Too Many Failures, RP

WHEN YOU HEAR the news that you have prostate cancer, what are you going to do? Rather than panic, you must accept the facts and begin the learning process. Your exit strategy from this dilemma will be to determine how your cancer will be managed. Proven treatment options range from a conservative management program of diet, wellness management, antioxidants and specific nutritional supplements we call chronic disease management (CDM) with no impact on your quality of life to radical surgery with a major impact. Deciding how you will treat your prostate cancer will become the single most important decision you will make for the remainder of your life. Ultimately, your decision must be acceptable to you and your family and be effective while minimizing undue risk, complications and side effects.

Prostate cancer is a disease that does not discriminate, wreaking havoc on all men irrespective of age, ethnicity, education, financial or social status. **When it comes to the topic of prostate cancer, all men are equally ignorant, regardless of education (obviously excepting doctors who should know the topic better than the public at large).** Prostate disease in general and prostate cancer specifically is the most common and dominant disease that men face, while representing a diseased organ that must be understood and dealt with by men

of all ages. Often times referred to as a disease of healthy men, prostate cancer has no boundaries, no conscience and will strike most time with no warning other than an elevated prostate specific antigen (PSA) blood test. Your only defense is to become educated on the disease, get motivated and proactive. Your goal is to maintain an optimal PSA of less than 1.0 ng/ml. Many men who fail to heed this warning will pay the ultimate price with their lives. Many more will be spared but asked to endure a life of subtraction, losing many of the qualities from life that make being a man so special.

Statistics on Prostate Cancer

While prostate disease is arguably the number one health risk that men face, prostate cancer is the most prolific organ cancer that men acquire in their lifetime as well as the second leading cause of cancer death, behind lung cancer. One in five to six men will be diagnosed with prostate cancer in their lifetime. Prostate cancer occurs most often in older men. African-American men have a rate of prostate cancer that is twice their Caucasian counterparts. According to the American Cancer Society, an estimated 218,890 men will be diagnosed with prostate cancer this year while in excess of 27,000 men will die from the disease. **This translates into a new case of prostate cancer diagnosed every three minutes while a man dies from the disease every 16 minutes of every day.** With the baby boomer generation aging into their 50s and 60s, at 5,000 men per day; the expectation is for 50,000 men to lose their lives annually from prostate cancer by the year 2020. While men in their 60s or older experience the news that prostate cancer has been detected most frequently, data shows 30 percent of 30-year-old men will acquire the disease only to have their lives spared initially as the cancer incubates for upwards of 15 to 20 years

before the impact is realized with a rising PSA blood test. **When you decide to become motivated to learn more about this disease is your decision; what you learn about the disease and how you treat the disease is the heart and soul of this book.**

Radical Prostatectomy— 'Gold Standard' or Educated Guess

Historically, radical prostatectomy (total surgical prostate removal) has been the most common treatment offered and rendered when prostate cancer is diagnosed. The irony of treating the most prolific male cancer most frequently with radical prostatectomy is that the failure rate will be unacceptably high while essentially equal regardless of the approach utilized including the DaVinci Robot technique. While prostate cancer is being detected earlier, there is no convincing data to suggest a significant survival advantage of radical prostatectomy over brachytherapy (radioactive seed implants), as example, with or without external beam radiation, cryosurgery or a treatment strategy called chronic disease management (CDM) (refer to the CDM chapter for a comprehensive review of this concept). **In other words, there is significant data to suggest alternative therapies like CDM may make a better first choice of treatment if overall survival is relatively unaffected by the specific therapy selected. Why should you undergo a major radical surgery with significant complications and side effects if it's not going to make a difference in your survival? You should not!**

If 10 men with prostate cancer are lined up and evaluated, doctors cannot reliably predict who will ultimately be cured and who will fail. In my opinion, this is primarily due to a lack of discrimination regarding where the disease is actually

located; principally, the extent of disease. Patients showing more favorable disease characteristics may have better survival rates, but **the fact remains that we cannot predict the final outcome of treatment**. Some patients with "good" cancers will perish of prostate cancer regardless of any treatment we can offer, and some with "bad" or very aggressive cancers may survive even with minimal treatment. **Until we have better tools (or utilize better tools, not currently accepted) that allow us to make truly reliable predictions, the best we can say is that radical prostatectomy can possibly cure 60-70 percent of prostate cancer patients. To state more clearly, we can't accurately predict who will be cured and who won't be cured using our present diagnostic and treatment modalities. To be sure, regardless of our surgical skill level, the outcome and cure rate from major radical prostate surgery is unpredictable. This point is validated by Hendrick Isbarn, M.D. and collaborators at the University Hospital Hamburg-Eppendorf in Hamburg, Germany in their research published in the British Journal of Urology (International Edition) in 2009. Specifically, they found that the biochemical recurrence (BCR) rate for prostate cancer was 40% at 10 years. Unfortunately, this is an unacceptably high rate of prostate cancer recurrence; representative of all radicals performed worldwide, in my opinion.**

