Informed Prostate Cancer Support Group Inc.
"A 501 C 3 CORPORATION ID # 54-2141691"

MARCH 2014 NEWSLETTER

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We Meet Every Third Saturday (except December)

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Editor: Gene Van Vleet

Next Meeting
Mar. 15, 2014
10:00AM to Noon

Meeting at

Sanford-Burnham Auditorium

10905 Road to the Cure, San Diego CA 92121

SEE MAP ON THE LAST PAGE

Sunday, March 09, 2014 Volume 7 Issue 2

What We Are About

Our Group offers the complete spectrum of information on prevention and treatment. We provide a forum where you can get all your questions answered in one place by men that have lived through the experience. Prostate cancer is very personal. Our goal is to make you more aware of your options before you begin a treatment that has serious side effects that were not properly explained. Impotence, incontinence, and a high rate of recurrence are very common side effects and may be for life. Men who are newly diagnosed with PC are often overwhelmed by the frightening magnitude of their condition. Networking with our members will help identify what options are best suited for your life style.

Be your own health manager!!

PROSTATE CANCER IT'S ONLY 2 WORDS, NOT A SENTENCE

February Meeting Recap

Dr. Christopher Kane, Professor and Chair of the Urology Department at UC San Diego, discussed enhanced prostate cancer detection and risk stratification using MRI targeted biopsies and genetic testing.

The challenge in understanding prostate cancer is that it is a very common disease but only a minority of cases are serious enough to require treatment. There is more and more discussion that maybe low risk prostate cancer should be named something different so as not to trigger unnecessary treatment reactions. Over the last 10 years the link

Video DVD's

DVD's of our meetings are available in our library for $10ea. Refer to the index available in the library. They can also be purchased through our website: http://ipcsg.org

Click on the 'Purchase DVDs" button.

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between diagnosis and treatment approaches 100%. Therefore there is a great need for risk stratification of prostate cancer. There has been a 39% reduction in deaths from prostate cancer in the U.S. and the developing world in the last 25 years. Serum testing (PSA) for prostate cancer significantly reduced the chances of dying from it. However this has an associated risk of over-detection--defined as treating a disease that would never have caused harm in a man's lifetime. The PSA test is a poor screening test. It is a highly sensitive test in detecting the presence of prostate cancer but it is not specific. Most men with an abnormal PSA do not have prostate cancer. Therefore, a majority of these men with an abnormal PSA need more testing to determine if they need treatment. Another issue is that men who are treated often have bad side effects which can include surgical complications, erectile dysfunction and incontinence.

This all means that better methods of screening must be developed in order to specifically define the risk. Most of the medical associations dealing with prostate cancer now share the goal of developing specific testing methods. Men who are unlikely to benefit should not be screened, i.e. men over 75 who have had normal screenings throughout their lifetime should discontinue testing. Men at the proper age to benefit (40-65) should be screened, especially those with the highest risk. This can be determined by ethnicity, family history and single-nucleotide polymorphism (SNP) testing. This is a genetic test of a patient that can be done at any point in their lifetime that can identify the risk of developing prostate cancer. Therefore it could be used to identify if and when a person needs to be screened. PSA specificity can be improved using PSA isoforms such as cPSA, Free PSA, PSI, PCA3, TMPRSS ERG and by MRI. MRI is clearly associated with the grade of cancer.

The standards of risk stratification are : PSA, Clinical Stage, Gleason Grade, Number and extent of positive biopsies, PSA velocity/ PSA kinetics, Obesity and Imaging . Imaging can include bone scans, CT scans and MRI. New to screening and risk management are MRI "fusion biopsies" for men with rising PSA and prior negative prostate biopsies or men having active surveillance repeat biopsies. This allows identification of lesions and directed biopsies for enhanced diagnosis. The value of a fusion biopsy as an initial evaluation is debatable because of cost but should be considered for repeat biopsies especially for those with a rising PSA and those on active surveillance.

Molecular risk stratification goes beyond Gleason grade. Three companies have been approved for these tests in the last year. For men who have had a biopsy, Myriad's "Prolaris" better predicts the chance for recurrence. It uses tissue from the already-performed biopsy. (see article on page 8) Another equally good similar test is Genomic Health's "Oncotype DX". The "Decipher" test is different in that it looks at tissue from radical prostatectomies to predict the possibility of recurrence after surgery.

