

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF)
MEDICINE,)
)
Petitioner,)
)
vs.) Case No. 09-5457PL
)
BERNARD J. ZARAGOZA, M.D.,)
)
Respondent.)
_____)

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was held in this case before Larry J. Sartin, an Administrative Law Judge of the Division of Administrative Hearings, on February 17, 2010, by video teleconference between Lauderdale Lakes and Tallahassee, Florida.

APPEARANCES

For Petitioner: Robert A. Milne
Assistant General Counsel
Diane K. Kiesling
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Department of Health
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For Respondent: Rolando A. Diaz, Esquire
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STATEMENT OF THE ISSUES

The issues for determination are whether Respondent Bernard J. Zaragoza, M.D., violated Section 456.072(1)(bb), Florida Statutes (2007), as alleged in an Administrative Complaint filed by the Department of Health before the Board of Medicine on June 30, 2008; and, if so, what disciplinary action should be taken against his license to practice medicine in the State of Florida.

PRELIMINARY STATEMENT

This case began with the filing by the Department of Health before the Board of Medicine of an Administrative Complaint, DOH Case Number 2007-38874, against Respondent Bernard J. Zaragoza, M.D., an individual licensed to practice medicine in Florida. On or about August 4, 2008, Respondent, through counsel, filed a letter in which, among other things, the allegations of fact contained in the Administrative Complaint were disputed and a formal administrative hearing was requested.

On October 6, 2009, the matter was filed with the Division of Administrative Hearings with a request that an administrative law judge be assigned to conduct proceedings pursuant to Section 120.57(1), Florida Statutes (2009). The matter was designated DOAH Case Number 09-5457PL and was assigned to the undersigned.

The final hearing was scheduled to be held on January 19 through 21, 2010, by video teleconference between sites in Miami

and Tallahassee, Florida, by Notice of Hearing by Video Teleconference entered October 16, 2009. The hearing was continued at the request of Respondent and re-scheduled for February 17, 2010. The hearing was to be held in Miami. On February 9, 2010, an Amended Notice of Hearing by Video Teleconference was entered.

On February 16, 2010, the parties filed a Revised Joint Pre-Hearing Stipulation. That pleading contains stipulated findings of fact which have been included in this Recommended Order.

On February 17, 2010, an Order Granting Motion for Official Recognition filed by Petitioner was entered.

During the final hearing, Joint Exhibits 1 through 3 were admitted. Petitioner presented the testimony of Respondent and had Petitioner's Exhibits 4 through 6, and 10 through 14 admitted. Petitioner also presented the rebuttal testimony of Christian Birkedal, M.D. Respondent offered the deposition testimony of Danny Sleeman, M.D. The transcript of the deposition of Dr. Sleeman was admitted as Respondent's Exhibit 6.

The one-volume Transcript of the final hearing was filed on March 4, 2010. By Notice of Filing Transcript entered the same day, the parties were informed that the Transcript had been filed and that their proposed recommended orders were to be

filed on or by March 15, 2010. Both parties timely filed proposed orders. The post-hearing proposals of both parties have been fully considered in rendering this Recommended Order.

All references to Florida Statutes in this Recommended Order are to the 2007 version, unless otherwise indicated.

FINDINGS OF FACT

A. The Parties.

1. Petitioner, the Department of Health (hereinafter referred to as the "Department"), is the agency of the State of Florida charged with the responsibility for the investigation and prosecution of complaints involving physicians licensed to practice medicine in Florida. § 20.43 and Chs. 456 and 458, Fla. Stat.

2. Respondent, Bernard J. Zaragoza, M.D., is, and was at the times material to this matter, a physician licensed to practice medicine in Florida, having been issued license number ME 67920.

3. Dr. Zaragoza's address of record is 3100 Coral Hills Drive, Suite 207, Coral Springs, Florida 33065.

4. Dr. Zaragoza is certified in general surgery by the American Board of Surgery.

5. Dr. Zaragoza has not been the subject of any investigation, claim, or complaint relating to his professional career other than this matter.

