Our guest speaker at the August meeting was Karen Kunz, Medical Science Liaison, Myriad Genetics. She spoke about the Prolaris genomic test to help determine the risk factor of prostate cancer. Prolaris is a prognostic test developed to assess the aggressiveness of prostate cancer by measuring the intensity of tumor cell replication in the prostate tissue. Because the most common hallmark of cancer and its aggressiveness is rapidly growing tumors, Prolaris directly measures the tumor.
mor cell dynamics and provides an individualized score for each patient by rigorous quantitative evaluation of the RNA expression levels of genes related to cell proliferation. The test combines the patient’s PSA, Gleason and other clinical pathological features with the expression pattern of the tumor to predict meaningful patient outcomes. Prolaris has been validated in 4 published clinical studies. These studies include patients who have undergone radical prostatectomies and those that have not received curative treatment. It has lately been well publicized that there is an overtreatment problem in PCa. The quandary has always been that in order to deal with it we think we need to treat it. Yet we know that many men will have PCa and live out their full life without having to treat it. On the other hand there are issues with under treatment causing recurrence. Prolaris addresses these issues.

Prolaris looks at a man’s 10 year risk of PCa specific mortality, whether a man has a chance of biochemical recurrence after treatment and whether or not they are likely to have some disease progression. Prolaris is indicated for use for men who have organ confined disease classified as very low, low or intermediate risk. Prolaris is also indicated for organ confined disease that falls into the high risk category and men that have had a radical prostatectomy. In Prolaris scoring, the lower the number the better---even negative numbers are better. In studying over 2,000 laboratory tests, about 45% of the time Prolaris will give a result consistent with the clinical T stage. The other 55% is almost equally divided between those that fall into a more aggressive or less aggressive risk group.

The Prolaris score shows, based on the risk group the patient was already put in by their doctor, how that patient compares with other patients in their risk group. It also gives the U.S. distribution percentile for the same risk group. Lastly it calculates the mortality rate which is a 10 year risk for mortality if a patient does not receive treatment.

The question of cost obviously arose. The cost for this type of test is in the $3000+ range. Most of the time insurance will pay. The Myriad promise is that when any physician orders any Myriad test, Myriad will do the work with the patient’s insurance company to make sure it is pre-approved before they run the test. If for any reason your submission is completely denied, you will be told what your out-of-pocket amount will be and asked if you are okay with it or not.

As usual, more specific information will be available on the DVD of the meeting which will be available by the September 20th meeting at the library or on our website: http://ipcs.org/shop/

FUTURE MEETINGS

**September 20, 2014** - Roundtable Discussion. A panel of members will speak about their treatment experiences, followed by networking among members

**October 18, 2014** - A.J. Mundt, M.D., Professor and Chair, Department of Radiation Oncology UCSD, John P. Einck, M.D., Associate Clinical Professor Radiation Oncology UCSD: Radiation Therapy for Prostate Cancer: Current Treatments and New Developments.

**November 15, 2014** - Richard Lam, M.D. Research Director, Prostate Oncology Specialists: Androgen Deprivation Therapy and recent treatment developments.

December, 2014. **NO MEETING**
ON THE LIGHTER SIDE

This is the story of four people named Everybody, Somebody, Anybody, and Nobody. There was an important job to be done and Everybody was asked to do it. Anybody could have done it, but Nobody did it. Somebody got angry about that, because it was Everybody's job. Everybody thought Anybody could do it, but Nobody realized that Everybody wouldn't do it. Consequently, it wound up that Nobody told Anybody, so Everybody blamed Somebody.

The two biggest problems in America are making ends meet and making meetings end.

"I think I’ve discovered the secret of life -- you just hang around until you get used to it." — Charles M. Schulz

"Nothing travels faster than the speed of light, with the possible exception of bad news, which obeys its own special laws." — Douglas Adams

"Never underestimate the power of stupid people in large groups." — George Carlin

The aspiring psychiatrists were attending their first class on emotional extremes. "Just to establish some parameters," said the professor to the student from Arkansas, "What is the opposite of joy?"

"Sadness," said the student.

And the opposite of depression?" he asked of the young lady from Oklahoma.

"Elation," said she.

"And you sir," he said to the young man from Texas, "how about the opposite of woe?"