Active surveillance is now the number one choice for low risk prostate cancer. Repeat biopsies are an integral part of this choice. A study at UCSF found that about 34% of the men on active surveillance had an increase in their Gleason Grade and the majority of that increase was from 3+3 to 3+4 and the majority of the upgrades were in the first or second biopsy within 30 months of the original biopsy. An integral part of active surveillance is image guided biopsies. Dr. Kane showed many comparative slides showing the increase effectiveness of fused MRI imaging. Dr. Karow has been brought on board at UCSD to implement an effective program for this technology.

Dr. Kane's presentation includes much more relevant information including responses to audience questioning—available on the DVD of this meeting which will be available by the next meeting through the library or from our website: http://ipcsg.org/shop/

FUTURE MEETINGS

March 15, 2014 - Dr. Russell Low, Medical Director of Sharp and Children's MRI Center. DCE MRI Techniques for Prostate Cancer Diagnosis and Surveillance.

April 19, 2014 - Dr. Fabio Almeida, Medical Director Southwest PET/CT Institute. Dr. Almeida returns to present updated information relating to Carbon C-11 Acetate PET/CT imaging for recurrent prostate cancer.

May 17, 2014 - Roundtable.

June 21, 2014 - Dr. Irwin Goldstein, Director of Sexual Medicine, Alvarado Hospital speaks about the effects of PCa treatments on sexuality and Dr. Andrew Goldstein updates his work in stem cell research in relation to PCa.

July 19, 2014 - David S. Karow, M.D., Ph.D., Assistant Clinical Professor of Radiology, Director of Body MRI, will be presenting "New imaging innovations in prostate cancer detection and targeted biopsies".

August 16, 2014 - Karen Kunz, Medical Science Liaison, Myriad Genetics. Prolaris Genomic Test as an aid

ON THE LIGHTER SIDE

Our Tax Dollars At Work

"People say nothing is impossible, but I do nothing every day." — A.A. Milne, Winnie-the-Pooh
"If you try to fail, and succeed, which have you done?" — George Carlin
"Life is worth living as long as there's a laugh in it." — L.M. Montgomery, Anne of Green Gables
"In politics, stupidity is not a handicap." — Napoleon
"Those people who think they know everything are a great annoyance to those of us who do." — Isaac Asimov

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My neighbor has a circular driveway... He can't get out.
Why are there interstate highways in Hawaii?
Why is it that when you transport something by car, it's called a shipment, but when you transport something by ship, it's called cargo?
How do they get a deer to cross at that yellow road sign?
When it rains, why don't sheep shrink?

NOTEWORTHY ARTICLES

Summary of the PCF Retreat

Edited from February PCRI Insights 2014 Vol. 17 Iss. 1
By Mark Scholz, M.D., Prostate Oncology Specialists

Over the years, as the pace of scientific advancement accelerates, the new science being presented becomes even more hopeful and innovative. The best meeting each year is hosted in October by the Prostate Cancer Foundation (PCF). The meeting is put together by Howard Soule, the PCF director of research. This year was the PCF's 20th annual meeting. It consisted of two full days of presentations, each averaging about fifteen minutes long. The sheer volume of new information is delightfully overwhelming.

A good number of presentations are at the basic science level and therefore have little relevance to the average reader of Insights. Research into basic science is designed to elucidate the fundamental biology and biochemistry of tumor cells. It is a laborious and expensive process designed to work out the "basic blueprints" of cancer function. The idea is to build a scientific foundation for the future discovery and rational design of new drugs. I'll try to summarize the presentations that may be of greater interest to our readers.

A Retrospective on Surgery

Historically the PCF has focused on developing treatments for advanced disease. However, this year they hosted a 45-minute panel session of five famous prostate doctors to discuss the modern role of surgery. Dr. Holden, the medical director of the PCF moderated a discussion with Patrick Walsh, Phil Kantoff, Chris Logotheitis, and Eric Klein (three urologists and two medical oncologists). Howard Sandler, a radiation therapist was asked to chime in from the audience.

