

STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF )  
MEDICINE, )  
 )  
Petitioner, )  
 )  
vs. ) Case No. 07-3511PL  
 )  
ANTHONY BRIGNONI, M.D., )  
 )  
Respondent. )  
\_\_\_\_\_ )

RECOMMENDED ORDER

Pursuant to notice, a final hearing was held in this case on January 30, 2008, in Port Charlotte, Florida, before Susan B. Harrell, a designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Staci Braswell, Esquire  
Ephraim Livingston, Esquire  
Department of Health  
4052 Bald Cypress Way, Bin C-65  
Tallahassee, Florida 32399-3265

For Respondent: Sean M. Ellsworth, Esquire  
Ellsworth Law Firm, P.A.  
404 Washington Avenue, Suite 750  
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STATEMENT OF THE ISSUES

The issues in this case are whether Respondent violated Subsection 458.331(1)(t), Florida Statutes (2002),<sup>1</sup> and, if so, what discipline should be imposed.

PRELIMINARY STATEMENT

On March 13, 2007, the Department of Health (Department) filed an Administrative Complaint before the Board of Medicine (Board), alleging that Respondent, Anthony Brignoni, M.D. (Dr. Brignoni), violated Subsection 458.331(1)(t), Florida Statutes. Dr. Brignoni requested an administrative hearing, and the case was forwarded to the Division of Administrative Hearings on July 30, 2007, for assignment of an Administrative Law Judge to conduct the final hearing.

The final hearing was originally scheduled for October 5, 2007. The final hearing was rescheduled two times. On January 16, 2008, Petitioner filed a Motion to Amend Administrative Complaint. The motion was granted by Order dated January 28, 2008.

On January 28, 2008, Petitioner filed Petitioner's Motion for Official Recognition. The motion was granted at the final hearing, and official recognition was taken of Subsection 458.331(1)(t), Florida Statutes, and Florida Administrative Code Rule 64B8-8.001.

The parties filed a Joint Pre-hearing Stipulation and agreed to certain facts contained in paragraph 5 of the Joint Pre-hearing Stipulation. To the extent relevant, those facts are incorporated in this Recommended Order.

At the final hearing, Petitioner called Lynne Greenockle and Edward J. Zelnick, M.D., as its witnesses. Joint Exhibits 1 and 2 were admitted in evidence. Petitioner's Exhibit 1 was admitted in evidence. At the final hearing, Dr. Brignoni testified in his own behalf and called James W. Orr, Jr., M.D., as his witness. Respondent's Exhibit 1 was admitted in evidence.

The parties agreed to file their proposed recommended orders within ten days of the filing of the transcript of the final hearing. The Transcript was filed on February 25, 2008. The parties timely filed their Proposed Recommended Orders, which have been considered in the rendering of this Recommended Order.

#### FINDINGS OF FACT

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43 and Chapters 456 and 458, Florida Statutes (2007).

2. At all times material to the Amended Administrative Complaint, Dr. Brignoni was licensed to practice medicine in the State of Florida pursuant to Chapter 458, Florida Statutes, having been issued license number ME 59140. Dr. Brignoni is board-certified in obstetrics and gynecology.

3. On September 5, 2002, patient C.W. presented to Dr. Brignoni, who diagnosed her with severe dysplasia, vulvar intraepithelial neoplasia. Dr. Brignoni recommended that C.W. undergo a wide local excision of vulva/vaginal lesion.

4. On September 12, 2002, C.W. went to Charlotte Regional Medical Center for Dr. Brignoni to perform the wide local excision of vulvar intraepithelial neoplasia. Prior to the surgery, Dr. Brignoni had issued a card which indicated the supplies and instruments that he would need for a procedure such as the one that he was going to perform on C.W. The card is kept at Charlotte Regional Medical Center so that the supplies and instruments can be prepared and available at the time the procedure is scheduled to be performed. The card called for acetic acid to be supplied for the procedure, but no strength was specified.

5. Acetic acid is commonly used during gynecological procedures to highlight abnormal areas. In the instant case, it would be used to highlight the lesion that was to be excised. When acetic acid is used for such a purpose, the acceptable concentration is approximately three-to-five-percent.

6. Typically, when Dr. Brignoni arrives in the operating room to perform a procedure, all liquids and instruments required for the procedure are prepared and ready for use. A

surgical technician is responsible for assembling the liquids and instruments needed for the procedure.

7. When Dr. Brignoni began the excision on September 12, 2002, the surgical technician had not placed any acetic acid on the cart which housed the supplies and instruments needed for the procedure. Dr. Brignoni requested that acetic acid be obtained, and the circulating nurse went to the pharmacy to procure the acid. Dr. Brignoni did not request any specific concentration of acetic acid. The circulating nurse came back with a bottle of 100 percent acetic acid and decanted the acid into a container which she gave to the surgical technician.

8. Dr. Brignoni took a piece of gauze saturated with the 100 percent acetic acid and swabbed the vulva area. He immediately noticed that area was peeling. This was not the reaction that would have occurred using a three-to-five-percent solution. Dr. Brignoni asked the surgical staff what solution did they give him, and he was shown the bottle containing a 100 percent concentration of acetic acid.

