TRANSCRIPTION of PHONE CONVERSATION –

April 19, 2017 Dr. Ronald Wheeler with Sharon Weaver

Just wanting to know what's taking so long? What's going on?

The demand to have this treatment under my guidance grows every day. The real issue here is getting cooperation from other people who will assist the process. The whole world, it seems, are "biopsy biased," if you will. Biased in the sense that the doctors want to do biopsies on everybody. The reasons they want biopsies on everybody (I finally understand why) is because when they do a procedure on someone and fail to get the expected results, they want to fall back on the fact that an individual does in fact have cancer (definitively) or not. Now we know that Carl has cancer definitively, based on the MRI. But the "standard of care" within the industry says that without a piece of tissue, you can't say there is cancer. In Carl's case, he can be treated with HIFU for anything we say he has, or that I can confirm that he does indeed have. So as an example, if his PSA is greater than 1.0, I've proven already (and it's in my book) that all men with a PSA of 1.0 or higher have prostatitis. So I know that Carl has some measure of inflammation in his prostate, called "Prostatitis. "So if Carl decides that he's going to have HIFU, based on prostatitis, or based on any disease of his prostate, it's totally appropriate to do a HIFU procedure. In his case, he and I both know he has prostatitis. No one cares if he has prostate cancer or not, because we are going to annihilate or ablate the entire prostate. So if the other guys (urologists) were to do it, you'd say to them, "If the FDA says to Dr. Wheeler that he can treat a guy without a biopsy, why can't you?"

Could anyone go to a urologist and request a HIFU treatment, based on the fact that he has prostatitis?

Yes, based on the FDA ruling. The FDA has approved HIFU for ablation of prostate tissue. So it doesn't matter what kind of disease Carl has as he's entitled to be treated regardless. But the doctors themselves will not take the risk without a biopsy because they want something to fall back on in the event the treatment doesn't go as advertised.

In my case with Carl, I don't have any issues as my intent will be to ablate his entire prostate while utilizing my Intellectual Property and I'm going to get rid of all the disease in his prostate, defined by what I've performed in over the last 160 plus cases where I've used that same technique routinely. So in my case, I could do a procedure that's going to be superior to what Carl could get anywhere else.

Would HIFU also help the inflammation, even if there was no cancer there?

Yes, of course! It's going to get rid of all the inflammation which could develop into prostate cancer later. As an example, I had a guy who used to come to my office, virtually every week. He was complaining to me about his prostatitis. He couldn't sit down for long periods of time, because it felt like he was sitting on a 'golf ball'. He just felt the pressure. This was about 6 years ago. I said to him, "Terry, the procedure for you is obviously HIFU. If I treat you with HIFU, your prostatitis is going to go away." He said, "Really? And you can do that without harming me in other ways?" I said, "Absolutely!" So, I treated him with HIFU, and I never saw him again for prostatitis. He let me know he was doing great and I wished him well. He's not camping out on my doorstep anymore. So the bottom line is the prostatitis will be taken care of as well.

So therefore, in Carl's case, because of our ability to understand the MRI scan, we know he has something more than just prostatitis. So that's the whole issue related to Carl. The state of Florida, does not allow me to be a Medical Director of my own center as there is a disagreement with them. For this reason, I have to get another

doctor to become my Medical Director. I can't be the Medical Director because of the issues I'm having with the State. I have someone who has agreed to and wants to be my Medical Director, but he's not totally clear on how to fill this application out. So he's still working on that. I will look at that, maybe as early as tomorrow. Once I look at it and know what's going on with him, then I'll know where we are with him being the Medical Director at my center here or someone else. With this person in place, we could treat Carl, as an example, with him being the Medical Director and me doing the procedure.

And at that point, it will just take a couple of days for you to be in operation?

Once that application is received by the State's Agency, and reviewed and subsequently approved, then we would be good to go. So we're not months away. We're not. We are truly weeks away, I believe. There's another location that I've noted in the Naples/Ft. Myers area where there is a surgery center as well. I wanted to clear the air with those guys, so I talked with the main guy down there. He knows about my 'dust up'with the State, and said, "I want to know that all that we're doing is in line with the rules and regulations." So I said to him, "Dan! Everything we're doing is consistent with what the State allows. The FDA says that you don't even need a biopsy to prove prostate cancer (PC) as HIFU is not indicated for PC. The reason is simple, in the research trial, the doctors that were involved did not do well enough with their outcome data regarding prostate cancer, to receive a designation to treat prostate cancer now that its approved." I think he learned something with me talking to him.'

Say that again. I didn't quite get the point. They didn't approve of you doing a HIFU treatment without a biopsy. Because, why?

That is correct. The reason is – there were research trials done to validate HIFU benefiting PC. They made the HIFU protocol and their respective manufacturers jump through hoops, if you will. And these hoops that they're asked to jump through are 4 or 5 year studies. They want to see proof that this particular procedure is as good as you say it is, and makes sense. They're never going to take a look at my data, because my data is the best in the world, by at least 20 percentage points. Then they're going to look at the worst data that they can find. At that point, they toss out the best and toss out the worst (the 2 extremes), and take a look at the rest. So that's just how studies go.

