

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF)
MEDICINE,)
)
Petitioner,)
)
vs.) Case No. 00-2588
)
IRA W. FREILICH, M.D.,)
)
Respondent.)
_____)

RECOMMENDED ORDER

A formal hearing was held by Daniel M. Kilbride,
Administrative Law Judge, Division of Administrative Hearings,
in the above-styled case on October 30 and 31, 2000, in Orlando,
Florida.

APPEARANCES

For Petitioner: Robert C. Byerts, Esquire
Agency for Health Care Administration
Post Office Box 14229
Tallahassee, Florida 32317-4229

For Respondent: Richard S. Womble, Esquire
Rissman, Weisberg, Barrett, Hurt,
Donahue & McLain, P.A.
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Orlando, Florida 32801

STATEMENT OF THE ISSUES

Whether Respondent violated various provisions of
Chapter 458, Florida Statutes, to wit: (1) Subsection
458.331(1)(t), Florida Statutes, 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, with regard to patients known in this record as B. D., S. R., L. R. and E. M.; (2) Subsection 458.331(1)(g), Florida Statutes, by utilizing liquid injectable silicone in his treatment of patients B. D., S. R., L. R. and E. M., in violation of the Federal Food Drug and Cosmetic Act and thereby failing to comply with a statutory or legal obligation placed upon a licensed physician; and (3) Subsection 458.331(1)(u), Florida Statutes, by utilizing liquid injectable silicone, an investigational device not approved for general medical use or for use in plastic surgery, and not conforming to prevailing standards of medical practice in Altamonte Springs or any other community in Florida, thereby engaging in experimentation on a human subject.

If Respondent is guilty of said violations, what discipline should be imposed.

PRELIMINARY STATEMENT

On May 25, 2000, Petitioner, the Department of Health, filed an Administrative Complaint against Respondent, Ira W. Freilich, M.D. Respondent filed an election of rights disputing the allegations of fact contained in the Administrative Complaint and petitioned for a formal

administrative hearing before an Administrative Law Judge (ALJ) appointed by the Division of Administrative Hearings (DOAH).

The case was forwarded to DOAH, the case was set for hearing on October 30 and 31, 2000, in Orlando, Florida, and discovery ensued.

On October 30, 2000, this tribunal took up the various motions of the parties. At the outset, the ALJ denied Respondent's Motion to Dismiss the Administrative Complaint. As Respondent had no objection, the ALJ took Official Recognition of Section 458.331, Florida Statutes, and Rule 64B8-8.001, Florida Administrative Code, the Board of Medicine Rule applicable to this case. Following oral argument, the ALJ granted Petitioner's Motion for Taking Official Recognition of the Recommended Order and Final Order in Department of Professional Regulation v. Richard Samitier Cardet, for the limited portion of that case relevant to the issues in this case. Following further consideration, the ALJ granted Petitioner's Motion for Taking Official Recognition of pertinent portions of the United States Code and the Code of Federal Regulations, to wit: 21 USC Sections 321, 331, 351, 360c, 360e, 360j, 360k and 379a, as well as 21 CFR Sections 812.1, 812.2, 812.3, 812.5, 812.7, 814.1, 814.2, 812.36, and 860.3. The parties filed their Prehearing Stipulation on October 27, 2000.

This tribunal determines that Petitioner, through its employees, agents, servants and/or representative, including employees of the Agency for Health Care Administration, improperly obtained copies of the office charts maintained by Respondent concerning his patients B. D., S. R., L. R. and/or E. M. from an anonymous source. The records were obtained by an unknown person and provided to Petitioner without patient authorization, an appropriately obtained subpoena, or through issuance of an appropriate search warrant and/or legal process of any type. The improperly obtained charts were used to assist the investigating agency in pursuing this matter. The only records submitted into evidence by Petitioner were copies of the improperly obtained charts. However, no evidence was offered which would indicate that Petitioner sought or solicited these patient charts, and no authority has been cited which prohibits Petitioner from using the material contained in the patient charts of B. D., S. R., L. R. and E. M. in this proceeding under the facts and circumstances of this case. Further, Respondent has not demonstrated extreme prejudice such that it would require the exclusion of these documents.

