# STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH,	)		
BOARD OF MEDICINE,	)		
	)		
Petitioner,	)		
	)		
vs.	)	Case No.	11-4240PL
	)		
ZANNOS GREKOS, M.D.,	)		
	)		
Respondent.	)		
	)		

## RECOMMENDED ORDER

On October 16 through 19, 2012, a final hearing was held in this case in Naples, Florida, before J. Lawrence Johnston,

Administrative Law Judge, Division of Administrative Hearings

(DOAH).

#### APPEARANCES

For Petitioner: Robert A. Milne, Esquire

Ian Brown, Esquire
Department of Health

Bin C-65

4052 Bald Cypress Way

Tallahassee, Florida 32399-3265

For Respondent: Richard G. Ozelie, Esquire

Law Offices of Richard G. Ozelie, LLC

750 South Dixie Highway

Boca Raton, Florida 33432-6108

#### STATEMENT OF THE ISSUE

The issue in this case is whether the Board of Medicine should discipline Respondent, Zannos Grekos, M.D., on charges

arising out of a stem cell treatment performed on a patient on March 24, 2010, and the subsequent death of the patient.

## PRELIMINARY STATEMENT

Petitioner, Department of Health (DOH), filed an Administrative Complaint against Respondent charging that the stem cell treatment he performed on the patient, D.F., on March 24, 2010, fell below the standard of care; was not justified by the medical records; was performed without the patient's informed consent; was an exercise of influence over the patient to exploit her for financial gain; and was the "wrong" procedure in that it was not medically justified or appropriate. Respondent disputed the charges and requested a hearing, which was provided by DOAH.

At DOAH, the hearing was scheduled and continued three times, discovery was conducted, the Administrative Complaint was amended twice, and a pre-hearing stipulation was filed. At the final hearing, the third count, alleging exploitation for financial gain, was dropped.

At the final hearing, DOH called the following witnesses:

Sara Norden, a DOH investigator; Jeffrey Colino, M.D., a

treating neurologist; J.F., the patient's husband; Ricardo

Parra, a certified vascular technician (CVT); Mark

Moscowitz, M.D., an oncologist; Richard Roland, M.D., a treating

critical care physician at Naples Community Hospital; Manfred

Borges, M.D., the Collier County Medical Examiner; Patrick
Mathias, M.D., a cardiologist; Respondent, both for limited
factual testimony at the hearing and by deposition; Roy
Armbinder, M.D., a hematologist and oncologist; and, by
deposition, Thomas Freeman, M.D., a professor at the University
of South Florida, College of Medicine. Petitioner's Exhibits 1
through 5 and 7 through 18 were received in evidence.
Respondent called the following witnesses: Todd
McAllister, Ph.D., a non-physician expert in stem cell
therapies; Mark May, an emergency medical services (EMS)
technician; Mary Louise Fylstra, Respondent's office manager;
Raymond Lineas, a CVT expert; Jeffrey Colino, M.D.; Respondent's
mother, Effie Grekos; and several of Respondent's stem cell
patients. One Joint Exhibit (Dr. Colino's medical records for
D.F.) was received in evidence.

Transcripts of the final hearing, and of a hearing held on October 31, 2012, on Respondent's objections to the deposition testimony of Dr. Freeman, have been filed. The parties filed proposed recommended orders, which have been considered.

## FINDINGS OF FACT

1. Respondent is licensed as a medical doctor in Florida, holding license ME 61912. His medical practice is in Bonita Springs, Florida. Respondent is board-certified in

cardiovascular disease and board-eligible in internal medicine.
Respondent also performs stem cell treatments.

- 2. D.F. was born February 10, 1941. She first began to see Respondent in October 2007 for numerous medical complaints. She had peripheral neuropathy, secondary to chemotherapy for cancer, and complained of a loss of feeling in her hands and especially in her feet. She also complained of poor balance, inability to walk with an appropriate gait, and diplopia. In addition to Respondent, D.F. saw several other physicians, including a neurologist, but saw little or no improvements.
- 3. In February 2010, D.F. consulted with Respondent to determine whether stem cell therapy, which he advertised, could help her. Respondent proposed an injection of stem cells from her bone marrow, through a catheter, into the arterial circulation of her brain. Respondent told the patient that the treatment possibly could improve her neurological deficits and that she would be no worse off if it did not achieve the desired results.
- 4. Although D.F. had medical conditions that possibly could respond to appropriate stem cell treatment, the evidence was clear and convincing that her peripheral neuropathy would not respond to an injection of stem cells into the brain or central nervous system.