The Texan replied, "Sir, I believe that would be giddy-up."
FDA expands approval for Xtandi caps
SEPTEMBER 11, 2014 from Drugstore News

SAN FRANCISCO, Calif. and TOKYO, Japan — Medivation and Astellas Pharma on Wednesday announced that the Food and Drug Administration approved a new use of Xtandi (enzalutamide) capsules to treat patients with metastatic castration-resistant prostate cancer. The new approval follows a priority review of the supplemental new drug application that was based on results of a phase-three Prevail trial.

The FDA’s first approval for Xtandi in August 2012 was for patients with metastatic CRPC who had previously received chemotherapy. The new indication approves the drug for use in men with metastatic CRPC who haven’t received chemotherapy. Metastatic CRPC is cancer that has spread beyond the prostate gland and has progressed despite treatment to lower testosterone, the companies stated.

The FDA’s priority review and approval of this new indication for XTANDI now enables the use of an important therapy by patients with metastatic castration-resistant prostate cancer at all stages of their disease,” said Sef Kurstjens, M.D., Ph.D., chief medical officer of Astellas Pharma and president of Astellas Pharma Global Development. “We are pleased that these patients now have XTANDI available as a treatment option.”

The Lowdown On Testosterone Supplement and Low T
Posted: 9 Sep 2014 By Ralph Blum Prostate Snatchers Blog;

Low testosterone or “low T,” also called hypogonadism, affects millions of aging men. Testosterone levels normally peak in a man’s 20s, then fall by 1% to 2% per year. Indisputably, low T is responsible for reduced sex drive and sense of vitality, erectile dysfunction, decreased energy, and diminished muscle mass and bone density. As the poet T.S. Eliot reminded us, time the healer is also time the destroyer.

Men through the ages have tried outlandish cures for impotence, including chewing the roasted penis of a wolf! More recently they have plunged the family jewels into cold baths, choked down heaping spoonfuls of wheat germ, swallowed vitamins and most recently stockpiled Viagra.

When, in 1939, two scientists shared the Nobel Prize for Chemistry for their work in isolating and identifying testosterone, the mad rush for injected, implanted, inhaled or absorbed versions of the hormone began, promising, in the words of one product’s pitch, “power, performance, passion.”

In 2013, U.S. sales of testosterone reached $2.4 billion. According to Global Industry Analysts, the market is projected to swell to $3.8 billion by 2018. Moreover, in 2013, 7.5 million prescriptions for testosterone were written. And all this is happening without explicit FDA approval. There have been few, if any, large, randomized studies on the long-term risks or benefits of testosterone supplementation. Some maintain that we are undergoing a massive science experiment with unknown risks. But foggy science has not deterred Big Pharma from spending untold millions to encourage those of us who are wan, limp and flabby to climb onto the low T bandwagon.

Meanwhile, the most heated debate is centered on whether testosterone fuels prostate cancer. Not long ago, the consensus was that, as far as prostate cancer cells were concerned, testosterone was nature’s perfect food. It was like spinach to Popeye. Suppressing the hormone is still a standard part of treating the disease. But attitudes are changing.

The debate goes something like this: If it’s true that testosterone fuels prostate cancer, why do most men develop the disease when they are older and their testosterone levels are dropping? Others, how-

(Continued on page 5)
ever, point out that when men take hormone therapy that virtually stops the production of testosterone, tumors regress. So wouldn’t the opposite be true--adding testosterone should be expected to accelerate tumor growth? I personally believe that my episode of hormone treatment—monthly Lupron injections over a 15 months’ period—helped to delay the growth of my non-aggressive cancer for many years.

So far a few small studies of using testosterone in men with prostate cancer have shown fairly positive results. For example, men who had been treated for prostate cancer and who then received testosterone therapy did not appear to have an increased risk of recurrent disease. But it’s impossible to make broad, generalized statements based on these studies. Chances are the result will depend on a number of variables, not the least of which is the seriousness of the cancer. It seems likely that a man with low-risk of disease recurrence would also have low-risk of testosterone creating a problem. Therefore, it would seem ridiculous to deny that man testosterone when it would improve his quality of life.

