STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,

Petitioner,

vs. Case No. 16-4348PL

DOUGLAS M. BURKS, M.D.,

Respondent.
_____/

RECOMMENDED ORDER

On October 12 and 13, 2016, Administrative Law Judge J. Lawrence Johnston held the final hearing in this case in Tampa.

APPEARANCES

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For Respondent: Augustine Smythe Weekley, Esquire
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STATEMENT OF THE ISSUE

The issue in this case is whether the Board of Medicine (Board) should revoke or otherwise discipline the Respondent's medical license for violating section 458.331(1)(t) and (u), Florida Statutes (2011), by using experimental stem cell therapy

that did not meet the standard of care and by not getting the patient's informed consent.

PRELIMINARY STATEMENT

The Petitioner filed an Administrative Complaint charging the violations in August 2015. The Respondent disputed the charges and asked for a hearing. The matter was referred to the Division of Administrative Hearings in July 2016.

At the final hearing, the medical records of patient J.F. were received as Joint Exhibit 1. The Petitioner called Marilyn Glassberg, M.D., as an expert witness, and the Petitioner's Exhibits 1, 2, and 5 were received in evidence. The Respondent testified and called Raghavendra Vijayanagar, M.D., as an expert witness. The Respondent's Exhibits 1, 2, 5, and 11 were received in evidence; objections to the Respondent's other exhibits were sustained.

The Transcript of the hearing was filed on October 31. The parties agreed to file proposed recommended orders by November 30. The proposed recommended orders have been considered.

FINDINGS OF FACT

1. The Respondent is licensed to practice medicine in Florida. He holds license ME 45186. He is a board-certified anesthesiologist.

2. In mid-2011, the Respondent began working at Jouvence Medical in Sarasota and was offered the opportunity to take over the stem cell medicine practice of Dr. Feinerman, who was treating patients with lung disease using an intravenous autologous stem cell procedure. The Respondent had no formal training in stem cell medicine, which is not normally practiced by anesthesiologists, but the Respondent observed Dr. Feinerman perform his stem cell procedure and correctly concluded that he was fully capable of performing it himself. In addition, the Respondent had strong interest in stem cell medicine and gained some knowledge of it from studying literature while seeking stem cell therapy for his elderly father, who has chronic obstructive pulmonary disease.

3. On September 14, 2011, patient J.F. presented to the Respondent at Jouvence with a number of medical issues, including post-polio syndrome and end-stage idiopathic pulmonary fibrosis (IPF). The standard of care for end-stage IPF is supportive management, including oxygen, which was offered and being provided by the patient's primary physician and pulmonologist, who referred the patient to Jouvence for a stem cell treatment that might provide additional health benefits and possibly extend the patient's life, or even cure him.

4. On seeing the patient on September 14, 2011, the Respondent appropriately took his history, reviewed his medical

records and various test results, and offered the autologous stem cell procedure he learned from Dr. Feinerman. The Respondent adequately explained to the patient how the procedure would be performed and how much it would cost. He told the patient that results were not guaranteed, but that some patients reported receiving benefits from the treatment. The patient signed a consent form acknowledging and documenting what the Respondent told him.

5. It certainly was true that the procedure's hoped-for results were not guaranteed, but just saying that was inadequate to inform the patient.

6. The procedure proposed by the Respondent essentially consisted of: a 60 cubic centimeter (cc) blood draw, and intravenous infusion of 150 micrograms (mcg) of Neupogen; concentration of the drawn blood in a centrifuge; and, the next day, peripheral intravenous infusion of 10 cc's of the patient's concentrated blood, together with 100 cc's of saline solution.

7. According to the Respondent, the treatment would confer maximum benefits by delivering mesenchymal stem cells directly into the patient's fibrotic lungs and also by stimulating the patient's bone marrow to produce additional mesenchymal stem cells that would migrate to and concentrate in the lungs. Once in the lungs, the mesenchymal stem cells theoretically would

differentiate and regenerate healthy, non-fibrotic lung tissue to replace fibrotic tissue.

8. Mesenchymal stem cell treatments to regenerate heart tissue have been successful, and it is hoped that these treatments increasingly will replace heart transplants and surgeries. The similar use of mesenchymal stem cells for lung disease is being studied in vigorously regulated and controlled FDA-approved trials, which are experiments on human subjects. Safety trials were held in 2015 and 2016. So far, the trials have not progressed beyond safety trials; trials to determine efficacy have not begun.

