



PRESIDENT'S MESSAGE

Welcome to Summer after the Stay at Home quarantine and the ongoing changes to our daily lives that none of us could have ever imagined. Most of us understand the necessity for doing everything virtually – and we are staying grateful for all we have that helps us to weather this pandemic; we are committed to staying healthy.

Our fight against Prostate Cancer continues, COVID-19 or not. Many of us are looking into what happens now with delays in diagnosis, in treatment, in follow-up. We are investigating and researching if any of the prostate cancer treatment modalities cause our immune systems to become less efficient. Many of our activities have been cancelled, and others are now scheduled to be done virtually, such as the American Urologic Association (AUA) which was held online June 27 and 28; and the annual ASCO Meeting which was held virtually on May 29-31, 2020 (see report in this issue). Our 2nd Annual CPCC/UCSF Patient Conference on Prostate Cancer, scheduled for June 6, 2020 but then postponed until September of this year, has now been completely re-scheduled for June 2021. The 16th Annual Meeting of the National Alliance of State Prostate Cancer Coalitions (NASPCC), scheduled for October 9-11, 2020, will now be held January 29-31, 2021 (and we are keeping our fingers crossed that the January dates will work).

In March we lost a long-standing, devoted Board Member, Sam Wells, to whom we presented an Award for Outstanding Service in January 2017. Sam was on the CPCC team that walked the halls of the State Capitol in Sacramento and who helped make IMPACT a permanent program to help underserved men with prostate cancer in California. He was dedicated and tireless, and always a gentleman. We will miss him as we continue our fight against prostate cancer.

For the first time ever, CPCC has taken out an ad in the quarterly California Family Physician, with links to our Website and to our Informed Decision-Making Laminates. In the current edition, our ad is on Page 25 of 32. We are thrilled at the thought that we will be connecting with physicians who will utilize our Laminates to help patients.

We know that the need for support, for knowledge, for effective tests and treatments continues as strongly as ever. CPCC is working to make sure that those men and families who need the services of support groups can still find support. We are working to find a way to make that happen, virtually, for those groups who are interested. In the meantime, please reach out to us if we can help in any way. Write me at mgrey@ucsd.edu, or our Board Members Frank Balthis (frankbalthisphoto@gmail.com), or Beverly Nicholson (beverlynicholson@comcast.net).

Keep up the fight against prostate cancer! -- Best regards, Merel Grey Nissenberg, President

POSTPONED: 2ND ANNUAL CPCC/UCSF PATIENT CONFERENCE ON PROSTATE CANCER ORIGINALLY PLANNED FOR JUNE 6, 2020

The 2nd Annual CPCC/UCSF Patient Conference on Prostate Cancer, last held on June 8, 2019 at UCSF Medical School, has been postponed until June 2021. It will take place at Mills College in Oakland which has capacity for 400 attendees. In the meantime, you can view the videotapes from last year's conference by visiting the University of California UCTV Website at: <https://uctv.tv/2019-prostate-cancer-conference/>. The 2019 conference videos have been accessed nearly 144,000 times.

FOCUS ON CALIFORNIA PROSTATE CANCER SUPPORT GROUPS: CPCC SURVEYS CALIFORNIA SUPPORT GROUPS REGARDING UTILIZATION OF ONLINE MEETINGS DURING COVID-19 PANDEMIC

In April, the CPCC Board expressed concern about how California prostate cancer support groups are responding to help their members while social distancing and other precautions to decrease the risk of COVID-19 spread stopped in person meetings. CPCC recognized that support group participants share special bonds with their groups. How to connect with individuals facing prostate cancer issues during this period of social isolation presents many new challenges to support group leaders. At the same time the Board recognized that groups may have concerns about how to use online platforms while protecting men's privacy and security.

On April 10th, a survey designed by Frank Balthis, CPCC Board member, was sent out to over 90 individuals representing about 65 prostate cancer support groups in the State. Below are the results of the survey.

Survey Results:

1. Sixteen group leaders responded to the survey.
 - 8 of the leaders were lay leaders (prostate cancer survivors)
 - 7 were professional facilitators. 1 did not specify.
2. 9 of 16 groups were holding online meetings.
 - 8 groups used Zoom and 1 used Go to Meeting.
3. The average attendance for online meetings was 14.
 - The high attendance was 24 and the low was 4.
4. Estimates regarding devices used varied greatly from group to group.
 - Most were rough estimates, from 100% computer use to 80 % smart phone use.
5. All of the leaders using Zoom reported positive feedback from members.
 - Comments ranged from "Bravo" to "acceptable given the alternatives." "Go to Meeting" was used by one group was satisfactory. It was chosen for use by that group because of security issues reported regarding ZOOM leading members to express concerns.

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- Zoom users addressed security by requiring passwords and waiting rooms. They also were careful to go over the basic rules for privacy. Good faith HIPPA rules were followed.
- Those not holding online meetings were concerned about privacy, liability, and security issues. Those groups are using phone calls and e-mails to stay in touch.

Please contact Frank Balthis at frankbalthisphoto@gmail.com, Merel Grey at mgrey@ucsd.edu, or Beverly Nicholson at beverlynicholson@comcast.net if you have other comments, wish to share your experiences or if CPCC can be of any additional support. **If your local group does not have online meetings plan, consider the CancerCare online support group option described below.**



PROSTATE CANCER ONLINE SUPPORT GROUP

CANCERcare®

ABOUT THE SUPPORT GROUP

In partnership with the National Alliance of State Prostate Cancer Coalitions (NASPCC), CancerCare is offering a 15-week online support group is for people diagnosed with **prostate cancer** who are currently receiving treatment. In this group **led by an oncology social worker**, patients give support to each other and share resources and information.

Start Date - Monday, June 1, 2020 (*Group accepts new members after start date.*)

[TO JOIN THIS SUPPORT GROUP, PLEASE USE THIS LINK](#)

The support group:

- Reduces feelings of loneliness, anxiety, and distress
- Helps you learn new ways of coping
- Increases feelings of hope and empowerment
- Provides you with practical information about treatment and resources
- Helps you communicate better with your medical team and loved ones

To join this group, you will need to complete our online registration process. After joining this **password-protected group**, you can read and post messages 24 hours a day, 7 days a week. Currently, CancerCare's online support groups are only available to people residing within the United States (including Puerto Rico and U.S. territories).



