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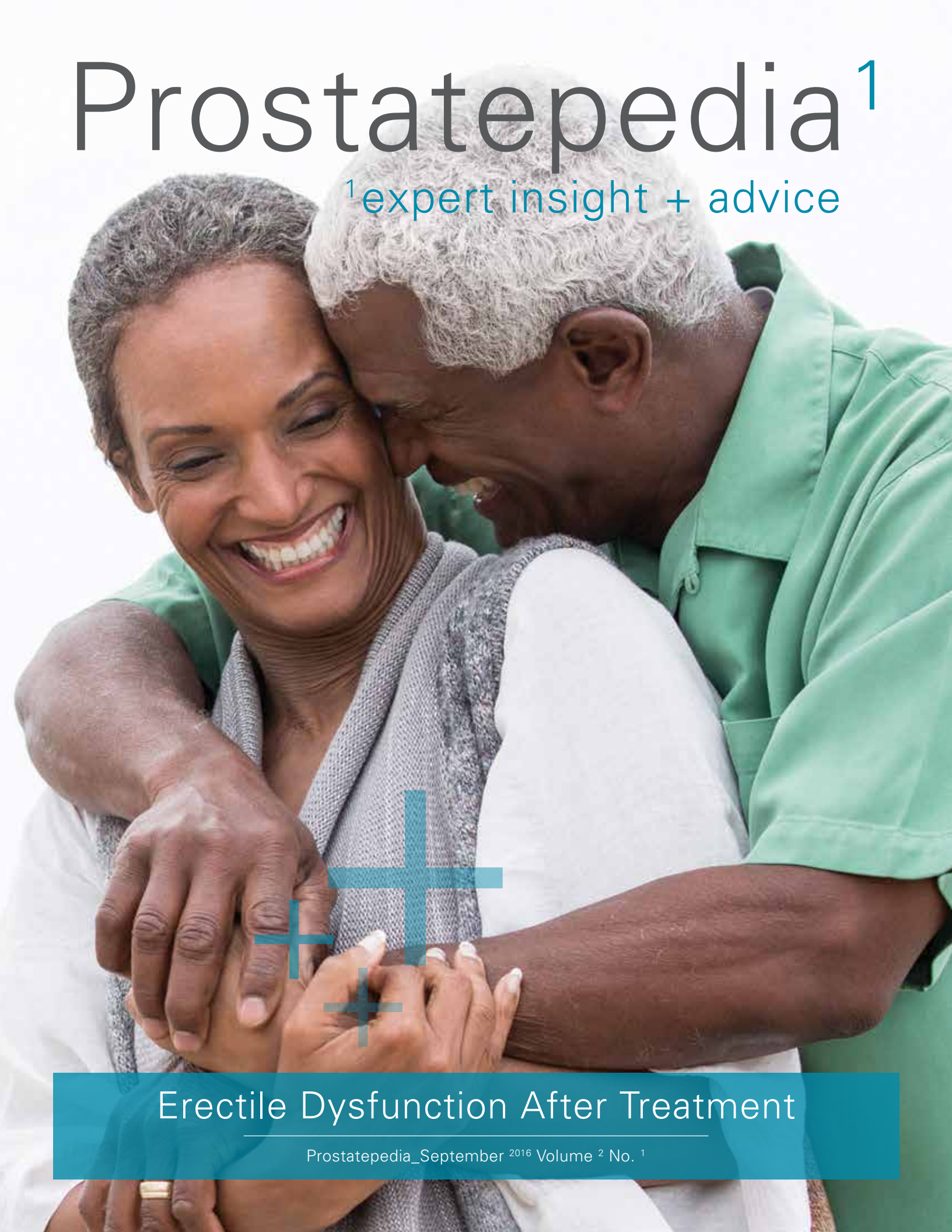

Erectile Dysfunction After Treatment

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In this issue....

This month, we're talking about erectile dysfunction (ED) in men with prostate cancer. The three major prostate cancer treatment tools—surgery, radiation, and hormonal therapy—all result in serious sexual dysfunction in a majority of men. And ED treatment options each pose serious issues with side effects, effectiveness, and cost.

Viagra and related drugs can be helpful for many men. There is extensive medical literature that supports using these drugs after surgery or radiation. Most medical oncologists do not focus on sexual function. I think this may, in part, explain why we do not have well-established programs to counter sexual dysfunction in men on hormonal therapy. With that in mind, I thought it might be worthwhile to mention what has worked in my clinic.

Hormonal therapy can cause severe ED. As a result, the Viagra drug family often does not pose sufficient activity to facilitate vaginal penetration. Fortunately, two drugs have been shown in randomized trials to significantly improve the effectiveness of Viagra. The first drug is losartan, a blood pressure drug that blocks angiotensin, a hormone that causes blood vessels to contract. By blocking the action of angiotensin, losartan causes blood vessels to relax. As erections require relaxation of the arteries to the penis, the benefit of losartan is obvious.

Cabergoline is the second drug that has been shown to improve the effectiveness of Viagra. Cabergoline is a long-acting, very potent dopamine agonist that has been shown to act as an aphrodisiac in both men and women. A randomized trial comparing Viagra alone to Viagra in addition to cabergoline showed improved sexual performance in the cabergoline arm.

While there are a range of other treatment options for men who have been on hormonal therapy and for whom Viagra is not sufficient, I have seen the most success with penile injections and penile implants. Both approaches have a high success rate in our patients, but many men are reluctant to inject their penises and even fewer have elected to get a penile implant. However, those patients who have elected to get penile implants have been very satisfied with the result. As one patient said, "I push a bulb in my scrotum and I get an erection. It stays up until I push a second time. I wasn't that good at 17!"

The bottom line? Talk to your doctor about erectile dysfunction after treatment.

Charles E. Myers, Jr., MD

Contents:

Mission:

We aim to provide useful current information about prostate cancer and its treatment. This information and the products and media advertised in this publication are advisory only. Individuals pictured are models and are used for illustrative purposes only. Please consult your physician for specific medical or therapeutic advice.

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Mohit Khera, MD
Erectile Dysfunction

Dr. Khera, a urologist specializing in male infertility, male and female sexual dysfunction, and declining testosterone levels in aging men, is the Director of the Laboratory for Andrology Research and the Medical Director of the Executive Health Program at Baylor College of Medicine in Houston, Texas.

Prostatepedia spoke with him recently about erectile dysfunction after prostate cancer.

How did you come to focus on prostate cancer?

Dr. Mohit Khera: I am a urologist by trade, but I did not initially go into medicine. First, I got my MBA and Masters in Public Health. I worked as an analyst for two years in Boston before going to medical school. When I got to medical school, I fell in love with urology because I like to operate *and* I like to see patients. As more men are getting older, there is going to be a real need for urologists.

In academic urology, you're asked to super-specialize, which means you pick one area of specialty. For example, in my practice, we have one person who specializes in prostate cancer, bladder cancer, and kidney stones. For the last nine years, my area of specialization has been sexual dysfunction for men and women and hormone replacement therapy.

I also have a passion for research: I conduct a lot of clinical trials. I also started a lab called the Laboratory for Andrology Research. We do basic science research and run studies looking at ways to improve sexual function and testosterone delivery.

> *"If you don't use the penis, it will atrophy."*

How common is erectile dysfunction after prostate cancer?

Dr. Khera: If you look at the literature, the data can vary significantly: anywhere from 10% to as high as 90%. You see such a wide fluctuation, because there are so many variables. A critical factor is surgeon skill. Surgeons who have more skill in preserving the cavernosal nerves have better outcomes.

But there are other factors, such as patient comorbidities; some people believe the testosterone levels matter or whether the man has a willing partner. Our research was one of the first to show that patients with a partner who wants to engage in sexual activity tend to recover their erectile function faster. That makes sense: they have someone to have sex with. Men without a willing partner may not recover as quickly because there is less motivation to recover.

Think of the penis as a muscle, like your biceps muscle muscle in your arm. If I put your arm in a cast today and then took the cast off after six months, there would be significant atrophy of that muscle. It would be withered. The penis is the same. If you don't use the penis, it will atrophy.

Erectile dysfunction rates start to increase significantly in men in their 50s. What else happens in the lives of men in their 50s? Their partners usually go through menopause. These men are not having sex; that's when you start seeing a significant amount of erectile dysfunction.

Men who have a willing partner are more motivated to use the medications to engage in sexual activity and to exercise those muscles. That tends to result in better erectile function down the road.

Are some prostate cancer treatments associated with a higher rate of erectile dysfunction than others?

Dr. Khera: Cryotherapy tends to have the highest rate of erectile dysfunction. Cryotherapy basically means freezing the prostate. When you freeze the prostate, you also generally freeze the nerves and if you freeze the nerves, you get erectile dysfunction. The rate for erectile dysfunction following cryotherapy is quite high, but then most patients don't do cryotherapy.

The majority of men in this country choose either surgery or radiation. Surgery has a higher rate of erectile dysfunction in the immediate post-operation period. Over the course of 12 months, men tend to regain their erectile function. Radiation tends to affect the patient later, say five to 10 years down the road, and can increase the erectile dysfunction rates in this population.

What about hormonal therapy?

Dr. Khera: Hormonal therapy is not considered a primary therapy; it is an adjuvant or neoadjuvant therapy. Hormonal therapy can have a devastating impact on erectile function. It significantly reduces testosterone levels. That is how it works. When you reduce testosterone levels, you reduce a man's ability to get an erection.

We use hormonal therapy in men with high-grade disease when we give them radiation. We also use hormonal therapy in men with metastatic prostate cancer. Sometimes we use hormonal therapy in men with high-grade cancer with a rising PSA after radical prostatectomy.

Again, hormonal therapy is not considered primary therapy. These are adjuvant therapies.

