbacks are instrumental to furthering efforts to better understand a disease and how to treat it. They are also an indication of the incredible difficulty in developing medicines to treat cancer," said PhRMA President and CEO John J. Castellani. "These setbacks serve as a reminder that to make progress, we need a public policy framework that supports drug development in combination with promising science so that we can bring important innovations to patients."

Significant advancements in the treatment of diseases like cancer are typically the result of cumulative innovation over time, rather than a single breakthrough in treatment. Every success – and every "failure" – builds on previous advances to improve patients' lives. Research has shown that cancer is actually a set of more than 200 extremely complex diseases and discovering medicines that effectively treat each one is a difficult task.

"While it is incredibly disappointing to see a promising new drug candidate eliminated from the pipeline, researchers take immeasurable learnings from every setback and build upon each one to develop effective therapies for patients," said Castellani.

The release of the "Researching Cancer Medicines: Setbacks and Stepping Stones," report comes in advance of the Turning the Tide Against Cancer National Conference on October 9, 2014. At the meeting, Castellani will join other health care stakeholders to discuss ways to improve cancer care and promote innovation. For more information, please visit <http://turningthetideagainstcancer.org/>.

To learn more about the discovery and development process, from initial research to delivery of life-saving medicines, please visit <http://www.fromhopetocures.org/pipeline-of-hope/>.

View the full "[Researching Cancer Medicines: Setbacks and Stepping Stones](#)" report.

About PhRMA

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$550 billion in the search for new treatments and cures, including an estimated \$51.1 billion in 2013 alone.

Find PhRMA Online

Website – www.phrma.org

- See more at: <http://>

www.phrma.org/media-releases/new-report-past-drug-failures-help-create-the-war-on-cancers-next-successes#sthash.R7X43L8K.dpuf

Dr. Ethan Basch, co-chair of the ASCO/CCO panel of experts that developed the guidelines, said in a news release from the two groups.

"There are a lot of nuances about treatment selection in terms of disease stage and what prior therapies the patient received," he said. "We hope this guideline will help doctors and patients make informed treatment decisions."

After a prostate tumor becomes resistant to hormonal treatment, other therapies may come into use. But the ASCO/CCO team said they took men's quality of life into consideration as well when they drew up their guidelines.

"Including quality of life data in the guideline helps people understand how the different treatments will make them feel," Dr. Andrew Loblaw, co-chair of the ASCO/CCO expert panel, said in the news release. "We also have to be conscious of cost, because it can affect access to treatment and quality of life."

The new guidelines for hormone therapy-resistant tumors that have spread (metastasized) include the following recommendations:

Continue hormone-deprivation therapy indefinitely, either in drug or surgical form;

Offer patients one of three treat-

ment options -- abiraterone/prednisone, enzalutamide, or radium-223 (if cancer has spread to the bones) -- in addition to hormone deprivation, "as all three treatments are associated with improved survival, quality of life, and favorable balance of benefits and harms";

When considering chemotherapy, docetaxel/prednisone should be an option but side effects must be discussed;

Offer cabazitaxel to men whose disease worsens even if docetaxel has been tried, but again, discuss side effects;

Offer sipuleucel-T to men with no symptoms or minimal symptoms of cancer;

Offer mitoxantrone, but include a discussion of the drug's "limited clinical benefit and side effect risk";

Offer ketoconazole or the anti-androgen therapies bicalutamide, flutamide or nilutamide but discuss the limited clinical benefit for these three medications;

Do not offer the drugs bevacizumab (Avastin), estramustine, or sunitinib;

Begin discussion of palliative care early on while discussing treatment options.

The experts on the panel said the optimum sequence in which various treatment should be given remains unclear, but "ongoing clinical trials are exploring this question, as well as potential benefits of combining various treatments."

The new guidelines are based on a review of 56 randomized clinical trials published since 1979, the panel experts said.

According to the American Cancer Society, prostate cancer remains the leading cancer type for men, other than skin cancer. More than 233,000 new cases of prostate cancer are diagnosed in the United States each year, and almost 30,000 men die from the illness annually. But most men diagnosed with prostate cancer don't die from it. More than 2.5 million American men diagnosed with the disease are still alive.