9. Upon learning that he had applied 100 percent acetic acid to C.W.'s vulva area, Dr. Brignoni irrigated the area with over a liter of sterile water. He determined that he could proceed with the procedure, which he did. Prior to proceeding with the procedure, he did not consult with a physician familiar with chemical burns in determining whether it was appropriate to

continue with the procedure. Dr. Brignoni did check with an emergency room physician after the procedure to confirm that he treated the burn correctly by irrigating with sterile water.

10. As a result of the use of 100 percent acetic acid rather than a three-to-five-percent solution, C.W. experienced second degree burns in the area of her vulva and buttock. The normal time for the healing of a wide local excision of the vulva area is four to six weeks. C.W. healed in approximately eight weeks.

11. Edward J. Zelnick, M.D., testified as an expert for the Department. Dr. Zelnick was licensed to practice medicine in Florida in 1975 and is board-certified by the American Board of Obstetrics and Gynecology. Currently, Dr. Zelnick is the chief executive officer and clinical researcher at Horizon Institute for Clinical Research. The last time that Dr. Zelnick performed a surgical procedure was in 1998.

12. James Orr, M.D., testified as an expert for Dr. Brignoni. Dr. Orr has been board-certified in obstetrics and gynecology and gynecologic oncology since 1984. Currently, he is the medical director of Lee Cancer Center at Lee Memorial Hospital in Fort Myers, Florida, and is the director of Gynecologic Oncology and Gynecologic Oncology Research at Lee Cancer Center. He is a former associate professor of Obstetrics and Gynecology at the University of Alabama Birmingham School of

Medicine and a clinical professor in the Department of Obstetrics and Gynecology at the University of South Florida.

13. Dr. Orr has performed wide local excisions of the vulva area hundreds of times, and teaches this procedure to residents and medical students. It is Dr. Orr's opinion that it is not standard procedure for a surgeon to specify the concentration of acetic acid for such a procedure. The normal strength of acetic acid used in a wide local excision of the vulva area is understood to be three-to-five-percent, and the standard-of-care requires a physician to simply ask for acetic acid without specifying the concentration. Dr. Orr's opinion is credited.

14. It was Dr. Orr's opinion that Dr. Brignoni correctly irrigated the area after the application of the acetic acid and that there was no reason for Dr. Brignoni to stop the procedure after the irrigation. The biggest risk to the patient would have been stopping the procedure and putting the patient under anesthesia for a second time. Dr. Orr's opinion is credited.

#### CONCLUSIONS OF LAW

15. 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. (2007).

16. The Department has the burden to establish the allegations in the Amended Administrative Complaint by clear and

convincing evidence. Department of Banking and Finance v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996). The Department has alleged in the Amended Administrative Complaint that Dr. Brignoni violated Subsection 458.331(1)(t), Florida Statutes, which provides that the following acts constitute grounds for disciplinary action:

Gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. As used in this paragraph, "repeated malpractice" includes, but is not limited to, three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$25,000 each to the claimant in a judgment or settlement and which incidents involved negligent conduct by the physician. As used in this paragraph, "gross malpractice" or "the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances," shall not be construed to require that a physician be incompetent to practice medicine in order to be disciplined pursuant to this paragraph.

17. The Department alleged in the Amended Administrative Complaint that Dr. Brignoni violated Subsection 458.331(1)(t), Florida Statutes, in the following ways:



- a. by failing to confirm the concentration of acetic acid prior to applying the acetic acid to Patient C.W.;
- b. by failing to use an acceptable concentration of acetic acid during the preparation of Patient C.W.; and/or
- c. by continuing with the lesion excision without fully assessing the extent of Patient C.W.'s injury and/or allowing sufficient time for the injury to heal before doing the operation.

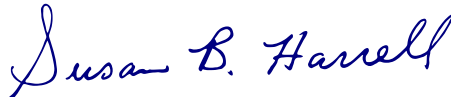
18. The Department has failed to establish by clear and convincing evidence that Dr. Brignoni fell below the standard-of-care in his care and treatment of C.W. The standard-of-care does not require a surgeon to specify the concentration of acetic acid when performing a wide local excision of the vulva area. Dr. Brignoni expected that the staff would provide him with a three-to-five-percent concentration of acetic acid and had no reason to believe that he had been given a greater concentration of acetic acid when the scrub technician gave him the acetic acid that was used in the procedure on C.W. The standard-of-care does not require a physician to specify a three-to-five-percent concentration of acetic acid when requesting acetic acid, and the standard-of-care does not require that a physician confirm the strength of acetic acid when he is handed the solution during a surgical procedure. Dr. Brignoni appropriately irrigated the area where the acetic acid had been applied and did not violate the standard-of-care when he continued with the procedure after the irrigation was

complete. Thus, the Department has failed to establish that Dr. Brignoni violated Subsection 458.331(1)(t), 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. Brignoni did not violate Subsection 458.331(1)(t), Florida Statutes, and dismissing the Amended Administrative Complaint against Dr. Brignoni.

DONE AND ENTERED this 23rd day of April, 2008, in Tallahassee, Leon County, Florida.



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SUSAN B. HARRELL  
Administrative Law Judge  
Division of Administrative Hearings  
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Filed with the Clerk of the  
Division of Administrative Hearings  
this 23rd day of April, 2008.

ENDNOTE

<sup>1/</sup> Unless otherwise indicated, all references to the Florida Statutes are to the 2002 codification.

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.