Is erectile dysfunction after prostate cancer a result of the treatments a man gets, or is there something about the cancer itself that causes erectile dysfunction?

Dr. Khera: The diagnosis itself can cause psychogenic erectile dysfunction. In other words, many men can have an increase in erectile dysfunction rates after they receive a diagnosis, but before surgery.

Many women are also concerned. (I had the wife of a prostate cancer patient call me to ask if she could get cancer if she had sex with her husband.)

The fact that you have a cancer in the genital region has a psychological impact and can effect sexual function. You're worried about what is going to happen. However, more severe erectile dysfunction usually happens after surgery.

Today, most patients have nerve-sparing prostatectomies, which means that we spare the nerves during surgery. After surgery, many patients experience a process called neuropraxia, which means temporary paralysis of the nerves because they've been manipulated. It can take some time for those nerves to recover. We know that full recovery of erectile function typically occurs about 12 months after surgery.

Are there other reasons, aside from the sexual life of a couple, to be concerned about erectile dysfunction after prostate cancer? Are men with erectile dysfunction more prone to depression or heart disease, for example?

Dr. Khera: Men with erectile dysfunction are much more likely to have a heart attack or stroke. Erectile dysfunction can be the first sign of a heart attack or stroke.

"This is finally a potential cure for erectile dysfunction."

The theory is based on arterial diameter theory, first described by Dr. Francesco Montorsi. Dr. Montorsi explained that the penile arteries are 1 to 2 mm. The coronary arteries are 3 to 4 mm. The carotid arteries are 5 to 6 mm and the peripheral arteries could be slightly larger. The penile artery usually becomes occluded or blocked first because it's the smallest.

The Prostate Cancer Prevention Trial demonstrated that 15% of men who develop erectile dysfunction today will have a heart attack or stroke within seven years. Other studies have shown the same.

Another study by Dr. Montorsi demonstrated that men who have a heart attack or stroke, on average, develop erectile dysfunction three years prior to having a heart attack or stroke. Depending on which study you look at, most show that erectile dysfunction is the first sign of heart disease.

If a man walks into my clinic with erectile dysfunction and has two cardiac risk factors—say hypertension and obesity—then I send him for a cardiac evaluation, because I fear he may have occult cardiovascular disease.

Isn't it true that most men with prostate cancer have cardiovascular disease as well?

Dr. Khera: Not necessarily. Keep those separate. Men, as they get older, are likely to have cardiovascular disease.

And it is true that prostate cancer is a disease of older men, but prostate cancer in itself has nothing to do with cardiovascular disease. The diseases are completely separate. If someone has prostate cancer, cardiovascular disease is not a risk factor for prostate cancer.

Now, men with erectile dysfunction are much more likely to be depressed.

"Erectile dysfunction can be the first sign of a heart attack or stroke."

What concerns most men with erectile dysfunction is that there isn't a cure for it. Almost everything that we currently do to treat erectile dysfunction doesn't solve the problem. The disease gets worse every year; we're just putting a Band-Aid on the problem, masking it. Viagra doesn't fix it. Viagra just covers your problem while the disease process gets worse every year.

Eventually, Viagra stops working. All of these medications stop working.

What are some of the treatments available?

Dr. Khera: We can divide them into three levels.

Level 1 is typically associated with Viagra-like drugs: Viagra, Levitra, Cialis, and Stendra. These medications are effective. Seventy-five percent of patients with erectile dysfunction take these medications. They are effective, but they're not effective forever. And they do have some side effects, such as headaches, flushing, nasal congestion, and back pain.

Other first-line therapies include the vacuum erection device, which is literally a vacuum. It brings the blood into the penis. You place a band at the base of the penis to keep it erect. The urethral suppository is another option. A urethral suppository is made of a vasodilator called prostaglandin; the suppository is placed into the urethra. It causes the penis to dilate and thereby induces an erection.

In these Level 1 therapies, I usually use sex therapy for patients. Sometimes I also use amino acids such as arginine, carnitine, and citrulline. These amino acids have been shown to be helpful because they are precursors to nitric oxide.

Level 2 therapies include an injection to the penis. These Level 2 medications dilate the blood vessels. A man injects his penis a maximum of every other day, alternating sides so he doesn't develop a scar. These injections are effective.

But if the Level 2 options don't work, we turn to Level 3. I perform a surgery called an insertion of a penile prosthesis where I implant a device into the man's body with a pump in the scrotum and two cylinders in the penis. The surgery is very effective and allows a man to engage in sexual activity without being dependent on medications.

How do you determine which of these treatments is appropriate for which patient?

Dr. Khera: Cost, compliance, convenience, and efficacy.

We also look at the adverse safety profile, or adverse effects. Some people will take Viagra, but get very bad headaches. Others take Cialis and get back pain.

Also, remember that Viagra is very expensive. Now many patients get their medications online at compounding pharmacies, but typically, Viagra is expensive.

Are these medications usually covered by insurance?

Dr. Khera: Usually they're not covered by insurance. That is why they're so expensive. Unfortunately, even after prostate cancer they're not covered by insurance.

Why do you think that is?

Dr. Khera: Erectile dysfunction is not recognized as a true medical condition, which is unfortunate. It's considered recreational, so the medications are not covered. This is really unfortunate.

Especially since so many men with erectile dysfunction also experience depression…

Dr. Khera: Absolutely.

Are there any newer treatments for erectile dysfunction on the horizon?

Dr. Khera: I think the way of the future will be stem cells for the treatment of erectile dysfunction. We are currently conducting these studies at Baylor. In this new therapy, we take abdominal fat and process the stem cells. We then inject these processed stem cells back into the penis. Thus far, there have been two stem cell studies on post-radical prostatectomy patients that had very promising results.

This is a cure. This is finally a potential cure for erectile dysfunction.

I am currently conducting an FDA-approved trial assessing stem cells to treat ED. Pp1

John P. Mulhall, MD
Erectile Dysfunction After Hormonal Therapy

Dr. John Mulhall is the Director of the Male Sexual and Reproductive Medicine Program at Memorial Sloan Kettering Cancer Center in New York City and the author of *Saving Your Sex Life: A Guide for Men with Prostate Cancer.*

Prostatepedia spoke with him recently about erectile dysfunction after prostate cancer.

How did you come to focus on erectile dysfunction after prostate cancer?

Dr. Mulhall: I'm from Ireland. I came to the United States to do my urology residency.

Part of the way through my residency, I read an article in the *New England Journal of Medicine* about impotence, as it was called then, by a chap named Dr. Irwin Goldstein. He was in Boston. I had some research time left during residency, so I went to Boston to do research with Dr. Goldstein.

Before I left, and before I finished my residency, I knew I wanted to do sexual medicine. At the end of my residency, I returned to Boston to do a fellowship in sexual and reproductive medicine.

After that, I went to Loyola University in Chicago, Illinois, for six years. (They have a very big cancer center and a big prostate cancer population at Loyola.) I worked with Dr. Robert Flanigan, a famous urologic oncologist, while I was there.

After Loyola, I came to New York to work at Memorial Sloan Kettering Cancer Center, where I have been for the last 14 years. Here at Memorial Sloan Kettering Cancer Center, we see about six hundred new prostatectomy patients a year. We see about a hundred triple therapy patients a year—serving radiation and hormone therapy.

I'm a big believer in survivorship. It isn't good enough to just say, "Mr. Jones, we took your prostate out. You should be happy." I'm interested in treating quality-of-life issues associated with a prostate cancer diagnosis, as well as treating the cancer. That is my motto.

How common is erectile dysfunction after prostate cancer?

Dr. Mulhall: It is fairly common that some men have a dip in erectile function with a diagnosis of prostate cancer. The diagnosis of any cancer is very stressful. Men get high levels of adrenaline. Adrenaline is an anti-erection chemical. Men start doing more poorly in the bedroom. Erectile dysfunction becomes a self-fulfilling prophecy.

"Hormonal therapy is lethal to sexual function."

From a therapeutic standpoint, it is very difficult to answer how common erectile dysfunction is after prostate cancer. But essentially 100% of men on hormone therapy have erectile dysfunction. Nearly all will fail to have an orgasm. Most are going to end up with penile shortening. Nearly everyone will have no significant libido.

There is about a 50% chance of a man being functional with or without a pill two years after prostatectomy. (Understand that there are many factors that go into that, including the patient's age, baseline erectile function, and marital status.)

Erectile function preservation rates are about the same three years after radiation treatment as after prostatectomy.

When patients come to see us before surgery or radiation, I tell them, "I could do radiation or surgery. Which would you like?" I add, "Never base your decision on erectile function, because unfortunately, the erectile dysfunction rates are

about the same three years after both, provided you had a good treatment at a center of excellence."

These are broad figures, but again, other factors weigh in: a patient's age, baseline erectile function, comorbidities, what kind of radiation or prostatectomy the patient had, and whether or not he also had hormone therapy. All of these factors weigh in. We have no programs to predict whether or not a man will have erectile dysfunction after treatment. So it is very difficult to give a blanket number.

Let's talk about erectile dysfunction after hormonal therapy. Why is there such a high percentage of erectile dysfunction after hormonal therapy? Because the treatment removes testosterone?

Dr. Mulhall: Yes. You need testosterone for erectile tissue health. You don't need a huge amount of testosterone for erectile tissue health, but you do need *some*. You may have heard of hypogonadism, which is the medical term for low testosterone. When you are agonadal, when you have no testosterone or you've castrated all the testosterone, your erectile tissue undergoes degeneration over time. It turns to collagen—a scar.

It is estimated that somewhere between four and six months of androgen deprivation therapy (ADT) leads to permanent structural damage to erectile tissue. You develop a condition called venous leak. (Venous leak was first studied in castrated rats. You castrate a rat and the erectile tissue turns to collagen. You can then analyze that collagen and study it as a model.)