Petitioner also withheld copies of the improperly obtained documents which hampered Respondent's ability to present a defense to Petitioner's claims to the Probable Cause Panel. At the Administrative Hearing, Petitioner's file did not contain

the entire report. Thus, Petitioner's complete investigative report was never provided to Respondent as required and as fairness would dictate. Subsection 455.225(10), Florida Statutes, requires Petitioner to provide Respondent with a copy of its investigative file. Petitioner complied only after multiple requests and years of delay and then did not provide the entire file. However, many of the material facts in this matter are not in dispute, and Petitioner's omissions do not require further sanctions.

At the hearing, Petitioner's Exhibits 1 through 13 were received in evidence. Leave was granted to file two exhibits, certified copies of the disposition of two Federal cases, after the conclusion of the hearing. Respondent introduced four exhibits, which were received in evidence.

Thomas A. Fiala, M.D., patient S. R., David Williams, and Terri Smathers testified for Petitioner. Petitioner tendered Dr. Fiala, who was accepted as an expert in the field of plastic surgery and in the use of soft tissue augmentation. Mr. Williams was accepted as an expert in the field of chemistry. Petitioner also presented the testimony of Lija Scherer and Suzanne Parisian, M.D. Dr. Parisian was accepted as an expert in the Food and Drug Administration's regulation of medical devices and as an expert in the Food and Drug Administration's regulation of liquid injectable silicone.

Respondent called Sorrel S. Resnik, M.D., and Respondent testified in his own behalf. Dr. Resnik was accepted as an expert in the field of dermatology. Respondent was accepted as an expert in the practice of dermatology.

The parties requested thirty days from the filing of the Transcript in which to file Proposed Recommended Orders. On November 7 and 27, 2000, Petitioner filed certified copies of Exhibits 14 and 15, as authorized at the hearing. On January 18, 2001, Petitioner filed copies of the version of Rule 64B8-8.001, Florida Administrative Code, applicable to the time period of Respondent's activities. The Transcripts were filed December 26, 2000. The parties timely filed their Proposed Recommended Orders on January 29, 2001. Each of the parties' post-hearing submittals has been given careful consideration in the preparation of this Recommended Order.

FINDINGS OF FACT

1. Respondent is and has been at all times material hereto a licensed medical physician in the State of Florida, having been issued license number ME 0046912.

2. Petitioner is the state agency charged with regulating the practice of medicine pursuant to Section 20.42, and Chapters 456 and 458 Florida Statutes.

3. Respondent is board-certified in dermatology.

4. Patient S. R. presented to Respondent for dermatological care and treatment on or about June 13, 1996, July 18, 1996, and September 20, 1996. Patient S. R. went to Respondent to receive facial injections for wrinkles.

5. Respondent presented patient S. R. with alternative treatments for her wrinkles, in the form of collagen, pork collagen and a synthetic he identified as silicone. Respondent indicated that he had used silicone before on hundreds of people and that there were no risks associated with its use. Respondent indicated to patient S. R. that silicone was better than collagen because it lasted longer, was not absorbed by the body, and did a better job of "plumping out" the wrinkle.

6. Respondent indicated to patient S. R. that the Food and Drug Administration (FDA) had not approved the use of Liquid Injectable Silicone (LIS) for facial injection. Respondent told patient S. R. that the reason LIS had not been approved by FDA was politically based and LIS should never have been banned. Respondent stated that he had purchased the material from a physician who had a quantity of it when he retired.

7. S. R. executed a written consent for the treatment.

8. Respondent utilized LIS in his treatment of patient S. R. injecting it into her face between her eyebrows, near her nose, and at the corners of her mouth. Respondent charged

patient S. R. a fee for the silicone injections. Some of the LIS has migrated into her neck, and some has migrated into her lip, where it remains today.

9. Patient B. D. presented to Respondent for dermatological care and treatment on or about September 17, 1996. Respondent utilized LIS in his treatment of patient B. D. during that visit, and he charged patient B. D. a fee for silicone injections.

