

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

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| DEPARTMENT OF HEALTH, BOARD OF |) | |
| MEDICINE, |) | |
| |) | |
| Petitioner, |) | |
| |) | |
| vs. |) | Case No. 01-3212PL |
| |) | |
| MARC S. SCHNEIDER, M.D., |) | |
| |) | |
| Respondent. |) | |
| _____ |) | |

RECOMMENDED ORDER

Administrative Law Judge (ALJ) Daniel Manry conducted the administrative hearing of this proceeding on December 4 and 5, 2001, in Fort Myers, Florida, on behalf of the Division of Administrative Hearings (DOAH).

APPEARANCES

For Petitioner: Britt Thomas, Esquire
Agency for Health Care Administration
2727 Mahan Drive
Tallahassee, Florida 32308

For Respondent: Carol A. Lanfi, Esquire
1000 Riverside Avenue, Suite 800
Jacksonville, Florida 32204

Albert Peacock, Esquire
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Tallahassee, Florida 32312

STATEMENT OF THE ISSUES

The ultimate issues in this case are whether Respondent violated Section 458.331(1)(m) and (t), Florida Statutes (1997),

respectively, by failing to keep medical records that justify the course of treatment and 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; and, if so, what penalty, if any, should be imposed against Respondent's license to practice medicine. (All chapter and section references are to Florida Statutes (1997) unless otherwise stated.)

PRELIMINARY STATEMENT

On July 10, 2000, Petitioner filed an Administrative Complaint against Respondent. Respondent timely requested an administrative hearing.

At the hearing, Petitioner presented the testimony of three witnesses, including one expert, and submitted 12 exhibits for admission in evidence. Three of the exhibits consisted of the deposition testimony of three expert witnesses. Respondent testified in his own behalf, as an expert, and presented the live testimony of three witnesses, including two experts. Respondent submitted nine exhibits for admission in evidence.

The identity of the witnesses and exhibits in the case and any attendant rulings are set forth in the four-volume Transcript of the hearing filed on January 17, 2002. At the request of the parties, the ALJ extended the time for filing the proposed recommended orders ("PROs"). The four-volume

Transcript was filed January 17, 2002. Petitioner and Respondent timely filed their respective PROs on February 8, 2002.

FINDINGS OF FACT

1. Petitioner is the state agency responsible for regulating the practice of medicine in Florida pursuant to Sections 20.165 and 20.43 and Chapters 455 and 458. Respondent is licensed as a medical physician in Florida pursuant to license number ME0050478. Respondent has been a Board-certified plastic surgeon at all times material to this proceeding.

2. The Administrative Complaint involves one patient who undertook elective plastic surgery. The record identifies the patient as E.O. in order to preserve the patient's confidentiality. In summary, the Administrative Complaint alleges that Respondent departed from the acceptable standard of care by: failing to perform the surgical procedure elected by E.O.; performing a surgical procedure other than the procedure E.O. authorized; failing to document a reason for changing the procedure; failing to advise the patient of the risks associated with the procedure performed; performing breast augmentation with implants that were too large; and failing to document a reason for using the larger implants.

3. On December 31, 1997, E.O. presented to Respondent for consultation regarding reconstruction of her left breast. At the time, E.O. was approximately 48 years old.

4. E.O.'s medical history included an abdominal hysterectomy, a biopsy of the right breast, two biopsies of the left breast, and a diagnosis of cancer in the left breast. A partial mastectomy of the left breast and radiation therapy resulted in significant scarring.

5. The left breast had a concave, depressed area in the left side. The depressed area extended from the upper part of the breast, near the outer pectoral muscle, halfway to the nipple. The nipple on the left breast was pulled to the outside toward the depressed area. E.O. also suffered ptosis, i.e., the appearance of drooping, that was not related to her medical history.

6. The radiation therapy to the left breast had caused a burn injury that left internal scar tissue. The scar tissue was not pliable and was not suitable for manipulation during plastic surgery.