9. The FDA-approved trials of stem cell treatments for lung disease are much different from the procedure performed by the Respondent. They involve the extraction, concentration, and characterization of tens or hundreds of millions of mesenchymal stem cells from human donors and the use of those stem cells to treat human subjects. The Respondent's treatment was so different from these trials that it did not even require FDA approval.

10. It was unrealistic for the Respondent to think it likely that the procedure he performed on J.F. would result in regeneration of lung tissue. Blood contains a minimal number of mesenchymal stem cells. Neupogen is a granulocyte colony-stimulating factor that is administered (usually in multiple

doses over a relatively long period of time, especially when administered through the peripheral veins, as done in the Respondent's procedure) to chemotherapy patients to amplify the development of white blood cells called neutrophils. Neutrophils are hematopoietic stem cells, which do not differentiate as mesenchymal stem cells do. The two injections of Neupogen administered in the Respondent's procedure would not be expected to increase the production of mesenchymal stem cells significantly. There was no reasonable expectation that the procedure performed by the Respondent would introduce a significant amount of mesenchymal stem cells into the patient's lungs so as to achieve the maximum hoped-for benefit of regenerating lung tissue.

11. There had been anecdotal reports that patients have benefited from the treatment offered to J.F. by the Respondent. Since the functioning of stem cells in the body was not well known at the time, it was possible that some of the reported benefits are real. It is possible that the introduction of even a small number of stem cells, either mesenchymal or hematopoetic, could reduce inflammation in the lungs and stimulate the production of additional stem cells in the bone marrow. (There also could have been benefits from a placebo effect, even if not intended by the Respondent.)

12. The procedure performed by the Respondent was fairly benign. Since the patient's own blood was being used, there was little or no risk of rejection. There is a risk of infection from any blood draw and infusion. While the risk of infection was relatively small, the harm to a patient in J.F.'s condition from any infection would be significant and could result in the loss of lung tissue. Loss of consciousness was another risk from the procedure that was small but serious for a patient in J.F.'s condition. There also was some risk of pulmonary emboli, albeit small.

13. The patient survived the procedure performed on September 14 and 15, 2011. The evidence was not clear, but it suggested that the patient was neither harmed nor benefited. About a month later, the patient's condition worsened and he died, which was not unexpected given his dire medical condition.

14. After J.F. died, his life partner R.C. asked the Respondent to return the $5,000 he had paid for J.F.'s procedure. The Respondent referred him to Jouvence, which declined to return the money. R.C. filed a complaint with the Department of Health, which investigated and filed the pending Administrative Complaint.

15. Shortly after J.F. died, the Respondent decided to discontinue offering the procedure to similar patients because

the small chance of benefits did not outweigh the risk of infection.

16. As to the charge that the Respondent practiced below the standard of care, the standard of care for the patient J.F. was supportive management, which the patient's other doctors already were providing. The Respondent offered the patient the possibility of a health benefit beyond the standard of care. Although the chances of complete success were extremely small to nonexistent, there was a chance of some health benefits, and the concomitant risks were not clearly unreasonable. The procedure was performed in an appropriate manner in all other respects.

17. As to the charge of experimentation without giving informed consent, the Respondent should have been more forthright in disclosing to the patient that his chances of receiving a medical benefit were very small and that the chances of a cure or an appreciable lengthening of his life were extremely small. It was not enough to say "results are not guaranteed."

CONCLUSIONS OF LAW

18. Section 458.331(1)(u), Florida Statutes (2011), provided that performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent is grounds for discipline by the Board.

19. Section 458.331(1)(t) provided that committing medical malpractice as defined in section 456.50 is grounds for discipline by the Board of Medicine. The Board was required to give great weight to the provisions of section 766.102, Florida Statutes, when enforcing section 458.331(1)(t). Medical malpractice is defined in section 456.50 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. Section 766.102 provided that the prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.

20. In a penal proceeding, the prosecutor must prove the allegations and charges by clear and convincing evidence. Dep't of Banking & Fin. v. Osborne Stern & Co., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

21. Clear and convincing evidence "requires more proof than a 'preponderance of the evidence' but less than 'beyond and to the exclusion of a reasonable doubt.'" In re Graziano, 696 So. 2d 744, 753 (Fla. 1997). As stated by the Florida Supreme Court, the standard:

> [E]ntails both a qualitative and quantitative standard. The evidence must be credible; the memories of the witnesses must be clear and without confusion; and the sum total of the evidence must be of sufficient weight to convince the trier of fact without hesitancy.