So why is radical prostatectomy performed so often? While this is a great question, the answer is very elusive. We hear phrases like, "that's what I was trained to do," "it's the 'Gold Standard' in prostate cancer treatment," "and it's the only way that we can be sure that all of the cancer is gone" or "this procedure gives you the best chance for a cure." **When a patient asks a doctor for his best recommendation and the only procedure he performs is a radical prostatectomy, what do you expect him to say?** Even if the doctor also performs seed

implantation therapy and cryosurgery but believes the radical approach is best for most patients; do not expect him to give a glowing endorsement for either of the other two choices. While doctors are supposed to be unbiased in their approach, it is difficult for most physicians to remain completely objective. It's not their fault. They are just expressing what they know based on their training and experience. **The Hippocratic Oath states, "We must first do no harm." This should still be the starting point for any decision related to treatment of prostate cancer.** Finally, remember that treating prostate cancer is also a business. The insurance industry rewards some treatments substantially more than others. Physicians are only human and will tend to be influenced by the very high financial rewards from the insurance industry for surgery or radiation therapy over conservative treatments that aren't reimbursed well. Furthermore, physicians may own shares of radiation therapy centers that are highly reimbursed by Medicare and most insurance companies. **Even given their best intentions, it's hard for many physicians to be totally objective in their recommendations when they can earn $20,000 or more per patient by referring you to their radiation center.**

Physician Practice Patterns

In a survey of more than 500 urologists reported on in the Journal of the American Medical Association (JAMA), the question was asked of urological surgeons; what approach should be taken with a 65-year-old male with a newly diagnosed prostate cancer associated with a Gleason score of 7 and a PSA less than 10 ng/ml? For those unfamiliar with the meaning of Gleason score, refer to the glossary and/or the pathology section of this book for a review. For those more familiar with the term, a Gleason score of 7 represents a moderate to poorly

differentiated cell type, commonly encountered in approximately 30-35 percent of all cases of prostate cancer. To the surprise of no one, a traditional urology line of thought or 'party line' was endorsed by 90 percent of the urologists polled, thereby recommending a radical prostatectomy for this patient. While this opinion from a surgeon may come as no surprise, there is minimal documentation to support the strength of such an opinion.

In an effort to establish diversity of opinion, noting that doctors would only recommend what was best for the patient; radiation oncologists were asked their recommendation for the same patient scenario with the same cancer characteristics. The majority of radiation oncologists followed the dictum of their residency-training manual and recommended brachytherapy (radioactive seed implantation) or external beam radiation or a combination of both. **Patients, who seek these professional opinions, must be mindful that it may be difficult to get a totally objective opinion from a physician who is biased based on how he was trained and how he practices. It is often said and bears restating; "If all you have is a hammer, it is amazing how everything begins to look like a nail."**

In this imperfect world, the burden for an improved understanding of the disease and its various treatments, unfortunately, becomes the responsibility for each patient, individually; notwithstanding their lack of adequate education. This doesn't seem quite fair to the vulnerable patient doing little to diminish the anxiety experienced when the diagnosis is made. Based on a likely rush to judgment that is commonly experienced when the diagnosis of prostate cancer is made, patients are encouraged to become increasingly aware of the peril and consequences associated with prostate cancer treatment prior to the diagnosis, not after.

Taking the time to evaluate your options is supported by a research study performed at Johns Hopkins Medical Center. What they demonstrated is that while the diagnosis of prostate cancer must be taken seriously, a delay in treatment of months or even years may not change the course of the disease and the outcome. While this will likely depend on the specific characteristics of disease identified in a given patient, the news is nonetheless heartening as the task to fully understand the disease and the various treatment options is significant. It will take a concerted effort and ample time by all who choose to be well versed.

Better Imaging, Better Decisions, Better Results

This book intends to serve the many worried men with prostate cancer and their families as a fair and objective resource to help in understanding the disease you are now facing and the options available to you. By taking a fresh look at the available scientific information and explaining it in a new and unique way, it's our intention to help you make a truly informed decision about your treatment choices and ultimately about your future.

