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Antonia C. Novello, M.D., M.P.H., Dr.P.H. Commissioner Dennis P. Whalen Executive Deputy Commissioner

November 6, 2001

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Leslie Eisenberg, Esq. NYS Department of Health 5 Penn Plaza – 6th Floor New York, New York 10001 Alan Lambert, Esq. LaBarbera & Lambert PC 60 East 42nd Street New York, New York 10165

Joseph Burrascano, M.D. 68 Old Trail Road Watermill, New York 11042 Joseph Burrascano, M.D. 139 Springs Fireplace Road East Hampton, New York 11937

RE: In the Matter of Joseph Burrascano, M.D.

Dear Parties:

Enclosed please find the Determination and Order (No. 01-265) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), and §230-c subdivisions 1 through 5, (McKinney Supp. 1992), "the determination of a committee on professional medical conduct may be reviewed by the Administrative Review Board for professional medical conduct." Either the licensee or the Department may seek a review of a committee determination. All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

James F. Horan, Esq., Administrative Law Judge New York State Department of Health Bureau of Adjudication Hedley Park Place 433 River Street, Fifth Floor Troy, New York 12180

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board. Six copies of all papers must also be sent to the attention of Mr. Horan at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

Tyrone T. Butler, Director Bureau of Adjudication

TTB:cah Enclosure

STATE OF NEW YORK DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF JOSEPH BURRASCANO, M.D.



DETERMINATION AND ORDER BPMC #01-265

BENJAMIN WAINFELD, M.D. NISHA K. SETHI, M.D. and MS. CAROLYN

SNIPE, duly designated members of the State Board for Professional Medical Conduct, appointed by the Commissioner of Health of the State of New York pursuant to Section 230 (1) of the Public Health Law, served as the Hearing Committee for this matter pursuant to Sections 230(10) (e) and 230 (12) of the Public Health Law. Jane B. Levin, Esq., Administrative Law Judge, served as the Administrative Officer for the Hearing Committee.

After consideration of the entire record, the Hearing Committee submits this determination.

SUMMARY OF THE PROCEEDINGS

Notice of Hearing and Statement of Charges dated:

Answer dated:

Pre-Hearing Conference:

August 29, 2000 October 10, 2000 October 10, 2001

Hearing Dates:

Deliberation Dates:

Place of Hearing:

Petitioner appeared by:

Respondent appeared by:

October 26, 2000 November 6, 20, 2000 December 13, 2000 February 7, 21, 28, 2001 March 22, 2001 April 11, 12, 19, 26, 2001 May 10, 23, 2001 July 11, 18, 25, 2001 September 4, 2001

October 4, 10, 25, 2001

NYS Department of Health 5 Penn Plaza New York, N.Y.

Donald P. Berens, Jr. General Counsel NYS Department of Health By: Leslie Eisenberg, Esq. Associate Counsel

LaBarbera & Lambert PC 60 E. 42nd Street New York, NY 10165 By: Alan Lambert, Esq.

WITNESSSES

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For the Petitioner:

- 1) Peter C. Welsh, M.D.
- 2) Pat Cooney

For the Respondent:

- 1) Joseph Burrascano, M.D.
- 2) Howard Sklarek, M.D.
- 3) Brian Fallon, M.D.
- 4) Michael Cichon, M.D.

STATEMENT OF CHARGES

The Statement of Charges essentially charges the Respondent with professional misconduct in that he practiced with negligence and gross negligence, incompetence and gross incompetence, failed to maintain records, practiced fraudulently, and ordered unwarranted tests and treatment. The charges are more specifically set forth in the Statement of Charges, a copy of which is attached hereto and made a part hereof.¹

FINDINGS OF FACT

Numbers in parentheses refer to transcript pages or numbers of exhibits. These citations represent evidence found persuasive by the Hearing Committee in arriving at a particular finding. Conflicting evidence, if any, was considered and rejected in favor of the cited evidence.

GENERAL FINDINGS

1. Joseph Burrascano, the Respondent, was authorized to practice medicine in the State of New York on or about April 3, 1981 by the issuance of license number 145623 by the New York State Education Department (Pet. Ex. 2).

¹ The Statement of Charges was amended as follows: Allegations H and I were withdrawn, and Allegations A.4, C.3, D.3, F.4 were withdrawn in part.

2. Respondent has maintained a practice in internal medicine in East Hampton, New York since the summer of 1981. All patients at issue herein were treated by the Respondent between 1992 and 1998 in East Hampton. The Respondent is not board certified in internal medicine or infectious disease (Pet. Ex. 1; T. 1481, 1743).

3. East Hampton and other communities on Long Island are endemic for Lyme disease. Respondent testified that very early in his practice he developed a special interest in this illness, that at least 2/3 of the patients he sees are for tick-borne illnesses, that he attends Lyme disease conferences, has authored book chapters on Lyme in <u>Conn's Current Therapy</u> (1997) and <u>Current Therapy of Infectious Disease</u> (2001), has testified about Lyme disease for state and federal authorities, chaired a Center for Disease Control ("CDC") committee on surveillance criteria for Lyme disease, and has now seen 5,000 to 7,000 patients for the evaluation of Lyme Disease (Resp. Ex. AA, B; T.1481-3, 1487, 1491, 1703, 1743).

4. Lyme disease is a tick-borne syndrome caused by infection with the spirochete Borrelia Burgdorferi. The bacteria are excreted by the tick and inoculated into the skin where it multiplies. Once the organism has multiplied locally it can disseminate (Pet. Ex. 14, 16, 19, 21; T. 87).

5. A majority of patients with Lyme disease get a characteristic skin lesion called erythema migrans, between 3 and 30 days after a tick bite. Erythema migrans is considered to be pathognomonic of Lyme disease. The erythema migrans rash is a red lesion that grows fairly rapidly. It is a bulls-eye-like pattern with the tick bite and dark red hues at the center, lighter pink around the edges. Generally, the rash is not itchy or painful. Some patients are unaware that they have a rash, and not every patient will develop a rash (Pet. Ex. 14, 16, 17, 19, 21; Resp. Ex. E; T. 87-89, 93-95, 167-168, 2464).

6. Lyme disease is commonly seen in stages - early or acute Lyme disease and late disseminated Lyme disease. In the acute phase, a patient may develop symptoms including fever, headaches, muscle aches and pains and abnormalities involving the heart, joints and nervous system. Cardiac involvement may result in varying degrees of heart block. Joint involvement is mostly large joint arthritis. Nervous system manifestations include facial nerve palsy, meningitis and/or encephalitis (Pet. Ex. 14, 16, 17, 19, 21; Resp. Ex. E; T. 89-91, 110-111, 513-516).

7. If a diagnosis is made within the first few weeks of the disease, and the patient is treated with appropriate antibiotics, the vast majority of patients will be cured (Pet. Ex. 16, 19; T. 89-91, 500).

8. If the disease remains untreated, some patients spontaneously remit. However, patients who do not remit may develop problems associated with late Lyme disease involving the nervous system and the joints. Nervous system complications can include encephalitis manifested by cognitive defects, meningitis, facial nerve problems and neuropathy with spinal pain or paresthesias. Joint involvement is typically large joint arthritis, primarily of the knee. These patients may require further treatment with oral or intravenous antibiotics (Pet. Ex. 14, 16, 17, 19, 20, 21; Resp. Ex. G, H, N, T, Z; T. 90-93, 128, 228, 513-518, 731, 923, 939-940, 2944-6, 2592-96).

9. Patients can become re-infected with Lyme disease if they have recurrent tick bites because the immune system does not develop adequate immunity to prevent reinfection (T. 931).

<u>10.</u> A diagnosis of Lyme disease is made by a thorough evaluation of the patient, including a history and physical examination. In the early stages of Lyme disease, where a rash is clear, a reasonably prudent physician need not do any further tests. Where there is no erythema migrans, serologic tests may be used as an adjunct to a clinical diagnosis of Lyme disease, although none of the serologic tests provide an absolute diagnosis (Pet. Ex. 16, 17, 19, 21; Resp. Ex. E; T. 95-98).

11. Laboratory confirmation of infection deals with the body's immunologic response against an organism. A positive immunologic response however, does not always indicate active Lyme disease. As a result, the CDC recommends a two-tier testing system (Pet. Ex. 16, 17, 19, 20, 21; T. 98-99, 938,1516).

12. An ELISA is the first screening blood test. Although test results may be affected by prior antibiotic use, a negative result usually indicates that the person probably does not have Lyme disease. A positive result raises the possibility of infection, although it does not provide a definitive diagnosis. Therefore, a positive or equivocal ELISA test should be followed by another blood test, the Western immunoblot ("WB") (Pet. Ex. 14, 16, 17, 19, 20, 21; T. 98-101, 370-371, 696, 2598, 2814-16).

13. Because there may be some ambiguity from reader to reader in interpreting the WB test, the CDC developed and promulgated criteria indicating how to interpret WB test results. The WB is divided into categories: immunoglobulin M ("IgM") and immunoglobulin G ("IgG"). Upon initial infection the WB will be negative. Thereafter, as the body mounts an immunologic response, antibodies will be produced. IgM is the first antibody produced when the immune system confronts an infectious disease, usually appearing within the first four weeks of infection. IgM should be considered positive if two out of three bands are

present. After the first four weeks, IgM starts to decrease and, within the first two to six weeks of infection, IgG increases. IgG should be considered positive if five out of ten specific bands are present. No individual band is diagnostic for Lyme disease and if less than five bands appear, the result may not be significant (Pet. Ex. 16, 17, 19; T. 103-106, 117-18, 174-176, 307, 530-32, 543-545, 576, 950-51, 1566-68, 1707-08).

14. It is possible to have Lyme disease without a history of erythema migrans rash and with negative serologic testing (Resp. Ex. E, V; T. 543, 575).

15. A lumbar puncture is a standard test to determine if a person has central nervous system Lyme disease. When tested, the majority of patients with neurologic Lyme disease have abnormal findings in their spinal fluid, although it is possible to have a negative test and still have CNS Lyme disease which needs treatment (Pet. Ex. 16, 17, 21; Resp. Ex. H; T. 68-70, 248, 518-19, 651, 744-45, 796-97, 809: 2608. 2610).