There has been a major push for reconsidering testosterone therapy from the large population of men who have been treated for prostate cancer over the last 10-25 years. No surprise there. Which of us wouldn’t prefer to be firm and sharp rather than soft and dull? But remember, marketers are spending millions to raise our expectations, and testosterone is not a silver bullet.

In September, the FDA is gathering a group of experts for a T summit. But it’s doubtful if they will clarify a topic that has more guesses and theories than real answers based on reliable information. Bottom line it is our decision when the conditions are right to use testosterone, and when to refrain. As the old saying goes, “You pays your money and you takes your choice.”

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Researchers grow prostate cancer organoids in the lab; advances expected in personalized treatment
From Medical News Today September 8, 2014

Research led by investigators at Memorial Sloan Kettering Cancer Center has shown for the first time that organoids derived from human prostate cancer tumors can be grown in the laboratory, giving researchers an exciting new tool to test cancer drugs and personalize cancer treatment.

The researchers, whose results were published in Cell, successfully grew six prostate cancer organoids from biopsies of patients with metastatic prostate cancer and a seventh organoid from a patient’s circulating tumor cells. Organoids are three-dimensional structures composed of cells that are grouped together and spatially organized like an organ. The histology, or tissue structure, of the prostate cancer organoids is highly similar to the metastasis sample from which they came. Sequencing of the metastasis samples and the matched organoids showed that each organoid is genetically identical to the patient’s cancer from which it originated.

"Identifying the molecular biomarkers that indicate whether a drug will work or why a drug stops working is paramount for the precision treatment of cancer," said Yu Chen, MD, PhD, Assistant Attending Physician in the Genitourinary Oncology Service and Human Oncology and Pathogenesis Program at MSK. "But we are limited in our capacity to test drugs - especially in the prostate cancer setting, where only a handful of prostate cancer cell lines are available to researchers."

With the addition of the seven prostate cancer organoids described in the Cell paper, Dr. Chen's team has effectively doubled the number of existing prostate cancer cell lines.

"We now have a new resource at our disposal that captures the molecular diversity of prostate cancer. This will be an invaluable tool we can use to test drug sensitivity," he added.

The use of organoids in studying cancer is relatively new, but the field is exploding quickly according (Continued from page 4)
to Dr. Chen. In 2009, Hans Clevers, MD, PhD, of the Hubrecht Institute in the Netherlands demonstrated that intestinal stem cells could form organoids. Dr. Clevers is the lead author on a companion piece also published in Cell today that describes how to create healthy prostate organoids. Dr. Chen's paper is the first to demonstrate that organoids can be grown from prostate cancer samples.

The prostate cancer organoids can be used to test multiple drugs simultaneously, and Dr. Chen's team is already retrospectively comparing the drugs given to each patient against the organoids for clues about why the patient did or didn't respond to therapy. In the future, it's possible that drugs could be tested on a patient's organoid before being given to the patient to truly personalize treatment.

After skin cancer, prostate cancer is the most common cancer in American men - about 233,000 new cases will be diagnosed in 2014. It is also the second leading cause of cancer death in men; 1 in 36 men will die of the disease.

Despite its prevalence, prostate cancer has been difficult to replicate in the lab. Many mutations that play a role in its growth are not represented in the cell lines currently available. Cell lines can also differ from their original source, and because they are composed of single cells, they do not offer the robust information that an organoid - which more closely resembles a living organ - can provide.

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**New Promising Prostate Cancer Drug Profiled**

From Prostate Cancer News Today

A new drug candidate to treat challenging cases of prostate cancer, galeterone (VN/124-1), has provided strong preliminary results in clinical trials, leading the U.S. Food and Drug Administration (FDA) to put it on a fast track for approval.

The compound was developed 10 years ago in the laboratories of the University of Maryland School of Medicine and will now enter a Phase III clinical trial in hospitals and clinics across the U.S. and Canada.

"I can think of maybe one other drug in the 30 years I've been doing oncology that showed these kind of results. This is an incredibly promising start for this medicine," Dr. Kevin J. Cullen, director of the University of Maryland's Marlene and Stewart Greenebaum Cancer Center, said in a Baltimore Sun interview.

The compound began as collaboration between two Maryland University researchers, Angela M. H. Brodie and Vincent C.O. Njar, as a drug to block production of estrogen in breast cancer. However, Dr. Brodie hypothesized whether the strategy used for estrogen could also be applied towards androgens, testosterone, and dihydrotestosterone, which fuel prostate cancer.

