BEFORE THE BOARD OF MEDICINE

DEPARTMENT OF PROFESSIONAL REGULATION,

Petitioner,

vs.

JOYA L. SCHOEN, M.D.,

DPR CASE NO. 0068738
DOAH CASE NO. 87-4351
LICENSE NO. ME 0020200

Respondent.
_____/

FINAL ORDER

This cause came before the Board of Medicine (Board) pursuant to Section 120.57(1)(b)9., Florida Statutes, on December 3, 1988, in Miami, Florida, for the purpose of considering the Hearing Officer's Recommended Order, DPR's Exceptions to Recommended Order, and Petitioner's Response to DPR's Exceptions to Recommended Order (copies of which are attached hereto as Exhibits A, B, and C, respectively) in the above-styled cause. Petitioner, Department of Professional Regulation, was represented by Stephanie A. Daniel, Attorney at Law. Respondent was present and represented by Salvatore A. Carpino, Attorney at Law.

Upon review of the Recommended Order, the Exceptions and other pleadings and motions, the argument of the parties, and after a review of the complete record in this case, the Board makes the following findings and conclusions.

FINDINGS OF FACT

1. The finding of fact in Paragraph 24 of the Recommended Order is rejected on the basis that it is supported solely by hearsay. All other findings of fact set forth in the Recommended Order are approved and adopted and incorporated herein.

2. There is competent substantial evidence to support the findings of fact approved and adopted.

CONCLUSIONS OF LAW

1. The Board has jurisdiction of this matter pursuant to Section 120.57(1), Florida Statutes, and Chapter 458, Florida Statutes.

2. The conclusions of law set forth in the Recommended Order, except for that in paragraph 12, are approved and adopted and incorporated herein. Given the Hearing Officer's failure to find that the diagnosis or treatment was experimental, the issue of prior written consent is immaterial to the analysis of the applicability of Section 458.331(1)(u), Florida Statutes.

3. There is competent substantial evidence to support the conclusions of law.

RULINGS ON EXCEPTIONS

The Board denies Petitioner's Motion to Strike Exceptions to Recommended Order which were based on the contention that the Exceptions were untimely filed. The Board finds that since the Hearing Officer served the Recommended Order by mail, the parties had 25 days rather than only 20 days within which to file

Exceptions. See Rules 28-5.103 and 28-5.404, Florida Administrative Code.

1-4. Petitioner's first four exceptions are rejected on the basis that the evidence cited was not hearsay or, even if it were, it was subject to a hearsay exception, as urged by Respondent in her written response.

5. Petitioner's fifth exception is accepted; the finding of fact complained of is supported only by hearsay evidence. Such a finding of fact is contrary to the dictates of Section 120.58, Florida Statutes.

6. Petitioner's sixth exception, which is to Conclusion of Law number 12, is rejected. Although the Hearing Officer failed to make a completely unequivocal findings as to whether cytotoxic testing is or is not an experimental procedure, he did state in ruling on Petitioner's proposed findings of fact (No. 5) that he could not make a "categorical finding" that the cytotoxic test was considered to be "purely experimental." (Emphasis supplied.) If the testing was not shown to be experimental, then Respondent was not required to obtain prior written consent.

Upon a complete review of the record in this case, the Board determines that the disposition recommended by the Hearing Officer be ACCEPTED and ADOPTED. WHEREFORE,

IT IS HEREBY ORDERED AND ADJUDGED that the Administrative Complaint filed in this cause is DISMISSED.

This order takes effect upon filing with the Clerk of the

Department of Professional Regulation.

DONE AND ORDERED this 12th day of December, 1988.

BOARD OF MEDICINE

Emilio D. Echevarria

EMILIO D. ECHEVARRIA, M.D.
CHAIRMAN

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF PROFESSIONAL REGULATION AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN 30 DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing FINAL ORDER has been provided by certified mail to Joya L. Schoen, M.D., 1900 North Orange Avenue, Orlando, Florida 32804 and Salvatore A. Carpino, Attorney at Law, One Urban Centre, Suite 750, 4830 West Kennedy Boulevard, Tampa, Florida 33609; by U. S. Mail to William C. Sherrill, Jr., Hearing Officer, Division of Administrative Hearings, 2009 Apalachee Parkway, Tallahassee, Florida 32302; and by interoffice delivery to Stephanie A. Daniel, Attorney at Law, Department of Professional Regulation, 130 North Monroe Street, Tallahassee, Florida 32399-0750 at or before 5:00 p.m., this 16th day of December, 1988.

Martha J. Laird

FILED

Department of Professional Regulation
AGENCY CLERK

STATE OF FLORIDA
DEPARTMENT OF PROFESSIONAL REGULATION
BOARD OF MEDICINE

DEPARTMENT OF PROFESSIONAL REGULATION,

Petitioner,

vs.

JOYA L. SCHOEN, M.D.,

Respondent.