16. The Lyme Urine Antigen Test ("LUAT"), looks for pieces of Lyme bacteria in a person's urine. The LUAT is a proprietary test, only offered at IGeneX, a California laboratory. During the time period at issue herein, it was accepted for use by the New York State Department of Health and used by physicians. In the last year and a half, its accuracy has been questioned, and since April of 2000 IGeneX has not been permitted to test samples from New York for Lyme disease, although it is still used in other states (Pet. Ex. 13, 16, 17; T. 101-02, 309-10, 698, 1367, 1372-1373, 2150, 2605-6, 2384).

17. A SPECT scan is a nuclear medicine study that shows blood flow in the brain. It may be useful in distinguishing between organic and psychiatric illness. People with CNS Lyme disease can have organic brain changes and may demonstrate blood flow abnormalities. Other diseases also cause these types of abnormalities (Resp. Ex. R; T. 152-153, 372-375, 506, 715, 2662-64, 2659-60, 2728, 2871).

18. When making a diagnosis of Lyme disease, a reasonably prudent physician must consider the full range of differential diagnoses. There are numerous conditions that may have symptoms similar to Lyme, including but not limited to, pneumonia, strep throat, meningitis, other tick-borne diseases, arthritis, subacute bacterial endocarditis, chronic fatigue syndrome, fibromyalgia and depression (Pet. Ex. 16, 17, 19, 21; T. 33-35, 96-97).

19. The standard treatment for Lyme disease as articulated by the Infectious Disease Society of America, the American College of Rheumatologists and the CDC is as follows: first line therapy for early Lyme disease includes oral Doxycycline, Amoxicillin or Ceftin for 10 days to 3-4 weeks; for Lyme arthritis, oral Doxycycline for 2-4 weeks; for patients with heart block, Rocephin for 2-4 weeks. Patients with neurological Lyme disease are generally not effectively treated with pills because oral antibiotics do not pass the blood brain barrier. As a result, first line therapy for central nervous system Lyme disease usually consists of Rocephin/Ceftriaxone or Claforan/Cefotaxime, administered intravenously for 2-4 weeks. The optimal doses and duration of therapy have not been unequivocally established, and physicians may vary antibiotic usage (Pet. Ex. 14, 16, 17, 19, 21; Resp. Ex. J, N; T. 106-108, 110, 126, 326, 341, 480-486, 918-919, 2587, 2591, 2593-97).

20. Treatment with parenteral or IV therapy involves risk, including line sepsis and infection (T. 143-144, 363, 510-511).

21. A Jarisch-Herxheimer reaction ("Herxheimer") is a temporary reaction that occurs in someone with an infectious disease after he is treated with a drug that causes death of the bacteria. Patients experiencing a Herxheimer generally feel worse for a short period of time. This may occur in approximately 10% of people with Lyme disease who are treated with antibiotics (Pet. Ex. 16, Ex. 17; Resp. Ex. H; T. 96, 846-848, 1455-1456, 1459).

22. Babesiosis is a parasitic disease, with similarities to malaria, contracted from the bite of a tick. Babesiosis can be transmitted by the same tick that transmits Lyme disease, and is considered a co-infection. The parasite lives inside the person's red blood cells and causes the red blood cells to rupture. Untreated babesiosis may result in prolonged illness, including fatigue, muscle aches, weight loss, fever, ohills and sweats, although some people remain asymptomatic (Resp. Ex. X, Y; T. 977, 1083, 1425-1426, 2158-59).

23. A diagnosis of babesiosis can be made by taking a patient history, including possible tick exposure, and by performing an appropriate physical examination to document suggestive clinical findings. In addition, a gram stained smear of the red blood cells can be ordered to see whether the parasite is inside the person's red blood cells, although this test is not always positive in patients with the disease (Resp. Ex. Y; T. 979-980, 1455, 3265).

24. Serologic paired antibody testing, can be useful, but not dispositive, in diagnosing acute babesiosis. To support a diagnosis of babesiosis by this method, an initial blood specimen is drawn, antibodies are measured and then, approximately two weeks later, a second specimen is drawn and antibodies are measured again. A serologic diagnosis of babesiosis is based on a four-fold increase in the level of antibodies, indicating that the

immune system has been stimulated by the infection. The presence of antibodies to the babesiosis organism in only one test can reflect prior exposure to the organism. Successful treatment can result in a negative titer (T. 980-981, 1040, 1455,2168).

25. During the time period relevant herein, the standard treatment for babesiosis was a combination of Clindamycin and Quinine, for 10 to 14 days (Pet. Ex. 16; Resp. Ex. X, Y; T. 982, 986, 1087-1088, 1176-1177, 1455).

26. Ehrlichiosis is a bacterial infection transmitted by a tick bite. There are two types of ehrlichia bacteria that infect humans: human monocyctic ehrlichia and human granulocytic ehrlichia. Most people infected with ehrlichiosis present with a high fever and can exhibit severe headaches, shaking chills, muscular aches and pains and a flu-like illness, although it can present in a more mild form. Ehrlichiosis can cause a rash, which is different than the rash that is characteristic of Lyme disease.• There is no known human form of chronic ehrlichiosis and, if active ehrlichiosis goes untreated, it can be fatal (T. 983, 1041-1042, 1080, 1084-1085, 2160, 2163-2164, 2171-72).

27. The diagnosis of ehrlichiosis is made by history and appropriate physical examination to determine if the person's history and presentation is consistent with the signs and symptoms common to ehrlichiosis. The laboratory diagnosis of ehrlichiosis is established by a CBC with suggestive findings, as well as paired antibody testing. There must be a rise in the level of antibodies to indicate active infection (T. 983-84).

28. The standard treatment for a person infected with ehrlichiosis is oral Doxycycline for seven days (Pet. Ex. 16; T. 984-986).

FINDINGS OF FACT AS TO PATIENT A

29. Respondent treated Patient A from on or about February 11, 1992 through on or about April 27, 1998 (Pet. Ex. 3).

30. At Patient A's initial visit on February 11, 1992, Respondent noted that she was here for a "Lyme disease evaluation/consult." Patient A had been previously diagnosed by her physician in New Jersey with Lyme disease, and had been treated by him with intravenous antibiotics. After she developed a PICC line infection, the antibiotics had been discontinued. A note in that physician's medical record states that the patient was to see Dr. Burrascano for consideration of further IV treatment (Pet. Ex. 3, 3a, T.164, 1526, 2795-96).

31. At the time of the initial visit, the patient had been off antibiotics for two weeks, and she complained of headaches, a sore neck, muscle pain, weight loss, joint pain, fatigue, shakes, bad balance, poor speech and a "foggy brain." The chart documents a past medical history, a physical examination, and stool testing for c. dificile because of the patient's complaint of diarrhea. At that visit, the Respondent prescribed Vancomycin for the possible recurrence of c. dificile (Pet. Ex. 3, 1505, 2796-98).

32. Respondent testified that he reviewed Patient A's prior medical records, which are in evidence, at the patient's initial visit. Patient A had previously been treated as an inpatient at Hamilton Hospital in New Jersey in July, 1991, where she had undergone an extensive evaluation, including antibody and LUAT tests, four lumbar punctures, various blood tests, and endocrine, neurological and psychological consultations. Her symptoms,

including severe headaches and joint problems, were attributed to her diagnosed Lyme disease. She was also diagnosed with hypoadrenalism (Addison's Disease) and thyroid problems. She had been treated with multiple prolonged courses of antibiotics, including IV Rocephin, Primaxin and Timentin for previous episodes of Lyme disease prior to seeing Respondent, as well as medications for her adrenal and thyroid problems (Pet. Ex. 3, 3a; T. 169, 172, 270, 472, 579, 1505-09, 2802-03, 2918, 2921, 2924, 2676).

33. Patient A saw Respondent seven times between February and May of 1992 as a consultant for parenteral antibiotic treatments of her CNS Lyme disease. During that time, he advised re-starting Primaxin intravenously through April 30, 1992, added oral Biaxin to the treatment regime, and prescribed Diflucan for a yeast infection. Patient A continued to see her local physician during this time, and the Respondent did not order any laboratory testing, although he did monitor her IV therapy with the local infusion company (Pet. Ex. 3, T. 120-22, 207-08, 327, 2674, 2795).

34. On April 30, 1992 the intravenous therapy was completed and the chart notes that the patient was feeling much better. The Respondent saw the patient on May 18, 1992, and he prescribed a follow up course of a combination of oral antibiotics, including Biaxin, Ceftin, and later Augmentin as the patient's symptoms changed (Pet. Ex. 3; T. 327, 334, 2674, 2596, 2936).

35. Patient A returned to see Respondent one year later, on June 23, 1993. She was still under the care of her local physician, and reported that she was still suffering from the same sort of symptoms. Respondent documented a physical examination, and drew multiple blood tests, including an immunologic work-up. All test results were normal, with the exception of a high IgM for Lyme. The Respondent prescribed Amoxicillin (Pet. Ex. 3, T. 365).

36. Four years later, on March 25, 1997, the Patient returned to see the Respondent. She reported a new tick bite in August 1996, with the tick testing positive for Lyme. At the time of that visit, she had had a positive ELISA, and received twelve weeks of antibiotics from her New Jersey physician. She had also had a neurological evaluation and the consult letter is part of the chart. All serologies were negative for Lyme, babesiosis and ehrlichiosis. One LUAT of three tested positive for Lyme. The Respondent diagnosed bilateral Bell's palsy, which occurs in CNS Lyme disease, and ordered a SPECT scan, which was abnormal. He advised her current New Jersey physician, to give high dose oral Doxycycline, and when the patient failed to improve, added IV Rocephin (Pet. Ex. 3, T. 346, 2674, 2982).

37. On June 5, 1997 in response to a patient report of no improvement, the Respondent ordered an increase dosage of Rocephin delivered in a pulsed treatment. On June 23, 1997 the patient called to report a PICC line infection, for which she was treated locally. The patient next visited on July 10th, and the Respondent ordered a continuation of the Rocephin through August. The chart contains numerous faxes to the Patient's local physicians as well as notations of telephone calls concerning her care (Pet. Ex. 3; T. 129-139, 430-41, 343-46, 362, 580, 604, 1613-1615, 2969).

38. Patient A returned to the Respondent's office on September 11, 1997. At that time, he documented that she had undergone hyperbaric oxygen therapy ordered by her New Jersey physician for four weeks, and had felt better until one week prior to this visit, when symptoms related to the PICC line infections increased. She was to have another immunotherapy work-up in New Jersey and a SPECT scan (Pet. Ex. 3).

