'Prostate Biopsies Really Do Spread Prostate Cancer cells'

ARGUABLY, MORE THAN a million men per year receive the news that a biopsy must be performed; as the risk of cancer is significant when the Prostate Specific Antigen (PSA) rises above 4.0 ng/ml. According to historical data from the American Cancer Society and others, 20-30 percent of men biopsied will be found to have prostate cancer when the PSA is associated with 4 or higher but less than 10.0 ng/ml. Unfortunately, when a biopsy is performed, many men suffer immeasurably from the trauma inflicted when intrusive needles have been punched through the rectal wall repeatedly varying in numbers from 12 to 24 cores (most commonly), and upwards of 86 biopsy cores when a mapping procedure is performed transperineally. Interestingly, the highest number of biopsies I have ever noted was 86; a dubious record when saturation or a mapping biopsy was performed by a physician in Central Florida. While the majority of men experience 12 biopsy needle punches, virtually all men experience something negative or untoward related to lifestyle issues with the procedure. To be certain, virtually all men experience passage of blood in their urine, bowel and ejaculate while still others experience unremitting pain,

incontinence and assorted sexual dysfunctional challenges including impotency.

Still others may follow the path of a Neurosurgeon concerned about his rising PSA who went to a major Medical Institution on the East coast. While it is unclear whether this physician ever had prostate cancer, he never made it out of the hospital; dying from septic shock in 2010. Biopsied men are hospitalized upwards of 5% of the time due to high fever, chills and non-stop shaking called rigors. It is my opinion, the contamination of bowel bacteria, (principally E. Coli) into the blood stream is far more common than reported. **While death rarely occurs (less than one percent of the time), it is 100 percent for the man who dies.**

Competing with a biopsy is a 3 Tesla magnetic resonance imaging scan described by Peter Scardino, M.D., Chairman of the Departments of Urology and Surgery at Memorial Sloan Kettering (MSK) as the **"next greatest diagnostic test"** in improving our understanding of prostate cancer. **Men have a choice of biopsies or imaging to find a cancer at the Diagnostic Center for Disease™.** The decision for biopsy is associated with significant false negatives while imaging can be associated with false positives. When the skill set in imaging can be correlated to biopsy in a blinded manner, evidence will show that only the most skilled in prostate MR interpretation will have the fewest false positives, while the false negative rate with random 12 core biopsies can only be enhanced by a needless, expensive and life threatening saturation biopsy. When you compare a 20-30 percent yield from biopsy to a greater than 90 percent positive yield of cancer from imaging, there is little debate that random biopsies, common place in medical practices across the country, must be replaced by imaging or minimally preceded by imaging allowing for a targeted biopsy assuming a biopsy is ever done.

Let's put this into perspective. Doctors will generally wait until your PSA reaches 4.0 ng/ml or higher before a prostate biopsy is recommended. They will tell you (the patient) it is "the standard of care" which actually means virtually nothing. What I am asking for from any "expert" is a clarification for the quality associated with the so-called "standard of care." Is it a Gold Standard, a Silver Standard, a Bronze Standard or a Tin Standard? **From where I sit, a Tin Standard fits as a 20-30 percent yield for prostate cancer fails to win Gold, Silver or Bronze in any competition. In fact, the last time I looked, a student who scores a 20-30 percent on any test, fails that test.** Who among us would establish a standard of care and allow it to be enduring for decades with a paltry yield of 20-30 percent? In four words: "no one," except urologists. Why would well-educated men and women in urology practice support this diagnostic exercise if they know of the risk for tracking cells beyond the prostate (needle tracking) as evidenced in the literature? **In three words, they should not.** Why aren't doctors as concerned with a rising PSA under 4 as over 4 when prostatitis is the number one reason PSA rises? Among others: David Bostwick, M.D., Michael Karin, Ph.D. and the American Association of Cancer Research (AACR) have been saying for years that inflammation of the prostate leads to prostate cancer. **Why aren't more resources put into prevention than cure? Why don't doctors at least admit the chance of needle tracking, knowing that references exist in their respective journals that support the spread of prostate cancer cells with a biopsy?** In two words, **they should**. How is it that imaging rules diagnostically with virtually every other visceral (organ) disease yet with prostate cancer, we refuse to accept imaging or advance the cause for understanding imaging better? How is it in the twenty-first century that a leader in urology like Peter Scardino, M.D. is allowed to protect the "diagnostic turf"

in favor of biopsies simplistically by stating, "At our institution (MSK), we diagnose prostate cancer through random biopsies."! I can only assume that if university leaders stand in unity for random biopsies, they would also support fishing in the Dead Sea or duck hunting in the parking lot of any supermarket by firing random rounds of buck shot into the air expecting a duck or goose to land in their basket. If all I have stated seems preposterous, how about playing darts without a dart board. Who among us would take a drive of any distance in an unknown city without a map or GPS with high confidence of returning to the original starting location? The chance of being successful in any of these scenarios is virtually non-existent. There is only one reason doctors would eschew imaging in lieu of random biopsies. **Follow the money.** It has to be about the economics of medicine that dictate trying to hold onto a practice pattern that is not supported by the best science. Maybe this is a defined plan of obsolescence or futility in a $2.5 billion dollar a year business, called: Prostate Biopsy.