7. During E.O.'s initial visit with Respondent on December 31, 1997, Respondent noted E.O.'s prior medical history and radiation treatment. He noted the bilateral ptosis and the left breast deformity.

8. Respondent recommended bilateral implants for the purposes of reconstructing the left breast and for achieving symmetry between the breasts. Respondent and E.O. did not agree on a plan of treatment during the initial visit but did agree to a second visit.

9. On January 16, 1998, E.O. presented to Respondent for her second visit. After further consideration of E.O.'s case, Respondent made a specific recommendation of bilateral augmentation with prostheses, in the form of implants, and a latissimus dorsi flap (LDF) procedure to correct the depression in the left breast. An LDF procedure would have resected, or removed, the scarring in the left breast and would have replaced the resulting divot with healthy tissue. Respondent would have obtained healthy tissue by moving a flap of tissue and muscle from the patient's back underneath the patient's outer tissue layers and placing the flap internally in the left breast. E.O. agreed with Respondent's recommendation.

10. E.O. agreed to the bilateral augmentation because Respondent advised her that an implant in her right breast was necessary to achieve appropriate symmetry. E.O. did not agree to the augmentation because she wanted larger breasts. Respondent assured E.O. that her breast size would increase only about one-half cup. Respondent's records do not include a reference to the size of the implants to be used.

11. Respondent indicated he would seek preauthorization from the insurer for the LDF procedure with protheseses. The LDF procedure required E.O. to stay overnight in the hospital following surgery. Surgery that omitted the LDF procedure could have been performed in "same-day" surgery. Respondent and E.O. did not discuss or agree upon any plan of treatment.

12. On January 21, 1998, E.O. presented to Respondent for a third time. E.O.'s husband, L.O., was also present. Respondent discussed the LDF procedure with E.O. and L.O. Respondent stated that he believed the LDF procedure was necessary to fill-in the left breast after Respondent resected the radiated tissue as part of the reconstruction of E.O.'s left breast. Respondent, E.O., and L.O. did not discuss other treatment options. On January 21, 1998, Respondent requested authorization from E.O.'s insurer for breast reconstruction surgery that included an LDF procedure with the use of a prosthetic implant.

13. On February 12, 1998, E.O. presented to Respondent for a fourth time. E.O. had additional questions about the surgery that included questions regarding the insurance coverage for the surgery. E.O. and Respondent did not discuss the LDF procedure or other treatment options.

14. Respondent scheduled the surgery for February 26, 1998, at the Columbia Regional Medical Center Southwest Hospital

("Columbia" or the "hospital"). On February 24, 1998, E.O. presented to Columbia for a preoperative workup.

15. At the preoperative workup, E.O. executed a written informed consent document that authorized Respondent to perform a, "Lat Flap with implant left Breast and Right endoscope augmentation." Respondent also signed the informed consent. E.O. did not consent to another procedure different from that stated in the informed consent. Nor did E.O. and Respondent agree upon a different procedure.

16. Hospital records, including the Short-Stay History and Physical completed on the day of surgery and signed by Respondent, show that the procedure to be performed was an LDF procedure with implants. The hospital records are devoid of any indication that E.O. did not wish to undergo the LDF procedure or that E.O. expressed any reservations about the procedure.

17. On the morning of February 26, 1998, E.O. fully expected to undergo the LDF procedure. E.O. presented to Columbia anticipating an overnight hospitalization that was consistent with an LDF procedure. E.O. brought with her the personal belongings she would need for an overnight hospitalization. The applicable standard of medical care required Respondent to perform the LDF procedure so long as it was medically reasonable to do so.

18. On February 26, 1998, Respondent performed surgery on E.O. that included an implant in each breast. However, Respondent did not perform the LDF procedure. Rather, Respondent created breast flaps by incising existing scar tissue and utilizing the incised scar tissue to fill in the depression in the left breast. Respondent did not resect the scar tissue and replace it with healthy tissue.

