STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,

Petitioner,

vs. Case Nos. 16-6136PL
16-6148PL
RONALD EVAN WHEELER, M.D., 16-6149PL
16-6150PL

Respondent.
_____/

RECOMMENDED ORDER

Pursuant to notice, a formal administrative hearing was conducted before Administrative Law Judge Mary Li Creasy by video teleconference with locations in Sarasota and Tallahassee, Florida, on December 8, 2016.

APPEARANCES

For Petitioner: Jack F. Wise, Esquire
Department of Health
Bin C-65
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Tallahassee, Florida 32399

For Respondent: Christopher J. Schulte, Esquire
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STATEMENT OF THE ISSUES

Whether Respondent, a licensed physician, violated the applicable standard of care by diagnosing prostate cancer in four patients, and recommending and participating in a course of treatment for these patients, without confirming prostate cancer through tissue biopsy results; and, if so, what is the appropriate penalty?

PRELIMINARY STATEMENT

On March 21, 2016, Petitioner, Department of Health, Board of Medicine, referred the four above-captioned cases seeking disciplinary sanction of the medical license of Respondent, Ronald Evan Wheeler, M.D., to the Division of Administrative Hearings (DOAH). On the next day, DOAH assigned Administrative Law Judge J. Lawrence Johnston to conduct the proceeding. These four cases were consolidated on March 23, 2016, and the matter was set for hearing for June 15 through 17, 2016.

This matter was continued until August 17 and 18, 2016, and was transferred to the undersigned on August 9, 2016. On August 12, 2016, the parties reached a proposed resolution and filed a Joint Motion to Relinquish Jurisdiction Without Prejudice, which was granted.

On October 14, 2016, Petitioner filed a Motion to Re-Open Proceeding because a final agreement was not reached. The motion

was granted and the matter was re-opened and re-set for December 8 and 9, 2016.

The hearing was held as scheduled on December 8, 2016. Joint Exhibits 1 through 8 were admitted into evidence. At the hearing, Petitioner presented the testimony of Dennis Donahue, M.D., its expert witness. Petitioner's Exhibits 1 through 14 were admitted into evidence.

Included in Petitioner's exhibits were the deposition transcripts of Patients G.P., J.W., K.S., and V.P., offered in lieu of live testimony. Petitioner also provided the transcripts of the Patients' other physicians: Joel Gelman, M.D. (physician for Patient G.P.); M. Eric Brewer, M.D. (physician for Patient J.W.); Jeffrey Jump, M.D. (physician for Patient K.S); and Vipul Patel, M.D. (physician for Patient V.P.). Also included was the deposition transcript of Sarat Sabharwal, M.D., a board-certified urologist, who was identified as an expert by Respondent.

Respondent testified on his own behalf and presented the testimony of Stephen Leslie, M.D., as an expert witness. Respondent's Exhibits 1 through 6 and 8 through 20 were admitted into evidence.

A two-volume Transcript of the proceeding was filed on January 9, 2017. Both parties filed timely proposed orders,

which were given due consideration in the preparation of this Recommended Order.

Unless otherwise indicated, citations to the Florida Statutes or rules of the Florida Administrative Code refer to the versions in effect at the time of the alleged violations.

FINDINGS OF FACT

1. Petitioner is responsible for the investigation and prosecution of complaints against medical doctors licensed in the state of Florida, who are accused of violating chapters 456 and 458 of the Florida Statutes.

2. Respondent is licensed as a medical doctor in Florida, having been issued license number ME 46625.

3. Respondent is not board-certified in any specialty recognized by the Florida Board of Medicine.

4. Respondent has never had disciplinary action against his license to practice medicine.

Respondent's Practice

5. Since his residency concluded in 1985, Respondent has practiced urology. For more than 20 years, the focus of his practice has been prostate disease, its diagnosis, and treatment.

6. In 2006, Respondent became the lead investigator for a General Electric study regarding its 3-Tesla magnetic resonance spectroscopy imaging machine (3T MRI-s) as part of an

Institutional Review Board measuring the heat generated by the machine to ensure the safety of patients.

7. Between 2006 and 2010, 1,600 prostates were scanned with a 3T MRI-s as part of the study. Respondent reviewed the results of each radiology report associated with these scans and compared them to the clinical data he had for each patient. Respondent also completed a double-blind study of 200 of these patients who had prostate biopsies during 2008 and 2009, as well as the 3T MRI-s, correlated the results of the biopsies and the scans, and became convinced that the 3T MRI-s technology alone is a positive predictor of prostate cancer 95 percent of the time.

