IN THE DISTRICT COURT OF APPEAL OF FLORIDA
FIRST DISTRICT

RONALD WHEELER, M.D.) Appellant,)) v.)) **STATE OF FLORIDA DEPT. OF**) **HEALTH, BD. OF MEDICINE,**) Appellee.)	CASE NO. 1D17-1661 L.T. No.: 2012-03027 2012-16053 2013-06688 2014-19909

INITIAL BRIEF OF APPELLANT RONALD WHEELER, M.D.

Stephen Marc Slepin, Esquire
Of Counsel
The Maddox Horne Law Firm
Florida Bar No. 0100290
502 North Adams Street
Tallahassee, FL 32301
Telephone: (850) 222-6020
Facsimile: (850) 222-1249
Email: slepin@maddoxhorne.com

Attorney for Appellant

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STATEMENT OF THE CASE AND FACTS

This is an appeal pursuant to §120.68, F.S., from Final Order of the DOH Board of Medicine, Index 448, adopting the Recommended Order of the DOAH Administrative Law Judge, Index 333, imposing the penalties of Revocation of License, Fine of $30,000 and Costs of $79,993.30 for violation of §158.331(I)(t)1 falling below the "standard of care" for four patients during the 2008 – 2013 period. [Motion For Stay was denied by Order of this Court, 5-26-17.]

All references shall be to the INDEX OF RECORD ON APPEAL, I___, and for the convenience of the Court discrete citations to the Record shall be:

Bd. – Final Order of the Board of Medicine.

Tr. – Transcript of DOAH proceedings, Vols. 1 and 2.

R.O. – Recommended Order.

Ex. – Exhibits in DOAH proceedings.

STATEMENT OF THE CASE

The ALJ stated in 30 pages the issue as "whether Respondent … violated the standard of care for diagnosing prostate cancer in four patients, and recommending and participating in a course of treatment for those patients, without confirming

prostate cancer through tissue biopsy results; and if so, what is the appropriate penalty?" [Appellate Wheeler disputed and disputes the premise of that issue.]

The DOH filed four Amended Administrative Complaints (patients G.P., 2012; J.W., 2012; K.S., 2013; V.P., 2014) alleging violation of §458.331(1)(t)1, F.S., medical malpractice by practicing below the standard-of-care as defined at §766.102, F.S. ("prevailing" standard of care in Medical Malpractice "damages" actions) in the 2008-2013 period. I 16-35.

From the April 20, 2017 FINAL ORDER of the Board of Medicine, I 488, appeal was timely taken.

STATEMENT OF FACTS AS FOUND

Pursuant to DOAH hearing of 12-8-16, the Administrative Law Judge (ALJ) entered a Recommended Order of 2-24-17 (I 333) *finding* that Dr. Wheeler had no prior disciplinary action against his medical license (p.4), prostate disease has been the focus of his practice for 20 years, and he was lead investigator for the General Electric study of the 3-Tesla Magnetic Resonance Spectocscopy (3T MRI-S) imaging machine (Ibid.) which scanned 1,600 patients between 2006-2010 and a Double Blind study of 200 of the patients who had biopsies (p.5), and he came to believe that the 3T MRI-S technology alone is a positive predictor of prostate cancer 95% of the time. (Ibid.). The ALJ found that all expert witnesses and Dr. Wheeler attested that the standard-of-care is to use a needle tissue biopsy [of the prostate

gland] "to identify prostate cancer" — absent which a reasonably prudent physician cannot "diagnose or treat" prostate cancer. (p.5). Biopsies are usually performed to diagnose prostate cancer if the patient has a common risk factors, notwithstanding that needle biopsies have a false-negative-rate of 20%-50% when missing cancerous tissue (pp.5-6) and carry risk of complications (p.6). Dr. Wheeler believes that a risk of needle biopsy is "seeding" or "needle tracking" which may spread any prostate cancer located, and bases that on one 2002 *Journal of Urology* article and 1991 Johns Hopkins University School of Medicine study (p.6), not the "prevailing view in Florida." (p.7).

Dr. Wheeler's 2012 book, in evidence, asserts his belief (pp. 7-8), and that the use of the 3T MRI-S is the "truth serum" of prostate cancer diagnosis. (p.8). Dr. Wheeler holds himself out as The Diagnostic Center for Disease "as specializing in "non-invasive diagnosis (MRI/MRIS) without biopsy" as "integral" to diagnostic evaluation of prostate cancer." (Ibid.). He also held himself out as an expert in HIFU (High Intensity Focus Ultrasound) *alternative* to insertion of radioactive seeds into the prostate or radiation or surgical removal of the prostate, by using focused waves to ablate issue. (Ibid.).

The ALJ found that the Florida standard-of-care precludes HIFU in the absence of confirmatory tissue biopsy. (p.9). Prescription of Casodex, Bicalutamide

suppresses testosterone, as does Trelstar, to shrink the prostate. And there are side effects. The smaller prostate gland is easier to work with. (Ibid.).

Patient G.P. had a 2005 biopsy, enlarged prostate, benign prostate hyperplasty, but his biopsy was negative. G.P. rejected another biopsy as his PSA level rose, and sought an alternative to biopsy. After a 3T MRI-S scan, Dr. Wheeler was unsure of results, but that G.P. was "high risk" because his father had died of prostate cancer. Dr. Wheeler prescribed Avodart for the hyperplasty and recommended regular PSA screening. In December 2009 G.P.'s PSA level rose, Dr. Wheeler prescribed Casodex. By February 10, 2010. G.P.'s PSA level decreased, but he had urinary frequency and pain; so Dr. Wheeler performed an ultrasound and digital rectal exam [DRG] and told G.P. that "it was likely" he had prostate cancer but "could not be sure without a biopsy" — though his records reflect a diagnosis of prostate cancer without a tissue biopsy. Dr. Wheeler offered a targeted biopsy based on MRI scans, and discussed his concerns regarding "needle tracking." (pp. 10-11). But G.P. made clear that he did not want a biopsy, and wanted HIFU. Dr. Wheeler advised G.P. of the risk of erectile dysfunction, but not the possibility of urinary stricture problems. In April 2010 G.P. underwent the HIFU procedure. (p.11). April 2010 G.P. saw a Michigan urologist for diminished urinary stream and pain. (Ibid.). G.P. had procedures to relieve a urinary stricture and then its symptoms. (p.12). Dr. Gelman found significant urinary stricture and performed a TURP or transurethral

resection of the prostate, and samples of prostate tissue were negative for prostate cancer -- and filed a complaint against Dr. Wheeler for omission of biopsy. (Ibid.).