Is it the State of Florida that's doing this?

No, this is the FDA (Federal agency – Food and Drug Administration). They have the power to approve it or not. Each year at the FDA's national meeting, they give updates, talk about various points of contention, explain how to get grants, etc. At the end (of their discussion), they started talking about HIFU, and what the pitfalls were with HIFU. In 2014, they had nothing good to say about HIFU. Nothing at all. In 2015, even though they said this about the competitor to the model I use (I've used both). The model I use now is the model out of France – the Ablatherm. The model I used prior to that was the model out of Indianapolis, IN – is the Sonablate 500.

Those are the machines that you're talking about?

Yes, I used to perform HIFU with the Sonablate 500, but now I use the Ablatherm technology. And that's the one I'll continue to use because it is superior to the Sonablate, and it is also robotic. So, in the FDA annual meeting in 2014, (the FDA Representative stated), "based on everything we've seen from Sonablate, they need to go back to the drawing board". Because they (doctors working with the Sonablate 500) were asked specifically, "Why are these results so bad?" They asked that question. So these guys that stand up to speak in support of the approval process, some that I know from my Residency days at LSU. One stood up and said he wanted to know why these results were so poor? Somebody else gets up and says, "It's probably because the doctors that we trained weren't well-enough trained." Now they're getting warm, and they're getting closer to what took place. To operate the Sonablate 500, it requires 3, 4 or 5 cases for training, and that's it! No more,

and you're ready to go on your own. I can tell you, that's not enough. You need to do at least 30 cases if not 50 to be proficient.

I read an article about the importance of getting an experienced doctor with this.

You absolutely must have an experienced doctor involved! So, the fact is the doctors without experience know me and they know my data is the best in the world. There's nobody who competes although they can be trained.

So, Germany is a country that's very well-thought-of as one that does HIFU. The data that comes out of Germany would just cause your blood to boil, because you would be so upset with it. You'd say "This is terrible!" If we equated this to a university setting, this is 'C level' work, as in "average." Looking at my data, I get an 'A' for mine. My outcomes based on PSA nadir and MRI testing post treatment are much better. I could talk to you all afternoon about why my technique is so much better. Suffice it to say, because of my imaging skill set, I know where this cancer is, and my ability to treat to within a tenth of a millimeter of the rectal wall, allows for me to avoid an untoward injury to Carl and/or cause harm the rectal wall. I've done lots and lots of cases to prove this point. So I know exactly what I have to do, how it has to be done, and so forth.

I've taken guys, for example, with PSA scores of 44.6. Prior to 2013, I could not have treated him. Resolution of cancer can only occur if the cancer in question is organ confined. Since January of 2013, I started putting additional energy into the prostate. And that's what is called my Intellectual Property (IP). That Intellectual Property is in a patent pending mode right now. But still, I'm the only one who can treat in that manner without issue. Others can do it, but once I get my patent, they will have to pay a significant price for their ignorance. So, if other doctors don't want to be beholding to me, they will want to treat only patients with a Gleason score of 3+3=6 or risk failing to resolve the cancer with the patient taking all the risk. So, the only patients that they can treat are those with PIRADS (Prostate Imaging and Reporting System) scores of 2 or 3. These PIRADS scores have an equivalency to a Gleason Score of a 3+3=6 with a limited (yet real) opportunity to become aggressive.

I'm sure Carl's PIRADS score is a 4 or a 5. That's a significant cancer, an aggressive cancer. That's not the kind of cancer that can be treated by another HIFU treating doctor successfully while having the patient do well. A patient with a PIRADS score of 4 or 5 is not going to do well, because he didn't receive an adequate energy to kill an aggressive cancer. Sharon, you and Carl are being very patient. I'm trying to get something done as soon as I can. I was talking to the doctors in Naples, Ft. Myers yesterday who have a machine. I said, "We are doing everything within the constructs of the FDA". Remember that the FDA said that "the doctors did not get a designation for Prostate Cancer because they did not prove to the satisfaction of the FDA that they could do this HIFU procedure efficiently and effectively enough, based on outcome data, to get an indication for Prostate Cancer." So these words mean that we as a Urologic body have average doctors treating patients in an average fashion.

So, when they were looking for proof, they (the FDA) won't accept your data, as it has to be their own. And they don't have the experience that you have.

That's correct. The doctors involved in the trials don't have the experience. They didn't know how to discover something. They were just like Sunday drivers, hanging out in the passing lane, letting others go around them however they can. I'm the world's expert at this based on the data alone. If they're getting a "C grade" out of Germany and "C grade and a B minus grade" out of France, with low level cancers, they're getting a "D grade" out of France. With more aggressive cancers like Carl has, they're getting a "C or D grade". We can't have that! Carl needs somebody to treat him that has an "A rating". There is nobody in the world (yet) that can do the job for him that I can. I know it's hard to believe, but it won't be hard to believe once I get out of this issue with the State, and/or prove my point, decisively.