In re Davey, 645 So. 2d 398, 404 (Fla. 1994) (citing, with approval, Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983)); see also In re Henson, 913 So. 2d 579, 590 (Fla. 2005). "Although this standard of proof may be met where the evidence is in conflict, it seems to preclude evidence that is ambiguous." Westinghouse Electric Corp. v. Shuler Bros., 590 So. 2d 986, 989 (Fla. 1991).

22. Section 456.41, Florida Statutes (2011), authorized the Respondent to offer and provide complementary or alternative health care treatments. This was defined by statute as "any treatment that is designed to provide patients with an effective option to the prevailing or conventional treatment methods associated with the services provided by a health care practitioner." § 456.41(2)(a), Fla. Stat. "A health care practitioner who offers to provide a patient with a complementary or alternative health care treatment must inform the patient of the nature of the treatment and must explain the benefits and risks associated with the treatment to the extent necessary for the patient to make an informed and prudent decision regarding such treatment option." § 456.41(3), Fla. Stat. The information

communicated can be communicated to the patient orally or in written form, either directly to the patient or to the patient's legal representative. § 456.41(3)(b), Fla. Stat.

23. In 2015, Florida enacted the "Right to Try Act" for eligible patients with a terminal condition. § 499.0295, Fla. Stat. This law specifies the use of medical cannabis but also authorizes the use of any "drug, biological product, or device that has successfully completed phase 1 of a clinical trial," even if it "has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration." § 499.0295(2)(c)1., Fla. Stat Written informed consent is required, to include: an explanation of currently approved products and treatments; attestation that the patient concurs with the physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life; identification of the specific investigational drug, biological product, or device that the patient is seeking to use; a realistic description of the most likely outcomes of using the investigational drug, biological product, or device; a statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the investigational drug, biological product, or device unless

required to do so by law or contract; a statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment with the investigational drug, biological product, or device and that hospice care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements; and a statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless a contract between the patient and the manufacturer of the investigational drug, biological product, or device states otherwise. § 499.0295(2)(e), Fla. Stat. "If an eligible patient dies while using an investigational drug, biological product, or device pursuant to this section, the patient's heirs are not liable for any outstanding debt related to the patient's use of the investigational drug, biological product, or device." § 499.0295(6), Fla. Stat.

24. Section 499.0295, Florida Statutes, does not apply to this case because it was not enacted until 2015. If it did apply, the Respondent would not have met its requirements.

25. The Petitioner did not prove by clear and convincing evidence that the Respondent violated section 458.331(1)(t) by practicing medicine below the applicable standard of care. The procedure performed by the Respondent for the patient J.F. was a

complementary or alternative health care treatment authorized by section 456.41. However, the Respondent did not meet the requirements of that statute because he did not explain the benefits and risks associated with the treatment to the extent necessary for the patient to make an informed and prudent decision regarding the treatment option.

26. The Petitioner proved by clear and convincing evidence that the Respondent violated section 458.331(1)(u) by performing a procedure or prescribing a therapy that would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

27. The Respondent contends that the decision in State Board of Medical Examiners of Florida v. Robert J. Rogers, M.D., 387 So. 2d 937 (Fla. 1980), requires his complete exoneration on all charges. In Rogers, the board reprimanded the physician for performing chelation therapy for arteriosclerosis and ordered him to discontinue the practice, notwithstanding that a definite minority of physicians used chelation therapy, there was no proven risk to patients, and the patients were not being misled about the benefits of the procedure. That made the board's disciplinary action an unreasonable exercise of police power. At least insofar as discipline against the Respondent for not providing J.F. with enough information to give his informed consent, Rogers is distinguishable.

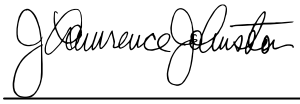
28. Florida Administrative Code Rule 64B8-8.001(2)(a) (Rev. June 21, 2011) provided the range of disciplinary penalties typically imposed for violations of section 458.331(1)(u). Section (3) of the rule provided aggravating and mitigating factors to consider for a deviation from the typical penalty range.

29. Under the rule, the penalties for a violation of section 458.331(1)(u) ranged from a one-year suspension, followed by probation, and 100 to 200 hours of community service, to revocation or denial and an administrative fine of $1,000 to $10,000. Consideration of the aggravating and mitigating factors in the rule warrant a penalty below the guidelines. In this case, probation and a $1,000 fine is all that is warranted.

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 the Respondent guilty of a violation of section 458.331(1)(u); placing him on probation for one year; and fining him $1,000.

DONE AND ENTERED this 20th day of December, 2016, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
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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.