Patient J.W., a retired dentist, had two prior biopsies, negative for cancer. (pp 12,13). He wanted no further biopsies, but his PSA was again elevated. Dr. Wheeler did a sonogram and MRI, and diagnosed prostate cancer, but did not recommend biopsy. (p.13). Another urologist in Alabama recommended active surveillance, and J.W.'s PSA levels declined. (pp. 13,14). That urologist filed a complaint against Dr. Wheeler "for cancer diagnosis and recommending treatment in the absence of a pathological specimen." (p.14).

Patient K.S. had elevated PSA, but no family history of prostate cancer. He had two biopsies, negative for cancer, but was concerned about rising PSA and sought "alternative treatments..." (p.14). Dr. Wheeler performed an ultrasound and said he was "concerned" that K.S. had prostate cancer. HIFU was recommended (p.15). Dr. Wheeler declined to perform a needle biopsy "because it pushes cancer further into the prostate," and the MRI would tell whether K.S. had prostate cancer. An MRI was performed. A week later Dr. Wheeler called: a Gleason 7 aggressive prostate cancer treatable by HIFU, cost $32,000. (Ibid.). K.S. visited his doctor — who said no one can diagnose cancer without a tissue biopsy. So K.S. opted for active surveillance, and PSA tests showed decreased PSA. K.S.'s wife filed a complaint against Dr. Wheeler. (pp. 15-16).

Patient V.P. from Alaska had elevated PSA of 6.3, with no family history of cancer, and his urologist suggested a biopsy, which V.P. learned was painful. (p.16). He sought "alternatives" and saw Dr. Wheeler who perform a digital rectal exam and found a much enlarged prostate. (Ibid.). Dr. Wheeler performed an ultrasound and told V.P. "I'm telling you right now have prostate cancer." (p.17). Dr. Wheeler prescribed Bicalutamide and Trelstar to wipe out testosterone and slow growth of the prostate. Dr. Wheeler told V.P. that prostate biopsies are "dangerous and metastasize cancer cells." Dr. Wheeler wanted V.P. to have an MRI to visualize the "amount of cancer," and offered a private placement investment in a HIFU company at $50,000. V.P. underwent an MRI, which images Dr. Wheeler showed V.P. "areas of concern," and said V.P. had "extensive prostate cancer" with short-time to decide on HIFU. Dr. Wheeler prescribed Bicalutamide and, afterward, Trelstar to atrophy the prostate for HIFU. (p.17). Concerned about cost if HIFU were unsuccessful, V.P. asked about proton therapy in California, and Dr. Wheeler discouraged anything but HIFU. (Ibid.). V.P. returned with a check for $10,000 deposit, but overheard Dr. Wheeler telling a radiologist to include the word "cancer" on reports, and the radiologist saying it was "impossible" to make such diagnosis. So V.P. left. (pp.18-19). V.P. then saw an Orlando urologist who said "not possible to diagnose prostate cancer without a biopsy." Also, he disputed that prostate biopsies can spread cancer. That doctor performed a digital rectal exam, found a "slightly

enlarged" prostate, normal and smooth, and expressed doubt of any prostate cancer. A biopsy was negative for cancer. (p.19). The medications prescribed by Dr. Wheeler produced "significant side effects..." (p.20).

Standard of Care: experts were "unanimous" that from 2008 - 2013 the standard precluded diagnosis or treatment of prostate cancer absent tissue biopsy. (Ibid.). Experts say a reasonably prudent physician wouldn't tell a patient he had prostate cancer nor prescribe medication, nor suggest treatment "based upon an ultrasound or MRI." (p.20). Dr. Wheeler claims that he advised each patient that needle biopsy was the definitive test, but one he disfavored due to "the possibility" of needle tracking. (Ibid.). Dr. Wheeler's testimony "is not credible in light of the credible testimony of the "the three patients...," and his testimony that he offered the option of needle biopsy" is wholly inconsistent with "his own book" and on his "website." (pp.20,21). The patients' perception re. needle biopsies are "at least, in part" influenced by their discussions with Dr. Wheeler and his "over-inflating, the infinitesimally small possibility of needle tracking," inconsistent with standard of care. (p.21). Dr. Wheeler claims that the four patients insisted they did not want needle biopsy, so it was appropriate to diagnose on "a preponderance of the evidence and concordance of data," and move forward with treatment plan, medications, and HIFU. (Ibid.). In the 2008-2013 period for patients "suspected of having prostate

cancer" but having "refused a needle biopsy," was to prescribe active surveillance, frequent PSA testing, "and to offer no other treatment." (pp. 21,22).

Ultimate Factual Determinations (at p. 22, *et seq.*): Clear and Convincing Evidence of medical malpractice re. G.P., J.W., K.S., V.P. by failure to obtain biopsy before "confirming" the patient had— or diagnosing the patient with -- cancer; prescribing Bicalutamide (Casodex) absent tissue biopsy "confirming" cancer without a biopsy for G.P. and V.P.; prescribing Trelstar absent biopsy "confirming" cancer for V.P.; recommending or facilitating HIFU without "confirming" cancer by biopsy for G.P., J.W., K.S., V.P.; and participating in or assisting in HIFU treatment without biopsy showing cancer for G.P. (p.22).

Dr. Wheeler's EXCEPTIONS to Findings of Fact, I 409, were all rejected by the Board of Medicine. I 450 and 488, Bd.

[Dr. Wheeler's disputation of these ALJ findings as adopted by the Board of Medicine shall be asserted under ARGUMENT *infra*.]

SUMMARY OF ARGUMENTS

I. The Board of Medicine (adopting the Recommended Order of the ALJ) impermissibly penalized the content-based First Amendment freedom-of-expression of Appellant, and misconstrued §381.026, F.S. (Patient's Bill of Rights) and §456.41, F.S. (Complementary or Alternative Health Care Treatment), and erroneously found "clear and convincing evidence" of violation of medical practice requirements.

II. The penalty imposed upon a discipline-free physician (Revocation of license, A $30,000 fine, $79,993.30 in costs) regarding four patients shocks the judicial conscience and derives in significant part from Appellant's content-based expression.

ARGUMENTS AND STANDARDS-OF-REVIEW

ARGUMENT I

The State's Penalization Of Content-Based Expression And Misconstruction Of Amendments I And XIV (U.S. Constitution), And Of §§381.026, F.S. And 456.41(1)(A), F.S. Constitute Prejudicial And Reversible Error.