But if they were looking at your data and your outcome, they would see that you have an "A rating or grade", but they don't believe it?

Well, the way it works is that they always chop off the top and the bottom because they want to be unbiased.

And you've always been at the top.

Well, not always, but this is with HIFU-EEA, and this is something I can take ownership of. So, I understand this! For me to develop this now enables me to have an intellectual property that is patent pending—that's huge! The other guys don't know when or how to do that, and they choose not to do that. As an example, one of the doctors out in Santa Rosa, north of San Francisco (whom I know). He treated a patient whom I've talked to, with a 3+4=7 on his Gleason score. He did not have a PIRADS score because the doctor did not use an MRI. I use the MRI procedure on everybody. So, he treats this guy with a 3+4=7 score. Now that's an intermediate grade cancer. And he failed to resolve this cancer for this patient. He failed because his PSA is rising, following the treatment as evidence that he's failed to be cured.

So, that's the difficult situation that we're in. So, for me to be the Lone Ranger (if you will), or the new Sheriff in town, I'm the only doctor that does this procedure to the extent as I do. Now there are others that are equally experienced with a single pass of energy, but they don't know what I know, and/or they're concerned about doing it for personal or professional reasons. They're concerned that maybe I have the upper hand, and they don't want to pay me for my patent pending procedure. If they use it, they will have to pay me. This urology group that I work with is somewhat collegial in many ways, but it's also very divisive in others.

One of the doctors who should have assisted me in trial, initiated the issue that I have with the State's DOH figurehead. He was the guy that basically introduced me to HIFU. I knew about the procedure through him. And I knew to learn all I could about it, again, starting with him. Because once I learned about it, I wanted to see who else is doing it and how are they doing it. So early on, my procedures have always had better outcomes than theirs, but just marginally. Sometimes I would fail, and scratch my head, and try to figure out why I'd failed, because I did everything as I was supposed to do it. The Sonablate 500 machine has this tissue-colored monitoring called TCMs, and I did that perfectly. So, I'm always looking to do everything in the best way that I can. And … I'm an imaging guy, so I know what I'm seeing. For a guy like me, I was not understanding why I would fail to resolve disease on anyone assuming the procedure was represented properly to us.

And then it dawned on me that I was treating tissue that was more dense than the energy applied could defeat, consistent with aggressive Prostate Cancer. It's like comparing the density of balsa wood to that of teak wood. Balsa would snap in your hands, but the teak is much more dense, and would take a powerful saw to cut through. Therefore, something more needed to be done to deal with this dense tissue in order to resolve or cure the disease. The answer resulted in a quantum leap in energy that has resulted in an outstanding outcome to the betterment of a man with Prostate Cancer.

So that's when you thought of putting more energy into it?

That's correct. So that happened starting in January of 2013. So at this point, I've done over 140 cases since that time. I've only been throttled because of the State of Florida Agencies with mis-guided individuals have been chasing me around since 2013. This all will go away, but I have to go through the process. I can't make it different than what it is. I'm willing to face whoever it is that wants to challenge me. I'm willing to face whatever critic I'm facing, no matter where or whom they are. So I don't run from things; I walk toward things and analyze things to the betterment.

So in a nutshell, what is the problem with the State of Florida?

So the State of Florida claims (their only claim) that I said to four patients that they had prostate cancer without a biopsy to prove it. They said this action was beneath the "standard of care". So, let's say that they thought that they were right, that it's beneath the standard of care. So now we have to figure out how this really happened, and what did I really say. The only thing I would've said would be similar to what I said to Carl. I told Carl that

he has a problem because the MRI says he has a problem. My ability is unique in the industry. There is no urologist who knows imaging any better than I do. Nobody!

You would shake your head and say, "This is crazy. This is absolutely insane. How are they taking a notable doctor, who has figured this all out, and not understand that he's just so much better than most everybody else? Instead, we need to get the other doctors caught up with what he (Dr. Wheeler) knows". That's the way it should be done. But the State sees it differently. Th e State's trying to protect an industry. I don't care about the industry. I care about treating patients and I care about excellence in outcomes to defeat a disease. So, when the State accuses me of saying to four people that they had Prostate Cancer without a biopsy, I would say that I understand that. But I would never say that. In fact, I told them all that based on the Radiologist's opinion, there was a high likelihood or probability of a Cancer being present. I can't tell anybody definitively that they have cancer, however, it is not about stating absolutely, he has a cancer or doesn't have it -- even in Carl's case. Now I've gotten to be expert with imaging, in Carl's case with a PIRADS of 4 or 5, there is little else that Carl can have other than Prostate Cancer. Anybody who is as well-schooled in imaging, as me or the NIH professionals know what the images will produce with a properly placed biopsy. I've already done the studies on that, to affirm that. And that's all been submitted to the State of Florida. So, I am very unique in the industry. And the State thinks that by getting rid of me, there will produce "calm in the valley." To the contrary, the population will be heard and it will not be with eliminating me.