EVOLUTION OF PROSTATE CANCER TREATMENT: A UROLOGIST'S PERSPECTIVE AN INTERVIEW WITH LEONARD S. MARKS, MD

Dr. Leonard Marks is a Professor of Urology and the deKernion Endowed Chair in Urology at the David Geffen School of Medicine at UCLA. He received his medical degree from the University of Texas in 1969. After graduation, he served an internship and surgical residency at UCLA/Harbor General Hospital. For two years he served on active duty as Lt. Cdr. in the U.S. Public Health Service. In 1973 he returned to UCLA as a post-doctoral research scholar and completed his urology residency at UCLA in 1978. He then established his private practice in Los Angeles continuing to be involved in clinical research. Dr. Marks founded a non-profit research organization, Urological Sciences Research Foundation, to further his academic interests. He re-joined the UCLA faculty full-time in 2009. He currently serves on the Board of the California Prostate Cancer Coalition.

Dr. Leonard Marks is in an excellent position to discuss the evolution of prostate cancer treatment. During a recent interview, he shared his perspective on the incredible improvements in treatment that he witnessed during his career, now spanning five decades. Dr. Marks remembered urologists who played key roles in the specialty of urology and prostate cancer treatment. The hard work of pioneers in the field led to the dramatic decline in the prostate cancer death rate over past 40-50 years. According to the American Cancer Society, the prostate cancer death rate has declined by 52%, from a peak of 39.3 (per 100,000) in 1993 to a low of 18.8 in 2017. However, prostate cancer remains the 2nd leading cause of cancer deaths in men in US. (*Cancer Facts and Figures 2020, ACS*)

Dr. Marks remembers one of the early influential physicians, Dr. Elmer Belt, an associate professor of urology and clinical professor of surgery at the University of California, Los Angeles School of Medicine in the 1940's. After World War II, Dr. Belt was one of the leading proponents of establishing a second medical school in California at UCLA. He convinced then Governor Earl Warren who happened to be his patient, to support this idea. The plan was approved and signed into law by Gov. Warren in October 1945. (*Reference <https://medschool.ucla.edu/history>*). Dr. Belt then convinced his nephew, Willard Elmer Goodwin, to move to UCLA from Johns Hopkins to establish the Department of Urology in the early 1950's. Dr. Goodwin became the founding chair of the Division of Urology in the Department of Surgery at the UCLA School of Medicine in 1951, establishing the foundation for it to become the center of excellence it is today.

Reference: From the guide to the Willard Goodwin collection of William Osler correspondence, 1893-1947, (University of California, Los Angeles. Library. Louise M. Darling Biomedical Library History and Special Collections for the Sciences

The 1970's

Dr. Marks recalls that during his internship in the early 1970's, patients diagnosed with prostate cancer usually had advanced disease with metastasis to the bones and soft tissue. No early detection

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methods were routinely available except for a lucky finding on a physical exam. Effective treatment options were limited. Although the first radical prostatectomy (RP) was performed in 1904, in the 1970's the surgery was thought of as a very sophisticated and complex procedure. When RP was on the operating room schedule blood banks were put on alert because twenty units of blood loss was common, and the complication rate was high.

Hormonal therapy was the mainstay for treatment of advanced prostate cancer, thanks to the work of pioneering researchers in previous decades. Dr. Charles Higgins had discovered the effectiveness of castration for the treatment of advanced prostate cancer in 1941. He was awarded the Nobel Prize in Physiology and Medicine for this discovery in 1966. Later, Dr. Andrew Schally discovered the structure of luteinizing hormone releasing hormone and developed the means to synthesize it. He and Roger Guillemin received the Nobel Prize in Physiology and Medicine in 1977 for this work. These developments set the stage for the research efforts that led to the discovery of the many drugs used today for hormonal manipulations starting with the FDA approval of Leuprolide in 1985.

After completing his residency at UCLA in 1978, Dr. Marks went to the Netherlands on a sabbatical to study with urologists who were exploring how to spare nerves during RP, to decrease surgical morbidity and to improve quality of life. At that time RP's were performed about 150,000 times a year. In 1983 Dr. Patrick Walsh at Johns Hopkins, previously at UCLA, published his work and established the nerve-sparing radical prostatectomy technique. Dr. Marks took that new skill into the community as he started his private practice, teaching other physician this new approach. Looking back on Dr. Walsh's early work, Dr. Mark notes most of those patients had Gleason Score 6 disease. Today those patients may have avoided surgery altogether with active surveillance or focal therapy.

The 1980's

In the early 1980's urologists realized that the chances of curing prostate cancer were improving. Prostate Specific Antigen (PSA) was identified in blood in 1979 and the PSA blood test was approved by FDA for monitoring prostate cancer in 1986. PSA was not approved for screening and early detection screening until 1994. Dr. Marks followed the PSA story from Day 1 and was involved early on in PSA research. He collaborated with Hybritech Inc., San Diego, CA, providing samples for the research to establish the clinical use of PSA testing. Although the PSA test is not perfect, its development played an important role in prostate cancer treatment. By the end of the 1980's PSA was the major driver of radical prostatectomy surgeries. Dr. Marks recalls that elevated PSA levels brought

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men into urology offices. The development of Viagra in 1989 made radical prostatectomy more acceptable to men. Senator Robert Doyle and his wife, Elizabeth shared their story with the public after his prostate cancer diagnosis. They talked openly about erectile dysfunction (ED) and the role of Viagra. As a result of their efforts, more men came to urologists seeking treatment for ED and then were tested and diagnosed with earlier stage, curable prostate cancer. Fortunately, around 1988 an ultrasound guided biopsy device was approved, allowing urologists to perform biopsies in outpatient settings.

The 1990's

PSA testing continued to increase the number of men being diagnosed with prostate cancer or seeking a prostate cancer work up. The availability of Leuprolide (Lupron) to treat advanced prostate cancer had a big impact on prostate cancer treatment in the 1990's. For example, orchiectomy was rarely recommended since Lupron could be administered, thus sparing men this disfiguring surgery. However, Dr. Marks recognizes that Lupron was overused and abused by some urologists. Unfortunately, government reimbursed for the drug generously and drug companies gave physicians financial incentives to use it. Four urologists went to jail for abuse. Now FDA monitors these practices closely and regulations prevent such abuses.