When you don't have testosterone, erectile muscle degenerates. When erectile muscle degenerates, you are nonfunctional.

But you also need testosterone for drugs like Viagra to work. When you have no testosterone, drugs like Viagra or Cialis don't work very well at all.

Is erectile dysfunction after hormonal therapy permanent?

Dr. Mulhall: That depends on how long you've been on hormonal therapy. If you're on ADT for two to four months and you've had minimal erectile tissue damage, then the expectation is that you'll get back to being at least as functional as you were *before* you went on hormone therapy. If you were on ADT for a year, it's extremely likely that any erectile tissue damage is permanent.

When I speak at patient conferences, I tell the audience that when somebody says you need ADT, your first question should be: "What is the survival benefit?" A good oncologist should be able to tell you, "The survival benefit in someone like you is six months or six years." You then have to decide if you want to pursue hormone therapy.

Medical oncologists get wrapped up in the whole concept of undetectable PSA. PSA is undetectable because you have no testosterone; you need testosterone to make PSA. To me, undetectable PSA is an artificial security. Of course, there is a percentage of men who become ADT-resistant. They're on ADT, but their PSA starts to go up.

Hormonal therapy is lethal to sexual function. Over 90% of men on hormone therapy have no sex drive. The 10% of men with sex drive have what is called *intellectual* libido, but they really have no *visual* libido. (Visual libido is when you see something erotic and become aroused. Intellectual libido is: "I've been with my wife for thirty

years. I love her. We used to have a great sex life and we really *should* be making more love.)

Most men need testosterone for their visual sex drive. Men on hormone therapy are in a state called *sexual neutrality*. Sexual neutrality refers to the concept: "I don't think about sex, but I have it and it's a positive experience." Very much like a post-menopausal woman.

"Keep going back until all your questions are answered."

Are different kinds of hormonal therapy associated with higher or lower rates of erectile dysfunction?

Dr. Mulhall: There is no head-to-head data on that. We do have a current project looking at it, though, and are about to get some data.

But if you look at the literature, it's really bizarre. There are three endpoints that are looked at. The first is return to noncastrate level. That is simply defined as when the man gets back to a testosterone level of over 50. This is clinically meaningless: if his testosterone level dips to four then returns to 50, he still has all the symptoms of almost no testosterone.)

The second endpoint is a *return to normal*. Normal testosterone is variably defined as high as 200, to 300.

The final endpoint, which we practically never see in the literature, is *return to baseline*. The man who, before ADT, has a testosterone level of 700, but after treatment has a testosterone level of 300. His testosterone level may be considered normal, but he has had a 400-point drop. He is going to be profoundly symptomatic.

But there are no head-to-head studies looking at one hormonal therapy treatment versus another. There would probably be no significant difference between the various forms of hormonal therapy, because all hormonal therapy is about lowering testosterone levels.

If Drug A and Drug B both reduce a man's testosterone to castrate levels, then he is going to have problems with both. It doesn't really matter whether he is on an agonist, antagonist, Zytiga (abiraterone), or Xtandi (enzalutamide).

The question that is not very well answered is the impact of being on an antiandrogen like Casodex (bicalutamide). You would imagine that if you were going to block the testosterone receptor that would be as bad for erectile function as being on Lupon (leuprorelin). If the testosterone can't function, then it doesn't matter what your testosterone level is. But there is very little data on it.

Why do you think that is?

Dr. Mulhall: The focus is on what can we do to prolong your life so you can be around for your grandchildren. Most oncologists don't have any training in sexual health. In general, oncologists give poor expectations to patients. They don't talk about the sexual and nonsexual side effects of hormone therapy.

I'm the one who often has to talk to patients about their glycemic control, bone density, or cardiovascular risk. If an oncologist is going to talk about

sexual function, invariably that discussion is about sex drive. It's not about erectile function. It's not about ejaculation. It's not about achieving orgasm.

Most oncologists look at the five-year or disease-free survival rates. They're not talking to you about quality of life.

Why do you think most men aren't talking to their doctors about erectile dysfunction after prostate cancer? Or is it that the doctors aren't talking to men about it?

Dr. Mulhall: I think it's both. There is a famous cartoon in our field: the patient is sitting on the table and the doctor is standing nearby. A thought bubble above the patient's head reads: "I hope he brings it up." A thought bubble above the doctor's head reads: "I hope he brings it up." How can you make a doctor comfortable talking about sexual function and sexual health when they get an average of two hours of training in medical school on sexual health?

What should patients do about this?

Dr. Mulhall: Patients need to be proactive. If sexual health is important in your life and you're discussing treatment with your surgeon, your radiation oncologist, or your medical oncologist, you need to bring it up. If your doctor is smart, he or she will say, "This isn't what I do, but I send patients to a specialist named Dr. Jones. Why don't you go talk to him about that before you make your decision about your treatment."

That is what really needs to happen. We need direct-to-consumer advertising. Why does Pfizer do so much direct-to-consumer advertising for PD-5 inhibitors? Because physicians aren't asking questions. We need to empower patients to start the conversation.

If a patient is going to talk to his doctor before treatment, what kinds of questions should he ask?

Dr. Mulhall: The first thing a patient should say is, "I want to declare to you that my sexual health is critically important to me. I have a loving wife. We're sexual beings. Sex is a critically important component of our relationship." Get that out on the table. Then ask, "I want you to tell me how your treatment is going to affect my sexual function: my erection, my sex life, my orgasm, and my ejaculation."

Be proactive. If the doctor is being honest and reasonable, he or she will discuss it with you. If he or she won't discuss it with you, find someone who will.

Fight for your sexual health, particularly after prostatectomy and radiation. In three years' time, when your prostate cancer has been cured and you're left with no erections and a short or crooked penis, you'll think you should have done some work beforehand to optimize your recovery. Proactivity is critically important. Patients think doctors will tell them everything they need to hear, but doctors tell patients everything *doctors* think patients need to hear.

Go in with a series of questions. If the doctor says, we're running out of time, then ask when you can make your next appointment to talk. Keep going back until all your questions are answered.

Many patients spend more time choosing a plumber than a doctor. The cancer is diagnosed. The lights are flashing. Men think, "I'm going to die of cancer!" But the reality is that most people with Gleason 6 or Gleason 7 cancers are not going to die of prostate cancer.

But there are very few people in this world who hear they've been diagnosed with cancer and are not immediately afraid they're going to die.

Dr. Mulhall: Absolutely. That is why we need to empower patients.

Almost every week, I have a man sitting in my office with tears in his eyes saying, "If I had known it was going to be like this, I would never have done it. I would have not treated my prostate cancer."

First thing is to take a big deep breath, then gather information. You have to have your eyes wide open. Know what you're getting into.

If you go to a prostatectomist first, you've got a 95% chance of getting a prostate surgery for your prostate. If you go to a radiation oncologist first, you've got an 85% chance of getting radiation.

That is why a sexual medicine specialist should see every patient. There are plenty of us. We don't have a dog in the fight. We don't care if you do surgery. We don't care if you do radiation. We're going to tell you how to get the best out of your surgery or radiation and remind you to ask your radiation oncologist why you need hormone therapy.

If sexual health is an important part of your life, particularly if intercourse is an important part of your life, then talk about how you can maximize preservation of sexual function.

I suppose if you have a plan in place before treatment even starts, you're better able to deal with any side effects.

Dr. Mulhall: The most important thing is realistic expectations.

I just published a paper for which we asked men within two months of their prostatectomy about their recollection of what they were told before the procedure. Forty percent said, "I never recall being told I'd never ejaculate again." This is the most basic sexual consequence of a prostatectomy and yet 40% of patients don't remember being told about it.

Now, maybe they *were* told and they just were focusing on their cancer. Or maybe they weren't told. But you need to be proactive.

Are erectile dysfunction treatments covered by insurance?

Dr. Mulhall: A third of men have decent coverage; a third have no coverage; and a third have some coverage. The average number of pills covered per month for insured patients is about six. We also have a generic Viagra. We'll have a generic Cialis next year.

Didn't you say that Cialis and Viagra don't really work for men on hormonal therapy?

Dr. Mulhall: Yes. If you're on hormone therapy and your testosterone level is zero, you're not going to respond well to Cialis or Viagra. You may end up having to do penile injections, or something like that.

Any final advice for patients?

Dr. Mulhall: If sex is important to you, declare that. Have a good discussion with your doctor. If you think your doctor can't talk to you about it, find a sexual medicine doctor who will. Pp

Jean-Francois Eid, MD
The Penile Implant After Prostate Cancer

Dr. Jean-Francois Eid, of New York City's Advanced Urological Care, is a urologist who specializes in treating advanced erectile dysfunction.

Prostatepedia spoke with him recently about penile prostheses after prostate cancer.

How did you come to focus on erectile dysfunction?

Dr. Eid: I became interested in erectile dysfunction as a medical student. Back in the early 1980s, I heard a urologist lecture about penile implants. During my residency at NewYork-Presbyterian Hospital, we had an ultrasound machine in the department of urology. Nobody was using it, so another Urology Fellow and I started using the machine to do blood flow studies on patients with erectile dysfunction.

I became interested in using penile injections to provide patients with erections. I went from being interested in the *diagnosis* of erectile dysfunction to being interested in *treating* patients with penile injections. Back in the 1980s, we didn't have pills like Viagra and Cialis. We didn't really have any options that worked.

Throughout my training, I always preferred delicate reconstructive procedures that needed fine, precise work, rather than extirpative procedures to remove a big tumor. I found extirpative procedures to be less technically challenging.

