June 2, 2017

Re: Open letter to my trusting patients

Dear friends,

I write this letter with a heavy heart but also with an option for the future. At 2:30 am on June 2, 2017 each of you are being asked (via this letter) to believe in a person who has your back and who can conquer the disease that you have. I must admit at the opening that I am not perfect but my integrity is beyond reproach. Similarly, I am not trying to win a popularity contest with doctor or patients.

It is true my license to practice medicine has been temporarily revoked (in Florida) while I am presently in an appeals process at the Appellate Court. Over the ages, people in medicine who are innovators, researchers or inventors are often criticized by the establishment. I can identify with Pasteur, Lister, Jenner, Salk and others. While I am not saying I qualify to be mentioned in the same breath with these courageous individuals, I believe the fight we have for "freedom of choice and decision making" has to be supported and embraced by the establishment. A procedure (like a prostate biopsy) that is associated with death due to Septic Shock (albeit rare) can never be encouraged without total inclusion of a patient's right to say no. When a patient says no, it sends a message to all, including medical professionals and society as a whole, that the consequences of such action have significant risk and likely an unacceptable risk. While many doctors believe the benefit of a biopsy far outweighs the risk, I am not so convinced now that imaging has caught hold in the USA and around the world, in part because of my research.

I am a man of faith and should tell you that I do not work alone. I believe all things happen for a reason and truly need to be understood when possible, if not accepted based on faith alone. As for me, I can only give credit to my creator. I believe many of you who have chosen to ignore a biopsy have done it for a reason and the reason is simple. **You understand the term "needle tracking" as a concept that potentially spreads prostate cancer cells and most certainly encourages an inflammatory response called prostatitis.** When you look at prostatitis as a disease entity, the American Association of Cancer Research (AACR) headed up by Johns Hopkins and embraced by virtually all of academia ... to show that prostatitis evolves into a cancer over time. Examples of other inflammatory conditions that lead to a cancer include Cervicitis, Esophageal inflammation (Barrett's Esophagitis), Pancreatitis, Colitis, Gastritis and more. Cancers coming from chronic inflammation is also endorsed by Michael Karin, PhD at the University of California at San Diego.

Relevant to the role of imaging as a favored technology to diagnose prostate cancer, we do not need to look beyond my research and the work of the National Institutes of Health (NIH). Between 2006 and 2010, I was the Principal Investigator for General Electric to evaluate their 3T magnet. I did a study whereby all patients (N=200) who entered the study had to have had a biopsy (positive for prostate cancer) and a 3T MRIS scan. This was a consecutive series and double blinded. While the study has not been published in the literature it has been presented in a Poster format at many Urology events. The study results showed a positive predictive value (PPV) of 95%, showing that imaging found all but 5% of the cancers but more importantly all of the aggressive cancers similar to what you have noted in a

PIRADS of 4 or 5. This study while seminal was validated by the NIH in 2011 with their published study on 46 patients diagnosed by biopsy and then followed up with an imaging scan for confirmation. I will enclose these documents in your email so you can focus in on the points at hand. In their research, the PPV was 98-100%. What these studies show empirically is that a 3.0T MRI scan is an exceptional surrogate marker for prostate cancer with a very high level of confidence. We know that a typical 12 core biopsy is associated with upwards of a 50-60% false negative rate commonly missing apical and anterior cancers. **To restate, needle tracking is real and as long as death is a complication of a biopsy (which it is), patients should have a choice to accept or reject this very traumatic procedure.** Recently, I had a 48 year old patient and former Police officer who came to me with blood in his urine and ejaculate following an awkward slip in a pool he was repairing. I did an ultrasound which showed nothing to be abnormal but due to a low Testosterone level associated with a low PSA level, I ordered a 3.0T Multi-parametric MRI scan. This scan showed a well-defined yet highly suspicious area of concern for prostate cancer associated with a PIRADs of 5 out of 5.

Despite his lack of interest in a biopsy, he was talked into one by another Urologist on a second opinion visit. 19 needle sticks later he had a high grade cancer identified as well as a subsequent suspicious area in his lung field 3 months after the biopsy. Further review showed a site of metastasis in his lungs believed to be from the biopsy. In effect one of his needle biopsies went through the prostate and entered a vein leading to the heart and subsequently to his lungs. Rare as this may be, it shows once again the possible peril with a biopsy. In this case, the prognosis is poor as the cancer in the prostate was ineffectively treated at the prostate level. HIFU without my intellectual property is not indicated for aggressive cancers as sound waves cannot kill the cancer cells predictably. So this patient went to the wrong doctor for HIFU and was coerced into a biopsy that has sadly changed his life forever.