CLERK Sherrill Cope

DATE 11-4-88

DOAH NO. 87-4351
DPR NO. 0068738

DPR'S RESPONSE IN OPPOSITION TO MOTION TO STRIKE EXCEPTIONS TO RECOMMENDED ORDER

Petitioner, Department of Professional Regulation, ("DPR") hereby files its Response in Opposition to the Motion to Strike Exceptions to Recommended Order filed by Respondent, Joya L. Schoen, M.D., ("Respondent"), and in support thereof states as follows:

1. The Recommended Order in this case was entered on September 26, 1988 and service of the Recommended Order was made to both parties by U.S. Mail. Rule 28-5.404, F.A.C., provides that parties may file exceptions to Findings of Fact within 20 days of the service of the Recommended Order. In addition, Rule 28-5.103, F.A.C., provides in part:

> Five days may be added to the prescribed time limits when service is made by mail.

2. DPR filed its Exceptions to the Recommended Order on October 19, 1988 by hand delivery to the agency clerk for the Department of Professional Regulation. The deadline for filing Exceptions to the Recommended Order was October 21, 1988, twenty-five (25) days after the entry of the Recommended Order. Thus,

the Exceptions filed by DPR were timely filed pursuant to Rule 28-5.404 and 28-5.103, F.A.C. Consequently, Respondent's Motion to Strike is without merit and should be denied.

WHEREFORE, the Petitioner, Department of Professional Regulation, moves the Honorable Florida State Board of Medicine for the entry of an Order denying Respondent's Motion to Strike Exceptions to Recommended Order.

Respectfully submitted,

NEWELL & STAHL, P.A.
817 North Gadsden Street
Tallahassee, Florida 32303-6313
904/681-3883

Thomas W. Stahl
Attorney for Petitioner

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true copy of the foregoing Response in Opposition to the Motion to Strike Exceptions to Recommended Order have been furnished to: MR. SALVATORE A. CARPINO, Attorney at Law, One Urban Centre, Suite 750, 4830 West Kennedy Boulevard, Tampa, Florida 33609; by U.S. Mail this 2nd day of November, 1988.

Attorney

STATE OF FLORIDA
DEPARTMENT OF PROFESSIONAL REGULATION

FILED
Department of Professional Regulation
AGENCY CLERK
CLERK Melinda W Dagnan
DATE 10-19-88

DEPARTMENT OF PROFESSIONAL REGULATION,

Petitioner,

vs.

JOYA L. SCHOEN, M.D.,

Respondent.

CASE No. 87-4351
DPR No. 0079581

DPR'S EXCEPTIONS TO RECOMMENDED ORDER

Petitioner, Department of Professional Regulation (DPR), hereby files its Exceptions to the Recommended Order filed on September 26, 1988, and in support thereof states as follows:

1. DPR takes exception to Finding of Fact No. 18. There is no competent evidence to support the Hearing Officer's finding that patient K.H. had read The Yeast Connection by William G. Crook, M.D. (Res. Exh. No. 1) at the time she first visited Respondent's office. There is no competent evidence to support the finding that patient K.H. had concluded that she preferred the cytotoxic test because she thought it would be less stressful than other allergy tests. These findings are based solely on the hearsay testimony by Dr. Schoen and are not corroborated by any competent evidence in the record.

2. DPR takes exception to Finding of Fact No. 19. There is no competent evidence to support the Hearing Officer's finding that patient K.H. was fully aware that the diagnosis of systemic candidiasis and treatment by Nystatin was a new theory. The Hearing Officer's finding is based on Dr. Crook's book, The Yeast Connection, which was admitted as hearsay evidence and is not

subject to any exceptions to the hearsay rule under the Florida Evidence Code (TR.73; Res. Exh. No. 1). The Hearing Officer found that the "inference" that patient K.H. was fully aware of the fact that Dr. Crook's theories are not accepted by mainstream medicine was further corroborated by the affidavit of patient K.H. (Res. Exh. No. 8). The affidavit of patient K.H. is also hearsay and cannot be used to corroborate the hearsay contained in Dr. Crook's book. See, MacPherson vs. School Board of Monroe County, 505 So.2d 682 (Fla. 3rd DCA 1987) (hearsay evidence is admissible in an administrative hearing to corroborate or explain other evidence, but it may not be used to support a finding that is not otherwise supported by competent, substantial evidence). The Hearing Officer improperly used the hearsay contained in patient K.H.'s affidavit to corroborate the hearsay contained in Dr. Crook's book.

3. DPR takes exception to that portion of Finding of Fact No. 20 in which the Hearing Officer found that patient K.H. told Respondent that she was horrified of needles and that she wanted to try cytotoxic testing and treatment with Nystatin before being tested by an allergist. This finding is based solely on the hearsay testimony by Respondent.

4. DPR takes exception to Finding of Fact No. 21. There is no competent substantial evidence to support the finding that patient K.H. understood that the cytotoxic test was an out-of-the-mainstream test and was perhaps not proven. The Hearing Officer's finding is based solely on the hearsay testimony of Respondent and the hearsay affidavit of patient K.H.

MacPherson, supra.

5. DPR takes exception to Finding of Fact No. 24. The finding is based solely on the hearsay affidavit of patient K.H. There is no competent evidence in the record to support a finding that Respondent obtained full, informed, and written consent from patient K.H. prior to treating patient K.H. with cytotoxic testing and Nystatin therapy.