8. According to both parties' experts, as well as Respondent, the standard of care in Florida and throughout the United States is to use a needle tissue biopsy to identify prostate cancer. As admitted by Respondent, medical schools teach that needle biopsy is "the way" to diagnose prostate cancer. Absent a biopsy showing malignant tissue, it is not possible for a reasonably prudent physician to diagnose or treat prostate cancer. Biopsies are usually performed to diagnose prostate cancer if a man has a combination of risk factors, such as family history, an abnormal digital rectal exam, and/or increasing levels of Prostate Specific Antigen (PSA).

9. However, needle biopsies for prostate cancer carry a false negative rate of 20 to 50 percent, which means that a

standard 12-point needle biopsy (where 12 samples of tissue from different locations in the prostate are sampled) often misses cancerous tissue. Prostate needle biopsies are sometimes painful and carry a risk of complications, including common complications such as bleeding and infection, and the unlikely complications of septic shock and death.

10. Respondent is convinced that there is a significant risk from a prostate needle biopsy to spread prostate cancer cells outside the prostate capsule, which is referred to as "seeding" or "needle tracking." Respondent's belief is founded upon a one-page 2002 article published in the American Urological Association, Inc.'s Journal of Urology (Journal), which refers to two cases in which a tumor was discovered in the rectal wall after prostate biopsies and cryoblation.[1/] The tumors were suspected of being the result of needle tracking from prostate cancer biopsies. Significantly, this article makes clear that needle tracking resulting from prostate biopsies are rare and "exceedingly uncommon."

11. Respondent's concern, regarding prostate biopsies spreading prostate cancer, is also in part founded upon a one-paragraph 1991 Journal abstract reporting a Johns Hopkins University School of Medicine study of 350 patients in which needle tracking was suspected in seven patients (two percent).[2/] According to Respondent, his belief that prostate biopsies spread

prostate cancer is "intuitive," although he acknowledges this is not the prevailing view in Florida. Respondent argues that doctors do not want to believe needle tracking takes place with prostate biopsies and suggests there is a financial motivation for doctors to require a positive biopsy before definitively diagnosing prostate cancer.

12. Respondent is so convinced of the dangers of needle biopsies for prostate cancer that he published a book, Men at Risk: the Dirty Little Secret – Prostate Biopsies Really Do Spread Prostate Cancer Cells, in 2012, which he provides to all his patients. In his book, Respondent states:

> **For me, a 3T MRI scan is the best objective marker to a diagnosis of prostate cancer.**
>
> **To summarize, patients must answer one question. Should I agree to a prostate biopsy procedure where it has been proven to spread prostate cancer cells or do I keep my fingers and toes crossed, hoping for the best? In two words, . . . "absolutely not." To me, the decision is easy – the literature validates avoiding random biopsies and supports imaging with a 3 T magnet.**
>
> There is no other organ in the human body where diagnosis is dependent on sticking needles randomly and blindly into a delicate organ in an attempt to find cancer. **This practice is archaic, patently barbaric, unacceptable and preferentially favored by virtually all urologists.**
>
> Beyond the obvious benefit to being able to see a cancer and its pattern of invasion with the 3.0 Tesla MRI scan, there is no other

> exam or scan that competes in terms of diagnostic accuracy or predictability.
>
> **The discerning patient will soon recognize that guessing where cancer is located, through random biopsies, is for the less informed.**[3]

13. Respondent refers to the use of 3T MRI-s as the "truth serum" of prostate cancer diagnosis. During all times material hereto, Respondent held himself out as a urologist who could diagnose and treat prostate cancer without a needle biopsy. In fact, the four patients at issue in this case found Respondent through an Internet search. Respondent defines his office, the Diagnostic Center for Disease (DCD) as, "A comprehensive prostate cancer diagnostic center in Sarasota, Florida specializing in non-invasive diagnostics (MRI/MRIS) without biopsy as an integral part of the diagnostic evaluation of prostate cancer."[4/]

14. Respondent also advertised himself as "a world expert in High Intensity Focused Ultrasound (HIFU), having diagnosed and treated more patients for prostate cancer from more countries than any other treating doctor in the world."[5/] HIFU is a treatment alternative to brachytherapy (the insertion of radioactive seeds into the prostate), radiation, and prostatectomy (the surgical removal of the prostate gland) for prostate cancer and uses highly focused ultrasound waves in a small area to create intense heat, which destroys prostate cancer tissue. HIFU was not an approved treatment for prostate cancer

in the United States until October 9, 2015, at which time the Food and Drug Administration (FDA) approved the use of the Sonablate machine for prostate tissue ablation. Prior to that time, Respondent referred his patients to treatment facilities in Mexico and the Caribbean where he performed HIFU treatments.

15. The standard of care in Florida precludes treating prostate cancer with HIFU in the absence of a tissue biopsy confirming the presence of cancer. In order to be eligible for HIFU treatment, in addition to a positive diagnosis, the patient's prostate gland must be less than 40 grams. HIFU is not appropriate on patients with multiple calcifications in their prostate because they interfere with the treatment.

