STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case No. 00-4048PL
HOWARD E. GROSS, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative Hearings, by its duly-designated Administrative Law Judge, Jeff B. Clark, held a formal hearing in this case on Tuesday, December 5 and 6, 2000, in Orlando, Florida.

APPEARANCES

For Petitioner: Ephraim D. Livingston, Esquire
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For Respondent: Robert D. Henry, Esquire
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STATEMENT OF THE ISSUE

Whether disciplinary action should be taken against the license to practice medicine of Respondent, Howard E. Gross, M.D., based on allegations that he violated Subsection

458.331(1)(t), Florida Statutes, as alleged in the Administrative Complaint in this proceeding.

PRELIMINARY STATEMENT

By Administrative Complaint dated August 24, 2000, Petitioner, Department of Health, Board of Medicine, alleges that Respondent, Howard E. Gross, M.D., a licensed physician, violated provisions of Chapter 458, Florida Statutes, governing medical practice in Florida. Petitioner alleges 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, as required by Subsection 458.331(1)(t), Florida Statutes. Petitioner alleges that while performing a ventriculogram, Respondent failed to ensure the accuracy and safety of the material he injected into the patient, which resulted in the injection of free air instead of dye into the patient.

Petitioner forwarded the Administrative Complaint to the Division of Administrative Hearings on October 2, 2000. A Notice of Hearing was entered on October 10, 2000, setting the case for hearing on November 16 and 17, 2000, in Orlando, Florida. Respondent moved to continue the hearing date from November 16 and 17, 2000, and an Order continuing the hearing to December 5 and 6, 2000, was entered.

At the final hearing, Petitioner presented two witnesses: A. Allen Seals, M.D., an expert witness, and Cathleen Lauderback, R.N. Petitioner offered three exhibits which were admitted into evidence.

Respondent presented three witnesses: Respondent, Howard E. Gross, M.D.; Kevin Browne, Jr., M.D., an expert witness; and Marcia A. Bryant, R.C.T. Respondent offered five exhibits, all of which were admitted into evidence.

At the conclusion of the hearing, the Administrative Law Judge advised each party of the option of providing proposed recommended orders and memoranda of law. The court reporter filed the Transcript of the hearing on January 16, 2001. The parties filed a Joint Motion for Extension of Time to File Proposed Recommended Orders and Memorandums of Law on January 3, 2001, requesting 15 days from the filing of the Transcript to file Proposed Recommended Orders and Memorandum of Law; the Administrative Law Judge granted the motion.

Petitioner filed its Proposed Recommended Order on January 31, 2001. Respondent filed his Proposed Recommended Order and Memorandum of Law on January 31, 2001.

FINDINGS OF FACT

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

1. Petitioner is the state agency charged with regulating the practice of medicine in the State of Florida pursuant to Section 20.43, Florida Statutes, and Chapters 455 and 458, Florida Statutes.

2. At all times material to this proceeding, Respondent was a licensed physician in the State of Florida, having been licensed in 1971 and issued license number ME 0017039. Respondent has never been disciplined previously.

3. Respondent is board-certified in internal medicine (1970) and cardiovascular diseases (1973). He is an interventional cardiologist. He has practiced medicine in Orlando since 1971. For the past 10 years, he has done a high-volume catheterization practice. In the most recent one-year period, he did approximately 500 interventional procedures and 400 diagnostic procedure, and in almost all instances, the catheterization involved a ventriculogram.

4. On or about February 18, 1997, patient L. D. L., an 84-year-old male with a history of coronary artery disease, presented to Orlando Regional Medical Center, for catheterization and possible rescue angioplasty to be performed by Respondent. Respondent performed a cardiac catheterization on the patient.

5. During the catheterization procedure, Respondent advanced a 6-French pigtail catheter into the patient's left

ventricle and performed a ventriculogram by injecting what he thought was approximately 20cc of ionic dye, utilizing a MEDRAD injector.

6. During the catheterization procedure, Respondent noted that he did not obtain opacification of the left ventricle and noted that free air was in the left ventricle.

7. In fact, Respondent injected the patient with approximately 15cc to 20cc of free air rather than dye. As a result, the patient suffered cardiac arrest, and his blood pressure fell to zero.

8. Respondent initiated various life-saving measures to counter the effects of the injection of free air, which were unsuccessful, and the patient was pronounced dead at approximately 1:55 p.m., as a result of cardiac arrest brought on by an air embolus.

9. At the time, Orlando Regional Medical Center (hereinafter "ORMC") had a policy/procedure (No. 3233-MEDRAD-0001) for Cardiac Catheterization Laboratory (hereinafter "Cardiac Cath Lab") personnel (Respondent's Exhibit 1). It delineated specific procedures to ensure "the use and safe applications of the power injector." In particular, it states the procedure to be employed by Cardiac Cath Lab staff in loading the MEDRAD injector.

10. At ORMC and other hospitals, Cardiac Cath Lab personnel load the MEDRAD injectors without physician supervision. As explained by both expert witnesses, loading the syringe with dye is a very simple task for a nurse or scrub tech to perform.