My work continues to fascinate me. The patient evaluation requires thorough history-taking and some psychological insight, which is something I enjoy doing. At the same time, you want to make the patient feel comfortable; erectile dysfunction is a somewhat personal and delicate issue. There is a little art and empathy involved in communicating with someone suffering from erectile dysfunction.

> *"When a man has erectile dysfunction, he thinks about it all the time."*

I find it extremely gratifying to make somebody potent again without leaving any traces of the surgery. My goal is to conceal and hide the implant so the patient feels completely normal.

When a man has erectile dysfunction, he thinks about it all the time. It's not something that affects him only in the bedroom. After a while, it fatigues, occupies, and depresses the brain. Every time he sees a love scene in a movie theater or he goes out to have drinks with friends or somebody makes a joke or he sees an attractive person, he is reminded that he has erectile dysfunction. It depresses men tremendously.

The first thing a patient will say after he gets a penile implant is, "I'm a new man. I feel so free. You gave me a new life." It's sort of bizarre, because you would think that somebody would say that if you saved them from cancer or from a heart attack and not from erectile dysfunction.

How does a penile prosthesis work?

Dr. Eid: There are two types of penile implants. One type of penile implant, is always firm and is called a semi-malleable implant. The other is a saline-filled inflatable implant.

The inflatable implant was invented in 1973 and FDA-approved in 1975. It consists of two cylindrical plastic tubes that are placed inside the shaft of the penis and are connected to a pump that is concealed inside the

scrotal sac. The pump is connected to a small reservoir the size of a ping-pong ball that stores the saline when an erection is not needed. The saline fluid is transferred into the cylinders by activating the pump when the patient is interested in being sexually active. It's a hydraulic device that is manually activated. It mimics a physiological erection, while also allowing the penis to become flaccid when an erection isn't needed.

There are two manufacturers, both in the state of Minnesota. Boston Scientific is in Minnetonka. Coloplast is in Minneapolis.

In which patients is the inflatable pump used?

Dr. Eid: This is a great treatment for advanced ED that does not respond to medications such as Viagra or Cialis. In order to optimize the outcome, we have every possible device size available in the operating room; the penis is measured during the procedure, and the correct cylinder size placed in order to maximize the size and quality of the erection. It's difficult to tell which implant is appropriate for which patient until then. The choice of device brand depends on the patient's anatomy, his age, his partner's age, his manual dexterity, whether he has scar tissue, his body habitus, etc.

There are some special considerations for prostate cancer patients regarding reservoir placement (the little ping-pong-ball-like structure that stores the saline fluid). After robotic prostatectomy, surgeons do not close the peritoneum, which is a layer of tissue that separates the abdominal cavity from the pelvis.

Therefore, in order to safely place the reservoir, I perform a second separate incision about one to one-half inch either on the right or the left side of the lower abdomen. The reservoir is then placed from above, underneath the abdominal muscles, and the tubing is tunneled into the scrotal sac to connect with the pump tubing. A separate incision is unnecessary for patients following radiation therapy and is only needed for patients following robotic prostatectomy.

Are there any other considerations for prostate cancer patients?

Dr. Eid: The data on potency after prostate cancer surgery varies tremendously. If you look at the European data published by independent third parties, post-surgery erections returned to normal in fewer than 10% of men. Another 20% responded to pills like Viagra or Cialis. Seventy percent of men after robotic prostatectomy do not respond to oral medication.

Patients need to know that if they wait for more than two years after surgery and recovery of erections hasn't occurred, then it's appropriate to consider a penile implant.

Some patients do use penile self-injections. There are two types of penile injection medication. Caverject and Edex are FDA-approved and can be purchased in drug stores. These injections are safe for long-term use.

There are other types of medications, such as Trimix (mixture of papaverine, phentolamine, and prostaglandin E1), which are not FDA approved for penile self-injection but are most often used by post-prostatectomy patients. Penile scarring, deformity, and shortening will occur over the long run. Trimix should only be used for a couple of years while waiting to see if recovery of potency will occur.

How long does a penile implant last?

Dr. Eid: Penile implants will last anywhere from 15 to 20 years. But when they break, they are easily replaced.

Infection of the device is the most dreaded complication and occurs because of bacterial contamination of the implant during the surgical procedure. The rate of infection varies according to surgeon's talent, experience, and surgical volume. This can be as high as 15% or as low as 2%. Our infection rate is 0.47% based on 3,028 consecutive implants since January 2006. We update our data on a regular basis.

Specialists will have a much lower infection rate. It's important for patients to seek out the most experienced doctor. Think of a penile implant as one would a root canal procedure. You want to see a root canal specialist, rather than a general dentist for it.

Seeing a specialist is very important, because it minimizes the risk of infection, maximizes the size of the penis, and optimizes the placement of the pump and concealment of tubing and incision. Specialists also make smaller incisions, which reduce areas of skin numbness, preserving sensation and ability to achieve orgasm.

Do you advise patients to specifically ask about infection rates when evaluating doctors?

Dr. Eid: Yes, but very few places actually track their infection rates and it's often difficult to obtain this data.

How should patients evaluate a specialist?

Dr. Eid: There are clues to look for. If you walk into a doctor's office and you don't see any information on

penile implants, then you can guess that not a lot of implants are being performed by that practice.

If the doctor sees female patients as well as male and performs mostly general urological procedures, then this automatically indicates that the physician hasn't done a lot of penile implants. (There just isn't enough time in the day to do all these things.)

If the doctor has assistants do some of the ED evaluation and some of the medical treatment of erectile dysfunction—a physician assistant does the penile injections—then you know that the doctor is not really involved and interested in treating erectile dysfunction. He will not have the opportunity to discuss penile implants with many patients.

If you ask about penile implants and the doctor doesn't volunteer a list of patients who already have had a penile implant placed by his practice that you can talk to, this also would indicate that not a lot of implants are being performed there.

If the doctor doesn't have models of all the different types of implants that you can look at and manipulate, and if you ask for information on penile implants and all you get is a pamphlet from the company itself and nothing written by that physician, then this also indicates that the procedure is not frequently performed in that practice.

If you schedule the procedure and find that the staff doesn't really know about insurance reimbursement, that's also a clue that they're not frequently scheduling the implant procedure.

If you ask the doctor, "Do you like to have a representative from the company there during the procedure?" and he says yes, then, you know that he is not going to have a choice of which implant to use. (If a representative from one company is there, the doctor is less likely to use an implant from another company, even if the other company's implant fits you better.)

If you ask directly about infection rates, he may say, "My infection rate is very low." But looking for clues is a much cleverer way of finding information about how many implants a doctor actually does.

"Seek the most experienced physician you can find in order to maximize chances of success."

How much does an implant cost? Is it usually covered by insurance?

Dr. Eid: These devices have been around since 1973 and the procedure is reimbursed by most commercial insurances including Medicare.

More recently insurance plans have increased their deductibles and some will play games. They claim to cover the procedure, but won't pay for the implant device. This is a newer occurrence and is absurd.

If a patient is paying cash, the device itself costs from $8,000 to $10,000. When you add the cost of the operating room, anesthesia, and the surgeon's fee, it can add up to about $25,000, depending on the facility used.

It is recommended to have this procedure performed in a clean

outpatient ambulatory surgery center and to avoid a hospital stay. Ambulatory facilities charge less than hospitals. (The operating room and anesthesia fees are much cheaper.)

"Patient and partner satisfaction with penile implants is greater than 90%."

I suppose if the device lasts 20 years, $25,000 isn't a bad deal.

Dr. Eid: No, it's not. There are a lot of other medical procedures that are much more expensive.

Is there anything else men should know about the penile implant or other options available to treat erectile dysfunction after prostate cancer?

Dr. Eid: One feels completely normal with a penile implant. Everything is preserved; nothing is removed from the patient to put in the penile implant. Also for many, the implant restores a fuller penile anatomy. The penis doesn't retract when the implant is not in use, so the flaccid penis appears larger.

After prostatectomy, some patients will have difficulty with urination if the patient is overweight and the penis retracts. A penile implant will also help in this situation.

Patient and partner satisfaction with penile implants is greater than 90%, but as with any medical procedure, seek the most experienced physician you can find in order to maximize chances of success. Pp1

Clinical Trial: Arthur Burnett, MD Erythropoietin + Erectile Function After Surgery

Dr. Arthur Burnett is the Director of both the Basic Science Laboratory in Neuro-Urology and the Sexual Medicine Fellowship Program at Johns Hopkins University in Baltimore, Maryland.

Prostatepedia spoke with him recently about a trial he's running that offers men erythropoietin *before* surgery to improve the speed at which they recover sexual function *after* surgery.

What area of prostate cancer treatment do you specialize in?

Dr. Burnett: I specialize in cancers in the pelvic area, as well as pelvic reconstructive surgeries as they relate to the urogenital system. I have a unique perspective and have made some major scientific contributions in the area of sexual medicine.

I combine a solid understanding of surgery for prostate cancer with an understanding of the functional (sexual, urinary, etc.) aspects after prostate cancer. Some urologic surgeons just do prostate cancer surgeries and then move on to the next patient. There are also urologists involved in sexual medicine who offer treatments, but don't really understand what nerve-sparing is all about or what is really going on with pelvic surgery. They make suggestions based on what they think they know without really being quite as dedicated and knowledgeable as others. I cross both sides, which is not as common as people might think.

How long does it take a man to recover his ability to have an erection after prostatectomy?

Dr. Burnett: Patients who undergo prostate cancer surgeries, or any intervention for localized prostate cancer, will endure some aspect of erectile dysfunction or urinary control problems, because the prostate is in a very precarious part of the body. Even though we do prostate cancer surgery better than we did 25 years ago with regard to preserving nerves and blood vessel tissue crucial for the functioning of penile erection, men still don't have the best immediate outcomes, meaning it takes a long time to recover the ability to have an erection despite improved surgical techniques.