- 5. D.F. signed three "informed consent" forms in early 2010. DOH attempted to prove that there were serious irregularities in some of the consent forms—namely, that patient and witness signatures were forged. DOH did not prove this charge by clear and convincing evidence. The greater weight of the evidence indicated that the signatures on the forms were authentic and valid.
- 6. On February 17, 2010, the patient signed a Consent and Acknowledgement Form for PRP and/or BMAC [bone marrow aspirate concentrate] Procedure. It confirmed the patient's election to undergo "a state of the art treatment that involves using my own adult stem cells . . . with full knowledge of the possible risks and complications that may exist with the procedure." She acknowledged "that though rare, serious risks may be associated with this procedure and may include infection, stroke, heart attack, kidney failure and death."
- 7. On February 20, 2010, the patient signed a Cell Therapy Product Supply Agreement with Regenocyte Worldwide, Inc., a corporation owned and controlled by Respondent and registered in Panama. This agreement informed the patient that she was paying Regenocyte for the cells to be used in her stem cell treatment, as well as Respondent's "facility fees," which would be paid to Respondent by Regenocyte. It also informed the patient that her stem cell treatment "has shown statistically significant

efficacy and safety in the clinical trial sponsored by the cell producer and in patients treated outside the clinical trial." Regenocyte declined to warrant or quarantee the effect of the therapy on the patient. The agreement informed the patient that she was paying for a "product . . . made from your own cells." The agreement defines "Cell Therapy Product" as "a biological product containing Patient's own cells." The patient was cautioned that although the stem cell product would be made from her own cells, it was possible that she could have adverse effects from the procedure or the cells themselves, even though "no adverse effects from the cells have been shown in any patient treated so far with Regenocyte's cells, in or out of our clinical trial . . . " The form had the patient acknowledge that her treatment was "innovative and novel" and that Regenocyte was making no guarantee or warranty as to its effect or that it would cure the patient. Finally, the form had the patient acknowledge her understanding "that though rare, serious risks may be associated with this procedure and may include, but certainly not limited to infection, stroke, heart attack, kidney failure and death." The agreement also had the patient alone assume all risk after careful review of her medical condition. It stated: "Although adverse effects have not been shown in clinical trial with these cells[,] adverse effects and danger exists in all surgical procedures and unknown consequences

related to a new therapy, even autologous (your own cells) therapy." The form had the patient waive all liability, except for negligence or willful misconduct.

- 8. The procedure was scheduled for March 24, 2010, at Respondent's facility. The patient arrived at Respondent's facility before 9 a.m., accompanied by her husband and her friend, Effie Grekos, who is Respondent's mother. There, she signed another form, this one consenting to a procedure described as "bone marrow aspirate [BMA] and delivery of cells" and an angiogram of the carotid arteries "[w]ith full knowledge of the possible risks and complications of the procedure." The form had her also agree: "My doctor has discussed with me the nature and purpose of this procedure, the risks involved, and the possibility of complications with no guarantees or assurance."
- 9. Respondent was delayed and did not arrive at the facility until after noon. At approximately 1 p.m., the patient was taken to the cath lab, sedated, and anesthetized.
- 10. When the procedure began, Respondent used four syringes to aspirate a total of approximately 240 cubic centimeters (cc's) of bone marrow from the iliac crest of D.F.'s hip bone. The bone marrow was aspirated through a 170 to 260 micron-sized blood filter and stored in a standard blood collection bag for later use.

- 11. Respondent then inserted a catheter into a blood vessel in the patient's groin and advanced it up through her circulatory system and, ultimately, to her carotid and vertebral arteries. Via the catheter, he performed a cerebral angiogram with contrast to visualize the carotid and vertebral arteries prior to infusion of the patient's autologous BMA. The angiogram confirmed that there was no blockage, but it revealed that the patient's right vertebral artery was dominant, meaning it was larger and supplied more blood to the brain than the left vertebral artery, which was narrowed by plaque burden. For that reason, the left carotid and left vertebral arteries were not aggressively pursued and were not cannulated for injection of contrast during the angiogram.
- 12. A cerebral angiogram itself is an inherently risky procedure. Even if performed flawlessly, there is a one percent chance that a stroke will ensue. This is because the vasculature in the brain and brain stem is the most delicate and dangerous vasculature in the body. The carotid artery is about seven millimeters (mm) in diameter, the vertebral arteries narrow from about three mm in the neck to about 2.0 to 2.5 mm in the brain, where they become the basilar arteries that supply blood to the cerebellum and medulla via smaller and smaller branches culminating in capillaries that are just 8 to 10 microns (thousandths of a mm) in diameter. Blood cells are

