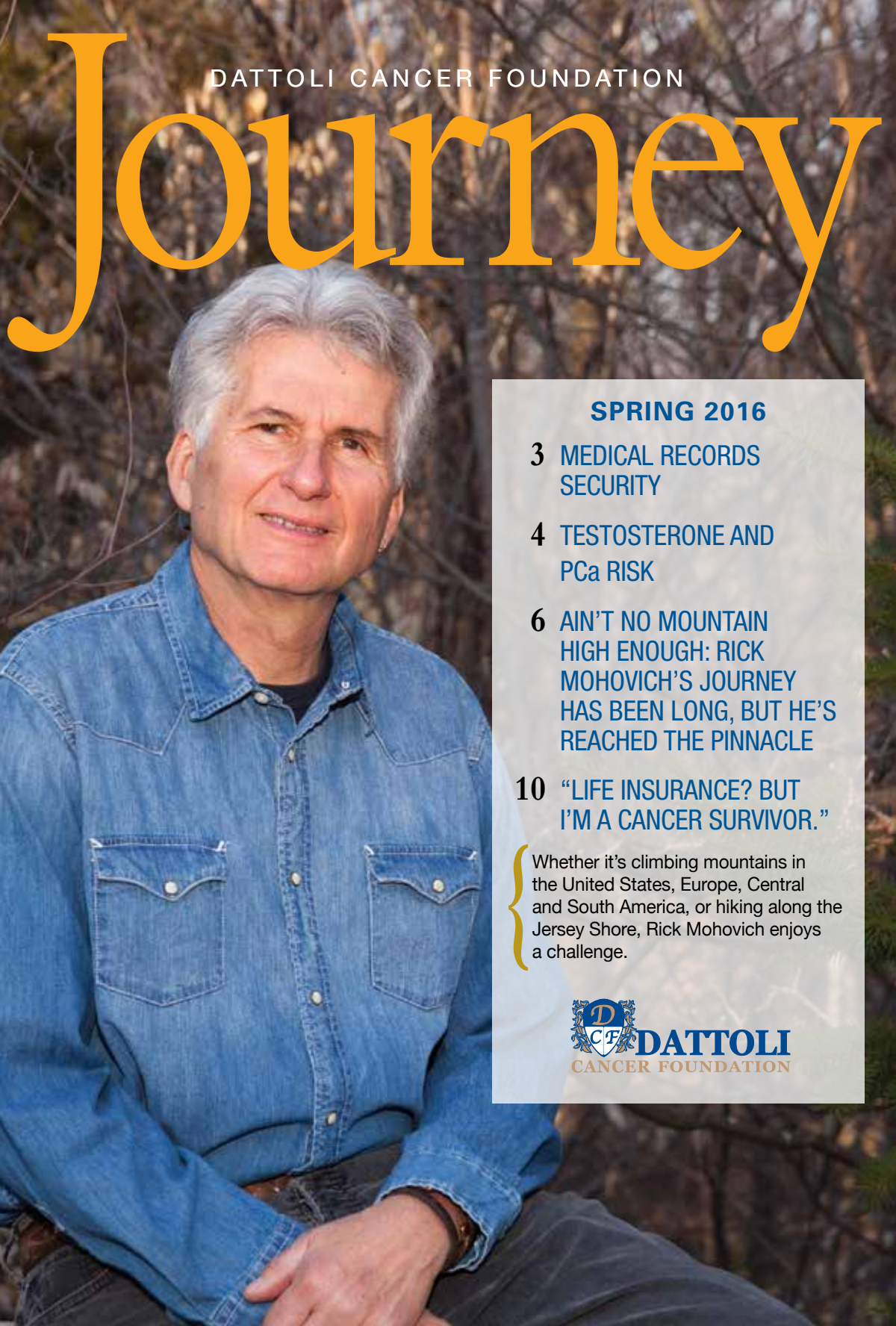
DATTOLI CANCER FOUNDATION

Journey



SPRING 2016

Whether it's climbing mountains in the United States, Europe, Central and South America, or hiking along the Jersey Shore, Rick Mohovich enjoys a challenge.