[Mixed Standards of Review (1) as to First Amendment and Statutory misconstruction, *De Novo* review: *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992); *Dr. Bernard Wollschlaeger, et al. v. Governor, State of Fla., et al.*, 848 F.3d 1293 (U.S. 11th Cir. Ct. Appeals); (2) and as to Statutory Interpretation, *De Novo* review: *Hill v. Douglas Davis, etc.*, 70 So.3d 572 (Fla. 2011); (3) and as to "clear and convincing" evidence, *Punsky v. Clay County Sheriff's Office, et al.*, 18 So.3d 577 (1 DCA 2009), *reh. den.*; *McKesson Drug Co. v. Williams*, 706 So.2d 352, 353-354 (1 DCA 1998); *School Bd. Of Seminole County v. Renaissance Charter School*, 113 So.3d 72 (5 DCA 2013), *reh. den.*, for this Court to determine.]

1. CONTENT-BASED EXPRESSION

Dr. Ronald Evans Wheeler, free of disciplinary action for over 20 years, expressly believes, and expressed his beliefs to patients, in his book, on his website

in the useful diagnosis of prostate disease (by PSA tests, digital rectal examination, chemical test concordance of data) that needle biopsy of prostates can cause the spread of any cancer struck by the needle, that "false negatives" of biopsies occur where the needle doesn't strike a cancer cell, that high intensity focused ultrasound (HIFU) can have beneficial effects, that under §381.026 patients have the choice of medical attention, that he may provide alternative medical services, and that Bicalutamide and Trelstar shrink the prostate gland, and that ablation of prostate tissue can be beneficial — None of which is proscribed by law, and where governmental penalization of such clinical expression is unlawful.

Like Edward Jenner (castigated for pox injections to combat smallpox), Louis Pasteur, Jonas Salk, and Albert Sabin (introduction of polio to prevent polio— with Drs. Salk and Sabin disagreeing), or Charles Darwin for his 1859 "Origin of Species", science evolves and those on the cutting edge challenge static beliefs, Dr. Ronald Evans Wheeler has openly challenged static medical science beliefs. Which expression is protected from government penalty under Amdt. 1, U.S. Constitution as incorporated in the 14th Amdt, requiring heightened scrutiny. *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 563–567, 571–572 (2011), And "content-based regulations [of expression] are presumptively invalid." *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992).

See, *N.A.A.C.P v. Button*, 371 U.S. 415, 438-444 (1963), (holding that the Virginia claim to insure high professional standards or to prohibit professional misconduct, may not ignore constitutional rights); *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 566 (2011) (Doctors . . . "must be able to speak frankly and openly to patients." and at 578-579, "the state may not burden the speech of others in order to tilt public debate in a preferred direction."); *Kleindienst v. Mandel*, 408 U.S. 753, 762 (1972) (this court has referred to a First Amendment right to "receive information and ideas."); *Trammel v. United States*, 445 U.S. 40, 51 (1980) ("the physician must know all that a patient can articulate,"); *Virginia State Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771-772 (1976) (the state cannot broadly restrict truthful speech based on content); *Ashcroft v. ACLU*, 535 U.S. 564, 573 (2002) ("government has no power to restrict expression because of its . . . content."); *Reed v. Town of Gilbert, Ariz.*, 135 S.Ct. at 2226 (2015) (content-based speech restriction must survive strict scrutiny); *Police Dept. of Chicago v. Mosley*, 408 U.S. 92, 95 (1972) ("the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content."); *Turner Broad. Sys. Inc. v. FCC*, 512 U.S. 622, 641 (1994) (the risk of such restriction is "to suppress unpopular ideas or information ..."); *McCullen v. Coakley*, 134 S.Ct. 2518, 2529, 189 L.Ed.2d 502 (2014) (content-

based regulation of speech threaten the existence of an "uninhibited marketplace of ideas in which truth will ultimately prevail.").

And the history of content-based regulation or restriction of physician speech is shocking – the Chinese Cultural Revolution, the Soviet government in the 1930's, the Nazi Third Reich. See, "Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice," P. Berg, 74 B.U.L. Rev. 201, 201-202 (1994). Cited in concurring opinion, *Dr. Bernard Wollschlaeger, et al., v. Governor, State of Florida, et al.*, 843 F.3d 1293 (Feb. 16, 2017) at 27-28.

This is of the most significant pertinence herein precisely because:

A. In 2014 when the Board of Medicine was presented with three of the four administrative complaints and the Dept. of Health's proposed settlement with Dr. Wheeler, the Board rejected the settlement and, convulsed with horror at the allegations (without any hearing on those administrative complaints), and fulminated against Dr. Wheeler. See, MOTION FOR STAY (Appellant's Reply of May 5, 2017).

B. The Recommended order of the ALJ (as adopted by the Board of Medicine), I 333, R.O. p.21 (of 2-24-17); I 488, Bd. (of April 20, 2017), ruled Dr. Wheeler's testimony "not credible" and patients' remembered or recollected testimony "credible" based upon Dr. Wheeler's outspoken medical opinions

(his book, his website, his statements) despite his medical records in evidence at Joint Exhibits, 1 – 8, I 273 - 3355.

2. Sections 381.026, F.S. and 456.41, F.S.

Section 381.026, F.S. is "Florida Patient's Bill of Rights and Responsibilities." Sub-section (3) provides that healthcare providers are to give their patients "a general understanding of the procedures to be performed and to provide information pertaining to their healthcare" to enable informed decisions, and provide "the available treatment alternatives, and substantial risks and hazards inherent in the treatments." See also, Sub-section (4), 3. Sub-section (4) (d), 3 provides:

> A patient has the right to access any mode of treatment that is, in his or her own judgment and the judgment of his or her healthcare practitioner, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of §456.41.

Section 451.41 F.S. "Complementary or alternative health care treatments," gives patients "informed choices for any type of healthcare they deem to be an effective option... " §451.41(1), F.S.:

> ... It is the intent of the legislature that citizens be able to choose from all healthcare options, including the

> prevailing or conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing or conventional treatment methods...

