

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF)
MEDICINE,)
)
Petitioner,)
)
vs.) Case No. 09-1577PL
)
JOSEPH DANIEL LABS, M.D.,)
)
Respondent.)
_____)

RECOMMENDED ORDER

Pursuant to notice, a final hearing was held in this case on June 23 and 24, 2009, in Naples, Florida, before Susan B. Harrell, a designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Shirley L. Bates, Esquire
Diane K. Kiesling, Esquire
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265

For Respondent: Louis J. La Cava, Esquire
Stephens, Lynn, Klein, La Cava,
Hoffman & Puya, P.A.
101 East Kennedy Boulevard, Suite 2500
Tampa, Florida 33602

STATEMENT OF THE ISSUES

The issues in this case are whether Respondent violated Subsections 458.331(1)(m), 458.331(1)(t), and 458.331(1)(bb),

Florida Statutes (2005),¹ and, if so, what discipline should be imposed.

PRELIMINARY STATEMENT

On November 24, 2008, the Department of Health (Department) filed an Administrative Complaint with the Board of Medicine against Respondent, Joseph Daniel Labs, M.D. (Dr. Labs), alleging that Dr. Labs violated Subsections 458.331(1)(m), 458.331(1)(t), and 456.331(1)(bb), Florida Statutes. Dr. Labs requested an administrative hearing, and the case was forwarded to the Division of Administrative Hearings on March 26, 2009, for assignment of an Administrative Law Judge to conduct the final hearing.

On June 16, 2009, the parties filed a Joint Pre-hearing Stipulation in which they stipulated to certain facts contained in Section E of the Joint Pre-hearing Stipulation. To the extent relevant, those facts have been incorporated in this Recommended Order.

At the final hearing, the Department called the following witnesses: W.S.; Alexia Marciano, M.D.; and Frank Lomagistro, M.D. Petitioner's Exhibits 1 through 6 and 11 were admitted in evidence. The Department was given leave to file Petitioner's Exhibit 12 as a late-filed exhibit. The Department filed Petitioner's Exhibit 12 on June 26, 2009, and it is admitted. Additionally, the Department proffered Petitioner's Exhibit 13.

At the final hearing, Dr. Labs testified on his own behalf and called Francis W. Reiger, M.D., as a witness. Respondent's Exhibits 1 through 5 were admitted in evidence.

The two-volume Transcript was filed on August 3, 2009. At the final hearing, the parties agreed to file their proposed recommended orders within ten days of the filing of the Transcript. On August 5, 2009, the Department filed an unopposed Motion for Extension of Time to File Proposed Orders. The motion was granted by Order entered August 6, 2009, extending the time for filing proposed recommended orders to August 28, 2009. The parties timely filed their Proposed Recommended Orders, which have been considered in rendering this Recommended Order.

FINDINGS OF FACT

1. The Department is the State of Florida agency charged with regulating the practice of medicine in Florida pursuant to Section 20.43 and Chapters 456 and 458, Florida Statutes.

2. At all times material to the Administrative Complaint, Dr. Labs was a licensed medical doctor within the State of Florida, having been issued license number ME 61579.

3. Dr. Labs is certified by the American Board of Surgery and the American Board of Plastic Surgery.

4. In April 2006, W.S. went to see Dr. Labs for a consultation. In the late 1980's, W.S. had had breast implants

placed by a physician in Texas. In 1995, another physician did a mastopexy to lift her breasts. W.S. wanted Dr. Labs to replace the breast implants that had been in place since the late 1980's with smaller implants, to reduce the size of her breasts by excising tissue, and to lift the breasts with a mastopexy. She was under the impression that the implants which she currently had had been placed underneath the pectoral muscle, and she told Dr. Labs that she wanted to have the new, smaller implants also placed underneath the muscle, meaning subpectoral placement.

5. Dr. Labs agreed to place the implants subpectorally. There are two ways that implants can be placed subpectorally. The first method involves placing the implant entirely under the muscle and then suturing the implant in place. There is very little migration of the implant with this method because the implant is tightly held by the muscle. The second method is called a dual-plane technique. In this method, a portion of the implant is placed under the pectoral muscle and a portion of the implant is covered by the glandular or lower part of the breast.

6. Dr. Labs performed a bilateral reduction, mastopexy, and implant exchange on W.S. on April 25, 2006. His operative report described the procedure as follows:

The patient was taken to the operating room after being marked in the standing position. She was placed in the supine position for

smooth induction of anesthesia. Sequential compression boots were placed for DVT prophylaxis. The procedure began with de-epithelization of skin above each nipple for reinset. Scars were then excised around the nipple and from the vertical incision beneath the nipple to inframammary fold. Skin flaps were elevated and, then the central nipple pedicle preserved. Implants were removed, and breast tissue was excised laterally. The implants were then replaced with silicone implants after Betadine irrigation and surgical glove change. The removed implants were 220cc. The replaced implants were 175cc, and each breast was subjected to a 75 gram reduction. Towel clips were placed, and the patient was placed in the sitting position. Symmetry was excellent at the conclusion of the procedure. Multiplayer inset was then performed. The patient was placed in a sterile bulky dressing and Ace wrap. She returned to the recovery room in satisfactory condition, having tolerated the procedure well. Final sponge, needle and instrument counts were correct at the conclusion of the procedure. The patient was given explicit postoperative instructions for the care and maintenance of her wound and will be seen again in followup at the plastic surgery office.