39. Five months later, at an office visit in February, 1998, the patient had been off antibiotics for two weeks, and generally felt better. She did report increased symptoms related to stress, arising after her father's recent death. The Respondent ordered parvovirus titers, which were increased, and LUAT testing with one positive result. The Respondent gave the patient an injection of Bicillin and prescribed Valtrex (Pet. Ex. 3).

40. The patient returned three weeks later, on March 19, 1998, with complaints of abdominal pain. After examination, the Respondent diagnosed c. dificile, thrush and vaginal yeast. He stopped all antibiotics, and prescribed Flagyl for the c. dificile and a topical vaginal treatment. She called on March 26th, reporting that she was seeing her local physician and at her last visit of April 6, 1998, with increased symptoms, she was advised to re-start intravenous Primaxin under the care of her current New Jersey physician (Pet. Ex. 3).

41. The Respondent was acting as a Lyme disease consultant in his care of Patient A, although he occasionally made adjustments in medications she was taking for conditions other than Lyme disease. In addition to the Respondent, Patient A was also seen at various times during the period of Respondent's care, by her primary care physicians, a neurologist, endocrinologist, psychologist and psychiatrist (Pet. Ex. 3; T. 194, 363, 2677-78, 2795).

42. Respondent maintained records that accurately documented his care and treatment of Patient A (Pet. Ex. 3; T.1692, 2988).

CONCLUSIONS AS TO PATIENT A

43. The Petitioner did not prove by a preponderance of the evidence that Respondent failed to meet minimally acceptable standards of medical practice in his care of Patient A. Allegations A and each of its subparagraphs are not sustained.

FINDINGS OF FACT AS TO PATIENT B

44. Respondent treated Patient B from on or about January 17, 1994 through on or about July 5, 1996, at Respondent's office. (Pet. Ex. 4)

45. At the initial visit on January 17, 1994, Respondent documented that the purpose of the visit was a Lyme disease evaluation. He reviewed Patient B's records from his prior physician, Dr. Horowitz in Hyde Park, NY. Dr. Horowitz had ordered a WB, which showed two positive bands, and had treated the patient's Lyme disease with Suprax and Zithromax without improvement. Patient B, a 60-year old man, lived in an area endemic for Lyme, and had a one-year history of CNS symptoms, mood swings and sexual dysfunction. The Respondent noted that Patient B felt well but that his wife, who was a former patient of the Respondent, and a clinical psychologist who treated Lyme patients, insisted he be tested for Lyme disease. At the conclusion of the visit, Respondent documented that there was no clear evidence of Lyme disease, but that he would continue the prior physician's treatment of oral antibiotics (at an increased dose) because it might be beneficial for future problems (Pet. Ex. 4; T. 622-23, 661, 1989, 2003, 2018, 2053-61).

46. The Respondent, Dr. Cichon and Dr. Fallon testified that the patient had Lyme disease based on his history and symptoms and other physician evaluations (T. 1977-80, 2727-28, 3145, 3149).

47. Dr. Welch acknowledged that CNS Lyme can be treated in the absence of a positive blood test or spinal tap if the patient had clinical symptoms (Resp. Ex. V, T. 442, 744, 960).

48. Three months later the patient returned to the Respondent's office on April 13, 1994. The chart documented that he had been off antibiotics for a month and was asymptomatic and felt well. Lyme serology was negative for IgG and IgM, and a LUAT was also negative. The Respondent did not prescribe any treatment (Pet. Ex. 4, T. 1990).

49. Four months later, the patient returned, on August 17, 1994 with increased symptoms of memory loss and a report for fatigue and rashes. At that time, WB, ELISA and LUAT tests for Lyme were negative. The Respondent testified that the patient had a second episode of Lyme disease, which was in the early stage when these tests would not yet be positive, and began antibiotic treatment (Pet. Ex. 4; T 1991-94, 2005).

50. The next office visit was a few months later, in October, 1994. The patient was still suffering from the CNS symptoms, as well as chest pains and impotence. One of three LUATS was positive for Lyme, and the Respondent prescribed oral Bicillin and Ceftin (Pet. Ex. 4, T. 737, 2011-2013, 2731, 3160).

51. In December of 1994 the patient underwent coronary bypass surgery, and was taken off antibiotics by his cardiologist. The antibiotics were restarted with the permission of the cardiologist a month later. The chart contains the cardiologist's record (Pet. Ex. 4).

52. The patient returned to see the Respondent on March 29, 1995 feeling "pretty good" although still somewhat weak post-operatively. He had been on Bicillin and Ceftin since February, but still exhibited some CNS symptoms. The Respondent prescribed a continuation of the antibiotics, and prescribed Elavil, which was later switched to Welbutrin (Pet. Ex. 4, T. 2015-16).

53. Two months later, in July, 1995, the patient had stopped taking his beta-blocker, as well as the Bicillin and Ceftin, and reported increased energy and memory, and in September was still feeling well off antibiotics. An ELISA performed at that time was negative, and the WB had only three positive bands. No further treatment was ordered (Pet. Ex. 4, T. 2022.)

54. A year later, on July 15, 1996 the patient returned. He reported a tick bite on July 3, 1996 and that his local physician had treated him for a third episode of Lyme with Amoxicillin. The patient had problems with memory and cognition, and the Respondent recommended a SPECT scan, which indicated some decreased blood flow. The Respondent did not order a lumbar puncture, although he did recommend neuropsychiatric testing. Although a lumbar puncture might have been helpful, it was not required to make a diagnosis and begin treatment given the clinical symptoms and past history (Pet. Ex. 4; Resp. Ex. G, H, V; T. 745, 2006-2008, 2027–2029, 2032, 2731, 3165).

55. The Respondent maintained records that accurately reflected his care and treatment of Patient B (Pet. Ex. 4, T.2032, 3166).

CONCLUSIONS AS TO PATIENT B

56. The Petitioner did not prove by a preponderance of the evidence that Respondent failed to meet minimally acceptable standards of medical practice in his care of Patient B. Allegations B and each of its subparagraphs are not sustained.

FINDINGS OF FACT AS TO PATIENT C

57. Respondent treated Patient C from on or about July 19, 1995 through on or about February 20, 1998, at Respondent's office (Pet. Ex. 5).

58. Patient C had been referred to the Respondent by another physician, Dr. Kershaw, and presented with initial diagnoses of Lyme disease (confirmed by ELISA and Western Blot tests), Hashimoto disease, and previous rhinoplasty. Patient C lived in an area endemic for Lyme, and had a history of a tick bite without rash. At the initial visit on July 19, 1995, Respondent also noted that in October 1994, Patient C began to experience symptoms including balance problems, fatigue, back pain, shortness of breath, hair loss, disorientation and lightheadedness (Pet. Ex. 5; T. 871-874).

59. Respondent documented a complete history and physical on the initial visit, and appropriate documentation of follow-up visits. During the time that Respondent treated Patient C, the chart also documents a neurological consult and lumbar puncture with an elevated CSF protein, three thyroid function tests, immune status testing, a pulmonary function test, a B12 level and an EKG (Pet. Ex. 5; T. 856, 864, 868, 871-6; 2744, 3191, 3210).

60. There is evidence in the record to support a diagnosis of Lyme disease for Patient C, including a tick bite in an area endemic for Lyme, neurologic complaints and joint pain, and an elevated CSF protein, Lyme antigen test and positive bands on a WB test (Pet. Ex. 5, T. 860, 871-872, 875, 2744. 3188, 3193).

61. Respondent treated Patient C with parenteral antibiotics as follows: Claforan from September 29, 1995 through November 8th, and Rocephin from November 8th through December 15th. This was followed by oral antibiotics: Ceftin from December 16, 1995

through January 25, 1996, when Respondent switched the medication to Doxycycline. Respondent maintained Patient C on Doxycycline until late August 1996 (Pet. Ex. 5; 860, 2745, 3198, 3200-05).

62. Respondent's chart indicated that Patient C had a Herxheimer reaction after treatment with Claforan began, on or about November 2, 1995. The chart also documents a known allergy to penicillin, and Respondent referred Patient C to an allergist who ruled out a drug allergy to Claforan. When the patient developed a rash, the Respondent stopped the Claforan, and placed Patient C on Rocephin. On or about November 15, 1995, Respondent noted elevated liver function tests and stopped the medication for several days, repeating the liver function studies. He thereafter resumed treatment and the patient's liver function returned to normal while on the medication (Pet. Ex. 5, 863, 894, 897, 904, 909-10, 3191, 3196-97, 3206).

63. The Respondent's chart notes that throughout the course of treatment, Patient C continued to complain of headaches, aches, fatigue and weakness, although there are some notes indicating that Patient C periodically felt better (Pet. Ex. 5, T. 3204).

64. Respondent documented laboratory testing for Patient C including LUATs, ELISA, and WB to confirm the Lyme diagnosis made by the previous physician. Respondent also ordered antibiotic blood level testing to see whether the antibiotic serum levels were at a therapeutic dose and changed medication accordingly (Pet. Ex. 5, T. 884-8, 891-2, 3198, 3209-10).

65. The Respondent maintained records that accurately documented his care and treatment of Patient C (Pet. Ex. 5, T. 2105).

CONCLUSIONS AS TO PATIENT C

<u>66.</u> The Petitioner did not prove by a preponderance of the evidence that Respondent failed to meet minimally acceptable standards of medical practice in his care of Patient C. Allegations C and each of its subparagraphs are not sustained.

FINDINGS OF FACT AS TO PATIENT D

67. Respondent treated Patient D from on or about January 24, 1994 through on or about May 18, 1998, at Respondent's office (Pet. Ex. 6).

68. On the initial visit of January 24, 1994, the chart documents that Dr. Perry Orens referred Patient D to Respondent, for a second opinion regarding IV therapy for the Lyme disease that had been diagnosed by Dr. Orens with laboratory testing. Respondent documented a physical examination and complaints of neurological symptoms, including eye pains, pins and needles, and poor balance, as well as generalized aches and pains. The patient reported in detail that she had had evaluations and consultations with several specialists, including a lumbar puncture prior to seeing the Respondent but the record does not contain any reports by other physicians, or note that Respondent spoke with any other physicians (Pet. Ex. 6; T. 1022, 1026-28, 1111, 2125-33, 2275-6, 3237).