6. DPR takes exception to Conclusion of Law No. 12. The unrebutted evidence in this case shows that cytotoxic testing is an experimental procedure. The fact that a "substantial minority" of physicians in Florida may have at one time used cytotoxic testing does not rebut the competent and substantial evidence presented by DPR which established that cytotoxic testing is experimental in nature (TR.47, 49-51; Pet. No. 2). There is no evidence to support the Hearing Officer's conclusion that Respondent fully discussed the diagnosis and treatment and that patient K.H. was fully informed by Dr. Schoen as to the experimental nature of cytotoxic testing. There is only hearsay evidence to support the conclusion that patient K.H. gave her consent to the treatment by Respondent. The after-the-fact affidavit from patient K.H. is hearsay and cannot be used to support a finding that patient K.H. gave written consent to cytotoxic testing. Section 458.331(1)(u), Fla. Stat., provides that the performing of any procedure or therapy which would constitute experimentation on a human subject "without first obtaining full, informed, and written consent" is a ground for disciplinary action. The evidence shows that Respondent did not

obtain a complete and informed consent from patient K.H. prior to instituting cytotoxic testing on patient K.H.

Respectfully submitted,

NEWELL & STAHL, P.A.
817 North Gadsden Street
Tallahassee, Florida 32303-6313
904/681-3883

Thomas W. Stahl
Attorney for Petitioner

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing Notice of Telephone Deposition For Perpetuating Testimony has been furnished to: MR. SALVATORE A. CARPINO, Attorney at Law, One Urban Center, Suite 750, 4830 West Kennedy Boulevard, Tampa, Florida 33609; by U.S. Mail this 19th day of October, 1988.

Attorney

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF PROFESSIONAL REGULATION, BOARD OF MEDICINE,

Petitioner,

vs.

JOYA L. SCHOEN, M.D.,

Respondent.

Case No. 87-4351
(DPR No. 0068738)

RECOMMENDED ORDER

The formal administrative hearing in this case was held before William C. Sherrill, Jr., Hearing Officer, in Orlando, Florida, on May 23, 1988, and May 24, 1988, by telephone. The issue in this case is whether the Respondent has violated sections 458.331(1)(u), (q), and (t), Fla. Stat.(1985) in treatment of a patient, K. H., from June to December, 1985. Appearing for the parties were:

For the Petitioner:

Robert D. Newell, Jr., Esquire
Newell & Stahl, P.A.
817 North Gadsden Street
Tallahassee, Florida 32303-6313

For the Respondent:

Salvatore A. Carpino, Esquire
One Urban Centre, Suite 750
4830 West Kennedy Boulevard
Tampa, Florida 33609

The Petitioner presented 7 exhibits which were admitted into evidence, and the testimony of James E. Quinn, M.D., Eugene F. Schwartz, M.D., Joseph Akerman, M.D., and Merry Paige. The Respondent presented 8 exhibits which were admitted into

evidence, and the testimony of Jeffrey Zavik, Joya Schoen, M.D., and Robert M. Stroud, M.D. There is a transcript. The parties have submitted proposed findings of fact and conclusions of law.

Findings of Fact

1. The Respondent, Joya L. Schoen, graduated from medical school in 1966.

2. Dr. Schoen is board eligible in psychiatry. T. 195-96. She had three years residency in general psychiatry and a two year fellowship in child psychiatry. From 1967 to about 1979, she practiced in psychiatry. Dr. Schoen has been licensed by the State of Florida since 1973.

3. The Respondent's father was a physician, and in 1979, she began to take over his practice in general medicine. The Respondent took about three years to discontinue her psychiatric practice and assume her father's general practice. T. 196.

4. On June 14, 1985, a patient, who will identified by her initials, K. H., was referred to Dr. Schoen by another physician, Dr. Mengel. T. 197. Her symptoms were an inability to concentrate, "spaciness," pervasive fatigue, P.M.S. (premenstrual syndrome), and irregular periods. Her symptoms were aggravated by certain foods, fumes, and perfumes. T. 217.

5. K. H. had discovered that dairy foods and foods containing high carbohydrates aggravated her condition, and she was then avoiding them in her diet. T. 218.

6. K. H. had already been seen by a Dr. Mengel, and he had recommended that she receive allergy testing. T. 198.

7. Dr. Schoen had K. H. take the RAST I.G.E. test. T. 217. The RAST I.G.E. test is a screening test to determine, in a general sense, whether a patient has allergies. T. 216; (Supplemental Transcript, ST) ST-14. The degree of allergy is related to the score. A score over a hundred is considered a positive indication of the presence of allergies. T. 217. K. H.'s score on the RAST I.G.E. test was 1,993, T. 85, which was an extraordinarily high level, T. 88-89, indicating a probability of a high degree of allergy. T. 217, ST-14.

8. The RAST test, like the cytotoxic test, is performed on blood samples, and thus is not traumatic to the patient. T. 222. All witnesses viewed this test as an acceptable test.

9. Dr. Schoen also did a general screening for allergies, and determined that environmental allergies were not very high. T. 218. That left food allergies to be investigated. Id.

10. Cytotoxic testing tests for food allergies, or more precisely, for adverse reaction of white blood cells to foods. T. 218, 233. The cytotoxic test confronts samples of the patient's blood with certain foods. The reaction of the leukocytes in the patient's blood is observed. ST-12; T. 47. Foods which cause reactions are then selectively removed from the patient's diet, and the increase or decrease of the allergy is observed. In this way, by trial and error, it is hoped that the particularly food to which the patient is allergic will be identified.