Healthcare practitioners are free to offer these with the same requirements associated with prevailing or conventional treatment methods. In which regard, physicians must inform patients of the nature of such treatment and explain the benefits and risks thereof, §456.41(3), F.S., and do so "orally or in written form," §456.(3)(b), F.S., and may "without restriction, recommend any mode of treatment that is, in his or her judgment, in the best interests of the patient, including complementary or alternative health care treatments" in accordance with the provision of his/her license. §456.41(3)(c), F.S. Nevertheless, however problematic in light of the forgoing, the statute does not alter provisions of individual practice acts requiring practice within their respective standards of care. §456.41(5), F.S.

Which brings us to the evidence before the ALJ.

Dr. Dennis Donohue was Appellee's expert witness, and his understanding of standard-of-care requirements is "a compilation of pretty much my education, what I've read, meetings, colleagues, experience, everything rolled into one." Tr. Vol I, 21, with the readings being "Medical Literature, Journals. (ibid.). Patients' PSA levels are not singularly determinative of prostate cancer, and he has used magnetic resonance imaging (Id at 22-24) to direct needle biopsies (Id at 25). PSA (prostate-

specific antigen levels) can result from various causes including "prostate cancer." (Id at 22-23). Other tests include family history, digital rectal exam, prostate ultrasound. (Ibid.). Magnetic resonance imaging is utilized for suspected prostate cancer, but is not singularly determinative of cancer. (Id at 24). He doesn't know any Florida urologists who believe that needle biopsies carry "clinically significant risks of spreading prostate cancer." (Id at 25). Biopsies — needles inserted *via* the rectum or perineum into the prostate gland — are definitive for prostate cancer diagnosis. (Id at 26). Absent which there can be only a strong suspicion. (Id at 27). The standard-of care requires a biopsy and tissue diagnosis before telling a patient that he has prostate cancer. (Ibid.). He sometimes uses Casodex to shrink the prostate and make high focus ultrasound treatment more effective, (Id at 28) after tissue diagnosis of cancer. (Id at 30). And if the patient does not want a biopsy, Dr. Donahue is to educate the patient "help him make an informed decision on what to do." (Id at 31). HIFU destroys cancer tissue -- and Donahue has done about 30 (Id at 32) --but first a tissue biopsy and favorable prostate. (Id at 32-33).

On Cross-Exam, Dr. Donahue testified that he went, before 2015 FDA-approval, to the Bahamas to do HIFU (Id at 41) and DOH counsel asserted that "the efficiency of HIFU is not really at issue in this case,..." (Id at 42). At Tr. 43, Dr. Wheeler's counsel argued that Dr. Donahue misstated the FDA position that Casodex and Trelstar are "simply used for prostate tissue ablation, not only for

prostate cancer," which DOH counsel stated wasn't "relevant to the ultimate issues being litigated in this case." The FDA statement of October 9, 2015 is that high intensity ultrasound is "for prostate tissue ablation." (Id at 44). The ALJ sustained objection to questioning re. HIFU being limited to, or transcending, prostate cancer. (Id at 45, 46). Dr. Donahue uses Casodex and Trelstar to "shrink the prostate" and "not just [for] HIFU,..." (Id at 46, 47). He agrees that the four patients did not want biopsies. (Id at 50). As to the use and interpretation of MRI after his 1983 graduation from medical school, Dr. Donahue began viewing MRI images "Just within the last couple of months." (Id at 51). It "is an evolving part of medicine" and "everything is — in medicine is evolving. I mean, it's not a — is not a static science." (emphasis supplied) (Id at 52). Dr. Donahue refers out MRIs and does not look at the pictures. (Id at 52-54).

Dr. Donahue has not read the publications of the National Comprehensive Cancer Network. (Id at 55). The American Urological Ass'n guidelines say, as to diagnosis, that every patient is to be treated individually, but he does not know what NCCN or AUA say with respect to diagnosis and treatment of prostate cancer. (Id at 56). However, prostate MRI is within the standard-of-care, and that became true as of five years ago. (Ibid): "It's evolving." (emphasis supplied) (Id. At 57).

So as to new and emerging technology, how does it become standard-of-care? "...articles are written, studies are done." (Ibid). He agrees that each care and each

technology is taken on a case by case basis: "Right." (Id at 57-58). But he doesn't know how a cancer lesion appears on an MRI (Id at 58), because he doesn't interpret MRIs, nor know what DFI is, and has only heard of PIRADS (Id at 58-89), all MRI technology. He just looks for "the recommendation of the radiologist . . . a one-paragraph synopsis . . ." (Id at 60). Asked if he even knows the significance of a PIRAD score, the ALJ sustained objection to the question! (Id at 61). Nor does he know the meaning of DWI, nor ADC. (Ibid.). Nor does he know what the Creatine and Choline citrate ration is – all important to Dr. Wheeler – Dr. Donahue says ". . . that's out of my realm." (Id at 61,62). The same for ADC, apparent diffusion coefficient. (Ibid). Note: A glossary of terms appears at pp. 338, Respondent's Exhibit 20, I 962.

Biopsy has risks such as false negatives, infection, bleeding, rarely death. (Ibid). And "about half the time we miss cancers that are present" re. biopsies (Id at 63, 64), and even biopsies under ultrasound control may miss cancers 50% of the time. (Id at 66). Negative or missed cancers "is an evolving area." (Id at 63, 64). And if the index of suspicion is high, Dr. Donahue goes "to the next MRI . . ." (Ibid). So with 50% of cancers missed by biopsies (Id at 66), this doctor would not treat for cancer, but would tell the patient of his "index of suspicion" and observe (Id at 68, 69) and leave it to the patient's decision: patient choice. (Ibid).

Dr. Donahue and Dr. Wheeler agree on much. Standard of Care is divined from colleagues, experience, literature, tec. Both use MRI, do ablations, shrink prostates by medications – but Appellee's expert, unlike Dr. Wheeler, isn't familiar with MRI-data-terms or chemical concordances. And absent biopsy, which gives "false negatives" 50% of the time, Dr. Donahue does nothing but talk to patients and observe.

Dr. Stephen Leslie was called as Dr. Wheeler's expert. He opined that Dr. Wheeler adhered to the standard-of-care (per the records reviewed). (Id at 74).

