STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case Nos. 01-4406PL
	)	01-4407PL
LARRY DEE THOMAS, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

A formal hearing was held in the above-styled consolidated causes before Daniel M. Kilbride, Administrative Law Judge, Division of Administrative Hearings, on May 1 through 3, 2002, in Winter Haven, Florida.

APPEARANCES

For Petitioner: Kim Kluck, Esquire
Richard J. Shoop, Esquire
Agency for Health Care Administration
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For Respondent: William R. Huseman, Esquire
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STATEMENT OF THE ISSUES

AS TO CASE NO. 01-4406PL

Whether Respondent's license as a physician should be disciplined for the alleged violation of Section 458.331(1)(t), Florida Statutes, in that Respondent failed 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, by failing to treat the patient's preoperative coagulopathy and/or failing to use an alternate vein that would have allowed visualization of the shunt placement into the vein thereby reducing the risk of causing a hemorrhage given the patient's preoperative history, and, if so, what penalty should be imposed.

AS TO CASE NO. 01-4407PL

Whether Respondent's license as a physician should be disciplined for the alleged violation of Section 458.331(1)(t), Florida Statutes, by failing 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 by failing to distally clamp part of the arteries prior to manipulation of the aneurysm and by failing to ensure periodic monitoring of the patient's condition postoperatively for evidence of ischemia or other problems and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

By Administrative Complaint dated May 8, 1999, Petitioner, Department of Health, alleged in DOH Case No. 1994-12341 that Respondent, Larry Dee Thomas, M.D., violated provisions of Chapter 458, Florida Statutes, governing the practice of medicine in Florida. The single count of the Complaint relates to preoperative and operative events surrounding the venous shunt procedure that Respondent performed on Patient D.J.P in February 1994. Respondent contested the allegations of the Complaint and timely requested a formal administrative hearing. Petitioner forwarded the Complaint to the Division of Administrative Hearings on October 15, 2001, requesting the assignment of an Administrative Law Judge and a formal hearing pursuant to Sections 120.569 and 120.57, Florida Statutes.

On June 12, 2001, Petitioner filed an Administrative Complaint against Respondent. The Administrative Complaint alleges in DOH Case No. 1999-57795 that Respondent violated Section 458.331(1)(t), Florida Statutes. Respondent timely executed his Election of Rights form and requested a formal hearing pursuant to Sections 120.569 and 120.57(1), Florida Statutes. By letter dated October 10, 2001, and filed on November 14, 2001, the matter was referred to the Division of Administrative Hearings. The matter was initially assigned to Administrative Law Judge Susan B. Kirkland, who set the case for

final hearing on January 9 and 10, 2002, and consolidated the two cases for hearing. Two continuances were granted, and the hearing was ultimately held on May 1 through 3, 2002, before the undersigned Administrative Law Judge.

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At the hearing and prior to the commencement of Petitioner's case-in-chief, several motions pertinent to this case were decided. Petitioner filed motions for official recognition of Section 458.331, Florida Statutes, and Rules 61F-20.001 and 59R-8.001, Florida Administrative Code. Both motions were granted without objection. Petitioner's Motion in Limine to exclude the testimony of Frank Seller, M.D., who would testify as an expert medical witness on behalf of Respondent, was denied.

Petitioner presented the testimony of John W. Kilkenny, III, M.D.; Helga Gion, M.D.; Felicia Whitmer, Surgical Technician; and Rene Myers, Registered Nurse. Petitioner's Exhibit 1, the curriculum vitae of John W. Kilkenny, III, M.D., was admitted into evidence.

Respondent testified on his own behalf and presented the testimony of William Z. Yahr, M.D. Respondent's Exhibit 1, the curriculum vitae of William Z. Yahr, M.D., and Respondent's Exhibit 2, the curriculum vitae of Respondent, was admitted into evidence.

Joint Exhibit 1, the relevant medical records of Patient D.J.P. from Dr. Carey, Dr. Thomas, and Winter Haven Hospital, was admitted into evidence as a composite exhibit.

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Petitioner presented the testimony of four witnesses: Kenneth M. Begelman, M.D., testified as an expert on behalf of Petitioner; Doris Gutierrez, the recovery room nurse; Patient H.H.; and her daughter T.H. Petitioner offered one exhibit, the curriculum vitae of Kenneth M. Begelman, M.D., which was admitted in evidence.

Respondent presented three witness: Frank Zeller, M.D., testified as an expert on Respondent's behalf; Dale Wickstrom-Hill, M.D., the anesthesiologist on duty during the abdominal aortic aneurysm surgery performed on Patient H.H. and Respondent testified on his own behalf. Respondent offered two exhibits, which were admitted into evidence and numbered as follows:

2. Curriculum vitae of Larry D. Thomas, M.D., Respondent's Exhibit 2

3. Cat scan images of Patient H.H.'s abdomen - Views A & B, Respondent's Exhibit 3

Petitioner and Respondent stipulated to a Joint Exhibit, which included a portion of Patient H.H.'s medical records pertinent to the allegations contained in the Administrative Complaint, which was admitted into evidence as Joint Exhibit 1. The parties also

submitted a duplicate of Joint Exhibit 1, which was admitted as Joint Exhibit 1A.

A Transcript of the hearing was ordered. The hearing was transcribed by two different reporting companies. Volumes 2 and 3 of the Transcript of the proceeding were filed on May 28, 2002. Volume 1 of the Transcript of the proceeding was filed on May 31, 2002. The parties timely filed their Proposed Recommended Orders. Both parties' proposals have been given careful consideration in the preparation of this Recommended Order.

FINDINGS OF FACT

Based on the evidence adduced at the final hearing, and the entire record in this proceeding, the following findings of fact are made:

FACTS COMMON TO BOTH CASES

1. Petitioner is the state agency charged with regulating the practice of medicine pursuant to Section 20.42, Florida Statutes, Chapters 456 and 458, Florida Statutes.

2. At all times relevant to this proceeding, Respondent was a licensed physician in the State of Florida, having been issued license number ME 0036360. Respondent is board-certified in thoracic and general surgery.