16. Because a smaller prostate gland is easier to work with, prior to undergoing HIFU treatment, patients are often prescribed Bicalutamide (also known by its brand name, Casodex) and Trelstar. Bicalutamide suppresses the uptake of testosterone and Trelstar suppresses the production of testosterone, with both drugs having the effect of shrinking the prostate gland. Side effects of these drugs include hot flashes, weakness, and a sense of a loss of well-being.

Facts Related to Patient G.P.

17. Patient G.P., a 69 year-old retiree, had a prostate biopsy performed in December 2005 after a rise in his PSA level. This biopsy was negative for prostate cancer, but Patient G.P.

was diagnosed with an enlarged prostate and benign prostate hyperplasty (BPH).

18. In May 2008, Patient G.P. learned through a physical exam for a life insurance policy that his PSA level was elevated. After another check of his PSA level in November 2008, Patient G.P. was advised to undergo another prostate biopsy. Because his first prostate biopsy was painful, Patient G.P. searched the Internet for alternatives to biopsy and learned of Respondent and his use of the 3T MRI-s at the DCD in Sarasota for diagnosing prostate cancer.

19. Patient G.P. traveled to Florida from Michigan to meet with Respondent on January 5, 2009. Patient G.P. underwent a 3T MRI-s scan at Respondent's office. Respondent told Patient G.P. that he was unsure of the results because they were consistent with BPH and not prostate cancer. However, Respondent advised Patient G.P. was considered "high risk" because his father died from prostate cancer in 2002. Rather than undergoing any treatment at that time, Patient G.P. was prescribed Avodart for his BPH and agreed to active surveillance (A.S.) whereby he would receive regular PSA screening.

20. When Patient G.P.'s December 2009 PSA level went up after being on Avodart for most of the year, he was concerned and telephoned Respondent's office. Respondent prescribed Casodex

based upon his telephone call with Patient G.P. on January 15, 2010.

21. By February 2010, G.P.'s PSA level decreased significantly, but not as much as he believed it should have after taking Casodex for several weeks. Patient G.P. also experienced urinary frequency problems and pain. He returned to Respondent's office where Respondent performed an ultrasound and digital rectal exam. Respondent told Patient G.P. it was likely he had prostate cancer, but that he could not be sure without a biopsy. However, Respondent's medical records reflect that Respondent diagnosed Patient G.P. as having prostate cancer without a tissue biopsy.[6/] Respondent offered to do a targeted biopsy based on an MRI scan. Respondent also discussed his concerns regarding needle tracking from biopsies with Patient G.P.

22. Patient G.P. made it clear he did not want a biopsy, and he wanted to proceed to HIFU. Respondent advised Patient G.P. of the risk of erectile dysfunction following HIFU, but did not discuss the possibility of urinary stricture problems.

23. In April 2010, Patient G.P. traveled to Mexico where the HIFU procedure was performed by Respondent. In March 2011, Patient G.P. saw a urologist in Michigan about his diminished urinary stream and pain. The urologist used a reamer to open Patient G.P's urethra, but on April 15, 2011, he went to the

emergency room because he was completely unable to urinate. Patient G.P. was catheterized and subsequently underwent electro-vaporization on April 25, 2011, to relieve the urinary stricture. In August 2011, Patient G.P. also underwent hydro-dilating in an attempt to relieve the symptoms of his urinary stricture.

24. In September 2011, Patient G.P. saw board-certified urologist Dr. Joel Gelman, who specializes in urethral reconstruction. At that time, Patient G.P. was advised that his urinary stricture, caused by the HIFU treatment, was a significant problem because his urethra was closed off almost to the bladder neck. Dr. Gelman performed a transurethral resection of the prostate (TURP).

25. As part of the TURP procedure, Dr. Gelman took samples of Patient G.P.'s prostate tissue and no evidence was found of prostate cancer. Although Patient G.P. had no complaints regarding his course of treatment from Respondent, Dr. Gelman filed a complaint against Respondent because he was concerned that Respondent prescribed medications and performed HIFU on Patient G.P. for prostate cancer without a tissue biopsy.

Facts Related to Patient J.W.

26. Patient J.W., a 74 year-old retired dentist, had two biopsies performed in 2005 and 2007 ordered by his urologist in

Alabama in response to elevated PSA levels. No evidence of malignancy was found.

27. Patient J.W.'s PSA level was again elevated when tested in March 2012. He was reluctant to have another biopsy because the first two were painful. Patient J.W. was told about Respondent by a friend, and he viewed Respondent's website. Patient J.W. was interested in consulting with Respondent because Respondent advertised he had an MRI machine that could detect cancer cells, and Respondent believed prostate biopsies spread cancer.

