Prostate cancer - Latest Research

Transcript of interview with Professor Peter Scardino and Dr John Mulhall in the "The Health Report" radio broadcast by Dr Norman Swan on 23 August 2010

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Note: The transcript for the Scardino segment is on pp 1-7 and for the Mulhall segment on pp 7-12

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Norman Swan: Good morning and welcome. This morning on the *Health Report* nothing on the election but appropriately though, we're still heading below the belt.

Find out about the latest exercise craze; penile rehabilitation, how sometimes if you don't use it you lose it. And to a very controversial little gland -- the prostate.

Men face lots of dilemmas about their prostates only the first of which is whether to be screened for cancer with a blood test called the PSA. In recent years prostate research has really picked up and much more is known than used to be about how best to predict which men should make which choices including when to say no to treatment.

Memorial Sloan-Kettering Cancer Center in New York has a huge reputation for its work on prostate cancer. And that's where Peter Scardino works and researches. He's the Chairman of the Department of Surgery and heads the Prostate Cancer Program there. His particular interest is obtaining better evidence to help men and their doctors make better decisions.

Peter Scardino: It's a big problem in prostate cancer because there are so many choices. There are choices about whether or not to have PSA testing, whether or not to have a biopsy if you have an abnormal test. If a cancer is found whether or not to have treatment, which treatment to have, surgery, radiation, even for men with advanced prostate cancer there are decisions about when to start hormone therapy or whether or not to use additional treatments. So throughout the spectrum of prostate cancer patients are tormented by the decision making that they have to participate in.

Norman Swan: So let's take a walk through this. Let's talk about prediction and the man who is otherwise healthy and is thinking of a PSA screen. Is there anything that can predict that he would be more likely to benefit from a PSA than not have it done?

Peter Scardino: The tools we have have to do with family history, has anyone in your family had prostate cancer, particularly a father or a brother or first degree relative?

Norman Swan: At any age or particularly young?

Peter Scardino: We'd say at any age if you have a father or a brother who has prostate cancer your risk is two or threefold that you'll be diagnosed in your lifetime. If you have two first degree relatives say a father and a brother your risk goes up to

six or eightfold and if you have three it goes above tenfold. Another important clue is your ethnic background. So generally Asians have a lower risk of prostate cancer, the highest risk of any people in the world is African Americans.

Norman Swan: Why is that?

Peter Scardino: We don't really understand why, it's probably a combination of genetic predisposition and diet. We know for example if Japanese move to the States they become at higher risk of prostate cancer, their children are at greater risk and their grandchildren even greater risk.

Norman Swan: Do they ever reach the risk of Caucasians?

Peter Scardino: Not quite.

Norman Swan: Are there any other cancers that put you at risk of prostate cancer?

Peter Scardino: There's a slight association between prostate and breast cancer so if you're a man and breast cancer is common in your family you're at increased risk of prostate cancer and vice versa. The level of that risk is small though. Age is another very important risk factor. You know prostate cancer increases with age faster than any other cancer.

Norman Swan: So here's the thing, if you've got a risk of say colon cancer in your family and it's a high enough risk you don't go and do a faecal occult blood test to test your stool for blood, you go and have a colonoscopy. So the regular screening test is not something you have if you've got a very strong family history. Is the PSA, this rather crude blood test, the right test if you've got a strong family history or should you go straight to a prostate biopsy?

Peter Scardino: The PSA test is such a powerful predictor of your risk of having prostate cancer that it dominates all other factors. Granted it's flawed so you have to understand when it can give you reliable information and when it can't.

Norman Swan: Diet -- what do we know about diet?

Peter Scardino: We know that diet is a strong risk factor for prostate cancer.

Norman Swan: Which element is it, is it the saturated fat, is it red meat, what is it?

Peter Scardino: It's dietary fat is as narrow as the epidemiologist have been able to make it but it certainly seems to be the total caloric content of your diet particularly the dietary fat.

Norman Swan: So you've had a PSA test and it comes back a bit raised, you're on the roller coaster now, there's a possibility you've got a risk of having prostate cancer. The next question is do you go on and allow the urologist to do a biopsy?

Peter Scardino: If your PSA seems elevated for your age what you want to do in the first place is see how valid it is. So the very first thing I recommend people do is wait a couple of months and repeat it.