In general, though, patients do recover from surgery better now. We're more proficient at the surgery and so men get their continence back faster. Their fatigue lasts not a year, but a few weeks. Soon they're back to their normal daily activities.

They're left wondering where their erections are. But lack of erections has more to do with the shock the nerves and blood vessels **surrounding** the nerve tissue undergo even with very delicate surgeries. Many patients are really unhappy with that fact. They think, "I've had a supposedly nerve-sparing operation. I'm back to normal activities, but I'm hearing it may take months for my erections to come back?"

While we've improved on all other aspects of this surgery, I consider erection recovery to be the last frontier of recovery from prostate cancer surgery. While we strategize with medications like Viagra, erection rehabilitation or penile rehab, and things of that sort, nothing has really come forward to help men recover erections better and faster. Sometimes it takes a year or two for a man to recover his erections. There really has been a major move afoot to scientifically understand why erection recovery takes so long, and to think scientifically about what can be done about it.

There is a lot of misinformation and misconception out there that taking Viagra or Cialis every day is going to rejuvenate the erection response after prostate cancer surgeries, or even after radiation. The truth of the matter is that trial results on these medications over the past 15 years have not been impressive.

It's nice that we have some interest in newer surgical approaches like robotic prostatectomy, but there is nothing inherent about robotic surgery that guarantees you'll get function back any faster. There is still potential trauma to the surrounding nerves and blood vessels under any form of surgery. Most likely you'll have the best response with a master surgeon, whether the surgeon is doing open or robotic procedures. But the reality is that these nerves will be traumatized even in the best hands. We need to continue to think about new ways to help the nerve tissue recover.

What is the thinking behind giving erythropoietin to men before surgery?

Dr. Burnett: Almost 10 years ago, we discovered that erythropoietin, a hormone made in the kidney that helps make red blood cells, is a very potent hormone and growth factor. We've also discovered that erythropoietin has some amazing effects on tissue health, recovery, and regeneration. We've made some original contributions to that understanding in my laboratory: 10 years ago, I studied erythropoietin in animal model studies that mimic nerve regeneration in men undergoing prostate cancer surgeries.

We're now bringing erythropoietin to patients in this setting. Erythropoietin is an FDA-approved drug that can be prescribed. While it's been used to help drive red blood cell count in those with anemia, we have asked if it could be used in men undergoing prostate cancer surgeries to rejuvenate the tissue, nerves, and blood vessels in the pelvic area inadvertently traumatized by this operation.

We have given erythropoietin to some patients and just followed them. Many seem to do better and that has prompted us to go back and do a formalized controlled blinded study. (Any time you give someone a medication, and both patients and investigators *know* they're on it, there is potential for bias. That is why the ultimate form of a study is a randomized controlled trial done in a blinded fashion.)

We had a bit of a setback about two or three years ago when we started the trial. There were some reports of thromboembolic events in people chronically taking these medications at high doses. There were reports of some complications because the dosing was possibly too high with long-term dosing.

Treatment includes a few perioperative doses the day before, the day of, and the day after surgery. We think we're not using excessive dosing, but you can imagine regulatory agencies were concerned, based on other studies and clinical observations, that our patients might be predisposed to getting blood clots. We were on hiatus for a good year or two to get FDA approval after we revamped the trial with lower dosing. We have now restarted enrollment.

What can patients expect during the trial?

Dr. Burnett: This trial is only offered at Johns Hopkins University in Baltimore, Maryland. Patients need to consider having the surgeries done by myself, or one of my colleagues involved in the trial. We do the erythropoietin dosing preoperatively, around the time of surgery. A patient can't have the surgery elsewhere and then come to me six months later and ask for erythropoietin. That is not what the trial is about. After the surgery and dosing, you go home like anybody else. We see how you recover within the next year or two with serial surveys that we send to you.

How To Get Involved…

If you're interested in participating or would like more information, contact Dr. Arthur Burnett at aburnet1@jhmi.edu or 410-614-3986.

So patients don't necessarily need to live within a commutable distance to Baltimore, do they? They could have the surgery and then return home.

Dr. Burnett: Yes. Patients at a great distance away might be possible participants.

What kind of patients are you looking for?

Dr. Burnett: We want patients who are preoperatively potent and have opportunities for sexual activity after surgery. Someone who is in poor health, but still eligible for prostate cancer surgery; who does not have a partner or who is not sexually active; or who has poor erections before surgery would not be someone we can enroll. Rather, we're looking for men between 50 and 60 or younger, with no competing medical illnesses, who are preoperatively potent, and have partners.

What about men who have had previous treatments like radiation therapy or focal therapy?

Dr. Burnett: Then they're excluded, because these other treatments confound any assessment of what we're doing. We'd like to try to protect from acute trauma to the nerve and blood vessel tissue.

What about existing cardiovascular disease?

Dr. Burnett: We'll have to judge. In general, if somebody is healthy enough to go through the surgery, is otherwise preoperatively potent, has a partner, and has an early enough stage disease that we're not removing any nerve tissue, they *could* possibly be a candidate. Pp1

Paul Nelson: Online Erectile Dysfunction Support

FrankTalk.org, an online discussion group for men with erectile dysfunction, is the brainchild of prostate cancer patient Paul Nelson.

Prostatepedia spoke with Paul about his journey and the thinking behind FrankTalk.

Why did you start FrankTalk?

Mr. Nelson: I was diagnosed with prostate cancer the day before my father died of the same disease. I was 46. I had surgery very quickly, because that's what everyone said I had to do given that I was so young. In retrospect, I'm glad it's out and that it's over.

That was eight years ago. I discovered there is a lot of online support for cancer patients. After I had the surgery, I assumed there would be online support for the sexual side effects of cancer. I went online and searched and searched. I just kept coming up with one commercial after another, or one scam after another. Even the medical information sites all said the same thing. It was very vague.

I was frustrated and said to my wife, "There's nothing online about erectile dysfunction!" She's a librarian. She said, "You're just searching for the wrong terms." One day at work she texted me: "My God! You're right. There is *nothing* online."

There were prostate cancer discussion boards, but they weren't focused on erectile dysfunction. They are for men fighting prostate cancer! I thought that surely there must be a patient organization for men with erectile dysfunction. Wrong again.

"America is uncomfortable with sex."

After I complained about it for several months, my wife told me to shut up and start my own online group. Here we are eight years later.

FrankTalk is a patient support site. We are an online community of men talking about our experiences with erectile dysfunction. We talk about what erectile dysfunction does to your view of yourself as a sexual person and how you cope sexually and emotionally. It is not a medical site. You can get medical information from other patients—how to do a penile injection or how to use a penis pump—but the heart and soul of the site is men discussing the frustrations, triumphs, and disappointments of dealing with sexual dysfunction.

Do you include only men with erectile dysfunction after prostate cancer?

Mr. Nelson: We now have men with erectile dysfunction who do not have prostate cancer, as well, but we started off with only prostate cancer patients.

When I started the site, I was a patient at Mount Sinai Hospital. Dr. Natan Bar-Chama was the urologist in charge of erectile dysfunction following surgery. When he found out what we were doing, he said, "This is much bigger than prostate cancer. There are millions of men out there with erectile dysfunction who have no resources." And so we opened up to those without prostate cancer.

We still have a huge number of prostate cancer patients on the site, but by no means is it a prostate cancer/erectile dysfunction-only site anymore. That's just where it started.

That was actually a big discussion on the site for a long time: it doesn't

"We have doctors who shouldn't be expected to be sexual medicine experts forced into playing that role."

matter what your erectile dysfunction comes from, you still need help. No matter what the cause, the pain of having it is still the same.

Do you think men with erectile dysfunction are reluctant to seek help?

Mr. Nelson: America is uncomfortable with sex. The world is uncomfortable with sex. Men in our culture believe their male identity is firmly rooted in the penis. It's tragic.

Unfortunately, most physicians are uncomfortable as well. They get zero training in sexual medicine in medical school. People don't realize that urologists are surgeons first and foremost. They're trained to cut; they do not get classes in human sexuality in medical school. They don't take classes on erectile dysfunction. It really puts them in an awkward spot to have men ask for help with erectile dysfunction. We have doctors who shouldn't be expected to be sexual medicine experts forced into playing that role.

It's a double whammy. We've got a culture of men for whom it's scary to talk about sex and about sexual failure or sexual difficulties. They're then presenting themselves to doctors who really don't have much training in sexual medicine. It's a complicated problem.

What are some of the psychological problems associated with erectile dysfunction?

Mr. Nelson: Depression is first and foremost.

When men can't have intercourse, or the trial and the pain of going through injections or pills is too much, they tend to withdraw. They avoid sex. Men stop having sex. Their wives mostly just want intimacy. But because men are hardwired in our culture to just want intercourse, they just stop having sex. They stop touching their wives completely, because it makes them feel like a failure or broken or dysfunctional. It's easier to just avoid it completely.

"It destroys marriages far more frequently than anyone talks about."

Meanwhile, their partners are thinking, "What happened? He doesn't he love me anymore. I'm not attractive. I'm too old."

Women will often say, "It doesn't matter that you can't have an erection." But yes, it *does* matter to men. The man feels stupid that it bothers him. It's really a complex problem.

Part of the problem is that couples don't know how to talk about it. They don't have the tools to talk about it. They don't have the vocabulary. It destroys marriages far more frequently than anyone talks about. It's tragic.

That's why support groups like ours are important. It's worth seeking help. Pp[1]

Kathie Houchens: Wives Talk About Erectile Dysfunction

Kathie Houchens's husband, Dave, was diagnosed with prostate cancer in 2001. She now leads a support group for the wives, partners, and caregivers of prostate cancer patients in Columbus, Ohio.