11. Cytotoxic testing was available in 1985, and had been available since at least 1979. Approximately ten thousand cytotoxic tests were conducted from 1979 to 1986 by the laboratory that performed the cytotoxic test for Dr. Schoen for K. H. T. 158. Hundreds of physicians ordered cytotoxic testing from this laboratory; some physicians ordered it repetitively. T. 171. See also T. 101. The users of the cytotoxic test were primarily medical doctors, but were also doctors of osteopathy, chiropractors, and dentists. T. 172-73. The laboratory ceased performing the test in 1986 due to increasing questions concerning the efficacy and reliability of the test and the advent of better tests. T. 165-67.

12. A large number of physicians have used the cytotoxic test at one time or another. ST-12; T. 172-73.

13. Dr. Schoen traveled to Washington, D. C., to learn more about cytotoxic testing. T. 234. She also discussed the utility of the test with another physician. T. 233. Dr. Schoen has used the cytotoxic test about forty or fifty times; in some cases the test has led to marked improvement in the patient's condition, and in other cases, the test has not been helpful. T. 219. She was not aware of any patient having been harmed by use of the test. T. 221.

14. Cytotoxic testing for food allergies ordinarily was less expensive than skin testing. T. 190-92.

15. In August, 1983, the Health Care Financing Administration, United States Department of Health and Human Services, issued in the Federal Register a notice that cytotoxic

testing would not be reimbursed by that agency under Medicare coverage. P. Ex. 3. The notice in the Federal Register noted that "there was a wide range of conflicting views regarding the efficacy of cytotoxic food testing . . . ." P. Ex. 3, p. 37717. The article discusses a number of evaluations of the test, some favorable to the test, and many unfavorable.

16. Cytotoxic testing is a subjective test, T. 47, and is considered by some physicians to be experimental and useful only in research. T. 50. Nonetheless, as discussed above, a large number of physicians disagreed, and used the test in their practice from 1979 through 1985.

17. Since 1985, other tests have come along that are more reliable than the cytotoxic test, and the cytotoxic test is no longer given. T. 220-21. Currently, Dr. Schoen does not use the cytotoxic test, but uses tests like the RAST test in part because it is covered by insurance, and cytotoxic testing is not. (The other reason is that the laboratory that performed cytotoxic testing for Dr. Schoen has discontinued the test.) T. 222.

18. When she arrived at Dr. Schoen's office, K. H. had read The Yeast Connection by William G. Crook, M. D. (R. Ex. 1), and asked Dr. Schoen to give her a cytotoxic test. T. 197-98. K. H. had concluded that she preferred the cytotoxic test because she thought it would be less stressful than other allergy tests. T. 198. She also wanted to be given treatment with the drug Nystatin in hopes that she could avoid shots, desensitization, and a long and expensive process of allergy treatments. T. 199.

19. It is inferred that K. H. was fully aware that the diagnosis of systemic candidiasis and treatment by Nystatin as described by Dr. Crook was a new theory. This inference is based upon the fact that she had been to several physicians, none of whom turned to Dr. Crook's theory, and that she was familiar with Dr. Crook's book. T. 198-99. It is evident from Dr. Crook's book, which is entitled in part "A Medical Breakthrough," and in the first few pages communicates an awareness that the theory is quite new and still not accepted by mainstream medicine. R. Ex. 1. This finding of fact is further corroborated by the affidavit of K. H. R. Ex. 8.

20. Dr. Schoen gave K. H. reading material about cytotoxic testing and discussed with K. H. the nature of the cytotoxic test and the alternative procedures that were available, that is, to be referred to a physician who specialized in allergies, and to undergo allergy testing by skin testing using needles and shots. See T. 25, 199. This finding is corroborated by the affidavit of K. H., wherein K. H. states that Dr. Schoen explained to K. H. that cytotoxic testing was accepted by only a minority of physicians. R. Ex. 8. K. H. said that she was terrified of needles, and was so allergic to so many things that such testing might make her worse. K. H. wanted to try cytotoxic testing and treatment with Nystatin before trying testing by an allergist. T. 202, 236.

21. K. H. understood that the cytotoxic test was an out-of-the-mainstream test and was perhaps not proven. T. 199; R. Ex. 8.

22. Dr. Schoen's written records of treatment of K. H. do not show consent of K. H. to take the cytotoxic test, or advice to K. H. by Dr. Schoen that the test was experimental and that other alternatives existed. T. 54.

23. Dr. Schoen did not make a written record of her advice to K. H. concerning the cytotoxic test, or of K. H.'s understanding of the nature of the test.

24. The affidavit of K. H., R. Ex. 8, constitutes after-the-fact written evidence of such explanation by Dr. Schoen and consent and understanding by K. H.

25. Failure to obtain written consent from K. H. prior to cytotoxic testing had no adverse effect or potential adverse effect to the health of K. H. T. 68.

26. Dr. Schoen directed that K. H. be given a cytotoxic test. T. 218.

27. Dr. Schoen diagnosed K. H.'s condition as allergies and systemic candidiasis. T. 218.

28. Dr. Schoen prescribed treatment with Nystatin and a diet that avoided yeasty foods, such as dairy foods and foods containing high carbohydrates. T. 218.