about the same size, meaning they must pass through the capillaries single-file. Anything larger will clog the capillaries and result in a stroke.

- 13. Due to the risks involved, great care must be taken in performing a cerebral angiogram. The contrast used is not thicker than blood and is clear so that it can be determined before injection via syringe that it does not contain any particulate matter, bubbles, blood clots, or anything that could cause a stroke. In addition, the minimum amount of contrast is used-usually not more than eight cc's.
- 14. After the cerebral angiogram, Respondent proceeded to insert the patient's autologous BMA into the catheter in the patient's groin and infused it into the patient's carotid and vertebral arteries, where the BMA entered the cerebral circulation of the patient's brain. The patient's autologous BMA was not filtered again, concentrated, or processed in any manner before infusion.
- 15. BMA is very different from the contrast used in a cerebral angiogram. It is thick, aggregates, and contains not only stem cells but also blood cells and other particulate matter, including fat cells and bone spicules. In the treatment attempted by Respondent, particulate matter naturally occurring in BMA, up to the diameter of the filter used in obtaining the BMA, was allowed to enter into the patient's cerebral

circulation. It was not possible to determine exactly what particulate matter was in the BMA being infused. However, it is clear from the evidence that due to the size of the filter, the size of the blood vessels in the brain where the BMA was infused, and the very large amount of BMA infused in this fashion (at least 180 cc's and perhaps up to 240 cc's), it was virtually inevitable that the procedure would clog blood vessels in the brain and cause a major and very possibly fatal stroke.

- 16. Respondent should have known the grave risk of the procedure he performed on the patient. Instead, he denies the gravity of the risk. He testified that he did not know what would happen as a result of the procedure.
- 17. The procedure ended at 5:15 p.m. Respondent left the facility and had his CVT and medical office staff assist the patient and her husband. About half an hour later, the patient's husband joined his wife in recovery. At the time, the patient still was under the influence of her sedation and anesthesia. She was sleepy, groggy, uncommunicative, and unable to walk.
- 18. The patient remained in recovery until about 6:45 p.m., when it was decided that the sedation and anesthesia had worn off enough for Respondent's staff to help the patient's husband and Effie Grekos get the patient into her husband's car to be driven home. The patient still could not walk without

considerable assistance, was still somewhat sleepy and groggy, and was not speaking normally although she was able to communicate somewhat. They left the office about half an hour later.

- 19. When they arrived home, it was close to 8 p.m. The patient's husband and Respondent's mother helped get the patient into the house. Once there, against the instructions of Respondent's staff, the patient's husband allowed his wife to sit up in a reclining chair, instead of confining her to bed rest. For the next hour or two, the patient remained in the chair. She was able to communicate, but still was not speaking normally.
- 20. Respondent's mother left and returned to her home at approximately 9 p.m. The patient's husband went to sleep in his bedroom, leaving his wife in the reclining chair. A few hours later, the patient fell onto the floor, hit her face and mouth on the couch, and began to vomit uncontrollably. When the patient's husband found her on the floor, he tried to help her up, cleaned up the vomit, and called 911.
- 21. The North Naples Fire Department arrived at the scene first, followed some time later by the EMS technicians. The EMS technicians had no present recollection of the patient and relied on their written report, which was ambiguous in some respects. It states the patient was found on the floor in the

bedroom but does not clearly state who found her or how she got It states the patient's skin color was pale, meaning abnormal, and that she was lethargic but that she responded to verbal contact. However, a computer-generated entry on the report form states the patient was "alert." That entry was triggered by a score of 14 out of 15 on the Glasgow Coma scale, which meant she was not "unresponsive" or "lethargic" but "responded to verbal contact," although she did not speak spontaneously and did not look at anyone until they spoke to her. It reports that the patient said she got up to go to the bathroom and fell forward to the carpeted floor, striking her head on the couch. The patient was not considered to be incoherent or immobile, but her husband had to sign her name for her on the report form. The report states that the patient had a cervical injury and pain, but also states that the fall was mild in severity.