There are other people doing HIFU in the country, aren't there?

There are. But they're getting very mediocre results.

Do they always use a needle biopsy for diagnosis?

They always use the needle biopsy to find the cancer. And if they don't get it, they will keep on doing biopsies on you. I had a patient who came to me from a VA center across this State. A urologist sent him to me saying, "I know you're doing this study with GE and this MRI machine. I want you to take a look at this patient and see if you can help me. I've biopsied this guy 5 years in a row. I've done 10 core biopsies each time and I can't find any cancer. Can you help me?" So I agreed to take a look at him. So, I did the MRI scan on him in my office (at that time I had the MRI scanner right in my office). I don't have it any longer as the local radiologists had caught up with me from a knowledge point of view. They know what I know now. Stated another way, I know what they know now as well. So, the Radiologists are better prepared to do it as I no longer have time to do all facets that is required other than re-reading the scan. After scanning this patient in my office, I called his urologist and told him I'd found the cancer, that it was within the anterior horn on the left side of his prostate. But he had no clue what that location would be. He didn't know the anatomy of the prostate well associated with the scan. Crazy as it is, most Urologists don't know what I know. I told him if he wants to find the cancer, I will draw him a picture so he would know exactly where to put the needle. There was silence on the other end of the phone. Finally, I said, "Bob, are you still there?" He responded, "Yes, I'm still here."

"So what do you think of my proposal?"

He said, "Ron I sent this man to you because I've lost confidence in my ability to find the cancer. And now that you've found the cancer, I want you to prove to me that through your technique, that YOU can stick a needle in that and find it." The DOH head man needs to hear about this as does the Governor and Board of Medicine.

I said to him, "Very well. Send him back"

So now I'm telling you about the "inner sanctum", if you will, of urology. This is what happens when you get to be an expert. And the expert rules, obviously, at the end of the day. So he sent the patient back to me, and I had every confidence that I was going to hit what I was intending to hit. I did what we call a "cognitive biopsy." Cognitive means to use my brain to look at it spatially, that is where that prostate really is, and where that area is in the prostate. So I knew where that was. So that's called a "cognitive biopsy." What they do nowadays is

take the MRI image, overlay it with an ultrasound, and they know exactly where that cancer is on ultrasound. So they can actually stick a needle exactly in that area, and find the cancer in most cases.

So did YOU do a needle biopsy on him, then?

I did the biopsy, and I found his cancer. Of course, I would do a biopsy on him. So, I sent the patient back to his doctor. He was obviously thrilled that I found it. Here's the sadness. This unfortunate patient had to wait 5 years to find his cancer. He had to endure 5 years of futility. The patient's PSA had to go from 8 to 18. That's terrible! So, in Carl's case, we've got to have it (the PSA) under control, with medication. So we're still looking to get him done. But you don't really know how lucky you are to have found me. I'm going to tell you one more story that you'll have to tell Carl:

I'm going to play the recording for him this evening. So he'll hear it all

So, you're recording this? This is good. So I'm going to tell you one more story. This story is about a gentleman in Wyoming who was running for a Senate seat in Wyoming. He has no interest at all in getting a biopsy. He has that right as all patients have a civil right to deny any procedure associated with harm. So, in his case, I was getting push back by these other doctors, because they wanted me to do biopsies as well. And I said, "Gentlemen, I've done many biopsies in my career. There's a better way now. It's called a 3T MRI scan. I said to them collectively, "you guys (referencing the doctors) haven't caught onto that yet, because you're still stuck in the past." And they get paid for doing the biopsies. There's nothing wrong with that, if you cannot see the light. They're trying to protect the pathology industry. It's OK, if that's what they want to do. Nonetheless, this patient in Wyoming did not win the primary, so he's not going to be in the State Senate as he wanted to be. He's a pilot and he started reviewing his options. He talked to a doctor at UCLA, another from USC and yet another one in Beverly Hills and found some things that are positive. One of the things, my patient stated to me was … "they're going to charge me half the price of your treatment." I said, "That sounds really good. I'm impressed with that. So let's see what they're going to do." He retorted, "They're going to do the HIFU treatment for me." And I said, "But not all HIFU treatments are the same. Remember, I would add additional energy called EEA (enhanced energy application)". I added, "I don't think they will do that."

I knew that no matter who treated him, all individuals (in academics) would want a biopsy to prove the cancer, even though no biopsy is required by the FDA. He hadn't had a biopsy and I knew they wouldn't treat him without a biopsy. I knew his cancer was on the right side which I confirmed on reviewing his MRI scan. So I told him, "Here's what I want you to do. Have two needles put in your prostate on the right side. Only two! Hopefully you won't die from that, because there's only 2 needles, not 12 or 20. As long as the doctor knows his left from his right and adjusts for the position of the patient, I would guarantee he will find the cancer." So, he found his local Urologist who agreed to do only 2 biopsies, which surprised me; but I was happy to hear it. So, the doctor does 2 biopsies and low and behold, cancer was found, just like I said it would. This guy had a PIRADS of 5, the worst that he can have. That means that on a Gleason score scale, he's going to have an 8, a 9, or a 10. So that's the worst cancer that he could possibly have. I knew going along with his 9.7 PSA that he needed a bit of luck. So I asked the patient (the fellow that ran for the Senate) what happened with his biopsy, he said it came back, just as you suspected, with a Gleason score of 9 (4+5). I said, "That's a bad cancer." He said, "Yes, I know. I know!" So, I said, "So what are you going to do now?"