One of the most common treatments for severe prostate cancer is drug-induced castration, a procedure that shuts down androgen production from the testicles. However, Dr. Njar and Dr. Brodie were looking for a way to fight prostate cancer that continued after castration.

Galeterone blocks the interaction between androgen and its receptor on prostate cells, damaging the receptor and impeding future hormone signaling.

These early investigational results were published in 2005 on the Journal of Medicinal Chemistry, showing that the compound was a potent inhibitor of human prostate tumor growth and significantly more effective than castration.

Some years later, Tokai Pharmaceuticals, a company located in Cambridge, Massachusetts, named and licensed galeterone and started preforming clinical trials in 2009.

So far, a total of 200 patients have already enrolled in the trial, with 24 out of the 49 patients from the first phase showing a 30% reduction in prostate specific antigen (PSA) and 11 showing a 50% cut. In the second phase, 51 patients also showed significant PSA reductions, with 82% experiencing reductions of about a third. Furthermore, galeterone caused none of the adverse effects associated with chemotherapy, including nausea and hair loss.

In the third phase of the trial, researchers want to compare galeterone to existing treatments, a process that could take more than a year. However, the FDA fast track approval could help to reduce the time necessary to bring this drug into the market.
NETWORKING

The original and most valuable activity of the INFORMED PROSTATE CANCER SUPPORT GROUP is “networking”. We share our experiences and information about prevention and treatment. We offer our support to men recently diagnosed as well as survivors at any stage. Networking with others for the good of all. Many aspects of prostate cancer are complex and confusing. But by sharing our knowledge and experiences we learn the best means of prevention as well as the latest treatments for survival of this disease. So bring your concerns and join us.

Please help us in our outreach efforts. Our speakers bureau consisting of Lyle LaRosh, Gene Van Vleet and George Johnson are available to speak to organizations of which you might be a member. Contact Gene 619-890-8447 or gene@ipcsg.org to coordinate.

Member and Director, John Tassi is the webmaster of our website and welcomes any suggestions to make our website simple and easy to navigate. Check out the Personal Experiences page and send us your story. Go to: http://ipcsg.org

Our brochure provides the group philosophy and explains our goals. Copies may be obtained at our meetings. Please pass them along to friends and contacts.

Ads about our Group are in the Union Tribune 2 times prior to a meeting. Watch for them.

FINANCES

We want to thank those of you who have made special donations to IPCSG. Remember that your gifts are tax deductible because we are a 501(c)(3) non-profit organization.

We again are reminding our members and friends to consider giving a large financial contribution to the IPCSG. This can include estate giving as well as giving in memory of a loved one. You can also have a distribution from your IRA made to our account. We need your support. We will, in turn, make contributions from our group to Prostate Cancer researchers and other groups as appropriate for a non-profit organization. Our group ID number is 54-2141691. Corporate donors are welcome!

If you have the internet you can contribute easily by going to our website, http://ipcsg.org and clicking on “Donate” Follow the instructions on that page. OR just mail a check to: IPCSG, P. O. Box 4201042, San Diego CA 92142

WE NEED HELP

All services for our group are performed by volunteers. As is usual in our type of organization we have a few doing a lot for many. We need people to step up and help in the following areas:

1. Fund Raising. We need help from anyone with any knowledge or willingness to become involved in acquiring grants to support our organization. We need someone to organize fund raising activities.

2. Information Technology. Any techies out there that can help take advantage of the facilities available where we meet--such as live remote conferencing.

Anyone interested please contact: Gene Van Vleet, Chief Operating Officer. 619-890-8447 gene@ipcsg.org or Lyle LaRosh, President 619-892-3888 lyle@ipcsg.org
Directions to Sanford-Burnham Auditorium
10905 Road to the Cure, San Diego, CA 92121

Take I-5 (north or south) to the Genesee exit (west).
Follow Genesee up the hill, staying right.
Genesee rounds right onto North Torrey Pines Road.
**Do not turn into the Sanford-Burnham Medical Institute or Fishman Auditorium**
Turn right on Science Park Road.
Turn Left on Torreyana Road.
Turn Right on Road to the Cure (formerly Altman Row).