Prostatepedia spoke with Kathie recently about how to cope when your partner has erectile dysfunction.

What was your husband's struggle with erectile dysfunction after treatment like?

Ms. Houchens: My husband's initial treatment was surgery. For that first year of recovery, I was afraid I would hurt him if we were too active too soon. It was difficult to know what to do, but we were able to trust that we could rediscover ways to stay connected physically in spite of this new normal.

We had been married almost four decades then, so we knew that we could maintain our close relationship, even if it meant making adjustments. Physical touch contributes to a feeling of unity and acceptance. It is more than just body awareness. It is also a spiritual and emotional bond.

Dave is a scientist and cancer researcher. He has spent a career looking for and finding answers. Prostate cancer became his new focus as he looked into options for additional help with sexual function. In 2001 few, if any, cancer centers offered programs in penile rehabilitation. If your doctor or clinic offers it, take advantage of it. It can make a difference. We did not have that option, so our first step was to ask for a Viagra prescription.

For many years, Viagra was fine. Yes, it had side effects that could be bothersome. I sometimes felt guilty if he viewed the world through a blue haze or suffered a stuffy head that made sleeping difficult. But he was willing to make that sacrifice to have the physical relationship we wanted.

The Viagra pills kept getting more and more expensive, though. At one point, it was about $35 a pill—and it wasn't covered by our insurance. It's rare for most people to find it covered by insurance. We gave Cialis a try, too. For a while it seemed to be an improvement. Another advantage was that taking it near mealtime was not a problem, as it was with Viagra. The price, however, was about the same as Viagra.

Our treatment journey also included two separate year-long courses of Lupron hormone ablation, as well as salvage radiation, in 2009. It all takes its toll on sexual function.

In the last year, we have been using penile injections: Trimix, prepared at a compounding pharmacy. Penile injections are efficient. There are no side effects. It's affordable. For us, for right now, it's the best of all worlds.

It may not be the right choice for everybody. There are inconveniences involved, because it has to be refrigerated. We've just been on a two-week trip. It would have been a challenge to carry the preparation along and keep it cold during air travel, in B&Bs, or even when visiting family. But two weeks is two weeks. A longer trip would have been more difficult, but there are many other ways to keep the intimacy of a relationship alive.

We are all aging, with or without prostate cancer. Our bodies decline and diminish in spite of all we do to eat right, exercise, and keep mentally fit. We would like to think we could stop the aging process, and there are marketing geniuses that would like to convince you it is possible, but there comes a point when couples find that intimacy issues for men and for women call for some extra help.

There is some psychology involved. Sometimes it is helpful to get counseling to help to stay on track, or at least jump-start what may seem like low battery power. The brain is actually the most important sex organ. When we talk about treatment for erectile dysfunction, we're not just talking about reprogramming the penis, but also about reprogramming thought processes. Being able to relax, to feel cherished, to be free to play together in a mindset of happy possibility can produce miracles. An anxious mind signals adrenalin to be pumped into your bloodstream and that will short-circuit an erection. Dr. John Mulhall's book, *Saving Your Sex Life*, has been the most informative source we have found to understand the mysterious world of erectile dysfunction.

Do you have any advice for women concerned about erectile dysfunction after prostate cancer?

Ms. Houchens: Every couple has a different idea of where they want to be on the other side of treating prostate cancer. But, almost universally, women start out by saying, "Save my husband's life; sex isn't the most important thing." As I learned early on, that is the least helpful thing you can say to your husband. To say, "It will be okay if we can't have sex anymore" is like saying, "It wasn't ever any good anyway so I won't miss it." Even if your intention is to help take the pressure off and allow that penile performance loss may be the toll you pay for his staying alive.

In our support group, we help each other learn to say, "Yes, we've got some challenges ahead, but keeping our intimate life nourished and creative is prime to our relationship. I'm willing to do what I need to do to help you get back to where we want to be."

Unfortunately, many couples report that their urologist or surgeon never warned them about erectile dysfunction. Or if they were told, it was in gentle terms—hopeful, and promising good outcomes. Doctors don't want men to not choose treatment out of fear of losing sexual function, even for a short term. They may mention erectile dysfunction, but in a positive way that emphasizes a high percentage of return to pretreatment function. In younger men, that is more likely, but there will be some adjustment in most men. Radiologists, too, need to have this discussion with patients and their partners.

Initially, Dave went to his urologist on his own. The books he brought home from the post-biopsy appointment laid out all the treatment choices. It was overwhelming to me, but I trusted his choice since he is a scientist with a career in researching cancer treatment. He decided what he wanted to do and scheduled surgery for the next month. Women don't usually go to their husband's dental or eye appointments, so it may feel strange to think you would go to a urology appointment with him. I recommend it, though. Two pairs of ears hearing what the doctor is saying and two questioning minds wanting to get answers will benefit you both in the long run. Prostate cancer is a couples' disease. Women need to be a part of every conversation regarding treatment and recovery.

Maybe you both heard the doctor say that most of his patients have erections back by the end of the first year. Maybe they say six months. Whatever it is, you don't think to ask how that is measured. We want to think positive thoughts, so naturally we say to ourselves, to each other, "Yes! We can do this. We will be normal again, soon." We want to believe that all will be well. We are stressed out at this point and grab at any hope. Unfortunately, we don't think to ask (how could we know?) by what standard do you measure an erection for your statistics? It may not be an erection good enough for penetration. There are levels of success. Be inquisitive. Keep open to reality.

The crisis kicks in when, post-treatment, things are not working out as "promised" or as we imagined they would. I think Dave and I were realistic in our expectations, so erectile

dysfunction did not come as a surprise. However, in support groups we have facilitated, it is a big topic of concern that there is so much to figure out about erectile dysfunction. It can be a challenging learning curve.

For us, the now 15-year process of adapting to life with cancer recovery and, currently a durable remission of the disease, has been an opportunity to explore feelings that in earlier years got lost in our busy lives. (We raised three children and were involved in our careers.) When cancer enters your life, something shifts. We were awakened to the importance of honest communication and deep sharing of hopes, dreams, needs, and values. The cancer journey and all that came with it has brought us even closer together.

Where do you suggest women find information and support for themselves and their partners?

Ms. Houchens: I would start by asking your doctor, but don't stop there: look to other sources. If you don't want to go to a doctor's office, get online help. Be careful, though, as there are both good and not-so-good websites. A trusted local doctor or support group facilitator could point you to some reliable ones.

Knowledge is power. Stay informed. New therapies are coming along all the time, so find out where and when there are conferences you can attend to learn about the latest innovations. Read articles and books that relate to your needs.

You are your own best advocate. If you hear of a speaker somewhere, make the effort to go, even if it means a two-hour drive. If it means a weekend in New York to hear a lecture, then make it a holiday. Go to a support group. If you're in a support group, you may find people whose shared

experiences will inform your decision-making. Start your own women's support group if you need to. I think women do better when they have somebody they can talk to, when they can open their hearts and be heard and understood and not judged.

It is important to be reminded that you are not alone. Women are strong, and as I have seen them experience a support group for the first time, sometimes they just cry. Their tears are a mix of relief (somebody really understands me); of sadness (I have been holding all this inside because I didn't want to upset my husband, partner, or children, etc.); and exhaustion (I can lay my burden down with this group. I am not alone anymore.) From that point comes new energy to face whatever comes next.

I remember my very first support group meeting. The group shared experiences and stories as we went around the small circle of women. One lady was in tears because her husband was dealing with both erectile dysfunction and incontinence. The urine leakage seemed to be a huge hindrance to their intimacy. The others present were able to hold the space for her to fully express her anguish over the situation. While problem-solving is not the work of a support group, helping each person go into their own deep knowing of what might improve a situation is.

Others, who shared their own experiences, opened a discussion that informed us all. In the end it helped us know that we can keep our feet on the ground, be open to whatever our situation is, and, with a sense of humor and hope, be present to our partner's needs to build a future together that brings pleasure to us both. Pp1

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Who is XTANDI for? XTANDI is a prescription medicine used to treat men with prostate cancer that no longer responds to a medical or surgical treatment that lowers testosterone and that has spread to other parts of the body.

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Important Safety Information

Who should not take XTANDI?

XTANDI is not for use in women. Do not take XTANDI if you are pregnant or may become pregnant. XTANDI can harm your unborn baby. It is not known if XTANDI is safe and effective in children.

Before you take XTANDI, tell your healthcare provider if you:

- Have a history of seizures, brain injury, stroke or brain tumors.
- Have any other medical conditions.
- Have a partner who is pregnant or may become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with XTANDI. If your sexual partner may become pregnant, a condom and another form of birth control must be used during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control. See "Who should not take XTANDI?"
- Take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XTANDI may affect the way other medicines work, and other medicines may affect how XTANDI works. You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI.

How should I take XTANDI?

- XTANDI is four 40 mg capsules taken once daily.
- Take XTANDI exactly as your healthcare provider tells you.
- Take your prescribed dose of XTANDI one time a day, at the same time each day.
- Your healthcare provider may change your dose if needed.
- Do not change or stop taking your prescribed dose of XTANDI without talking with your healthcare provider first.
- XTANDI can be taken with or without food.
- Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules.
- If you miss a dose of XTANDI, take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your

prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI in one day.

- If you take too much XTANDI, call your healthcare provider or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much XTANDI.

What are the possible side effects of XTANDI?

XTANDI may cause serious side effects including:

- **Seizure.** If you take XTANDI you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure. Your healthcare provider will stop XTANDI if you have a seizure during treatment.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your healthcare provider will do a test to check for PRES. Your healthcare provider will stop XTANDI if you develop PRES.