DATTOLI CANCER FOUNDATION

ALEX STAFFORD

You could be somebody's buddy!

FROM THE EDITOR

What would we do without our friends? They are the ones who laugh with us when we are happy, cry with us when we are sad and stand by us in the tough times. When you were first diagnosed with prostate cancer, I bet you wished you had a good, trusted buddy who had gone through the same thing, so you could pick their brain and ask all the questions you were afraid to ask anyone else. Maybe you did have a friend like that, and if so, I'd bet you are even closer now that you have shared something as monumental as conquering your fears and facing your prostate cancer diagnosis.

Knowing that men are sometimes reluctant to join a support group of strangers, finding a friend may be difficult for the newly diagnosed patient. He may put up a tough front – "I'm a strong man, and I can handle this" – when in reality, deep inside he is afraid, confused and depressed.

At Dattoli Cancer Center, over the years we have asked our patients to volunteer to be a part of our "Encouragers" outreach. The Encouragers are men who have completed treatment and are willing to talk to others about their experience. In the everyday hustle-bustle, we may not have asked YOU to participate. I am rectifying that now. I am enclosing a form for you to complete and return, if you would be interested in being an "Encourager."

This is how the program works: When a potential new patient seems to be wavering, our staff members will ask if he would like to talk with a former patient. If he does, we consult the Encouragers list.

We try to find two or three men whose profiles closely match the potential patient. We try to match them by age at diagnosis, PSA and Gleason score. Sometimes this is difficult. Many of our original volunteer encouragers have been on the list for a decade or more. So, if they were diagnosed and treated at 65 years of age, they could now be 80 or older.

In the past 15 years, our protocol has changed, and what a patient experienced 15 years ago is quite different from what we can do now. We need more recent "grads" to add to our list of encouragers.

Many of you have valuable experience and perspective that could be helpful to the next generation of Dattoli patients. We would never divulge your name and personal information without your express permission in advance, but if you feel that YOU could be helpful to another guy, and you would like to volunteer, please send me your information.

Complete the enclosed form, then scan it and email it to me – or just fill it out and return it in the envelope included in this issue of *Journey*. If you have any questions about the Encouragers program, please feel free to phone me at 941.365.5599.

Thanks for being a friend!
Virginia 'Ginya' Carnahan, APR, CPRC

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Dattoli Cancer Foundation
A 501(c)(3) not-for-profit organization

Journey is published by the Dattoli Cancer Foundation. Established in 2000, The Dattoli Cancer Foundation increases awareness about the importance of PSA screening; offers current, accurate information about leading-edge treatment; and fosters research leading to improved treatment options for prostate cancer.

Publication developed by Consonant Custom Media, LLC, 1990 Main Street, Suite 750, Sarasota, FL 34236 941.309.5380.

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Medical Records Security

DESPITE ADVANCES IN DATA SECURITY, RECENT BREACHES PROVIDE A HARSH REMINDER TO STAY ON TOP OF ONLINE ACCOUNTS.

Perhaps you or a friend received notice recently that your medical records had been "hacked." If you had ever used the services of 21st Century Oncology (or one of its affiliated urologists), you probably got the letter informing you of their security breach. Letters were sent to 20 million individuals.

Dattoli Cancer Center takes medical records security very seriously, and our IT director has installed every conceivable program to safeguard your medical records.

However, as good as data security can get, there always seems to be some hacker out there just a step ahead!

Why would someone want your medical records? It's not your medical information they are after, but sensitive details such as social security and credit card numbers.

I know of one physician in Sarasota who was among the 20 million patients that received the breach of data letter. He told me that someone had subsequently filed an income tax return in his name and opened a credit card. By receiving notice of the breach, he was alerted to stay on top of his personal banking and tax profiles.

Let this be a reminder to you to periodically review your online banking and credit card accounts. Just a few minutes on a regular basis will give you confidence that you are the only one accessing them. J

Testosterone: Friend or Foe?

