

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF)
MEDICINE,)
)
Petitioner,)
)
vs.) Case Nos. 02-0165PL
) 02-0219PL
WILLIAM HAMMESFAHR, M.D.,)
)
Respondent.)
_____)

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was held in this case on May 15 and 16, 2002, in Clearwater, Florida, and on May 24, 2002, by telephonic conference before Susan B. Kirkland, a designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Shirley J. Whitsitt, Esquire
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STATEMENT OF THE ISSUES

Whether Respondent violated Subsections 458.331(1)(d), 458.331(1)(n), and 458.331(1)(t), Florida Statutes, and, if so, what discipline should be imposed.

PRELIMINARY STATEMENT

On December 11, 2001, Petitioner, Department of Health, Board of Medicine (Department), issued an Administrative Complaint against Respondent, William Hammesfahr, M.D., (Hammesfahr), alleging that he had violated Subsection 458.331(1)(t), Florida Statutes, in his treatment of M.T.; that he had violated Subsection 458.331(1)(d), Florida Statutes, by engaging in false advertising regarding his treatment for strokes; and that he had violated Subsection 458.331(1)(n), Florida Statutes, by exploiting M.T. for financial gain. Hammesfahr requested an administrative hearing, and the case was referred to the Division of Administrative Hearings (DOAH) for assignment of an administrative law judge on January 11, 2002. The case was assigned DOAH Case No. 02-0165PL.

On December 17, 2001, the Department filed an Administrative Complaint against Hammesfahr alleging that he had violated Subsection 458.331(1)(d), Florida Statutes, by engaging in false advertising regarding his treatment for strokes. Hammesfahr requested an administrative hearing, and the case was

referred to DOAH on January 15, 2002, for assignment of an administrative law judge. The case was assigned DOAH Case No. 02-0219PL.

By order dated January 30, 2002, the two cases were consolidated. The cases were noticed for final hearing on March 20, 2002. On February 20, 2002, Hammesfahr filed Respondent's Motion for Continuance, which was granted by order dated February 27, 2002. The final hearing was rescheduled for May 7 and 8, 2002. On March 6, 2002, Respondent filed another motion to continue the final hearing. The motion was granted, and the final hearing was rescheduled for May 15 and 16, 2002. The rebuttal testimony was heard by telephonic conference call on May 24, 2002.

By Order dated April 26, 2002, official recognition was taken of Section 456.41(1), Florida Statutes, and of the staff analysis and legislative history regarding the enactment of Section 456.41, Florida Statutes. At the final hearing, official recognition was taken of Chapters 456 and 458, Florida Statutes, and Chapter 64B8-8, Florida Administrative Code, as it existed from May 14, 1998, through December 28, 1999.

At the final hearing the Department called Dr. Harold Friend, Dr. David Scales, and Dr. Steven Novella as its witnesses and presented the testimony of Dr. Thomas Hoffman,

Dr. Steven Novella, M.T., and J.T. by deposition. Petitioner's Exhibits 1 through 16, 18, and 19 were admitted in evidence.

Hammesfahr called the following witnesses: Brent Bohne, Dr. Alexander Gimon, Diane Hartley, Larry Senko, and Dr. William S. Russell, and presented the testimony of Dr. William Flanagan, Dr. Jacob Green, Larry Senko, Frank Famiano, Robert Keys, and Stephen Putnall by deposition. Respondent's Exhibits 1, 2, 4 through 11, 12A, 12B, 13A, 13B, 14, and 17 through 25 were admitted in evidence. Respondent's Exhibits 15 and 16 were proffered. Respondent was given leave to file a clean copy of Respondent's Exhibit 25 as a late-filed exhibit. Respondent filed Respondent's Exhibit 25 on October 31, 2002.

The parties agreed to submit their proposed recommended orders within 30 days of the filing of the transcript. The final volume of the five-volume Transcript was filed on July 15, 2002. The parties requested that the time for filing proposed recommended orders be enlarged. The requests were granted, extending the time for the filing of the proposed recommended orders to August 19, 2002. The parties timely filed their Proposed Recommended Orders, which have been considered in rendering this Recommended Order.

FINDINGS OF FACT

1. Hammesfahr is a licensed physician in the State of Florida, having been issued Florida License ME 52212 on

February 8, 1988. He is board-certified in neurology and pain management.

2. Hammesfahr's office is located in Clearwater, Florida, where he maintains a practice treating patients who have had strokes. A stroke is a blockage of an artery in the brain that causes damage to the brain. As a result of the stroke certain cells within the brain will die, and the victim will develop a multitude of deficits, including paralysis, loss of vision, sensory loss, and memory problems.

