

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

Final Order No. DOH-11-473-^{ERO}MQA
FILED DATE - 2-23-11
Department of Health

By: Angel Sanders
Deputy Agency Clerk

IN RE: The Emergency Restriction of the License of
Zannos G. Grekos, M.D.
License Number: ME 61912
Case Number: 2010-14317

ORDER OF EMERGENCY RESTRICTION OF LICENSE

The State Surgeon General, ORDERS the emergency restriction of the license of Zannos G. Grekos, M.D. Dr. Grekos holds license number ME 61912. His address of record is 9500 Bonita Beach Road, Suite 310, Bonita Springs, Florida 34153. The following Findings of Fact and Conclusions of Law support the emergency restriction of Dr. Grekos' license to practice as a physician in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of medicine pursuant to Chapters 20, 456 and 458, Florida Statutes. Section 456.073(8), Florida Statutes (2010), authorizes the State Surgeon General to summarily restrict Dr. Grekos' license to practice as a physician in the State of Florida in accordance with Section 120.60(6), Florida Statutes (2010).

2. At all times material to this order, Dr. Grekos was practicing as a physician in the State of Florida, pursuant to Chapter 458, Florida Statutes.

3. At all times material to this order Dr. Grekos was board certified in Cardiovascular Disease and Internal Medicine.

4. The Department conducted an investigation of Dr. Grekos from September 3, 2010 through November 11, 2010.
5. The investigation arose as a result an experimental stem cell treatment Dr. Grekos performed on patient DF.
6. The investigation prompted a Departmental medical expert's review of DF's medical records.
7. The Departmental medical expert is board certified in Internal Medicine, Hematology and Oncology; he provided his opinion to the Department on February 7, 2011.
8. The Departmental medical expert opined that Dr. Grekos' treatment of Patient DF fell below the standard of care and unnecessarily caused her death.
9. 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).
10. 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.

11. 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.

12. 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.

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

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

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

20. 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.

21. The Department's medical expert opined on Dr. Grekos' treatment of CS as follows: ..."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."..."The use of unorthodox stem cell transfusions for diseases that have shown no benefit can be extremely dangerous."..." I felt that the physician did not meet applicable standards of care as outlined in the Florida Statutes. I felt that his care was substandard and dangerous. He did not provide quality care to this individual, and his standard of care was extremely negligent in my opinion. It is also my opinion that the patient's complaints and symptoms were not properly addressed by this

physician and that the treatment provided to the patient had no proper medical foundation for success. It was my impression that the patient died directly as the result of the unorthodox and unproven treatment administered to the patient by Dr. Grekos."..."It was also my impression the injection of bone marrow aspiration material into the carotid artery was unnecessary and that it led directly to the patient's demise. I felt that his procedure was entirely experimental and certainly not an accepted or proven treatment in the State of Florida. Not only is that treatment dangerous and unwarranted, its continued use in other patients would be unacceptable."..."In summary, I feel the standard of care was far below normal and dangerous, if not criminal. I feel that this practice should be stopped immediately. I feel that it is unfortunate that a patient had to die in the State of Florida before attention was brought to this very dangerous, highly experimental, unorthodox, and not scientifically proven procedure."

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: 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; by performing a procedure that had no substantial medical and scientific value for the treatment of DF's neuropathy; by performing a procedure that had no proper medical foundation for success; by performing a procedure that was entirely experimental and not an accepted or proven treatment in the State of Florida; by performing a procedure that was dangerous and unwarranted; by performing a procedure that was medically unnecessary and very dangerous; and, by performing a procedure that placed the patient at an inordinate risk of death and/ or serious injury.

24. 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.

25. 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.

26. 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.

27. 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.

28. Section 120.60(6), Florida Statutes (2010), authorizes the Department to summarily restrict a physician's license if the Department finds that the physician presents an immediate serious danger to the public health, safety, or welfare.

29. A physician licensed in the State of Florida is one of a small number of licensed professionals allowed to perform invasive medical procedures and provide treatments that can save the lives of their patients in this state. The

legislature has vested a trust and confidence in these licensed professionals by permitting them to perform these invasive medical procedures and to provide treatments. Medically unproven highly experimental stem cell treatment involving the injection of autologous bone marrow aspirate into a patient's cerebral circulation for the treatment of neuropathy presents a danger to the public health, safety, or welfare, and does not correspond to that level of professional conduct expected of one licensed to practice medicine in this state.

30. Dr. Grekos has demonstrated, through his violation of 458.331(1)(t), (m), and (n) Florida Statutes (2010), a flagrant disregard for the duties and responsibilities imposed upon a physician practicing in the State of Florida and for the health and welfare of his patients and for the citizens of this state. Dr. Grekos' egregious and inappropriate injecting of autologous bone marrow aspirate into DF's cerebral circulation for the treatment of DF's neuropathy constitutes a breach of the trust and confidence that the Legislature placed in him by issuing him a license to practice medicine.

31. Dr. Grekos' actions demonstrate such a propensity to embark on highly dangerous invasive medically unproven experimental stem cell treatment involving the injecting of autologous bone marrow aspirate into a patient's cerebral circulation for the treatment of neuropathy that it is clear that Dr. Grekos will continue to provide this highly dangerous and medically unproven treatment of the type listed above in violation of Section 458.331(1)(t), (m), and (n), Florida Statutes (2010), unless action is taken to prevent him from doing so.

An emergency order of restriction is necessary to protect the public from this danger.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2010), and Chapters 458, Florida Statutes (2010).
2. 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.
3. Dr. Grekos violated Section 458.331(1)(m), Florida Statutes, (2010), by failing to keep medical records that justify the course of treatment of patient DF.
4. 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.
5. Dr. Grekos' continued unrestricted practice as a physician constitutes an immediate serious danger to the health, safety, or welfare of the public and this summary procedure is fair under the circumstances to adequately protect the public.


In accordance with Section 120.60(6), Florida Statutes, (2010), it is

ORDERED THAT:

1. The license of Zannos G. Grekos, M.D., license number ME 61912 is immediately restricted from providing any stem cell treatment including but not limited to the injection of autologous bone marrow aspirate.

2. A proceeding seeking formal discipline of the license of Zannos G. Grekos, M.D., to practice as a physician will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes (2010).

DONE and ORDERED this 22nd day of February, 2011.



State Surgeon General
Department of Health

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