MESSAGE FROM MICHAEL DATTOLI, MD

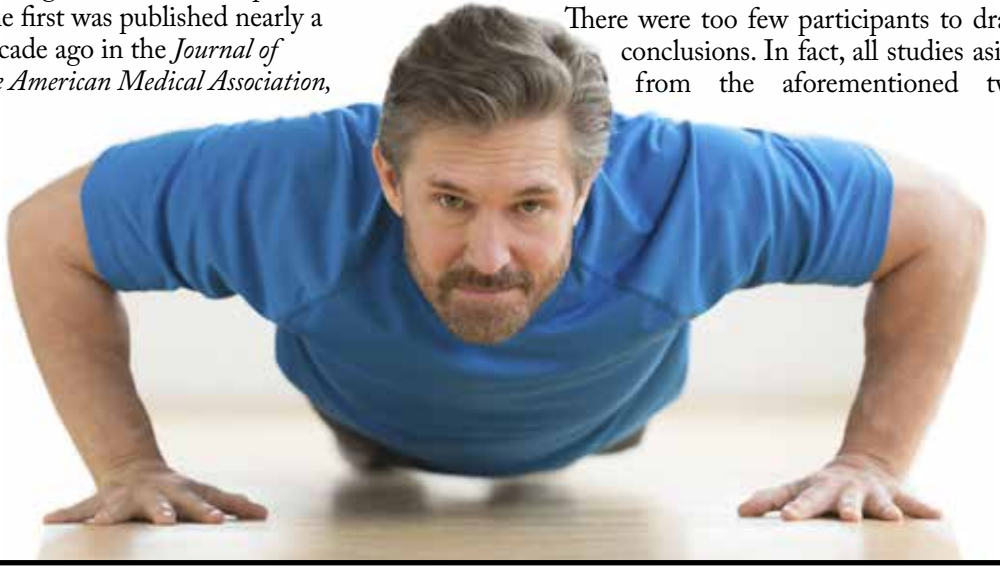
One of the most contentious subjects related to prostate cancer is the role of testosterone – its influence on the development of prostate cancer, its impact on tumor growth, and more recently, its possible ability to slow the growth of prostate cancer.

For decades, the generally held belief within the oncology field has been that testosterone is a food source for prostate cancer, and as such it should be avoided using exogenous methods (e.g., pills, injections or gels). When some body-builder type athletes have been found to have prostate cancer, one of the first questions is, "Have you been taking testosterone supplements?" There is an almost remorseful undertone if the answer is "yes."

For nearly 75 years, the relationship between prostate cancer and testosterone was indisputable. Dr. Charles Huggins in the 1940s and Dr. Edward Messing in the 1960s identified that removing a man's testicles (surgical castration) put advanced prostate cancer into remission and almost immediately reduced bone pain.

There are now at least two landmark studies looking at testosterone replacement in men. The first was published nearly a decade ago in the *Journal of the American Medical Association,* and a more recent one was published in the *New England Journal of Medicine.* To date, these have been the only trials that used well designed, randomized double blind, placebo controlled methods. Eligibility criteria included: age 65 or greater and average testosterone levels of <275 ng/dL. Exclusive criteria included a *history of prostate cancer* and/or a history of high cardiovascular risk. Neither of these studies demonstrated statistically significant benefits to numerous parameters. Only "small gains" were appreciated, and these benefits waned over a few months to a few years. All agree these non-significant gains must be weighed against negative side effects of testosterone, such as potential development of prostate cancer and the well documented negative impact on cardiovascular health (myocardial infarction, thrombo-embolitic events, strokes, etc.).

A small study published in the *New England Journal of Medicine* in 2010 comparing testosterone gel to placebo gel reported no benefit to the patient with respect to vitality or walking status, but slightly better mood and increased libido. The conclusion: There were too few participants to draw conclusions. In fact, all studies aside from the aforementioned two



were retrospective studies comprised of very small patient populations.

It should be noted, however, that patients often do benefit from placebos, with the percentage varying tremendously depending on the process being studied and psychological conditioning. A Harvard study published in the *New England Journal of Medicine* in 2011 reported that the placebo effect appears to be most pronounced when treatment success depends largely on the subjective (vs. objective) experience of patients, with positive responses up to 40%. So placebos may provide positive effects, and they typically do not cause untoward side effects.