The true nature of the disease must be completely understood before any meaningful decision is made on how to proceed when the diagnosis of prostate cancer is made. While it is critical to determine the extent of disease in order to select the best treatment strategy, it is equally important to realize the severe limitations of our present diagnostic process based upon our current outdated imaging tools and biopsy techniques. For this reason, we are very excited about Magnetic Resonance Imaging with or without Spectroscopy (MRI or MRIS) discussed in more detail later and throughout this book. MRI performed with a 3.0 Tesla magnet or equivalent alternative may well be the best diagnostic modality for the detection of prostate cancer prior to a biopsy or to establish true organ confinement

once the diagnosis of prostate cancer has been confirmed by a biopsy. **Intuitively, imaging must be done before a biopsy (if a biopsy ever makes sense); not after.** The 3 Tesla MRI, diagnostic modality provides the most accurate cancer imaging technology available. The outstanding image quality ensures the best chance for realistic decision-making leading to ultimate success. This scan, which we call the "Ultimate Prostate Scan," provides precision prostate cancer localization allowing us to determine whether the tumor is truly organ-confined prior to any proposed therapy. **If organ confinement is not reliably established, the scientific data does not support radical surgical removal of the prostate.** The MRI Scan provides a true road map of objective imaging excellence to validate cancer localization while spectroscopy, when utilized as an additional sequence, allows us to understand the biochemical components of the tissue in question. Together, these scan sequences are integral to changing the paradigm relevant to the diagnosis and subsequent treatment of prostate cancer.

Chronic Disease Management

Prospective study data associated with our research treatment protocol evaluated the benefit of diet and nutrition versus prostate cancer. The study, entitled, **"Is it necessary to cure prostate cancer when it is possible,"** represented in the Journal, Clinical Interventions in Aging, supports the concept of allowing men the opportunity to live with prostate cancer much like patients would live with diabetes or arthritis rather than undergo surgical organ removal or radiation. If men decide later to attempt to cure the disease with surgery or radiation, their chance of success should not have been significantly diminished by the delay. In other words, **taking our time to evaluate all issues related to the diagnosis and treatment of prostate**

cancer allows us to avoid a rush to judgment. Quite frankly, by delaying the definitive decision making, anxiety is reduced and the advantages and disadvantages of every therapy can be studied in more detail and become better known. **You cannot fully appreciate the consequences of your treatment decision until you completely understand the lifestyle you will have to accept when the choice is made.**

The key to the success of our research treatment protocol relates to the ability to suppress or resolve the signs and symptoms of inflammation (non-bacterial prostatitis) through diet and a prostate-specific patented dietary supplement we developed called *Peenuts*®. This formula represents a unique and synergistic blend of vitamins, minerals, herbs and amino acids. Its special ability to reduce prostatic inflammation has been scientifically validated by improvements in white blood cell counts (a universal sign of inflammation) associated with the prostate secretion or expressed prostatic secretion (EPS) obtained at the time of digital prostate exam, as well as a decrease in PSA levels, given its success with widespread use as a stand-alone treatment for prostatitis. While diet plays an important role, the road to success without surgery or radiation requires optimizing all of our dietary and nutritional resources to fight the cancer. This will become quite apparent once you have reviewed the dietary and nutritional sections of this book.

In our prospective study, mentioned above, 30 patients with known prostate cancer were evaluated over an average time frame of 49 months. During this time, their only treatment was dietary modification and our scientifically designed prostate anti-inflammatory supplement *Peenuts*®. By the end of the study, 28 out of the 30 patients noted a marked improvement or decrease in their PSA levels (the recognized marker of prostate cancer disease activity) averaging 55 percent. This degree of improvement is truly remarkable and has never been reported

before in such a large study group without using hormonal therapy, surgery or radiation. While we are certainly pleased with the outcome, we were not really surprised, as we have noted similar significant improvements in thousands of patients over the years while using this supplement. This concept of nutritional optimization and chronic disease management has not been studied adequately as it has never received priority funding. It is our hope that visionary philanthropists who understand and embrace our beliefs, will come together to provide the capital necessary to validate our research as well as promote a prostate cancer prevention trial. The Prospective Study (PROCAP Trial), touched on above, will be described in its entirety in the Appendix.

One of the major advantages of the CDM approach is that you can always change your mind. If the cancer at some point appears to be escalating, notwithstanding a CDM protocol, you can still choose any of the more aggressive treatment options such as radiation therapy, radioactive seed implants, radical prostatectomy surgery, high intensity focused ultrasound (HIFU) or cryotherapy. Meanwhile, you will have enjoyed whatever time the CDM approach provided with minimal side effects or complications.