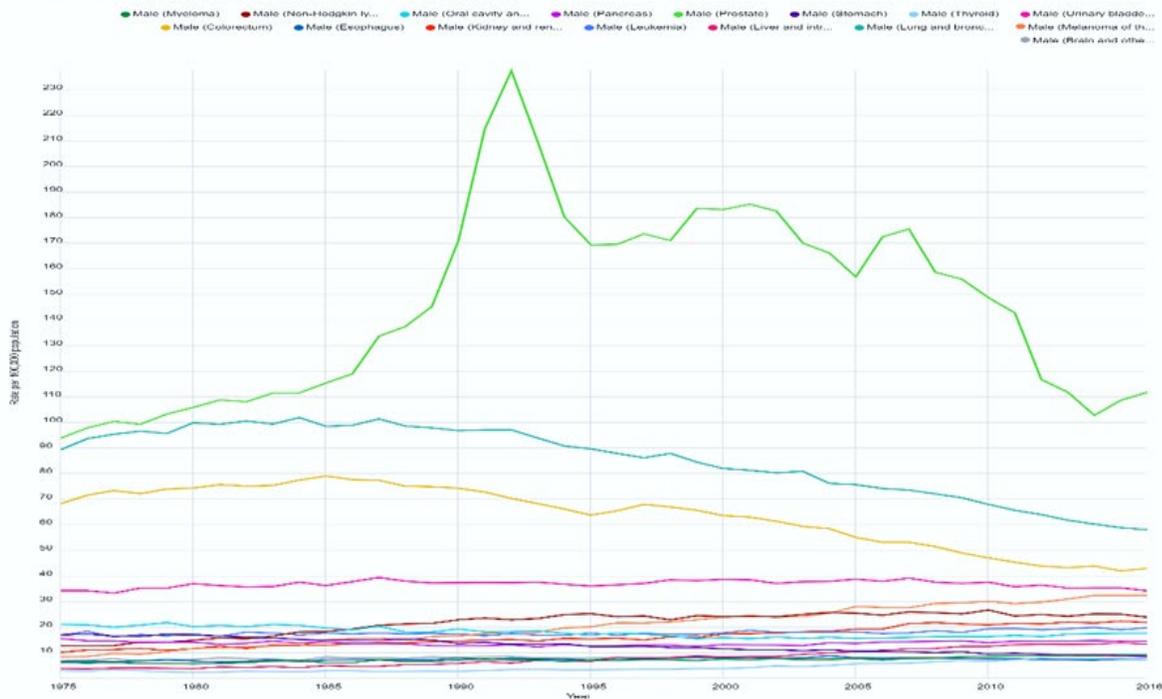
The 2000's – Present

The last twenty years brought yet more improvements to prostate cancer treatment. With the advent of Active Surveillance (AS), the number of RP surgeries declined in US in favor of AS and minimally invasive treatments for men with low risk prostate cancer. AS, pioneered in mid-1990's, was considered heresy at first. After extensive research, was recognized as the standard of care for men with low risk prostate cancer. In addition, drug therapy options continued to multiply, especially for the treatment of advanced prostate cancer. Dr. Marks remembers when the only drug treatment was Lupron. Now over twenty drugs are FDA approved for use.

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Trends in incidence rates, 1975-2016

Per 100,000, age adjusted to the 2000 US standard population.



Data Source: Surveillance, Epidemiology, and End Results (SEER) 9 registries, National Cancer Institute, 2019
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CancerStatisticsCenter.cancer.org

In 2020, it is estimated that 191,930 new cases of prostate cancer will be diagnosed in the US and 33,330 men will die from the disease. This graph illustrates that incidence rates for prostate cancer spiked in the late 1980s and early 1990s, mostly due to increased screening with the prostate-specific antigen (PSA) blood test. Incidence rates decreased since 2000, and then increased in recent years, most likely due to reduced PSA screening. The prostate cancer death rate has declined by 52%, from a peak of 39.3 (per 100,000) in 1993 to a low of 18.8 in 2017. This remarkable decrease in prostate cancer mortality is attributed to earlier detection and advances in treatment. (Cancer Facts & Figures 2020 ACS)

The use of MRI guided prostate biopsies changed the world of prostate cancer treatment again. Dr. Marks saw the importance of better imaging in his practice and supported its development, partly due to frustration with biomarkers. For his patients “seeing was believing”. If he could show a man a picture of a spot in the prostate, it was much more convincing than saying PSA is elevated. He was an early advocate of targeted biopsies using MRI when new imaging techniques permitted. Ultrasound guided biopsies were imperfect, only showing shadows. Conventional US biopsy may or may not represent accurately what is the prostate. Even though needles were placed systematically the biopsy was still essentially a blind biopsy. He initiated MRI/ultrasound fusion prostate biopsies at UCLA in 2009. The ability to find cancers with MRI, bring it into diagnostic suite using image fusion, and put the biopsy needle in a specific region was a game changer. Studies show that this technique finds significant prostate cancer in 80-85% of cases and characterizes prostate cancer more accurately. The

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physician can now tell a man if he has a serous cancer or not. Dr. Marks uses this biopsy technique on all patients in the AS Program. If he finds a small area of Gleason 6 in a prostate, the chances it will upgrade to a more aggressive is 30-40%. With this method men on AS can be followed with more accuracy because the same spot can be accurately biopsied from year to year. This ability has reduced the number of men who stop AS due to upgrading to 10 %.

Barriers to the use of MRI Ultrasound Fusion Biopsies include:

1. The skill of the radiologist. Reading prostate MRI requires advanced training and experience. The American College of Radiology has a certification program which establishes who is an expert. The Prostate Imaging-Reporting and Data System (PI-RADS) which standardizes the MRI interpretation is now universally accepted.
2. Urologists must invest in the fusion image machine. There are a dozen models. The Eigen Co. in Grass Valley, CA makes one of the commonly used machines, the Artemis.
3. Urologists need training to learn the technique.
4. Pathologists need additional experience. For example, core biopsies from targeted biopsies each need to be placed in separate bottles with a label identifying each sample's location. In the past core biopsies were placed together in one botte.

Now Dr. Marks is leading the development of focal therapy (partial gland ablation), the next mega trend in prostate cancer treatment. The ability to target cancers with MRI imaging has made this treatment option possible. Focal therapy options include: High-Intensity Focused Ultrasound (HIFU), Cryosurgery, both FDA approved, and the newest treatment, Focal Laser Ablation. Focal Laser Ablation is the precise application of heat via laser to a tumor. In 2018, Dr. Marks and his co-investigator, Shyam Natarajan were awarded \$3.1 million research grant by the National Institutes of Health to study MRI-guided focal laser ablation. Their previous work demonstrated the feasibility and safety of this technique. Dr. Marks says that focal laser ablation provides a middle ground for men to choose between radical prostatectomy and active surveillance, while avoiding serious side effects such as erectile dysfunction and urinary incontinence. This treatment is sometimes called “super surveillance.” The procedure is done in an outpatient setting, a major advantage. A man walks into a clinic with prostate cancer and an hour or two later, walks out without prostate cancer.