I have another case of a 69 year old gentleman (running for the Florida State Senate) who survived a biopsy and subsequently referred to me. He had heard about my reputation in treating aggressive cancers of the prostate. His PSA value was 44.6 ng/ml. The biopsy was associated with a Gleason Grade of 4 which is associated with an aggressive cancer. His PIRADS was a 5 out of 5 consistent with a very aggressive cancer independent of the biopsy. I immediately began to suppress the disease and had a very difficult but necessary disclosure to make to the patient. I told him that only through prayer and the "grace of God" would he have any chance for a promising survival. The chance of his case not being associated with microscopic spread was virtually non-existent. He had heard about my intellectual property that is now in a patent pending status and also knew of my successes in treating aggressive cancers with HIFU. His case would test my skill set to the maximum in all regards. His 3 month PSA blood level was undetectable (a very good sign) and now his 1 year PSA remains undetectable in May of 2017 at less than 0.02 ng/ml. **This case is truly a miracle that only took place because he like so many others have trusted in me and my work ethic with help from above.** While I intend on getting a post treatment scan to be absolutely sure of his cure, his PSA, which is a marker of disease activity, is undetectable and frankly unbelievable. My data was reviewed by the former Chairman of the Department of Urology at the University of Florida (UF) who stated my data on aggressive disease has never been seen (ever) in the history of Urology. His assessment of my research (which continues) is an extremely powerful commentary from someone who has lead one of our pre-eminent academic learning centers at UF Gainesville.

I want the same miracle for each of you as well. Many of you have heard me talk about nadir (the lowest) PSA value post treatment (most commonly seen within the first year following a procedure). So

no matter the treatment, whether a Radical Prostatectomy, Radiation (even IMRT, Proton Beam) or HIFU, the nadir must be less than 0.2 ng/ml. Relevant to HIFU a study from Europe of success stories on low grade prostate cancer shows a cure in all patients so long as the PSA nadir is ≤ to 0.30 ng/ml (N=15,000) in patient participants. **Every quality doctor must have this data so you must ask for it always. This is the only way to compare "apples to apples" as the saying goes.** The nadir of PSA in 402 patients from Toronto, Canada published in 2012 in the British Journal of Urology, International Edition shows a value of **0.38 ng/ml**. This significantly high number means they (my Canadian colleagues) are not very good at curing prostate cancer which is borne out by a 24% failure on Gleason scores of 6 (3+3) cancers and a 30.5% failure rate on Gleason Scores of 7 (3+4) or (4+3) at 4 years post HIFU. By intention, they do not treat highly aggressive prostate cancer consistent with a PIRADS of 5. In a comparison to my research, I studied 67 patients including some with very aggressive cancers with only 1 failure. My nadir of the PSA is **0.13 ng/ml** at more than 8 years. My chief competitor in Sarasota, Florida is Vituro Health. Their leading treating Urologist is Stephen Scionti, M.D. In his study of whole gland treatments (N=43) since FDA approval at slightly more than 1 year, his PSA nadir is **0.69 ng/ml** referencing a Focal Cancer meeting where he was speaking. His nadir data is reflecting an inability to be successful on patients with aggressive disease something he has not mastered as yet. My data set on aggressive cancers (N=38) shows a nadir of **0.097 ng/ml**, reflecting my enhanced energy application (EEA) when cancers require it. I have determined all men with an element of PIRADS 4 or 5 warrant additional energy.

All of this comes with a doctor less than appreciated in the State of Florida. This person is me. I am accused of stating a patient had prostate cancer albeit not definitively in 4 patients. The presumption of cancer was based on a concordance of data including a 3.0T MP-MRI scan. To level the playing field, Vituro Health has treated two my patients with suspicion of an aggressive cancer without a biopsy. One was treated in May, 2017 so we must wait on follow up data in his case but the other patient was treated in January, 2017 and his first PSA value is too high at **0.35 ng/ml**. This is difficult for me to swallow as the disease is not gone and a second treatment will be required in an attempt to salvage the patient. The best chance at cure (for any patient) is the first time HIFU is used as a single treatment.

While I believe I have exceptional talent and am special as you are very special to me and your family structure. Each of you deserves the best and that may need to be done outside of the USA where I have the respect of others and the ability to treat. Minimally, with this letter, you are now better educated and invited to contact me if you are remotely interested in me treating you. If not, I will wish all the best in your journey with hope for a successful outcome. **Remember, the winning hand is curing your disease as noted by a very low nadir of PSA value.** My friends intended to read this message include among others: **EA, CR, FD, CW, JB, EP, DC, JRD, JS and DS**. You will know who you are. May God Bless you to allow you to know I can still help you if you will allow me to treat you outside of the USA. I am part of the solution and not part of the problem. You did not ask for this disease to come your way so minimally, I want to look out for you and beat the disease you have.

All the best to my brothers,

With the greatest respect and sincerity,

Dr. Ron