29. K. H. took Nystatin as prescribed by Dr. Schoen from June, 1985, to November, 1985.

30. This is the course of treatment recommended by William G. Crook, M. D., for systemic candidiasis. Id.

31. Dr. Schoen told K. H. that Nystatin is usually given to treat candidiasis, and that the drug is virtually nontoxic and safe. She also told K. H. that Nystatin was not

something a regular physician would prescribe for her condition, but that it was widely used among physicians that she knew with safe results. T. 201. This finding is corroborated by the affidavit of K. H. R. Ex. 8.

32. Nystatin is one of the safest drugs available to physicians today, having no serious side effects. ST-9. It is well-tolerated by patients. T. 45.

33. Nystatin is an antifungal medicine that is frequently used to treat localized candidiasis.

34. The alternative course of testing and treatment by an allergist would perhaps take one to three years, and would ultimately be quite a bit more expensive than the testing and treatment selected by Dr. Schoen, due to the need in such alternative treatment for numerous physician visits and shots. T. 203-04. This finding of fact is corroborated by the medical report of Elmer M. Cranton, M. D. R. Ex. 7, p. 2.

35. Some maladies are difficult to diagnose, but may be diagnosed through trial therapy. Trial therapy is a course of nontoxic therapy without a specific diagnosis. If health improves during such therapy, it is concluded that the patient had the disease treatable by such therapy. T. 200, 205. It is not uncommon in medicine for a physician to prescribe a course of treatment that in fact works to either cure the malady or relieve the symptoms, but no one understands scientifically why it works. T. 205-06. This finding of fact is corroborated by R. Ex. 6, attachment: "'Think Yeast'--The Expanding Spectrum of Candidiasis," reprinted by "The Journal of the South Carolina

Medical Association," and by R. Ex. 1, "A Special Message for the Physician," p. 2.

36. The diagnosis of systemic candidiasis cannot be tested by conventional scientific tests. This finding of fact is corroborated by R. Ex. 4, p. 10.

37. It may take many months, or a year or two years, for a patient to respond to Nystatin treatment. Dr. Schoen saw no significant improvement in K. H. from June, 1985, to November, 1985, when she was her patient. T. 236.

38. K. H. had psychological problems when she visited Dr. Schoen. Dr. Schoen was aware that K. H. had psychological problems, but determined that she deserved a chance to receive the treatment Dr. Schoen selected because it was not harmful, and might be of help to her in her case. T. 201. Dr. Schoen assessed K. H.'s circumstances and determined that medical treatment should be attempted first, and that psychological treatment was then not appropriate. Her conclusion was based upon her observation that due to K. H.'s symptoms (irregular memory, spaciness, and fatigue), K. H. would not be capable of participating in psychological therapy. She also noted the dysfunctional condition of her parents as an additional reason that psychological treatment was not appropriate at that time. T. 202-04. Finally, K. H. was a newly converted fundamentalist Christian, and had turned to religion for emotional help. She had psychological counseling suggested to her, but apparently did not follow up on the suggestion. Under these circumstances, Dr. Schoen concluded that psychological counseling was not possible

at that time. T. 238. Dr. Schoen did not discuss these conclusions with K. H. There is no evidence that she should have discussed these conclusions with K. H.

39. Dr. Robert M. Stroud graduated from medical school in 1956, and is licensed to practice in Florida, Alabama, and North Carolina, and is board certified in internal medicine, allergy, immunology, and rheumatology. His board certification in immunology was in 1974. Dr. Stroud practices in Ormond Beach, Florida, and specializes in allergy and rheumatology. ST-4,6. Allergy is a subspecialty of internal medicine. ST-15. He was a professor of medicine at the University of Alabama for 14 years, teaching medicine, microbiology, and immunology. ST-3. He has been a clinical professor at the University of Florida since 1982. ST-4, 6. Dr. Stroud was accepted as an expert in medicine, allergy, and immunology. ST-7.

40. Dr. Stroud uses the diagnosis "yeast allergy" or candida allergy" in his practice, and by that diagnosis, means the same thing as systemic candidiasis. ST-7. He views the condition as an allergic reaction to yeast on the surface of membranes. Id.

41. When Dr. Stroud makes the diagnosis of yeast allergy, or if he strongly suspects that diagnosis, the treatment he prescribes is a yeast elimination diet and Nystatin administered orally. ST-9.

42. Dr. Schoen discussed K. H.'s case with Dr. Crook, and Dr. Crook told Dr. Schoen that he agreed with her diagnosis and course of treatment. T. 206-11; R. Ex. 6. Dr. Schoen also

discussed K. H.'s case with Elmer Cranton, M. D., and Dr. Cranton told Dr. Schoen that he agreed with her diagnosis and course of treatment. T. 211-15; R. Ex. 7. (Both of these findings of fact find that Dr. Schoen was in fact told this by both physicians. To the extent that the opinions of these two physicians are offered for the truth of the opinions, the evidence is hearsay, but is corroborative of the finding of fact which follows.)