19. Immediately after the surgery, Respondent advised L.O., without explanation, that Respondent did not perform the LDF procedure and that E.O. was doing well. Columbia discharged E.O. on the same day of surgery. During the trip home in their car, L.O. advised E.O. that Respondent did not perform the LDF procedure. E.O. was surprised but groggy from medication.

20. No medical reason prevented Respondent from performing the LDF procedure. Respondent encountered no difficulties or complications during surgery that precluded the LDF procedure. Moreover, there were medical reasons not to incise the scar tissue and use it to fill in the depression in the left breast. Irradiated scar tissue is not well vascularized, is not pliable, and is not easy to manipulate.

21. The only reason that Respondent offered for failing to perform the LDF procedure was that E.O. expressed concern over the procedure. Respondent testified that E.O. expressed her concern to Respondent when Respondent was in the holding area

marking E.O.'s breasts for surgery. The holding area is an area that is physically separate from the operating room.

22. E.O. did not expressly ask Respondent not to perform the LDF procedure. Rather, Respondent inferred that E.O. did not want him to perform the LDF procedure. As Respondent testified during cross examination:

Q. And you had a conversation with her wherein she expressed some concern about the latissimus dorsi flap procedure; is that correct?

A. The tenor of her conversation indicated some concern. She did not say to me please don't do it, but the tenor of her conversation was that there was concern when I was marking her for it.

Transcript (TR) at 624.

23. Respondent claims that the conversation with E.O. occurred when Respondent was in the holding area marking E.O. for surgery. Respondent's testimony during cross examination is illustrative.

Q. And your testimony is that, is the holding area an area different than the actual operating room.

A. Yes.

* * *

Q. I would like for you to look to the first line of this operative report, under procedures. It says the patient was brought to the operating room, and marked in the sitting position, then laid supine.

A. Yes.

Q. Doesn't that note say that you did not mark this patient in the holding area, but you marked her in the operating room?

A. It sure does.

Q. And are you telling me today that this is in error?

A. That is absolutely in error. I have never marked a patient in the operating room.

TR at 625.

24. Respondent's claim that he had a conversation with E.O. in the holding area before surgery is refuted by E.O. The testimony of E.O. concerning this factual issue is credible and persuasive. The testimony of E.O. is consistent with the operative report stating that E.O. was marked in the operating room rather than in the holding area.

25. Respondent did not see E.O. in the holding area prior to surgery and did not have a conversation with E.O. in which E.O. expressed some concern over the LDF procedure. E.O. received preoperative medication in the holding area and was not capable of carrying on a conversation with Respondent in the operating room and was not capable of making an informed consent to a different procedure. If it were determined that Respondent had a conversation with E.O. in the holding area while marking her for surgery, there was ample time to amend the informed

consent document to reflect a different treatment plan agreed to by E.O. and Respondent.

26. The actual surgery performed by Respondent was a procedure that was different from the LDF procedure authorized by E.O. The actual surgical procedure performed by Respondent was not a lesser included procedure of the LDF procedure.

27. The applicable standard of care would have required Respondent to amend the informed consent document under the facts and circumstances testified to by Respondent. An informed consent should include all anticipated treatment options. The informed consent signed by E.O. and Respondent did not include any options to the LDF procedure.

28. Even if it were determined that the actual procedure performed is a lesser included procedure of the LDF procedure, E.O. did not consent to the lesser included procedure. The performance of a lesser included procedure for which E.O. was not informed and to which E.O. did not consent departs from the applicable standard of care.

29. The procedure performed by Respondent during surgery increased the risk of failure and the need for subsequent surgery by using scar tissue rather than resecting the scar tissue and using healthy tissue to fill in the left breast. Respondent failed to inform E.O. of the increased risk of the procedure actually utilized by Respondent.