7. Dr. Labs took out the 220cc implants and placed 175cc implants in the same pocket where the 220cc implants had been placed. The 220cc implants which Dr. Labs removed had a small rim of the superior portion of the implants placed underneath the muscle. The remaining portion of the implants were subglandular.

8. Dr. Labs placed the superior medial portion of the 175cc implants between .5 and 2.5 centimeters under the

muscle, meaning that about ten percent of the implants were placed under the muscle. The remainder of the implants was subglandular. The method used by Dr. Labs was the dual-plane method and is considered to be a subpectoral placement.

9. W.S. signed a consent form, which included an explanation of risks associated with open capsulectomy with breast implant exchange surgery. The risk of implant displacement was explained as follows:

Displacement or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. Difficult techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to correct this problem.

10. Subsequent to the surgery by Dr. Labs, W.S. began to experience problems with her breasts. The breasts were distorted, became an odd shape and stuck out more than her breasts had done with the implants placed by the Texas physician. Her breasts were bulging in the front and middle. W.S.'s breasts became uncomfortable, and W.S. was unable to lie on her stomach. The breasts did not look or feel natural; they were stiff, hard, and tight. The problems began to occur not long after the surgery; however, the distortion was not present until a month after the surgery.

11. On December 6, 2006, W.S. visited Alexia Marciano, M.D., a board-certified plastic surgeon, for a consultation concerning the problems she was having with her breasts. On examination, Dr. Marciano noted that W.S. had pseudoptosis, which means there was some loose skin, but the nipple was still above the inframammary fold. Dr. Marciano observed that W.S.'s breasts were distorted, irregular in shape and position. There were capsular contractures, which are scar tissue that forms around the implants. The capsular contractures were a grade IV,² which means that one could look at the breast and visually see the tightening. To Dr. Marciano, the implants appeared to be on top of the muscle, based on "the superficiality and the position of the implants in relation to the skin above and to the pectoralis muscle on the upper portion of the chest and on palpation."³ W.S. advised Dr. Marciano that she wanted to have surgery to correct the problems she was having with her breasts and that she wanted to have smaller implants placed under the muscle.

12. On January 19, 2007, Dr. Marciano performed a capsulectomy, which is moving the capsule or shell of the scar around the implant; an explantation of the silicone implants, which is removing the current implants; and an augmentation, which is putting in new implants. When Dr. Marciano made incisions in each breast to find the capsules, she found the

capsules right beneath the subcutaneous tissue, which is basically right beneath the skin and above the pectoralis major muscle. Although Dr. Marciano found the implants which had been placed by Dr. Labs, above the major pectoralis muscle, she could not determine where the implants were actually placed by Dr. Labs at the time he performed the implant exchange on W.S.

13. Dr. Marciano removed the silicone implants, identified the pectoralis muscle, incised the inferior edge of the pectoralis muscle, and dissected the plane underneath the muscle. Dr. Marciano placed new implants, which were 150cc's, on both breasts. The new implants were placed entirely underneath the muscle, and the small opening that was made in muscle fascia was closed with sutures so that the implants were in a closed pocket.

14. Capsular contraction, such as W.S. experienced, can cause the implants to move. Additionally, during the early stages after an implant has been placed, there is more potential for the implant to move before the capsule forms. Based on the evidence presented, the logical inference is that the capsular contraction caused the implants placed by Dr. Labs to move from underneath the pectoralis muscle so that the implants came to rest in a subglandular position as Dr. Marciano found them.

15. There were no medical records admitted in evidence from the Texas physician who placed the original implants in the

1980's. Based on what Dr. Labs found when he exchanged the implants, it is probable that the Texas physician used the dual-plane method to insert the implants, meaning that a portion of the implants were subglandular. This scenario comports with one of the hypotheses set forth by the Department's expert, who surmised that, based on the preoperative photographs taken by Dr. Labs, it appeared that the Texas physician may have placed the original implants in a subglandular position rather than in a subpectoral position. If the Texas physician had used a dual-plane method and placed a small portion of the implants under the rim of the pectoralis muscle, then a large portion of the implants would appear to be placed in a subglandular position as surmised by the Department's expert; when, in fact, the implants had been placed subpectorally as that term is commonly understood by plastic surgeons. Dual-plane placement also comports with W.S.'s distinct impression that the original implants had been placed under the muscle.