VARYING VIEWPOINTS

As recently as 2013, publications were full of articles warning against the use of testosterone therapy based on "new" research confirming the dangers of increasing prostate cancer risk and the potential for development of myocardial infarction, congestive heart failure, strokes and death.

The original and longstanding belief that testosterone causes detrimental effects on prostate cancer stems from the "**androgen hypothesis**," based on historical and current observations that men having prostate cancer experience a rapid decline in PSA while ceasing prostate cancer progression when testosterone is reduced with oral or injectable hormonal agents or surgical castration. Meanwhile, PSA and cancer progression accelerates once testosterone reducing methods are stopped. Moreover, even when men no longer respond to hormones ("castrate resistant"), they still benefit from further lowering of testosterone using Zytiga® and Xtandi®.

An article from Brink-zone.com, published in August 2014, stands to turn the old thinking on its head. It is entitled "Testosterone and Prostate Cancer – Bye Androgen Hypothesis, Welcome Saturation Model – Time for a Paradigm Shift."

This new "**saturation model**" attempts to explain the paradoxical observations that prostate tissue is highly sensitive to changes in serum testosterone at low concentrations but becomes less reactive to higher concentrations of testosterone. A "*threshold effect*" occurs when increasing androgen concentrations reach a limit beyond which it no longer affects androgen-driven changes in prostate tissue growth. Contributing to the saturation model is the finite ability of androgens to bind to the androgen receptor (AR). This model suggests that maximal androgen-AR binding ("saturation") occurs at fairly low androgen levels. This "*saturation point*," subject to individual variation, is believed to be around 230 ng/dL in clinical practice. Thus, major organization guidelines began to state: "There is no conclusive evidence that testosterone therapy increases the risk of prostate cancer or benign prostatic hyperplasia. There is also no clinical evidence that testosterone treatment will convert subclinical prostate cancer into clinically detectable prostate cancer."

Now the opposite end of the spectrum is being promulgated. A 2015 article on the Cancer Network website asks this question: "Can Testosterone Treat Prostate Cancer?"

It references a very small sample of men (16) with asymptomatic metastatic prostate cancer, who had rising PSA levels and evidence of resistance to androgen deprivation therapy. The men were treated with three 28-day cycles of testosterone and two weeks of VP-16 chemotherapy. The men who had declining PSA levels after three cycles continued to receive testosterone injections alone.

Seven of the men had 30 to 99 percent decreases in PSA levels. Four of these men stayed on therapy for 1 to 2 years and had steady low PSA levels. Of the remaining nine men, seven had no changes in their PSA levels, one died due to pneumonia and sepsis from the chemotherapy, and

CONTINUED ON PAGE 11

Ain't No Mountain

FOR RICK MOHOVICH, THE JOURNEY HAS BEEN LONG BUT HE'S REACHED THE PINNACLE.
BY DAVID CHESNICK

Rick Mohovich has climbed mountains all over the world: El Misti in the Peruvian Andes, Mt. Cotopaxi in Ecuador, Mt. Blanc in France, Mt. Shasta in California, Glacier National Park in Montana, and the Tuolumne Meadows in Yosemite.

But perhaps the highest mountain he's climbed and the bravest journey he's taken has been the one he took to conquer prostate cancer.

His journey began back in the '90s when a yearly checkup revealed his PSA count had started rising. By 1997, it had reached 4, and Rick's doctor decided to do a biopsy. On Halloween night that year, while the then 53-year-old contractor from northern New Jersey was working, he got a call saying the test proved positive.

"I went to a urologist who tried to sell me on having surgery immediately," Rick told us. "I wasn't terribly confused or upset, but I knew that I didn't want surgery. So I started looking around."

For Rick, "looking around" included seeing a nutritionist and making dietary changes, such as cutting out red meat, eating more vegetables, and juicing. And there were other lifestyle changes: doing stress therapy, exercising, taking vitamins and supplements, attending seminars, and reading everything he could on the disease while taking what he calls an "aggressive, watchful waiting approach."

This went on for seven years, during which time Rick had his PSA checked two to four times a year, carefully charting its progress. When it reached 10, he began talking to those people that he had met along his journey in life who were familiar with the disease, as well as with family and friends. His decision was to have a radical prostatectomy.