Clinical Case Study #1

Let's take a look at an actual clinical case that allows us to better understand the present state of prostate cancer treatment and the associated angst that comes with the diagnosis. Jon F., a 54-year-old Caucasian male, was diagnosed with prostate cancer with a Gleason score 6 (3+3) associated with a PSA of 4.2ng/ml. (A Gleason 6 designation comprises the most common prostate cancer cell type identified). It is also recognized to be a cancer type that predicts a reasonably favorable clinical

outcome. This is the group of patients that Pat Walsh, M.D. and the team at Johns Hopkins and other major centers of excellence operate on to establish their respective outcome data, thereby validating their treatment choice of radical prostatectomy for prostate cancer. Ironically, this is also the group of cancers that many experts, like Michael Barry from Harvard, believe are over-treated. In other words, it's possible and maybe even likely that many men with this classification of prostate cancer would do equally well with a radical prostatectomy (assuming cure), radiation, radioactive seed implantation, HIFU or with a more conservative approach like Chronic Disease Management (CDM) (reference the Prospective Diet & Nutritional Study). **It is for this reason that word needs to be spread throughout the world that CDM may be a reasonable and viable alternative to radical prostatectomy or radiation when this category of cancer is diagnosed.**

Based on Jon's relative youth and patient fear of impending death from a presumably predictable cancer, the patient agreed to a radical prostatectomy at the urging of his family and surgeon. Six years later, the patient's PSA was rising consistent with a treatment failure. **A progressive rise in PSA following any attempt to cure indicates the failure of the operation (or any definitive therapy) to cure the disease. This is also called biochemical failure or disease relapse.** A rise in PSA despite the complete surgical removal of the prostate tells you that the disease had escaped the prostate prior to or at the time of the surgery. Most often, prostate cancer cells look to find a new source of nourishment in the lymph nodes or bones (or both) when they escape the prostate capsule. It is estimated that the range of disease recurrence following radical prostatectomy or radiation is 30-40 percent and possibly as high as 40-60 percent by 7-10 years. The earlier the rise in PSA following surgery or radiation and/or the failure to lower the PSA to less than 0.5

ng/ml suggests that the disease is more aggressive and was likely systemic at the time of the definitive curative therapy. In other words, when the disease was thought to be localized or confined to the prostate it had already spread microscopically and undetectably to other structures or organs. Unfortunately this information does not help us after the fact except to predict a troubled and probable aggressive clinical course that will likely hasten the patient's demise. The only way to have avoided this outcome is to have avoided the surgery that tried to get rid of the disease in the first place. Confused? Join the millions who, like you, need to learn a new way of thinking about prostate cancer, including how to properly evaluate the various treatments and how to take charge of their care and their futures. **Minimally the failure of Jon F. to be cured calls into question our ability to cure anyone with certainty and should help slow the march of the confused and anxious to the operating room door.**

The medical literature suggests the failure to completely and permanently cure a patient when radical prostatectomy or radiation is performed, bodes poorly for the patient. Specifically, according to Anthony D'Amico of Harvard Medical School and colleagues, when the PSA doubling time (the time it takes for the PSA number to double) is less than three months following radical prostatectomy or radiation, the patient has a 20 times increased risk of dying from prostate cancer within 6-10 years. Our own clinical research concurs, showing the clinical course observed for the patient who isn't cured by radical prostatectomy or radiation will be much more aggressive, giving us less time to fight the battle than the individual who chose a more conservative treatment, such as the strategic CDM protocol. Examples will be provided throughout this book that will make this point very clear.

Returning to the case of Jon F. there were issues other than a rising PSA following the failed attempt at cure with a radical

prostatectomy. Ever since the operation, this patient has been a sexual cripple; meaning that he did not achieve adequate erections despite the use of erectile stimulating drugs including but not limited to medications like Viagra (the little blue pill), Cialis, Levitra (PDE-5 inhibitors) or Caverject (an injectable treatment for ED). Jon also complains of urinary leakage, which would have been more tolerable if only the operation was a success. **What is sad is that this patient should have been cured; as his disease characteristics were quite favorable, suggesting that anything short of cure is a significant failure. This case history establishes very clearly why a more conservative approach may have been the better first choice.** Unfortunately, Jon had never been told that he could live a long and prosperous life with the prostate remaining untouched using a more conservative approach like the CDM protocol. Had this happened, Jon would not have been the first patient discussed in this chapter.