Source: http://www.pcf.org/site/c.leJRIROrEpH/b.9202953/k.CC83/New_Guidelines_for_Treating_Advanced_Prostate_Cancer.htm?msource=sept14np

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Watchful Waiting May Not Be Best for Black Men With Prostate Cancer

By Robert Preidt
HealthDay Reporter

September 8, 2014 (HealthDay News) -- Monitoring early stage prostate cancer instead of treating it may not be appropriate for all patients, especially black men, a new study indicates.

According to background information with the study, there is currently controversy among oncologists over the best way to handle early stage prostate cancer, with some experts suggesting that regular monitoring -- known as watchful waiting -- of the disease is the best approach because it avoids overtreatment.

But this new study suggests that watchful waiting may not be suitable for all men with early stage prostate cancer, especially black patients.

"We know that African-American men have more aggressive prostate cancer than Caucasian men," Dr. Kosj Yamoah, chief resident in the department of radiation oncology at Thomas Jefferson University in Philadelphia, said in a university news release.

"Our study shows that African-American men who are diagnosed with a low-grade cancer at first -- the cancers that are sometimes watched rather than treated -- are more likely to develop aggressive

disease sooner than Caucasian men," he said.

The researchers analyzed the medical records of men who were confirmed to have low-grade prostate cancer and had surgery to remove part or all of their prostate. Among these patients, blacks were more likely to have cancer progression and worse outcomes than whites.

Seven years after surgery, rates of disease control were 90 percent among whites and 79 percent among blacks, the study found.

The findings were published Sept. 8 in the journal *Urologic Oncology*.

The researchers are still searching for molecular clues that would help identify black prostate cancer patients who have the highest risk of disease progression and those most likely to benefit from watchful waiting.

More information

The U.S. National Cancer Institute explains the [treatment options for early-stage prostate cancer](#).

Source: http://www.pcf.org/site/c.leJRIROrEpH/b.9202947/k.65D8/Watchful_Waiting_May_Not_Be_Best_for_Black_Men_With_Prostate_Cancer.htm?msource=sept14np

DNA Blood Test Might Identify Status of Prostate Cancer

HealthDay Sept. 17, 2014 | 4:00 p.m. EDT + More
By Mary Elizabeth Dallas, HealthDay Reporter

WEDNESDAY, Sept. 17, 2014 (HealthDay News) -- A blood test that measures DNA from a prostate cancer tumor could provide doctors with a better assessment of the state of a man's disease, a new study suggests.

If used routinely, this blood test could reveal when treatment for advanced prostate cancer stops working and actually begins promoting tumor growth, the researchers suggested.

"Our study showed that a steroid treatment given to patients with advanced prostate cancer and often initially very effective started to activate harmful mutations and coincided with the cancer starting to grow again," study leader Dr. Gerhardt Attard, from the Institute of Cancer Research (ICR) in London, explained in an ICR news release.

"In the future, we hope to routinely monitor genetic mutations in patients with advanced disease using just a blood test -- enabling us to stop treatments when they become disease drivers and select the next best treatment option. We need to confirm these findings in larger numbers of patients, but using these types of blood tests could allow true personalization of treatment for prostate cancer patients, based on the cancer mutations we detect," he explained.

Using a blood test to measure circulating tumor DNA levels is less expensive and less invasive than needle biopsies. This test could be an effective way to monitor the emergence of treatment-resistant prostate cancer, the study published on Sept. 17 in *Science Translational Medicine* suggested.

"Drug resistance is the single biggest challenge we face in cancer research and treatment, and we are just beginning to understand how its development is driven by evolutionary pressures on tumors," Paul Workman, interim chief executive at the ICR, said in the news release. This discovery "reveals how some cancer treatments can actually favor the survival of the nastiest cancer cells, and sets out the rationale for repeated monitoring of patients using blood tests, in order to track and intervene in the evolution of their cancers," Workman said.

"There are currently too few treatment options for men living with advanced stage prostate cancer. Not only do we desperately need to find more treatments for this group of men, we also need to understand more about when those that are available stop working and why," Dr. Matthew Hobbs, deputy director of research at Prostate Cancer UK, said in the news release.

"This research is important as it shows that there might be a new way to monitor how a man's cancer is changing during treatment, and

that could help us to pinpoint the stage at which some drugs stop being effective. In the future, this could arm doctors with the knowledge they need to ensure that no time is wasted between a drug that stops working for a man and him moving on to another effective treatment," Hobbs said.