FACTS RELATED TO CASE NO. 01-4406PL

3. Patient D.J.P. was a 54-year-old female with a history of liver resection for carcinoma. Patient D.J.P. had contracted Hepatitis C in the 1960s from a blood transfusion, after being the victim of a gun shot wound during a robbery at a convenience store.

4. Patient D.J.P. subsequently had developed cirrhosis secondary to the Hepatitis C. Cirrhosis is a scarring process of the liver that results in the displacement of the normally functioning liver tissue.

5. A healthy liver processes lymphatic fluid back into the bloodstream. However, a cirrhotic liver cannot properly process the lymphatic fluid back into the bloodstream. Therefore, lymphatic fluid backs up within the liver and weeps out the covering over the liver and into the abdominal cavity.

6. Patient D.J.P. presented to Respondent on February 1, 1994, after being referred to Respondent by Michael Carey, M.D., the primary care physician, for evaluation for implanting a peritoneal venous shunt. A venous shunt is a conduit designed to take ascitic fluid from the abdomen and put it back in the vascular system. The shunt removes the fluid from the abdominal cavity and transports it to the vascular system where it can be absorbed. The procedure is for the patient's comfort and does

not prolong the patient's life. The procedure is for patients with end stage liver disease.

7. After obtaining a medical history and conducting a physical examination, Respondent's assessment of the Patient D.J.P. was massive ascites secondary to cirrhosis and previous liver resection. Respondent believed that Patient D.J.P. was a candidate for a venous shunt procedure due to the fact that she was very symptomatic from her massive ascites and she was on the maximum medical therapy.

8. The mortality rate for this type of procedure is between 5 and 25 percent or at the very least, one-in-twenty patients would die from this procedure. Complications associated with this type of procedure include disseminated intravascular coagulopathy (hereinafter referred to as "DIC") which may lead to the general worsening of the disease or death. The patient was informed of this mortality rate as well as of the complications associated with this procedure.

9. Patient D.J.P. decided to think about the procedure and contact Respondent's office when she wanted the shunt inserted.

10. On February 10, 1994, Patient D.J.P. called Respondent's office and asked to have the shunt inserted as soon as possible. Respondent scheduled the procedure for February 14, 1994, and signed the written surgical consent form.

11. Prior to the surgery, lab tests were performed on Patient D.J.P. The lab report indicated that the patient's prothrombin time was 14.3, with a normal range being 10.7-12.8. Prothrombin time ("PT") is a measurement of one aspect of the blood clotting mechanism. This was considered slightly abnormal and not an indication of a clotting problem or coagulopathy.

12. Respondent decided it was not necessary to address Patient D.J.P.'s abnormal PT prior to the procedure by preoperatively administering Vitamin K or fresh frozen plasma.

13. On February 14, 1994, Patient D.J.P. was transported to the operating room at approximately 12:10 p.m. After Patient D.J.P. was placed under general anesthesia, Respondent began the venous shunt operation at approximately 12:34 p.m. Respondent attempted to access the right jugular vein to insert the shunt. He found this vein to be unusable because it was too scarred from previous surgeries. Respondent then proceeded to access the right subclavian area to insert the shunt. Once the shunt was inserted into the subclavian area, Respondent positioned it in the superior vena cava. The shunt was noted to be in position in the superior vena cava. Respondent then removed eight liters of ascitic fluid from the abdominal cavity. After removing the ascitic fluid, he then put one liter of saline into the abdominal cavity to dilute any remaining ascitic fluid which allowed any

remaining fluid to be more easily absorbed into the vascular system. The Patient's central venous pressure dropped from 8 to 2. Hespan and Albumin were then administered to replace any lost volume and it helped to increase the colloidomotic pressure. At this point, Patient D.J.P.'s central venous pressure (CVP) increased from 2 to 14 or 15. This is a faster than normal rate. Upon finding that the shunt was operating well, Respondent closed the abdominal portion and the patient was extubated.

14. Petitioner claimed that fluoroscopy was not used to ensure that the shunt was positioned in the proper place. A Fluoroscope is like a real-time X-ray. A fluoroscope has two parts to it: a C-arm, which goes above the patient and underneath the bed, and two screens where the doctor can see what is going on. The C-arm is approximately 5-and-a-half feet tall. It is below the standard of care to do a venous shunt procedure without using a fluoroscope. It would enable Respondent to visualize the placement of the shunt.

15. Felicia Whitmer, a scrub technician, and Rene Myers, a circulating nurse, prepared the operating room for Patient D.J.P.'s procedure on February 14, 1994. Both Felicia Whitmer and Rene Myers testified that there was no fluoroscope in the operating room on February 14, 1994. Respondent testified that there was a fluoroscope in the operating room on February 14,

1994, during Patient D.J.P.'s procedure and that he used it to assist him.

16. The evidence is not clear and convincing that the fluoroscope was not used during the course of the operation.

17. It is considered within the accepted standard of care to access the right subclavian vein to insert a shunt of this type because this vein follows a gentle curve or path. With this gentle curve in the vein, there is less risk of damage, i.e. puncture, to the vein. In contrast, the left jugular vein follows a more sharp-angled 70-degree bend-curve in the vein where one risks the danger of the shunt coming out of the bottom of the vein or perforation and, thereby, damaging the vein.

18. Respondent ordered an X-ray to confirm placement of the shunt and catheter. The X-ray revealed that the shunt had good positioning but the right lung was filled with fluid. The patient was re-intubated and Respondent inserted a chest tube into the patient which would expand the patient's lung, oxygenate the patient and allow for fluid removal. Three or four liters of fluid were removed. The fluid was originally serous and pink tinged and shortly thereafter, turned bloody. Respondent noted that there was bruising around the wounds. Additionally, the patient's breathing became shallow and her blood pressure began to deteriorate.

19. Resuscitative efforts were performed and Respondent re-entered the shunt area to clamp the shunt to prevent any ascites from flowing into the venous system and to prevent further coagulation and massive bleeding. Despite heroic resuscitative efforts, the patient's condition continued to deteriorate and the patient died.