"I'm going to call the guys out in California and see what they say." He said, I told him, "OK, I have one question that I want you to ask them. Only one question. Ask them, 'Based on your Gleason 9 cancer, what's the percentage chance they will cure or resolve your cancer. So he waited for another 10 days to 2 weeks before they finally called him back. He asked them what took you guys so long. "Well, we don't have good news for you, but we needed to call you, and here we are." They told him that he has a less than 60% chance of being cured. That's a D or an F! So I asked him how he felt about that. I'm just talking to him like regular people, and trying not to go overboard; just checking if he is catching what I'm saying. When I asked him how he felt about that, he said, "I think it's terrible!" So now I know he's thinking properly, because it is terrible. I asked him,

"What did I tell you?" He said, "You told me that you could cure me to the tune of in the 90% range." I said, "You're correct! The only reason I didn't say 100 % is because your PSA is over 8.5." I don't recall what Carl's PSA was.

I think it was up to 12 PSA at one point.

There you go. That's even more reason to keep it under control. But at any rate, this man had a 9.7 PSA. So I told him I'm sticking to what I said. I don't care about the Gleason grade, because I have an Intellectual Property that will allow your success, assuming it is truly organ confined. So, I can put additional energy (EEA) into your prostate, but the other guys are going to be a little bit hesitant about doing it, if at all. They're going to want to follow the manufacturer's guidelines on how to treat. So, with them, you're going to get a single pass of energy—no additional energy.

So, he said, "Look, I'm coming to you. I'm not going to them. And whatever it costs me, it costs me. I need to be cured of this disease if you can do it. I want you to give me your best shot. And I feel like I have my best shot with you."

And in fact, he does. So now, I have since treated him. He was treated back in December while in March I got his first reading, 3 months after the treatment. This patient told me that his PSA in March was 0.014. I said, "That's fabulous. Fabulous!" So, that's an outstanding number. The guys out in California would have failed miserably. And then he would have come begging to me to re-treat him. And I'm not sure that I would have been able to do the same job with satisfaction.

Sharon's question: So, that brings the question up: If you were treating somebody in December, why didn't you treat Carl in December?

We didn't treat Carl in December because remember, Carl didn't have a biopsy either.

Sharon, Carl's wife answers, "Oooooh!"

So, this guy felt like he was giving into this because he knew that, wherever he went, except with me, they would require a biopsy result. So Carl still doesn't require a biopsy, and Frank still does not require a biopsy with me either. But the place where we took Frank DID to the shame of the doctor refusing to listen to reason.

That brings me back to the Ft. Myers/Naples area. I've talked "turkey" or real issues with these guys yesterday, and they're now understanding that everything I'm doing … so, they're a little upset about this 'dust up' that I had with the State of Florida. I said, "You've got to understand something. It's the MRI scan that allowed me to tell them that they had any chance of having prostate cancer. Of course, their PSA would also be an indicator, depending on how high it was." In Carl's case, a PSA of 12 ng/ml would be an indicator as well. Minimally, Carl had Prostatitis an indicator of a diseased prostate. My bet would be that if no cancer is found on a biopsy, the cancer was missed. Frank, the fellow with a PSA of 9.7, would tell me pretty much the same thing similar to Carl's PSA. So, when you look at the PSA along with the digital rectal exam, an ultrasound and what I can see on the MRI, it all tells a unique story. You put it all together, and you pretty much know what's going on.

In my case, I've already done 200 patients with biopsy and MRI. I've done that study. (You didn't know this before this discussion). In that study (this is a consecutive series), to get into the study, you had to agree to a biopsy, and you had to have had a 3T MRI scan. So, it's a double-blinded study between Professionals in a sense. Neither camp knew the result of the other. To restate, the biopsy camp didn't know what the MRI camp reports and the MRI camp doesn't know what the biopsy camp knows. So, they're both blinded to what's going on. They only know what they know from their procedure. The MRI camp knows what the MRI says. The biopsy group knows what the biopsy showed. I was the one that collated that data, so I was neutral. All I did was separate the data and learned from it. As I looked at it, I realized that we had a great report on our ability to

find the cancers. From that study, which was basically available in 2008, we were able to show that we had a 95% positive predictive value or PPV.

So, even though the State of Florida is saying that I'm performing beneath the "standard of care," the probability of having a cancer comes because of what the Radiologist reports relevant to what the MRI scan said, not because of what I'm saying. I didn't just imagine this. I have scientific evidence to back me up. I have 95% PPV. So, I correctly found all but 5% of the cancers through imaging. I also found many cancers that were not found by the biopsies. So that was helpful too.