10. Patient L. R. presented to Respondent for dermatological care and treatment on or about March 15, 1996, April 12, 1996, May 3, 1996, June 13, 1996, July 15, 1996, August 12, 1996, September 3, 1996, and October 24, 1996. He used LIS in his treatment of patient L. R. on eight occasions for lip augmentation and charged patient L. R. a fee for the silicone injections.

SILICONE

11. Respondent did not use silicone oil or symethicone in his treatment of patients.

12. Respondent does not know the particular make up of the substance that he used to treat patients. Respondent does not know the origin of the substance since he purchased it from a physician who was retiring. Respondent did not purchase the LIS he used for injections from any authorized supplier of medical products. The LIS Respondent used for injections into patients

came from a bottle which previously contained lidocaine. The bottle was either labeled by Respondent or unlabeled. The label did not contain a lot number, expiration date, manufacturer, or otherwise appear to be a proper label. The source container of the substance did not have a label or manufacturer's name on it.

SOFT TISSUE AUGMENTATION

13. Soft tissue augmentation involves a process in which a material is introduced into an area of the body, usually at a very superficial level, just underneath the surface of the skin, in order to provide enhanced contouring and an improved appearance of the area being treated. Typically, soft tissue augmentation is intended to improve the appearance of a wrinkle, or the contour of a bony prominence, or enhancing the volume of the lips or other areas. Soft tissue augmentation is an elective procedure. Patients usually present themselves to the physician with complaints related to facial aging or loss of soft tissue volume in the face.

14. The typical method of introducing the subsurface substance is by injection, although solid implants are sometimes surgically placed. Materials used for filling soft tissues should have a number of specific properties, such as being inert, sterile, nonimmunogenic, and nonmigratory. Soft tissue fillers can be autologous or manmade. Autologous materials come

from the patients's own body. Manmade materials include bovine collagen and Fibral.

15. LIS is a liquid or gel-like substance that can be injected through a fine gauge needle into various areas of the body for soft tissue augmentation. LIS is not the same product as symethicone, other orally administered silicone products, or silicone used for lubrication. LIS is not the same product as silicone oil.

16. LIS, when used for soft tissue augmentation, has unacceptable side effects. The side effects include migration of the material from the point where it is originally placed, the formation of palpable nodules of granulated inflamed tissue, and inflammatory or infective life changes, such as chronic redness, and ulcerations.

17. LIS is not appropriate for use as a soft tissue filling agent because it does not meet standards for safety, predictability, and reliability. The safety and efficacy of LIS does not depend upon the amount injected.

18. Medical devices are devices that produce a medical effect but do not use a pharmacological mode of action like a drug. Medical devices do not chemically react with the body and are not metabolized by the body. Medical devices are classified on the basis of their potential risk to human health. Class one devices pose so low a risk that no premarket review by the FDA

is required. As the risk increases so does the likelihood that the FDA must do a premarket review to establish the existence of valid scientific data to support the conclusion that a device is safe and effective. Class III devices are considered the highest risk devices.

19. LIS is a medical device, as defined in 21 USC Section 321(h), because it is a long-term implant which is not intended to chemically react with the body and is not metabolized by the body. The FDA considers LIS a class III medical device based upon its interpretation of 21 USC Section 360j(1).

20. Beginning in 1976, under the Medical Device Act, the FDA regulated LIS as a transitional class III medical device, an item formerly regulated as a drug for which the safety and effectiveness of the product had not been demonstrated. LIS has been regulated by the FDA as a medical device since 1976 under the authority of the Food Drug and Cosmetic Act, the Medical Device Act of 1976 and the Safe Medical Device Act of 1990.

21. In order for any person to market a class III transitional device he or she must submit a premarket application (PMA) to FDA under 21 USC Section 360c and demonstrate the product's safety and efficacy through clinical trials authorized under an investigational device exemption (IDE) pursuant to 21 USC Section 360j(g). After it began regulating LIS as a medical device, the FDA denied an

application from Dow Chemical for an IDE to conduct a clinical trial of LIS for cosmetic use. No other entity has submitted an application for an IDA or PMA regarding LIS.