69. Respondent documented agreement with the proposed therapy, but at the end of the initial visit, Respondent noted "recommend follow-up here in 2-3 months". Patient D did return to see Respondent on May 17, August15, August 31, September 31, September 19, and November 3, 1994 and once each in January and May of 1995. Respondent testified that during this time period, he was acting as a consultant, "ratifying" the prescription of Doxycycline by another physician and therefore was not responsible for as thorough an

evaluation of Patient D was would be necessary had he been her primary physician. On each of these visits the chart notes a physical examination of Patient D. Various visits document adjustments in the dosage levels of medication, care of the gastric distress side effects of Doxycycline, an order for an EKG, a referral for physical therapy and a consult report addressed to the Respondent, laboratory test orders, and new prescriptions, including one for Doxycycline which caused the pharmacy filling the prescription to call Respondent to question the dose (Pet. Ex. 6, T. 2134-35, 2244, 2252, 2257, 3238, 3243-44).

70. Almost two years later, on February 13, 1997, Patient D returned to see the Respondent. He testified that he became her primary physician thereafter. At that visit, the patient, who lived in an area endemic for Lyme, reported possible new tick exposure, but no rash, and had multiple complaints, including CNS complaints and joint pain, similar to the symptoms she had reported in 1994. There is no documentation of an elevated temperature or an acute illness. Respondent examined and evaluated the patient. He ordered multiple tests to diagnose the patient's illness, including a LUAT, an ELISA, a Western Blot, thyroid testing and an EKG. Based on the results, he concluded that the patient had a new, third episode of Lyme (a second episode in 1993 had not been diagnosed and treated by Respondent) (Pet. Ex. 6; T. 1061, 1065, 1067-68, 1070, 1074, 3256-59).

71. Suspecting co-infection, the Respondent also ordered a babesia serology, which was positive for both IgG and IgM and the Respondent concluded the patient had babesiosis (Pet. Ex. 6, Resp. Ex. X, T. 1079,1081, 1083, 2165-68, 3272-75).

72. On February 13th Respondent also ordered antibody tests for both types of ehrlichiosis, as well as a CBC. The CBC was not suggestive for ehrlichiosis. The test results came back with elevated IgG, indicating later disease, and negative IgM for both forms of ehrlichiosis, an unusual result. In the absence of positive clinical findings, this laboratory result is inconclusive and perhaps erroneous (Pet. Ex. 6; T. 986-987, 1042-1043, 1080, 1083-1086, 2171-2174).

73. The patient was called on March 3, 1997 to discuss the test results, and she saw the Respondent on March 12, 1997. He prescribed intramuscular Gentamycin for the babesiosis, and requested approval for these treatments from Patient D's insurance company. On March 27th Patient D's insurance company denied the Gentamicin treatment for babesiosis, stating it was not the usual treatment. (Pet. Ex. 6; T. 986-988, 1038-1040, 1042-43, 1080-81, 1083, 1132-35, 2746-47, 2214-2219, 3255).

74. On March 27, 1997 after receiving the insurance company denial for Gentamycin, Respondent prescribed oral Clindamycin and Quinine (Pet. Ex. 6; T. 988-990, 1090, 1121-1123, 2178-2182, 2212, 2214-2219, 3265-67).

75. On April 2, 1997 after Patient D reported that she could not tolerate the oral medication, the Respondent decided to switch the antibiotic to IM Gentamicin and on April 3rd the Respondent documented that he would appeal to the insurance company to allow this treatment. A follow-up visit on April 14th documents no abatement of symptoms, and the Respondent gave the patient a test dose of IM Gentamycin in his office, which was tolerated by the patient (Pet. Ex. 6; T. 1089, 2178-80, 2196).

76. The patient was referred to an allergist, and after receiving clearance from the allergist, Respondent prescribed IM gentamycin for two weeks. After lab testing revealed the blood level of the antibiotic to be low, he increased the dosage for the last three days of treatment (Pet. Ex. 6, T. 1122, 2176, 2187, 2197, 3280).

77. At the May 19, 1997 visit Patient D reported still feeling ill, with no signs of improvement. The chart documents that the babesiosis treatment has been completed, and the Respondent now prescribed oral Ceftin for the treatment of Patient D's Lyme, as well as IV Doxycycline for 'late" ehrlichiosis. The IV treatment was disallowed by the patient's insurance company, which stated it was not the appropriate treatment for ehrlichiosis (Pet. Ex. 6; T. 986, 993, 1085, 1103, 2184, 3282).

78. At the June 30, 1997 office visit, the patient still did not report any abatement of symptoms after six weeks of oral Ceftin. At that time, the Respondent ordered Ceftin blood levels, and added oral Doxycycline treatment (Resp. Ex. 6; T. 885-86, 888, 1113,1116, 2184).

79. Patient D next visited the Respondent on September 27, 1997. Noting she still felt ill, the Respondent prescribed Elavil (an anti-depressant), and repeated the babesia titer done seven months earlier.

80. On October 7, 1997 the Respondent called the patient, stating that the second test for babesiosis was still positive. He prescribed Mepron and Zithromax for 21 days for babesiosis, telling the patient to hold the Ceftin during that time (Pet. Ex. 6; 994, 1086, 2192, 3284-85).

81. An office visit of November 11, 1997 documents that the patient was still feeling poorly. She had completed the Mepron and Zithromax treatment for babesiosis and had resumed the Ceftin for Lyme, and was having new symptoms. The Respondent's chart poses the question of a possible Herxheimer reaction to the Zithromax. The Respondent stopped the Ceftin, and re-started the Zithromax at a higher dose for six weeks (Pet. Ex. 6; T. 1107, 2193-96, 3289).

82. On January 26, 1998, the patient was still feeling ill, and the Respondent continued the Zithromax, and Elavil, and added Plaquenil, an anti-inflammatory medication (Pet. Ex. 6, T. 994, 2194, 3285).

83. At the March 23, 1998 office visit the patient was continued on the same medications, with the exception of the Plaquenil, and Mepron was added for 21 days (Pet. Ex. 6; T.994, 2192).

84. The last chart visit documented for Patient D was on May 18, 1998, at which time the patient resumed Plaquenil, and was still on Zithromax and Elavil. Improvement in eye and joint pains was noted, and the patient was to continue treatment and return in eight weeks (Pet. Ex. 6).

85. The Respondent maintained records that accurately reflected his evaluation and treatment of Patient D (Pet. Ex. 6, T. 1120).

CONCLUSIONS AS TO PATIENT D

86. The Petitioner proved by a preponderance of the evidence that Respondent was negligent in his treatment of Patient D because he inappropriately treated Patient D for ehrlichiosis without sufficient clinical and laboratory evidence that she had the disease. Factual allegations D.2.b, D2.c, D.2.e, D.2.g, and D.3 and D.7 with regard to ehrlichiosis

only are sustained, and those parts of the allegations with regard to Lyme disease and babesiosis are not sustained. No other allegations with respect to negligence are sustained.

87. The Petitioner failed to prove by a preponderance of the evidence that Respondent was incompetent in his treatment of Patient D. No allegations with respect to incompetence are sustained.

88. The Petitioner failed to prove by a preponderance of the evidence that the Respondent was grossly negligent in his treatment of Patient D. No allegations with respect to gross negligence are sustained.

89. The Petitioner failed to prove by a preponderance of the evidence that the Respondent was grossly incompetent in his treatment of Patient D. No allegations with respect to gross incompetence are sustained.

90. The Petitioner failed to prove by **a** preponderance of the evidence that Respondent's treatment of Patient D was fraudulent. No allegations with respect to fraudulent treatment are sustained.

91. The Petitioner failed to prove by a preponderance of the evidence that Respondent failed to maintain records that accurately reflected his evaluation and treatment of Patient D. No allegations with respect to failure to maintain records are sustained.

FINDINGS OF FACT AS TO PATIENT E

92. Respondent treated Patient E from on or about September 3, 1993 through on or about February 3, 1998, at Respondent's office (Pet. Ex. 7).

93. At Patient E's initial visit on September 3, 1993, Respondent documented that Patient E had an erythema migrans rash, evidence of early Lyme disease. The Respondent ordered an Elisa test, which was negative as is common in early Lyme. He also ordered a

Western Blot test, which was positive for IgM antibody, which is often seen in early Lyme. He prescribed oral Amoxicillin and Probenecid for six weeks (Pet. Ex. 7, T. 1166, 1225, 2291, 1203-06, 2301, 3353-54).

94. On October 4, 1993 the patient returned for a follow up visit, and the chart documents that the Lyme disease had been treated and the patient was symptom free (Pet. Ex. 7, T. 2302-03, 3355).

95. On May 16, 1994 the patient returned for another follow up visit, and had Elisa and Western Blot tests. The chart noted that the patient should return in six months (Pet. Ex. 7, T. 2305-06).

96. In September 1994, the patient had repeat Lyme serologies, with both positive and negative results. She saw the Respondent on September 26th to discuss the lab results. At that time, she reported that she had recently become widowed, and had difficulty sleeping. The chart also documents a thickly coated tongue. The Respondent prescribed a sleeping medication and Diflucan for the possible thrush for 21 days (Pet. Ex. 7, T. 1236, 2322, 2338, 2770, 3385-86).

97. Fifteen months later, on December 3, 1996 Patient E presented to the Respondent with a one-month history of fatigue and joint pains. The Respondent examined the patient, and ordered a Western Blot, which was positive. He questioned whether the patient might have another episode of early Lyme disease, and prescribed six weeks of oral Amoxicillin and Probenecid (Pet. Ex. 7, T. 1216, 1220, 1225, 2338, 3355, 3357).

98. The patient next visited the Respondent on March 24, 1997. At that time she still complained of musculoskeletal pain and afternoon fatigue. The Respondent ordered blood antibiotic levels and continued the patient on antibiotic therapy. On March 31st he increased

the Amoxicillin dose based on the laboratory test results. (Pet. Ex. 7, T. 1226-28, 1246, 3368).

99. On the June 2, 1997 visit the patient had been off the Amoxicillin for three and a half weeks, her tongue was clear, and she felt well. The chart notes that she was to come back in two months (Pet. Ex. 7; T. 1217, 1230).