High Enough

ONE STEP BACK, 43 STEPS FORWARD

A doctor from NYU performed the surgery in 2004. While his prostate was removed, there was nerve sparing that saved Rick from impotence. With the surgery over, he thought he was out of the woods but he continued to stay informed, attending seminars and maintaining his relationships with the men he'd met that shared his experience. He also continued to have his PSA checked regularly.

For the first two years, all was normal. But in 2007, there was a gradual rising of his

CONTINUED ON PAGE 8

Ain't No Mountain High Enough

CONTINUED FROM PAGE 7

PSA count. The diagnosis from his doctor was that there was cancer in his prostate bed that had latched onto surrounding tissue when his prostate was removed.

It was then that Rick remembered having seen Dr. Michael Dattoli at one of the many seminars he'd attended.

"I recall being impressed with how extensively and exquisitely he spoke about the disease and possible treatments. I was overwhelmed by his knowledge and intelligence about it."

Rick contacted the Dattoli Cancer Center and like so many others, he received a call back from the doctor that evening. They had an extensive phone conversation, during which Rick shared his history and Dr. Dattoli suggested a possible treatment. In August, Rick came to Sarasota and received a hormonal injection. He returned two months later to begin a round of radiation.

Because there was no prostate, brachytherapy, an additional treatment for the Center's patients, was not called for. Instead, Rick went through 43 rounds of targeted radiation.

"It was five days a week, with breaks for weekends and holidays," Rick said. "I was able to fly home on weekends because my daughter, Lynette, is a pilot with United."

The treatment ended in the middle of December. Rick has been back every year for the last nine years to have a full checkup that includes blood tests, a rectal probe, and a bone and full body scan.

Nine years since radiation with no recurrence. Nine years during which Rick has been part of an extraordinary group of guys that climb mountains.

PROMISES TO KEEP AND MILES TO GO

After the removal of his prostate, Rick read about a mountain climbing group, Cancer Climb & Trek for Prostate Awareness, sponsored by the Prostate Awareness Foundation run by Ken Malik in California.

"We talked on the phone a few times and

PHOTOS BY JEFFREY STECCATO

Great Explorations
Previous spread: Glacier National Park, August 2010; climbing the Ausangate Mountains of Peru; walking the Jersey Shore.

This spread: Another challenge, restoring a classic wooden boat; Rick and June at home in Upper Saddle River, NJ.

he offered me the chance to participate in a hike in Yosemite. It was a camping experience of five or six days with other guys from around the country and around the world who had had the disease and those who had been touched by it, like friends and family members."

"It was kind of crazy. We went the first week of September. It was raining and the rain quickly turned to snow. We set up tents, but it was so cold that the water in the toilets froze and the seats were cold – no need to say more. But we climbed five or six peaks in the Tuolumne Meadows, reaching heights of 10,000 feet.

"It was my first mountain climbing experience and while it wasn't anything death defying, it was still challenging to wind our way to the summits. The altitude alone gave you a buzz, but the gorgeous scenery and fresh air, as well as the chance to talk to other guys who'd been through it and share stories, just hooked me on the experience."

He's now been on 11 climbs and treks: three to Yosemite; two to Mt. Blanc in France (where he admits to falling off his diet); twice to Peru, where he climbed 19,300 feet to the summit of Mt. Misti; and once to Bolivia, Ecuador and Montana. This year the group will be traveling to Italy together to conquer Mt. Paradiso.

It was particularly comforting for Rick to be part of the group when his cancer returned. And it's also meant a lot that his son, Shawn; daughter, Lynette; son-in-law, Curtis; and daughter-in-law, Lilli, have all supported him by participating at one time or another. He jokes that his beloved wife of 50 years, June, stays in the hotel. But we're sure she's proud of the extraordinary things her guy is doing.

In addition to climbing, Rick is an avid hiker who belongs to three or four groups that regularly take day hikes of five, 10, even 30 miles along the Jersey Shore. On the day we spoke to the now 72-year-old, he was preparing for a Sunday hike with temperatures predicted to be in single digits. No big thing for a man that plans to live to be 100.