3. Between 1998 and 2000, Hammesfahr advertised his treatment for stroke patients and included the following statements in some of his advertisements:

Using advanced technology, Dr. Hammesfahr has developed a sophisticated method to help restore blood flow to the damaged areas of the brain after a stroke. With increased blood flow to these areas, the brain can heal.

Dr. Hammesfahr is the first physician to treat and successfully reverse the effects of stroke using vasodilators.

These advertisements have appeared in Florida and in airline magazines, which travel throughout the country.

4. In some of his advertisements, Hammesfahr indicated that based on an evaluation of the first 67 patients who went through the therapy 82 percent had major improvement, 11.9 percent had minor improvement, and 6 percent had no improvement.

He further indicated that the study showing these results was peer-reviewed.

5. Generally, Hammesfahr's treatment protocol is based on the concept of dilating blood vessels in the brain to optimize neurological function and neurological recovery. He uses vasodilator medications to dilate blood vessels in the brain and to increase blood flow into the brain. Various methods are used to monitor the therapy and improvement, including ultrasound, physical examinations, neuropsychological and physical therapy testing, EEG, transcranial Doppler, and blood pressure monitoring. Medications used to dilate the blood vessels include ACE inhibitors, calcium channel blockers, nitrates, alpha and beta blockers, and sympatholytics.

6. After a stroke has occurred, brain cells in the center of the stroke are destroyed and cannot be revived. The area next to the stroke center is called the penumbra and consists of brain cells that are damaged and might recover. Hammesfahr does not claim that his treatment protocol can restore the brain cells that have been destroyed. He does claim that by using his protocol there may be some recovery in the damaged areas, where the blood vessels have restricted and narrowed. The medications dilate the vessels and increase the blood flow to the damaged areas.

7. The recovery of a stroke patient consists of three phases: acute, subacute, and chronic. The acute phase occurs from the onset of the stroke to the next few days or weeks thereafter. The subacute phase starts at the end of the acute phase and lasts for approximately six weeks to three months. However, in certain cases it might last as long as 18 months. The chronic phase is the last phase, which commences at the end of the subacute phase and lasts for an indefinite period. Hammesfahr usually treats stroke patients who are in the chronic phase, but has also treated patients in the other phases of stroke recovery.

8. When a patient contacts Hammesfahr concerning his stroke treatment, the patient will be sent a new patient package, which describes the phases of treatment, contains articles written by Hammesfahr concerning his treatment, and includes a fee schedule. Hammesfahr has different treatment plans from which the patient may choose to participate. The costs for the treatment vary according to the plan; the longer the patient is seen in Clearwater by Hammesfahr, the more costly the treatment. The average patient seen by Hammesfahr opts for the three-week plan.

9. If a patient decides that he wants to be treated by Hammesfahr, the patient is required to see his primary care physician, provide the physician with the articles contained in

the new patient package, and obtain his medical records from the physician. The primary care physician is to perform certain tests on the patient and give a medical clearance for the patient to travel to Clearwater, Florida, for treatment by Hammesfahr. The patient is also sent a package of materials, which includes a medical history form to be filled out by the patient and brought to Hammesfahr when the patient comes to Clearwater for treatment.

10. When the patient initially presents for treatment at Clearwater, the patient is given an explanation of the treatment by Hammesfahr and his staff. Patients are advised that there are no guarantees that the treatment will be successful. An intake is performed to make sure that the needed forms are properly completed, including a history of the patient to determine that the patient's primary care physician has given the patient a clearance to come to Hammesfahr for treatment, and to review the medical records of the patient. A physical examination is performed on the patient.

11. The patient is given a schedule for the time that the patient will be in treatment in Clearwater, and Hammesfahr's staff reviews the schedule with the patient.

12. Tests are performed on the patient in Hammesfahr's office such as the transcranial Doppler ultrasound to generally determine the blood velocity.

13. The patient is sent to Diane Hartley, a physical therapist, for testing of gross motor function, and to Dr. Alexander Gimon for neuropsychological testing. The tests given by Ms. Hartley and Dr. Gimon are standardized tests, for which the patient normally pays additional fees. The initial tests by Ms. Hartley and Dr. Gimon are given to form a baseline for a comparison with later test results. Those patients who are three-week patients will also have examinations by Ms. Hartley and Dr. Gimon at the end of their treatment period. The test results are compared with the test results taken at the beginning of the treatment period.