In light of the acknowledged fact that surgery is unnecessary for low-risk prostate cancer it was fascinating to hear Dr. Klein and Dr. Walsh (the two surgeons on the panel) talk about the great research benefits and wonderful pathologic information we have obtained from actual prostates, the same ones that have been surgically removed over the last 20 years. As if this somehow gave purpose and meaning to the millions of men who have been treated with radical surgery! Patients in the audience must have felt a chill run up their spines at the cold blooded disregard for all the unnecessary, surgically-induced human suffering.

During the panel discussion both Dr. Kantoff, a medical oncologist, and Dr. Sandler, a radiation oncologist, were unwilling to make any remarks that could be construed as disagreement with Dr. Walsh. Therefore I apparently risk repercussions by disagreeing with a sweeping statement made by Dr. Walsh, "Men with high-risk disease treated with surgery don't need hormonal therapy." To be fair, I agree with Dr. Walsh that some favorable types of high-risk disease can forgo hormonal therapy. However, there is

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a least one piece of compelling evidence that men in the high-risk category treated with adjuvant hormone therapy experience lower relapse rates according to a large prospective study published in the Journal of Clinical Oncology by Dr. Tanya Dorff from USC.

My favorite quote from the panel discussion was from Chris Logotheitis, the medical oncologist from MD Anderson. He said, "If surgery was a new drug under evaluation for approval by the FDA to treat low-risk prostate cancer—it would never be FDA approved."

On another note, Dr. Klein, the urologist from the Cleveland Clinic expressed the optimistic belief that all the new genetic tests that help confirm that low-risk prostate cancer is really low-risk such as Prolaris and OncotypeDX, will lead doctors to restrain themselves from the overuse of surgery and radiation. Personally, I am not so optimistic that the ingrained systematic overtreatment of men with low-risk disease will be so easily revolutionized.

New Immune Therapy

I am particularly excited about new treatments with the potential for harnessing the immune system to fight cancer. The immune system is very complex with many moving parts. The T-cells are a component of the immune system that is utilized to attack cancer cells directly. However, cancers often "cloak" themselves from the immune system using mechanisms to "blind" the T-cells to their presence.
Some of the new immune-based therapies work by awakening the immune system to "see" the cancer cell and attack it. Provenge is one such example, a FDA approved treatment for prostate cancer that sensitizes the immune system to the PAP antigen. At the meeting, new research was presented describing a newly created antibody that focuses T-cells on a different target, the PSMA antigen, a protein located on the surface of cancer cells. This new therapy uses a uniquely designed cancer-specific antibody that has been chemically altered to guide activated T-cells directly to the surface of the cancer cell.
Improving the Identification of High-Risk Prostate Cancer

Another important area of development in cancer therapy is what I call the reconnaissance aspect of cancer treatment. In military terms, you can't fight the enemy if you don't know the strength of his forces and their specific location. New research presented at the meeting gave details about the discovery of a new gene product called SCHLAP-1 that helps predict the likelihood of future metastases. SCHLAP-1 appears to have predictive power on the same order as Gleason score or possibly, even better. Most of you are already familiar with cancer grading using Gleason and how it is critically important in distinguishing low-grade from high-grade disease. The availability of a new predictive factor of this stature would be a wonderful addition to our clinical armamentarium.

Promiscuous Hormones

It has long been suspected that when the androgen receptor gets blocked, the cancer cell's lack of access to testosterone stimulates a switch in the cancer cell to start using other hormones like progesterone or cortisol as a substitute to feed itself. Research presented at the meeting seems to confirm this. However, these findings are preliminary as the studies were laboratory based rather than clinical studies in humans. We will have to wait to find out if these new discoveries are clinically factual or just an artifact of an artificial lab environment.

Getting a Leg Up on The FDA for Approving New Drugs

One of the biggest factors slowing down the new-drug FDA approval process is the requirement that all new medications demonstrate a survival advantage in a clinical trial. Ironically, this immutable demand from the FDA becomes harder to fulfill as the number of effective drugs increases. Just in the last few years Provenge, Zytiga, Xtandi, Xofigo, and Jevtana have become available. Many experts believe that it is not ethical to study new, unproven drugs until all the proven drugs have been tried and found to be inef-

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fective. So as more and more effective drugs get approved, fewer and fewer patients will be available for participation in clinical trials and the ones who are eligible to participate will have very advanced, treatment-resistant disease.