Norman Swan: Because there's no rush.

Peter Scardino: There's no rush to diagnose the cancer number one and PSAs can be quite variable particularly if you're a man in your 50s or over 50 your prostate begins to enlarge, that makes the PSA go up and it also makes the PSA more variable. One day you may walk in the doctor's office and your PSA is up a bit, you wait six or eight weeks and have it tested and it's back down again and you know you don't have to worry. So we often say it's the lowest that the PSA gets that we're most interested in, not the highest that it gets.

Secondly have a good digital rectal exam, have the doctor feel the prostate gland because a bit of an elevated PSA combined with a palpable nodule now your risk of having cancer goes up. But you repeat it, it's still a bit elevated, the digital rectal exam was normal, do you have a biopsy? This is a key inflection point for men to make a decision. My own prejudice is to get the information but act on it wisely. The PSA might be up from a serious life threatening cancer I would want to know if I had that but it could also be elevated for reasons that have nothing to do with cancer, but you get a biopsy and by coincidence the biopsy happens to run into a few cancer cells in your prostate because we know there are cancer cells in the prostate in at least one out of every three men over the age of 50 and the more biopsies you do the more these incidental clusters of cancer cells...

Norman Swan: And nothing may ever happen with them?

Peter Scardino: And it may have nothing to do with the PSA elevation that brought you to the biopsy in the first play, and may pose no threat to your health. So be careful, once you have the biopsy now is the time for some thoughtful, sober thinking.

Norman Swan: Let's back up a bit, in Australia you've got urologists, some who will do eight punch biopsies, some will do twelve punch biopsies and some will do twenty-four punch biopsies. The more punches you do the more likely you are to find those wisps of cancer cells and the more likely you are to think you've actually got real cancer. What is the evidence? How many punches should he or she be doing in your prostate?

Peter Scardino: I think the basic evidence would show that about ten samples are adequate to find most serious cancers. The chances that you would miss a serious cancer are no more than about 10% if you have ten cores. So whether you have eight, ten, twelve cores you're generally sampling around the prostate and that's about the right number. Six is probably too few, and twenty-four is unnecessary. One biopsy has what we would call a 90% sensitivity for detecting cancer that would be important for you to know but it's not 100% accurate.

Norman Swan: So the biopsy is positive, now here's the rub -- you've got to operate on best available evidence, you've got to operate on 48 people over 5 years to save one life. So there's a wastage rate of 48 to 1in the operative decision making that's going on at the moment unless there's a way of predicting it better. Is there yet?

Peter Scardino: Well I think there are better ways than some of the published data and the common thinking. So the data you're referring to came from the European randomised screening trial, they said they had to diagnose 48 cancers. Now not all 48 of those men were actually treated, about a third of them were actually not treated in order to save one life and that study extended over a nine year period. So it was one

life over nine years and that's a high ratio. There's no question more men are treated than need to be treated but there's a new study that came out from the Swedish arm of the European randomised trial that was published last month that has 14 year data instead of 9 year data. So by 14 years 20,000 men in Sweden, the men who got PSA testing were now half as likely to die as the men who didn't instead of 20% less likely. And the number needed to be diagnosed and treated dropped from 48 to 12 so the glass is half full.

So 12 to 1 is a little less outrageous than 48 to 1. It's still a lot of men diagnosed with cancer for every life you saved and I think that's the message we have to get across to people that while there are forms of prostate cancer that are potentially lethal and should be treated, many cancers, we would estimate somewhere around a third to a half of all men being diagnosed with prostate cancer today have a form of prostate cancer that's not going to kill them and they do not need to be...

Norman Swan: Can they be identified?

Peter Scardino: Better than people think and they can. There are a couple of relatively simple tools to identify them so one tool is to simply repeat the biopsy. A biopsy in prostate is different than a lumpectomy or a biopsy in a breast cancer. In a breast cancer you see a specific lump, you remove that lump that's seen on a mammogram and you look at that. In prostate cancer there usually is no lump or lesion, the needles are put in in a random way and so you may be occasionally underestimating the cancer but you're also often overestimating the amount of cancer that a person really has. So by doing a second biopsy we found that about one in four times you do another biopsy a few months after the first one and you find a much more extensive, higher grade, dangerous cancer than you thought. Three out of four times you find either nothing, you do a biopsy and you simply miss this little tiny cancer you had in the first place, or again you confirm there's a little tiny cancer present.