20. The cause of death was determined to be DIC and severe coagulopathy from drainage of the ascitic fluid into the venous system.

21. Respondent made the determination that the patient did not have preoperative coagulopathy. Respondent testified that if the patient did have preoperative coagulopathy, he would not have performed the procedure because the patient would not be able to make the clotting factors well enough for problems that would occur after the shunt was inserted. It was Respondent's opinion that the patient did not have a serious clotting problem. Based on her lab report, Patient D.J.P. had a slightly abnormal PT and this was not an indication of a clotting problem.

22. Respondent reviewed the lab reports and determined the PT (the measurement of one aspect of blood clotting mechanism), to be only slightly elevated. It measured 14.3 with a normal range being 10.7-12.8. Moreover, the PT International Normalized Ratio (INR) (which is the standardized measurement of PT) was

1.63 where the therapeutic range was 2-3. Therefore, this was slightly below average.

23. Dr. Yahr testified that an abnormal clotting problem is a clinically evident problem and not an incident of a lab number. If Patient D.J.P. had a clotting abnormality, adverse conditions or symptoms would have been evident with the incisions that were made prior to the shunt being opened. Rather, normal clotting reactions occurred. Coagulation occurred right after the shunt was opened and the ascitic fluid began to flow into the atrium. Dr. Yahr testified that the etiology of the coagulation was the body's reaction to the ascitic fluid after the shunt was opened. Accordingly, it was Dr. Yahr's opinion that Respondent did not fail to treat the preoperative coagulopathy because upon his examination of the patient, he determined that no such preoperative coagulopathy existed prior to the procedure. Dr. Yahr testified that the patient did not have abnormal bleeding. Her liver failure was the result of scarring and abnormal liver function. Therefore, administration of clotting factors such as Vitamin K and fresh frozen plasma was not indicated or medically necessary.

24. Petitioner presented the expert testimony of John W. Kilkenny, III, M.D. Dr. Kilkenny is board-certified in general surgery and has been for 11 years and is currently a professor with the University of Florida College of Medicine, Department of

Surgery in Jacksonville, Florida, a position which he has held for the last six years. According to Dr. Kilkenny, Patient D.J.P.'s elevated PT was a cause for concern in that it was an indication that the patient's ability to clot or coagulate was diminished.

25. It is not clear and convincing that the standard of care required that the elevated PT be treated by infusing fresh frozen plasma or Vitamin K.

26. Respondent did not violate Section 458.331(1)(t), Florida Statutes, by failing to use an alternate vein that would allow visualization of the placement of the shunt. Respondent first attempted to access the right jugular vein to insert the shunt but found it be unusable because it was too scarred. Respondent, acting as a reasonably prudent physician and using sound medical judgment, accessed the right subclavian area to insert the shunt. After the shunt was inserted into he subclavian vein, Respondent claimed he was able to visualize the placement of the shunt by the use of fluoroscopy. Furthermore, the operative notes seemed to indicated that the procedure was performed under fluoroscopic control and the shunt was found to be in position. Therefore, Respondent accessed an appropriate alterative vein-the subclavian vein, which allowed visualization, with the assistance of fluoroscopy, of the placement of the shunt.

27. As to the second issue, Dr. Kilkenny opined that the standard of care requires direct visualization for insertion of the shunt. By not accessing a vein under direct visualization, such as with Respondent's subclavian approach, the surgeon is, in essence, hunting for the vein, and risking damage to the wall of the vein that may not be evident immediately. The rapid rise in CVP from 2 to 14 or 15 was also a concern for Dr. Kilkenny because it was not normal, and did not mean that the shunt was placed correctly of that the shunt was functioning properly. Dr. Kilkenny noted that it was unlikely that the bleeding in the chest cavity was caused by damage to an intercostals vessel when the chest tube was inserted because the chest X-ray that was taken prior to insertion of the chest tube showed a complete opacification of the right side and a shifting of the major vessels within the middle of the chest over to the left side. According to Dr. Kilkenny, the chest X-ray indicated that there had already been some sort of bleeding in the right chest prior to the insertion of the chest tube. Dr. Kilkenny disputed Respondent's theory that Patient D.J.P. died as a result of DIC. Dr. Kilkenny asserted that Respondent fell below the standard lf care in that, given Patient D.J.P.'s rapid decompensation, he failed to consider whether the patient's subclavian vein had been damaged, a condition which could have been addressed surgically.

28. Dr. Yahr opined that Patient D.J.P. died of DIC that occurred within a short period of time after Respondent opened up the shunt and ascitic fluid was introduced into the atrium of the heart. Although Dr. Yahr further admitted that the bleeding in the chest could have occurred as a result of damage to the subclavian vein, and that it was below the standard of care to access the subclavian vein without using fluoroscopy, the evidence is not clear and convincing that either event occurred.

29. It is found that Petitioner has failed to establish by clear and convincing evidence that the standard of care required Respondent to use an access site that allowed direct visualization of the placement of the shunt into the vein, or that Respondent failed to use fluoroscopy in order to directly visualize insertion of the shunt into the subclavian vein.

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30. On August 22, 1997, Patient H.H., a 55-year-old female, was diagnosed with an abdominal aortic aneurysm measuring approximately 4.5 cm transverse diameter and beginning approximately 1-2 cm below an enlargement or swelling, of a blood vessel resulting in a weakening or thinning out of the vessel wall.

31. On November 28, 1997, Patient H.H.'s aneurysm had grown to 5 cm within a three-month period and was occluded with partial thrombosis with a true lumen around 2.7 cm and extended down to

the bifurcation of the abdominal iliac. This put the patient at risk for rupture of the aneurysm.

32. Thrombosis is a blood clot within a vessel or within the vascular system. It does not embolize (travel) from another part of the body. It starts in a particular vessel and causes its damage from there. It is an acute clot that occurs in the vessel secondary to stasis (non-moving) or some kind of coagulation or clotting deficiency or abnormality. Thrombotic activity most often begins by occluding the smaller vessels in the vascular system, such as those smaller veins located in the feet.