30. Respondent failed to practice medicine with the level of care, skill, and treatment recognized by a reasonably prudent similar physician as acceptable under similar conditions and circumstances. First, Respondent failed to perform the procedure that E.O. authorized. Second, Respondent performed a procedure that placed implants in E.O.'s irradiated left breast without resecting the irradiated scar tissue. Third, Respondent failed to inform E.O. of the increased risk associated with the procedure Respondent utilized during surgery. Finally, Respondent failed to document in the records a reason or rationale for performing a surgical procedure other than the LDF procedure authorized by the patient.

31. Prior to surgery, Respondent agreed to use the smallest implants possible. During surgery, Respondent placed very large implants in E.O.'s breasts. Respondent used a 480 cc implant in the left breast and a 460 cc implant in the right breast. Respondent used the large implant in the left breast, rather than the LDF, in an attempt to stretch the tissue, including the scar tissue, and to fill in the depression in the left breast. Respondent used the large implant in the right breast for symmetry.

32. E.O. did not consent to the use of large implants in either breast. Rather, E.O. authorized the smallest implants

possible. Respondent utilized implants that increased E.O.'s cup size from a small C cup to a DD cup.

33. The weight and volume of the large implants stretched E.O.'s skin and exacerbated her ptosis. After surgery, E.O.'s clothes did not fit. A DD cup size was sometimes too small.

34. An accepted method of determining the effect of implants is to sit the patient up on the operating table prior to completing surgery. Respondent did not sit E.O. up on the operating table to view the effect of the implants. Respondent had a complete range of implant types and sizes available for use during surgery.

35. Respondent failed to practice medicine with the level of care, skill, and treatment recognized by a reasonably prudent similar physician as acceptable under similar conditions and circumstances. Respondent utilized implants that were not authorized by E.O. by placing overly large implants in E.O.'s breasts. Respondent failed to utilize the implants authorized by E.O. by failing to use the smallest implants possible. Respondent failed to document in the records a reason or rationale for using implants other than those authorized by E.O.

36. Respondent's failure to practice medicine in accordance with the applicable standard of care caused substantial harm to E.O. At the first postoperative visit on March 2, 1998, E.O. asked Respondent why he did not perform the

LDF procedure. Respondent stated that he had determined that E.O. could do without the LDF procedure.

37. E.O. also expressed concern over the large size of her breasts. Respondent explained that the large size was attributable to swelling and that it would take several months for the swelling to dissipate. Until that time, it was impossible to assess the final result.

38. During subsequent visits on March 11 and 18 and on April 3, 1998, E.O. expressed concern over the size and appearance of her breasts. However, she continued to trust Respondent and to accept his assurances that she needed to be patient and allow the swelling to go down before forming any final opinions regarding the outcome of the surgery.

39. During a visit on May 1, 1998, Respondent examined E.O. and acknowledged that the procedure actually performed on February 26, 1998, did not produce the desired result. The implant and incised scar tissue had not stretched and filled in the left breast. Respondent advised E.O. that she needed the LDF procedure.

47. E.O. elected for Dr. Brueck to perform reconstruction surgery on her. However, problems with insurance coverage delayed the surgery until July 11, 2000. The surgery included bilateral reconstruction with bilateral implant and mastopexy.

E.O.'s breast size was a B cup after surgery. E.O. was very pleased with the results of the surgery.

CONCLUSIONS OF LAW

48. DOAH has jurisdiction over the parties and the subject matter. The parties received adequate notice of the administrative hearing. Section 120.57(1).

49. The burden of proof is on Petitioner. Petitioner must show by clear and convincing evidence that Respondent committed the violations alleged in Administrative Complaint and the reasonableness of any proposed penalty. Department of Banking and Finance, Division of Securities and Investor Protection vs. Osborne Stern and Company, 670 So. 2d 932, 935 (Fla. 1996); State ex rel. Vining v. Florida Real Estate Commission, 281 So. 2d 487 (Fla. 1973); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1st DCA 1987).