A second-opinion physician is to discuss treatment options, both common ones and uncommon or alternative ones "as long as they are recent," after taking a history, reviewing records, x-rays or MRIs, PSA's, any biopsies. (Id at 75). He does MRIs, biopsies (ibid.), knows PIRADS scoring system for questionable lesions on MRI, now applying the European consensus — numbers 4 and 5 almost conclusive of cancer. (Id at 76). The Wheeler records show that the four patients "likely had prostate cancer — but not clear that he made a definitive diagnosis." (Id at 77, 78). Absent a definitive pathological diagnosis, the diagnosis has to be qualified, bearing in mind that a "biopsy may miss the cancer,..." (Ibid.). Biopsy may pose health risks for some patients. (Id at 79). Patient K.S., for example, would have to come off blood thinners for some time, and that poses dangers. (Id at 80). It is a "recommendation" that biopsy precede the treatment, despite complications

— unlike Europe where MRI may be a substitute. (Id at 81). "Needle tracking" from biopsy has been reported for a few people, and is a risk to be discussed with a patient. (Id at 82).

That Tesla 3T MRI favored by Dr. Wheeler has, over the last 10 years, "become a de facto standard..." And the 3T machine is to get a good image. "Urologists had to learn how to deal with the information..." and to identify questionable lesions." (Id at 84, 85) Before treatment "a diagnosis is necessary, not necessarily a tissue diagnosis," although that is currently preferred. The tissue diagnosis does "not necessarily" equal Diagnosis, inasmuch as patients decline biopsy but have "strong evidence... [of] cancer" — such as PSA, which if over 4 is suspicious, and over 20 is highly suspicious. (Id at 84-86). In some cases we make diagnosis without "tissue confirmation" because the patient's life is at risk from cancer. Factors are the anatomy, the T2 image; the "diffusion" or DWI as weighted image, and the ADC or apparent diffusion coefficient, and the PIRAD score by addition of factors. (Id at 87-89). The MRI will also show extra capsular extension of a cancer, and local lymph nodes. (Id at 89, 90). "A lot of experts" believe in an MRI is diagnostic of prostate cancer within a reasonable degree of medical probability, and tissue biopsy is "confirmatory." (Emphasis supplied). (Ibid.). Biopsy can provide confirmed histological tissue diagnosis, but for that a penalty must be paid in terms of "risks" of infection, pain, bleeding. (Id at 90). The 3T MRI

is an "evolving" technology. (Id at 90). HIFU is not a high side effect compared to other procedures — maybe 10% to 20% risk of strictures "which is relatively low." (Id at 92). There are no AUA or NCCN guidelines for patients who refuse biopsy, and "you are kind of left in limbo..." (Ibid.). It would violate standard-of-care not to inform such patient of HIFU. (Id at 93). Dr. Leslie uses Casodex, Trelstar to shrink tissue, or stop progression of cancer. And side effects are "relatively mild."

All four of these patients had a "high index of suspicion" based on PSA and history. (Id at 94). All had lesions, so it was within the standard-of-care to inform the patients of HIFU. (Id at 96-98). That was a "duty." (Ibid.). "We make a diagnosis without tissue all the time..." (Emphasis supplied). (Ibid.). Renal tumors' biopsies risk "tracking seed" and risk of bleeding; and even benign tumors are dangerous. (Id at 98, 99). Even as to prostate cancer a bone scan may suffice if consistent with the pattern expected from prostate cancer. "So even prostate cancer, we don't absolutely require a tissue diagnosis." (Emphasis supplied). (Ibid.). Physicians must, even in 2008-2013, inform patients of their options. (Id at 101). Indications for HIFU is in the evolution stage, and we're learning how best to use HIFU, but must inform the patient. (Id at 102).

On Cross-Exam, Dr. Leslie, who doesn't practice in Florida, contributed to Dr. Wheeler's book (Vol. II, at p. 111). See, Respondent's Exhibit 20 at I 962, [fully explaining the risks, procedures, MRI data, etc. of relevance.] Given the evolution

above-mentioned, in 2008-2013 the MRI alone was not considered "definitively diagnostic" for prostate cancer (Id at 115), because it didn't provide then the same level of cellular detail as biopsy tissue. In 2008-2013, determination of prostate cancer with "certainty" was by "histological tissue of malignancy..." (Id at 116). Absent "confirmatory biopsy" in 2008-2013 a physician would have to qualify a diagnosis of cancer (Ibid.) -- as Wheeler did. (Id at 94). Three of the patients made the "claim" that Dr. Wheeler told them that they had prostate cancer. (Id at 117). It is an hypothesis unproven that biopsy had high risk of spreading cancer (Id at 118) -- and Dr. Wheeler "believes that they [biopsies] could spread cancer." [Emphasis supplied]. (Id at 119). In patient K.S.'s case, a biopsy would "be at increased risk." (Id at 122). Patient G.P. actually underwent HIFU. (Id at 123). But it is within the standard-of-care to recommend or facilitate HIFU since patients rejected biopsy, and HIFU is a reasonable option. (Id at 124, 125). He assumes they got accurate information re. biopsies. (Id at 125). It was within the standard-of-care for Dr. Wheeler to recommend or facilitate HIFU for these patients without confirmatory biopsy. (Id at 129, 130).

On Re-Direct, the complications of HIFU are also associated with other treatments. (Id at 131, 132) and HIFU is less costly, with virtually equivalent efficiency, with "far fewer side effects." (Id at 132). As to what the patients long afterward remembered about what Dr. Wheeler told them: "...patients don't always

remember what they're told." (Id at 134). A physician must not be censored and prevented from giving an honest opinion. (Ibid.). "...we know that when you stick needles in cancerous tissue, you can spread tumor cells into the bloodstream. You break blood vessels, you free up tumor cells." (Id at 136). Such belief is not wrong or right, "it's just an opinion." (Id at 137) -- which is why we need "second opinions." (Ibid.).

Dr. Wheeler testified at Vol. II, Transcript, beginning at Tr. 141. He has been in private practice of Urology since 1985 addressing "prostate specific issues." (Id at 141-143). He was the principal investigator of the General Electric 3T HDx magnetic technology from 2006-2011. (Id at 144). He scanned roughly 1,600 patients. (Id at 145). Beginning in 2006 as an "evolutionary process" there was a working hypothesis that the 3T MRIs would be efficacious in diagnosing prostate cancer, and the AUA Western Section of Urology wanted to know of his study of 200 patients which showed the "positive predictive value of the MRI, put together in 2008, of 95 percent" (Id at 154). A "double-blinded study," Respondent's Exhibit 3, I 867, showing the metabolites of cell functions. (Id at 156). A key formula was "creatine plus chlorine divided by citrate,..." (Ibid.). This was "confirmed by a biopsy." (Ibid.). It was presented at New York University in 2010 at conference, and recently to the AUA Western Section of Urology. (Id at 156, 157). See, Respondent's Exhibit 20, I 962. Exhibit 4, I 876, "Multiparancetric MRI in Prostate

Cancer Diagnosis and Treatment: 7 years of Clinical Experience" was a presentation, as was Exhibit 5, I 1877. (Id at 157, 158). See also, Ex. 6, I 1878. Exhibits 3, 4, 5, 6 present the data obtained. He, like Dr. Donahue, keeps up with AUA publications (Id at 161), including AUA's "update series." (Id at 161, 162. He relies on publications labeled Exhibits 7-19, I 878 - 895. Id at 160-169).