22. LIS is a class III transitional device for which a medical device application has been rejected as not safe and effective. In the absence of the FDA approval under an IDE or PMA, a physician may not use a class III transitional device in the United States to treat patients.

23. Respondent asserted that he injected LIS in patients under the concept of "off label" use. The FDA considers LIS an adulterated device. Since at least 1990, the FDA has considered LIS an "adulterated" product within the meaning of the Food Drug and Cosmetic Act. Under the concept of "off label" use, an approved drug may be prescribed for a use other than one approved by the FDA, because the product has been demonstrated as safe and effective. However, in the absence of an approved product, there can be no "off label" use. LIS is neither an approved drug nor an approved medical device. Therefore, there can be no appropriate "off label" use of LIS.

24. In the 1970s and 1980s the FDA became aware of the use of LIS outside the approved Dow Chemical clinical trial. The FDA cited Dow Chemical for not controlling the use of their product. The FDA also prevented new supplies of LIS from coming into the United States through the imposition of an import

detention. The FDA has released warnings, bulletins, and adverse publicity to try to curtail the use of LIS. The FDA communicated directly with medical organizations and physicians themselves, including physicians in Florida, to inform physicians to stop using LIS because the FDA considered the use of LIS illegal. The documents the FDA published and distributed to physicians stated that the FDA has not approved the use of LIS for injection, and the documents indicated that the FDA prohibits doctors from marketing, promoting, or selling LIS.

25. The FDA has prosecuted physicians based upon their use of LIS for soft tissue augmentation. Injunctions have been entered against at least two physicians prohibiting them from marketing, distributing, and using LIS. The FDA's position regarding the prohibition on the use of LIS was disseminated in the broadcast media in the early 1990s. The FDA provided public notice, through press announcements, that the FDA and the Federal courts had compelled several physicians to stop injecting liquid silicone into patients to correct wrinkles and acne scars. FDA's announcements further stated that the use of LIS is illegal unless and until the product is approved by the FDA for either marketing or investigational studies. These announcements were disseminated to physicians' groups, physicians' societies, and specialty boards.

26. The State of Florida, in conjunction with the FDA, also took action against another physician, in part, upon his use of LIS generally and specifically based upon his injection of LIS into a patient's lips to create a "Paris Lips" appearance.

27. The use of LIS for soft tissue augmentation has not been approved by the FDA. LIS is not an approved soft tissue augmentation product for the United States and was not an approved product in 1996. In 1996, the FDA viewed the use of LIS by a physician as an illegal, prohibited act.

28. Respondent was aware of the FDA's position prior to his treatment of patients B. D., S. R., L. R. and E. M. in 1996.

29. A reasonable and prudent physician would not inject a large amount, i.e., more than .05 cc of LIS into a patient. A reasonable and prudent physician would not inject LIS into a patient's lips or other parts of her body.

30. By utilizing LIS in his treatment of patients B. D., S. R., L. R. and E. M., Respondent failed to comply with a statutory and legal obligation placed upon a licensed physician.

31. Respondent, by utilizing LIS in the treatment of a patient, engaged in experimentation on a human subject without fully informed consent from any of the patients.

CONCLUSIONS OF LAW

32. The Division of Administrative Hearings has jurisdiction of the parties and the subject matter pursuant to Sections 120.569 and 120.57, Florida Statutes.

33. Pursuant to Section 456.073, Florida Statutes, the Board of Medicine is empowered to revoke, suspend, or otherwise discipline the license of a physician for violation of Subsection 458.331(1), Florida Statutes.

34. Revocation of license proceedings are penal in nature, State ex rel. Vining v. Florida Real Estate Commission, 281 So. 2d 487 (Fla. 1973) and must be construed strictly in favor of the one against whom the penalty would be imposed.