28. Patient J.W. traveled from Alabama to meet with Respondent at the DCD on May 14 and 15, 2012. After a sonogram and MRI, Respondent diagnosed Patient J.W. with prostate cancer. Respondent discussed a treatment plan which included what Respondent called "chemical castration" for a period of six months, to be followed with a trip to Mexico for HIFU treatment at the cost of $32,000.00. Respondent did not suggest any other treatment options to Patient J.W. or recommend a tissue biopsy.

29. The idea of "chemical castration" scared Patient J.W., who sought a second opinion in June 2012 from another urologist, Dr. M. Eric Brewer. Dr. Brewer told J.W. that HIFU was not an accepted treatment in the United States for prostate cancer. Patient J.W. declined to go forward with treatment by Respondent. Dr. Brewer recommended A.S. and, as recommended by Dr. Brewer,

Patient J.W. has his PSA level checked every six months. Patient J.W.'s PSA levels have decreased without any treatment.

30. Dr. Brewer discussed Patient J.W.'s case with his partners, the tumor board, the president of the Southeastern Urological Association, and the president of the American Board of Urology, who unanimously advised Dr. Brewer to file a complaint with Petitioner against Respondent for cancer diagnosis and recommending treatment in the absence of a pathologic specimen.

Facts Related to Patient K.S.

31. Patient K.S. is a 62-year-old video producer and editor from Tennessee. He has no family history of prostate cancer. Patient K.S. had his PSA level tested in 2005 and 2009, at which time it was considered elevated.

32. Patient K.S. was referred to a urologist by his primary care physician. After again showing elevated PSA levels, Patient K.S. underwent a prostate biopsy in 2011 and 2012. Neither biopsy was positive for prostate cancer. However, Patient K.S. and his wife were concerned about his rising PSA level and sought a second opinion.

33. Patient K.S.' wife was concerned that if her husband had prostate cancer, his local urologist would recommend removal of the prostate. She researched alternative treatments on the Internet and found Respondent's website.

34. On October 15, 2012, Patient K.S. and his wife traveled to the DCD in Sarasota to meet with Respondent. Respondent initially performed an ultrasound on Patient K.S. and then told Patient K.S. he was "concerned" Patient K.S. had prostate cancer. He recommended HIFU treatment to Patient K.S.

35. Respondent made it clear to Patient K.S. that Respondent would not perform a needle biopsy because it pushes cancer further into the prostate. Respondent told Patient K.S. that the MRI would make it clear whether Patient K.S. had prostate cancer. Later that same day, Patient K.S. had an MRI performed at the DCD.

36. Approximately a week later, Patient K.S. received a telephone call from Respondent with the MRI results who told Patient K.S. that based on the MRI, he had Gleason 7 prostate cancer, a fairly aggressive form of prostate cancer that could be treated with HIFU in Mexico the following month. This was followed up with an e-mail from the DCD to Patient K.S. demanding a payment of $32,000.00 within three days to schedule the HIFU procedure in Mexico. Patient K.S.' wife immediately secured a bank loan for the $32,000.00

37. Due to the seriousness of the diagnosis and the rush for payment for HIFU, Patient K.S. visited his primary care doctor for another opinion. Patient K.S' primary care doctor, Dr. Jeffrey Jump, told him that no one can diagnose prostate

cancer as a Gleason 7 without a tissue biopsy. Further, it was a "red flag" to Dr. Jump that a cash payment of $32,000.00 was expected in such a short time frame to schedule treatment.

38. After speaking to Dr. Jump, Patient K.S. decided not to have HIFU and instead opted for A.S. Subsequent PSA level tests for Patient K.S. have shown a decrease in his PSA level. Patient K.S.' wife filed a complaint with the Petitioner against Respondent.

Facts Related to Patient V.P.

39. Patient V.P. is a 63-year-old construction worker and guide from Alaska. He has no family history of prostate cancer.

40. In August 2013, at age 60, Patient V.P. had his first physical examination. As part of the exam, he took a PSA test, which showed an elevated PSA level of 6.3. As a result, Patient V.P. was referred to a urologist who recommended a biopsy.

41. Patient V.P. heard from friends that prostate biopsies are painful, so he looked on the Internet for alternatives. Patient V.P. found Respondent's website, which claimed Respondent could diagnose prostate cancer without a biopsy by using new MRI technology.

42. Patient V.P. traveled to Sarasota to meet Respondent on September 11, 2013. Respondent performed a digital rectal exam and told Patient V.P. that his prostate was much enlarged.