The NIH (National Institute of Health) comes along in 2011. Their study took 46 men whereby all men would agree to a Radical Prostatectomy if a cancer was found at the time of biopsy. Their study was a consecutive series in this way – the patients had to have cancer on a biopsy, and they had to agree to have their prostate removed afterwards for imaging purpose. They (the NIH) then compared the data. Obviously, I like the NIH because I like people who study variables, metrics and analytics as well as people who perform excellent research with clinical value. So what did their study show? They had cancers found on 46 consecutive patients, and they took out the prostates of 46 men. I believe I sent this information to Carl and he's probably already read it. Then they created a mold (like a plaster of Paris type mold) and then took the prostate that they had taken out "en bloc" as a whole gland with seminal vesicles. They then put the Prostate on top of this plaster stand and put it into the scanner at a height consistent with where it would be in a human. They then looked to see what the scanner showed relevant to the location of a cancer from imaging versus where the biopsy showed it to be. The results were amazing. So they came back with their results. Remember, my data had come back to have 95% positive predictive value. So that means my confidence in finding the cancer will be 95%. The NIH results came back as 98% to 100% Positive Predictive Value. The men who had aggressive cancers had PIRADS scores of 4 or 5 and were commonly found when needles were placed into these lesions. For certain, the more aggressive the cancer the more likely they're going to find the cancers with the MRI. So, obviously, me finding a cancer in Carl would be consistent with what the NIH found.

So, nobody's practicing below the standard of care here. Nobody. What the State Agencies are getting wrong is, they're not really understanding that – yes, the patient heard from me that he had a high likelihood for a cancer, but the cancer is based on what the MRI scan result was, as presented to me to be by the Radiologist, who read the scan. So, when they finally understand this, they will say, "This doesn't seem right as Dr. Wheeler shouldn't be challenged here, because the Radiologist predicted the finding. So, maybe it's the Radiologists who are practicing below the standard of care, because they're the ones who said a cancer is likely. But the Radiologist's job is to tell us if there's a problem or a concern radiologically.

The Radiologists are somewhat non-committal about this at times. They are what we call "hedgehogs." The hedge seems to separate one side from another, and the hedge would be in the middle. So, the hedgehog is not going to take a definitive position unless there is a measure of certainty offered. He will say, "Based on what we see here, we have high suspicion, or moderate suspicion, or low suspicion of prostate cancer." They're going to call it something, but they won't say exactly and definitively that it's cancer but rather speak to the likelihood of a cancer. They will say that an area or lesion would be amenable to a biopsy. On the other hand, biopsies are not always necessary nor desirable to all patients equally.

So now we have a doctor in Urology (me) who's on both sides of this discussion or debate. I've done it all. In MY world, I know I can call it cancer with high likelihood, because I've already done the study, and I've seen the results of the biopsies. So, I privy of this information. The NIH (2011) has validated MY data (2008). We're talking in circles here. And none of us are being maliciously intent on doing something incorrectly, so it's not a bad thing. In research, I think what's really upsetting to everyone is – they don't want to have to do it my way. And they (the State's Health Agencies) don't have to, if they don't want to. But you're not going to get any patients to come see you because the more I stay at this, the more convincing I will be to all patients that if you want to see me, you will have to get in line. (Carl's already in line, by the way. And he's going to be one of my first two patients treated. Just to let you know how top priority he is with me.) So given that, any other

doctor will find it difficult to convince a patient who needs to be treated. This is in two areas – one, if you don't have the MRI, the patient's going to know that I said, "You have to have an MRI." And beyond that, I'm going to say to the patient, "If you have an MRI that has a PIRADS of 4 or 5, that doctor's not going to be able to cure you. And I will be virtually 100% correct with that comment. So why would that patient go to that doctor when he has a PIRADS of 4 or 5? Unfortunately, the patients are not that aware relative to the science. As we're talking, you can understand what the issues are, and can realize that I haven't done anything of significance wrong.

It just seems like they're not listening or paying attention to your data and your record.

That's right. They're not. That's exactly what's going on. And that says to you that this sounds like a witch hunt. And you'd be correct. Or it sounds like it could be a vendetta that somebody has, and you'd be correct there as well. So, there's a man in Miami whom I trained under to learn the buttons to operate the HIFU machine. Basically, he showed me what buttons to push and when to push them. He didn't teach me anything about imaging, because I already knew imaging. I just wanted to learn how the machine works. I was approved as an expert in the very first weekend. I was involved in approximately 20 cases over 5 days. So I was credentialed by them in those 5 days.

Credentialed in what? In using the HIFU machine?