33. On December 2, 1997, Patient H.H. first met with Respondent, who performed a complete medical history and physical examination and confirmed the presence of a 5 cm abdominal aneurysm. Patient H.H. was a 55-year-old female who smoked 1-and-a-half packs of cigarettes per day, had a blood pressure of 182/104 despite the fact that she was taking 50 mg Atenolol for hypertension (high blood pressure), and had a 30 percent blockage of the coronary artery. Previously, she had a cardiac catheterization, followed by an angioplasty of the femoral vessel in her left leg. Patient H.H. advised Respondent that her legs gave out on her after she walked two blocks, but that she did not have associated chest pain.

34. Respondent confirmed earlier diagnosis of Patient H.H.'s medical condition as single vessel coronary artery disease, abdominal aortic aneurysm, hypertension, and claudication with femoral occlusive disease. Respondent also found diminished femoral pulses and palpable Dorsal pedal pulses present in both feet. Patient H.H.'s medical records indicated that this smoker of 30 years suffered from diabetes, peripheral vascular disease, intermittent clottication of the leg, hypertension, atherosclerotic disease, hypercoagulopathy, anthithrombin III deficiency, high cholesterol, and diminished protein and pH levels. Respondent prescribed prescription medication, Procardia to lower Patient H.H.'s blood pressure and Zyban to help her stop smoking. He recommended that the patient return in a week for follow-up.

35. On December 15, 1997, Respondent continued to prepare Patient H.H for surgery. He again advised her to stop smoking and to purchase and take medication to help her stop smoking. Patient H.H.'s blood pressure was lower, 144/84, and although she had not purchased or taken the medication, she reduced her smoking down to one-half pack of cigarettes per day. Respondent then advised Patient H.H. to make plans to undergo the abdominal aortic aneurysm ("AAA") repair. Patient H.H. informed Respondent that she wanted to wait a little longer while she made financial arrangements to pay for the surgery. Respondent advised Patient

H.H. to completely quit smoking before the surgery and advised her to return in one month for additional preoperative evaluation.

36. On January 12, 1998, Respondent continued to prepare Patient H.H. for surgery by ordering a cardiac clearance (thallium evaluation) of the patient's heart to ensure she could tolerate the surgery before attempting the AAA repair.

37. On February 3, 1998, Patient H.H. presented for the thallium evaluation of the heart and, on February 9, 1998, obtained cardiac clearance for repair of the AAA.

38. On February 11, 1998, Respondent continued to prepare Patient H.H. for AAA surgery and suggested she donate two units of blood which would be used during the surgical procedure. Respondent scheduled AAA repair surgery for March 6, 1998.

39. Respondent advised Patient H.H. of the risks associated with AAA surgery and specifically mentioned the risk of a heart attack, bleeding, kidney damage and loss of legs. He also advised that the risks associated with intra-operative AAA repair include spontaneous rupture, embolization of material from the wall distally, myocardial infarction, bleeding, injury to viscera of the small vessels, devascularization of the colon causing ischemic colitis, death, kidney blockage. Patient H.H. indicated she understood the risks and despite the risks associated with

this type of surgical procedure, including the risk of death, she agreed to the procedure.

40. Preoperative testing by angiogram was not required for Patient H.H. The aneurysm was a massive aneurysm presenting a very serious health risk of imminent rupture. The size of Patient H.H.'s aneurysm (5 cm) made AAA repair an emergency in a sense because there was almost a 100 percent chance of rupture with in the next six months. Any findings determined by angiogram would not have changed the outcome of the case because Respondent had to definitively treat the aneurysm first. Additionally, an angiogram is a very expensive test and Patient H.H. expressed a concern about her financial situation with respect to the AAA repair. It is reasonable to not do studies that a physician does not feel are absolutely necessary. The patient's financial concerns are part of the pathology.

41. On March 6, 1998, Patient H.H. was admitted to Winter Haven Hospital and filled out and signed the Special Authorization for Medical and/or Surgical Treatment form indicating her consent to the surgical procedure which Respondent was to perform. She indicated that she understood the risks associated with such surgical procedure.

42. Paragraph two of the informed consent form states in pertinent part:

> I hereby certify that I have given complete and informed consent for the above named operation and/or procedures, and Dr. L. Thomas has explained to me the reason why the above-named operation and/or procedure are considered appropriate, its advantages and possible complication, if any, as well as possible alternative modes of treatment. I also certify that no guarantee or assurance has been made as to the results that may be obtained.

43. The operative procedure on the consent form was signed by Patient H.H. at 6:10 a.m. on March 6, 1998. Surgery indicated on the consent form was for a resection abdominal aortic aneurysm (AAA repair).

44. After Patient H.H. was taken to the operating room and administration of anesthesia began, Respondent performed his routine preoperative check of femoral and pedal pulses. Checking for femoral and pedal pulses is the type of preoperative work-up Respondent routinely performs while he waits for the anesthesia to take its effect on the patient.

45. The operative report indicates that the abdominal aneurysm was "very large" extending quite high within 1-2 cm from the renal vein and down to and involving the common and hypogastric arteries and noted to be "quite saccular" with "impending rupture in the near future at the neck." The common iliacs were noted to be "quite large and aneurysmatic." The external iliacs were soft but extremely small, "approximately 4-5 mm in size, certainly less than half, more like 1/4 the size of a

normal iliac" but nevertheless usable vessels to make his anastomosis.

46. As Respondent was bluntly dissecting (separating the tissues using the fingers) the aortic aneurysm from the venous plexus to position his proximal clamp when one of the lumbar veins was encountered and mass bleeding occurred.

47. The venous plexus is a grouping of veins located under the aorta that can best be described as a wagon wheel. The system has a hub and all the veins in the grouping extend outward from the hub. If one of the veins in the grouping is injured, it will bleed heavily, but the bleeding is controllable. The lumbar veins are part of the venous plexus and a tear of the lumbar vein is a known risk during this type of surgery.

48. Patient H.H. suffered the loss of three times the amount of blood as would have been routinely expected. The sudden blood loss caused the patient's condition to rapidly deteriorate.