A percentage drop in PSA after treatment has been repeatedly proposed as a measure of treatment effectiveness rather than survival. PSA actually works well in some situations such as with chemotherapy or hormonal therapy. However, PSA can be notably inaccurate as has clearly been demonstrated with Provenge and Xofigo as neither causes a consistent decline in PSA though both have shown to improve survival.

At the meeting Dr. Howard Scher presented some hopeful information about ongoing studies that rely on measuring a decline in circulating tumor cells (CTC) in response to therapy as an accurate method for the early prediction of long term survival. The actual protocol proposed by Dr. Scher used CTC levels in combination with a measurement of an enzyme in the blood called lactate dehydrogenase (LDH). Using this proposed system, patients with advanced disease were divided into three risk categories. "Low-risk" patients had normal CTC and LDH levels. "High-risk" patients had a CTC count above five. "Intermediate-risk" patients had an elevated LDH with a normal CTC count. What's exciting is that this system has already been tested and validated to predict survival. Dr. Sher is planning to propose this new system for evaluating new drugs to the FDA in the near future. If successful, substituting the measurement of CTC for the existing system of measuring survival could really speed up the new-drug approval process.

Finally, A Way to Detect Microscopic Metastases?

Victor Velculecu from Johns Hopkins presented his work which suggests that the presence or absence of microscopic residual disease can be detected with new genetic tests called genomic analysis. If this work is confirmed it could revolutionize the way we treat cancer. For example, right now many men are treated with long term hormonal therapy after radiation because of the possibility that microscopic metastases are present. If an accurate test were available that could confirm that a patient is totally free of metastases, that patient could safely be advised that long-term hormonal therapy is unnecessary!

Reducing the Side Effects of Xofigo?

Dr. Morris presented some fascinating information about the function of injectable Radium (Xofigo) which was recently approved by the FDA. Xofigo is generally well tolerated but the most common side effect, if a side effect occurs, is GI related. This appears to occur because after the Xofigo is injected into the blood stream it lands in the bone and attacks the cancer. However, some of the Xofigo is not taken up by the bone and gets excreted through the small intestine. Therefore, the excess radioactivity passes sequentially through both the small bowel and the large bowel. Apparently the dose of radiation is too small for most men to feel it. However, some men are more sensitive and experience nausea or diarrhea as a result. Men who have GI symptoms from Xofigo (since the side effects caused by radiation are related to both dosage and duration of exposure) might want to consider taking a laxative to accelerate the bowel transit time.

Botox for Prostate Cancer?

At the meeting some fascinating data showed the dependence prostate cancer cells have on growth factors secreted by the nerves in the prostate. One of the possible culprits is a hormone called vasointestinal peptide. A study was performed by injecting Botox into half of the prostate of men with known bilateral cancer. The other side of the prostate was injected with an inactive salt solution. A month later the men underwent radical prostatectomy. After surgery it was confirmed that the cancer regressed on the side of the prostate that was injected with Botox. The physician presenting went on to theorize that the

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development of neuroendocrine prostate cancer, a feature that is common in advanced hormone refractory prostate cancer, is really nothing more than cancer evolving its own "nerves" so it has plenty of nerve growth factors to feed on. A paraphrased quote from him would perhaps read as follows, "Under stress [of hormonal therapy] the cancer makes its own nerves."

Conclusion

The little snippets of information I have shared with you in this short article do no justice whatsoever to the absolute deluge of quality science that was presented at the two-day meeting. The PCF is doing a wonderful job of raising money and distributing it wisely to the best researchers in the world. Howard Soule and his excellent team should be greatly commended for the wonderful work they are doing to encourage the development of effective new prostate cancer treatments. It's hard to believe the PCF had called this meeting a "retreat." The way things are going I would recommend renaming it an "advance." Happily, the development of new treatments for prostate cancer is moving forward at a furious pace.