14. The patient receives an orientation session in which the patient is informed of the responsibilities that the patient has during the course of treatment. Such responsibilities include taking blood pressure measurements at prescribed times of the day, charting the results of the blood pressure test, and seeing and providing the patient's primary care physician with the blood pressure readings. The patient must drink eight glasses of water a day, unless the patient has a heart disease, and must avoid certain types of foods that are vasoconstrictors.

15. Once the patient completes the treatment at Hammesfahr's office, the primary care physician will take over the medical management of the patient's treatment. Hammesfahr's office will confer with the patient's primary care physician

after the patient leaves Hammesfahr's office to discuss the monitoring of the patient and the altering of the patient's medication. One week after returning from treatment in Clearwater with Hammesfahr, the patient must see his primary care physician.

16. In October 1999, a friend of M.T. mailed M.T. one of Hammesfahr's advertisements. As result of receiving the advertisement, M.T. contacted Hammesfahr's clinic and sought treatment from him for a stroke which she suffered in May 1999. Hammesfahr sent M.T. an information package and a videotape. The package contained articles written by Hammesfahr, a description of the different programs available, and a price list for the programs.

17. M.T. decided that she would try a three-day program for \$3,000. There was a dispute as to exactly which program M.T. received when she went to Clearwater. The only two programs which Hammesfahr listed as costing \$3,000 were the Executive Stroke Prevention Program and the One-Week Evaluation and Treatment Program.

18. The Executive Stroke Prevention Program was described as follows:

This is a three (3) day program in which patients will undergo CAT scan and MRI at our facility, state of the art computerized EEG, and transcranial ultrasound to look at the blood vessels of the brain. They will

undergo a comprehensive medical review and family review, as well as recommendations for lowering one's chances of a stroke or to treat if there has been a stroke in the past.

This program is not covered by insurance.

19. The One-Week Evaluation and Treatment Program was described as follows:

This program is designed for those who want to start the stroke program and have the program advanced to a level which makes it significantly easier for the family physicians at home and neurologists to continue the program safely and rapidly. The first days [sic] involved in the initial evaluation, as well as any testing such as EEG and ultrasound testing, if necessary, and CT scans and MRIs as well as blood tests, followed by days two through five being involved in the initiation of medical treatment in that either treating the previous stroke or preventing future strokes. Recommendations are then made to the family physician or neurologists for caring through on this program.

20. There was an additional three-day program, Initial Evaluation and Treatment, which listed for \$2,000 and provided the following:

This is a three (3) day consultation and evaluation with recommendations for treatment. This program is designed for patients who are interested in treatment of their stroke by their family physicians at home. A comprehensive evaluation will be made by our physicians as well as treatment recommendations. This evaluation will include review of CAT scans or MRIs and blood tests, and when appropriate, computerized EEG testing, neuropsychological

testing, and ultrasound evaluations. The program is approximately three days.

21. Prior to traveling to Hammesfahr's clinic, M.T. was directed by Hammesfahr to obtain medical tests from her primary care physician, which she did. The tests included a CT scan of the brain, a CMP, liver profile, CBC with different platelets, Westergren's sed rate, EEG, CVA, and EKG. She was also required to take and write down her blood pressure two times a day for a week before going to Hammesfahr's clinic. M.T. also filled out a medical history form and a system review checklist prior to her visit to Hammesfahr.

22. In a letter dated February 12, 2000, to M.T. on Hammesfahr's letterhead, his office staff described the treatment that M.T. would receive as follows:

Your first visits with us will be quite long. So, plan accordingly. On your first day, you will have a consultation with the doctor. The second day you will have diagnostic testing in our office, and an appointment with Dr. Gimon for a neuro-psychological evaluation and Diane Hartley for a physical therapy evaluation. Both of these doctors will be calling you to set up these appointments. The neuro-psychological testing will help us to evaluate any memory changes. You will probably see Dr. Gimon again towards the end of your treatment. On Tuesdays and Thursdays there is an orientation session outlining what we will be doing here in the office and [sic] explaining our treatment program will be given out. Each new patient must attend one of these sessions. Every day thereafter, your visit will be at least two (2) hours

long. As you know, our treatment consists of sessions in this office each day Monday through Friday for the duration of your therapy. Please note: No warranties or guarantees can be made regarding the time, the degree, or the duration of improvement with this therapy.