49. Dr. Wickstrom-Hill, Anesthesiologist, testified that had Respondent not controlled the blood loss, and had not maintained Patient H.H.'s vital signs, she would have died.

50. Using sound medical judgment, Respondent elected to bypass the aneurysmatic common iliacs and make his anastomosis of the graft to the external iliacs in order to not disconnect or separate the aortic or common iliac aneurysms from the iliac

vein. This is a very fragile vessel and could have resulted in further massive bleeding and possible death of the patient.

51. A reasonable prudent physician faced with a similar circumstance and situation would not attempt to mobilize the aneurysm further if doing so would cause additional massive blood loss and possible death of the patient.

52. The hypogastric arteries (a/k/a the internal iliacs) serve to provide the pelvic viscera (bladder, rectum, etc.) with blood.

53. During the AAA repair, Respondent performed an embolectomy on both legs following manipulation of the aneurysm. The purpose of this procedure was to remove any debris which may have dislodged from the aneurysm and flowed distally to the legs. The procedure involves running a Fogarty catheter down the femoral arteries as far as the catheter will go, then inflating a balloon located at the end of the catheter. Once the balloon is inflated, the surgeon will extract the catheter, pulling the debris out of the artery. This process is repeated as necessary to remove all debris. Fresh clot was obtained from both legs, indicating a lack of debris.

54. Prior to completing the anastomosis of the bifurcated graft to the aorta and external iliacs respectively, Respondent ran a Fogarty catheter down proximal (back into the graft itself), to remove any debris in the graft itself. Finally, he

back-bled the graft (allowed blood to flow out of the graft, to, again, ensure that there existed no debris in the graft).

55. On March 7, 1998, Patient H.H.'s medical condition stabilized such that Respondent felt it safe to return Patient H.H. to the operating room to undergo an additional embolectomy of the legs and an endarterectomy of the right femoral artery. The record demonstrates that Respondent believed he collected embolic debris from the femoral arteries.

56. However, based upon the pathology report and the testimony of Dr. Zeller, the debris removed from Patient H.H. during this procedure was acute blood clots and atherosclerotic plaque. This finding is consistent with thrombotic material and not a result of debris coming from another location as it tends to demonstrate that Patient H.H. had a clotting disorder consistent with her medical history. The record also demonstrates that upon completion of the procedure, Patient H.H. was noted to have excellent pulses in the superficial and profunda femoral arteries distal to the anastomosis with good emptying and filing of the vessels.

57. Before, during, and after the AAA repair, Respondent used Heparin (an anti-clotting drug) in an effort to prevent the formation of clots throughout Patient H.H.'s vascular system. Intraoperatively, on March 3, 1998, Respondent administered 10,000 units of Heparin. Normally a patient will respond to

5,000 units. Despite giving Patient H.H. twice the normal amount of Heparin, Patient H.H. continued to have a lowered clotting time. It is noted in the medical record that Patient H.H. had an Antithrombin III deficiency. Antithrombin III is one of the factors that control how blood in the human body clots. Patient H.H.'s Antithrombin III deficiency is a hereditary defect that contributed significantly to her continued clotting despite the use of pharmacological intervention (substantial amount of Heparin). Respondent testified that in his medical training and experience, Patient H.H.'s Antithrombin III deficiency level was near fatal.

58. Because Patient H.H. was hypercoagulative, thus causing the small vessels to clot off, on March 13, 1998, Patient H.H. underwent bilateral above the knee amputations. Hypercoagulopathy is a tendency to clot without anything being done - the blood just clots. This can be caused by a lower-than-normal blood pressure for a period of time and by having an Antithrombin III deficiency.

59. Respondent observed during the surgery that this patient was hypercoagulative because he could see the blood clotting in the wound despite the fact that Patient H.H. was on twice the normal amount of Heparin.

60. Respondent practiced within the standard of care at all times during the treatment of Patient H.H. Blood-flow going

retrograde back into the common and iliac aneurismal sacs did not place Patient H.H. at a risk of rupture. The operative report clearly demonstrates that the aortic aneurysm involved the common iliacs and extended below the hypogastric arteries. The operative report also demonstrates that the external iliacs were extremely small, approximately one-quarter of the normal size. A reasonable and prudent surgeon, faced with a similarly situated patient with a massive sized aneurysm and the extremely small size of the distal external iliacs, would conclude that the pressure gradient now being carried to the graft rather than to the aneurysm would diminish flow to the aneurysms making the possibility of rupture unlikely. Moreover, the aneurysms were filled with calcified atherosclerotic plaque and other thrombotic (non-mobile) material. Dr. Begelman testified that calcified aneurysms do not tend to rupture as much.

61. On direct examination, Dr. Begelman, Petitioner's expert, could not conclusively determine whether Respondent's surgical treatment of Patient H.H. fell below the standard of care and that distal clamping is an intra-operative decision to be made by the surgeon. Dr. Begelman who testified that he accepted Respondent's opinion that the iliacs were too large or too thin walled and could not distally clamp the aneurysm and that such decisions are those made by the surgeon on the case.

Drs. Begelman and Seller and Respondent testified that it is usual and customary during this type of surgical procedure to distally clamp the aorta and that it is expected of a reasonable and prudent surgeon to make every attempt to do so. Nevertheless, all three doctors recognized that there are times when you cannot or should not distally clamp if to do so would cause further injury to the patient or death.

62. Patient H.H. presented with very massive aneurysms of both the aorta and common iliacs making distal clamping impossible without sacrificing the hypogastric arteries thus placing Patient H.H. at risk for further injury or death.

63. Petitioner's expert accepted Respondent's assessment of the condition of the iliacs and that Respondent did not want to dissect the iliacs off the iliac vein, which one needs to do in order to tie off distally. Dr. Begelman testified that he could not ascertain whether Respondent fell below the standard of care with respect to Respondent's treatment of Patient H.H. intraoperatively.

64. Respondent acted within the standard of care and, therefore, did not violate Section 458.331(1)(t), Florida Statutes, when he did not clamp the distal arteries before manipulation of the aneurysm.