6. Dr. Zaragoza graduated, Summa Cum Laude, from the University of Miami with a bachelors degree. He earned his medical degree from Harvard Medical School.

7. Dr. Zaragoza performed a five-year surgical residency program at New York Medical College's Westchester County Medical Center. During his residency, Dr. Zaragoza performed hundreds of laparoscopic procedures, including laparoscopic cholechstectomies (removal of the gallbladder).

8. A laparoscopic surgery is a technique in which the abdomen is entered through small incisions rather than "opening up" the abdomen. Normally, for abdominal laparoscopic surgery, incisions are made at the belly button. This is the point which is usually closest to the peritoneal cavity, thus reducing the distance from the skin the surgeon must work through and the surgeon has a broader view of the abdomen.

9. By October 2007, Dr. Zaragoza had performed in excess of 2,000 laparoscopic cholecystectomy procedures.

B. Patient J.C.

10. On October 1, 2007, Patient J.C., a male, 83 years of age, presented at Northwest Medical Center, located in Margate, Florida, for treatment of abdominal pain and vomiting. Patient J.C. had reported with the same symptoms a month earlier and had been diagnosed with chronic cholecystitis, a chronic

inflammation of the gallbladder due to the blockage of the bile ducts by gall stones. It is a life-threatening condition.

11. Patient J.C. was admitted by Rafael Rodriguez, M.D., who requested a consultation by Mark Shachner, M.D., Dr. Zaragoza's partner. Dr. Shachner confirmed a diagnosis of acute cholecystitis and, in light of the failed conservative therapy which Patient J.C. had undergone since his first visit and the potential threat to his life, Dr. Shachner recommended surgery.

12. It was concluded that Patient J.C. would undergo an attempted laparoscopic cholecystectomy. Dr. Zaragoza was to perform the procedure.

13. It was concluded that a laparoscopic procedure was the appropriate procedure for Patient J.C. due to his medical history: atrial fibrillation, Alzheimer's disease, hypertension, and diabetes. He had also undergone prior abdominal procedures. The parties did not dispute that a laparoscopic procedure, because it was likely to reduce post-operative complications, was the best type of surgical procedure for Patient J.C.

14. Patient J.C., as a result of a prior gastrectomy, had a long midline incision extending from the Xiphoid upper abdomen to below the belly button. As a result of this surgery, Patient

J.C. had extensive adhesions of tissue up to the midline.

Patient J.C. had also undergone an appendectomy.

15. It was concluded that, due to Patient J.C.'s condition and abdominal surgical history, rather than entering at the belly button and risking injury to any structures that were adhered to the midline, a "right-sided" incision point would be used. The Department does not dispute the appropriateness of this decision.

16. Unfortunately, by using a right-sided incision point, Dr. Zaragoza's visualization of Patient J.C.'s abdominal cavity was reduced.

17. Patient J.C. and his family were fully informed of the nature of the proposed surgical procedure and the risks, after which Patient J.C. signed a written consent for surgery. The written consent included an authorization to "take whatever action(s) and to perform whatever procedures(s) they deem necessary and advisable, which may be in addition to or different from those now planned" and an acknowledgement that the surgery to be performed "may result in perforation or injury to adjacent organs or structures."

18. None of the witnesses convincingly testified that the authorization included the authority to remove healthy organs or that the acknowledgement included any suggestion that a healthy organ might be completely removed.

19. Surgery was scheduled for October 2, 2007.

20. Dr. Zaragoza began the surgery with a right-sided approach, freeing up the area and attempting to identify important structures in the right upper quadrant of the abdomen. In particular, the important structures Dr. Zaragoza attempted to locate were the liver, colon, and the gallbladder.

21. Dr. Zaragoza encountered extremely heavy adhesions (8 on a scale of 1 to 10) in Patient J.C.'s abdomen. Dr. Zaragoza considered the risks of continuing or switching to an open abdomen procedure and correctly concluded it was best to proceed.