22. The patient was taken by ambulance to North Collier Community Hospital at approximately 2 a.m. Although the patient's husband had been unable to contact Respondent by calling his office telephone, Respondent was contacted by the hospital staff and, at approximately 5:30 a.m., had the patient transferred and admitted to Naples Community Hospital. There, she was diagnosed as having had a stroke that caused debilitating and irreparable damage to the cerebellum and

medulla of her brain. The patient never recovered or improved, and she died on April 4, 2010.

- 23. There was conflicting testimony and evidence as to the cause of the stroke and how quickly the stroke progressed after the procedure. The patient's husband testified that his wife showed symptoms that, if factual, would have signified an immediate, massive stroke early in the evening, soon after the procedure ended. The testimony of Respondent's mother, and to a lesser extent, Respondent's staff and the EMS technicians, contradict the husband. However, the expert testimony was that the symptoms of a cerebellar infarct, which is the kind of stroke suffered by the patient, can vary depending on a number of factors. Respondent's medical staff, his mother, and the EMS technicians could have confused the patient's stroke symptoms with the symptoms of her pre-existing medical conditions, which included poor balance and an unnatural gait, as well as the effects of anesthesia -- especially since they did not have knowledge of the details of the procedure performed by Respondent or the medical significance of those details.
- 24. Based on all the evidence, it appears that the patient suffered a cerebellar infarct early in the evening, during or shortly after the procedure, and that the stroke progressed in waves over time. In this scenario, a blockage in small blood vessels of the brain initially deprives the tissues directly

served by those vessels of oxygen. In no more than six hours of being deprived of oxygen, the brain tissue dies. As tissues die from oxygen deprivation, they swell, which compresses and closes off nearby blood vessels, depriving additional tissue of oxygen, and the process continues in waves. As the stroke progresses, it becomes more and more debilitating.

- 25. Respondent argues that the evidence is consistent with either a stroke caused by the cerebral angiogram, with no contribution from the infusion of BMA, or an immediate, massive stroke caused by the patient's fall at her house.
- 26. As to the latter argument by Respondent, there was a contusion on the patient's face as a result of her fall, but it was minor, and it is unlikely to have caused an immediate, massive stroke. It is much more likely that the patient's stroke was caused by the procedure. As to the former argument, there is a one percent chance that a cerebral angiogram will produce a stroke, even if performed flawlessly. However, in this case, the chances are much greater that the patient's stroke was caused by the infusion of BMA. (The absence of evidence of BMA in the brain on autopsy is explained by the action of naturally-occurring macrophages that clean up the dead tissue and other foreign matter, which would have decomposed and eliminated evidence of the BMA.)

# Count I - Standard of Care

- 27. The evidence was clear and convincing that
  Respondent's stem cell treatment provided to D.F. on March 24,
  2010, fell below 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. No such health care provider
  would have provided the treatment, which almost certainly would
  result in a serious stroke.
- 28. The evidence was clear and convincing that
  Respondent's care after the stem cell treatment provided to
  D.F., on March 24, 2010, fell below 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. Any such
  health care provider would have recognized the likelihood of a
  serious stroke and, if the procedure was attempted contrary to
  the standard of care, would not have then left the patient with
  his CVT and medical staff; rather, emergency transfer to an
  appropriate hospital setting would have been required.

## Count II - Adequate Medical Records

29. DOH attempted to prove that Respondent's medical records were inadequate because they did not substantiate that he was attempting to treat conditions capable of responding to

intra-cranial infusion of stem cells. That allegation was not proven by clear and convincing evidence. Respondent's medical records indicated that he also was attempting to treat neurological deficits other than peripheral neuropathy that could be treated with appropriate intra-cranial infusion of stem cell (assuming informed consent). No medical records could justify the procedure Respondent attempted on D.F. on March 24, 2010.