That's right… in using the Sonablate 500. That machine is a puzzle. The Ablatherm is also a puzzle, but not to the same extent, because it's a robotic puzzle. Once I set the plan in motion, the machine takes over. Now, I'm still watching every single shot. You cannot take your eye off of the computer screen. This takes a keen eye, or a trained eye to know this. When I get an error message that comes up, I'm going to pay attention to the error. The error message may say "Too much water in the balloon," meaning there's too much separation from the probe transducer to the rectal wall or there's too much water. Some of it has to be taken out and realigned. Or it could be not enough water, and you have to add more. There could be lots of reasons for an error and as a technician you have to be prepared for a plethora of issues. So, my point is, the puzzle that is a robot (the Ablatherm or Focal One is a far safer device. And it is easier to use the far-safer technique which is easier to teach to a doctor that's maybe not quite as involved as I am. It's easier to teach that doctor how to do the procedure, because the robot's going to do part of it. All you have to do is make sure the robot does what it's supposed to do. So now you're getting the essence of all of this.

Tomorrow, I will be giving their HIFU Team a call in the Ft. Myers/Naples/Bonita Springs area.

OK. Because I was wondering how long that should take.

Who knows for sure. I don't really know for sure, but I would say at least a couple of weeks. Now our center was already credentialed before, but the doctor who was in place was the same doctor who wants me to do biopsies. I told this person, "This makes no sense! If you want to create a consent that allows this person to be treated, and a consent that identifies the biopsy as the standard of care and identifies that the patient doesn't want to do a biopsy, and he's signing and admits that he doesn't want to do a biopsy, should be all that would be needed. Well and good!" And in the consent form it says that the patient could die from the biopsy, and that he could bleed from every orifice below his waist for up to 6-8 weeks. So, I'm being as literal in that depiction of the facts as I could possibly be, so that anybody that looks at this consent can say that it's a wonderful consent, and it's all-inclusive. And yes, it is. It's an 8 page consent. So, this same person said to me, "I agree with you, Ron. We should be able to create a consent to allow patients to come and be treated without a biopsy." I said, "I want you to put this into words that YOU need in this consent, and I'll put them on paper and send it back to you. I did that, and he said, "That looks good." But then he reverted back, a little bit like a turtle sticking his head out from the shell, saying one thing, then all of a sudden, the next time you go by the turtle, his head's pulled back in the shell. That just means he's not open for business that day. So he wants biopsies now. He changed his mind.

That's why you need another Medical Director.

That's correct. So I don't like people that waffle. I hate to say that this guy's waffling. He's way too credentialed, as the former chairman at the University of Florida Department of Urology. He's told me over and over that my data is the most incredible data that he's ever seen. He's very complimentary of me and what I've done, and my skill set. But he still doesn't want to work with me unless I have a biopsy. So, that boots him out. He's gone.

Yea. Well, I really needed to talk with you. Thank you so much for spending this time with me. It's really helpful.

Well, I had to. I know it's gnawing at you, and I'm not just sitting around with no agenda. I figure that somebody's got to blink, sometime. And I'm just trying to figure out at what point they're going to blink. And if something changes with me, and maybe the circumstance is changing enough that they would blink and say, "OK, upon further review, let's work with you now."

Yea. I just hope that we're not waiting for months here. It's been going on and on."

I know. It's unfortunate, but I have to stack all of my guys. I now have many guys who are just like Carl. Many guys that are being patient. Now remember, Frank was on that team, but he got a biopsy. That was the difference maker. That allowed him to go from the minor leagues, where they think I'm hanging out, to the major leagues where they think they're hanging out. I'm having fun with analogies on this, but there is a serious side to this. And it's a State being stupid about something they shouldn't be stupid about. I will promise you that I will keep you in the loop. Something is eminent, whether it comes from one person or another, or comes from the Bonita Springs guys.

Yes, it would help he we would get a little bit of information once in awhile, especially if it is something that is moving forward. It's so discouraging, because when we don't hear anything, we wonder, "What is going on?"

I know. I had a guy who is a farmer in Iowa. He has absolutely said, "There is no way on God's green earth that anybody will ever touch me with a biopsy needle! It will not happen." And it won't happen in his case. Carl may be bending here a little now. So if he is, I would go back and take a look at his scan again, and I'll see how confident I would be that I could hit the cancer. And I could still do that. But all patients that are treated at this center are biopsy-positive. So you can see what I'm saying. So Carl may say, and you may say. . . . Now let me tell you one more patient, and then I'll zip it, and let you think about all this stuff.

I want to tell you about Hank, out in Oklahoma City. Let's see, you guys are in Kansas, so you are next door. He owns a bunch of grocery stores. He's the CEO of this group of grocery stores. He's a very successful businessman. His PSA is in the 12-14 range. His wife Susan is a nurse, and his wife said to me, "There is zero doubt that Hank will ever have a biopsy." So now, I need to reach out to the nurse's union or association. So Susan would not allow Hank to have a biopsy. Now Hank may have buckled on his own, but not under her watch.

That's impressive, coming from a nurse!