22. Dr. Zaragoza freed up extensive adhesions and was able to correctly identify the liver. Unable to identify the gallbladder and due to the extensive adhesions in the area of the intestine, Dr. Zaragoza stopped the procedure in order to retrieve a CT scan of the area and personally evaluate the images. In order to expedite receipt of the CT study, Dr. Zaragoza scrubbed out and personally walked to the radiology suite.

23. After returning, Dr. Zaragoza read the CT scan and the radiologist's interpretation, which indicated that the gallbladder was posterior to the transverse colon. Dr. Zaragoza returned to Patient J.C., mobilized the colon to free it from

the liver and attempted to locate the gallbladder behind the colon where he expected it to be.

24. What Dr. Zaragoza found behind the transverse colon was a dark, thickened, and solid structure in the anatomical position which the CT scan and radiologist report suggested the gallbladder would be located.

25. While the gallbladder, which consists of a water sac, is normally soft, pink, and pliable, this is not the case with an inflamed and infected one. Given Patient J.C.'s history of chronic cholecystitis with an acute cholecystitis secondary to the blockage of bile ducts by gallstones, Dr. Zaragoza was expecting to find a dark, thickened, and solid gallbladder in Patient J.C.

26. Concluding that the structure he had located was the gallbladder, Dr. Zaragoza freed the organ of surrounding tissue, freeing away without incision adhesions to the organ, bringing the organ into position for removal. As Dr. Zaragoza began to free up the fat tissue around what he believed were the bile duct and blood vessels of the gallbladder, the organ ruptured, revealing a solid mass. Dr. Zaragoza believed that the mass was a tumor, which Dr. Zaragoza had encountered in other gallbladder surgeries.

27. Dr. Zaragoza continued the procedure, separating the gallbladder for removal. While dividing what he believed was a

cystic duct, Dr. Zaragoza encountered a bifurcation that did not correspond to the anatomy of the gallbladder. At this point, Dr. Zaragoza decided that surgery needed to be converted from laparoscopic to an open procedure. After doing so, a frozen section of the organ was sent to pathology for evaluation, in order to obtain a rapid evaluation of the tissue.

28. The pathology report revealed that the organ that Dr. Zaragoza had removed from Patient J.C. was a healthy kidney.

29. Dr. Zaragoza thereupon located the gallbladder by examining the dense adhesions around the colon, a risky procedure. Ultimately Dr. Zaragoza was required to cut into the transverse colon where he located the gallbladder, which had eroded into the transverse colon.

30. Dr. Zaragoza then completed the surgical procedure, removing the gallbladder.

31. Patient J.C.'s family was immediately advised of what had taken place; that Dr. Zaragoza had removed a kidney, in addition to successfully removing the gallbladder.

32. The removal of a healthy kidney involves a medical procedure totally unrelated to removal of an unhealthy gallbladder. Removal of a healthy kidney is not a known or expected complication of gallbladder removal. Dr. Zaragoza's removal of Patient J.C.'s kidney during gallbladder surgery constituted a "a wrong-site procedure, wrong procedure, or an

unauthorized procedure, or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition." The Department's proposed findings of fact 12 through 20 contained in the Department's Proposed Recommended Order, are accurate, support the ultimate findings of fact made in this paragraph and are subordinate thereto.

33. Proposed findings of fact 36 through 38 of Respondent's Proposed Order in large part accurately reflect the difficulty of the surgery performed on Patient J.C. Even the Department's own expert noted that he thanked God Patient J.C. had not been his patient. The suggestion in paragraph 26 that the removal of the kidney was "simply an unwanted complication associated with this cholecystectomy procedure" is, however, not supported by the weight of the evidence.

CONCLUSIONS OF LAW

A. Jurisdiction.

34. The Division of Administrative Hearings has jurisdiction over the subject matter of this proceeding and of the parties thereto pursuant to Sections 120.569 and 120.57(1), Florida Statutes (2009).