## Count III - Informed Consent

- 30. DOH contends that the patient did not give informed consent, in part, because Respondent did not test to ensure that the autologous BMA to be infused actually contained stem cells. However, Respondent has conducted a trial to confirm the efficacy of BMA as a source of stem cells. There is medical and scientific literature documenting this, and Respondent's non-physician stem cell expert testified that BMA is an efficacious source of stem cells. DOH did not prove that the autologous BMA infused in the patient was devoid of stem cells, or that it did not contain enough to be efficacious.
- 31. DOH also contends that the patient did not give informed consent, in part, because Respondent infused BMA, not a processed BMAC product. The signed consent forms themselves proved this allegation clearly and convincingly.

- 32. The evidence also was clear and convincing that, taken together, the written consents did not adequately inform the patient of the true risk of the treatment Respondent proposed. They informed the patient regarding the risks of aspiration of bone marrow from the iliac crest, a cerebral angiogram using contrast, and the infusion of a processed BMAC product; they implied that the procedure Respondent proposed would not entail any greater risks.
- 33. The evidence was clear and convincing that Respondent did not give the patient unwritten information regarding the proposed treatment or its risks. To the contrary, in defending against the allegations in this case, Respondent has denied that there was any additional risk.

### Count V - "Wrong Procedure"

34. DOH attempted to prove that the procedure performed by Respondent had no basis in medicine or science and was a wrong procedure, in part, because he performed it to treat peripheral neuropathy, which would not respond to intra-cranial infusion of stem cells. However, taken together, the evidence was that Respondent proposed the procedure to treat neurological deficits, other than peripheral neuropathy, that could be treated with appropriate intra-cranial infusion of stem cells (assuming informed consent).

35. Respondent presented the testimony of its nonphysician stem cell therapy expert, evidence concerning medical and scientific literature about stem cell treatment, and evidence of a trial conducted by Respondent on the efficacy of BMA as a source of stem cells. This evidence proved that intracranial infusion of stem cells to treat neurological deficits in the brain and central nervous system, while innovative and perhaps investigational, has a medical and scientific basis and can be appropriate under certain circumstances, including informed consent. Respondent's evidence also proved that BMA is an efficacious source of stem cells and sometimes achieves results as good or better than processed BMAC products. However, Respondent's evidence did not address or refute DOH's clear and convincing evidence that there is no medical and scientific basis for the treatment Respondent attempted to perform on D.F. on March 24, 2010, which clearly was a "wrong" procedure.

#### CONCLUSIONS OF LAW

36. Because it seeks to impose license discipline, DOH has the burden to prove its allegations by clear and convincing evidence. See Dep't of Banking & Fin. v. Osborne Stern & Co.,

Inc., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510

So. 2d 292 (Fla. 1987). This "entails 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 Henson, 913 So. 2d 579, 590 (Fla. 2005) (quoting Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983)). "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., Inc. v. Shuler Bros., 590 So. 2d 986, 988 (Fla. 1st DCA 1991).

37. Count I of the amended Administrative Complaint charges Respondent with medical malpractice as defined in section 456.50, Florida Statutes (2009), 1/2 regarding the treatment he performed on D.F. on March 24, 2010, in violation of section 458.331(1)(t), Florida Statutes. 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." According to section 766.102(1), Florida Statutes, such a failure occurs upon:

a breach of the prevailing professional standard of care for that health care provider. 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.

- 38. In this case, DOH proved by clear and convincing evidence that Respondent committed medical malpractice as defined in section 456.50 regarding the stem cell treatment he performed on D.F. on March 24, 2010, and thus violated section 458.331(1)(t). The infusion of approximately 240 cc's of unconcentrated, grossly filtered BMA into the cerebral circulation of the patient via the vertebral arteries had virtually no hope of success because of the very high probability that it would cause the patient to have a serious stroke. Respondent should have known this and should not have attempted the procedure.
- 39. Count II of the amended Administrative Complaint charges Respondent with failure to keep medical records that justified the treatment he performed on D.F., on March 24, 2010, in violation of section 458.331(1)(m). This charge was proven only in the sense that no medical records could have justified the procedure performed in this case.
- 40. Count IV of the amended Administrative Complaint charges Respondent with performing professional services not duly authorized by the patient, in violation of section 458.331(1)(p). This charge was proven by clear and convincing evidence. In order for the patient to have given informed

consent, she would have had to know that Respondent intended to infuse BMA, not a BMAC product, and that the treatment Respondent was attempting had virtually no hope of success and probably would result in the patient having a serious stroke.

Respondent did not so inform the patient.

