

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

DEPARTMENT OF HEALTH,

Petitioner,

v.

DOH CASE NO.: 2012-03496

ZANNOS G. GREKOS, M.D.,

Respondent.

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Medicine against Respondent, Zannos G. Grekos, M.D., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.
2. At all times material to this order Respondent was board certified in Cardiovascular Disease.

3. At all times material to this complaint Respondent was a licensed physician within the State of Florida, having been issued license number ME 61912.

4. At all times material to this Complaint Respondent's address of record was 9500 Bonita Beach Road, Suite 310, Bonita Springs, Florida 34153.

5. On February 23, 2011, the State Surgeon General entered an Emergency Restriction Order (ERO) pursuant to Section 120.60 (6), Florida Statutes, immediately restricting Respondent from "providing any stem cell treatment including but not limited to the injection of autologous bone marrow aspirate."

6. The foregoing ERO was initiated after one of Respondent's patients died shortly after a stem cell treatment involving the injection of autologous bone marrow aspirate into the patient's cerebral circulation.

7. At all times material to this complaint the ERO was in full force and effect.

8. The Department conducted an investigation of Respondent starting on March 5, 2012.

9. The investigation was prompted by a complaint from the medical examiner for District 20 in Naples, Florida.

10. The investigation arose as a result of an experimental stem cell treatment Respondent performed on patient R.P. on March 2, 2012 and R.P.'s subsequent death later the same day.

11. R.P. had contacted Respondent's company Regenocyte Therapeutic LLC., about stem cell treatment for R.P.'s pulmonary hypertension and pulmonary fibrosis, he was invited to come to Bonita Springs by Respondent's marketing office to have a stem cell procedure which would stabilize him so that further stem cell treatment could then be performed in the Dominican Republic.

12. Respondent charged eight thousand dollars (\$8,000.00) for this treatment. Patient R.P. had paid Respondent's company Regenocyte Therapeutic LLC, the eight thousand dollars (\$8,000.00) by wire transfer.

13. Regenocyte Therapeutic LLC is a Florida company owned and or controlled by Respondent. Its website describes the treatment that it performs and also states:

Adult stem cells are extracted from the patient's own blood via a standard blood draw. At Regenocyte Therapeutic, the naturally occurring stem cells in the blood are cultivated into millions of Regenocyte Adult Stem Cells. The Regenocyte Stem Cells are sent to

our international treatment center and are administered into the area of need for the patient.

14. On March 2, 2012, despite the existence of the above mentioned ERO, Respondent performed a stem cell treatment on patient R.P., a 77 year-old male, to treat his pulmonary hypertension and pulmonary fibrosis.

15. Respondent started to perform this stem cell treatment on the morning of March 2, 2012 by harvesting from patient R.P.'s abdomen approximately 90cc of adipose tissue through a large gauge needle inserted for that purpose.

16. Adipose tissue routinely contains stem cells.

17. Unbeknown to Respondent, he markedly disrupted the tissues of the lower abdominal wall during the insertion of the needle to harvest R.P.'s adipose tissue and produced extravasation (a discharge or escape as of blood, from a vessel into the tissues) within the abdominal wall.

18. Respondent had this adipose tissue couriered to a laboratory in Boynton Beach to have the stem cells concentrated by a technique known as ultrasonic cavitation. In the meantime Respondent instructed R.P. to return five hours later that afternoon for the completion of the stem cell treatment upon the return of his concentrated cells from the laboratory.

19. At approximately 1:00 pm, R.P. felt pain and a bloating of his abdomen which had become distended, he and family members in attendance reappeared at Respondent's offices in Bonita Beach Road at approximately 1:30 pm.

20. Respondent examined R.P. and found a hematoma of the abdomen (an abnormal localized collection of blood in which the blood is usually clotted or partially clotted and is usually situated within an organ or a soft tissue space, such as within a muscle) but did not further evaluate R.P. despite these new symptoms of pain and abdominal distension.

21. While R.P. waited for the return of the concentrated stem cells, Respondent's staff made R.P. comfortable.

22. Respondent's staff suggested to R.P. that his discomfort may have been as a result of Respondent having "nicked" a vein when the adipose tissue was being obtained and that this would resolve itself and was not a matter of concern.

23. At approximately 4:30 pm, a courier arrived at Respondent's Bonita Beach offices with the concentrated material from the "laboratory" in Boynton Beach.

24. This laboratory turned out to be a small office in a strip mall; the person that allegedly operated the machine that performed the ultrasonic cavitation on the sample of R.P.'s adipose tissue was unsupervised and was not licensed either by the Florida Board of Medicine or by the Florida Board of Clinical Laboratory Personnel.

25. Other than it being visually inspected by the machine operator after the ultrasonic cavitation was completed, the machine operator did not test the treated and concentrated material (the material) arising from the harvesting of R.P.'s adipose tissue prior to it being couriered back to Respondent; the material was returned in a syringe held in a temperature controlled container.

26. Ultrasonic cavitation is according to the laboratory a process to dissociate the fat cells and blood vessels contained within the adipose tissue, thereby obtaining multi-potent, mesenchymal or stromal vascular fractions for use in human subjects for the production of SVF;

Stromal Vascular Fraction (SVF) is the lipoaspirate obtained from tumescent liposuction minus the fat cells (adipocytes). Apart from adipocytes, the SVF contains a variety of other cells such as pre-adipocytes, endothelial cells, smooth muscle cells, pericytes, fibroblasts, and adult stem cells (ASCs). In addition, the SVF also contains blood cells from the capillaries supplying the fat cells.

27. At approximately 5:00 pm, Respondent infused or directed that patient R.P. be infused with approximately 60cc of the concentrated stem cell material that had been subjected to ultrasonic cavitation by Intelicell.