23. On February 20, 2000, M.T. signed a Waiver for Use of Medications, which stated:

I am, or my caregiver is, aware that I have had a neurological disease and have failed to respond to other types of medications used in the conservative management of my condition. . . . Options available to me at this time are those now used at the Florida Neurological Institute. I am aware that the medications used in this therapy are medications that have FDA approval. However, I am also aware that the FDA has not approved these medications in the doses and number of medications used here at the Institute. I am aware that Dr. Hammesfahr has published many articles on his therapy. I am aware of the fact that, during the past two years, the Institute has treated many patients with similar conditions and that most have had at least some improvement in the symptoms associated with their problem. I have, and my caregiver has, been counseled regarding this theory under which this therapy is being promulgated. Upon arrival at the Florida Neurological Institute, I and my caregiver, will see and listen to the videotapes available regarding this therapy. I have, or my caregiver has, read this waiver and understands its contents. I am, and my caregiver is, aware that there is no indicated use for this therapy now. I have had all questions I may have concerning the use of these medications answered, I agree to undergo the use of these medications as outlined in the material presented to me. As stated above, I am fully aware of the fact that this therapy probably will not be

covered by my insurance, but I wish to continue with this therapy as outlined to me in my training and information sessions. I also understand that no physician, or any other person in this office, can make any guarantees of success from this therapy. (Emphasis in the original)

24. On February 28, 2000, M.T., accompanied by her husband, presented to Hammesfahr's clinic in Clearwater, Florida, for treatment. On her first day at the clinic, she received an orientation. She was required to pay \$3,000 for her treatment. A staff member at Hammesfahr's clinic took M.T.'s blood pressure and directed M.T. to take her own blood pressure readings thereafter.

25. On the second day of treatment, February 29, 2000, M.T. was sent to Dr. Alexander Gimon, a neuropsychologist, for a 30-minute evaluation. A staff member of Hammesfahr's clinic gave M.T. a transcranial Doppler, a carotid artery ultrasound, and an electrocardiogram. A Physician's Office Visit History and Physical Examination Form was filled out with a date of "2-28-00" struck through at the top of the form and the date of "2-29-00" placed next to it. At the end of the form appeared a physician's statement signed by Hammesfahr and dated February 22, 2000, a week before M.T. presented for treatment, stating that he had "examined this patient, reviewed his/her history, and consulted with him/her and the caregiver regarding the treatment planned here at Florida Neurological Institute."

An Objective (Physical Examination) form was filled out, again with the date of "2-28-00" struck through at the top of the form and the date "2-29-00" placed next to it. The form does not indicate who performed the physical examination. The form does indicate that M.T.'s blood pressure and pulse readings were taken. M.T. met with Hammesfahr, who observed her gait and told her that he would send her back home and would work with her physicians. He did not prescribe any medications at that time and did not give M.T. any medications during her treatment at his clinic.

26. On March 1, 2000, M.T. was supposed to meet with the physical therapist, Diane Hartley, for evaluation at 8:00 a.m. When she arrived at Ms. Hartley's facility, no one was there to let M.T. in the building. When M.T. went into the facility, she did not like the looks of the building, describing it as "shoddy looking." She decided that she did not want to stay for an evaluation and left.

27. The fee Hammesfahr charged M.T. included the fees for Dr. Gimon and Ms. Hartley.

28. On March 1, 2000, M.T. and her husband returned home with the understanding that Hammesfahr would be contacting her doctors in Alabama to arrange for the administering of the medications. M.T. was told to make an appointment with her primary care physician for the week after she returned from

Clearwater. Hammesfahr first communicated with M.T.'s physicians by letter, dated April 5, 2000, asking them to administer the vasodilators and magnesium sulfate I.V.'s.

29. M.T.'s physicians in Alabama refused to administer the medications. M.T. did not take the vasodilators, which Hammesfahr wanted her physicians to administer; nevertheless, M.T. improved.

30. Based on the rate schedule presented to M.T. for Hammesfahr's various treatment programs, she should have received either the Executive Stroke Prevention Program or the One-Week Evaluation and Treatment Program. Hammesfahr was adamant that M.T. did not sign up for the Executive Stroke Prevention Program, and the evidence established that she did not receive this program. M.T. was given an itinerary that indicated that she would be treated by Hammesfahr for a week; however the evidence established that she did not receive the treatment that was supposed to be given in the One-Week Evaluation and Treatment Program, which promised that the initiation of medical treatment would be done on days two through five. Hammesfahr did not administer any medications or prescribe any medications for M.T. during her stay in Clearwater. The evidence does show that M.T. received the three-day Initial Evaluation and Treatment Program, for which she should have been charged only \$2,000.

31. Hammesfahr presented the expert testimony of Dr. Jacob Green, who is a board-certified neurologist, practicing in Jacksonville, Florida. He has been practicing for over 35 years. Dr. Green has written papers on the use of transcranial Doppler, and he is experienced in the treatment of acute and chronic stroke patients.