B. The Burden and Standard of Proof.

35. The Department seeks to have penalties imposed against Dr. Zaragoza's license through the Administrative Complaint that include suspension or revocation of his license and/or the

imposition of an administrative fine. Therefore, the Department has the burden of proving the specific allegations of fact that support its charge that Dr. Zaragoza violated the statutory provision alleged in the Administrative Complaint by clear and convincing evidence. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987); Pou v. Department of Insurance and Treasurer, 707 So. 2d 941 (Fla. 3d DCA 1998); Nair v. Department of Business and Professional Regulation, 654 So. 2d 205 (Fla. 1st DCA 1995); and § 120.57(1)(j), Fla. Stat. (2009)("Findings of fact shall be based on a preponderance of the evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute.").

36. What constitutes "clear and convincing" evidence was described by the court in Evans Packing Co. v. Department of Agriculture and Consumer Services, 550 So. 2d 112, 116, n. 5 (Fla. 1st DCA 1989), as follows:

. . . [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 evidence 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 the 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).

See also In re Graziano, 696 So. 2d 744 (Fla. 1997); In re Davey, 645 So. 2d 398 (Fla. 1994); and Walker v. Florida Department of Business and Professional Regulation, 705 So. 2d 652 (Fla. 5th DCA 1998)(Sharp, J., dissenting).

C. The Charges of the Administrative Complaint.

37. Section 456.072(1), Florida Statutes, authorizes the Board of Medicine (hereinafter referred to as the "Board") to impose penalties against Florida physicians ranging from the issuance of a letter of concern to revocation of the physician's license to practice medicine in Florida if the physician commits one or more acts specified therein.

38. The Administrative Complaint in this case alleges that Dr. Zaragoza violated the following provision of Section 456.072(1), Florida Statutes:

(bb) Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

39. In determining whether Dr. Zaragoza committed the alleged statutory violation, only those specific factual grounds

alleged by the Department in the Administrative Complaint may form the basis of a finding of violation. See Trevisani v. Department of Health, 908 So. 2d 1108 (Fla. 1st DCA 2005); Cottrill v. Department of Insurance, 685 So. 2d 1371 (Fla. 1st DCA 1996). Due process prohibits the Department from taking disciplinary action against a licensee based on matters not specifically alleged in the charging instrument, unless those matters have been tried by consent. See Shore Village Property Owners' Association, Inc . v. Department of Environmental Protection, 824 So. 2d 208, 210 (Fla. 4th DCA 2002); and Delk v. Department of Professional Regulation, 595 So. 2d 966,967 (Fla. 5th DCA 1992)."

40. In addressing the charges against Dr. Zaragoza, it is recognized that the Board is the agency which has been charged with responsibility for administering the Medical Practice Act, Chapter 458, Florida Statutes, and the rules relevant to this matter adopted by the Board. The Board's interpretation of those provisions of law that it has been charged by the legislature to administer must be given great weight. See Phillips v. Board of Dentistry, 884 So. 2d 78 (Fla. 4th DCA 2004).

41. It is also recognized, however, that "the conduct proved must legally fall within the statute or rule claimed [in the charging instrument] to have been violated." Delk v.

Department of Professional Regulation, 595 So. 2d 966, 967 (Fla. 5th DCA 1992). In deciding whether "the statute or rule claimed to have been violated" was in fact violated, as alleged, if there is any reasonable doubt, that doubt must be resolved in favor of the licensee. See Whitaker v. Department of Insurance and Treasurer, 680 So. 2d 528, 531 (Fla. 1st DCA 1996); Elmariah v. Department of Professional Regulation, Board of Medicine, 574 So. 2d 164, 165 (Fla. 1st DCA 1990); and Lester v. Department of Professional and Occupational Regulations, 348 So. 2d 923, 925 (Fla. 1st DCA 1977).

42. There is little, if any, dispute about what took place on October 2, 2007, during the surgical procedure performed by Dr. Zaragoza on Patient J.C. The evidence clearly and convincingly proved that the procedure was extremely difficult and, once fully understood, less shocking than at first blush. Ultimately, despite the difficulties encountered by Dr. Zaragoza and the unusual set of circumstances surrounding the surgery, the evidence proved clearly and convincingly that the removal of Patient J.C.'s kidney constituted "a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition."