But, Hobbs also noted that this is preliminary research and that the study size was small -- just 16 men. He agreed with Attard that the findings need to be confirmed in a larger study.

The researchers cautioned that any patients currently taking medication for advanced prostate cancer should continue to take their medications as prescribed and discuss any concerns about their treatment with their doctor.

More information
The U.S. National Cancer Institute provides more information on prostate cancer.

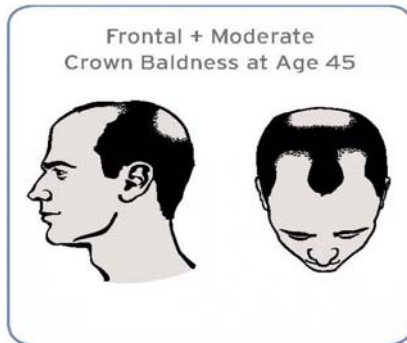
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Source: <http://health.usnews.com/health-news/articles/2014/09/17/dna-blood-test-might-identify-status-of-prostate-cancer>

Specific baldness pattern linked with increased prostate cancer risk

Last updated: 16 September 2014 at 8am PST

Men with a specific pattern of baldness at age 45 have a 40% increased risk of later developing aggressive prostate cancer, according to a new study published in the *Journal of Clinical*



cal Oncology.

Using a pictorial tool, the men identified in the questionnaire what their hair-loss patterns were at age 45. Image credit: American Society of Clinical Oncology

Increasingly, evidence is suggesting that both [prostate cancer](#) and male pattern [baldness](#) are linked to increased levels of androgens (male sex hormones) and androgen receptors.

In 2013, *Medical News Today* reported on a study from researchers at the University of Pennsylvania in Philadelphia, who found that African-American men who experience baldness [were 69% more](#)

[likely to develop prostate cancer](#) than those with no baldness.

That team - which examined 318 African-American prostate cancer patients with baldness (aged 39-86) and 219 African-American men who did not have prostate cancer (aged 33-93) - also found that the probability of aggressive prostate cancer doubled in men with frontal baldness.

Overall, frontal baldness was linked to high-stage and high-grade prostate cancer, while crown baldness was linked to low-grade prostate cancer.

Further examining the link between baldness and prostate cancer risk, researchers from the Division of Cancer Epidemiology and Genetics at the National Cancer Institute in Bethesda, MD, analyzed questionnaire data from 39,070 men aged 55-74 as part of the US PLCO Cancer Screening Trial.

Frontal and moderate crown baldness 'linked to higher risk of aggressive prostate cancer'

Using a pictorial tool, the men identified in the questionnaire what their hair-loss patterns

were at age 45.

During the follow-up period, 1,138 of the men in the study group were diagnosed with prostate cancer. The mean age at the time of diagnosis was 72, and 51% of the cases were defined as "aggressive" [cancers](#).

The researchers found that men who had frontal and moderate crown baldness were 40% more likely to develop aggressive prostate cancer, compared with men who did not have any baldness. However, the researchers found no link between male pattern baldness and a risk for non-aggressive prostate cancer.

Senior author Michael B. Cook, PhD, explains the results:

"Our study found an increased risk for aggressive prostate cancer only in men with a very specific pattern of [hair loss](#), baldness at the front and moderate hair-thinning on the crown of the head, at the age of 45. But we saw no increased risk for any form of prostate cancer in men with other hair-loss

patterns.

While our data show a strong possibility for a link between the development of baldness and aggressive prostate cancer, it's too soon to apply these findings to patient care."

Although the findings still need to be confirmed by further studies, the researchers believe that medical assessment of baldness may be useful in identifying men who are at increased risk for aggressive prostate cancer.

Next, the team will explore the relationship between male pattern baldness and risk of developing and dying from prostate cancer across two additional studies.

One of these studies will include a dermatological assessment of male pattern baldness, considered to be more reliable than the self-reporting recall method used in the questionnaire study.

Written by David McNamee

Source: <http://www.medicalnewstoday.com/articles/282592.php#.VBiMByrYUuA.facebook>

Copyright: Medical News Today

Radical Prostatectomy Rates Rising

Use of radical prostatectomy (RP) for localized prostate cancer (PCa) increased significantly from 2004 to 2011, whereas the use of radiotherapy (RT) decreased during that period, according to study findings presented at the 56th annual meeting of the American Society for Radiation Oncology in San Francisco.