This is the reason that patients must become increasingly aware that radical prostatectomy is not always what it is made out to be. **There are no guarantees even when you hear that "the surgery gives you your best chance at cure."** Improved awareness and understanding of the disease is the only defense that will allow the patient to fully comprehend all the options discussed; but more importantly, to walk away and calmly rethink what has been discussed absent the emotion of the moment.

Jon F. made a significant sacrifice for what was ultimately a failed chance at a cure. He would have been willing to live with the quality of life-limiting side effects of impotency and incontinence had the cure been reliably achieved. At this junction in Jon's life, he is now faced with the next set of tough questions that will require intelligent decisions related to how the disease will be managed moving forward. His choice at this point is to consider radiation therapy or CDM (active surveillance). Radiation,

replete with its own set of side effects, including but not limited to rectal bleeding, diarrhea, hematuria, urinary urgency, urinary frequency, scarring and radiation cystitis, is likely to worsen his already limited sexual function as well as further decrease his ability to control his bladder. A much more reasonable approach might be the use of a CDM or active surveillance protocol.

At this point, Jon's cancer will respond predictably well to hormone manipulation utilizing an anti-androgen (Flutamide, Casodex or Nilutamide) given intermittently. An anti-androgen prevents the remaining cancer cells from growing by depriving them of the male hormone testosterone, enabling residual cancer cells to die. There will be more about this concept in clinical case study number two. While his PSA was just beginning to rise from the low point of 0.2ng/ml, I would likely defer the use of an anti-androgen until the PSA becomes substantially higher. This would also allow us an opportunity to try other conservative measures to extend the PSA doubling time, as no one knows for sure that the disease cannot be stabilized (when optimal conservative measures are employed), while understanding no two cancers are exactly alike. Furthermore, proactive treatment with an LHRH-analog or anti-androgen (whether alone or in combination) at a lower PSA number may hasten the onset of hormone refractivity (disease resistance), a well-known consequence of hormonal manipulation. Additionally, **we should not discount the potential role of diet and nutrition to assist holding the cancer in check.** In an effort to prevent the PSA from rising to a higher and more definable number, we can use a range of products, supplements, vitamins or formulas associated with various mechanisms of action versus the cancer process in an effort to produce a successful outcome and prolong life. There are no reliable tests or examinations that can tell us with certainty exactly where the cancer is located or that the cancer will not respond to treatment with conservative measures now

that the radical prostatectomy has failed to cure the disease. At this point, we will assist Jon regardless of the choice he makes and do all we can to foster his success, including the application of a CDM protocol in the event radiation is chosen and fails. It is not as important why this clinical scenario happened with Jon, but rather, how we can prevent this from happening to the next generation of men diagnosed with prostate cancer.

Clinical Case Study #2

The case history and clinical experience of Carl L. is equally riveting for even the most learned or savvy prostate cancer patient. As a 60-year-old former All-American hockey defenseman at Michigan State University, who now resides in Green Bay, Wisconsin, Carl learned he had prostate cancer when his PSA reached 8.2ng/ml in October 2004. The year prior, his PSA was 3.9 ng/ml. When he asked his Urologist in 2003 if there was anything that could be done to try to lower the PSA, he was told the PSA was still in the normal range and not to be concerned. A 12-core biopsy performed a year later based on the 8.2ng/ml PSA, yielded a Gleason score 4+4=8 cancer in three of six biopsies on the left side and a cancer precursor cell type called High Grade PIN (prostatic intraepithelial neoplasia) on the right side. (See Glossary and Pathology Chapter for an improved understanding of these terms)

His biopsy clinical stage was T2b meaning that significant cancer was located in more than one quadrant on the left side of his prostate. Given the poorly differentiated cancer cell type, Carl went about the process of trying to determine the best way to defeat the disease. Three urologists representing three different urology practices had recommended that a radical prostatectomy was his only or best chance to survive the cancer. **One urologist went so far as to state; if he did not have**

the radical surgery, he would be "dead within one year." Concerned for his life and quite frankly scared beyond belief, Carl hastily decided that the radical surgery seemed like the only reasonable option. He had completed his pre-op evaluation and had even received the hospital wristband, identifying him to all hospital personnel as scheduled for surgery. At home, his wife Sandy was feverishly looking for other options as she did not feel comfortable about the choice that the man of her life had made. Several days prior to his early morning arrival at the hospital for the expected surgical procedure, Carl's life changed. Sandy had come across our website, **www.MrisUSA.com** and placed a toll-free call to our clinic. We had a chance to talk to Carl about the disease, his treatment options and what to expect from the surgery.