43. Respondent next performed a prostate ultrasound on Patient V.P. Immediately after the ultrasound, Respondent told Patient V.P., "I'm telling you right now you have prostate cancer." Respondent provided Patient V.P. with a prescription for Bicalutamide and Trelstar, which Respondent said would wipe out Patient V.P.'s testosterone and slow the growth of the cancer.

44. Respondent told Patient V.P. that prostate biopsies are dangerous and metastasize cancer cells. Respondent said that even though he knew Patient V.P. had cancer, he wanted an MRI to see the amount of cancer. Respondent also offered Patient V.P. the opportunity to participate in a private placement offering for a HIFU company he was forming for a minimum investment of $50,000.00.

45. The following day, Patient V.P. had an MRI and then met with Respondent to review the results. Respondent showed Patient V.P. his MRI images and pointed to areas of concern. Respondent told Patient V.P. he had extensive prostate cancer and that Patient V.P. did not have much time to decide whether to have HIFU because the cancer was about to metastasize.

46. Respondent told Patient V.P. to take the Bicalutamide for ten days and then return for an injection of Trelstar to atrophy his prostate and make him ready for HIFU in 90 days.

47. At Respondent's direction, Patient V.P. began the Bicalutamide and then returned to the DCD on September 20, 2013, for a three-month injection of Trelstar. During this visit, Patient V.P. questioned the cost if the HIFU was not successful in getting all the cancer and he needed further treatment. Respondent told Patient V.P. that he "doesn't miss," but an additional treatment of HIFU would cost another $10,000.00 to $12,000.00, in addition to the $32,000.00 for the initial treatment.

48. Concerned about these costs, Patient V.P. asked about going to Loma Linda, California, for proton therapy as an alternative. Respondent told Patient V.P. that proton therapy would cause bladder cancer and any alternative to HIFU would require a needle biopsy first. Respondent actively discouraged Patient V.P. from any non-HIFU treatment for prostate cancer.

49. As soon as Patient V.P. questioned Respondent about alternatives to HIFU, he was suddenly fast-tracked for HIFU scheduled October 24 through 26, 2013. He was told he needed to make a $10,000.00 deposit to hold the date and the total cost was $32,000.00.

50. Despite his concerns regarding the expedited scheduling of his procedure and the cost of the HIFU treatment, Patient V.P. returned to the office with a check for $10,000.00 to cover the cost of the deposit to hold the October treatment date. While

waiting to hand the check to Respondent's receptionist, Patient V.P. overheard Respondent on a speakerphone arguing with a radiologist concerning an MRI report. Respondent was insisting the radiologist include the word "cancer" on MRI reports and the radiologist insisted it was not possible for him to make such a diagnosis. After hearing this conversation, Patient V.P. immediately left Respondent's office with his check.

51. Patient V.P. subsequently discussed his experience with a trusted friend who practiced as a nurse in a cancer clinic. She, too, expressed concerns about diagnosing and treating prostate cancer without a biopsy. Patient V.P. was referred by this friend to Dr. Vipul Patel, a physician specializing in urologic cancer in Orlando.

52. Patient V.P. met with Dr. Patel on October 18, 2013. Dr. Patel advised Patient V.P. that it was not possible to diagnose prostate cancer without a biopsy. Dr. Patel also disputed that prostate biopsies can spread prostate cancer.

53. Dr. Patel performed a digital rectal exam and found Patient V.P.'s prostate to be slightly enlarged (which is not abnormal for a man of Patient V.P.'s age), normal, and smooth. Dr. Patel told Patient V.P. that he doubted he had prostate cancer. Patient V.P. then underwent a prostate biopsy by Dr. Patel, which was negative for prostate cancer. This was

surprising to Patient V.P. because Respondent led him to believe, based on the MRI, that his prostate was full of cancer.

54. Patient V.P. experienced significant side effects as a result of taking the medications ordered by Respondent. The Bicalutamide caused Patient V.P. to experience overwhelming depression, shakes, hot flashes, tunnel vision, and headaches. The Trelstar caused erectile dysfunction, increased frequency of hot flashes, night sweats, and made Patient V.P. so weak he was unable to work for eight months.

Standard of Care

55. As discussed above, the experts who provided depositions or live testimony in this case were unanimous in their conclusions that the standard of care in Florida from 2008 through 2013 precluded diagnosis or treatment of prostate cancer in the absence of a tissue biopsy. A reasonably prudent physician would not tell a patient he had prostate cancer based upon an ultrasound and/or MRI. A reasonably prudent physician would not prescribe medication, suggest treatment, or participate in treating a patient for prostate cancer, based upon an ultrasound or MRI.