32. Dr. Green is familiar with the protocol and procedure utilized by Hammesfahr in treating stroke patients. He has read articles written by Hammesfahr, reviewed patients' records, and spent a day in Hammesfahr's office observing Hammesfahr's practice and treatment protocol which is at issue in this case. While he was at Hammesfahr's clinic, Dr. Green observed Hammesfahr treat patients, reviewed medical records of patients when they first came to Hammesfahr for treatment, and compared the findings in those records to his observations of the patients' abilities. Dr. Green discussed the treatment and protocol with Hammesfahr. Based on his deposition testimony, Dr. Green had a good understanding of the treatment and protocol used by Hammesfahr for stroke patients.

33. Dr. Green described the standard of care for a stroke patient as "to do good by the patient, do no harm." According to Dr. Green, Hammesfahr's care and treatment and protocol complied with the standard of care.

34. Hammesfahr presented the expert testimony of Dr. William Scott Russell, Jr., a retired neurologist with 33 years of experience. In his practice, he had treated thousands of stroke patients. Dr. Russell retired in October 1998. Dr. Russell had first-hand knowledge of the protocol used by Hammesfahr when he treated Dr. Russell for an acute stroke. Prior to Dr. Russell's being treated by Hammesfahr, Dr. Russell had reviewed a paper written by Hammesfahr concerning Hammesfahr's treatment protocol for stroke victims using vasodilators. Dr. Russell considered the treatment protocol espoused by Hammesfahr to not be below the standard of care as of 1998.

35. In 1996, Dr. Russell experienced a stroke. When he awoke one morning, he was confused. He went to work and had difficulty with his abilities to speak and write. Dr. Russell realized that he was experiencing a stroke and had a technician in his office run an EEG. He had peer-reviewed some of Hammesfahr's papers prior to his stroke and was impressed with Hammesfahr's work. So, he contacted Hammesfahr and presented at Hammesfahr's clinic for treatment the day he experienced the stroke. Hammesfahr performed a transcranial Doppler on Dr. Russell and administered nitroglycerine to dilate Dr. Russell's blood vessels. Ten minutes after the nitroglycerine was administered, Dr. Russell's symptoms

disappeared. Within a reasonable degree of medical probability, the cause of his recovery was the use of the nitroglycerine.

36. Nitrates are used for acute stroke patients when the patient has an extremely high blood pressure. The nitrates lower the blood pressure and are given intravenously so that the medication can be discontinued immediately if the blood pressure should fall too low. There was no evidence presented to determine whether at the time that Hammesfahr administered nitroglycerine to Dr. Russell that Dr. Russell's blood pressure was high.

37. At the time of the final hearing, Dr. Russell felt that he had total recovery from the stroke deficits. He has reduced his intake of medications prescribed by Hammesfahr and has not had a return of the deficits.

38. The Department presented the testimony of four expert witnesses concerning the standard of care for treatment of stroke victims: Dr. Harold Charles Friend, Dr. Steven Novella, Dr. David F. Scales, and Dr. Thomas Hoffman.

39. Dr. Hoffman has been practicing neurology in Melbourne, Florida, since 1982. Approximately five to ten percent of his patients have had a stroke or a cerebral vascular disease. He has read some of Hammesfahr's advertisements and viewed Hammesfahr's article on Hammesfahr's Internet web site. Dr. Hoffman understands Hammesfahr's protocol to be the use of

medications to increase the cerebral blood flow and the use of the transcranial Doppler to direct the medication treatment by measuring the cerebral blood flow.

40. Dr. Hoffman does not agree that the use of vasodilators increases the blood flow to the brain. There is a loss of cerebral autoregulation when a stroke occurs. According to Dr. Hoffman, the use of vasodilators can decrease the blood flow to the brain and worsen neurological functioning in acute stroke patients.

41. It is the opinion of Dr. Hoffman that Hammesfahr's treatment of stroke patients falls below the standard of care for acute, subacute, and chronic stroke patients.

42. Dr. Steven Novella is a neurologist and an assistant professor at Yale University. He received his medical license in Connecticut in 1993 and obtained his board certification in neurology in 1998. He treats stroke patients and is familiar with the appropriate treatment for stroke patients.

43. Dr. Novella understands that the treatment for stroke patients which Hammesfahr advocates is the administration of vasodilators to expand blood vessels which have an insufficient blood supply due to constriction. He disagrees with Hammesfahr's theory, espousing that the blood vessels in the area of the brain that is not receiving enough blood flow will dilate as far as they can go and that the blood vessels will not

respond to the vasodilators because the blood vessels are already maximally dilated. Dr. Novella is of the opinion that vasodilators may be used for stroke patients to reduce the risk of another stroke when the patient is hypertensive, but that the vasodilators should not be used as a method of reversing deficits caused by stroke.