After a brief factual and straightforward discussion, Carl cut the hospital wristband from his arm and scheduled an appointment at our clinic in Sarasota, Florida. **In our conversation, we said nothing that would diminish his hope for a successful outcome, although we did inform, him that while radical prostatectomy may have provided his greatest statistical chance for cure, as represented by his three urologic consultations, no one informed him that the actual percent chance of a cure was only about 15 percent based on his high Gleason score and the known extent of his disease. In other words, statistically speaking, 85 percent of all prostate cancers represented by Gleason Scores of 8, 9 or 10 will have a disease recurrence within five years after a radical prostatectomy.** Carl was incredibly disappointed that no one had discussed these literature-based facts on the historical surgical outcome associated with this cancer grade, but rather opted for a 'leap of faith' to try to save his life. No one had allowed Carl and Sandy the opportunity to really understand that what they were about to do had very little chance of a cure. Once they

were made fully aware of all the facts, they decided that radical prostate surgery made very little sense and was obviously the wrong approach for them.

The Clinical Appointment—A Difference Maker

By making the commitment to see us in the clinic, Carl and Sandy had become a member of our extended family. During the three hour plus clinical evaluation and interview process, we reviewed all the viable alternatives including the option of allowing Carl to live with the disease through a protocol of CDM. Minimally, this option would buy us some time while not burning a bridge; allowing us to be more aggressive later if necessary or if an acceptable option presented itself that made sense when the risk-reward evaluation indicated. We were able to share other patient success stories using the CDM concept with Carl and Sandy. Together we created and accepted a treatment strategy that was intended to at least stabilize the cancer disease process. It was made very clear that we were in this together and we were as close as a telephone call. Based on his heightened disease status and aggressive Gleason Score, we elected to start him on an optimized CDM protocol that included a range of conservative treatments using various mechanisms of action to suppress the disease and make it less aggressive or even dormant.

First, Carl was placed on the Modified Mediterranean diet as well as our nutritional prostatitis supplement, Peenuts® to help resolve prostate inflammation. This was an important step as it has been shown that prostatitis can evolve or transform into prostate cancer. This has been confirmed by many research experts including the American Association of cancer Research (AACR), headed up by Johns Hopkins and independently by Michael Karin, PhD, David Bostwick, M.D., a world-renowned

pathologist and collectively, experts on prostate cancer. Carl was also started on Avodart or dutasteride (a 5-alpha reductase inhibitor) at 0.5mg daily to decrease the conversion of Testosterone to Dihydrotestosterone (DHT) as well as promote an anti-angiogenic component (decreases new blood vessel formation) while reducing the size of the prostate. We knew that the PSA could be decreased by some number less than half based on resolution of both benign prostatic hyperplasia and prostate inflammation. We were cognizant of the Prostate Cancer Prevention Trial (PCPT) data where Proscar or finasteride (another 5-alpha reductase inhibitor) was associated with a decreased incidence of prostate cancer by 25 percent when compared to placebo. While we had no data to show any specific benefit versus prostate cancer with this class of drug, we did not want the cancer to be exposed to DHT, the much more active form of the cancer growth promoting male hormone. Vitamin D3 (the active form of Vitamin D) was added for its benefit in decreasing prostate cancer cell proliferation, while Omega 3 fatty acids were added to enhance the heart healthy Omega 3:6 fatty acid ratio while also decreasing prostate cancer proliferation and free radicals.

The final integral piece of the treatment strategy was the use of Casodex (Bicalutamide), a non-steroidal anti-androgen, at 150mg per day. This dosage is much higher than the standard 50mg dose typically used here in the U.S., but is similar to the dose effectively used in Europe. We have had tremendous experience using Casodex at the higher dose as a monotherapy just as it is used in Europe. Notwithstanding the fact that 150 mg represents a higher dose than that typically used in the United States it is quite safe and effective when used intermittently. Specifically, the anti-androgen blocks a prostate cancer cell receptor, thereby inhibiting the growth of cancer. In other words, testosterone remains normal, but is preferentially blocked from its usual

action of attaching to the prostate cancer cell receptor at the nucleus, thus, allowing the cell to become disabled, dormant or even die. The concept is similar to what you would expect to see when you put a plastic child-resistant safety cap on an electrical outlet. No matter how hard you try to connect an electrical plug to the source of electricity at that outlet, you can't do it. That's the same way that Casodex blocks the interaction of testosterone with the prostate cancer cell receptor and promotes cell death or dormancy; preferentially over cell growth.