100. The patient next visited the Respondent on August 4, 1997. At that visit she reported a history of a tick bite three weeks prior. The Respondent noted that the patient reported increased muscle ache and fatigue, to the point that she was unable to work. He diagnosed a flare up of Lyme and oral thrush. The Respondent had babesiosis and ehrlichiosis antibody titers drawn on patient E. A CBC with a manual differential was suggestive of ehrlichiosis and babesiosis. Babesiosis and ehrlichiosis can occur at the same time in a patient, and untreated ehrlichiosis is potentially life threatening. He prescribed one month of oral Doxycycline for the ehrlichiosis and gave the patient an injection of intramuscularly magnesium for the muscle aches (Dept Ex. 7, 1188, 1192-1194, 1198-99, 1200-01,1231, 2329, 3348-51).

101. The antibody test results were positive for both ehrlichiosis and babesiosis, and on September 2, 1997 the Respondent prescribed Clindamycin and Quinine for 14 days, for the Patient E' babesiosis, during which time she was to discontinue the Doxycycline (Pet. Ex. 7; T. 1192, 1196, 1234).

102. The patient returned on October 27, 1997 and reported feeling somewhat better. The Respondent prescribed two more weeks of Doxycycline, and repeat blood tests in three months (Pet. Ex. 7).

103. On February 3, 1998, the patient tested negative for babesiosis (Pet. Ex.7; T. 1234).

104. The Respondent maintained records that accurately reflected his evaluation and treatment of Patient E (Pet. Ex. 7, T. 1120, 2211).

CONCLUSIONS AS TO PATIENT E

105. The Petitioner did not prove by a preponderance of the evidence that Respondent failed to meet minimally acceptable standards of medical practice in his care of Patient E. Allegations E and each of its subparagraphs are not sustained.

FINDINGS OF FACT AS TO PATIENT F

106. Respondent treated Patient F from on or about December 12, 1996 through in or about June 16, 1999, at Respondent's office. (Pet. Ex. 8)

107. Prior to Patient F's initial visit with Respondent, Patient F, a 35 year old male neurologist, developed a viral-like illness and then developed neurological symptoms which led to vision and balance problems. Patient F had an extensive evaluation at the Mayo clinic, where he was told that he might have a demyelinating disease, such as multiple sclerosis, and was treated with high doses of cortisone, a recommended treatment for MS. Patient F's condition deteriorated, and he then went to Massachusetts General Hospital ("Mass General") to be evaluated where he was also told he might have some form of demyelinating disease. Patient F continued to have neurological difficulties and was seen by several other specialists and had a variety of neurological tests that were negative for demyelinating disease (Pet. Ex. 8; T. 1269-1273, 1305-7, 1315).

108. Prior to seeing Respondent, Patient F spoke with Dr. Patricia Coyle, a neurologist with recognized expertise in Lyme disease. During his numerous evaluations, Patient F had a total of four spinal taps, which did not reveal any evidence of demyelinating disease or syphilis. His only positive tests were an ELISA and a CSF, which came back borderline positive. Dr. Coyle also performed an antigen-antibody capture test that was positive for Lyme. Dr. Coyle recommended that Patient F be treated for Lyme disease with six weeks of Rocephin (Pet. Ex. 8; T. 1276, 1307-13, 1320).

109. At Patient F's initial visit with Respondent, on December 12, 1996, Respondent noted that Patient F was a self referred neurologist from out of state, here for a Lyme evaluation, with no known tick bite, although possible exposure and rash, and a well documented history of neurological symptoms evaluated at the Mayo Clinic and Mass General, which despite numerous tests had no clear diagnosis. The chart contains the patient's prepared summary of these work-ups, and Respondent also noted Dr. Coyle's treatment. He documented an appropriate history and physical, and ordered diagnostic testing for Lyme and to rule out other diseases. He continued the prescriptions of Patient F's other physicians, and considered whether a SPECT scan might be helpful (Pet. Ex. 8; T. 1275-76, 1305-08, 1314, 1326, 2429, 3393).

110. Patient F continued to be seen by his local neurologist in Kentucky during the time he was seen by Respondent, and copies of that physician's notes are in the medical record (Pet. Ex. 8, T. 1328).

111. On January 30, 1997 Patient F called the Respondent and reported increased symptoms and a rash. The Respondent added Zithromax and Plaquenil to the patient's treatment regime, and adjusted the Rocephin dosage (Pet. Ex. 8; T. 3408-10).

112. Patient F had an office visit on March 17, 1997. At that time, he reported feeling better, and being able to read for the first time in months, although he still had neurological symptoms. Respondent ordered multiple tests, including a SPECT scan, which demonstrated generalized decreased perfusion and T cell studies, which showed immune deficiency. Because there had been only a partial response to the Lyme treatment, and because of the possibility of co-infection, Patient F was tested for babesiosis: an RNA test was positive, antibody tests were positive, and two positive fluorescent antibody peripheral smears were positive. The Respondent concluded that the patient had babesiosis, and in consultation with the patient's local neurologist, Respondent stopped the Rocephin and Zithromax, and began parenteral Doxycycline, and later a 14 day course of Gentamicin. The local physician was to test antibiotic blood levels (Pet. Ex. 8, 1332-1335, 1347-52, 2394-5, 3415-20).

113. On May 15, 1997 the chart documents that the patient was still on parenteral Doxycycline, and that the patient telephoned and reported that he was doing better and now able to walk in the house with a cane (Pet. Ex. 8).

114. At an office visit on June 2, 1997, the patient was documented to be feeling obviously better, was to continue on parenteral Doxycycline and to return in two months. A phone call documented a month later stated that the patient was still symptomatic on the Doxycycline, and the Respondent noted a Herxheimer reaction (Pet. Ex. 8).

115. The Respondent next saw the patient on August 11, 1997. At that time he documented increased neurological symptoms, and ordered more hematological tests, including a babesia titer that was positive. He prescribed intravenous gamma globulin because of the patient's own low level, and also Zithromax and Mepron for 21 days. After

noting periods of improvement and then a plateau in improvement, Respondent treated Patient F again with the same medications in January 1998 (Pet. Ex. 8., T.1295, 1324, 1358, 2398-99, 3431).

116. Patient F had a seizure disorder, diagnosed by a neurologist, which was documented by the Respondent and a history of having had a seizure after taking Bicillin. Nonetheless, in August 1997, Respondent prescribed intramuscular Bicillin for Patient F. After Patient F had another seizure, Respondent reduced the dose, but maintained the patient on Bicillin for five months as a treatment for Lyme disease, despite the recurrent seizures (Pet. Ex. 8, T. 1378-83, 1387-88, 2436-2437, 2381, 2447-48).

117. On March 23, 1998, the patient called and reported better vision and balance. The last chart entry was a report of a patient telephone call on May 12, 1998 at which time the patient reported he was doing well.

118. The Respondent maintained records that accurately reflected his evaluation and treatment of Patient F (Pet. Ex. 8, T. 1359, 2412, 3434).

CONCLUSIONS AS TO PATIENT F

119. The Petitioner proved by a preponderance of the evidence that Respondent was negligent in his treatment of Patient F by prescribing Bicillin on a continuous basis after the patient had a seizure while on the medication, and factual allegation F.3.d with respect to intramuscular Bicillin is sustained. No other allegations of negligence were sustained.

120. The Petitioner failed to prove by a preponderance of the evidence that Respondent was incompetent in his treatment of Patient F. No allegations with respect to incompetence are sustained.

121. The Petitioner failed to prove by a preponderance of the evidence that the Respondent was grossly negligent in his treatment of Patient F. No allegations with respect to gross negligence are sustained.

122. The Petitioner failed to prove by a preponderance of the evidence that the Respondent was grossly incompetent in his treatment of Patient F. No allegations with respect to gross incompetence are sustained.

123. The Petitioner failed to prove by a preponderance of the evidence that Respondent's treatment of Patient F was fraudulent. No allegations with respect to fraudulent treatment are sustained.

124. The Petitioner failed to prove by a preponderance of the evidence that Respondent failed to maintain records that accurately reflected his evaluation and treatment of Patient F. No allegations with respect to fraudulent treatment are sustained.

FINDINGS OF FACT AS TO PATIENT G

125. Respondent treated Patient G from on or about October 3, 1992 through on or about May 29, 1998, at Respondent's office. (Pet. Ex. 9)

126. Between 1992 and 1997 the Respondent saw Patient G on multiple occasions for routine visits. Patient G's husband was enrolled in an Alzheimer's day program close to Respondent's office, and she would often walk in for unscheduled visits after dropping him at the program. She reported that her first tick bite and erythema migrans rash had occurred in 1985, and the patient complained of multiple symptoms since that time, including episodic arthritis, chronic recurrent cystitis and CNS changes. All lab work including LUATs were negative during that time (Pet. Ex. 9; T. 2468).

127. On June 9, 1997, Patient G, who was now 69 years old, presented with an erythema migrans rash. At that visit, Patient G complained of chills, fever, earache, fatigue, joint pains and nausea, symptoms that could be consistent with Lyme disease, and a co-infection of babesiosis and/or ehrlichiosis. The Respondent tested the patient for Lyme and ordered a babesia serology, which was positive for IgG and negative for IgM. Ehrlichia testing was negative. The Respondent diagnosed acute Lyme, and suspected a co-infection of babesiosis. He prescribed Rocephin and oral Ceftin for the Lyme (Pet. Ex. 9; Resp. Ex. X, Y; T. 1423-24, 1428-35, 2473, 2476, 2500-01, 3461-63, 3466-67, 3476-78).

128. On June 25, 1997 the Respondent noted a Herxheimer reaction to the Rocephin, and reduced the patient's dosage. He gave the patient a test dose of Gentamycin in his office, and then prescribed a 14-day course of self-injected gentamycin IM for babesiosis (Pet. Ex. 9; T. 1428-1429, 2472, 3490-3491).

129. On a July 15, 1997 the patient was still feeling ill, and reported balance problems. She was maintained on Ceftin, and later given Augmentin (Pet. Ex. 9, T. 1410-11, 1442-43, 2842).

130. In July 1997 the patient saw Dr. Burger for a second opinion concerning her dizziness and double vision. He suggested that she see Dr. Coyle, but the patient did not go to see her (Pet. Ex. 9, 1447,2780).