Now when you've had that second biopsy and it comes up with nothing serious you've got a very high level of assurance that this is not a dangerous cancer. And I see people who come in for me for surgery, they've been found to have a little tiny area of cancer, they're convinced they have to have it out, I suggest they go through the second biopsy and we find either nothing on the second biopsy or again a small little cancer and they ask me what should I do now. And I say well it's your decision but if it was me I wouldn't let anybody touch me. This is not going to threaten your life and if you just go back to the doctor for regular checkups, a very cautious approach is come back every 6 months for a PSA and an exam maybe in a few years, two or three years we'll repeat the biopsy unless something comes up on the PSA or the digital exam and we'll watch you. And the chances by five years that you would need treatment is less than 25%, the chances that you would need any treatment if I watch you for 10 years is about one out of three. So most men with that kind of approach can be safely watched and will live out their life without the cancer bothering them.

It's a difficult message to get out to the public saying be thoughtful, prostate cancer can be a killer but don't panic just because someone has made a diagnosis. This could be an incidental finding of no threat to your life, find out which one it is. And you can find that out by what's in the needle biopsy, how many cores contain cancer, how wild

does it look under the microscope, what is the Gleason grade and use that kind of information along with the digital rectal exam findings and the PSA you can go right online there, a predictive model is available and find out what is the likelihood that your cancer is indolent. That is an innocent bystander versus an aggressive cancer.

Norman Swan: And where can you find those risk calculators?

Peter Scardino: Well one of them is on the Memorial Sloan-Kettering website it's mskcc.org anybody can get it, it's widely available to doctors and the public, you can follow the very easy instructions to put in your PSA, your age, the digital rectal exam findings, the biopsy findings, how many cores contain cancer, how many didn't contain cancer, you click on a button and it comes up and says what's the likelihood that you have an indolent cancer. And if the likelihood is 50/50 or greater I would be very, very cautious about being treated.

Norman Swan: So you've decided that it's nasty enough, you're going to have it treated. Do we know yet to predict whether or not a radical prostatectomy, that surgery is the best option? Or brachytherapy where you put in little seeds of radiation into the prostate or what they call external beam radiation which is the big guns from outside predicting which treatment is going to be the best for you?

Peter Scardino: We don't have good studies that compare one treatment to another; we do have the same predictive models in seeing how likely am I to be cured with surgery, how likely with radiation, and how likely with seed implants. Generally good cancers will produce good results with any of the treatments and bad cancers the results are not going to be as good.

Norman Swan: So it's more the side effect profile that suits you?

Peter Scardino: Yes, the side effect profile is different and I think you have to really learn about that that's why I encourage men to get a second opinion particularly from a doctor who is in a different speciality if you've been diagnosed by an urologist go talk to a medical oncologist or a radiation oncologist and try to see what makes most sense for you. Surgery tends to have the most immediate side effects; they tend to get better over time and a good long term profile in terms of controlling the cancer. Radiation is definitely better for those people who are very uncomfortable with the immediate side effects of surgery but radiation has some troublesome problems in the long run. Delivered well - that's the most important thing, delivered well you're going to get a good result with any of these.

Norman Swan: And then predicting progression once the cancer is out.

Peter Scardino: Again these nomograms can be very useful models and recurrences with any of these treatments are always manifested first by a rising PSA. Even if you have treatment the cancer will never truly be behind you, you'll have to watch this for the rest of your life and have your PSA tested and if the PSA begins to rise further treatment can be helpful. But again you go through the same decision making process.

Norman Swan: With breast cancer now they've discovered there's probably 5, 12, some people say even more than 12 different kinds of breast cancer when you actually look at hormones, receptors, gene profiles of the cancer and increasingly

they're tailoring breast cancer treatment to the genetic profile of the woman or the genetic profile of the tumour. Where are we at with that with prostate cancer?

Peter Scardino: We are at the very early stages. Some good examples of recent research have shown that you can actually measure the level of the androgen receptor.

Norman Swan: That's like testosterone, the male hormone?