In 2008-2013 Dr. Wheeler's medical license was not under any type of restriction, when he saw these four patients, nor before that. (Id at 186). He must tell patients of his clinical concerns (Id at 191), but not to dissuade them from biopsy. (Id at 190). But "false negatives" from biopsies, require fusing ultrasound and MRI, because "standard of care is an evolution... and we develop new ideas... all the time..." (Emphasis supplied). (Id at 194).

Patient G.P.'s chart is Joint Exhibit 1, I 2731 - 2972. G.P. was in the double-blind study, and Dr. Wheeler discusses with patients alternative treatments and biopsies and all options — but did not tell patients not to have biopsies. (Id at 200-202). In every case these patients said that they do-not-want biopsy, but he tells them that they can have biopsy. (Id at 203, 204). HIFU presents a 10% - 20% risk of stricture. (Id at 203). G. P. Consented to MRI, at (97) of this exhibit. (Id at 204-205). G.P. consented to MRI, at '97' of this exhibit. (Id at 204-205). G.P. had HIFU, to which he consented. (Id at 206-208). Dr. Wheeler had "informed consent" discussion with G.P. re. "alternative treatments." (Id at 208). Based upon a

concordance of evidence, he tells the patient that the likelihood of cancer "is high" but not definitively because he didn't have an a biopsy." (Id at 209, 210). This distinction between Diagnosis and Definitiveness is of the first importance, but was entirely blinked in the Recommended Order and Final Order below.

Dr. Wheeler discussed with all four patients "alternative diagnostic measures to include and not be limited to biopsy." (Id at 210). He tells them "all treatment options" and literature-based positives and negatives. (Id at 211). The "informed consent form" in evidence discusses various diagnostic modalities, and that biopsy is typically done to determine the presence of cancer. (Id at 213). And he had that discussion with these four patients — "it has to be covered" as it is his "opinion." (Id at 213, 214).

He also informs them that MP MRI has a 98% to 99% to 100% positive predictive value, but may use "a needle if you choose to do so." (Id at 215). Dr. Wheeler personally reviews MRI images. (Id at 216). The radiologist also reads the MRI images, Wheeler inputs his risk assessment. (Id at 217). The radiologist operates independently. (Id at 218). Correlation with chemical signature by MR Spectroscopy was not in patient G.P.'s case. (Id at 220). Risk was "moderate." (Ibid.). HIFU is the most patient-friendly procedure available, with the fewest side effects, (Id at 221) despite G.P.'s stricture or urethral narrowing as with 10% to 20%

of patients; and this risk was discussed with G.P. (Id at 221). G.P.'s medical charts at Joint Exhibits 1, 2, I 273 - 2972.

Patient V.P, charts Joint Exhibits 7, 8, I 3308 - 3355: Dr. Wheeler's "index of suspicion" was prostate cancer, though a subsequent biopsy by Dr. Patel was negative. (Ibid.). That biopsy is associated with a 20% to 50% "false-negative" chance and cancer was not found in the areas biopsied. (Id at 222). Biopsy procedures too have evolved. (Ibid.). A negative biopsy "never" establishes the absence of cancer. (Id at 223). Though he utilizes a radiologist, he challenges the information to benefit the patient. (Id at 224). And this radiologist/urologist dialectic took place with all four patients. (Id at 225). PIRADS — of which Appellee's expert at Tr. 58-59 has only heard (the prostate imaging, reporting and data system) -- is a calculation based on the Tr. weighted image, DWI, and dynamic contrast enhancement which are rated to ascertaining cancer. (Id at 225, 226). And the Gleason Score is a graded measurement of what a biopsy would reveal, (Id at 226) as accepted by U.S. and European radiologists. (Id at 226, 227). PIRADS studies are correlated with Gleason Score — which Dr. Wheeler discusses with patients. (Id at 227). Prescriptions: Casodex is prostate cancer specific, to suppress disease or shrink the prostate. (Id at 229). And Trelstar is to decrease testosterone and shrink the prostate, and could be in anticipation of HIFU or "some other formal procedure." (Id at 230). There is a lot of HIFU competition in Florida. (Ibid.).

On Cross-Exam, Dr. Wheeler notes that biopsy is a vital part of diagnosis, but "is not an exclusive part." (Id at 233). Respondent's Exhibit 9, speaks to the benefits of biopsy. (Ibid.). G.P. was not part of that study, Dr. Wheeler corrects himself, but was in the G.E. study. (Id at 235). If V.P. never had a biopsy, Dr. Wheeler's diagnosis is based on a preponderance of the evidence and concordance of the data. (Id at 236). Dr. Wheeler believes that he can diagnose prostate cancer without biopsy "based on a preponderance of evidence and concordance of data," (Id at 238) but has never denied that biopsy is a standard of care, "traditionally." (Id at 241). He believes that biopsies spread cancer cells, and the literature says it happens. (Id at 242). He did no biopsies on any of these four patients. (Id at 244). Prostate cancer does not always require treatment. (Id at 245). In fact, he often employs active surveillance or chronic disease management, and has never proposed cancer treatment or HIFU unless he believed it clinically necessary. (Id at 246). Dr. Wheeler prescribed Casodex to patient G.P., Bicalutamide to V.P., injected Trelstar in V.P. because if a PSA exceeds 8.5 he's in a realm of "possibility where he cannot be cured." (Id at 247, 248). But he did not diagnose "this guy with cancer before treating him," (Id at 248, 249) because that would have required a biopsy. He talked with patient J.W. about HIFU (Id at 249), but whatever J.W. said about HIFU being recommended "it does mean that he truly heard that," because when they hear the news of cancer they don't hear anything else. (Id at 250). Dr. Wheeler attempted to

facilitate HIFU for patient K.S. because "it makes sense with K.S." (Ibid.). The same for patient V.P., and performed HIFU for patient G.P. (Id at 251). He did, based on a combination of factors, determine that the patients had prostate cancer. (Ibid.). As to K.S. and G.P., They had PIRADS of 4, which is "aggressive prostate cancer." (Id at 253). MRI scans are the most accurate diagnostic tool, other than a biopsy, but with 20% to 50% "false negatives" from biopsies, and 98% to 100% positive predictive value for MRIs (based on NIH data), the physicians ought tell the patients of the closeness of those alternatives. (Id at 253, 254). [But see his deposition answer at id 254, 255.] Must have an MRI to avoid a "guessing game." (Id at 256).