131. In September, 1997 the patient still had poor balance and was still reporting visual symptoms, but the Respondent documented that the patient had some improvement while on the Ceftin and vitamin regime. In October, the patient remained symptomatic, and the Respondent questioned whether her balance problems were due to Lyme disease or to

previous Gentamycin therapy. Although he had measured her Gentamicin levels and found them to be non-toxic (Pet. Ex. 9; T. 1411, 2484).

132. Gentamicin is known to cause changes in balance and/or hearing and these side effects can occur during or after treatment. There are notes that Patient G was evaluated by several specialists, including an ophthalmologist, an allergist and an ENT, and she was found to have had 70% loss in the vestibular nerve. Lyme disease can cause this problem as well. The vestibular nerve is one of the nerves in the balance center that relates to one's ability to keep their balance and remain steady on their feet. (Pet. Ex. 9; T. 1403-1407, 2486, 2490, 2559, 3472, 3487).

133. In November 1997 the patient told the Respondent she was going to seek alternative therapy, and Ceftin was discontinued. At the next office visit in February, 1998 she reported feeling somewhat better, although still exhibiting some CNS problems. The patient was only taking vitamins at that time, and the Respondent gave her an injection of Rocephin. The last visit in March 1998 the record documents poor balance and vestibular problems, possible due to gentamycin (Pet. Ex.9).

134. The Respondent maintained records that accurately reflected his evaluation and treatment of Patient G (Pet. Ex. 9; T. 2516,3486).

CONCLSUSIONS AS TO PATIENT G

135. The Petitioner failed to proved by a preponderance of the evidence that Respondent failed to meet minimally acceptable standards with respect to his care of Patient G.

FINDINGS OF FACT AS TO FRAUD

136. There was no testimony that the Respondent intentionally ordered testing or prescribed treatment to Patients A through G that he knew was not warranted (T. 751,915, 1119, 1691, 1242, 1359, 1448, 2032, 2210, 2412, 2516, 2326, 2516, 2988, 3299, 3373, 3433, 3485).

137. There are four corrections made by the Respondent to Patient G's record. These are located on pages 9, 10, and 12 of the patient record. On the September 11, 1997 visit some words have been crossed out and written over. Respondent re-wrote over a word or words, several times, making it difficult to read the note. It appears that Respondent's record originally read "had diplopia after Babs RX" and that the written over note reads "had diplopia after July '97" (Pet. Ex. 9 page 9; T. 1415-1416).

138. On the notes from Patient O's October 15, 1997 visit, Respondent re-wrote over a word or words, several times, making it difficult to read the note. It appears that Respondent's record originally read "poor balance still after Babs RX" and that the written over note reads "poor balance still after July RX" (Pet. Ex. 9 page 10; T. 1415, 1417).

139. On the notes from Patient G's March 5, 1998 visit, Respondent re-wrote over a word or words, several times, making it difficult to read the note. In one place, it appears that Respondent's record originally read "history of TIAs and vestibular damage secondary to Genta" and that the written over note reads "history of TIAs and vestibular damage secondary to Borrelia". In another note from the same visit, Respondent's record appears to originally have read "long discussion re dizziness implications of Genta" and the written over note appears to read "long discussion re dizziness and implications of vestib" (Pet. Ex. 9 page 12; T. 1415, 1418-1419).

140. The Department's expert testified that these corrections were made with an intent to cover up Gentamicin toxicity caused by the Respondent's prescription of that drug (T. 1418-1419).

141. The Respondent acknowledged that Gentamicin can cause ototoxicity and 8th cranial nerve injury. He testified that there was no attempt to alter the medical record with an intent to deceive concerning this issue. Patient G's chart contains numerous other references to Respondent's prescription of Gentamicin for Patient G, documents complaints of dizziness from the patient, and includes an allergist's report on the use of the drug (Pet. Ex., T. 2504-2511, 348-83).

<u>142.</u> The Respondent testified that at that time it was his practice to make corrections in a medical record by cross-outs. An examination of other portions of the record of Patient G, which have nothing to do with Gentamicin, as well as the other patient charts in this matter, reveal numerous instances of records corrected in this manner. Respondent also acknowledged that in 1992 he had been told by the Medical Records Committee of Southampton Hospital that changes in his records should be made by cross-outs and initialing, rather than just writing over previously written orders (T. 2514-18, 3483-84).

143. Respondent testified that "now he knows better" and would make changes to his records differently today by "making a single line through the error so you can still see what is underneath" (T. 2515).

CONCLUSIONS AS TO FRAUD

144. The Petitioner failed to prove by a preponderance of the evidence that the allegations with respect to fraud and the making of a false report were sustained, because there was no evidence that the Respondent acted knowingly, falsely, and with the intent to deceive.

145. The corrections to Patient G's chart are the result of poor record keeping practices, rather than an intent to deceive others and cover-up the issue of Gentamicin toxicity. There are many other references in the chart to this issue as well as an allergist's consult note questioning whether Gentamicin had affected Patient G's 8th cranial nerve, and had there been an intention to conceal or mislead, these references would also have been changed or eliminated from the chart.

146. Factual allegations A and A.8, B and B.5, C and C.4, D and D.7, E and E.5, F and F.5, G, G6, and G.7 are not sustained with respect to fraudulent practice or the making of a false report.

VOTE OF THE HEARING COMMITTEE

(All votes were unanimous, unless specified.)

FIRST SPECIFICATION:

(Negligence) Sustained as to D.2.b, D.3.c, D.2.e, D.2,g, D.3 and D.7 with respect to ehrlichiosis only, and F.3.d as to Bicillin. No other allegations are sustained.

SECOND SPECIFICATION: (Incompetence) No allegations are sustained.

THIRD THROUGH ELEVENTH SPECIFICATIONS:

(Gross Negligence) No allegations are sustained.

TWELFTH THROUGH TWENTIETH SPECIFICATIONS:

(Gross Incompetence) No allegations are sustained.

TWENTY-FIRST THROUGH TWENTY-NINTH SPECIFICATIONS:

(Unwarranted tests or treatment) Sustained as to D.2.b, D.3.c, D.2.e, D.2.g, D.3 and D.7 with respect to ehrlichiosis only. No other allegations are sustained.

THIRTIETH THROUGH THIRTY EIGHTH SPECIFICATIONS: (Fraudulent practice) No allegations are sustained.

THRITY NINTH SPECIFICATION: (Failure to keep adequate records) No allegations were sustained.

CREDITABILITY OF WITNESSES

Dr. Peter Welch was the expert witness presented by the Petitioner. He testified for seven hearing days, and the Committee had a full opportunity to assess his credibility. Dr. Welch is board certified in internal medicine and infectious diseases, and has treated many Lyme disease patients, although he currently spends 70% of his time in hospital administration (T. 161). He has also served as a case reviewer for managed care companies to review cases of patients on long-term antibiotic therapy (T. 379).

The Committee found him to be an arrogant witness, who appeared to be on a crusade, constantly lecturing, rather than answering, after questions were posed to him. He answered every question emphatically, without equivocation, determined to get across his view that Respondent had acted improperly. On those occasions when he was confronted on cross examination with conclusive evidence, for example, that he had overlooked some portion of the medical record, or that the entire editorial staff of a particular journal shared

the Respondent's approach, he was reluctant to acknowledge his error. On other occasions when challenged he answered in a flip manner. For example, when asked what he would do if faced with a patient who did not improve after extensive treatment, he replied "when it happens you write an article about it in a journal and get it published" (T. 863).

Had Dr. Welch even appeared to <u>consider</u> viewpoints other than his own, as well as the documented chart evidence before drawing conclusions in his testimony, it would have added to his creditability.

The Petitioner also presented Pat Cooney, a Deputy Program Director for OPMC, who was highly credible and who testified about the selection of charts for review (T.1472-74).

The Respondent presented two expert witnesses. His first witness, Dr. Brain Fallon, a board certified psychiatrist with an interest in cognitive disorders in patients with Lyme Disease, who serves on the review board for the Journal of Spirochetal and Tick-Borne Diseases (T. 2577-79). He testified that he is currently involved in a \$4.7 million dollar grant from the NIH to study patients who have chronic Lyme disease and cognitive complaints that have been treated with long-term antibiotics (T. 2582).

Dr. Fallon testified in a straightforward manner. However, the Committee found that while his knowledge of SPECT scans was credible, and certainly within his specialty practice area, he was less reliable in his answers concerning other aspects of medical treatment of Lyme disease that were outside his specialty practice area.

The Respondent's second expert witness was Dr. Michael Cichon, who is board certified in internal medicine and infectious diseases. Although he has been involved in teaching medical students and fellows, Dr. Cichon has been primarily involved in private practice in Florida for twenty-five years (T. 2792).

Dr. Cichon testified that he has seen an increasing number of Lyme patients in his office practice, as many as 9 of the 33 patients he sees each day, many of which are winter residents of Florida who may have contracted Lyme elsewhere (T. 2791-2). The Committee found several aspects of his testimony disturbing: he did not appear to know much about the prevalence of Lyme in Florida, or proper reporting procedures to the Florida Health Department, or even the exact nature of his faculty appointment. Additionally, while less emphatic and dogmatic than Dr. Welch in presenting his view as to the proper treatment of chronic or recurrent Lyme, it was clear from his testimony that he follows the same approach as the Respondent, and considers him an expert in this area (T.3290).

The Respondent also presented Dr. Howard Sklarek, who has known the Respondent in a professional capacity for 15 years (T. 2462-3). He was a credible character witness, who testified that Respondent is a highly regarded physician in the community (T. 2463).

The Committee has had ample opportunity to assess the Respondent's demeanor and credibility, both over the course of this lengthy hearing (eighteen days over many months) and on his six days of testimony.

Dr. Burrascano exhibited a pleasant and even demeanor at all times, but he too had a viewpoint he was determined to present, and his answers to questions often seemed overprepared and lecture-like, complete with what appeared to be almost cross referenced chart and journal references. The Respondent has seen thousands of Lyme patients, and he appears convinced that his approach to the disease process is the correct one.

Two issues in particular were troubling to the Committee in assessing his credibility. One was the his testimony as to whether he was acting as a consultant or a primary care physician to certain patients – for example Patient D. The second area concerned his explanation of how he reviewed the extensive previous medical records of patients sent to him for Lyme evaluation, documenting in his charts various diagnoses and test results, without expressly stating the source of this knowledge. This could be misleading to subsequent treating physicians.