Peter Scardino: Yes, here you're measuring the signal that recognises the male hormone and tells the cell what to do in response to the male hormone. The research is clearly showing that those men whose prostate cancer have a high level of androgen receptor at the time of diagnosis are more likely to recur and those men are probably going to live a shorter period and we're just developing the test that can measure that in tumours. Another wonderful work from the University of Michigan that's characterised what's called a fusion gene, there's a common genetic mutation in prostate cancer, it happens in about half of all prostate cancers, where two genes fuse together -- one is a promoter or driver and the other is a growth factor. And when these two come together the promoter is driven by male hormone, by androgen.

Norman Swan: That's like an accelerator being stuck to the floor.

Peter Scardino: Exactly. A recent bit of work not even published yet has characterised prostate cancers by 24 different combinations of promoters and drivers and some of them seem to have a very low level of aggression, they're sort of like lawn mower motors. Others are souped up 12 cylinder race cars - that is the first sign that we are going to be able to start characterising prostate cancers from the get go by their basic biological mechanisms. So some of these smaller early cancers that we're not sure whether to treat or not we may find have the aggressive form of this fusion gene but at the same time other cancers that we think under the microscope look aggressive actually may not be at all.

A third wonderful study I was privileged to be a part of at the Memorial Sloan-Kettering was the first thorough going prostate genome evaluation. So we took several hundred prostate cancers and we characterised the genetic changes in four different ways. There's a relatively simple way you can look for extra copies of genes or a loss of a gene and you sort of get a fingerprint of a tumour that has certain genes gained and certain genes lost. And what we found was that about 40% of prostate cancers have virtually no gains or losses, they just look almost normal and a small subset of prostate cancer has an enormous number of gains or losses.

In the preliminary data the ones who had the multiple copy number losses were the ones where the cancer recurred early after surgery and the patient developed metastases. And I think that in the next three to five years that test will be verified to make much better, wiser decisions -- is your cancer one that's really dangerous and needs to be treated which some, but the minority of prostate cancers are, or is yours one that's really not going to spread and threaten your life -- leave it alone, keep an eye on it and don't go through the treatments and risk the side effects of treatments.

Norman Swan: Peter Scardino is Chairman of the Department of Surgery and heads the Prostate Cancer Program at Memorial Sloan-Kettering Cancer Center in New York. I'm Norman Swan and this is the *Health Report* here on ABC Radio National.

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Norman Swan: Speaking of side effects of treatment that's a critical part of decision making for any therapy but especially in prostate cancer where the risks include incontinence and erectile dysfunction. And erectile dysfunction in particular is what John Mulhall is on a mission about and often bypassing his fellow doctors in the process. He's Director of Sexual and Reproductive Medicine also at Memorial Sloan-Kettering and a pioneer of penile rehabilitation.

John Mulhall: I've spent 14 years in academic practice and sometimes I feel like I'm banging my head off a brick wall when I'm trying to educate physicians. Physicians have a tremendous level of discomfort talking about sexual health. The new strategy now is to go to patients to give them the questions that they should ask to optimise their sexual health outcomes after their prostate cancer therapy.

Norman Swan: So what are these questions?

John Mulhall: Well first of all I think that patients need to be better consumers; they need to look at the experience level of the physician they are choosing. It's estimated that a physician to optimise his expertise or her expertise in doing a radical prostatectomy is to have done 250 in total and to be doing about 50 a year. So I think a very basic question to ask would be I'm going to see Dr X do we have a sense for how many of these he has done?

The second issue is there's a lot of interest in the United States now and I believe in Australia in robotic prostatectomy and there's zero evidence at this point in time that

sexual function outcomes are any different between open and robotic but what patients don't understand is that if somebody has been in open prostatectomy for 10 years and has done a thousand of them but they are on robotic prostatectomy No. 21, their outcomes are not going to be as good as the 1000th patient that they've done as a open procedure.

So these are very pointed questions that are worth the patient's time asking. I've always encouraged patients to make a list of questions, to bring in a notebook, write down your questions beforehand, structure the interview, understand the physician has a finite period of time but if the physician doesn't answer all of your questions in that 15 minutes or so set up another appointment to go in on another occasion. For the vast majority of patients who have got prostate cancer no urgent decisions need to be made about what I'm doing and when I'm doing it. Go in with the questions that you think are important and get them answered.