Multiparametric MRI imaging and risk for clinically significant prostate cancer

Posted on February 25, 2014 by Sitemaster

A new paper in Urology suggests that combination of data from multiparametric magnetic resonance imaging (mpMRI) with traditional risk factors (Gleason score, clinical stage, PSA level, etc.) may be able to improve identification of men at risk for clinically significant prostate cancer at time of diagnosis.
Chamie et al. looked retrospectively at data from 115 patients who all underwent a multiparametric MRI at their institution and then went on to have a radical prostatectomy. They compared the patients on the basis of the historical Johns Hopkins criteria for active surveillance (the so-called "Epstein criteria") with and without the additional information available from the mpMRI.

Specifically, Chamie et al. were able to show that:

- 77/115 (67 percent) of their patients had a PSA level between 4.1 and 10.0 ng/ml.
- 104/115 (90 percent of their patient had a normal rectal examination.
- 78/115 (68 percent) of their patients had a biopsy Gleason score ≤ 6.
- 63/115 (55 percent) of their patients had ≤ 2 cores positive for cancer.
- 58/115 (50 percent) of their patients were pathologically staged with Gleason 7 or pT3 disease at prostatectomy.
- Of these 58 patients, the historical Epstein criteria failed to identify 12 patients (sensitivity, 79 percent; negative predictive value [NPV], 68 percent).
- Addition of apparent diffusion coefficient from mpMRI data improved the ability to accurately predict clinically significant disease at prostatectomy (sensitivity, 93 percent; NPV, 84 percent).
- MRI improved detection of large Gleason 6 lesions (≥ 1.3 ml, $P = 0.006$) or lesions of any size inclusive of Gleason ≥ 7 ($P < 0.001$).

The evidence of potential value of mpMRI scans in the early evaluation of men with localized prostate cancer (specifically in terms of the ability to identify those men who are and are not the best candidates for active monitoring as opposed to immediate treatment) is growing. However, the practical application of mpMRI is still a work in progress. There are cost factors and standardization factors that still need to be addressed in the use of mpMRI, as well as appropriate training of uroradiologists in the assessment of these mpMRI scans.

It should also be noted that Johns Hopkins personnel have indicated that they intending to revise and slightly broaden the Epstein criteria for eligibility for active surveillance, and this revision may well be

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relevant to the accuracy of the criteria alone as compared to the combination of the criteria with additional mpMRI data.

Treatment decisions significantly modified by Myriad's Prolaris for prostate cancer

Friday 31 January 2014 - 12am PST from Medical News Today.

Myriad Genetics, Inc. (NASDAQ: MYGN) has announced results from PROCEDE 500, a clinical utility study with its Prolaris test, at the 2014 ASCO Genitourinary Cancers Symposium in San Francisco, Calif. The study demonstrated the significant clinical value of Prolaris to physicians who are treating men with prostate cancer. Prolaris is a prognostic test that accurately predicts prostate cancer-specific death and metastases and has been validated in 11 clinical studies with more than 5,000 patients.

"Prolaris has opened the door to a new era of personalized cancer treatment for men with prostate cancer," said Michael Brawer, M.D. vice president of medical affairs at Myriad Genetic Laboratories. "The Prolaris score is a stronger predictor of prostate cancer death and recurrence than either Gleason score or PSA (prostate specific antigen), and delivers clinically relevant information not provided by any other prognostic test."

PROCEDE 500 is an ongoing prospective registry study designed to examine the clinical utility of Prolaris. Currently, 331 patients have been enrolled and 150 clinicians have completed surveys in 305 cases to assess the influence of the Prolaris score on clinical decision making. Results for these interim data show that in 65 percent of cases, physicians changed their intended therapy and selected a different treatment based on the Prolaris test score. In 40 percent of patients, physicians reduced the therapeutic burden on patients and opted for conservative management options such as active surveillance and watchful waiting. In 25 percent of cases, physicians increased treatments including the use of surgery or radiation, and in 35 percent of cases, physicians did not change their treatment plans. Full results from PROCEDE 500 have been submitted to a peer-reviewed medical journal for publication.

"As a clinical researcher, I advocate for evidence-based medicine. The Prolaris test score accurately tells me if a patient has an aggressive prostate cancer or not and guides my treatment decisions," said Ashok Kar, M.D., St. Joseph's Hospital in Orange, Calif. "As a practicing physician, I must ask the same question for every patient; should I use surgery or radiation, or should I use active surveillance and watchful waiting? Prolaris helps me answer this critical clinical question."