For patient G.P., looking at his chart, Spectroscopy shows a "moderate" risk assessment, but findings are "suspicious for prostate cancer." (Id at 257, 258). For patient J.W., the radiologist's impression is "a lesion that's suspicious for prostate cancer," but doesn't commit to prostate cancer. (Id at 260). But Dr. Wheeler gives his patients a "percentage chance" of cancer, (Id at 261), because we do not often or always get absolute proof, as negative biopsies proved. (Id at 262). For patient K.S., the radiologist's report shows "clinically significant disease is likely to be present," not definitively prostate cancer. (Ibid.). For patient V.P., the radiologist found "clinically significant cancer is equivocal" and "amenable to MRI-targeted biopsy,"

but not prostate cancer. (Id at 263). Although MRI is in many cases absolutely correct, one must consider "the entire clinical picture." (Id at 264). A PIRADS of 3 is less certain, whereas a PIRADS of 4 is more certain. (Ibid.). And as to the $25,000-$30,000 cost of HIFU, Dr. Wheeler gets very little due to costs of the facility and ancillary providers. (Id at 272).

At bottom, tissue biopsy is 100% definitive diagnosis "when it hits the target,..." (Id at 274) but they have a 20% to 50% "false negative rate,..." (Ibid.). In short, as to biopsies:

> I will never debate that it's not the standard of care. And it's very definitive when they hit it [the cancer]. The problem is, they don't hit it all that often. (Id at 276).

Thus, the physician must employ all tools and look at every piece of information clinically, and make an assessment to provide an opinion. (Ibid.).

The 3T MR, mpMRI, is "extremely complementary," and Dr. Wheeler's role *vis-à-vis* patients G.P., K.S., J.W., and V.P., is to tell the truth. (Id at 277). Dr. Wheeler's opinion about physicians' "dereliction of duty" appears at Tr. 278-279.

Finally, Appellee took the deposition of Dr. Savat C. Sabharwal, an expert witness, licensed in Illinois, Missouri, and Florida since 2013, specializing in Urology in which he is Board Certified. (Depo, pp 007-3010) being Pet. Exhibits 10, I 790. He does HIFU (Id at 014), and has observed Dr. Wheeler doing 10 to 25

HIFU's at Orlando's "Center for Digestive and Liver Disease" facility. (Id at 018). He — like Dr. Donahue — knows of the standard-of-care by education, current literature, his experience. (Id at 021). At 023-024, he opined that no procedure alone "is definitive" of prostate cancer: facts are few, but opinions abound. So, MRI is a newer test and "different urologists rely on different tests." (Id at 026). Is biopsy better than MRI?--"That's changing." (Id at 027). Biopsy is "the traditional teaching," (Id at 028) and diagnosing cancer without biopsy is not below the standard-of-care. He discussed other Urologists' opinions and cases. (Id at 029-032). Treatment of cancer without biopsy?--"Absolutely yes." (Id at 036-037). He has performed many HIFU's, including in Orlando (Id at 045), and it has fewer side effects than biopsy. (Id at 046-047). He has started agreeing with Dr. Wheeler that one gets a better diagnosis from MRI: as per England, National Cancer Institute, and University of Central Florida trial. (Id at 049-050). So, the standard-of-care is "a myriad of options." (Id at 051). Biopsies "quite often" miss the cancer and yield "false negatives." (Id at 060-061).

Yet, even Dr. Sabharwal expresses his own disagreements with Dr. Wheeler's opinions.

The patient records of the four patients are Joint Exhibits 1-8.

The prevailing standard-of-care — pre-dating high magnetic resonance imaging — is needle tissue biopsy with a "false-negative" rate of 20%-50%. And nothing in

the literature or testimony negates the evolved and evolving diagnostic excellence of such imaging. Dr. Wheeler offers biopsies and tells patient the truth of the risk, and offers the latest 3T MRI diagnostic, in the context of all clinical evidences of prostatic disease (not just cancer).

See "Professional Power and the Standard of Care in Medicine," ARIZONA STATE LAW JOURNAL (2012) at 1170: "... Disputes within the profession have revolved around whether there is a single, correct approach to patient care, or instead a number of correct approaches..." Also, pp. 1173, 1178, 1182, 1185-1186

And, as do other urologists, he considers family history, digital rectal examination, PSA levels, chemical coordinates, tissue ablation; and discusses same with patients. His HIFU treatment, based upon a concordance of all evidentiary data, has few predictable side effects.

There is in this record no "clear and convincing evidence" -- which is beyond preponderance -- of medical malpractice by Dr. Wheeler after 25 years specializing in prostate cancer. *Slomowitz v. Walker*, 429 So.2d 797 (Fla. 4th DCA 1983), *inter alia*. Under no statute has Dr. Wheeler malpracticed.

We attorneys are often qualified in court to give "expert" opinion of "reasonable (attorney) fees," and know that there is no once-for-all "reasonable" fee. It depends upon Locale, Work reasonably required, Qualifications of the attorney, Work actually done and its value in the case, *etc*. Thus, as Dr. Sabharwal stated

realistically, medical diagnosis presents, as to standard-of-care, "a myriad of options" (Id at 060-061) as medical science evolves.

The FINAL ORDER of the Board of Medicine ought, for the foregoing reasons inclusive of a want of "clear and convincing evidence" of malpractice, be reversed and the case(s) be dismissed.