56. Respondent claims that in each of these cases, he advised the patient that a needle biopsy was the definitive test for prostate cancer, but it was a method he did not favor due to the possibility of needle tracking. Respondent's testimony in

this regard is not credible in light of the credible testimony of the three patients that Respondent made clear he would not perform a needle biopsy and actively discouraged them from anything other than diagnosis by MRI and subsequent HIFU treatment. Respondent's suggestion, that he offered needle biopsy as an option, is wholly inconsistent with the title, theme, and contents of his own book, and the manner in which he defined his method of diagnosing prostate cancer at the DCD in his book and on his website.

57. It is self-evident that a patient's perceptions regarding the safety and efficacy of needle biopsies for prostate cancer detection are at least, in part, influenced by the discussion with the physician. Respondent's active efforts to dissuade these patients from having the one definitive test for prostate cancer, by dramatically over-inflating the infinitesimally small possibility of needle tracking, were wholly inconsistent with the standard of care.

58. Respondent claims that these four patients insisted they did not want a needle biopsy, therefore, it was appropriate to diagnose them on the basis of "a preponderance of the evidence and concordance of data" and move forward with a treatment plan, including medications and HIFU.

59. The standard of care in Florida during 2008 through 2013, for a situation in which a patient suspected of having

prostate cancer refused a needle biopsy, was to prescribe a course of A.S., including regular and frequent PSA testing, and to offer no other treatment.[7/]

Ultimate Factual Determinations

60. Petitioner established by clear and convincing evidence that Respondent committed medical malpractice in his treatment of Patients G.P., J.W., K.S., and V.P. by the following violations of the standard of care:

> a. failing to obtain and review prostate biopsy results before confirming the patient had, or diagnosing the patient with, prostate cancer (Patients G.P., J.W., K.S., and V.P.);
>
> b. prescribing Bicalutamide/Casodex to a patient without first confirming through a prostate tissue biopsy that the patient has prostate cancer (Patients G.P. and V.P);
>
> c. prescribing, injecting, or authorizing the injection of Trelstar to a patient without first confirming through biopsy results that the patient has prostate cancer (Patient V.P);
>
> d. recommending and/or attempting to facilitate HIFU treatment without first confirming through biopsy results that the patient has prostate cancer (Patients G.P., J.W., K.S., and V.P.); and
>
> e. participating in, and/or assisting with the performance of HIFU treatment for a patient without first confirming through biopsy results that the patient has prostate cancer (Patient G.P.).

Accordingly, Respondent is guilty of the offense defined in section 458.331(1)(t), Florida Statutes.

CONCLUSIONS OF LAW

61. DOAH has personal and subject matter jurisdiction in this proceeding pursuant to sections 120.569 and 120.57(1), Florida Statutes.

62. A proceeding to suspend, revoke, or impose other discipline upon a license is penal in nature. State ex rel. Vining v. Fla. Real Estate Comm'n, 281 So. 2d 487, 491 (Fla. 1973). Petitioner must therefore prove the charges against Respondent by clear and convincing evidence. Fox v. Dep't of Health, 994 So. 2d 416, 418 (Fla. 1st DCA 2008)(citing Dep't of Banking & Fin. v. Osborne Stern & Co., 670 So. 2d 932 (Fla. 1996)).

63. The clear and convincing standard of proof has been described by the Florida Supreme Court:

> Clear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

In re Davey, 645 So. 2d 398, 404 (Fla. 1994)(quoting Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983)).

64. Disciplinary statutes and rules "must always be construed strictly in favor of the one against whom the penalty

would be imposed and are never to be extended by construction." Griffis v. Fish & Wildlife Conserv. Comm'n, 57 So. 3d 929, 931 (Fla. 1st DCA 2011); Munch v. Dep't of Prof'l Reg., Div. of Real Estate, 592 So. 2d 1136 (Fla. 1st DCA 1992).

65. The grounds proving Petitioner's assertion that Respondent's license should be disciplined must be those specifically alleged in the Amended Administrative Complaint. See e.g., Trevisani v. Dep't of Health, 908 So. 2d 1108 (Fla. 1st DCA 2005); Kinney v. Dep't of State, 501 So. 2d 129 (Fla. 5th DCA 1987); and Hunter v. Dep't of Prof'l Reg., 458 So. 2d 842 (Fla. 2d DCA 1984).

Medical Malpractice

66. Section 458.331(1)(t) provides that it is a violation for a medical doctor to commit medical malpractice, as defined in section 456.50. Section 456.50(1)(g) defines "medical malpractice" as the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure.

67. Petitioner proved by clear and convincing evidence that Respondent violated section 458.331(1)(t) by falling below the standard of care for doctors in the state of Florida and by failing to obtain a tissue biopsy positive for prostate cancer before: diagnosing prostate cancer; recommending treatment for

prostate cancer; commencing treatment to shrink prostates with medications; recommending HIFU; and performing HIFU.