65. Respondent did not violate Section 458.331(1)(t), Florida Statutes, by sewing the bifurcated graft to the external

iliacs and making no attempt to disconnect the aneurysm from the common and internal (a/k/a hypogastric) iliacs. The common and internal iliac tissues were also diseased because of their involvement with the aneurysms coupled with the fact that the aneurysm and surrounding tissue was inflamed. Inflammation causes the tissues of the surrounding viscera to become sticky and by that, stick together making separation difficult and more prone to bleeding on manipulation. Normally, the surgeon must bluntly dissect (lift up) the distal end of the aorta in order to place the distal clamps on the aorta below the aneurysm. However, the inflammation present in Patient H.H.'s aorta made it impossible to mobilize (lift up) the distal aorta for clamping because the tissue was stuck to the iliac vein which could have caused Patient H.H. to suffer a lethal blood loss. Normally, blood loss associated with this type of surgery amounts to 500 ccs for the total surgery. Patient H.H. lost 1500 ccs during the manipulation of the aortic aneurysm to place the proximal clamp and a total of 2400 ccs during the entire surgery which represented a blood loss of nearly 25-40 percent respectively of her estimated total blood volume. Respondent used sound medical judgment by making no attempt to dissect the common iliac from the subordinate tissue because, in his training and experience, the separation of tissues would have caused further, possible lethal bleeding. Drs. Begelman and Zeller, experts for

Petitioner and Respondent respectively, testified that a reasonably prudent surgeon would not clamp below the common iliacs if to do so would sacrifice the hypogastric arteries and thereby cause irreparable harm or death to the patient. Dr. Zeller testified that the hypogastric arteries are of such importance that not clamping them, even at the risk of embolization, would nevertheless be within the standard of care.

66. Respondent closely monitored Patient H.H. postoperatively. A reasonable and prudent surgeon is not expected to remain in the recovery room with his post-surgical patient until the patient becomes stable. Rather, the reasonable and prudent surgeon is expected to utilize the nursing staff who are charged with attending to the patient and to keep the physician updated on the patient's medical condition.

67. Petitioner's witness, Doris Gutierrez, was the recovery room nurse on duty on March 6, 1998. Her duties included monitoring and reporting changes in Patient H.H.'s condition to Respondent. The record demonstrates that Respondent closely monitored Patient H.H. postoperatively by being in contact with the nursing staff and thereby giving orders for care and treatment to the nursing staff, either by telephone orders ("TO") or in person by verbal orders ("VO") to stabilize the patient.

68. While in the recovery room, Patient H.H. was intubated, on a respirator. Petitioner's witnesses, Doris Gutierrez,

confirmed Respondent's monitoring of Patient H.H. when she testified that she called Respondent several times to provide updates on Patient H.H.'s condition. The record demonstrates that postoperatively on March 6, 1998, Respondent wrote his initial order to the nursing staff at 12:30 p.m. while sitting in post-surgical recovery with Patient H.H. Thereafter, Respondent continued to monitor Patient H.H.'s condition and remained in communication with the nursing staff and wrote orders at 1:30 p.m., 2:30 p.m., 3:25 p.m., 5:00 p.m., 5:15 p.m., 8:15 p.m., and again on March 7, 1998 at 12:24 a.m.

69. Following his TO on March 7, 1998, at 12:24 a.m., Respondent next saw Patient H.H. 7 1/2 hours later, at 8:00 a.m., prior to taking Patient H.H. to the surgery room to perform the endarterectomy and embolectomy. Ms. Gutierrez testified that she does not always note when the doctor comes back into the recovery room to give orders. She could not testify as to events that took place after Patient H.H. was transferred to the Surgical Intensive Care Unit ("SICU"). She also stated she did not know how many times Respondent went to SICU because she did not work in SICU when Patient H.H. was transferred out of the recovery room. Ms. Gutierrez was also unable to testify as to when the last time was that Respondent came to the recovery room. Respondent testified that there is a difference between a TO and

a VO, the latter indicating that the physician was present in the room at the time he gave his order to the nurse.

70. The evidence is not clear and convincing that Respondent did not provide appropriate postoperative monitoring of Patient H.H.

CONCLUSIONS OF LAW

RELATING TO BOTH CASES

71. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this proceeding, pursuant to Sections 120.569 and 120.57(1), Florida Statutes, and Section 455.225, Florida Statutes.

72. Pursuant to Section 458.331(2), Florida Statutes, the Board of Medicine is empowered to revoke, suspend or otherwise discipline the license of a physician for the following violations of Section 458.331(1), Florida Statutes:

> (t) Gross or repeated malpractice or the failure to practice medicine with that level or care, skill and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. . . .

73. When the Board finds any person guilty of any of the grounds set forth in Subsection (1), it may enter an order imposing one or more of the following penalties.:

(b) Revocation or suspension of a license.

(c) Restriction of practice.

> (d) Imposition of an administrative fine not to exceed $10,000 for each count or separate offense.
>
> (e) Issuance of a reprimand.
>
> (f) Placement of the physician on probation for such a period of time and subject to such conditions as the board may specify, including, but not limited to, requiring the physician to submit to treatment, to attend continuing education courses, to submit to reexamination, or to work under the supervision of another physician.
>
> (g) Corrective action.

Rule 64B8-8.001(2)(t), Florida Administrative Code.

74. License disciplinary proceedings are penal in nature. State ex rel, Vining v. Florida Real Estate Commission, 281 So. 2d 487 (Fla. 1973). In this disciplinary proceeding, Petitioner must prove the alleged violations of Section 458.331(1)(t), Florida Statutes, by clear and convincing evidence. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne, Stern & Co., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987); and see Addington v. Texas, 441 U.S. 418 (1979).

75. The definition of "clear and convincing" evidence is adopted from Solmowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983), which provides:

> [C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the 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. The evidence must be of such weight that it produced in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

See also Smith v. Department of Health and Rehabilitative Services, 522 So. 2d 965 (Fla. 1st DCA 1988).