CONCLUSIONS OF LAW

16. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat. (2008).

17. The Department has the burden of establishing the allegations in the Administrative Complaint by clear and convincing evidence. Department of Banking and Finance v.

Osborne Stern and Co., 429 So. 2d 797 (Fla. 4th DCA 1983). The Department has alleged that Dr. Labs violated Subsections 458.338(1)(m), (1)(t)1., and (1)(bb), Florida Statutes, which provide:

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

* * *

(m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

* * *

(t) Notwithstanding s. 456.072(2) but as specified in s. 456.50(2):

1. Committing medical malpractice as defined in s. 456.50. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. Medical malpractice shall not be construed to require more than one instance, event, or act.

* * *

Nothing in this paragraph shall be construed to require that a physician be incompetent

to practice medicine in order to be disciplined pursuant to this paragraph. A recommended order by an administrative law judge or a final order of the board finding a violation under this paragraph shall specify whether the licensee was found to have committed "gross medical malpractice," "repeated medical malpractice," or "medical malpractice," or any combination thereof, and any publication by the board must so specify.

* * *

(bb) Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical, examination, or other diagnostic procedures. For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional.

18. Subsection 456.50(1)(g), Florida Statutes, defines "medical malpractice" as follows:

(g) [T]he failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Only for the purpose of finding repeated medical malpractice pursuant to this section, any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice as defined in this paragraph, shall be considered medical malpractice if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.

19. In the Administrative Complaint, the Department alleged that Dr. Labs violated Subsection 458.331(1)(t), Florida Statutes, in the following ways:

(a) By failing to perform a subpectoral implant as requested by Patient W.S.; or

(b) By failing to document the reason for placing the implants in a subglandular position and not in a subpectoral position as requested by Patient W.S.

20. The Petitioner has failed to establish by clear and convincing evidence that Dr. Labs placed the implants in a subglandular position. The implants were placed using a dual-plane method, in which a portion, albeit small, was inserted underneath the muscle. Based on the testimony of the experts who testified, as well as the testimony of Dr. Labs and Dr. Marciano, the use of a dual-plane method constitutes a subpectoral placement.

21. Dr. Marciano found the implants which had been placed by Dr. Labs in a subglandular position, but she could not say that Dr. Labs placed the implants in a subglandular position. The grade IV capsular contracture which W.S. experienced could easily have caused the small portion of the implants that were under the muscle to move to a subglandular position.

22. Petitioner has failed to establish by clear and convincing evidence that Dr. Labs failed to document why he placed the implants in a subglandular position. The evidence

does not establish that he placed the implants in a subglandular position. Thus, Petitioner has failed to establish by clear and convincing evidence that Dr. Labs violated Subsection 458.331(1)(t), Florida Statutes.

23. In the Administrative Complaint, the Department alleged that Dr. Labs violated Subsection 458.331(1)(m), Florida Statutes, "by failing to document the justification for the decision to place the implants in a subglandular position on [W.S.] instead of in a subpectoral position as discussed with [W.S.]." In the Administrative Complaint, the Department alleged that Dr. Labs violated Subsection 456.072(1)(bb), Florida Statutes, "by placing the silicone implants for Patient W.S. in a subglandular position instead of the subpectoral position Patient W.S. requested." The Department has failed to establish by clear and convincing evidence that Dr. Labs placed the implants in a subglandular position; therefore, the Department has failed to establish that Dr. Labs violated either Subsection 458.331(1)(m), Florida Statutes, or Subsection 456.072(1)(bb), Florida Statutes.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that a final order be entered finding that Dr. Labs did not violate Subsections 458.331(1)(m),

458.331(1)(t), or 456.072(1)(bb), Florida Statutes, and dismissing the Administrative Complaint.

DONE AND ENTERED this 14th day of October, 2009, in Tallahassee, Leon County, Florida.

Susan B. Harrell

SUSAN B. HARRELL
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 14th day of October, 2009.

ENDNOTES

^{1/} Unless otherwise indicated, all references to the Florida Statutes are to the 2005 version.

^{2/} Capsular contracture is a potential complication that can occur with any breast augmentation and usually occurs in a progressive manner. The more surgery that has been done to the breast, the greater the risk that capsular contracture can occur. The grading of the contracture means the degree of the stiffness and the degree of the thickness of the capsule and contracture. Grade IV is the greatest degree of scarring.

^{3/} Transcript Volume I, page 55.

COPIES FURNISHED:

Louis J. La Cava, Esquire
Stephens, Lynn, Klein, La Cava,
Hoffman & Puya, P.A.
101 East Kennedy Boulevard, Suite 2500
Tampa, Florida 33602

Shirley L. Bates, Esquire
Diane K. Kiesling, Esquire
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265

Josefina M. Tamayo, General Counsel
Department of Health
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399-1701

Larry McPherson, Executive Director
Board of Medicine
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399-1701

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.