43. The diagnosis of systemic candidiasis, or yeast allergy, as used by Dr. Stroud, is used by a thousand or more physicians in this country who practice internal medicine, osteopathy, and allergy medicine, and the number has been growing rather than diminishing. ST-10, 16-17. Serious research continues in this field, and a large number of physicians in the country have seriously investigated the possible link between candida and the immune system. ST-11. A substantial minority of physicians in Florida and in other states agree with the theories of diagnosis and treatment of Dr. Crook in The Yeast Connection, and believe that systemic candidiasis is a medically proper diagnosis. T. 225, 228-30, and the testimony of Dr. Stroud. This finding of fact is corroborated by R. Exs. 2, 6 (attachments), and 7, and T. 206-15.

44. The American Academy of Allergy has issued position papers disapproving the diagnosis of systemic candidiasis and cytotoxic testing, and calling them experimental. P. Ex. 2.

45. Dr. James E. Quinn is a medical doctor and has practiced family medicine in Sanford, Florida, for 11 years. He

has been board certified in family practice for the last 8 years. T. 10.

46. On about November 26, 1985, K. H. came to Dr. Quinn for treatment. Her sister and brother-in-law were concerned about the treatment she was receiving from Dr. Schoen, and told Dr. Quinn that the family felt that K. H. actually had an emotional problem. T. 10.

47. K. H. complained that she was being poisoned by the environment around her, by chemicals, by perfumes, and by foods. T. 11. She could not tolerate certain foods, would become confused when near perfume, and her period was irregular. T. 12. She was chronically fatigued. T. 12.

48. K. H. was examined by Dr. Quinn. Dr. Quinn diagnosed the existence of a severe emotional problem, but found no evidence of a typical amount of allergic disease. T. 11.

49. In Dr. Quinn's opinion, systemic candidiasis occurs only in association with severe illnesses in a general hospital setting, such as certain carcinoma, leukemia, AIDS, after chemotherapy, or after sustained use of antibiotics. T. 12-13, 22. This form of candidiasis occurs in identifiable areas, such as the esophagus, the bladder, or other systems. T. 22. Dr. Quinn was of the opinion that it would be proper to treat this form of systemic candidiasis with an infectious disease medication and with an antifungal agent such as Nystatin. T. 23-24.

50. Dr. Quinn had no familiarity with the concept of systemic candidiasis as set forth by Dr. Crook. T. 26.

51. Dr. Quinn had no personal experience with cytotoxic testing. T. 25.

52. Dr. Quinn saw K. H. only once, T. 19, and did not review Dr. Schoen's records for K. H. T. 26.

53. Dr. Quinn referred K. H. to a psychiatrist, Dr. Moises, for mental health evaluation, and referred K. H. to an allergist, Dr. Alidena, for an allergy evaluation. T. 13-14.

54. Dr. Alidena felt that K. H. possibly had mild food allergies. T. 18. She recommended a food elimination diet and wait for the psychiatric report. Id.

55. Dr. Eugene F. Schwartz is a medical doctor who has been in private practice specializing in adult and pediatric allergy and immunology since August, 1983, in Altamonte Springs, Florida. T. 28, 30. He is board certified in pediatrics and allergy and immunology. T. 29. He is a member of the American Academy of Allergy and Immunology, an organization composed of the largest number of board certified allergists and immunologists in the country. T. 41, 104.

56. Dr. Schwartz agreed with Dr. Quinn that systemic candidiasis occurred in certain severely debilitated patients, such as those with cancer, or having immune suppression problems. T. 37.

57. Dr. Schwartz was of the opinion that systemic candidiasis as described by Dr. Crook was not an appropriate diagnosis, and thus that prescription of Nystatin for such a diagnosis was inappropriate because the diagnosis "did not exist." T. 39-40.

58. Dr. Schwartz had two methods of diagnosing patients who thought that they had systemic candidiasis after reading Dr. Crook's book: to either find another cause of the problem, or to advise the patient that he (Dr. Schwartz) did not know what the cause of the problem was. T. 40, 44.

59. If a patient came in complaining of adverse reactions after eating certain foods, Dr. Schwartz would have prescribed a skin test for food allergies. T. 48.

60. Dr. Schwartz was of the opinion that the cytotoxic test was spurious and "quite experimental," and should be limited to research projects. T. 50.

61. Dr. Schwartz was of the opinion that Dr. Schoen's practice with respect to diagnosis of K. H. as having systemic candidiasis was "outside the mainstream of medicine, that other prudent physicians would not have done so." T. 65. He was also of the opinion that prescription of Nystatin was not proper, that use of cytotoxic testing was not proper, and that lack of written informed consent to the cytotoxic test was not proper. T. 66-67.

62. Dr. Schwartz believed that a minority of physicians thought that the diagnosis of systemic candidiasis is a proper diagnosis. T. 109.

63. Dr. Schwartz stated that Dr. Crook is one of the leading authorities with respect to the diagnosis of systemic candidiasis and treatment by use of Nystatin, T. 70, and agreed that there have been other articles supportive of Dr. Crook's views. Id.

64. Dr. Schwartz testified that the symptoms that K. H. presented to Dr. Schoen met the criteria for Dr. Crook's diagnosis of systemic candidiasis. T. 80. Dr. Schwartz also agreed that if the diagnosis of systemic candidiasis was proper, Dr. Schoen did prescribe the proper treatment as recommended by Dr. Crook, and that her prescription of Nystatin was proper as recommended by Dr. Crook. T. 42, 81.