ARGUMENT II

THE PENALTY OF LICENSE REVOCATION (Plus $79,993.30 in costs per an affidavit, and $30,000 in fines) SHOCKS THE JUDICIAL CONSCIENCE:

[Standard of Review: *De Novo*:

United States v. Bajakajjan, 524 U.S. 321, 336-337 (1998); *State of Florida v. Jones*, 180 So.3d 1085, 1088 (Fla. 4th DCA 2016); *Benjamin, etc. v. Tandem Healthcare, Inc.*, 998 So.2d 566, 570 (Fla. 2008); *Zingale v. Powell, et al.* (Fla. 2004), *reh. den.*; *Ocean Mile Galleries, Inc., et al. v. Huqucnos, et al.*, 351 So2d 1043 (Fla. 4th DCA 1977); *Sutton v. Logan* 184 So.2d 662 (Fla. 1st DCA 1966); *Mary MacLaughlin, et al. v. Red Top Cab & Baggage Co.*, 133 So2d 560 (Fla 3rd DCA 1961), *reh. den.*]

This argument arises in respect of Amendment VIII, Constitution of the United States and Article I, §17, Constitution of the State of Florida regarding excessive punishments.

We are herein concerned with a specialist in prostate disease who, in 25 years of discipline-free practice on the leading edge of the evolved and evolving practice and technology, is outspoken in his beliefs and their sources — which expression the Administrative Law Judge ruled to deprive him of credibility. And which the Board of Medicine (Appellee) adopted.

In 2014 upon the DOH complaints re. three of these four patients, before any hearing or findings, the Appellee Board rejected the DOH's proposal for settlement and excoriated this Appellant for his views. See, Appellant's Motion For Stay (denied by This Honorable Court).

Dr. Wheeler's leading work on MRI imaging, prescription of prostate-shrinking medications, *etc*., congruent with the other testifying urologists' practices, and HIFU ablationary use as also done by others, herein led to no permanent injury apart from predictable side effects discussed with all patients.

Thus, in the teeth of "disputes" among physicians relating to traditional, evolved, evolving standards-of-care, of which there are "myriad," as herein before briefed, Dr. Wheeler's license to practice medicine was revoked!

A disproportionate penalty, excessively harsh, and which ought shock the conscience of the Court. And a penalty predicated upon evidence which clearly fell short of the "clear and convincing" evidence of malpractice required for the ultimate penalty of revocation of his medical license (in which he has had a most significant property interest).

To put the state's imprimatur upon this "bridge too far," would be to signal dramatically a stifling of the progress of medical science, and to select governmentally one traditional (but already changing) view of standard-of-care.

As Johns Hopkins' physicians S. Denmeade and J. Issacs observed in the May 2002 issue of NATURE REVIEWS CANCER publication, there have been "remarkable changes in diagnosis and treatment [of prostate issues] over the past century..." Indeed, vivifying the evolution of prostate diagnostics, the JOURNAL of the NATIONAL CANCER INSTITUTE, Vol. 101, Issue 19, notes that PSA screening itself was first introduced in the U.S. as recently as 1987.

Although the prostate gland itself was first described by N. Massa in 1536, the prostatectomy procedure first occurred in 1904 at Johns Hopkins; and by mid-century that procedure was widely replaced by transurethral resectional prostate (TURP). Reduction of testosterone as a PSA-elevator came to the fore in C. B. Higgins' 1941 study.

Medical science is defined by evolutionary improvement. After all, bleeding by leeches was a treatment of reputable doctors!

The Cancer Treatment Centers of America notes, "MRI plays an important role in cancer diagnosis...," [copy appended] even as Biopsy "compared with other diagnostic tests for cancer ... often provide a more definitive diagnosis..." [Emphasis supplied].

Appellant Wheeler must not be sacrificed upon a cross of Static Science.

If, after review of the proceedings below and the exhibited expressions of the changes in medical beliefs, this Honorable Court should decline to reverse outright the Final Order of the Board of Medicine — as urged under Argument I, *supra* herein — then at the very least the penalty imposed by the Appellee Board of Medicine ought be reversed, and the cause remanded for consideration of a more reasoned and reasonable penalty.

CONCLUSION

For the foregoing reasons the Final Order of the Board of Medicine (Appellee) ought be ruled prejudicially and reversibly to have erred, and ought be reversed.

This Initial Brief is filed in good faith by undersigned counsel who, in 2015, with elevated PSA underwent a routine Biopsy of the prostate which issued in massive infection, urethral stricture, Vasculitis (bleeding arteries), catheterization for one week shy of 12 months, hospitalizations with blood clots of the lungs — and finally in 2016 one Mayo Physician who, after tissue ablation, took an alternate track and cured this patient. The 2015 physician and the 2016 physician were both fine doctors.

The Final Order below ought be reversed and the cause(s) dismissed.

Alternatively, if said Final Order is not reversed and the cause(s) dismissed, the Final Order ought be reversed and this cause remanded to the Board for a more reasoned and reasonable penalty.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the forgoing was furnished to Sarah Young Hodges, Esq. of Florida Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399 at Sarah.Hodges@flhealth.gov and Katelyn R. Levine, Esq. of Florida Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399 at Katelyn.Levine@flhealth.gov this 27th day of June, 2017.

Stephen Marc Slepin, Esquire

CERTIFICATE OF COMPLIANCE

I certify that this document is being submitted in Times New Roman 14-point font in compliance with the font requirements of the Florida Rules of Appellate Procedure.

Stephen Marc Slepin, Esquire

APPELLATE PROFFER

Cancer Treatment Centers of America: MRI article

Cancer Treatment Centers of America: Biopsy article

Dr. Wheeler's response to the appellate ruling:

In March, 2018, I received the worst news of my life. The State of Florida Appellate Court represented by 3 Judges or the equivalent of Pontius Pilate times 3 came to the same decision that Mary Creasy, the misguided, premeditated, fabricating and under-educated Administrative Law Judge had stated. In effect, her decision was affirmed by them. None of the 3 evil Judges felt they had to explain themselves. Sadly, all 4 of these individuals need to retire as their common sense has left them and they are collectively too old to learn anything more. In effect, all 4 Judges have agreed that I told four men the probability that prostate cancer was likely, based on a 3.T MP-MRI report generated by a very qualified Radiologist. Unfortunately, I am the fall guy despite merely reading the report to the patients individually. As a doctor, I would have been derelict of my duty had I not told these 4 patients what the scan indicated. With a diseased prostate, the FDA has stated that no biopsies are required if High Intensity Focused Ultrasound is used. Equally unfortunate is the legal system in Florida does not understand or appreciate a patient's right to freedom of choice or freedom to decide when it comes to avoiding a biopsy. A biopsy of the prostate is commonly associated with hospitalization associated with sepsis. The less fortunate have to accept dying as a consequence of their decision to have a biopsy rather than imaging. Few doctors will tell a patient that upwards of 50% of biopsies are falsely negative meaning the biopsies missed the cancer.