50. Petitioner satisfied its burden of proof. Clear and convincing evidence has both qualitative and quantitative requirements. The factual testimony of E.O., the testimony of Petitioner's experts, and the records submitted in the case satisfy both the qualitative and quantitative requirements for clear and convincing evidence.

51. The factfinder in this case determined that the factual testimony of E.O. was credible and persuasive. She distinctly remembered the material facts to which she testified.

Her testimony concerning the material facts was precise, explicit, and lacked confusion.

52. Respondent attempted to discredit E.O.'s testimony by relying on the absence of any notation in his records that E.O. was unhappy with her surgery and by relying on records indicating that the initial consultation was for implants rather than for breast reconstruction. However, Respondent does not rely on the operative report that shows that E.O. was marked in the operating room rather than in the holding area as asserted by Respondent. Such inconsistencies are neither credible nor persuasive to the trier of fact.

53. Respondent also seeks to discredit the testimony of Dr. Brueck on the grounds that Dr. Brueck is a subsequent treating physician with an interest in the outcome of his treatment of E.O. In addition, Respondent relies on an alleged business dispute between Respondent and Dr. Brueck that preceded the surgery performed by Respondent. See, e.g., Robinson v. Board of Dentistry, 447 So. 2d 930, 931-932 (Fla. 3d DCA 1984)(holding that the testimony of one interested witness does not rise to the level of clear and convincing evidence).

54. The holding in Robinson does not render the testimony of an interested witness inadmissible. It affects only the weight to be afforded such testimony.

55. The issue surrounding the testimony of Dr. Brueck is one of credibility rather than admissibility. Martuccio v. Department of Professional Regulation, Board of Optometry, 622 So.2d 607, 609 (Fla. 1st DCA 1993). The trier of fact in this case determined the testimony of Dr. Brueck to be credible and consistent with the testimony of another board-certified plastic surgeon presented by Petitioner. Even if the testimony of Dr. Brueck were disregarded, the testimony of the other three board-certified plastic surgeons presented by Petitioner satisfies the requirements of the clear and convincing standard.

56. During the administrative hearing, the ALJ requested the parties to brief the issue of whether the assertion by Respondent that E.O. consented to the procedure performed on February 26, 1998, during a conversation in the holding area is in the nature of an affirmative defense for which Respondent bears the burden of proof. The issue is moot because the clear and convincing evidence shows that E.O. gave no consent.

57. Petitioner showed by clear and convincing evidence that Respondent failed to practice medicine with the level of care, skill, and treatment recognized by a reasonably prudent similar physician as acceptable under similar conditions and circumstances. Respondent failed to perform the procedure that E.O. authorized; performed a different procedure that placed implants in E.O.'s irradiated left breast without resecting the

irradiated scar tissue; failed to inform E.O. of the increased risk associated with the different procedure; and placed overly large implants in E.O.'s breasts. In addition, Respondent failed to document in the records a reason or rationale for performing a surgical procedure other than the LDF procedure authorized by the patient and for using implants larger than those authorized by E.O.

58. Respondent caused significant harm to E.O. Respondent failed to correct the disfigurement of the left breast and exacerbated the ptosis that E.O. sought to correct. Respondent caused E.O. to undergo a second surgical procedure as well as pain, embarrassment, and discomfort from February 26, 1998, until July 11, 2000.

RECOMMENDATION

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

RECOMMENDED, in accordance with the terms of Petitioner's PRO, that Petitioner enter a Final Order finding Respondent guilty of violating Section 458.331(1)(m) and (t); issuing a written reprimand; imposing a fine of \$5,000; and requiring Respondent to complete, within one year, 20 hours of continuing professional education above and beyond that required to maintain licensure.

DONE AND ENTERED this 18th day of March, 2002, in
Tallahassee, Leon County, Florida.

DANIEL MANRY
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
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this 18th day of March, 2002.

COPIES FURNISHED:

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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.