AS TO CASE NO. 01-4406PL

Respondent's Motion to Dismiss

76. The conduct giving rise to this disciplinary proceeding occurred in 1994. The Probable Cause Panel did not make a determination that probable cause existed in this matter until May 5, 1999, nearly five years later. Subsequently, Petitioner filed its Administrative Complaint against Respondent on May 10, 1999. Immediately subsequent to this, Respondent filed his Election of Rights form and requested a formal hearing. Inexplicably, this matter was not referred to the Division of Administrative Hearings until October 15, 2001, almost two and a-half years after the request for hearing was filed.

77. Section 455.225(2), Florida Statutes, addresses time limitations of administrative disciplinary proceedings stating in part:

> The department and the Agency for Health Care Administration shall allocate sufficient and adequately trained staff to expeditiously and thoroughly determine legal sufficiency and

> investigate all legally sufficient complaints.

78. In 1997, the Legislature clarified the definition of "expeditiously," amending Section 455.225(2), Florida Statutes, to provide in part:

> For the purposes of this section, it is the intent of the Legislature that the term "expeditiously" means that the agency, for disciplinary cases under its jurisdiction, should complete the report of its initial investigative findings and recommendations concerning the existence of probable cause within 6 months after its receipt of the complaint. The failure of the agency, for disciplinary cases under its jurisdiction, to comply with the time limits of this section while investigating a compliant against a licensee constitutes harmless error in any subsequent disciplinary action unless a court finds that either the fairness of the proceeding or the correctness of the action may have been impaired by a material error in procedure or a failure to follow prescribed procedure.

Section 142, Chapter 97-237, Laws of Florida.

79. Florida Statutes, Section 455.255(2), articulates how Petitioner should expeditiously handle disciplinary proceedings in stating:

> The department shall also refer to the board any investigation or disciplinary proceeding not before the Division of Administrative Hearings pursuant to chapter 120 or otherwise completed by the department within 1 year after the filing of a complaint. The department, for disciplinary cases under its jurisdiction, must establish a uniform reporting system to quarterly refer to each board the status of any investigation or

> disciplinary proceeding that is not before the Division of Administrative Hearings or otherwise completed by the Department within 1 year after filing of the complaint.

80. The First District Court of Appeal addressed the issue of time limit violations and, furthermore, confirmed the criteria in which dismissal of a disciplinary proceeding is warranted in Carter v. Department of Professional Regulation, Board of Optometry, 613 So. 2d 78 (Fla. 1st DCA 1993). The court addressed the issue of time limitations in disciplinary proceedings and stated that the purpose of Subsection 455.225(2), Florida Statutes, was to direct the agency to "expeditiously investigate complaints" in order to protect the public and to assure timely due process to the licensee. The court interpreted this statute by stating,

> . . . and we must assume that the legislature used the words, "time limit" in subsection 455.225(3) advisedly to communicate clear legislative intent that complaints against licenses professionals regulated by the department and its boards should be expeditiously processed without unjustifiable delay. . . .

Id. at p. 80.

81. Following its certification, the Supreme Court of Florida concurred with the district court in its conclusion that the statutory time limits assured the licensee timely due process:

> . . . these time limits also accord to the licensee complained against the right to the

> speedy determination of the matters giving rise to the complaint and provide protection against the potential prejudice that flows form unreasonable delays, such as loss of documents, unavailability of witnesses and fading memories.

Carter v. Department of Professional Regulation, Board of Optometry, 633 So. 2d 3, at p. 5 (Fla. 1994).

82. Finally, the Supreme Court held in Carter that in order for a licensee to obtain a dismissal, he must show (1) a violation of the time limitations, and (2) that the delay may have impaired the fairness of the proceedings or the correctness of the action and may have prejudiced the licensee, citing Department of Business Regulation v. Hyman, 417 So. 2d 671 (Fla. 1982). However, the burden of proof in demonstrating that the delay prejudiced the licensee is on Respondent. Carter, 633 So. 2d 3, 7.

83. It is clear that Petitioner did not adhere to the statute of "reducing or closing an investigation or disciplinary proceeding, not before the Division or completed by the Agency, within one year of the filing of the complaint." The probable cause panel made its determination that probable cause existed in this matter, and subsequently the Administrative Complaint was filed on May 10, 1999, more than five years after the conduct giving rise to the allegations at issue. After Respondent filed

his Election of Rights a further delay of two-and-a-half years occurred without excuse or explanation.

84. The motion to dismiss is granted. There is a clear violation of the time limitation. As stated earlier, the probable cause panel did not make a determination as to whether any probable cause existed until May 1999 and further, the Administrative Complaint was filed on May 10, 1999, more than five years after the conduct giving rise to the allegations at issue. Former counsel for Respondent filed his Petition for Formal Hearing on May 20, 1999. However, it was not until October 2001, that Petitioner filed his Notice of Appearance on behalf of the Board of Medicine, more than two years after the Administrative Complaint was filed.

85. It is clear from the testimony of Petitioner's witnesses that Respondent has been prejudiced. Respondent has performed hundreds of surgical procedures since 1994. Upon cross examination, Respondent testified several times that he did not have an independent recollection of this procedure. He had to rely on the medical records to describe the details of the procedure. Additionally, Petitioner's witnesses testified to these events more than eight years after the procedure was performed. The first witness, Dr. Gion, testified that she would not have an independent recollection of this specific procedure without referring to her medical records. The remaining

witnesses testified that they participated in many procedures since 1994 and that there were things that they could remember and things that they may not remember. Moreover, one witness testified that there is very little that she remembered from that case and the other witness stated that it has been too long ago for her to remember clearly. Again, they testified, from memory, on an issued vital to this matter which occurred more than eight years prior to this hearing. The witnesses' statements were contrary to what was indicated on the operative notes. Therefore, it is clear that Respondent has met his burden to demonstrate that he has been prejudiced by the unreasonable delay in prosecuting this matter. As a result, this case should be dismissed.