43. Therefore, it is concluded that the Department has proved clearly and convincingly that Dr. Zaragoza has violated

Section 456.072(1)(bb), Florida Statutes, as alleged in the Administrative Complaint.

D. The Appropriate Penalty.

44. In determining the appropriate punitive action to recommend to the Board in this case, it is necessary to consult the Board's "disciplinary guidelines," which impose restrictions and limitations on the exercise of the Board's disciplinary authority under Section 456.072, Florida Statutes. See Parrot Heads, Inc. v. Department of Business and Professional Regulation, 741 So. 2d 1231 (Fla. 5th DCA 1999).

45. The Board's guidelines are set out in Florida Administrative Code Rule 64B8-8.001. Pertinent to this matter, Florida Administrative Code Rule 64B8-8.001(2)(ss), effective January 30, 2007, provides the following recommended range of penalties for a first time offence:

From a \$1,000.00 fine, a letter of concern, a minimum of five (5) hours of risk management education, and one (1) hour lecture on wrong-site surgery in the State of Florida to a \$10,000.00 fine, a letter of concern, a minimum of five (5) hours of risk management education, 50 to 100 hours of community service, undergo a risk management assessment, a one (1) hour lecture on wrong-site surgery, and suspension to be followed by a term of probation.

46. Florida Administrative Code Rule 64B8-8.001(3), effective January 30, 2007, provides that, in applying the penalty guidelines, the following aggravating and mitigating

circumstances are to be taken into account:

(3) Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. The Board shall consider as aggravating or mitigating factors the following:

- (a) Exposure of patient or public to injury or potential injury, physical or otherwise: none, slight, severe, or death;
- (b) Legal status at the time of the offense: no restraints, or legal constraints;
- (c) The number of counts or separate offenses established;
- (d) The number of times the same offense or offenses have previously been committed by the licensee or applicant;
- (e) The disciplinary history of the applicant or licensee in any jurisdiction and the length of practice;
- (f) Pecuniary benefit or self-gain inuring to the applicant or licensee;
- (g) The involvement in any violation of Section 458.331, F.S., of the provision of controlled substances for trade, barter or sale, by a licensee. In such cases, the Board will deviate from the penalties recommended above and impose suspension or revocation of licensure.
- (h) Where a licensee has been charged with violating the standard of care pursuant to Section 458.331(1)(t), F.S., but the licensee, who is also the records owner pursuant to Section 456.057(1), F.S., fails to keep and/or produce the medical records.
- (i) Any other relevant mitigating factors.

47. In its Proposed Recommended Order, the Department has recognized that the "level of aggravating factors is not high given the circumstances and the extensive mitigating factors"

which include the facts that: Dr. Zaragoza has had no previous discipline taken against his license; he has been practicing for 12 years without incident; his medical license was clear and active and had no restraints, or legal constraints; all the experts who testified in this matter were in agreement about the medical complications encountered and that the error was not caused by negligence or want of skill in Dr. Zaragoza's technique; and Dr. Zaragoza has been candid throughout this proceeding, before the Board and at hearing.

48. The Department has requested that it be recommended that Dr. Zaragoza be subjected to a fine of \$10,000.00, receive a letter of concern, undergo five hours of risk management education, and be required to perform 50 hours of community service.

49. The penalty requested by the Department, other than the absence of a suspension, followed by probation, and an hour lecture on wrong-site surgery are on the higher side of the range of penalties. Therefore, it will be recommended that the amount of the fine requested by the Department be reduced.

RECOMMENDATION

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

RECOMMENDED that a final order be entered by the Board of Medicine finding that Bernard J. Zaragoza, M.D., has violated

Section 456.072(1)(bb), Florida Statutes, as alleged in the Administrative Complaint; imposing a fine of \$5,000.00; issuing a letter of concern; requiring the completion of five hours of risk management education; and requiring that he perform 50 hours of community service.

DONE AND ENTERED this 6th day of April, 2010, in Tallahassee, Leon County, Florida.



LARRY J. SARTIN
Administrative Law Judge
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Filed with the Clerk of the
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This 6th day of April, 2010.

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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 these cases.