"Right now, I'm on track to make it. I keep planning hikes and trips. I want to watch my grandchildren – Lynette's twins, Aiden and Addison, who are not quite a year old, and Shawn's three-year-old, Keaton, and five-month-old, Leena – grow up. And if I make it to 100, I'll celebrate what will be my 78th anniversary with June.

We think it's a promise he'll keep. For Rick, there ain't no mountain high enough to keep him away from his goal. J

Life Insurance? But I'm a Cancer Survivor!

MEDICAL ADVANCEMENTS HAVE CHANGED THE WAY INSURERS LOOK AT CANCER, SO IF YOU'VE BEEN DISREGARDING LIFE INSURANCE IN YOUR FINANCIAL PLANNING, THINK AGAIN.

If you're a cancer patient or survivor, I can already hear you saying, "*Life Insurance? You must be kidding. I'm a prostate cancer survivor. No insurance company will insure me.*"

This reminds me of the scene in the James Bond film "Goldfinger," in which Q is briefing Bond on the special equipment in his new Aston Martin. His reaction to one particular feature is: "*Ejector seat? You must be joking.*"

In 1964, or even 25 years ago, it would not have been plausible to think about obtaining life insurance after a cancer diagnosis, but medical advancements have changed the way life insurance companies look at all forms of cancer, including prostate cancer.

Life insurance is probably more attainable than you think. Several insurers, such as Prudential, Lincoln Financial and John Hancock, regularly provide life insurance to prostate cancer survivors and some current patients.

As for the cost, life insurance premiums are at historic lows, and depending on the circumstances, insurers sometimes offer preferred rates. So, this might be a good time to see if you qualify. There are several ways to pre-qualify and get an informal idea of what to expect. It is not uncommon for standard, or even preferred, life insurance rates to be offered. Actual cases from Prudential and Protective describe men who were in their 60s when diagnosed, treated with seed implants and surgery, and now find themselves insurable at "preferred" and "standard nonsmoker" rates.

Some factors insurers consider include: age at onset, type of treatment, stage, Gleason score, current PSA level, and the presence of other medical conditions, such as diabetes or heart disease.

If you or a family member is a prostate cancer survivor, it's a good idea to reconsider how life insurance could play a role in your overall financial planning. For more information or to schedule a consultation, please call me at (941) 587-7810 or e-mail me at tomcannizzaro@aol.com.

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PHOTO BY CARMEN SCHETTINO

About Tom Cannizzaro:
Thomas V. Cannizzaro has over 30 years experience in the financial services industry, specializing in Life Insurance Based Financial Planning. Tom is a Certified Financial Planner™ (CFP®) and holds the Chartered Life Underwriter (CLU) and Chartered Financial Consultant (ChFC) designations. Tom has reviewed thousands of cases for individuals, businesses and non-profit organizations, and looks forward to working with you as a partner in providing customized life insurance-based financial planning solutions.

Testosterone: Friend or Foe?

CONTINUED FROM PAGE 5

one did not complete the study due to the unwanted side effects from testosterone.

Ten men underwent imaging scans to measure their disease – five of the men had tumor shrinkage of more than 50 percent, including one whose cancer was no longer detectable by imaging. All 10 men experienced reductions in PSA, including four whose PSA did not change during the trial and who were given testosterone-blocking drugs after the testosterone treatment.

This study came from the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University Medical School, and the study group was extremely small. Meanwhile, it must be emphasized that both testosterone and chemotherapy were used. A caveat stresses that timing in giving the testosterone therapy is extremely important and not easy to determine. This researcher warns against self-medication with over-the-counter testosterone supplements.

TESTOSTERONE SUPPLEMENTS

We can't ignore the exploitation of testosterone supplements in the marketplace. Testosterone products are among the top 10 highest grossing items offered through GNC®, the giant national vitamin and supplement house. They are touted as miracle "drugs" to skyrocket the libido, boost energy levels, enhance "performance," and create muscle mass! The ads proclaim that if you are 80 years old and want to feel like 20 again, you need a "testosterone boost."