65. Dr. Schwartz also conceded that a minority of physicians used cytotoxic testing to determine the presence of allergies to various given substances. T. 110.

66. Dr. Joseph Akerman has been in the general practice of medicine since 1952 in Apopka, Florida. He is board eligible in family practice medicine. T. 120. He was accepted as an expert witness in the practice of medicine, including the standard of care for general medical practitioners and family practitioners in the Orlando area. T. 122.

67. Dr. Akerman had never seen a case of systemic candidiasis. T. 124. Dr. Akerman would not use that diagnosis in his own practice, nor would he use the course of treatment prescribed by Dr. Crook. T. 124, 130. He was not familiar with any physicians who subscribed to Dr. Crook's theories. T. 131.

68. Dr. Akerman personally disagreed with Dr. Crook's theories. T. 130.

69. If Dr. Crook's theory of systemic candidiasis were correct, Dr. Schoen's diagnosis of systemic candidiasis in the case of K. H. was correct, in Dr. Akerman's opinion. T. 130.

70. On December 31, 1987, the Respondent filed a motion to dismiss the administrative complaint. The motion raised two issues: whether the probable cause panel considered some evidence that the violations alleged occurred, and whether the probable cause panel was composed of three members as required by law. Attached to the motion was a transcript from that portion of the meeting of the probable cause panel that considered the charges against the Respondent. That transcript was admitted into evidence as R. Ex. 4.

71. The probable cause panel met in Palm Beach, Florida, on August 21, 1987. Two members were present. The members present had been furnished the investigative report and a recommendation. R. Ex. 4, p. 3-5. The transcript shows who attended the meeting, but does not show the composition of the panel. The two members agreed with the administrative complaint. R. Ex. 4, p. 10-11, with one exception which apparently was deleted from the complaint. Id. at p. 10.

72. The Petitioner submitted an affidavit concerning the composition of the probable cause panel. P. Ex. 7. The affidavit is hearsay, and cannot be relied upon to make a finding of fact as to the composition of the probable cause panel.

73. There is no competent evidence in the record from which a finding of fact can be made that the probable cause panel in this case was composed of less than three members.

Conclusions of Law

1. The Division of Administrative Hearings has jurisdiction of the parties and the subject matter of this proceeding.

2. Rule 21M-18.006(2), Fla. Admin. Code, does not say that a probable cause panel must meet as three members, but only that the panel must be "composed" of three members. There is no evidence to support the Respondent's contention that it was not "composed" of three members. The fact that only two members attended is inconsequential since section 455.225(3), Fla. Stat., provides that a determination of probable cause shall be made "by a majority vote of a probable cause panel of the board." Accord, rule 21M-18.006(1), Fla. Admin. Code. Moreover, the three member panel is governed by normal rules governing the quorum of a collegial body. A quorum ordinarily means a majority of the members of the collegial body. Black's Law Dictionary. A quorum was present in this case. The presence of a quorum and the existence of a majority vote distinguishes this case from Kibler v. Department of Professional Regulation, 418 So. 2d 1081 (Fla. 4th DCA 1982).

3. The Kibler case ruled only that "there must be some evidence considered by the panel that would reasonably indicate that the violate alleged had indeed occurred." 418 So. 2d at 1084. In this case, the members of the panel present were given the investigative report, and stated they agreed with the allegations of the complaint. The only portion of the complaint with which one panel member disagreed was apparently deleted from the complaint. R. Ex. 4, pp. 4, 11, 9-10. This is an adequate "consideration" of "some evidence" as intended by Kibler.

4. The motion to dismiss the administrative complaint on these grounds should be denied.

5. Disciplinary action with respect to a professional license must be based upon clear and convincing proof of substantial causes justifying the sanction. Ferris v. Turlington, 510 So. 2d 292, 295 (Fla. 1987).

6. Disciplinary action with respect to a professional license is limited to offenses or facts alleged in the administrative complaint. Sternberg v. Department of Professional Regulation, Board of Medical Examiners, 465 So. 2d 1324, 1325 (Fla. 1st DCA 1985).

7. During the formal administrative hearing, the Petitioner dismissed the following paragraphs of the administrative complaint, and thus those allegations are no longer at issue in the this case: paragraphs 15-29 (count three, four, and five), and paragraphs 33-37 (count seven).

8. The remaining counts in the administrative complaint allege the following violations of Florida Statutes:

a. Count one, paragraph 12: violation of section 458.331(1)(u), Fla. Stat., "by performing any procedure or prescribing any therapy which, by prevailing standards of medical practice in the community, would constitute experimentation on a human subject, without first obtaining full, informed, and written consent."

b. Count two, paragraph 14: violation of section 458.331(1)(q), Fla. Stat., "by prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this

paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his intent."

c. Count six, paragraph 32: violation of section 458.331(1)(t), Fla. Stat., "by 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."

9. Tortious malpractice is absent where ". . . the treatment used is approved by a 'respectable minority of the medical profession' . . . ." In this context, tortious malpractice was defined in a fashion similar to the standard urged in the case at bar in count six: a ". . . professional obligation to apply the means * * * ordinarily and generally used by other physicians and surgeons of ordinary skill and learning * * * in Hillsborough County, Florida, and in similar communities." Baldor, et al. v. Rogers, 81 So. 2d 658 (Fla. 1954), affirmed in pertinent part on rehearing (1955).