35. Petitioner's burden of proof in this case is to demonstrate, by clear and convincing evidence, Respondent's failure to practice medicine in accord with the allegations contained in the Administrative Complaint. Department of Banking and Finance v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

36. Petitioner in this case has demonstrated, by clear and convincing evidence, 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 based upon his injection of LIS into his patients. The expert testimony

herein and the position of the Board of Medicine establish that the injection of liquid silicone is not an accepted medical procedure in Florida. Department of Health, Board of Medicine v. Richard Samitier Cardet (DOAH Case No. 92-5795, Board of Medicine Final Order dated March 25, 1994).

37. With respect to patient L. R., Respondent administered LIS directly into her lips in order to produce a " Paris Lips" appearance. The expert testimony in this case establishes that the injection of LIS into the lips deviated from the practice of a reasonable and prudent physician. In addition, the Board of Medicine has expressly condemned this particular procedure. Richard Samitier Cardet, supra; (injection of silicone into a patient's lips renders a physician subject to discipline under Subsection 458.331(1)(t), Florida Statutes). As Respondent utilized a procedure which has formed the basis of previous discipline by the Florida Board of Medicine and performed a procedure which experts agree contravenes what a reasonable and prudent physician would do, Respondent is subject to discipline under Subsection 458.331(1)(t), Florida Statutes.

38. Respondent's objection to Dr. Fiala's testimony, based upon Section 766.102, Florida Statutes, lacks legal support. The Statute does not exclude a specialist in one field from testifying against a specialist in another field. Green v. Goldberg, 630 So. 2d 606 (Fla. 4th DCA 1993); see Sims v. Brown,

574 So. 2d 131 (Fla. 1991). The pertinent inquiry is whether the testifying expert possesses the requisite training, experience and knowledge in the given field of medicine. Id. Dr. Fiala clearly and convincingly demonstrated that his training, education, and experience qualify him in the field of soft tissue augmentation, the field of medicine pertinent to this case.

39. Subsection 458.331(1)(g), Florida Statutes, requires that a physician perform statutory and legal obligations placed upon a licensed physician or be subject to disciplinary action. Petitioner has proven by clear and convincing evidence that Respondent failed to comply with numerous statutory obligations pertinent to medical devices found in Title 21 United States Code and the implementing regulations in Title 21 Code of Federal Regulations.

40. Subsection 458.331(1)(u), Florida Statutes, authorized the imposition of discipline upon physicians performing any procedure or prescribing any therapy which, by the prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent.

41. Petitioner has proven by clear and convincing evidence that Respondent utilized liquid injectable silicone, an

investigational device not approved for general medical use, thereby engaging in experimentation on a human subject.

42. By the terms of Rule 61F6-20.001, Florida Administrative Code (1996), the Board may impose discipline ranging from two years of probation to revocation or denial of the physician's license, and an administrative fine from \$250 to \$5,000 for a violation of Subsection 458.331(1)(t), Florida Statutes. For Subsection 458.331(1)(g), Florida Statutes, the Board may impose discipline ranging from a one-year suspension to revocation or denial and an administrative fine from \$250 to \$5000. For Subsection 458.331(1)(u), Florida Statutes, the penalty range is from a one-year suspension to revocation or denial and an administrative fine from \$250 to \$5,000. Rule 61F6-20.001(3), Florida Administrative Code (1996), address aggravating and mitigating circumstances.

43. In the instant case, Respondent violated Subsections 458.331(1)(t), (g), and (u), Florida Statutes, and the penalty ranges in Rule 61F6-20.001, Florida Administrative Code (1996), apply.

RECOMMENDATION

Based upon the foregoing, it is hereby

RECOMMENDED, that the Board of Medicine adopt the foregoing Finding of Facts and Conclusions of Law, and enter a final order finding Respondent guilty on all three counts in the

Administrative Complaint and impose a penalty of: a minimum of one-year suspension and until such time as Respondent appears before the Board, explains his actions in this case, and demonstrates that he can practice with reasonable skill and safety, at which time the Board may impose a period of probation with appropriate terms and conditions; a reprimand; and payment of an administrative fine of \$5,000.

DONE AND ENTERED this 21st day of March, 2001, in Tallahassee, Leon County, Florida.

DANIEL M. KILBRIDE
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 21st day of March, 2001.

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.