86. Alternatively, on the merits of the case presented, Petitioner has not met its burden of providing clear and convincing evidence that Respondent violated Section 458.331(1)(t), Florida Statutes. Based upon the testimony elicited at the final hearing, and the medical records, the proof presented does not produce a firm belief or conviction, without hesitancy, that Respondent deviated from the standard of care in this case. At best, the testimony is conflicting as to whether such a deviation occurred.

87. Petitioner presented the live testimony of four witnesses. The testimony of Helga Gion, M.D., cannot be given

great weight because it was not persuasive. Dr. Gion was the anesthesiologist during the surgical procedure. Dr. Gion testified that her role in the procedure was to administer general anesthesia. Her testimony consisted of identifying the various drugs administered to the patient during the procedure as well as advising of the various functions she monitored, such as blood pressure and pulse. Dr. Gion also indicated that an X-ray was taken of the patient's chest but could not testify to what the X-ray revealed since she was too far away from it. Dr. Gion further testified that since this procedure occurred in 1994, she did not have an independent recollection of this incident.

88. The testimony of Felicia Whitmer was also not persuasive. Ms. Whitmer was the surgical technician during the subject procedure. Ms. Whitmer testified that she assisted Respondent in this procedure and that there was no fluoroscopy machine in the operating room. However, she stated that she had recollection of the patient, D.J.P. Moreover, the witness stated that there was very little that she remembered from the case. Ms. Whitmer testified that as a surgical technician, she participated in approximately four procedures per day each year since 1994, and since this procedure was performed in 1994, there would be some things that she remembered and other things that she would not remember. Contrary to her testimony, the operation notes appeared to indicate that fluoroscopy was used in the

surgical procedure to ensure that the shunt was placed in position.

89. Likewise the testimony of Renee Myers was not persuasive. Ms. Myers testified that she was the circulating nurse the day of Patient D.J.P.'s surgical procedure. The witness testified that there was no fluoroscope in the operating room. She could not testify to the surgical procedure itself because the only thing that she saw was Respondent's back. Ms. Myers stated that as a circulating nurse she has participated in many procedures since 1994 and that there were some things that she remembered and some things that she was not able to remember. Finally, as previously discussed, despite the testimony, from her memory of a procedure that occurred more than eight years ago, that there was no fluoroscope in the operating room, the hospital records seem to indicate that fluoroscopy was used in this surgical procedure to assist Respondent in the placement of the shunt.

90. Finally, John W. Kilkenny, III, M.D., opined that Respondent fell below the standard of care in attributing the patient's death to DIC and by not considering other factors of a more mechanical traumatic fashion which could have been addressed in a surgical fashion. This opinion is not persuasive.

91. The Administrative Complaint is clear in its allegations and Petitioner must prove two issues: that

Respondent failed to treat the preoperative coagulopathy and that Respondent failed to use an alternate vein that would allow visualization of the shunt placement. Stating that the Respondent attributed the death to DIC clearly does not address either of the two allegations in the Administrative Complaint and is not relevant. Dr. Kilkenny further opined that Respondent should have aspirated the pleural effusion preoperatively. Again, this is not persuasive as it is beyond the scope of the allegations in the Administrative Complaint. Dr. Kilkenny further testified that Respondent fell below the standard of care by not accessing the vein that had direct visualization of the insertion of the shunt. Again, this is beyond the scope of the allegation in the Administrative Compliant. Petitioner, as well as Dr. Kilkenny, has focused, not on the visualization of the placement of the shunt, but rather on the visualization of the insertion of the shunt. The Administrative Complaint is very specific in its allegations stating in pertinent part, ". . . he failed to used an alternate vein that would have allowed visualization of the shunt placement. . . ."

92. Lastly, Dr. Kilkenny testified that Respondent fell below the standard of care by not administering fresh frozen plasma and Vitamin K preoperatively. This is not persuasive because Respondent testified that the patient did not have coagulopathy prior to the operation. Furthermore, Dr. Yahr, the

expert witness for Respondent, indicated the same, that Patient D.J.P. did not have preoperative coagulopathy prior to the surgery and further testified that coagulation did not occur until after the shunt was opened and ascitic fluid started flowing into the atrium.

93. The evidence submitted by Petitioner was less than clear and convincing. It consisted of the testimony of one expert witness. The witness only testified to the standard of care with respect to only one aspect of the allegation in the administrative complaint. The witness based his testimony concerning the allegation that Respondent failed to practice within the standard of care on a review of records that were taken more than five years after the procedure was performed by Respondent.

94. The testimony of Petitioner's three witnesses at the hearing was not persuasive. Eight years had passed since the subject surgery was performed. All the witnesses testified that due to the lapse in time, there would be things that they would remember and others that would not be remembered. Two of the fact witnesses testified, from memory, to an issue pertinent to this matter from a procedure that occurred more than eight years prior to the hearing. While the fact witnesses testified that there was no fluoroscope in the operating room, the operation notes, dictated almost immediately after the operation, indicate

to the contrary. The burden of proof is on Petitioner and must be satisfied with clear and convincing evidence. This burden was not satisfied. The difference of opinion between experts could not leave the trier of fact a firm conviction, without hesitancy, of the truth of the allegations contained in the Administrative Complaint.

AS TO CASE NO. 01-4407PL

95. The evidence submitted by Petitioner was less than clear and convincing. It consisted of the testimony of an expert witness who could not testify that Respondent's failure to distally clamp part of the arteries was a violation of the standard of care. It also consisted of testimony by Petitioner's fact witness who testified that Respondent did in fact ensure and adequately monitor Patient H.H. postoperatively.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine:

1. Enter a final order dismissing with prejudice the Administrative Complaint filed against Respondent in DOAH Case No. 01-4406PL, and DOH Case No. 1994-12341.

2. Enter a final order dismissing with prejudice the Administrative Complaint filed against Respondent in DOAH Case No. 01-4407PL, and DOH Case No. 1999-57795.

DONE AND ENTERED this 8th day of August, 2002, in Tallahassee, Leon County, Florida.

DANIEL M. KILBRIDE
Administrative Law Judge
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Filed with the Clerk of the
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NOTICE OF RIGHT TO FILE 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.