

**STATE OF FLORIDA  
DEPARTMENT OF HEALTH**

DEPARTMENT OF HEALTH,

Petitioner,

v.

DOH CASE NO.: 2010-14317

ZANNOS G. GREKOS, M.D.,

Respondent.

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**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 Dr. Grekos was board certified in Cardiovascular Disease and Internal Medicine.

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. The Department conducted an investigation of Dr. Grekos from September 3, 2010, through November 11, 2010.

6. The investigation arose from the complaints from DF's husband and one of her treating physicians.

7. The investigation arose as a result of an experimental stem cell treatment Dr. Grekos performed on patient DF and her subsequent death.

8. DF was a 69 year-old female with a history of infiltrating ductal carcinoma of the breast which was first diagnosed in 2006; since then she had completed six cycles of chemotherapy and then radiation followed by Arimidex (an adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer).

9. On February 17, 2010, DF consulted Dr. Grekos about stem cell treatment for her chemotherapy-induced neuropathy (damage to the peripheral nervous system including tingling, numbness, weakness and loss of sensation of the extremities) resulting from her cancer treatment.

10. Dr. Grekos' medical records show that on February 25, 2010, DF underwent carotid imaging with findings of approximately 0-29% bilateral stenosis (narrowing) of the carotid arteries.

11. On March 24, 2010, at the Regence Heart and Medical Center, Dr. Grekos performed a cerebral angiogram and then performed the experimental stem procedure when he injected autologous bone marrow aspirate into DF's cerebral circulation. Dr. Grekos then obtained selective angiograms after infusion of the bone marrow aspirate.

12. The treatment provided by Dr. Grekos to DF was neither authorized nor recognized by the Federal Drug Administration.

13. Dr. Grekos performed this procedure on DF as an outpatient in the late afternoon of March 24, 2010; DF, who was still under sedation when she was discharged home without fully waking

up, was carried into her home from the car, later that evening DF fell and struck her head.

14. The paramedics were called and transported DF to the North Naples Hospital Emergency Room at approximately 2:00 a.m. on March 25, 2010, with altered mental status.

15. A CT scan of her head showed significant swelling in the brain with effacement of the fourth ventricle and possible stroke and hemorrhage. DF was noted to have slurred speech, appeared very sleepy and was difficult to arouse.

16. Later in the morning of March 25, 2010, DF was transported to Naples Community Hospital for neurosurgical intervention. A ventriculostomy to relieve some of the pressure on DF's brain was successfully performed.

17. A further CT scan and MRIs were done which confirmed the presence of a severe brain stem injury and infarct of the cerebellum. DF remained on mechanical ventilation until April 2, 2010, when life support and all therapeutic intervention other than palliative measures were withdrawn.

18. DF's death on April 4, 2010, resulted from the infarcts of her left cerebella and left medulla.

19. Dr. Grekos' medical records did not contain medical justification for the injection of autologous bone marrow aspirate into DF's cerebral circulation as a treatment for DF's neuropathy.

20. Dr. Grekos' treatment of DF's neuropathy by the injection of autologous bone marrow aspirate into the cerebellar circulation had no substantiated medical and/or scientific value.

### **COUNT ONE**

21. Paragraphs 1 through 20 are adopted and realleged as though fully set forth.

22. Section 458.331(1)(t), Florida Statutes (2010), 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 (2010), 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 (2010), the Board shall give great weight to the provisions of Section

766.102, Florida Statutes (2010), 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.