Norman Swan: But sometimes it's really tough, I mean I've interviewed urological surgeons, one in particular a very well known one in the United States who tells me erectile dysfunction is almost unknown in his patients and others will be more honest and say the honest answer is every man is going to have erectile dysfunction to some extent after a radical prostatectomy. How do you interpret the answer if one of your questions is 'Dr am I going to be able to have an erection after surgery'?

John Mulhall: So first of all when physicians and surgeons say that there's no erectile dysfunction associated with radical prostatectomy that's untrue. If you walk into a doctor's office and say what are my chances of being functional without the use of a medication and they say 'well, somewhere in the range of 40% to 70%'. I think that physician is being honest with you. The fact is that to determine whether you're 40% or 70% chance of functioning without a medication are your age, your function before surgery and the nerve sparing status of the operation.

Norman Swan: So this is the next question, is what sort of surgery do you do Dr?

John Mulhall: I think that the average surgeon would be lying to you if he says I am going to guarantee that all of your nerves are going to be preserved. I think that's an inter-operative decision -- let me describe it like this. If the patient who listens to this can close his eyes or her eyes and think about this your erection nerves are like fibre optic cables, there are hundreds of them, they are in bundles but they're spread out. The prostate is like an orange and there's a layer of that cling wrap that you wrap your food in, you put it in your fridge and the fibre optic cables are buried in that cling wrap. And that cling wrap is divided and pulled away so the orange can be removed. The manoeuvres that are used to get the nerves away from the prostate damage the nerves so every patient is going to have some degree of temporary erection problems after surgery.

But the average patient when told everything will be fine believes that they are going to get back to where they were before surgery. And at the Memorial Sloan-Kettering in New York City, one of the pre-eminent centres for prostate surgery in the world, that figure is about 20% of men will get back to the exact same rigidity after surgery that they had before. So 80% of men while they may be functional will be functioning at nowhere near the same level they were beforehand and will probably be using a medication to augment their erectile rigidity. This information is very important for the

patient to appreciate because patients often misinterpret what the surgeon says. The surgeon comes out after surgery and says everything went great, the patient presumes that means the nerves were perfectly preserved and I'll be just fine when in fact that probably means that the operation took an hour and forty-five minutes, the blood loss was reasonable and...

Norman Swan: And we got the whole tumour.

John Mulhall: Right which of course is the primary intent; but sometimes patients think that the surgeon will tell them everything they need to hear. When the surgeon will tell them what he or she thinks they need to hear. Patients have to decide, what are the important questions, so that they get answered. Don't rely on the surgeon or physician to decide what you need to hear.

Norman Swan: And the other issue which can affect sexual function because of embarrassment and lack of confidence is incontinence.

John Mulhall: Oh absolutely, this is a huge issue particularly when we talk about penile rehabilitation. When men have incontinence they withdraw socially, they don't want to think about erection. But getting erections on a regular basis in the early stages after surgery and after radiation is critically important to the health of erectile tissue and nothing should stand in the way of that. I don't encourage our patients who are grossly incontinent to have sexual relations necessarily; I do encourage them to get erections. If you look at 12 months after surgery it's probably in the hands of an excellent surgeon, you're looking at a 2% chance of having gross incontinence where you're really dripping. But I think there are a large number of patients, probably 15% to 25% of men who are going to have to use a pad periodically.

Norman Swan: Without penile rehabilitation two years out compared to one month out how do things change when it comes to erectile dysfunction?

John Mulhall: The recovery of erections after prostatectomy is an 18 to 24 months time frame. The overwhelming majority of men at 1 month will have no function naturally or with a pill and that figure at 2 years with a pill, depending on how good their function was, they are looking at a 60% to 80% chance of being a pill responder at two years.

Norman Swan: Increasingly more men are choosing radiation particularly the seed form where you put it inside the whole prostate because it's reputed to have lower sexual effects - is that true?

John Mulhall: No, do not choose your surgery or radiation based on your erectile function. The outcomes at three years after intervention are about the same.

Norman Swan: OK, penile rehabilitation -- what's the evidence here?

John Mulhall: Penile rehabilitation is the idea that we use medications or devices to protect erectile tissue from degeneration. The anology is that if you take your arm and you put it into a cast for let's say a year you know your biceps is going to undergo atrophy. The same thing happens to erectile tissue except in erectile tissue that atrophy is permanent and so our job at the rehabilitation is to prevent that happening.