68. Respondent does not dispute that the existing standard of care is a tissue biopsy for the diagnosis and treatment of prostate cancer.[8/] However, Respondent asserts that he is on the cutting edge of medicine by diagnosing prostate cancer using 3T MRI-s and treating prostate cancer with HIFU, and it is time that the standard of care be modified in accordance with his practice.

69. In support of this contention, Respondent points to several recent articles which support the efficacy of this diagnosis and treatment protocol.[9/] Respondent also cites to section 456.41 which permits physicians to offer complementary and alternative health care treatments to patients.

70. Significantly, the articles relied upon by Respondent were published after the diagnosis and treatment of the patients at issue in this action. Further, these articles do not advocate for the use of MRI technology to diagnose prostate cancer. Rather, they suggest MRI has a developing role in guided prostate biopsy procedures for diagnosis and treatment of prostate cancer and emphasize that further study is needed.[10/]

71. While section 456.41 authorizes a health care practitioner to "recommend any mode of treatment that is, in his or her judgment, in the best interests of the patient, including

complimentary or alternative health care treatments, in accordance with the provisions of his or her license," the practitioner must inform the patient of the benefits and risks associated with the treatment for the patient to make an informed and prudent decision regarding the treatment option. § 456.41(3)(c), Fla. Stat. This section does not "alter, in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care." § 456.41(5), Fla. Stat.

72. Respondent grossly exaggerated the risks of prostate biopsy while shamelessly promoting MRI technology as the premier diagnostic tool for prostate cancer. Respondent lured patients from around the country to Florida with the false promise of a pain-free, accurate diagnostic procedure, and promoted an unapproved, expensive treatment outside the United States.

73. Respondent built his entire business model and advertised his services of prostate cancer diagnosis and treatment without a needle biopsy knowing this violated the standard of care. At a minimum, the conversation between the radiologist and Respondent overheard by Patient V.P. demonstrates that Respondent knew or should have known that prostate cancer diagnosis is not possible with a 3T MRI-s. Respondent is well aware that no other licensed physician in the United States is purporting to diagnose and treat prostate cancer without a tissue

biopsy, other than in exceptional circumstances, which did not exist for these four patients.

74. Whether Respondent was motivated by his sincere, but misguided, belief that prostate biopsies spread cancer, or by greed, is irrelevant to the determination of a violation. Respondent violated the standard of care by telling patients they had prostate cancer without a confirmatory prostate tissue biopsy. Respondent not only failed to disclose to these patients that 3T MRI-s technology cannot definitively diagnose prostate cancer but actively discouraged these patients from obtaining biopsies that we now know would likely show no cancer. Recommending a course of "chemical castration" and HIFU in the absence of a positive tissue biopsy violates the standard of care, constitutes malpractice, and is nothing less than barbaric.

Penalty Assessment

75. Respondent has no prior discipline against his medical license.

76. Petitioner imposes penalties upon licensees consistent with disciplinary guidelines prescribed by rule. See Parrot Heads, Inc. v. Dep't of Bus. & Prof'l Reg., 741 So. 2d 1231, 1233-34 (Fla. 5th DCA 1999).

77. Penalties in a licensure discipline case may not exceed those in effect at the time the violations were committed. Willner v. Dep't of Prof'l Reg., Bd. of Med., 563 So. 2d 805, 806

(Fla. 1st DCA 1990), rev. denied, 576 So. 2d 295 (Fla. 1991). Id.

78. At the time of the incidents, Florida Administrative Code Rule 64B8-8.001(2)(t) provided that for a first-time offender committing medical malpractice, as described in section 458.331(1)(t), the prescribed penalty range was from one year probation to revocation or denial and an administrative fine from $1,000.00 to $10,000.00. The recommended penalty for a second violation of section 458.331(1)(t) ranged from two years of probation to revocation and an administrative fine from $5,000.00 to $10,000.00.

79. Rule 64B8-8.001(3) provided that, in applying the penalty guidelines, the following aggravating and mitigating circumstances should also be taken into account:

> (3) Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. The Board shall consider as aggravating or mitigating factors the following:
>
> (a) Exposure of patient or public to injury or potential injury, physical or otherwise: none, slight, severe, or death;
>
> (b) Legal status at the time of the offense: no restraints, or legal constraints;
>
> (c) The number of counts or separate offenses established;

> (d) The number of times the same offense or offenses have previously been committed by the licensee or applicant;
>
> (e) The disciplinary history of the applicant or licensee in any jurisdiction and the length of practice;
>
> (f) Pecuniary benefit or self-gain inuring to the applicant or licensee;
>
> (g) The involvement in any violation of Section 458.331, F.S., of the provision of controlled substances for trade, barter or sale, by a licensee. In such cases, the Board will deviate from the penalties recommended above and impose suspension or revocation of licensure.
>
> (h) Where a licensee has been charged with violating the standard of care pursuant to Section 458.331(1)(t), F.S., but the licensee, who is also the records owner pursuant to Section 456.057(1), F.S., fails to keep and/or produce the medical records.
>
> (i) Any other relevant mitigating factors.