He notes that men with intermediate risk prostate cancer, about 40% of patients diagnosed using MRI guidance, may be eligible for this treatment. A major advantage of this option is that if the cancer recurs after focal treatment, men can be offered RP or other treatment with no more complications.

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Because of the strong appeal of this technique, Dr. Marks is concerned that it could be exploited. Therefore, he hopes that the current clinical trial will provide the data to prove that it is as safe and effective option and lead to FDA approval. Dr. Marks anticipates that cryosurgery and HI FU will still be in the mix as focal therapy options in the future, although a major disadvantage is that these techniques require general anesthesia and an operating room.

Dr. Marks is a strong proponent of educating men about prostate cancer. He supports the important work of CPCC, recognizing that it is critical to provide men with prostate cancer accurate and high-quality information. Dr. Marks regularly gives lectures and webinars available to the public. You can find his many informative presentations on You Tube. On the topic of focal therapy go to:

TargetedProstateBiopsy.com https://www.youtube.com/channel/UC5f9_ArkAKzzyPtzidWWgWA. He was a presenter at the 1st Annual CPCC/ UCSF Patient Conference on Prostate Cancer in 2019 at <https://www.youtube.com/watch?v=FGnRNT9zzvA>. *Submitted by Beverly Nicholson, RN*

REPORT FROM ASCO 2020

Merel Grey Nissenburg, California Prostate Cancer Coalition President

In the last few years, advanced prostate cancer has been examined in new ways and trials designed for various subtypes of advanced disease. There is **non-metastatic but castrate-resistant prostate cancer (no longer responsive to hormonal therapy) called nmCRPC**; there is **metastatic but castrate-sensitive prostate cancer (still responsive to hormonal treatment) called mCSPC**; and of course **metastatic castrate-resistant prostate cancer, called mCRPC (cancer that has spread beyond the prostate and which is no longer responsive to hormonal therapy)**. New drug approvals have included treatments for the non-metastatic space in order to postpone or prevent metastases (nmCRPC); and some of those drugs have now been approved or await approval in the metastatic hormone-sensitive prostate cancer space. It can be confusing. Added to that are emerging treatment possibilities based on genetic alterations (such as BRCA 1/2) and on other gene repair defects, so some of the prostate cancer treatments are in a new class of drugs including, for example, PARP inhibitors. Imaging in prostate cancer is also growing as a field in which some agents are being used for diagnosis and for treatment. Even immunotherapy in prostate cancer (Sipuleucel-T or Provenge) is being examined in combination with other agents to increase efficacy. This Report can only cover a fraction of the 200+ Abstracts presented last month.

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Although ASCO 2020 was held as a virtual, instead of an in-person event, there were important presentations in prostate cancer, available to online registrants, that provided data likely to affect clinical practice going forward. Some of the most significant presentations provided the updated data from the 3 major trials in non-metastatic, castrate-resistant prostate cancer (nmCRPC). These are the trials that examined apalutamide, darolutamide, and enzalutamide, all of which showed OS (overall survival) benefit for the study patients. In the first clinical trial, **SPARTAN**, presented by Dr. Eric Small of the Helen Diller Family Comprehensive Cancer Center at UCSF, apalutamide (Erleada) was found to offer a survival benefit versus placebo, even after crossovers to the active agent took place. [Abstract 5516] The trial tested apalutamide versus placebo for 1207 patients with non-metastatic castrate-resistant prostate cancer who had a PSA doubling time of 10 months or less. Previous reports had shown an improvement in metastasis-free survival with apalutamide. The median follow-up now was 52 months. The median OS for the apalutamide patients was 73.9 months versus 59.9 months with placebo. Time to chemotherapy was also improved with apalutamide. There was a clear survival benefit with apalutamide, and this is true even though 80% of the patients receiving placebo eventually received therapy either at progression or with crossover to apalutamide when the study was unblinded. This means the study looked at an active agent early, versus later. The clinically relevant results reported at ASCO 2020 added to the hopeful findings reported earlier in the trial.

Second, the final survival analysis of the **ARAMIS Trial** was also reported out at ASCO 2020 by Dr. Karim Fizazi of the Institut Gustave Roussy in Villejuif, France. [Abstract 5514]. Darolutamide (Nubeqa) showed significant overall survival (OS) over placebo along with delayed onset of cancer-related symptoms and later chemotherapy. [Abstract 5514] In this trial, 1509 patients were randomized almost 2:1 to either darolutamide twice a day or placebo, while continuing ADT. Crossover was allowed at the unblinding, and 170 patients crossed over to begin taking darolutamide. Although the median OS was not reached in either arm, darolutamide did reduce the risk of death by 31%. Key adverse events were similar in both arms, and the trial concluded that it was efficacious in both metastasis-free survival and OS.

The third Trial in the non-metastatic CRPC space with final data to report was the **PROSPER Trial**, the results of which were presented by Dr. Cora Sternberg of Weill Cornell Medicine and New York Presbyterian Hospital in New York. The earlier results of improved metastasis-free survival had now

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translated into an overall survival (OS) benefit of almost 1 year in patients receiving enzalutamide (Xtandi). [Abstract 5515] The enrolled patients had non-metastatic disease, a PSA doubling time of 10 months or less, and a PSA of at least 2 ng/mL at screening, who were randomized 2:1 to enzalutamide or placebo. The median OS was 67 months with enzalutamide and 56.3 months with placebo, a 27% reduced risk of death. Grade 3 or higher adverse events were seen in 48% of the enzalutamide patients versus 27% of patients in the placebo group. Finally, it was postulated that **PROSPER** offers prospective validation of metastasis-free survival as a potential surrogate endpoint for OS in non-metastatic castrate-resistant prostate cancer.

Finally, Abstract 5561 analyzed all three trials together, and confirmed the points about safety made by Dr. Fizazi, showing that darolutamide has a favorable safety compared with apalutamide and enzalutamide. Darolutamide showed a much lower incidence of fall, dizziness, mental impairment, hypertension, fatigue, and severe fatigue. Most importantly, darolutamide has significant lower blood-brain penetration - resulting, among other things, in a reduced amount of neurocognitive side effects.