EDITORS NOTE: Prolaris will be the subject of our meeting August 16th

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

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.

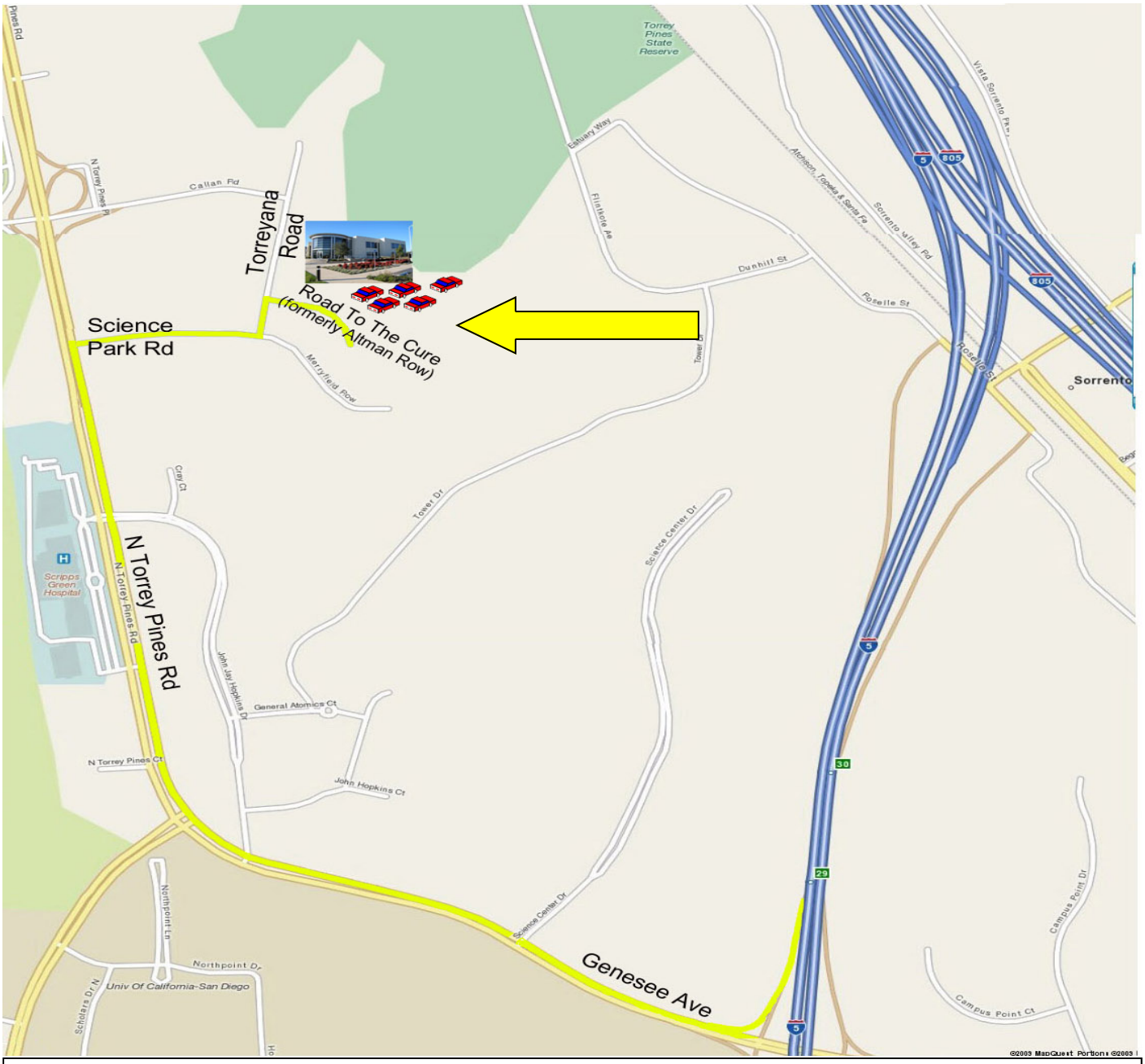
Anyone interested please contact: Gene Van Vleet, Chief Operating Officer. 619-890-8447 gene@ipcsg.org orLyle LaRosh, President 619-892-3888 lyle@ipcsg.org

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



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).