Well, it is impressive! So you can see that the nurse now is thinking medically. She's not just saying what a wonderful guy Dr. Wheeler is. What she's saying is, "This great guy Dr. Wheeler can treat my husband without a biopsy, and I don't want my husband to have a biopsy. I don't want any intrusion, because I know that even if my husband comes out of this OK, with a biopsy, I know that he'll still come out OK without a biopsy. And he'll likely be even better off, with no chance of spreading cancer cells." And I have proven that cancer cells are spread from biopsies as reported by Johns Hopkins. The State of Florida's Administrative Law Judge says the chance of spreading cancer cells is infinitesimal, and almost non-existent when this comment couldn't be

further from the truth. I told the State that they can't make that assumption. The Judge doesn't know science. She doesn't know from whence she's speaking.

Tornadoes happen in Kansas. So let's say someone moves to Kansas and asks a realtor about the dangers of living there. What about weather patterns? He might say, "Well, we do have tornadoes once in a while. And we may have vermin and some other negative things." Every State has something. In Florida, we have hurricanes. So the State does not understand something. If I'm allowed to give the interpretation that I'm telling you about right here, you are understanding my message loud and clear. But the law Judge told me in a matter of speaking to shut up. She told me to just answer the question. And I tried to answer the question, but because of her lack of science, she doesn't really know what I'm talking about.

If you believe that earthquakes take place, even though they may happen only one time, and you believe a tornado takes place, maybe only one time. Whatever you're talking about, if it happens once, it can happen again and again. I have an image in my book (page 596) that shows something right out of the Journal of Urology. It shows the rectal wall with something growing in the rectal wall. The image was taken three and a half years after a biopsy at that same location. The biopsy was positive for cancer. Now he has a lesion growing in the rectal wall. I would just submit to you – The law judge is just now showing the proper amount of respect for what takes place when needle biopsies are done, and what a sacrifice the patient is making. I would not want to be the patient whose rectal wall is infested with prostate cancer.

But the State says that it can happen, and it is one of the risks of doing a biopsy. So, I say, "Yes! Now you're talking!" Now that the doctors are going to talk about the risks of biopsy, I'm all in! And let the patient decide whether they are going to do it (the biopsy) or not going to do it. It now comes down to patient choice. When the law Judge says that it happens so scarcely that it almost never happens, I say, "You don't get the chance to say that!" And she looks at me sternly, and says, "I don't want you to talk anymore, until I'm ready to hear you. I'll allow you to talk then." So I have to shut my mouth. I'm at a point now with the State where I'm able to open my mouth again and talk. The law Judge is totally wrong. The patient has every right to avoid a biopsy. Carl has every right to avoid a biopsy.

The situation you're in is unfortunate, but you have to know that I feel like he's still OK. And I don't want you to wait much more. But I'm on the cusp of something. I'm talking with you today because I love you guys, as I do all the guys that are waiting help and assistance. But I don't have the kind of time to explain it to this level with each one. So if you truly have this recorded, what I would love for you to do, is after you've played it back for Carl, make it available to me so I could get it transcribed and edit where necessary for clarity.

OK. Yea! You know, I think Carl could do that.

If you could make a copy of that, it would be wonderful! And now, I would have something that I could send out to anybody at any time. We have touched base on virtually everything in this conversation. The conversation has been extraordinary, I think. But to have this transcribed onto 10 pieces of paper, let's say—who cares? As long as people can sit down and read this carefully, then they'll understand the frustration that I have, that you have, and that any person has (whoever is reading it). So, everybody will understand this, and that will be a wonderful educational process. That would be a wonderful tool that you would give to me, to have this conversation. I would read it as well, and just go back over it. I don't think there has been anything inaudible. I would still read it over and make sure it all made sense. I could fix this or that. But I haven't said anything that I would not say to a law Judge anywhere. And everything has been absolutely correct.

We have two camps. One camp is the State, who wants to protect the right of Urologists to do biopsies. I come along and say, you know, we always should have worked with the Radiologists, because they know something that we ought to know. So I happen to be in the minority – I get that. But I can tell you that I have talked with other Urologists that believe that it's the patient's choice. If it's a patient's choice—and it IS the patient's choice, to avoid a biopsy for all the reasons that I've talked about (bleeding, chance of death, the possibility of sepsis and being hospitalized). Johns Hopkins says it's up to 7% chance. Other people say it's less than that.

Well, if it's 7% and Hopkins is saying it, I don't think your clinic is equivalent to Johns Hopkins (speaking to a competing clinic). I say, "You haven't done the number of cases that they've done. They are going to be unbiased about this. They have had a death as well.

I actually knew of a patient that came from London, England. He came to Johns Hopkins because of their reputation. They have a great reputation. It's the doctors that make the reputation. They have great doctors. They are great in Urology. So this individual from England had a high PSA. He happened to be a Neurosurgeon, so that means he's dealing with the brain. And he's dealing with surgery of the brain, in association with brain cancers. He decides he's going to Johns Hopkins to find out what's going on with him. At Hopkins, he goes through a series of biopsies. He had sepsis, was put into the ICU unit, and he died. And here's my phone blowing up. We're going to have to stop. I'm getting so far behind.

Well, I surely appreciate your time, and we'll see what we can do on a copy for you. Thank you so much!

I appreciate that as well. Good talking, and I'll be back.

sjw 4-26-17