DETERMINATION OF THE HEARING COMMITTEE AS TO PENALTY

The Hearing Committee recognizes the existence of the current debate within the medical community over issues concerning management of patients with recurrent or long term Lyme disease. This appears to be a highly polarized and politicized conflict, as was demonstrated to this Committee by expert testimony from both sides, each supported by numerous medical journal articles, and each emphatic that the opposite position was clearly incorrect. It fact, it often appeared that the testimony was framed to espouse specific viewpoints, rather than directly answer questions posed. What clearly did emerge however, was that Respondent's approach, while certainly a minority viewpoint, is one that is shared

by many other physicians. We recognize that the practice of medicine may not always be an exact science, "issued guidelines" are not regulatory, and patient care is frequently individualized.

We are also acutely aware that it was not this Committee's role to resolve this medical debate, but rather to answer the questions raised in the Statement of Charges:

Did the Respondent act as a reasonably prudent physician in his care of Patients A through G or was his practice negligent or grossly negligent? Did he demonstrate an acceptable level of skill or knowledge to practice medicine or was he incompetent or grossly incompetent? Did he have a medically acceptable reason for every test and treatment he ordered? Did he practice medicine fraudulently by intentionally misrepresenting patient diagnoses and altering patient records? Did his records accurately reflect the care and treatment rendered to his patients?

This Committee carefully considered these questions in its lengthy deliberations, during which we reviewed all of the evidence presented in this matter over eighteen days of hearing. The Findings of Fact note many transcript cites, indicating our extensive review of the testimony, because given the conflicting testimony of the expert witnesses, we wanted to be satisfied that the Petitioner had met its burden of proving the allegations by a preponderance of the evidence. We conclude as follows:

With respect to negligence/gross negligence, the Petitioner did meet its burden of proving negligent conduct with respect to the treatment of Patient D, because of treatment for ehrlichiosis without sufficient evidence of the disease, and of Patient F, because of the problems with Bicillin and seizures in that patient.

With respect to incompetence/gross incompetence, the Petitioner failed to meet its burden of proving by a preponderance of the evidence that Respondent lacked the requisite skill or knowledge to practice medicine. The issues raised in this case pertained primarily to a medical debate in this field, rather than a demonstrated lack of competency by the Respondent.

With respect to a medically acceptable reason for every test or treatment, the Committee is fully satisfied that Respondent had an acceptable reason for his tests and treatment, with the exceptions noted above.

With respect to fraudulent practice or alteration of medical records with an intent to deceive, this Committee, while acknowledging Respondent did correct patient records in a less than satisfactory manner, is fully satisfied that Respondent had no fraudulent intent.

With respect to the accuracy of Respondent's records, the Committee finds that his records were, in fact, extremely thorough with regard to the medical care and treatment he rendered. We do note that a more definitive documentation of the Respondent's role as consultant, including the name and address of the referring physician, and documentation of the process of review of past medical records, including test results, would be an improvement over the Respondent's method of simply noting "here for Lyme disease consult/eval." Additionally the Respondent needs to change his method of correcting errors. Despite these flaws, however, the records do meet minimally acceptable standards and Petitioner simply did not meet its burden of proving the records inadequate.

The Hearing Committee has fully reviewed the full range of penalties available, from censure to **revocation**. It is our carefully considered decision that the Respondent should be suspended from the practice of medicine for six months, with the entire period of suspension stayed. During that period, the Respondent shall be on probation, under the supervision of a practice monitor, who is board certified in infectious diseases. It is our hope that the Respondent will use this time to clarify for himself, as well as his records, what his role in treating each patient is, whether it be as consultant or primary care physician; to carefully consider whether he has sufficient clinical evidence, as well as lab testing, to warrant treatment of a disease entity; and to review patients' responses to drug therapy.

ORDER

Based upon the foregoing, IT IS HEREBY ORDERED THAT:

- Respondent's license to practice medicine in the State of New York is hereby suspended for a period of six months, dating from the time of the service of this order, with the entire period of suspension stayed.
- During the period of suspension, Respondent shall be on probation, under the supervision of a practice monitor. The terms of probation are annexed hereto and made a part hereof.

Dated: New York, New York November \sim , 2001

BENJAMIN WAINFELD, M.D. Chairperson

NISHA K. SETHI, M.D. CAROLYN SNIPE

APPENDIX I

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NEW YORK STATE DEPARTMENT OF HEALTH STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT IN THE MATTER STATEMENT OF OF JOSEPH BURRASCANO, M.D. CHARGES

Joseph Burrascano, M.D., the Respondent, was authorized to practice medicine in New York State on or about April 3, 1981, by the issuance of license number 145623 by the New York State Education Department. Respondent is currently registered to practice medicine with the New York State Department of Education for the period of October 1999 through September 2001.

FACTUAL ALLEGATIONS

- A. Respondent provided care and treatment to Patient A from on or about February 11, 1992 through on or about April 27, 1998. (The names of patients are contained in the attached appendix.)
 - 1. Respondent failed to appropriately and thoroughly evaluate Patient A.
 - Respondent failed to adequately examine Patient A to determine if Patient A had conditions she reported including but not limited to Addison's disease and hypothyroidism.
 - 3. Respondent treated Patient A inappropriately in that he:
 - a. treated Patient A for Lyme disease without sufficient evidence that Patient A had Lyme disease.
 - b. prescribed parenteral antibiotics for Patient A.

- p.3
- maintained Patient A on antibiotic therapy for a prolonged period of time, with no abatement of symptoms.
- d. failed to follow-up appropriately on abnormal
 laboratory results and when Patient A developed
 adverse reactions to administered therapy.
- e. prescribed medications without medical necessity.
- f. failed to develop and carry out a logical treatment plan.
- 4. Respondent inappropriately ordered and/or performed laboratory JBL 919101 testing including but not limited to repeat Lyme serologies, Lyme urine antigen test, cellular immune function tests, T&B killer cell test and SPECT scan.
- Respondent failed to perform and/or note necessary diagnostic
 laboratory testing including but not limited to lumbar puncture,
 thyroid function tests, repeat blood cultures and, echocardiogram.
- 6. Respondent failed to refer Patient A to appropriate specialists for evaluation including but not limited to neurological evaluation and psychiatric evaluation.
- 7. Respondent failed to consult and follow-up appropriately with other treating physicians while adjusting medications for and treating Patient A.
- Respondent provided treatment and/or ordered testing for Patient
 A that he knew was not warranted.
- 9. Respondent failed to maintain records that accurately reflect the evaluation and treatment of Patient A.

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- Respondent provided care and treatment to Patient B from on or about
- January 17, 1994 through on or about July 5, 1996.
- Respondent failed to appropriately and thoroughly evaluate Patient B.
- 2. Respondent treated Patient B inappropriately in that he:
 - a. treated Patient B for Lyme disease without sufficient evidence that Patient B had Lyme disease.
 - b. prescribed medications without medical necessity.
 - maintained Patient B on broad spectrum antibiotic
 therapy and intramuscular injections, for an extended
 period of time, with no abatement of symptoms.
 - d. failed to develop and carry out a logical treatment plan.
- 3. Respondent inappropriately ordered and/or performed laboratory testing including but not limited to repeat Lyme serologies, Lyme urine antigen test and, SPECT scan.
- 4. Respondent failed to perform and/or note necessary diagnostic laboratory testing including but not limited to lumbar puncture.
- Respondent provided treatment and/or ordered testing for Patient
 B that he knew was not warranted.
- 6. Respondent failed to maintain records that accurately reflect the evaluation and treatment of Patient B.
- C. Respondent provided care and treatment to Patient C from July 19, 1995 through on or about February 20, 1998.

- p.5
- Respondent failed to appropriately and thoroughly evaluate Patient C.
- 2. Respondent treated Patient C inappropriately in that he:
 - a. treated Patient C for Lyme disease without sufficient evidence that Patient C had Lyme disease.
 - b. prescribed parenteral antibiotics for Patient C.
 - c. maintained Patient C on antibiotic therapy for a prolonged period of time, with no abatement of symptoms.
 - d. failed to follow-up appropriately when Patient C developed adverse reactions to administered therapy.
 - e. prescribed medications without medical necessity.
 - f. failed to develop and carry out a logical treatment plan.
- 3. Respondent inappropriately ordered and/or performed laboratory JBL 9/04/01 testing including but not limited to repeat Lyme serologies, Lyme urine antigen test, repeat blood levels for Ceftin and Doxycycline.
- 4. Respondent provided treatment and/or ordered testing for Patient C that he knew was not warranted.
- 5. Respondent failed to maintain records that accurately reflect the evaluation and treatment of Patient C.
- D. Respondent provided care and treatment to Patient D from on or about
 January 24, 1994 through on or about May 18, 1998.
 - 1. Respondent failed to appropriately and thoroughly evaluate

Patient D.