44. Dr. Harold Charles Friend is a board-certified neurologist, who has been practicing neurology for 26 years. He practices in Boca Raton, Florida. Approximately five to eight percent of his practice is dedicated to treating stroke patients. He is currently treating in excess of 500 stroke patients.

45. Dr. Friend has reviewed the charts of two patients of Hammesfahr, an article written by Hammesfahr, some of Hammesfahr's advertisements, some newspaper articles, and an article authored by Hammesfahr, which appeared on an Internet site. Dr. Friend also saw a patient in his office that had previously been treated by Hammesfahr. Based on the information from these sources, Dr. Friend incorrectly understood that Hammesfahr's methodology was to basically lower the blood pressure of his patients in an attempt to restore dead cells. He also concluded that the patients seen by Hammesfahr were also receiving physical therapy at the time of treatment.

46. Dr. Friend opined that Hammesfahr's treatment of chronic stroke victims did not comport with the standard of care recognized in the medical community. He further concluded that given the medications that Hammesfahr administers to his patients, that one would expect some adverse effects or no effect on the patients.

47. The only mention in the record of a patient's being harmed by Hammesfahr's treatment was by Dr. Friend. Dr. Friend reviewed a medical chart of a patient who had worsened after treatment by Hammesfahr and had to go to another physician, Dr. Nassar Elmansoury, to correct the problem. The patient had been prescribed Accupril, ten milligrams four times a day, and nitroglycerine cream. Both medications are vasodilators.

48. When the patient presented to Dr. Elmansoury, the patient was feeling worse and experiencing chest pain, dizziness, and disequilibrium. Dr. Elmansoury eliminated the nitroglycerine cream and reduced the amount of Accupril. Within two weeks, the patient was improved.

49. Dr. David F. Scales is a board-certified neurologist, who has been practicing for 34 years. He currently practices in the Jacksonville, Florida, area at the Jacksonville Neurological Clinic. About 50 percent of his in-patient practice consists of stroke patients. Stroke patients comprise about 20 to 25 percent of the entire practice.

50. Dr. Scales has reviewed the medical records of two of Hammesfahr's patients, articles written by Hammesfahr, literature provided by Hammesfahr to his patients, and Hammesfahr's Internet web site. Dr. Scales understands Hammesfahr's theory to be that vasodilators are administered to dilate the blood vessels in the brain so that more blood flows through the penumbra, reactivating neurons that were in a suspended state of activation. He does not agree with Hammesfahr's theory because the blood vessels in the penumbra would be dilated to the maximum and the medications would dilate blood vessels in other parts of the body, which would in turn take away or steal the blood flow from the blood vessels in the penumbra.

51. After reviewing the medical records of two of Hammesfahr's patients, M.T. and M.S., Dr. Scales was of the opinion that the treatment provided by Hammesfahr did not meet the standard of care for the treatment of stroke patients.

52. Having considered the testimony of the experts presented by the parties, it is determined that the standard of care for the treatment of stroke patients varies according to the stage, type, and severity of the stroke. In the acute stage, the patient is admitted to the hospital. A medical history is taken and a physical exam is given, followed by appropriate laboratory and imaging studies to determine the site

and cause of the stroke. For patients seen within three hours of the onset of the stroke, certain intravenous medications may be given in an attempt to break up the blood clot. For patients seen beyond the three-hour point, the treatment is maintenance of their blood pressure, monitoring of their vital signs, and treating any complications that may occur such as pneumonia and urinary tract infections. Patients may be given blood thinners to improve the flow of the blood, and medication to increase the blood pressure in the event the blood pressure is too low. Patients with severe hypertension, generally a blood pressure over 220 systolic or 120 diastolic, are given medications to lower their blood pressure. Patients with asymptomatic hypertension are treated judiciously during their hospital stay with anti-hypertensive medications, and the blood pressure is gradually lowered.

53. The standard of care for subacute stroke patients is a continuation of the treatment given in the acute phase. Patients will be started on rehabilitation therapy, which may include speech, occupational, and physical therapy.

54. The standard of care for chronic stroke patients, whom the physician is seeing for the first time, would be to take a history to determine what happened, review the medical records and any imaging studies that may have been done, and review the treatment they have had. The physician should assess the

patients' risk factors for stroke such as hypertension, hyperlipidemia, diabetes, and smoking and manage those factors aggressively. Treatment with antiplatelets such as aspirin or an anticoagulation medication might be indicated. An assessment of their neurological functional abilities should be done to determine whether aids, braces, further therapy, or home care could be beneficial.