Using the national cancer database, Phillip J. Gray, MD, of Massachusetts General Hospital, and colleagues identified 823,977 men diagnosed with PCa from 2004 to 2011. Of these, 38.5%, 42.7%, and 18.9% had low-, intermediate-, and high-risk disease, respectively, according to National Comprehensive Cancer Network guidelines.

In low-risk patients, active surveillance (AS) rates increased from 12.4% to 18.5% from 2004 to 2011 and RP rates rose from 40.3% to 54.4%. During the same period, brachytherapy (BT) rates decreased from 24.4% to 11.4% and the rates of external beam RT (EBRT) alone decreased from 18.2% to 13.4%.

Among men with intermediate-risk disease, AS rates increased from 6.1% to 7.3% and RP rates increased from 48.1% to 58.5%, whereas BT rates dropped from 12.1% to

6.4%. Rates of combined therapy with EBRT and androgen deprivation therapy (ADT) declined from 14.7% to 8.7%.

In the high-risk group, AS rates and EBRT monotherapy rates remained stable over the study period (about 8% and 10%, respectively), whereas RP rates rose from 30.6% to 41.3%, the researchers reported.

The rates of combined EBRT plus ADT declined from 30.4% to 28.0% and BT rates fell from 8.7% to 4.1%. Rates of primary ADT dropped from 7.2% to 5.8%.

On multivariable analysis, the researchers found that black men were 48% less likely than whites to undergo RP versus RT. Individuals without insurance and those covered by Medicaid were 34% and 50% less likely, respectively, than those with private insurance to have RP rather than RT. Patients living in low income areas also were less likely to undergo RP versus RT.

"I think one of the most surprising trends that we didn't expect to find was that, over the study period, the use of RP for patients went up by double digits across all risk groups," Dr. Gray told Renal & Urology News. "This was particularly striking for low-risk patients. While AS increased slightly for patients with low-risk disease,

Prostate cancer drug candidate shows great promise

the absolute number of patients on AS was low, and, during this time, rates of surgery were increasing. This suggests that it is primarily the patients that would typically be treated with RT who are being placed on AS, not the patients who are primarily discussing AS versus RP with their urologist.”

“The trend for increased use of surgery in high-risk disease is concerning,” Dr. Gray added. “Many patients with high risk disease who are undergoing surgery have indications for post-operative RT and perhaps hormonal therapy, and are therefore potentially being subjected to multiple treatments that can additively affect quality of life.”

As for why black men are less likely than whites to undergo RP, the reasons are unclear. “One hypothesis is that the majority of RPs are occurring at large academic centers,” Dr. Gray said.

“There are ample data to suggest that racial minorities lack access to high quality medical care. Additionally, minorities who live in rural areas may not have the resources that would allow them to travel to a center which could offer RP. Other socioeconomic factors may also be at play given the correlation between higher income and the receipt of RP.

Source: Renal and Urology News, October 2014

Dr. Vincent C.O. Njar and Dr. Angela M.H. Brodie have worked on developing galeterone for treating prostate cancer. (Lloyd Fox, Baltimore Sun / August 13, 2014) A white powdered chemical compound emerged from two University of Maryland School of Medicine laboratories more than 10 years ago with a name destined for oblivion, but a future that now looks promising as a treatment for the most challenging cases of prostate cancer.

Today, VN/124-1 is a drug candidate with a name — galeterone — a pharmaceutical company founded on its potential and a record of strong preliminary results in clinical trials with human patients.

The Food and Drug Administration has put galeterone on a fast track for approval to treat prostate cancer, which kills about 30,000 men a year in the United States. Researchers in hospitals and clinics across the country and in Canada are finishing the trial's second round and preparing for the third, expected to begin early next year.

Dr. Kevin J. Cullen, director of the University of Maryland's Marlene and Stewart Greenebaum Cancer Center, acknowledged that results are preliminary, but he said it's an auspicious beginning.

"I can think of maybe one other drug in the 30 years I've been doing oncology that showed these kind of results," Cullen said. He called it an "incredibly promising start for this medicine."