There are a few side effects from the use of Casodex as a monotherapy, including but not limited to a transient elevation in liver enzymes, mild breast tenderness or swelling and the potential for diarrhea. This side effect profile is generally very acceptable for the anticipated short interval of usage. The side effect profile, nonetheless, can be avoided using additional medications or supplements that would minimize and/or eliminate these concerns. Using this approach, we were able to avoid an LHRH-analog (Luteinizing Hormone Releasing Hormone), thereby, by-passing complete chemical castration associated with its host of undesirable side effects including but not limited to: lethargy, increased fasting blood sugars secondary to increased insulin resistance, muscle wasting, hypercholesterolemia, anemia, bone loss, hot flashes, cognitive changes, depression, mood swings and weight gain. When Casodex is used as an intermittent high dose monotherapy, disease specific anti-androgen treatment has a tremendous lifestyle advantage when compared to the more traditional therapy of an LHRH-analog alone or in combination with an anti-androgen (combined androgen blockade), discussed elsewhere in this book.

The decision was made to use the anti-androgen (Casodex) intermittently between PSA action points of 10.0 ng/ml and 1.0 ng/ml. This meant that at a PSA number of 10 ng/ml or higher

would mark the point where Casodex would begin and 1ng/ml or lower would indicate the point where the Casodex would be discontinued. Carl remained on the treatment protocol for 17 months total. During this timeframe, the Casodex was used for the first two months only, dropping the PSA (the marker of disease activity) from 13.0 ng/ml to 0.3 ng/ml. In effect, Carl had been off of Casodex for 15 months, while his PSA had remained stable at 1.7 ng/ml. This response represents a truly remarkable positive response for a very aggressive cancer. In his yearly follow-up appointment at our clinic, Carl's expressed prostatic secretion (EPS) white blood cell count (the number of WBC's associated with the expressed prostatic secretions) had gone from TNTC (too numerous to count) down to only 45 white blood cells when examined microscopically. This decrease in inflammatory cells is consistent with the use of the Peenuts® formula at 3 capsules daily as described in the Appendix. In effect, this represented a 91percent decrease in the inflammatory response (a process that we believe promotes prostate cancer evolution). The reduction in white blood cells in the expressed prostatic secretions can only be attributed to the dietary therapy and unique nutritional supplements used. Carl's urinary symptoms had also improved from a score of 10.5 (moderate symptoms on the International Prostate Symptom Score Index [IPSS-Index] to 1.5 (mild symptoms) in the same time frame, representing an improvement in symptoms of 86 percent. (Refer to the Appendix for the complete IPSS-Index.)

In his follow-up, rather than discussing his impending demise as predicted by one of his urologists, we celebrated a measure of victory versus an unpredictable and potentially deadly disease. We had demonstrated the success of CDM in a very difficult and potentially dangerous clinical scenario. While we believe this case represents one of the more spectacular responses of prostate cancer to CDM, highlighting Casodex as a monotherapy,

this should not diminish the impact of key nutrients and medications as outlined previously. While this case sounds "too good to be true," we always welcome calls from patients, critics and colleagues to discuss our approach or for an update on how Carl and Sandy are doing. Carl and Sandy would be happy to share their joyous experience with those who care to contact them as well! **Maybe someday, Carl and Sandy will be able to tell their story on a bigger stage, thereby bringing more than just hope to the hundreds of thousands of men who face the same uncertainty of prostate cancer every day.** Now, with the disease suppressed, Carl and Sandy decided to take yet, another step. They decided to take a calculated risk to get rid of the disease once and for all, by undergoing high-intensity focused ultrasound (HIFU) at a site outside of the U.S. under our supervision. HIFU is still under FDA review (at the time of book publication) and therefore not currently offered, in the United States of America as of March 2009. Carl's progress will be monitored by an MRI analysis of his prostate, using 3.0 Tesla Magnet MRI or equivalent to determine the extent or absence of disease **without the need for confirmation by additional biopsies.** Refer to the section on Magnetic Resonance Imaging (MRI or MRIS) for a better understanding of this technique as well as an explanation for the possible elimination of prostate biopsies as the procedure of choice to confirm treatment success or failure. **As of March, 2011, Carl's PSA number was less than 0.05 ng/ml or statistically the same as zero!** Not bad for a patient who was supposed to be dead within a year without a radical prostatectomy performed.

What will you do when Prostate Cancer is diagnosed?