28. The material, allegedly containing the concentrated stem cells was infused into R.P.'s blood stream for the treatment of R.P.'s pulmonary hypertension and or pulmonary fibrosis.

29. The foregoing stem cell treatment was performed in Respondent's medical office in Bonita Springs, Florida.

30. While the material was being infused into R.P.'s bloodstream R.P. arrested and was subsequently pronounced dead.

31. Respondent's medical records did not contain medical justification for the infusion of concentrated stem cells into R.P.'s circulation system as a treatment for R.P.'s pulmonary hypertension and/or pulmonary fibrosis.

32. Respondent's treatment of R.P.'s pulmonary hypertension and/or pulmonary fibrosis by the infusion of concentrated adult stem cells into the circulation had no substantiated medical and/or scientific value.

33. Respondent's treatment of R.P.'s pulmonary hypertension and/or pulmonary fibrosis by the infusion of concentrated adult stem cells into the circulation, violated the ERO entered on February 23, 2011.

34. The medical examiner performed an autopsy on R.P. on March 3, 2012.

35. Microscopic examination of R.P.'s fresh lung tissue (not fixed in formalin) obtained at the time of autopsy revealed that adipose tissue entered R.P.'s systemic circulation and was found throughout R.P.'s pulmonary arteries and capillaries.

36. The autopsy also grossly demonstrated the disruption of the tissues of the lower abdominal wall, the blood extravasation within the tissues of the lower abdominal wall, and the blood extravasation within the peritoneal cavity.

COUNT ONE

37. Paragraphs 1 through 36 are adopted and realleged as though fully set forth.

38. Section 458.331(1)(t), Florida Statutes (2011), provides that committing medical malpractice constitutes grounds for disciplinary action by the Board of Medicine. Medical malpractice is defined in Section

456.50(1)(g), Florida Statutes (2011), 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. For purposes of Section 458.331(1)(t), Florida Statutes (2011), the Board shall give great weight to the provisions of Section 766.102, Florida Statutes (2011), which provide 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.

39. Respondent failed to practice medicine with that level of care, skill and treatment in violation of Section 458.331(1)(t), Florida Statutes (2011), which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances in the treatment of R.P. in one or more of the following ways:

a. by performing a procedure that had no substantial medical and scientific value for the treatment of R.P.'s pulmonary hypertension and pulmonary fibrosis;

b. by performing a procedure that had no proper medical foundation for success;

c. by performing a procedure that was entirely experimental and not an accepted or proven treatment in the State of Florida;

d. by performing a procedure that was dangerous and unwarranted;

e. by performing a procedure that was medically unnecessary and very dangerous;

f. by performing a procedure that placed the patient at an inordinate risk of death and/or serious injury.

g. by injecting or causing the injection of an unknown material into R.P.'s circulation without any prior objective knowledge of the material's properties or the risks to the patient;

h. by failing to perform an adequate medical examination;

i. by failing to sufficiently evaluate the abdominal hematoma that R.P. presented with at 1:30 pm on March 2, 2012.

40. Based on the foregoing, Respondent has violated Section 458.331(1)(t), Florida Statutes (2011).

COUNT TWO

41. Paragraphs 1 through 36 are adopted and realleged as though fully set forth.

42. Section 458.331(1)(m), Florida Statutes (2011), subjects a licensee to discipline for failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

43. On or about March 2, 2011, Respondent violated Section 458.331(1)(m), Florida Statutes (2011), by failing to keep medical records that justified R.P.'s course of treatment.

44. Based on the foregoing, Respondent has violated Section 458.331(1)(m), Florida Statutes (2011).

COUNT THREE

45. Petitioner realleges and incorporates paragraphs 1 through 36 as if fully set forth herein.

46. Section 458.331(1)(g), Florida Statutes (2011), provides that failing to perform any statutory or legal obligation placed upon a licensed physician is grounds for disciplinary action by the Board of Medicine.

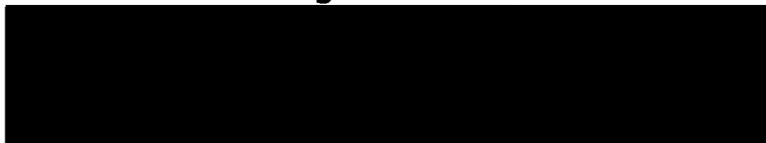
47. Respondent violated Section 458.331(1)(g), Florida Statutes (2011) by failing to comply with the lawful order of emergency restriction of his license entered on February 23, 2011.

48. Based on the foregoing, Respondent has violated Section 458.331(1)(g), Florida Statutes (2011), by performing a stem cell procedure on R.P. on March 2, 2012.

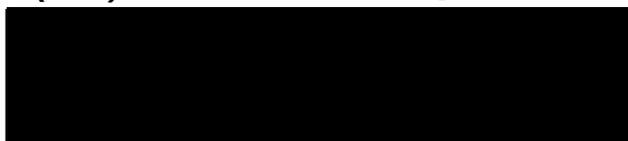
WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 23th day of March, 2012.

Steven L. Harris, M.D., M.Sc.
Interim State Surgeon General

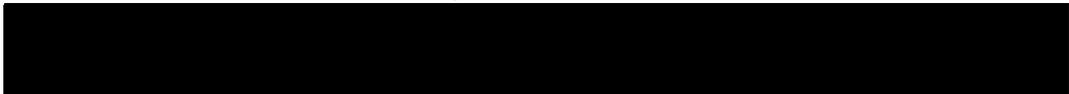


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DEPUTY CLERK
CLERK **Angel Sanders**
DATE **MAR 27 2012**

PCP Members: 
PCP: March 23, 2012

RAM/sdw

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Zannos G. Grekos, M.D., DOH Case Number: 2012-03496