11. In the instant case, the nurse loading the MEDRAD injector interrupted the loading procedure because she was concerned about the patient's lab values (kidney function) and was uncertain about what type of dye Respondent would order. Respondent was not yet in the Cardiac Cath Lab. The nurse anticipated asking Respondent which type of dye he wanted and then loading that type dye into the MEDRAD injector.

12. When she interrupted the loading procedure, the nurse left the plunger positioned in the syringe where it appeared that the syringe had been loaded with 20 to 25cc of dye and the injector arm pointing upward.

13. The nurse then left the Cardiac Cath lab to get her lead apron anticipating only a monetary absence from the lab. Unknown to her, Respondent entered the Cardiac Cath Lab within seconds after her departure.

14. Respondent was not in the Cardiac Cath Lab at any time while the nurse was manipulating the MEDRAD injector.

15. As the nurse secured her lead jacket, she was called to another patient to administer medication which required the presence of a registered nurse per hospital procedures.

16. In the nurse's absence, the catheterization and ventriculogram of the patient proceeded. The Registered Cardiovascular Technician (hereinafter "RCT"), observing the MEDRAD injector in what appeared to be a prepared state, wheeled it to the patient's side and lowered the injector arm into a position to receive the catheter.

17. The RCT testified that a MEDRAD injector would never be left as she found it, plunger at the 20 to 25cc mark and arm elevated, if the machine was not loaded with dye.

18. The ionic dye used in the procedure is clear and, due to the nature of the MEDRAD plunger and casing, it is extremely difficult to tell if dye is in the syringe.

19. Further compounding the difficulty in observing dye in the syringe is the fact that the lights in the Cardiac Cath Lab are lowered during the procedure to allow better visualization of the video monitor.

20. While the RCT positioned the MEDRAD injector at the patient's side, Respondent was in the process of entering the catheter into the patient, manipulating the catheter in the patient, visualizing its position in the patient's heart on the video monitor and monitoring hemodynamics.

21. Petitioner's expert witness testified that Respondent did justifiably rely on the Cardiac Cath Lab personnel to follow the procedure outlined in Respondent's Exhibit 1. The nurse and cardiovascular technician did not follow the policy/procedure and, as a result, allowed the presence of air in the MEDRAD injector.

22. After the catheter is properly located in the patient's heart, the external end of the catheter is attached to the MEDRAD injector.

23. Petitioner's expert witness opined the Respondent should have used extension tubing to effect the connection between the catheter and MEDRAD injector. Testimony revealed that extension tubing is used by many physicians who perform cardiac catheterization. Respondent's practice was not to use extension tubing.

24. Both Petitioner's and Respondent's expert witnesses agreed that Respondent's choice not to use extension tubing was a "technique" choice and did not fall below the "standard of care."

25. Petitioner's expert opined that Respondent should have been present in the Cardiac Cath Lab to observe the loading of the MEDRAD injector.

26. Testimony revealed that at ORMC and other hospitals it was the Cardiac Cath Lab staff's responsibility to load the

MEDRAD injector without the direct supervision of physicians and that physicians are rarely in the lab when the MEDRAD injector is loaded.

27. The "standard of care" does not require the physician to watch the loading of dye or the expulsion of air from the syringe in the loading process.

28. Petitioner's expert opined that Respondent should have performed a test injection (a process where a small amount of dye is injected into the heart prior to the main injection).

29. Respondent's expert testified that under certain circumstances (none of which is applicable to the instant case) test injections were appropriate; those circumstances occur less than 5 percent of the time.

30. Electing not to perform a test injection in the instant case does not fall below the "standard of care."

31. Petitioner's expert opined that Respondent should have observed a "wet to wet" connection between the catheter and the MEDRAD injector to ensure that no air is in the system. This is accomplished by withdrawing a small amount of blood from the catheter into the MEDRAD injector. Small air bubbles may appear between the blood and dye and are then "tapped" to rise to the top of the syringe.

32. However, Respondent performed the "wet to wet" connection and did not observe anything unusual. He has

historically performed some "wet to wet" connections where no air bubbles were present between the blood and dye as it appeared in this case.

33. The RCT confirmed that Respondent performed the "wet to wet" connection, looked for air in the syringe, and tapped on the syringe to loosen and expel air bubbles.

34. Respondent's expert witness testified that he performed an experiment creating a "wet to wet" connection with air in the MEDRAD injector syringe instead of dye. He found that the miniscus formed by blood and air in the syringe has an identical appearance to blood contacting dye in the syringe.

35. The "wet to wet" connection between blood and air in the syringe has the same appearance as a "perfectly clean", "wet to wet" connection between blood and dye in the syringe.

36. Respondent's expert witness testified that from five to ten percent of the time a "perfectly clean", "wet to wet" connection occurs in which no air bubbles appear between the blood and dye.

37. Petitioner's expert witness testified that the physician must make absolutely certain that no gross amount of air is injected into the patient, and, relying on his view that the Respondent as the physician was the "captain of the ship," he testified that "the injection of this volume of air during the ventriculogram fell below the cardiology "standard of care."