The most common side effects of XTANDI include weakness or feeling more tired than usual, back pain, decreased appetite, constipation, joint pain, diarrhea, hot flashes, upper respiratory tract infection, swelling in your hands, arms, legs, or feet, shortness of breath, muscle and bone pain, weight loss, headache, high blood pressure, dizziness, and a feeling that you or things around you are moving or spinning (vertigo).

XTANDI may cause infections, falls and injuries from falls. Tell your healthcare provider if you have signs or symptoms of an infection or if you fall.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of XTANDI. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Brief Summary on the following page and the Full Prescribing Information on XTANDI.com.

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What is XTANDI?

XTANDI is a prescription medicine used to treat men with prostate cancer that no longer responds to a medical or surgical treatment that lowers testosterone and that has spread to other parts of the body.

It is not known if XTANDI is safe and effective in children.

Who should not take XTANDI?

XTANDI is not for use in women.
Do not take XTANDI if you are pregnant or may become pregnant. XTANDI can harm your unborn baby.

What should I tell my healthcare provider before taking XTANDI?

Before you take XTANDI, tell your healthcare provider if you:

- have a history of seizures, brain injury, stroke, or brain tumors
- have any other medical conditions
- have a partner who is pregnant or may become pregnant. Men who are sexually active with a pregnant woman must use a condom during and for 3 months after treatment with XTANDI. If your sexual partner may become pregnant, a condom and another form of effective birth control must be used during and for 3 months after treatment. Talk with your healthcare provider if you have questions about birth control. See "**Who should not take XTANDI?**"

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. XTANDI may affect the way other medicines work, and other medicines may affect how XTANDI works.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed XTANDI.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take XTANDI?

- Take XTANDI exactly as your healthcare provider tells you.
- Take your prescribed dose of XTANDI one time a day, at the same time each day.
- Your healthcare provider may change your dose if needed.
- Do not change or stop taking your prescribed dose of XTANDI without talking with your healthcare provider first.
- XTANDI can be taken with or without food.
- Swallow XTANDI capsules whole. Do not chew, dissolve, or open the capsules.
- If you miss a dose of XTANDI, take your prescribed dose as soon as you remember that day. If you miss your daily dose, take your prescribed dose at your regular time the next day. Do not take more than your prescribed dose of XTANDI in one day.
- If you take too much XTANDI, call your healthcare provider or go to the nearest emergency room right away. You may have an increased risk of seizure if you take too much XTANDI.

What are the possible side effects of XTANDI?

XTANDI may cause serious side effects including:

- **Seizure.** If you take XTANDI you may be at risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have loss of consciousness or seizure. Your healthcare provider will stop XTANDI if you have a seizure during treatment.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** If you take XTANDI you may be at risk of developing a condition involving the brain called PRES. Tell your healthcare provider right away if you have a seizure or quickly worsening symptoms such as headache, decreased alertness, confusion, reduced eyesight, blurred vision or other visual problems. Your healthcare provider will do a test to check for PRES. Your healthcare provider will stop XTANDI if you develop PRES.

The most common side effects of XTANDI include:

- weakness or feeling more tired than usual
- back pain
- decreased appetite
- constipation
- joint pain
- diarrhea
- hot flashes
- upper respiratory tract infection
- swelling in your hands, arms, legs, or feet
- shortness of breath
- muscle and bone pain
- weight loss
- headache
- high blood pressure
- dizziness
- a feeling that you or things around you are moving or spinning (vertigo)

XTANDI may cause infections, falls and injuries from falls. Tell your healthcare provider if you have signs or symptoms of an infection or if you fall.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of XTANDI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XTANDI?

- Store XTANDI between 68°F to 77°F (20°C to 25°C).
- Keep XTANDI capsules dry and in a tightly closed container.

Keep XTANDI and all medicines out of the reach of children.

General information about XTANDI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XTANDI for a condition for which it was not prescribed. Do not give XTANDI to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about XTANDI. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about XTANDI that is written for health professionals.

For more information go to www.Xtandi.com or call 1-800-727-7003.

What are the ingredients in XTANDI?

Active ingredient: enzalutamide

Inactive ingredients: caprylocaproyl polyoxylglycerides, butylated hydroxyanisole, butylated hydroxytoluene, gelatin, sorbitol sorbitan solution, glycerin, purified water, titanium dioxide, black iron oxide

Manufactured by:
Catalent Pharma Solutions, LLC, St. Petersburg, FL 33716

Marketed by:
Astellas Pharma US, Inc., Northbrook, IL 60062
Medivation Inc., San Francisco, CA 94105
14L082-XTA-BRFS

076-1121-PM

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: August 2015

ZERO PROSTATE CANCER RUN/WALK 2016

Join Us for Prostate Cancer Awareness Month to Help End the Disease!

Support the one in seven American men affected by prostate cancer at one of these family-friendly events in 2016. Run or walk and receive a tech shirt and refreshments after the race. Kids 9 and under can take part in the Kids Superhero Dash for Dad and receive a cape.

Survivors and patients are the true ZERO's Heroes at our Run/Walks, and we're fighting for you. All survivors and patients will receive a special hat and shirt on race day. We fundraise, run, and walk in your honor in the hope that one day we will achieve Generation ZERO – the first generation free from prostate cancer.

REGISTER NOW! www.zeroprostatecancerrun.org

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Boston, MA – September 10, 2016
Charleston, SC – October 29, 2016
Cincinnati, OH – October 15, 2016
Columbus, OH – September 17, 2016
Corpus Christi, TX – October 22, 2016
Dallas/Fort Worth, TX – September 17, 2016
Dayton, OH – September 24, 2016
Des Moines, IA – September 17, 2016
Greensboro, NC – November 19, 2016
Harrisburg, PA – September 23, 2016
Jacksonville, FL – December 3, 2016
Kansas City, KS – October 8, 2016
Lincoln, NE – September 18, 2016
Miami, FL – September 24, 2016
Minneapolis, MN – September 17, 2016
Napa Valley, CA – September 17, 2016
Oklahoma City, OK – September 18, 2016
San Antonio, TX – September 18, 2016
San Diego, CA – September 10, 2016
San Francisco, CA – November 12, 2016
St. Louis, MO – September 17, 2016
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WHAT IS ZYTIGA® (abiraterone acetate)**?**

ZYTIGA® is a prescription medicine that is used along with prednisone. ZYTIGA® is used to treat men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body.

IMPORTANT SAFETY INFORMATION

Who should not take ZYTIGA® (abiraterone acetate)?

Do not take ZYTIGA® if you are pregnant or may become pregnant. ZYTIGA® may harm your unborn baby. Women who are pregnant or who may become pregnant should not touch ZYTIGA® without protection, such as gloves.

ZYTIGA® is not for use in women or children. **Keep ZYTIGA® and all medicines out of the reach of children.**

Before you take ZYTIGA®, tell your healthcare provider if you:

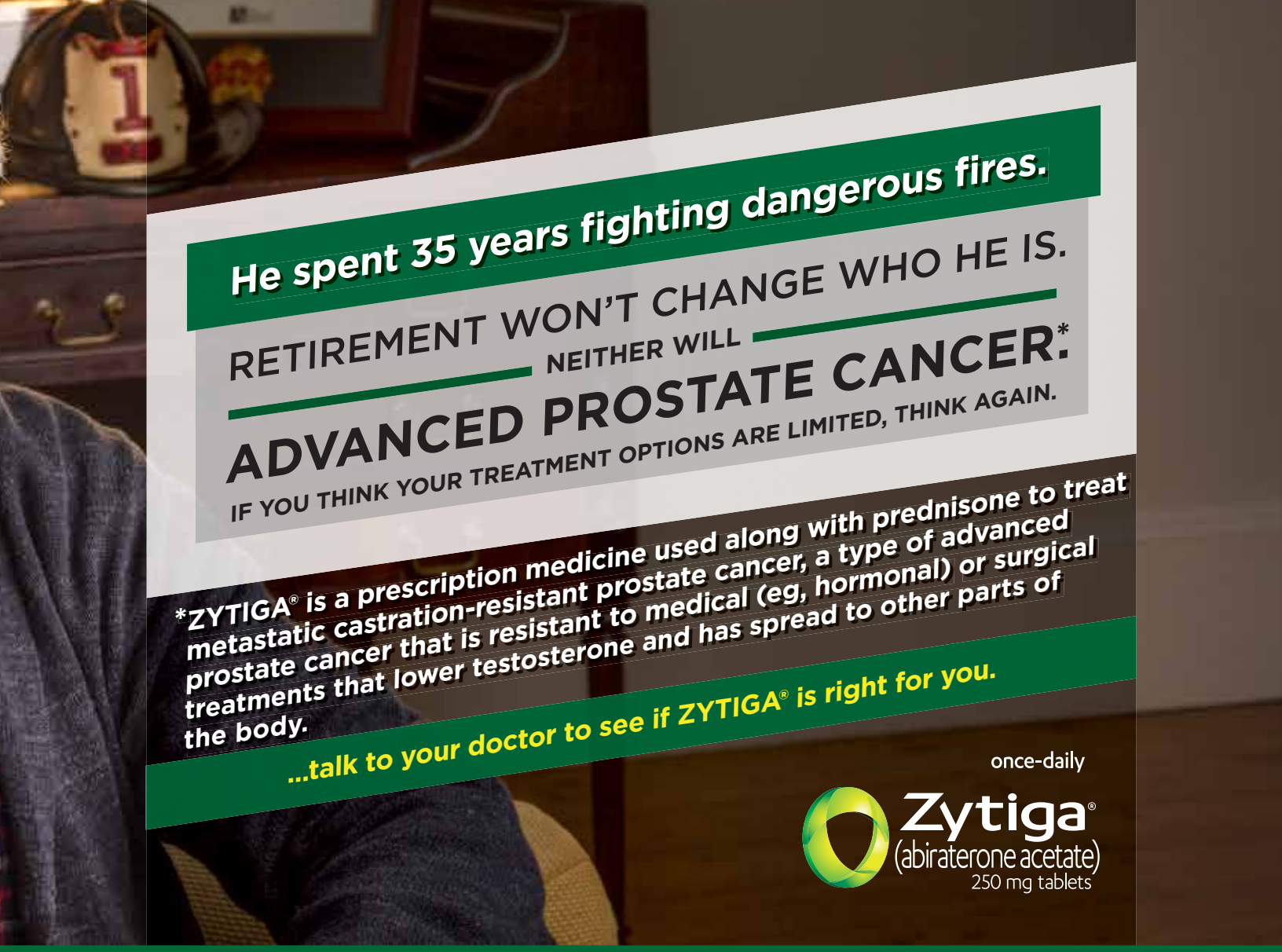
- Have heart problems
- Have liver problems
- Have a history of adrenal problems
- Have a history of pituitary problems
- Have any other medical conditions
- Plan to become pregnant **(See "Who should not take ZYTIGA®?")**
- Are breastfeeding or plan to breastfeed. It is not known if ZYTIGA® passes into your breast milk. You and your healthcare provider should decide if you will take ZYTIGA® or breastfeed. You should not do both. **(See "Who should not take ZYTIGA®?")**
- Take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZYTIGA® can interact with many other medicines.