Whether they increase prostate cancer risk or can actually assist in treating the disease remains to be seen. Of concern, across the country prescriptive forms of testosterone are currently being prescribed not only by endocrinologists, but also by internists, family practitioners, orthopedists, physical rehabilitation physicians and, of course, oncologists and urologists.

My partner, Dr. Joseph Kaminski, citing his recent experience at the Food and Drug Administration, is quick to point out that there are stringent FDA required warnings on all testosterone products about the potential of complications from use of these products.

Here is an example of the warning statements from one product:

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate should not take products containing testosterone.
- Exposure to testosterone may cause fetal harm to pregnant or breast feeding women.

The package insert goes on to warn about numerous other effects: worsening of benign prostate hyperplasia (enlarged prostate or BPH); sleep apnea; azoospermia (absence of sperm); venous thromboembolism (VTE), including deep vein thrombosis (DVT) or pulmonary embolism (PE); increased risk of myocardial infarction and stroke; edema with or without congestive heart failure. Many may result in death.

To sum it up, in 2015, Laurence Klotz, MD, (of Sunnybrook Health Sciences Centre, Toronto) offered this opinion in an article published in the *Nature Review Urology* journal:

> Testosterone is a potent hormone with a variety of physiological effects. The diagnosis of androgen deficiency has increased dramatically over the past decade, along with widespread use of testosterone supplementation therapy. The long-term effects of testosterone supplementation therapy are uncertain, and the risk of over-diagnosis and overtreatment of men who have a normal age-related decline in testosterone is substantial. The biology of the androgen receptor (AR) pathway is complex, and the saturation model does not take the heterogeneity of human prostate cancer into account. **Large-scale trials** to confirm the safety of testosterone with respect to the risk of prostate cancer and cardiovascular disease with reasonable confidence limits

CONTINUED ON PAGE 12

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Testosterone: Friend or Foe?

CONTINUED FROM PAGE 11

have not been done, and existing data are insufficient to exclude these adverse events. Instead, evidence suggests that prostate cancer could, in fact, be stimulated by testosterone supplementation therapy, and that the risk of cardiovascular events is increased. Overall, testosterone supplementation therapy seems to impose significant risks and should be used with extreme caution. [Emphasis added.]

CAUTION ADVISED

Our best advice is to seek advice only from a prostate oncologist who is well researched on testosterone replacement in men having prostate cancer, as this topic is so controversial that even general oncologists (and some uninformed prostate oncologists) may be unaware of the potential benefits and/or detriments associated with testosterone. I am of the position that "the jury is still out" and continue to not use testosterone replacement until better studies have matured, with rare exceptions. To date, only retrospective data based on extremely small patient populations have suggested that replacement testosterone may be safe in patients with prostate cancer. For replacement testosterone, my exceptions – with reservations and great trepidation – are:

- In patients who suffer from primary or secondary hypogonadism (excluding aging in the latter, as testosterone commonly diminishes naturally with age), and following 3 years of having undetectable PSAs, patients may initiate low doses of testosterone gel and titrated to moderately low to mid-normal range. These conditions may be caused by an inherited (congenital) trait or something that may occur later in life (acquired), such as through an injury or infection. According to the American Association of Clinical Endocrinologists (AACE), 30% of men older than 75 years have a testosterone level below the normal range of young men. The AACE has determined it to be highly controversial to supplement testosterone, even in these older men without a history of prostate cancer.

- In men who suffer from persistent hypogonadism (primary or secondary) who have had 5 consecutive years of undetectable PSAs and with initial presentation not containing a single high-risk feature (PSA ≥20, Gleason 8-10, clinical stage >T2c and elevated PAP). [Refer to AJCC Cancer Staging Manual, eighth edition, and my PAP studies published in the *Journal of Urology* in 2008.]

Don't risk your health on outrageous claims of this widely available but potentially dangerous product. Prostate cancer survivors should exercise extreme caution while prescribers should beware! Numerous law firms are lining up to do battle with the testosterone "industry," and two class-action law suits have already been filed.

If you would like references for material discussed in this article, please contact Ginya Carnahan at gcarnahan@dattoli.com.