38. Petitioner's expert rendered his opinion based upon his examination of the hospital records.

39. Respondent's expert rendered his opinion based upon his examination of the following:

a. Administrative complaint with supporting documents.
b. Dr. Allen Seals' (Petitioner's expert) report and deposition.
c. Agency for Health Card Administration investigative report.
d. ORMC's Code 15 report.
e. Respondent's February 21, 1997 memo for peer review purposes.
f. Hospital records.
g. Death résumé.
h. ORMC's MEDRAD policy/procedure.
i. Experimentation with a catheter and MEDRAD injector.

40. Respondent's expert testified that Respondent met the standard of care in the instant case because he practiced medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar circumstances.

41. Based on the totality of the evidence presented, the undersigned rejects the expert opinion of Dr. Allen Seals, M.D., Petitioner's expert witness, and accepts as being more credible the testimony of David P. Browne, Jr., M.D., Respondent's expert witness.

CONCLUSIONS OF LAW

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

43. License revocations and discipline procedures are penal in nature. Petitioner must demonstrate the truthfulness of the allegations in the Administrative Complaint dated August 24, 2000, by clear and convincing evidence. Department of Banking and Finance v. Osborne Stern and Company, 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

44. The "clear and convincing" standard requires:

> [T]hat the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; and 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 produces 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.

Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).

45. Petitioner must set forth the charges against Respondent with specificity, carrying the burden of proving each charge, and in the final order set forth explicit findings of fact and conclusions of law addressing each specific charge.

Davis v. Department of Professional Regulation, 457 So. 2d 1074 (Fla. 1st DCA 1984); Lewis v. Department of Professional Regulation, 410 So. 2d 593 (Fla. 2d DCA 1982).

46. Where Petitioner charges negligent violations of general standards of professional conduct, as in this case, Petitioner must present expert testimony that proves the required professional conduct, as well as the deviation therefrom. Purvis v. Department of Professional Regulation, 461 So. 2d 134 (Fla. 1st DCA 1984).

47. Petitioner has charged Respondent with violating the following relevant provisions of Subsection 458.331(1)(t), Florida Statutes:

> [T]he 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.

48. Relying on a "captain of the ship" theory, Petitioner implies that Respondent is responsible for the active negligence of the Cardiac Cath Lab personnel. Variety Children's Hospital, Inc. v. Perkins, 382 So. 2d 331 (Fla. 3d DCA 1980); Buzan v. Mercy Hospital, Inc., 203 So. 2d 11 (Fla. 3d DCA 1967). Where the Cardiac Cath Lab personnel are subject to Respondent's direct control, such might possibly be the case. In the instant case, the loading of the MEDRAD injector was a simple, ministerial function which does not require a physician's

supervision. Typically, the physician is not in the Cardiac Cath Lab when the machine is loaded and relies on the hospital's policy/procedure to be followed by the personnel who perform the loading. In the instant case, the evidence demonstrated that Respondent did not control the Cardiac Cath Lab personnel while they loaded the MEDRAD injector and that Respondent did those precautionary activities typically done by a reasonably prudent physician. Beaches Hospital v. Lee, 384 So. 2d 234 (Fla. 1st DCA 1980).

49. The clear statutory intent of Subsection 458.331(1)(t), Florida Statutes, is to impose discipline only for personal misconduct of the licensed physician. There is no language to clearly evidence a legislative intent to impose on a physician responsibility for the negligence or misconduct of others. Since disciplinary statutes are penal in nature and must be strictly construed against the enforcing agency, without a clear, unambiguous provision in the statute indicating legislative intent to hold the physician responsible for the negligent or wrongful act committed by another, the administrative agency is not authorized to so extend the effect of the statute. McDonald v. Department of Professional Regulation, 582 So. 2d 660 (Fla. 1st DCA 1991); Federgo Discount Center v. Department of Professional Regulation, 452 So. 2d 1063

(Fla. 3rd DCA 1984); Davis v. Department of Professional Regulation, 457 So. 2d 1074 (Fla. 1st DCA 1984).

50. Petitioner failed to prove that, under the circumstances, the Respondent deviated from the appropriate standard of care. While there is the proven occurrence of the tragic death of a patient undergoing a ventriculogram, that incident alone does not indicate Respondent fell below the standard of care.

51. Petitioner's expert witness testified that Respondent failed to do several things that he felt should have been done: (1) visually observe the loading of the dye; (2) performance of a test injection; and (3) use of extension tubing.

52. In each instance, persuasive evidence was presented that Respondent did not deviate from the standard of care at Orlando Regional Medical Center and other hospitals or for the procedure as performed by other physicians.

53. Such equivocal evidence on the critical allegations of "failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician . . ." does not satisfy the clear and convincing standard of proof imposed by Florida law.

RECOMMENDATION

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

RECOMMENDED that Petitioner enter a final order finding that Respondent is not guilty of violating Subsection 458.331(1)(t), Florida Statutes, as alleged in the Administrative Complaint.

DONE AND ENTERED this 13th day of February, 2001, in Tallahassee, Leon County, Florida.

JEFF B. CLARK
Administrative Law Judge
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Filed with the Clerk of the
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this 13th day of February, 2001.

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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.