Norman Swan: Does that mean that if I'm a man who hasn't had sex for three years, forget a prostatectomy, I'm going to find it hard to get erections after three years?

John Mulhall: The advantage of a man who hasn't had a prostatectomy is that the overwhelming likelihood is that he's getting nocturnal erections. Remember we get at least three erections every night of our lives whether we know it or not. Those men are being protected by those nocturnal erections. The average man post prostatectomy is not getting nocturnal erections for the first year and we know when you start going beyond four months after prostatectomy erectile tissue starts to degenerate. And when it does that you end up getting a condition called venous leak. In venous leak, the penis is like a tyre, there's a hose the blood flows through the arteries, the hose, and there's a valve mechanism. And when the erection tissue gets damaged the valve mechanism stops functioning and you leak blood back into the circulation. Very difficult to get a good erection, very difficult to maintain the erection, usually very poor respondence to pills and these are the patients who end up on long term penile injection therapy.

So rehabilitation is the idea that we are going to prevent that happening while we're waiting for the nerves to recover. The most commonly used treatments are low dose Viagra or Levitra, Cialis, and if a man is not getting an erection with those pills to use penile injections. We train a man or his partner how to inject the penis with a tiny needle, almost painless and that erection brings in blood, oxygen and stretches the penis which protects that muscle.

Norman Swan: He doesn't have to have sex he just needs to have an erection?

John Mulhall: Yes, you don't need to be having sex for rehab, what you do need is blood flow and stretch of that muscle inside the penis.

Norman Swan: What evidence is there that that makes a difference, have you done trials?

John Mulhall: Yes, the animal evidence is overwhelmingly positive. There are two randomised control trials, one of which is positive with Viagra, one of which is negative with Levitra. Now, people ask me all the time does that mean that Levitra is inferior to Viagra, I don't think so. Do I think that rehabilitation is rubbish because one trial is positive and the other is negative - no. I think the Levitra trial was not designed properly in the Pfizer trial and looking at Viagra it was designed properly.

Unfortunately we don't know if that's twice a week or seven times a week, we tell our patients to use it five nights a week and then two nights a week, we want them getting erections.

Norman Swan: So you take the drug on those occasions hoping that you get a natural erection and then two nights a week you masturbate?

John Mulhall: Essentially we want people taking low dose PDE5 inhibitor five nights a week and the idea there is that these medications protect the endothelium a critically important component of erectile tissue. And then two nights we want them getting an erection. They don't have to have sex, they don't have to have an orgasm and that erection if they respond to a full dose of Viagra, Levitra, Cialis, okay. 15% of our

patients do in the first six months, the other 85% are faced with a decision about doing penis injections.

Norman Swan: And how long does that rehabilitation go on?

John Mulhall: The regular use of low dose PDE5 inhibitor will go on for 12 months after surgery and then we encourage people to keep getting erections - two erections every week until their natural erections start coming back in. Somewhere between 10 and 14 months is where men start to see nocturnal erections reappear.

Norman Swan: How much does that increase your chances versus the arm that doesn't get it to doing it?

John Mulhall: That's a very difficult question to answer at the moment. The trial that's positive showed a sevenfold increase in the ability of a man to get back to where he was before surgery. And there's another trial which is not randomised and this is our data that shows that you triple the chances of getting back to being a natural erection responder, you double the chances of getting back to being a pill responder and you increase your chances of being an injection responder by 1.5.

Norman Swan: It could be quite expensive because you don't get reimbursed for your Viagra or your Cialis or whatever?

John Mulhall: So if you've no insurance coverage over the course of two years it will cost you probably something in the range of $2,500 Australian but if you're 50 years of age and you've 25 years of sex in front of you that's $100 per annum of your future sex life. What typically happens is that the people who do rehab are the ones who are most motivated, the people who are most frequently sexually active, men with younger partners, more interested partners. For the man who hasn't had intercourse in 10 years or whose wife isn't interested or he isn't interested rehab is not important.

Norman Swan: That's John Mulhall who's Director of Sexual and Reproductive Medicine at Memorial Sloan-Kettering Center in New York, a pioneer of penile rehabilitation.

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