10. Medical incompetence, negligence, and unprofessional conduct is absent where the treatment is recognized and used by a "definite minority" of the medical profession, even though the treatment is out of the main stream of medicine, where no fraud or deception as to the expected

results of the treatment has been conveyed by the physician to the patient, where the patient has been fully informed of the nature of the treatment and the possibility of no improvement, and the prescribed course of treatment is not harmful. Rogers v. State Board of Medical Examiners, 371 So. 2d 1037 (Fla. 1st DCA 1979), affirmed, 387 So. 2d 937 (1980).

11. In the instant case, K. H. was fully informed with regard to the diagnosis and treatment prescribed by Dr. Schoen, and fully understood the nature of the treatment, that the diagnosis and treatment were outside the main stream of medical opinion, and that other alternatives were available. The course of treatment was not intrinsically harmful any more than chelation therapy was intrinsically harmful in the Rogers case, supra. In both cases, the trial of one mode of treatment necessarily delayed resort to other modes of treatment, but that potential for "harm" is not sufficient. Finally, Dr. Schoen's diagnosis and mode of treatment was then accepted by a definite and significant minority of physicians.

12. The lack of written consent in this case is factually insignificant, given the clear and unrebutted evidence that Dr. Schoen fully discussed the diagnosis and treatment with K.H., and K. H. fully understood the explanation and gave her consent. Moreover, the affidavit from K. H. constitutes after the fact written consent, as well as a written record of that explanation.

13. Dr. Schoen's decision to defer treatment of the psychological problem was not shown by any credible testimony to

have been inappropriate. Dr. Schoen's reasons for such deferral were reasonable, and were not discredited by any witness.

Recommendation

For these reasons, it is recommended that the Department of Professional Regulation, Board of Medicine, enter its final order dismissing the administrative complaint against the Respondent.

DONE and ENTERED this 26th day of September, 1988, in Tallahassee, Florida.

William C. Sherrill, Jr.

WILLIAM C. SHERRILL, JR.
Hearing Officer
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Filed with the Clerk of the
Division of Administrative Hearings
this 26th day of September, 1988.

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Appendix to Recommended Order in Case No. 87-4351

The following are rulings upon proposed findings of fact which have either been rejected or which have been adopted by reference. The numbers used are the numbers used by the parties. Numbers have been sequentially attributed to the unnumbered paragraphs filed by the Respondent. Statements of fact contained in this appendix or adopted herein by reference are intended to be additional findings of fact.

Findings of fact proposed by the Petitioner:

5. A categorical finding that the cytotoxic test was considered to be purely experimental by allergists and immunologists cannot be made in view of the fact that many physicians used the test in the years in question.

8. The record cited does not contain evidence that Nystatin is a legend drug. Findings have been made that K. H. received this drug through prescription by Dr. Schoen.

9. The first sentence is not supported by the record cited. The second sentence is thus not relevant.

13. Since a substantial minority of physicians accept the diagnosis of systemic candidiasis as described by Dr. Crook, the word "only" in the first sentence is rejected. The second sentence is a true statement of the opinion of the majority of such physicians, but a substantial minority of physicians disagree.

14. All physicians who testified agreed that K. H.'s symptoms were consistent with the diagnosis of systemic candidiasis as described by Dr. Crook. It is true that K. H. did

not suffer from a severe illness of the type with which systemic candidiasis is also a potential associated diagnosis.

15. Since systemic candidiasis as described by Dr. Crook cannot be detected by testing, the lack of the tests set forth in this proposed finding of fact is irrelevant. Diagnosis by trial therapy is a medically accepted way to proceed where testing is ineffective for diagnosis.

16. Rejected for the reasons stated in findings of fact 11-14.

17. Rejected for the reasons stated in findings of fact 18-25.

18. Rejected for the reasons stated in findings of fact 30-36, 39-43, 62-64, and 69.

Findings of fact proposed by the Respondent:

1. The first sentence of this proposed finding of fact is subordinate to findings of fact that have been adopted. It is true, however, and is adopted by reference.

3. Mr. Zavik was accepted only as an expert in cytotoxic testing procedures. T. 164, 166, 169-70. He did not have expertise to express an opinion as to the jurisdiction of the Food and Drug Administration. The second sentence is cumulative and unnecessary.

9. The fourth sentence is cumulative and unnecessary. The sixth sentence is subordinate to findings of fact that have been adopted. It is true, however, and is adopted by reference.

14. These proposed findings of fact are not supported by the record cited. The summary of what Dr. Godorov said is confused and ambiguous.

17. The sixth sentence is cumulative and unnecessary.

23. The second sentence is irrelevant.

24. The second is subordinate to findings of fact that have been adopted. It is true, however, and is adopted by reference.

25 and 28. These proposed findings of fact are subordinate to findings of fact that have been adopted. They are true, however, and are adopted by reference.

29. The second is subordinate to findings of fact that have been adopted. It is true, however, and is adopted by reference.

31, These proposed findings of fact are irrelevant since the summary of what Dr. Godorov said is too confused and ambiguous to be a basis for a finding of fact.