80. A significant aggravating factor is that Respondent's actions exposed the public, and Patients J.W. and K.S., to potential severe physical injury, and treated Patients G.P. and V.P. resulting in severe injury. Aggravating factor (c) applies because Petitioner established four separate offenses committed by Respondent.

81. This is mitigated by Respondent's prior discipline-free history.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final order finding that Respondent violated section 458.331(1)(t), Florida Statutes, as charged in Amended Administrative Complaints; imposing a fine of $30,000.00; revoking Respondent's medical license; and imposing costs of the investigation and prosecution of this case.

DONE AND ENTERED this 24th day of February, 2017, in Tallahassee, Leon County, Florida.

MARY LI CREASY
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 24th day of February, 2017.

ENDNOTES

[1/] Respondent's Exhibit 18, Theresa M. Koppie, Brian P. Grady, and Katsuto Shinohara, Rectal Wall Recurrence of Prostate Adenocarcinoma, 168 J. of Urology 2120 (Nov. 2002).

[2/] Respondent's Exhibit 19, S.S. Bastacky, P.C. Walsh, and J.I. Epstein, Needle Biopsy Associated Tumor Tracking of

Adenocarcinoma of the Prostate, 145 J. of Urology 1003 (May 1991).

[3/] Ronald E. Wheeler, Men at Risk: the Dirty Little Secret – Prostate Biopsies Really Do Spread Prostate Cancer Cells, pp. 50, 128, 145, 148, 149 (2012).

[4/] Id. at 269.

[5/] Id. at back cover.

[6/] Joint Exhibit 1, page 51, "HIFU – Procedure Report for Prostate Cancer."

[7/] Respondent's expert, Sarat Sabharwal, M.D., suggested that if a patient has a particularly unique medical basis for refusing a needle biopsy, it might be appropriate to treat for suspected prostate cancer. However, Dr. Sabharwal admitted that based upon his review of the medical records of each of these patients, none of them had such a condition that would warrant treatment in the absence of a confirmatory tissue biopsy. Further, Dr. Sabharwal confirmed that "in the time period between 2008 and 2013, any patient that he [Respondent] attempted to treat for prostate cancer without a confirmatory biopsy would have resulted in a deviation from the standard of care." Petitioner's Exhibit 10, 54/25-55/9.

[8/] See Transcript of the final hearing, Vol. 2, 233/12-15; 241/6-22; 248/9-249/8.

[9/] Respondent's Ex. 8, Thomas P, Frye, Amichai Kilchevsky, Arvin K. George, and Peter Pinto, Multiparametric Magnetic Resonance Imaging for Prostate Cancer, 35 AUA Update Series Lesson 14, pp. 137-152 (2016); Respondent's Ex. 9, Baris Turkbey, Anna M. Brown, Sandeep Sankineni, Bradford J. Wood, Peter Pinto, and Peter Choyke, Multiparametric Prostate Magnetic Resonance Imaging in the Evaluation of Prostate Cancer, 66 CA: A Cancer Journal for Clinicians Issue 4, pp, 326-336 (July/Aug. 2016); Respondent's Ex. 10, Robert K. Nam, Christopher J.D. Wallis, Jessica Stojcic-Bendavid, Laurent Millot, Christopher Sherman, Linda Sugar, and Masoom A. Haider, A Pilot Study to Evaluate the Role of Magnetic Resonance Imaging for Prostate Cancer Screening in the General Population, 196 J. of Urology Issue 2, pp. 361-366 (Aug. 2016).

[10/] Frye et al., supra note 9, at 147 ("The potential future use of mpMRI is as a screening test in conjunction with PSA or novel biomarkers to provide a filter to identify patients who may

benefit most from undergoing prostate biopsy. Of course, determining the appropriate screening population will require careful investigation until widespread adoption of this approach can be implemented."); Turkeby et al., supra note 9, at 336 ("There are several challenges facing prostate mpMRI. First, the existing clinical data, although very compelling, cannot be categorized as "Level 1" evidence, as it is largely derived from single-institution studies. Larger, multi-institutional studies are needed before mpMRI becomes the standard of care."); Nam et al., supra note 9, at 364 ("This preliminary study suggests that it may be reasonable to consider prostate MRI for prostate cancer screening, although larger studies are required before implementation . . . In this pilot study, we found that prostate cancer screening using multiparametric prostate MRI is feasible for use in the general population. We propose that prostate MRI should be further evaluated in a prostate screening study.").

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.