If you are taking ZYTIGA®:

- Take ZYTIGA® and prednisone exactly as your healthcare provider tells you.
- Take your prescribed dose of ZYTIGA® one time a day. Your healthcare provider may change your dose if needed.
- Do not stop taking your prescribed dose of ZYTIGA® or prednisone without talking to your healthcare provider first.
- Take ZYTIGA® on an empty stomach. **Do not take ZYTIGA® with food.** Taking ZYTIGA® with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- No food should be eaten 2 hours before and 1 hour after taking ZYTIGA®.
- Swallow ZYTIGA® tablets whole. Do not crush or chew tablets.
- Take ZYTIGA® tablets with water.
- Your healthcare provider will do blood tests to check for side effects.
- Men who are sexually active with a pregnant woman must use a condom during and for one week after treatment with ZYTIGA®. If their female partner may become pregnant a condom and another form of birth control must be used during and for one week after treatment with ZYTIGA®. Talk with your healthcare provider if you have any questions about birth control.
- If you miss a dose of ZYTIGA® or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.

ZYTIGA® may cause serious side effects including:

- **High blood pressure (hypertension), low blood potassium levels (hypokalemia), and fluid retention (edema).**



Tell your healthcare provider if you get any of the following symptoms:

- Dizziness
- Feel faint or lightheaded
- Confusion
- Pain in your legs
- Fast heartbeats
- Headache
- Muscle weakness
- Swelling in your legs or feet

- **Adrenal problems** may happen if you stop taking prednisone, get an infection, or are under stress.
- **Liver problems.** You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with ZYTIGA® and during treatment with ZYTIGA®. Liver failure may occur, which can lead to death. Tell your healthcare provider if you notice any of the following changes:
  - Yellowing of the skin or eyes
  - Darkening of the urine
  - Severe nausea or vomiting
- The most common side effects of ZYTIGA® include:
  - Weakness
  - Joint swelling or pain
  - Swelling in your legs or feet
  - Hot flushes
  - Diarrhea
  - Vomiting
  - Cough
  - High blood pressure
  - Shortness of breath
  - Urinary tract infection
  - Bruising
  - Low red blood cells (anemia) and low blood potassium levels
  - High blood sugar levels, high blood cholesterol and triglycerides
  - Certain other abnormal blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

THESE ARE NOT ALL THE POSSIBLE SIDE EFFECTS OF ZYTIGA®.

FOR MORE INFORMATION, ASK YOUR HEALTHCARE PROVIDER OR PHARMACIST.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZYTIGA® can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider who prescribed ZYTIGA®.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088 (1-800-332-1088).

051527-160418

Janssen Biotech, Inc.
800 Ridgeview Drive
Horsham, PA 19044 USA

janssen

PATIENT INFORMATION
ZYTIGA® (**Zye**-tee-**ga**)
(abiraterone acetate)
Tablets

Read this Patient Information that comes with ZYTIGA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is ZYTIGA?
ZYTIGA is a prescription medicine that is used along with prednisone. ZYTIGA is used to treat men with castration-resistant prostate cancer (prostate cancer that is resistant to medical or surgical treatments that lower testosterone) that has spread to other parts of the body.

ZYTIGA is not for use in women.

It is not known if ZYTIGA is safe or effective in children.

Who should not take ZYTIGA?
Do not take ZYTIGA if you are pregnant or may become pregnant. ZYTIGA may harm your unborn baby.

Women who are pregnant or who may become pregnant should not touch ZYTIGA without protection, such as gloves.

What should I tell my healthcare provider before taking ZYTIGA?
Before you take ZYTIGA, tell your healthcare provider if you:
- have heart problems
- have liver problems
- have a history of adrenal problems
- have a history of pituitary problems
- have any other medical conditions
- plan to become pregnant. See "**Who should not take ZYTIGA?**"
- are breastfeeding or plan to breastfeed. It is not known if ZYTIGA passes into your breast milk. You and your healthcare provider should decide if you will take ZYTIGA or breastfeed. You should not do both. See "**Who should not take ZYTIGA?**"

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZYTIGA can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ZYTIGA.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ZYTIGA?
- Take ZYTIGA and prednisone exactly as your healthcare provider tells you.
- Take your prescribed dose of ZYTIGA 1 time a day.
- Your healthcare provider may change your dose if needed.
- Do not stop taking your prescribed dose of ZYTIGA or prednisone without talking with your healthcare provider first.
- Take ZYTIGA on an empty stomach. **Do not take ZYTIGA with food.** Taking ZYTIGA with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- No food should be eaten 2 hours before and 1 hour after taking ZYTIGA.
- Swallow ZYTIGA tablets whole. Do not crush or chew tablets.
- Take ZYTIGA tablets with water.
- Men who are sexually active with a pregnant woman must use a condom during and for 1 week after treatment with ZYTIGA. If their female partner may become pregnant, a condom and another form of birth control must be used during and for 1 week after treatment with ZYTIGA. Talk with your healthcare provider if you have questions about birth control.
- If you miss a dose of ZYTIGA or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.
- Your healthcare provider will do blood tests to check for side effects.

What are the possible side effects of ZYTIGA?

ZYTIGA may cause serious side effects including:

- **High blood pressure (hypertension), low blood potassium levels (hypokalemia) and fluid retention (edema)**. Tell your healthcare provider if you get any of the following symptoms:
  - dizziness
  - fast heartbeats
  - feel faint or lightheaded
  - headache
  - confusion
  - muscle weakness
  - pain in your legs
  - swelling in your legs or feet
- **Adrenal problems** may happen if you stop taking prednisone, get an infection, or are under stress.
- **Liver problems**. You may develop changes in liver function blood test. Your healthcare provider will do blood tests to check your liver before treatment with ZYTIGA and during treatment with ZYTIGA.

  Liver failure may occur, which can lead to death. Tell your healthcare provider if you notice any of the following changes:
  - yellowing of the skin or eyes
  - darkening of the urine
  - severe nausea or vomiting

The most common side effects of ZYTIGA include:

- weakness
- joint swelling or pain
- swelling in your legs or feet
- hot flushes
- diarrhea
- vomiting
- cough
- high blood pressure
- shortness of breath
- urinary tract infection
- bruising
- low red blood cells (anemia) and low blood potassium levels
- high blood sugar levels, high blood cholesterol and triglycerides
- certain other abnormal blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZYTIGA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZYTIGA?

- Store ZYTIGA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ZYTIGA and all medicines out of the reach of children.

General information about ZYTIGA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZYTIGA for a condition for which it was not prescribed. Do not give ZYTIGA to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about ZYTIGA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ZYTIGA that is written for health professionals.

For more information, call Janssen Biotech, Inc. at 1-800-526-7736 (1-800-JANSSEN) or go to www.Zytiga.com.

What are the ingredients of ZYTIGA?

Active ingredient: abiraterone acetate

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.

Manufactured by: Patheon Inc. Mississauga, Canada
Manufactured for: Janssen Biotech, Inc. Horsham, PA 19044

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: May 2016

051810-160421

Here. Right. Now.

Erectile Dysfunction affects half of all men over age 40[1]. Even if other therapies haven't worked for you before, the Coloplast Titan Touch penile implant can help you regain your confidence in the bedroom. Penile implants are custom-fit devices that are surgically placed to allow you to obtain an erection when desired.

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1. Nunes KP, Labazi H, Webb RC. New insights into hypertension-associated erectile dysfunction. Current Opinion in Nephrology and Hypertension. 2012;21(2):163–170.

Important Safety Information: A penile implant, also called a penile prosthesis, is concealed entirely within the body to address erectile dysfunction (impotence). The implant requires some degree of manipulation before and after intercourse to make the penis erect or flaccid. Penile implants are surgical solutions requiring a healing period and have risks associated with surgery such as pain, anesthesia reactions, repeat surgery due to infections, or mechanical problems with the device. The implant eliminates the possibility of a natural erection. Considerations in choosing a penile implant may include your medical condition, lifestyle, personal preference, and cost. This treatment is prescribed by a physician. Although many patients benefit from the use of this device, results may vary.Discuss the treatment options with your physician to understand the risks and benefits of the various options to determine if a penile implant is right for you. For further question, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.com

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bernadette.greenwood@desertmedicalimaging.com
(760)766-2047

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