55. Based upon the evidence presented, the treatment advocated by Hammesfahr is not within the generally accepted standard of care. However, the evidence is not clear and convincing that the treatment used by Hammesfahr is harmful to his patients. There is literature in the medical community that vasodilators can be used in the treatment of stroke as a measure to prevent future strokes.

56. There is evidence that in over 200 patients seen by Hammesfahr that a large percentage improved after being treated by Hammesfahr. Dr. Gimon tested a group of 168 stroke patients seen at Hammesfahr's clinic during the period of November 1999 to May 2000 and another group of 163 stroke patients seen during October 2000 through February 2001. The same battery of tests was administered to both groups. Dr. Gimon evaluated these patients on nine separate neurological evaluations that are standard instruments recognized in neuropsychology. The tests

measured identified areas of brain function, including verbal, visual, visual motor, and conceptual thinking.

57. Both groups of patients were tested prior to the treatment by Hammesfahr. The patients were tested again approximately 18 to 21 days after they began treatment at Hammesfahr's clinic. The test results showed that many patients showed improvements in the areas tested. The improvements noted were measured as to a statistical difference so that the findings could not be attributable to testing error. Some patients showed no improvement in all areas. The test results revealed that there was no neuropsychological deterioration of the patients tested.

58. Diane Hartley tested two groups of Hammesfahr's patients, who were treated at his clinic during the period of January to December 2000. Her tests were designed to measure functional motor improvement from a gross motor standpoint. She performed tests on the patients prior to their beginning treatment with Hammesfahr and again approximately two and one half to three weeks after the patients had begun treatment.

59. Of the 242 patients tested by Ms. Hartley, 221 patients demonstrated improvement in one or more of the areas tested and 21 patients showed no improvement. Of the patients tested, ten received physical therapy from Ms. Hartley while they were being treated by Hammesfahr. These ten patients

demonstrated a significant amount of improvement, which Ms. Hartley could not attribute solely to the physical therapy they received.

60. The evidence establishes that Hammesfahr informed his patients by the use of videos, orientation sessions, literature, and a web site on the Internet of the nature of the therapy and did not guarantee that the patients would improve as a result of the treatment. Patients were able to make an informed decision on whether to try Hammesfahr' treatment.

CONCLUSIONS OF LAW

61. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. Sections 120.569 and 120.57, Florida Statutes.

62. The Department has alleged that Hammesfahr has violated Subsections 458.331(1)(d), 458.331(1)(n), and 458.331(1)(t), Florida Statutes, which provide:

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

* * *

(d) False, deceptive, or misleading advertising.

* * *

(n) 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.

* * *

(t) Gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. As used in this paragraph, "repeated malpractice" includes, but is not limited to, three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$25,000 each to the claimant in a judgment or settlement and which incidents involved negligent conduct by the physician. As used in this paragraph, "gross malpractice" or "the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances," shall not be construed so as to require more than one instance, event, or act. Nothing in this paragraph shall be construed to require that a physician be incompetent to practice medicine in order to be disciplined pursuant to this paragraph.

63. The Department must establish the alleged violations by clear and convincing evidence. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne Stern and Company, 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1st DCA 1987).

64. Clear and convincing evidence requires that the evidence be credible; the facts to which witnesses testify must

be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue; and the evidence must produce in the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).

65. Petitioner seeks to discipline Hammesfahr for the methods that he uses to treat stroke victims. In a similar case, State Board of Medical Examiners of Florida v. Rogers, 387 So. 2d 937 (Fla. 1980), the Medical Board sought to discipline a physician for administering chelation therapy for arteriosclerosis. Chelation therapy is an infusion of a chelating agent into the blood stream over several hours. In Rogers, the Medical Board charged Dr. Rogers with a violation of Subsection 458.1201(1)(m), Florida Statutes (1975)¹, seeking to discipline his license and to prohibit Dr. Rogers from using chelation therapy in his practice. After an administrative hearing, the Medical Board entered a Final Order reprimanding Dr. Rogers, placing him on probation for one year, and ordering him to cease and desist from employing chelation therapy. The district court of appeal quashed the Final Order. The Florida Supreme Court affirmed the decision of the district court of appeal, stating:

Under the particular facts of this case, we conclude that the Board's action unreasonably interferes with Dr. Rogers' right to practice medicine by curtailing the exercise of his professional judgment to administer chelation therapy. The record before us fails to evidence a harmfulness as a reasonable basis for the Board's action in restricting use of this treatment. Cf. Golden v. McCarthy, 337 So. 2d 388 (Fla. 1976). Furthermore, the evidence demonstrates that no fraud or deception was exercised by Dr. Rogers upon his patients who were fully informed of the nature of the procedure and the possibility of no improvement. Sanctions were imposed against Dr. Rogers because he utilized a modality not accepted by the Board as having been proven effective, not because the Board found that the treatment was harmful or that Dr. Rogers had defrauded his patients into believing that chelation treatment was a cure for their conditions. The Board's findings do not support a conclusion of quackery, and the state-imposed limitation on the administration of chelation treatment has not been shown by the evidence to have a reasonable relationship to the protection of the health and welfare of the public.

Id. at 939-940.

66. Based on the Rogers case, Petitioner has failed to establish by clear and convincing evidence that Hammesfahr has violated Subsection 458.331(1)(t), Florida Statutes. Petitioner did not establish by clear and convincing evidence that the treatment harmed Hammesfahr's patients, that the patients did not make an informed decision to try the treatment, or that Hammesfahr used fraud or deception to make his patients believe that they would improve with the treatment he offered.

67. The treatment advocated by Hammesfahr could be considered an alternative health care treatment, which is "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." Subsection 456.41(2)(a), Florida Statutes. In Subsection 456.41(1), Florida Statutes, the Florida Legislature set forth its intent concerning the use of alternative health care treatment.

It is the intent of the Legislature that citizens be able to make informed choices for any type of health care they deem to be an effective option for treating human disease, pain, injury, deformity, or other physical or mental condition. It is the intent of the Legislature that citizens be able to choose from all health care options, including the prevailing or conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing or conventional treatment methods. It is the intent of the Legislature that health care practitioners be able to offer complementary or alternative health care treatments with the same requirements, provisions, and liabilities as those associated with the prevailing or conventional treatment methods.

68. Subsection 456.41(3)(c), Florida Statutes, provides that a physician may in his "discretion and without restriction, recommend any mode of treatment that is in his . . . judgment, in the best interests of the patient, including complementary or

alternative health care treatments, in accordance with the provisions of his . . . license."

69. Hammesfahr is offering an alternative treatment. He has met the requirements of Subsection 456.41(3), Florida Statutes, by providing his patients with the required information for the patients to be able to give an informed consent for the treatment.

70. Petitioner has failed to establish by clear and convincing evidence that Hammesfahr's advertising was false or deceptive. Many of Hammesfahr's patients have improved after being treated by Hammesfahr. Hammesfahr has had his study of his first 67 patients reviewed by peers in the medical community. While the peer review may not be the type that would be acceptable for many medical journals, it nevertheless is a study that was reviewed by peers. No evidence was introduced to show that other doctors are using Hammesfahr's methods; thus, he is the first physician to treat patients successfully to restore deficits caused by stroke.

71. Petitioner has established by clear and convincing evidence that Hammesfahr did violate Subsection 458.331(1)(n), Florida Statutes, as it relates to M.T. The price schedule furnished to M.T. indicated several services which Hammesfahr would perform for a set price. M.T. paid \$3,000 for treatment and did not receive the treatment that would be included for

either the Executive Stroke Prevention Program or the One-Week Evaluation and Treatment Program. M.T. received the services outlined in the three-day Initial Evaluation and Treatment, for which the cost was \$1,000 less than what M.T. paid. Hammesfahr did exploit M.T. for financial gain by charging her for services that she did not receive.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is

RECOMMENDED that a final order be entered finding that Hammesfahr did not violate Subsections 458.331(1)(d) and 458.331(1)(t), Florida Statutes; finding that Hammesfahr did violate Subsection 458.331(1)(n), Florida Statutes; placing Hammesfahr on probation for six months; and imposing a \$2,000 administrative fine.

DONE AND ENTERED this 20th day of November, 2002, in Tallahassee, Leon County, Florida.

SUSAN B. KIRKLAND
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 20th day of November, 2002.

ENDNOTE

1/ Subsection 458.1201(1)(m), Florida Statutes, provided:

(1) The board shall have authority to deny an application for a license or to discipline a physician licensed under this chapter or any antecedent law who, after hearing has been adjudged unqualified or guilty of any of the following:

(m) Being guilty of immoral or unprofessional conduct, incompetence, negligence, or willful misconduct. Unprofessional conduct shall include any departure from, or the failure to conform to the standards of acceptable and prevailing medical practice in his area of expertise as determined by the board, in which proceeding actual injury to a patient need not be established when the same is committed in the course of his practice whether committed within or without this state.

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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.