23. Dr. Grekos failed to practice medicine with that level of care, skill and treatment in violation of Section 458.331(1)(t), Florida Statutes (2010), which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances in the treatment of DF in one or more of the following ways:

a. by failing to show in the medical records the justification for injecting autologous bone marrow aspirate into DF's cerebral circulation for the treatment of DF's neuropathy;

b. by performing a procedure that had no substantial medical and scientific value for the treatment of DF's neuropathy;

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

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

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

24. Based on the foregoing, Respondent has violated Section 458.331(1)(t), Florida Statutes (2010).

### **COUNT TWO**

25. Paragraphs 1 through 20 are adopted and realleged as though fully set forth.

26. Section 458.331(1)(m), Florida Statutes (2010), 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.

27. On or about March 24, 2010, Dr. Grekos violated Section 458.331(1)(m), Florida Statutes (2010), by failing to keep medical records that justified DF's course of treatment.

28. Based on the foregoing, Respondent has violated Section 458.331(1)(m), Florida Statutes (2010).

### **COUNT THREE**

29. Paragraphs 1 through 20 are adopted and realleged as though fully set forth.

30. Section 458.331(1)(n), Florida Statutes (2010), subjects a licensee to discipline for exercising influence on the patient or client in such a manner as to exploit the patient or client for financial gain of the licensee or of a third party, which shall include, but not be limited to, the promoting or selling of services, goods, appliances, or drugs.

31. On or about March 24, 2010, Dr. Grekos violated Section 458.331(1)(n), Florida Statutes (2010), by exercising influence on the patient or client in such a manner as to exploit the patient or client for financial gain when he induced DF to submit to this procedure.

32. Based on the foregoing, Respondent has violated Section 458.331(1)(n), Florida Statutes (2010).

#### **COUNT FOUR**

33. Paragraphs 1 through 20 are adopted and realleged as though fully set forth.

34. Section 458.331(1)(p), Florida Statutes (2010), subjects a licensee to discipline for performing professional services which have not been duly authorized by the patient or client.

35. Informed consent requires that a physician sufficiently educate a patient as to the risks, benefits, and alternatives to a proposed treatment to allow a patient to consider the information prior to signing an "informed consent" form.

36. Prior to injecting autologous bone marrow aspirate into DF's cerebral circulation for the treatment of DF's neuropathy Respondent failed to adequately explain to DF:

a. the injection of a matrix of bone marrow material directly into the carotid artery of the patient has no substantiated medical and scientific value to treat the patient's peripheral neuropathy;

b. the use of unorthodox stem cell transfusions for diseases that have shown no benefit can be extremely dangerous;

c. that the treatment provided to the patient had no proper medical foundation for success; and/or

d. that this procedure was entirely experimental and certainly not an accepted or proven treatment in the state of Florida.

37. By failing to make this disclosure and explain the consequences of injecting autologous bone marrow aspirate into DF's cerebral circulation, Respondent failed to obtain DF's knowing and informed consent to the injecting of autologous bone marrow aspirate into DF's cerebral circulation for the treatment of her neuropathy.

38. Based on the foregoing Respondent violated Section 458.331(1)(p) Florida Statutes (2010).

**COUNT FIVE**

39. Petitioner realleges and incorporates paragraphs 1 through 20 as if fully set forth herein.

40. Section 456.072(1)(bb), Florida Statutes (2010), provides that performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition is grounds for disciplinary action by the Board of Medicine.

41. Respondent performed a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition by injecting autologous bone marrow aspirate into DF's cerebral circulation for the treatment of DF's neuropathy when Patient DF's diagnosis or medical condition did not warrant such procedure.

42. Based on the foregoing, Respondent has violated Section 456.072(1)(bb), Florida Statutes (2010), by performing a procedure

that is medically unnecessary or otherwise unrelated to Patient DF's diagnosis or medical condition.

**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 14th day of <sup>March</sup> ~~April~~, 2011.

State Surgeon General



Robert A. Milne

Assistant General Counsel

Florida Bar # 622338

DOH Prosecution Services Unit

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**FILED**

DEPARTMENT OF HEALTH  
DEPUTY CLERK

CLERK: *George Soudis*

DATE: MAR 14 2011

PCP Members: *Asikar, Rosenberg, Levine*  
PCP: *March 11, 2011*

## **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.**