Other interesting reports from ASCO 2020 included the Phase III **TITAN Trial** [Abstract 5006] which showed that for men with metastatic castrate-sensitive prostate cancer (mCSPC) (still responding to testosterone therapy), adding apalutamide to androgen deprivation therapy (ADT) improved radiographic progression-free survival (PFS) as well as overall survival (OS). This finding was the same, regardless of having had prior docetaxel. The earlier analysis had shown that TITAN had met both primary endpoints of OS and radiographic PFS. Now the final data presented here showed a 33% reduction in risk of death and a 52% decrease in the risk of disease progression, with 82% OS at 2 years in the apalutamide arm. TITAN included patients with both high- and low-volume disease. Of note, apalutamide has not yet been approved for these patients in the metastatic space who are still castrate-sensitive. **And** in the **ENZAMET Trial** [Abstract LBA2], results showed that 80% of men with metastatic castrate-sensitive prostate cancer (mCSPC) who received enzalutamide (a nonsteroidal antiandrogen) along with testosterone suppression therapy (standard of care) were alive after 3 years, compared to 72% of men who received testosterone-suppression therapy along with other nonsteroidal antiandrogens (bicalutamide, nilutamide, or flutamide). Dr. Neeraj Agarwal of the Huntsman Cancer Institute at the University of Utah reported on this data and said that the quality of life in the TITAN Trial was preserved in ENZAMET.

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The Phase III **PROfound Trial** demonstrated that in metastatic castrate-resistant prostate cancer (mCRPC), men with certain genetic defects, e.g. DNA damage repair mutations such as HRR (homologous recombination repair) gene alterations, and whose disease progressed while receiving enzalutamide or abiraterone, had longer progression-free survival (PFS) and better measures of response when treated with Olaparib (a PARP inhibitor) than with physician's choice of new hormonal therapy (enzalutamide or abiraterone). Notably, the Olaparib patients had better health-related quality of life than the other treatment arm. This is important because these metrics come directly from patients giving us their perspective. And with regard to health-related quality of life, in the **ARCHES Study** men with metastatic hormone-sensitive prostate cancer who received enzalutamide in addition to androgen deprivation therapy (ADT) were able to maintain high-functioning health-related quality of life (HRQoL). ARCHES was a Phase III trial of 1150 men; in earlier reporting it had shown that men who received enzalutamide with their ADT (as opposed to placebo) showed improved radiographic progression-free survival compared to those who only received ADT.

The **CARD Study** looked at the efficacy and safety in older patients with metastatic castrate-resistant prostate cancer (mCRPC) who received cabazitaxel versus abiraterone or enzalutamide. Significant improvement was seen in radiographic progression-free survival (PFS), progression-free survival, and overall survival (OS). The patients had all received docetaxel and progressed within 12 months on an alternative androgen-receptor-targeted-agent (ARTA): abiraterone or enzalutamide. CARD analyzed the impact of age (below 70 and 70 and older). Analysis showed that radiographic progression-free survival in the cabazitaxel arm was improved for both age groups. A higher rate of adverse events was reported in the older group for both arms. The overall survival benefit was seen even when patients had low hemoglobin, high baseline neutrophils to lymphocyte ratio, and high PSA values at baseline. Multivariate analysis of the results confirmed this was a true benefit.

A stunning result was seen in the Phase III **HERO Trial**, leading to relugolix soon becoming the first orally administered androgen deprivation therapy (ADDT) for advanced prostate cancer. 96.7% of patients in the study who received relugolix, an LHRH receptor antagonist, had sustained testosterone suppression to castrate levels through week 48, compared to 88% of patients in the control arm who received leuprolide acetate (Lupron), an LHRH agonist and the current standard of care. Patients were randomized 2:1 to either take relugolix orally once a day or Lupron through an injection every 3 months over the course of 48 weeks. Additionally, relugolix proved superior to Lupron on all of the study's

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secondary endpoints. This included a confirmed PSA response at day 15; the probability of castration and profound castration at day 15, and follicle-stimulating hormone suppression at week 24. Not to mention, the testosterone reductions with relugolix happened very quickly; 56% of patients had testosterone suppression below 50 ng/dL after just 4 days of treatment. This compared to 0% of the Lupron patients. The other major benefit occurred with respect to MACE (major adverse cardiovascular events), which occurred in only 2.9% in the relugolix group versus 6.2% in the Lupron group. This is a crucial finding because death from cardiovascular events is the most common cause of death in men with prostate cancer. A testosterone recovery sub-study also yielded much better results for the relugolix group (54% of men versus 3% on Lupron).

Other trial results of interest include a biomarker analysis of **KEYNOTE-199**, a trial of pembrolizumab in men with metastatic castrate-resistant prostate cancer (mCRPC) for whom docetaxel had failed. The Phase II KEYNOTE-199 demonstrated that pembrolizumab monotherapy had shown antitumor activity in those patients for whom docetaxel had failed (docetaxel-refractory). This presentation at ASCO was a look at the association between pre-selected molecular biomarkers and clinical outcomes. It was noted that tumor mutational burden and PD-L1 CPS (combined positive score for PD-L1 positive disease) were associated with a better PSA response. Unfortunately, the study had too few patients to draw any conclusions on overall survival (OS), disease control rate (DCR), and ORR. Further study was said to be warranted.

In the accruing Phase III **TALAPRO-2 study** of talazoparib (TALA) plus enzalutamide for patients with first-line metastatic castrate-resistant prostate cancer (mCRPC), the investigators will be looking at this parp-inhibitor for prostate cancer treatment. TALAPRO-2 will be a follow-up to **Phase II TALAPRO-1** which found that monotherapy with talazoparib appeared to have excellent antitumor activity in men with metastatic castrate-resistant prostate cancer (mCRPC) and BRCA 1/2 genetic alterations who had been pretreated with docetaxel.

There are so many combinations of therapies now being tested in prostate cancer – especially in the spaces of (1) metastatic, castrate-sensitive prostate cancer (mCSPC) and (2) non-metastatic, castrate-resistant prostate cancer (nmCRPC), along with the tentative use of drugs targeting genetic mutations and DNA alterations. Better outcomes are hopefully on the horizon.