So when the diagnosis of prostate cancer is made in your case, what will you do? Will you try to live with the disease or will

you want to remove the cancer at any cost? Is your goal a cure and if so, is this realistic and worth the price of side effects and potential complications? **While we never want to deprive you of hope; false hope and unrealistic expectations are unfair to you, the patient, who so desperately wants to succeed.** If a cure is possible, what are the true chances of success? Is it worth the risk when your chance of success is less than 50 percent? If a cure is impossible, what is the best strategy to ensure the best outcome? This is not as simple as just applying a radical prostatectomy or radiation therapy to a cancer but rather lies in **a multi-factorial approach** that may include a radical prostatectomy, HIFU or radiation but only if the odds of success are overwhelmingly in your favor and you are willing to take the risk. Our inability to reliably predict success or cure versus prostate cancer suggests that we should take our time and consider all of our options very carefully before the commitment is made to proceed with any definitive treatment. Get a second and even a third opinion. **If you act on impulse and make the wrong choice, you will have a lifetime to lament the error in judgment.**

An Icon in Urology Speaks Out

William Fair, M.D., former Chairman of the Departments of Urology and Surgery at the esteemed Memorial Sloan-Kettering Cancer Center was so frustrated with his inability to predict a successful outcome with radical prostatectomy or radiation for prostate cancer patients that he stated in a now famous speech from 2000; **"Based on everything we know about prostate cancer, I am not sure that it should not be treated as a chronic disease."** While we are not saying that radical prostatectomy is obsolete, we are saying that if we continue to apply the same therapy to every patient without a realistic understanding and

appreciation for the risks involved and our limited ability to predict treatment success, we should limit the procedure to only those who best qualify for the procedure, thereby supporting the greatest chance for success. **The future of radical prostatectomy may ultimately be doomed based on the public's increasing perception suggesting lack of physician understanding of the disease, greed and/or inappropriate dogma tied to a disease we know too little about.** What Dr. Fair may truly have been seeking was a moratorium on radical prostatectomy and radiation therapy until he and other research experts could figure out the natural history of the disease, thereby selecting patients for a treatment based on a sound strategy as opposed to a **"one size fits all"** mentality. **There is rarely a doctor among us who will share Dr. Fair's commentary with his newly diagnosed prostate cancer patients, much less investigate and embrace valid conservative options as appropriate care.** These conservative yet effective options will be addressed in later chapters that discuss minimally invasive treatment like high-intensity focused ultrasound (HIFU).

Will You Be Proactive or Reactive?

For men with PSA levels of greater than 1.0 ng/ml, it is not too premature to begin to think about the educational process in front of you. As you will learn later in this book, 20-30 percent of all prostate cancers are present in the PSA range of 1-4.0 ng/ml. **If you choose to wait, as you believe yourself to be too healthy, you could face the same tough decisions that Jon F. faced! In Jon's case, he never knew he had another option until it was too late.** On the other hand, you can think ahead and begin planning your strategy as if you had the disease while possibly avoiding the disease altogether. Will you be a willing participant when a biopsy is recommended when your PSA

exceeds 4.0 ng/ml (20-30 percent or more of biopsies are positive when the PSA exceeds 4.0 ng/ml) or will you reach out first to an improved technology like that available at the Diagnostic Center for Disease™ in Sarasota for a confirmational MRI scan? Random biopsies should be discouraged based on the sampling bias as well as the relatively low risk of prostate cancer on any given prostate biopsy procedure; not to mention the possible risk of spreading cancer cells (if present) beyond the prostate. Will what you have read thus far stimulate you to be proactive and try to avoid an inevitable disease by controlling prostatitis with dietary modifications and appropriate nutritional supplements? Or are you content to be reactive and take your chances that the disease won't come your way? Whatever your personality, whatever your choice, we are dedicated to making a difference with you when the time comes. **If cancer is inevitable, we want your case to be predictably successful giving you the opportunity to continue to take from life all that is yours.** The remaining chapters in this book are instructional and will make you think. What makes this book different from other prostate books is that we have brought together unique ideas and concepts, as well as international experts who are prepared to stand by the facts in a fair and balanced manner as well as respond to tough questions where they may not have the answer. For these and many other reasons, we encourage you to use this book as a learning tool, as a reference and as a guide to keep you health conscious while protecting your prostate and your heart. It has taken us years to do the research and additional years to write this book, so please take your time. Read it carefully and absorb it so that you are equipped to face the battle, should the disease ever present itself to you or a loved one.