Dr. Mario Eisenberger, heading the clinical trial at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, said the drug has had impressive results, but "I don't think anyone can say at this point in time whether galeterone is going to be better than the other" drugs already used to treat prostate cancer.

Before galeterone was a medicine, it was a compound born of a collaboration that began in 1996 between two University of Maryland researchers, Angela M. H. Brodie and Vincent C.O. Njar.

The approach was built on work for which Brodie has won some of the most prestigious awards in the field — research not in prostate but breast cancer. In the last 10 years, she won the Charles F. Kettering Prize and the Dorothy P. Landon-AACR Prize for Translational Cancer Research for her work in the 1970s and 1980s helping to develop compounds that block production of estrogen, the female hormone, that fuels the growth of most breast cancers.

More recently, she's turned her attention to prostate cancer, which feeds on the male hor-

mone. She wondered if the approach that worked with estrogen would work with the androgens, or hormones, that fuel prostate cancer: testosterone and the more potent dihydrotestosterone.

Up to now, one main treatment for the most challenging prostate cancers has been shutting down androgen production from the testicles. The procedure, referred to as castration, is most commonly done today by medication not surgery. The testicles produce about 90 percent of the body's androgen. Most of the rest is produced by the adrenal glands, and a small measure from the prostate tumor itself. Njar and Brodie were looking for a way to fight prostate cancer that continues after castration.

Their approach is one in a succession of hormone-based treatments that have been used for years, but it's different in combining several effects at once. This one works in three ways to interfere with androgen's effect on prostate cells. The medication decreases androgen production and interferes with the process by which the substance binds to the prostate cell molecule that responds to the hormone, known as the receptor. These effects have been produced before, but galeterone is the only medication that also appears to damage the receptor itself.

The triple threat showed impressive results in tests with mice about 10 years ago. Brodie and Njar and their research team published results in the *Journal of Medicinal Chemistry* in 2005, concluding that the compound "is a potent inhibitor of human prostate

tumor growth and is remarkably more effective than castration."

After that publication, Tokai Pharmaceuticals, a company in Cambridge, Massachusetts, named and licensed the compound as "galeterone." Clinical trials with human patients started in November 2009.

To fund its anticipated growth, Tokai applied in August to sell \$75 million of stock in an initial public offering. While its stock sale is pending, company officials are not available for comment.

According to information posted on Tokai's website, researchers have given the drug to 200 patients in the first two trial phases.

Of the 49 patients in the first trial, 24 showed 30-percent reduction in prostate specific antigen, or PSA, and 11 showed a 50-percent cut. Elevated levels of PSA can be, but are not necessarily, a marker for prostate cancer.

In the second phase, 51 patients — both with and without metastasis, or cancer spread beyond the prostate — followed for 12 weeks also showed significant PSA reductions. Of this group, 82 percent to 85 percent experienced reductions of about a third, three-quarters saw a reduction by at least half.

Cullen said he was struck by the results even in the first phase, conducted less for effects on the cancer than to see how well patients can tolerate the medication at low doses. With such low doses in the first phase of a

clinical trial, results like that are "almost unprecedented," he said. In the third phase of the trial, galeterone will be compared to existing treatments, Brodie and Njar said, and could take up to another year.

The FDA "fast track" can in some cases cut years off the time it takes to bring a drug to market, Eisenberger said.

Galeterone causes none of the adverse effects associated with chemotherapy, including nausea and hair loss. So far, Brodie said, the chief side effect could be deficiency of cortisol, but that has not been a problem so far. The hormone plays a role in regulating blood sugar, suppressing immune response and metabolizing fat, protein and carbohydrates.

Eisenberger said the effects can include fatigue and itching, but nothing requiring cortisol treatment.

Brodie and Njar are making no bold pronouncements at this point, just eagerly awaiting further results.

"We are cautiously optimistic," Njar said.

"It's a wonderful thing if we can save lives," Brodie said.

arthur.hirsch@baltsun.com
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Read more: <http://www.baltimoresun.com/health/bs-hs-sci-prostate-20140905,0,4351734.story#ixzz3Ee7Lt6fJ> Prostate cancer drug candidate shows great promise
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Lecturer
Series

**Poughkeepsie
Men to Men Group
Our brothers in support
and education**

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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