Another topic receiving attention at ASCO 2020 was advances in Prostate-Specific Membrane-Antigen (PSMA) Imaging. Because cancers of the prostate express high levels of PSMA, it has become

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a logical target for developing techniques in diagnosing and treating prostate cancer. “The Evolving Role of PSMA-Based Diagnostics and Therapeutics in Prostate Cancer” was in fact a presentation in an ASCO 2020 Education Session. Worldwide there have been almost 850 studies regarding PSMA PET imaging published in the last 4 years. PSMA-PET has been incorporated into European prostate cancer guidelines in the treatment of patients with persistent PSA after radical prostatectomy, and in the imaging of patients with biochemical recurrence. However, there is little data on overall survival. Theranostics is based upon a combination of a diagnostic biomarker and a therapeutic agent, and involves treatment of a target with a specific isotope. Various studies are underway. Additionally, there are several possible uses of PET imaging in advanced prostate cancer, and sometimes opportunities to combine more than one type of PET scan. In some reports, in as many as 76% of cases management of patients changed based on PSMA imaging. In just one example of a study using PSMA, the Phase III **CONDOR Trial** utilized 18-F-DCFPyL-PET CT for patients with biochemical recurrence (BCR). Results of the study found that PSMA-targeted PyL-PET/CT detected and localized occult disease in most of the patients with BCR who had had equivocal or negative imaging using conventional imaging, changing physician management in a majority of those patients.

There were also presentations on PSA and its involvement in various stages of prostate cancer and treatment, and on Circulating Tumor Cells (CTC’s) and their potential in this disease.

In immunotherapy, the only agent approved in prostate cancer by the FDA to date is Sipuleucel-T (Sip-T) (Provenge). In a randomized trial presented in an abstract at ASCO 2020, 32 patients with asymptomatic, bone-predominant metastatic CRPC without any visceral metastases larger than 1.0 cm, had been randomized 1:1 to Sip-T alone or with 6 doses of Radium-223. Men in the combination arm began Sip-T between the 2nd and 3rd doses of Radium-223. The primary immunological endpoint was PA2024-specific T-cell proliferation 6 weeks after the first Sip-T infusion. Clinical endpoints were radiographic PFS, PSA response equal to or greater than a 50% decline, AlkPhos response equal to or greater than a 30% decline, and safety. Findings were that the combination of Sip-T and Radium-223 was associated with improved clinical outcomes and a higher rate of PSA responses than Sip-T alone. The data was said to suggest a synergistic effect with the combination since neither Sip-T nor Radium-223 alone was associated with reliable PSA responses, but larger randomized trials are planned.

This year’s virtual ASCO 2020 offered a wealth of information and exciting and hopeful data. Work in all of these areas and others continues.

SAM WELLS, PROSTATE CANCER ADVOCATE EXTRAORDINAIRE, DIES AT AGE 80



CPCC Board member Sam Wells presented with the "Special Achievement Award" by President Merel Grey Nissenberg at the January 27, 2017 CPCC Board Meeting. "In Appreciation for the Years of Your Dedicated Service as a Volunteer Legislative Advocate for the Prostate Cancer Program at the California State Capitol."

California and CPCC gained a prostate advocate extraordinaire after Sam Wells was diagnosed with prostate cancer, in December 2002 at age 63. Sadly, Sam died at age 80 on March 29, 2020 in Sacramento, CA after a long illness. As Sam grappled with his own prostate cancer diagnosis and treatment, he learned the importance of becoming an advocate for himself. He soon put those lessons to good use, volunteering to help others facing prostate cancer. Sam became a member of the Greater Sacramento Prostate Cancer Support Group, sharing his experience with others, and volunteered as a Peer

Navigator Program at the UC Davis Comprehensive Cancer Center.

Sam did not stop there. He brought his professional expertise as "the guy who could resolve complex issues and put large projects back on track...and who generally took 'no' as a suggestion" to the

CPCC Board of Directors. He used these skills to advocate for California's IMPACT Program whose mission was to provide high quality free prostate cancer treatment to California men with little or no health insurance. Bill Doss, CPCC Board member, worked with Sam as they walked the halls of the State Capitol, meeting with legislators to protect the state funding for the program. He remembers Sam as a compassionate humanitarian and a great friend. "Sam had totally committed himself to this program to ensure that the lesser among us always received the necessary treatment for their prostate cancer."

Merel Grey Nissenberg, CPCC President, fondly recalls her work with Sam on as a CPCC Board member:

"I remember when I first heard about Sam Wells, and about the great job he was doing in Sacramento as an American Cancer Society Ambassador. CPCC was in existence for a few years by that time. When Sam agreed to join our CPCC Board, I knew we were in for a lucky treat: an amazing person to help us in our mission. I was so excited to hear Sam's ideas, and so thrilled with his passion, his willingness to tirelessly walk the halls of Sacramento with Bill Doss and Stan Mikkelsen to help with the IMPACT Program, and his support. He was a valuable resource, yes; but more importantly, Sam was kind, thoughtful, a passionate advocate, a good listener, and an enthusiastic help to all of us and to all the prostate cancer patients and their families who were fortunate enough to benefit from his work. I am so glad we were able to honor Sam in January 2017. We will miss his voice, his ideas, and his kind soul."

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Dr. Mark S. Litwin, IMPACT Director, at UCLA sent this remembrance of Sam's important contribution to the IMPACT Program:

“Sam Wells was instrumental in achieving the original renewal of the IMPACT Program that brought critical medical care to low-income, uninsured California men with prostate cancer. Through his lobbying efforts and securing strong legislative support for the Program, he remained steadfast in his involvement with the Program throughout the last 2 decades of his life. Sam was reliably the first to volunteer to help. He developed personal relationships with members of the California State Legislature, with whom he advocated passionately for vulnerable men with prostate cancer. He convinced the State to open a dialogue with the CPCC and established a collaborative relationship with them in support of the IMPACT Program and the men it serves. Through his efforts and those of his fellow CPCC members, he helped promote and maintain a Program that has enhanced and saved the lives of many men.”

In addition to Sam's work with prostate cancer, he had a distinguished 33-year career at IBM and was a man of many interests. Sam earned a degree in Mathematics and Meteorology from Oregon State University. He then served as a Weather Officer in the U.S. Air Force prior to starting his IBM career. Sam's free time was spent with his family coaching little league, building, flying, rebuilding remote control airplanes, tinkering in the garage, and vacationing at Lake Tahoe. He is survived by his wife of 57 years, Lynne, three children, nine grandchildren, and two great grandchildren. Services for Sam will be held later this summer, at a date and time to be announced. Condolences can be sent to Lynne Wells at 1230 Teneighth Way Sacramento, CA 95818.