Despite the fact that biopsies spread prostate cancer cells, treating physicians who have a vested interest in the biopsy business as it relates to the application of high-intensity focused ultrasound (HIFU) have convinced the Minister of Health in the Canadian Government, **'all men treated for prostate cancer in Canada must have a documented malignancy or no treatment can be rendered'. How can any governmental entity support a process that represents risk to its patient population without an independent review of all options by an unbiased panel of experts?** My Canadian colleagues have stated I have an unfair advantage by scanning prostates with a 3 Tesla MRI scanner, despite the fact I have correlated scans and biopsies in more than 200 patients proving the value of imaging to be far superior to random biopsies. This validated data was presented at New York University (NYU) in the summer of 2010

and supported by the research of Jurgen Futterer, M.D. from Nijmegen, the Netherlands.

In a case presentation at the NYU Meeting on Focal Treatment of prostate cancer, a well-known but traditional urologist was asked how he would manage a 62-year-old male with a 12 core biopsy proven GS 6 prostate cancer on the patient's right side (in 2/6 cores) and a stable PSA value of 4.5ng/ml over the past two years. The patient was interested in focal therapy as a means to eliminate the anxiety associated with living with a cancer that is less than predictable and without a question; less than a certainty of remaining indolent. The left side of the prostate noted no evidence of cancer associated with the previously performed biopsy. This particular doctor, who trained at Memorial Sloan-Kettering, stated he would now do a saturation biopsy to confirm the cancer previously diagnosed was in fact on the right side and that no cancer was noted on the left side prior to treating him for cure. I had trouble stomaching this absolute insanity of thought. Once the biopsies had confirmed that cancer is only present on the right side, focal treatment for cure would ensue using the HIFU technology.

Dr. Wheeler's response:

First of all, the notion that patients who undergo saturation biopsy can be cured is a stretch at best. The data would suggest that this just couldn't happen. Furthermore, why would any doctor want to impose on a patient intense pain and high risk for sepsis, not to mention bleeding from every conceivable pelvic orifice, when a 3 T MRI scan could be performed to validate the previous cancer diagnosis? In my model, I do not encourage random or saturation biopsies, however, I would not discourage a targeted biopsy under very controlled conditions assuming the scan does show specific suspicious regions of interest on the left side and the patient accepts the risk of needle tracking. Therefore, without

evidence of cancer on the left side, based on imaging, the patient would be scheduled for a partial HIFU procedure while protecting all structures on the left side including the neurovascular bundle (enables erections) as well as the urethra. **Compelling research data from the Diagnostic Center for Disease™ and others establishes that the 3 T MRI scan must dictate the next best steps for a patient previously diagnosed with prostate cancer, not repeated biopsies.** When given the choice of additional biopsies with their inherent risks versus imaging with a 3 T MRI, the patient will walk quickly away from the MSK trained physician's opinion supporting additional biopsies.

In my opinion, doctors will not change their practice patterns so the burden to change medicine must lie with outraged patients who must demand a scan from their insurance carriers in lieu of a biopsy as the best first step when a PSA value predicts the need for a biopsy or further evaluation.

Unless doctors begin to proactively advise patients of all risks associated with biopsies including "needle tracking," my prediction is some patient advocacy organization will support an investigation into legal proceedings for doctors who fail to offer adequate informed consent. For this reason, **I urge all doctors to tell their patients that the risk of the prostate biopsy for spreading Prostate Cancer cells is real with every prostate biopsy performed.** While individual doctors may believe the risk is minimal or non-existent, the literature does not corroborate this thought process. The best advice is to be "fair and balanced" in your presentation and allow patients to consider all options carefully before they commit to a biopsy. After all, **it is well documented through the work of Michael Barry, M.D., and others that 30-56 percent of all cases of prostate cancer are over treated while arguably 50-60 percent of prostate cancers are associated with a GS of 6 (3+3). This is a cancer that can be managed conservatively in most cases, so . . . what's the rush?**

Patrick Walsh, M.D. from Johns Hopkins Medical Center with fellow colleagues; Sheldon Bastacky, M.D. and Jonathan Epstein, M.D. (noted pathologist), are quoted in a Journal of Urology article (May 1991) stating, **"Our data suggest that subclinical seeding is a more prevalent process than was formerly believed. In particular, tumor seeding within the needle track can occur following transrectal biopsy, a phenomenon that had never been previously recognized. Furthermore, our study also demonstrates the novel finding of seeding following the thin needle biopsy gun technique. . . . This information seems not to be common knowledge among many physicians."**