- A1. Count V of the amended Administrative Complaint charges Respondent with performing a wrong procedure that was medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition, in violation of section 456.072(1)(bb). This charge was proven by clear and convincing evidence, not because it was performed solely to cure peripheral neuropathy (which was not proven), and not because there is no medical or scientific basis for the appropriate use of stem cells to treat neurological deficits other than peripheral neuropathy (which there is), but because the infusion of approximately 240 cc's of unconcentrated, grossly filtered BMA into the patient's cerebral circulation had virtually no hope of success and had a very high probability that it would cause the patient to have a serious stroke. In that sense, it was a "wrong" procedure.
- 42. Respondent attempts to escape discipline by resorting to section 458.331(1)(u), which prohibits "[p]erforming 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." The stem cell treatment attempted on D.F. on March 24, 2010, could be characterized as "experimentation on a human subject." It was not performed after "first obtaining full, informed, and written consent."
- Respondent also attempts to escape discipline by resorting to section 456.41, which authorizes "complementary or alternative health care treatments." However, this statute only authorizes effective options and requires that the licensee "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(1) & (2)(a). In this case, the stem cell treatment performed on D.F. on March 24, 2010, was not an effective option, and the patient was not given the information needed to give informed consent. In addition, this statute "does not modify or change the scope of practice of any licensees of the department, nor does it 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 and which prohibit fraud and exploitation of patients." § 456.41(5).
- 44. Florida Administrative Code Rule 64B8-8.001 (revised February 2009) provides disciplinary guidelines for proven violations. Subparagraph (1)(t) of the rule states that the

recommended ranges of penalties for the proven offense of gross malpractice alleged in Count I are from a year suspension, followed by three years probation, and 50 to 100 hours of community service, to revocation and an administrative fine from \$1,000 to \$10,000 (with licensee subject to reexamination). Subparagraph (1) (m) of the rule states the recommended ranges of penalties for the violation alleged in Count II, but penalties for Count II should not be added to the penalties for Count I since Count II was proven only in the sense that there are no medical records that could justify the procedure performed in this case. Paragraph (1)(p) of the rule states that the recommended ranges of penalties for the proven violation alleged in Count IV are from a reprimand and \$250 fine to a suspension for two years, to be followed a period of probation, 50 to 100 hours of community service, and an administrative fine from \$1,000 to \$10,000. Although they arise out of the same procedure, the penalties for Count IV should be added to the penalties for Count I because they are different violations. Subparagraph (1) (qq) of the rule states the recommended ranges of penalties for the proven violation alleged in Count V, but penalties for Count V should not be added to the penalties for Counts I and II since Respondent performed the "wrong" procedure in the sense that it constituted medical malpractice, not in the sense that it was a "wrong-site surgery."

45. Consideration of the totality of circumstances surrounding this case, most especially Respondent's continuing failure to recognize the complete inappropriateness of the procedure he performed on the patient and the inadequacy of the information he provided to obtain the patient's consent, together with the aggravating and mitigating factors under rule 64B8-8.001(3) (which are utilized to justify a departure from the disciplinary guidelines), supports the imposition of a penalty at the top of the ranges--namely, revocation and a \$20,000 fine.

## RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final order adopting the Findings of Fact and Conclusions of Law, revoking Respondent's license, and imposing a \$20,000 fine.

DONE AND ENTERED this 11th day of March, 2013, in Tallahassee, Leon County, Florida.

J. LAWRENCE JOHNSTON

Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675
Fax Filing (850) 921-6847

www.doah.state.fl.us

Filed with the Clerk of the Division of Administrative Hearings this 11th day of March, 2013.

#### ENDNOTE

All statutory references are to the 2009 version of the Florida Statutes.

#### COPIES FURNISHED:

Allison M. Dudley, Executive Director Board of Medicine Department of Health Bin C-03 4052 Bald Cypress Way Tallahassee, Florida 32399

Jennifer A. Tschetter, General Counsel Department of Health Bin A-02 4052 Bald Cypress Way Tallahassee, Florida 32399

Richard G. Ozelie, Esquire Law Offices of Richard G. Ozelie, LLC 750 South Dixie Highway Boca Raton, Florida 33432-6108

Robert A. Milne, Esquire
Ian Brown, Esquire
Department of Health
Bin C-65
4052 Bald Cypress Way
Tallahassee, Florida 32399-3265

#### 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.