NEW DRUGS AND TESTS APPROVED

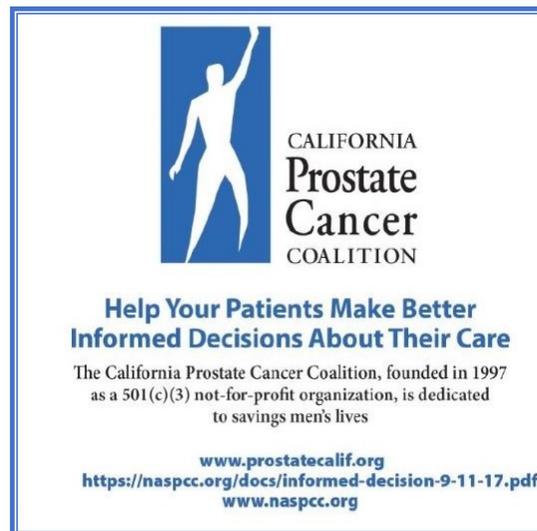
In late May, the FDA approved two new drugs for advanced, metastatic prostate cancer. The FDA approved Rucaparib, a PARP Inhibitor, for patients with BRCA 1/2-Mutant, Metastatic, Castrate-Resistant Prostate Cancer (mCRPC) who have been treated with an Androgen-Receptor-Directed Therapy and Taxane-Based Chemotherapy. Genetic personalization for prostate cancer patients is a big step moving forward. Then later that same week the FDA approved Olaparib, another PARP Inhibitor, for men with advanced metastatic prostate cancer. As the Prostate Cancer Foundation described it, “Olaparib is already FDA-approved for the treatment of other cancers, including breast and ovarian cancer. One of the benefits of Olaparib is that it has fewer side effects than chemotherapy. This drug, a pill taken by mouth, is approved for patients whose prostate cancer has spread outside of the prostate and has developed resistance to hormone therapy, who also have certain mutations in DNA repair genes.”

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While Rucaparib (“Rubraca”) is a third-line treatment for men with metastatic prostate disease, Olaparib (“Lynparza”) is a second-line therapy for men with certain genetic mutations who have failed hormone therapy.

Additionally, in the same week, Foundation Medicine in Boston received approval for its Companion Diagnostic test: Foundation One CDx for Lynparza (Olaparib), the PARP Inhibitor approved for certain men with advanced prostate cancer, as described above. In addition, Myriad Genetics has received FDA approval of BRACAnalysis CDx also a Companion Diagnostic for Lynparza in HRR-mutated Metastatic Castration-Resistant Prostate Cancer. That marks four recent approvals for men with advanced, metastatic prostate cancer.

----- *Meryl Grey Nissenburg*



CPCC AD IN THE CALIFORNIA FAMILY PHYSICIAN JOURNAL PROMOTES INFORMED DECISION-MAKING

The California Family Physician is a quarterly Journal distributed to thousands of family practice physicians and internists. To educate physicians about informed decision-making regarding prostate cancer early detection, CPCC placed an ad in the Journal’s Spring 2020 edition on page 25. The ad provides a link to the CPCC “Laminate on Informed Decision-Making”, a guide to help educate physicians and men about this important issue. The ad will run four times. View the digital magazine at: <http://epubs.democratprinting.com/publication/?m=21281&l=1>. View the Laminate on Informed Decision-Making at: <https://naspcc.org/docs/informed-decision-9-11-17.pdf>



WORKING INSIDE A CANCER HOSPITAL DURING COVID-19

Tiffany Razzo, MBA

Tiffany Razzo, MBA, is the Office Manager for the Department of Genitourinary Medical Oncology at MD Anderson Cancer Center where she has worked since 2017. She is on the Board of Directors of CPCC serving as Secretary since 2015. In this article she describes how her role and department have adapted to the COVID-19 pandemic.

So, what is it like to work at a major cancer hospital like MD Anderson during the COVID-19 outbreak? It has been an interesting experience so far. It all began on February 2nd when we received our first communication from senior leadership regarding the situation. Over the next month and a half, we would receive frequent notification from our senior leadership, letting us know the plans for operations during COVID-19.

On February 2nd, communication was sent out to the workforce, informing us that MD Anderson was closely monitoring the COVID-19 and following directions that were coming down from the Federal Government. MD Anderson activated their command center which has the responsibility to monitor changes in the situation and to provide advice to the senior leadership. The workforce was to continue hand hygiene, and employees who felt ill were asked to stay home. Work-related travel to China was put on hold, and all individuals traveling back from China were asked to self-isolate and contact employee health. For patients, clinic teams would start screening all patients and asking them if they had recently traveled to China.

On March 5th, we received communication that our command center was moving from level one watch to level two watch. The command center was expanding previous measures for the workforce and visitors. The workforce was asked to limit the number of individuals in meetings to no more than 15 people, encouraging everyone to utilize virtual platforms like WebEx and Zoom to conduct meetings. The patient screening questionnaire now included all international travel as well as travel from Florida and California.

On March 12th, we decided to let our teams begin working remotely and dismissed the staff at noon. By 2 pm, 99% of the workforce had disappeared, leaving only the management team in the office to close the day and lock up. I have been working at home since then, and it looks to be at least another 60 days before I will be back in the office.

Since then, I have been back to the office a handful of times to work each time feeling like I am walking into a scene from a horror movie. All administrative offices and research buildings have been

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cut off from any patient care areas. Entry points for employees have been set up, and everyone entering needs to go through a screening and is provided with a hospital-grade surgical mask. Temporary walls have been erected, keeping patients and employees away from one another. Some clinical spaces have been converted into COVID-19 floors, and our Cancer Prevention Center has been turned into a COVID-19 testing center. Research Facilities have been closed since then, and at this time, no experiments or testing can be conducted. Labs that process protocol specimens have also been closed, and some have been converted into COVID-19 lab testing sites.

As we adjust to this new normal, our goal continues to focus on patient care, but understand that the safety of the workforce and the patients are primary. We do not know how or when we will return to normal, but we continue to operate and work towards our goals of making cancer history!

DISEASE AND WAR

Dr. Arthur “Tony” Blain, CDR, MC, USN



As we commemorated V-E Day (Victory in Europe Day), May 8, 1945, the formal acceptance by the Allies of World War II of Nazi Germany’s unconditional surrender of its armed forces and the end of World War II in Europe, we are also reminded that the U.S. military has been a vital resource for fighting disease in peacetime and wartime, including our current worldwide coronavirus pandemic. Military leaders have added the Biosphere (emerging pathogens and infectious diseases) as the “seventh domain” of warfighting to the traditional sea, air, land, space, cyberspace, and logistical aspects of fighting a war.