In another area of intriguing thought, Mark Schoenberg, M.D., the Medical Director of International HIFU, the manufacturer and distributor of Sonablate 500 HIFU technology has recently gone out on a limb academically and declared that he and the Medical Advisory Committee at the Charlotte, N.C. based company have categorically dismissed the diagnostic skill set of the treating doctor and research of Jurgen Futterer, M.D., Claire Allen, M.D. and myself (MRI experts) as it relates to the 3 T MRI scanner, effective May 1, 2011. In a time when strength of conviction and doctors (not manufacturers) are deciding what is best for their patients, Dr. Schoenberg may be responsible for making a most egregious error in medical judgment, while flexing his academic muscles. His medical judgment or lack thereof could be the "kiss of death" for a fledgling business like International HIFU. Dr. Schoenberg's lack of leadership is evident as he has cowered to the pressure from traditionalists and walked away from the future of prostate cancer diagnostics while cementing his legacy to the past. Dr. Schoenberg has taken what I believe is an ill-advised step in declaring a procedure already approved in the U.S. for treatment of benign disease in females (Uterine Fibroids) and also indicated for BPH (benign prostatic hyperplasia) in

men and changed the rules preemptively exceptionalizing prostate cancer. He has declared that "old school" prevails; while assuring male patients who are treated with the Sonablate 500, high-intensity focused ultrasound technology, are also going to have to endure "needle tracking," to qualify for that technology. Dr. Schoenberg's best diagnostic model no longer supports the benefit of MRI imaging (at the very least), as an equivalent to a very poorly performing needle biopsy procedure. As stated earlier, **imaging has proven to be superior to the biopsy concept for all reasons.** Dr. Schoenberg has also eschewed the commentary of Sonablate 500 user, Joachim Deuster, M.D., from Heidelberg, Germany, who is concerned about biopsies causing "needle tracking," and has stated so in an article referenced in the appendix of this book. Finally, Dr. Schoenberg also puts Mark Emberton, M.D., a treating and research urologist in London, in a precarious position as Dr. Emberton is conducting MRI research sponsored in part by International HIFU and part of a much larger consortium of European urologists favoring 3 T MRI for its diagnostic capabilities in men suspected of prostate cancer. Patients are advised that MR Imaging is an acceptable and outstanding diagnostic tool for competing high-intensity focused ultrasound technology used primarily in Europe. Patients are also advised that additional information is available on the PanAm website (www.PanAmHIFU.com) or by calling the Diagnostic Center for Disease™ in Sarasota, Florida at (877) 766-8400.

In closing:

1. Doctors cannot and should not have the privilege to insist that patients get a biopsy when the number one reason PSA rises is prostatitis. Historically, very few MDs understand prostatitis!

2. Most doctors do not have the knowledge base or an adequate understanding of what the literature really says regarding "needle tracking" and therefore, do not have the right to categorically deny that "needle tracking" takes place with any patient at any time. To do otherwise is admitting ignorance and puts patients at undue risk!

3. Doctors must stop telling patients that "needle tracking" no longer is an issue since we have gone to smaller needles. The question here is whether the cell is smaller than a needle opening! There cannot be any doubt about this one! A cell is always smaller than the diameter of a needle!! I am surprised very qualified physicians are saying this! To say the least, it is unacceptable and cannot be tolerated!

4. Doctors should not be allowed to disassociate themselves from a patient who doesn't approve of all that the doctor wishes him to do. Maybe if the doctor follows this type of patient, improved knowledge may come from the experience. Patients should be allowed to pursue chronic disease management (CDM) protocols or a surveillance model when appropriate. Besides, physicians generally participate with insurance plans that say nothing about complete cooperation with a physician's way of thinking as a prerequisite to seeing the doctor. Once full disclosure of the facts has been articulated by the physician, there should not be any further issues when the patient chooses a different course of action!

5. Doctors should not be repeating a biopsy on a patient previously biopsied positive for cancer when they are in a surveillance or CDM protocol. Sampling bias associated with a biopsy procedure precludes this action while doing nothing more than fostering the **biopsy 'merry-go-round'** with the patient paying the ultimate price for this indiscretion. **Google: Michael Karin, PhD from the University of California at San Diego.** He does not have a vested interest or a 'dog in the hunt'! In my

opinion, patients should be scanned with a 3 T MRI scanner if more than 12 months has elapsed since the original biopsy. **This repeat scan is recommended even if the PSA is stable as it is still necessary to prove that cancer growth is not taking place (notwithstanding a stable PSA value).** Once stability of scan and PSA number is evident, confidence in the CDM protocol for the patient has been achieved. Changes in scan results or PSA value with or without additional information from other markers should be considered as the disease is monitored!

To summarize, patients must answer one question. Should I agree to a prostate biopsy procedure when it has been proven to spread prostate cancer cells or do I keep my fingers and toes crossed, hoping for the best? In two words . . ."absolutely not." To me, the decision is easy—the literature validates avoiding random biopsies and supports imaging with a 3 T magnet.