Disease is nothing new in war – it is often called the “third army” since it historically kills more troops and civilians than the actual war. Pneumonia, typhoid fever, diarrhea/ dysentery, and malaria caused two-thirds of the estimated 660,000 deaths of soldiers in the Civil War, which lead to a 2-year extension of the war. Yellow Fever almost completely prevented construction of the Panama Canal, killing 5,600 workers, until Army physician, Dr. Walter Reed, confirmed Cuban Dr. Carlos Findlay's theory and work 20 years earlier that Yellow Fever was transmitted by a mosquito rather than direct contact. World War I saw the Spanish flu, meningitis, typhoid fever, tuberculosis, measles, mumps,

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chickenpox, and bacterial pneumonia. Overcrowding and lack of social distancing on war ships was particularly dangerous for spread of disease in World War I.

This began to change in World War II, when antibiotics and vaccines became available, but tuberculosis, rheumatic fever, hepatitis, and tropical diseases such as malaria and dengue fever were still common. The Vietnam War only saw 78 deaths from malaria because of the effectiveness of weekly chloroquine-primaquine administration.

The 1918 Spanish flu pandemic, caused by the influenza H1N1 influenza virus, lasted from spring 1918 through summer of 1918 and infected approximately one third of the world's population or 500 million people with death rate estimates anywhere from 17 million to as high as 100 million people including about 675,000 deaths in the U.S. Our family lost my great grandfather, Giovanni Paventi, who arrived from Italy through Ellis Island in 1904 at age 18 only to succumb to the Spanish flu 14 years later in 1918 at age 32. In comparison, as of May 10, 2020, COVID-19 has infected more than 4 million people and more than 281,000 deaths including 1.3 million infected and 79,000 deaths in the U.S.

In April/May 2020 there were more than 45,000 Air and Army National Guard and thousands more Navy, Army, Army, and Marine Corps healthcare and other support professionals deployed in our national COVID-19 response. They work on hospital ships Mercy and Comfort, man field hospitals, and enter communities to assist civilian hospitals and nursing homes. The U.S. military has always been at the forefront of fighting disease on the domestic and humanitarian international fronts and always will be.



"Tony" Blain, MD, MBA, FAAFP, is a board-certified family physician in San Diego with 24 years of medical experience, both in the community and the military. He is a full-time family physician at the Naval Branch Health Clinic, North Island at Coronado. He has served in the military 29 years, currently as a Commander in the Navy Reserve stationed with Operational Health Support Unit (OHSU), San Diego. He was recently deployed as the Senior Medical Officer Public Health Emergency Officer at the Naval Medicine Readiness and Training Unit Albany Naval Branch Health Clinic Albany, Georgia. He is an Assistant Clinical Professor, Department of Family Medicine and Public Health University of California San Diego School of Medicine. In his "spare time" he participates in ultra-marathons and open water swimming. He is an Assistant Scoutmaster for his two

younger sons' Boy Scout troop, and a coach for youth soccer, basketball, and running. Dr. Blain is on the Board of Directors of CPCC. He developed a special interest in prostate cancer after his uncle was diagnosed with Stage IV metastatic prostate cancer at age 49. He can be reached at ablain@yahoo.com.

OTHER NEWS

- Looking for current information about COVID-19 issues of concern to men with prostate cancer? Go to the Prostate Cancer Foundation's COVID Resource page at:
<https://www.pcf.org/covid-19/>
- The National Alliance of State Prostate Cancer Coalitions (NASPCC) has published its Spring 2020 Newsletter called "The Blue Print". We urge you to read this informative newsletter on the www.naspcc.org website at: <https://naspcc.org/docs/NASPCC-NewsMarch2020.pdf>
- Prostatepedia, the outstanding online magazine edited and published by CPCC Board Member Jessica Myers-Schechter, has now become part of the National Alliance of State Prostate Cancer Coalitions (NASPCC). Jessica has done an amazing job and will continue to produce the Prostatepedia magazine for NASPCC. It will now be published quarterly (next issue is August 2020) and will be available for free on the www.naspcc.org website to read or to download as a pdf (starting with the August issue). It will also continue to be e-mailed out to a Distribution List. Anyone wanting to join that list please contact Merel Nissenberg at mgrey@health.ucsd.edu. NASPCC will also send out the Prostatepedia Digest, with medical and scientific articles and links, like what is posted on the CPCC Facebook Page.



NASPCC Webinar Series Presents:
“Exosome Testing and Liquid Biopsies – Risk Assessment for High-Grade Prostate Cancer: Home or Office Testing”

With Dr. Judd Moul, Professor, Duke University Medical Center. The Webinar will take place on

Wednesday, July 29, 2020 at 7:00 pm – 8:00 pm Eastern.

To register for this event, please click [here](#)



Judd W Moul, MD, FACS is the James H Semans MD Professor of Surgery at Duke University. In 2004, after completing a 26-year U.S. Army career and retiring as full Colonel in the Medical Corps, Moul became Chief of the Division of Urologic Surgery at Duke. Serving as Chief until 2011, he established the Duke Prostate Center (DPC) and directed the development of a DPC Outcomes database that contained the records of over 10,000 prostate cancer patients.

Dr. Moul serves on the editorial boards of *American Journal of Men’s Health*, *Urology* and *Prostate Cancer and Prostatic Diseases*. He serves on the Executive Committee for the American Joint Commission for Cancer (AJCC). Dr. Moul has published over 600 medical and scientific manuscripts and book chapters and has lectured at national and international meetings. He has been a visiting professor and invited guest lecturer at universities and national symposia, in addition to appearances on ABC, NBC, CNN, PBS, and other media as a prostate cancer authority. Honors and awards received have included the American Medical Association’s Young Physicians Section Community Service Award, the Sir Henry Welcome Research Medal and Prize from the Association of Military Surgeons of the United States, the Gold Cystoscope Award by the American Urological Association, the Baron Dominique Jean Larrey Military Surgeon Award for Excellence, the Order of Military Medical Merit from the Surgeon General of the US Army, and the Castle Connolly National Physician of the Year award in 2009.

This Webinar is sponsored by:



California Prostate Cancer Coalition Information



From the CPCC November 25, 2019 Board Meeting from left to right Board Members: Frank Balthis, CPCC President Merel Grey Nissenberg, Beverly Nicholson, CPCC Secretary Tiffany Razzo, and Jessica Myers-Schechter. Not pictured Arthur Lurvey, MD and CPCC Vice President Thomas Kirk. Pictured at right: Board member Westley Sholes.

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CPCC is a 501(c) (3) organization and, as such all contributions you make to CPCC are tax-deductible. Since we are an all-volunteer organization, we need financial resources to keep up our work including making essential information on prostate cancer available to men and families in California, holding annual support group leader's workshops, publishing a newsletter, maintaining our website, sponsoring educational conferences, and other related programs. Please help us continue to work for you! Thank you.