- 2. Respondent treated Patient D inappropriately in that he:
 - a. treated Patient D for Lyme disease without sufficient evidence that Patient D had Lyme disease.
 - b. treated Patient D for babesiosis and enrichiosis
 without clinical evidence that Patient D had those diseases.
 - c. prescribed parenteral therapy for Patient D.
 - maintained Patient D on antibiotic therapy for a prolonged period of time, with no abatement of symptoms.
 - e. prescribed multiple antibiotics and therapeutic agents for Patient D.
 - failed to follow-up appropriately when Patient D developed adverse reactions to administered therapy.
 - g. failed to develop and carry out a logical treatment plan.
- Respondent inappropriately ordered and/or performed laboratory
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 testing including but not limited to repeat Lyme serologies, Lyme
 urine antigen test, blood levels for Doxycycline and Ceftin,
 serologies for babesiosis and ehrlichiosis.
- Respondent failed to perform and/or note necessary diagnostic laboratory testing including but not limited to lumbar puncture, blood smears for babesiosis and ehrlichiosis and, serology for syphilis.
- 5. Respondent failed to perform an appropriate neurological

examination and/or failed to refer Patient D for neurological evaluation. 6. Respondent failed to refer Patient D for a psychiatric evaluation. 7. Respondent provided treatment and/or ordered testing for Patient D that he knew was not warranted. 8. Respondent failed to maintain records that accurately reflect the evaluation and treatment of Patient D. E. Respondent provided care and treatment to Patient E from on or about September 3, 1993 through on or about February 3, 1998. 1. Respondent failed to appropriately evaluate Patient E for babesiosis and ehrlichiosis. Respondent treated Patient E inappropriately in that he: 2. treated Patient E for Lyme disease with excessive а. and inappropriate medications. treated Patient E for babesiosis without clinical b. evidence that Patient E had babesiosis. maintained Patient E on antibiotic therapy for a C. prolonged period of time, with no abatement of symptoms. **d**. prescribed intramuscular vitamins and other medications without medical necessity. failed to develop and carry out a logical treatment e. plan. 3. Respondent inappropriately ordered and/or performed laboratory testing including but not limited to Amoxicillin levels. 6

- Respondent failed to perform and/or note necessary diagnostic laboratory testing including but not limited to blood smears, lumbar puncture and, vitamin B12 tests.
- Respondent provided treatment and/or ordered testing for Patient
 E that he knew was not warranted.
- 6. Respondent failed to maintain records that accurately reflect the evaluation and treatment of Patient E.
- F. Respondent provided care and treatment to Patient F from on or about December 12, 1996 through on or about 1998.
 - 1. Respondent failed to appropriately evaluate Patient F.
 - Respondent failed to refer Patient F for neurological evaluation and treatment.
 - 3. Respondent treated Patient F inappropriately in that he:
 - a. treated Patient F for Lyme disease with excessive medications.
 - b. treated Patient F for babesiosis without clinical evidence to indicate that Patient F had babesiosis.
 - c. maintained Patient F on antibiotic therapy for a prolonged period of time, without improvement of symptoms.
 - d. prescribed intramuscular and parenteral therapy for Patient F.
 - e. failed to develop and carry out a logical treatment plan.
 - 4. Respondent inappropriately ordered and/or performed laboratory testing algo glappi JBLincluding but not limited to multiple Lyme serologies, Lyme urine antiger test, serologies for babesiosis and ehrlichiosis and, SPECT scan.
 - 5. Respondent provided treatment and/or ordered testing for Patient F that he knew was not warranted.

- 6. Respondent failed to maintain records that accurately reflect the evaluation and treatment provided to Patient F.
- G. Respondent provided care and treatment to Patient G from on or about October 3, 1992 through on or about May 29, 1998.
 - 1. Respondent failed to appropriately evaluate Patient G for babesiosis.
 - 2. Respondent treated Patient G inappropriately in that he:
 - a. treated Patient G for babesiosis without clinical evidence that
 Patient G had babesiosis.
 - b. maintained Patient G on antibiotic therapy for a prolonged period of time, with no abatement of symptoms.
 - c. failed to follow-up appropriately when Patient G developed adverse reactions to administered therapy.
 - d. prescribed intramuscular and parenteral therapy for Patient G.
 - e. failed to develop and carry out a logical treatment plan.
 - 3. Respondent inappropriately ordered and/or performed laboratory testing including but not limited to Lyme urine antigen test, serologies for babesiosis and ehrlichiosis.
 - 4. Respondent failed to perform and/or note necessary diagnostic laboratory testing including but not limited to blood smears.
 - 5. Respondent failed to follow-up appropriately with Patient G's neurologist.
 - 6. Respondent knowingly, with intent to deceive, altered the record for Patient G on pages 9, 10 and 12.
 - 7. Respondent provided treatment and/or ordered testing for Patient G that he knew was not warranted.

8. Respondent failed to maintain records that accurately reflect the evaluation and treatment provided to Patient G. Respondent provided care and treatment to Patient H from on or about April H. 8,1993 through on or about December 3, 1996. 1. Respondent failed to appropriately and thoroughly evaluate Withdrawn Patient H. 2/28/04 2. Respondent failed to perform and/or note an appropriate JBL neurological examination. 3. Respondent treated Patient H inappropriately in that he: maintained Patient H on antibiotic therapy for a a. prolonged period of time, with no abatement of symptoms. b. prescribed medications without medical necessity. failed to develop and carry out a logical treatment C. plan. 4. Respondent inappropriately ordered and/or performed laboratory testing including but not limited to Lyme urine antigen test. 5. Respondent failed to perform and/or note necessary diagnostic laboratory testing included but not limited to lumbar puncture, cell count, protein level, sugar level, serology for syphilis and x-rays of joints. 6. Respondent provided treatment and/or ordered testing for Patient H that he knew was not warranted. 7. Respondent failed to maintain records that accurately reflect the evaluation and treatment provided to Patient H. 9

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Respondent provided care and treatment to Patient I from on or about March 17, 1993 through on or about June 1, 1998.

 Respondent failed to appropriately and thoroughly evaluate Patient I.

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- 2. Respondent treated Patient I inappropriately in that he:
 - a. treated Patient I for Lyme disease without sufficient evidence that Patient I had Lyme disease.
 - maintained Patient I on antibiotic therapy for a prolonged period of time, with no abatement of symptoms.
 - c. prescribed parenteral vitamin therapy and other medications without medical necessity.
 - d. failed to follow-up appropriately when Patient I developed adverse reactions to administered therapy.
 - e. failed to develop and carry out a logical treatment plan.
- 3. Respondent failed to perform and/or note an appropriate neurological examination and/or failed to refer Patient I for neurological evaluation.
- 4. Respondent inappropriately ordered and/or performed laboratory testing including but not limited to repeat Lyme serologies, Lyme urine antigen test and, serologies for babesiosis and ehrlichiosis.
- 5. Respondent provided treatment and/or ordered testing for Patient
 I that he knew was not warranted.

6. Respondent failed to maintain records that accurately reflect the

evaluation and treatment of Patient I.

SPECIFICATION OF CHARGES

FIRST SPECIFICATION

NEGLIGENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(3)(McKinney Supp. 2000) by practicing the profession of medicine with negligence on more than one occasion as alleged in the facts of two or more of the following:

Paragraph A and each of its subparagraphs and/or, B and each of its subparagraphs and/or, C and each of its subparagraphs and/or, D and each of its subparagraphs and/or, E and each of its subparagraphs and/or, F and each of its subparagraphs and/or, G and each of its subparagraphs and/or, H and each of its subparagraphs and/or, I and each of its subparagraphs. 2128 01 JS L

SECOND SPECIFICATION

INCOMPETENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(5)(McKinney Supp. 2000) by practicing the profession of medicine with incompetence on more than one occasion as alleged in the facts of two or more of the following:

2. Paragraph A and each of its subparagraphs and/or, B and each of its subparagraphs and/or, C and each of its subparagraphs and/or, D and each of its subparagraphs and/or, E and each of its subparagraphs

p.13

and/or, F and each of its subparagraphs and/or, G and each of its subparagraphs and/or, H and each of its subparagraphs and/or, H and each of its subparagraphs and/or, H and each of its subparagraphs.

THIRD THROUGH ELEVENTH SPECIFICATIONS

GROSS NEGLIGENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(4)(McKinney Supp. 2000) by practicing the profession of medicine with gross negligence as alleged in the facts of the following:

3. Paragraph A and each of its subparagraphs.

4. Paragraph B and each of its subparagraphs.

5. Paragraph C and each of its subparagraphs.

6. Paragraph D and each of its subparagraphs.

7. Paragraph E and each of its subparagraphs.

8. Paragraph F and each of its subparagraphs.

9. Paragraph G and each of its subparagraphs.

10. Paragraph H and each of its subparagraphs. 2/28/01 JBL

11- Paragraph I and each of its subparagraphs. 2/26 or J8 L

TWELFTH THROUGH TWENTIETH SPECIFICATIONS

GROSS INCOMPETENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(6)(McKinney Supp. 2000) by practicing the profession of medicine with gross incompetence as alleged in the facts of the following:

- 12. Paragraph A and each of its subparagraphs.
- 13. Paragraph B and each of its subparagraphs.

- 14. Paragraph C and each of its subparagraphs.
- 15. Paragraph D and each of its subparagraphs.
- 16. Paragraph E and each of its subparagraphs.
- 17. Paragraph F and each of its subparagraphs.
- 18. Paragraph G and each of its subparagraphs.
- 19 Paragraph H and each of its subparagraphe. 2 28/01 JBL

20. Paragraph I and each of its subparagraphs. 2/28/01 JBL

TWENTY-FIRST THROUGH TWENTY-NINTH SPECIFICATIONS UNWARRANTED TESTS/TREATMENT

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(35)(McKinney Supp. 2000) by ordering of excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient, as alleged in the facts of:

- 21. Paragraph A, A3 and each of its subparagraphs and, A4.
- 22. Paragraph B, B2 and each of its subparagraphs and, B3.
- 23. Paragraph C, C2 and each of its subparagraphs and, C3.
- 24. Paragraph D, D2 and each of its subparagraphs and, D3.
- 25. Paragraph E, E2 and each of its subparagraphs and, E3.
- 26. Paragraph F, F3 and each of its subparagraphs and, F4.
- 27. Paragraph G, G2 and each of its subparagraphs and, G3.
- 28. Paragraph H, H3 and each of its subparagraphs and, H4. 2128 0 JBC
- 29. Paragraph 1, 12 and each of its subparagraphs and, 14_ 2/28 (01 URL

THIRTIETH THROUGH THIRTY-EIGHTH SPECIFICATIONS

Respondent is charged with committing professional misconduct as defined by N.Y.

Educ. Law §6530(2)(McKinney Supp. 2000) by practicing the profession of medicine fraudulently as alleged in the facts of the following:

30. Paragraph A and A8.

31. Paragraph B and B5.

32. Paragraph C and C4.

33. Paragraph D and D7.

34. Paragraph E and E5.

35. Paragraph F and F5.

36. Paragraph G, G6 and G7.

37- Paragraph H and H6. 2/28/01 JBL

38. Paragraph | and 15. 2/28/01 JBL

THIRTY-NINTH SPECIFICATION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(32)(McKinney Supp. 2000) by failing to maintain a record for each patient which accurately reflects the care and treatment of the patient, as alleged in the facts of:

39. Paragraphs A and A9 and/or, B and B6 and/or, C and C5 and/or, D and D8 and/or, E and E6 and/or, F and F6 and/or, G and G8 and/or, H and H7 and/or, L and H6. 22801 JBL

DATED:

August 2 ♥ , 2000 New York, New York

ROY NEMERSON Deputy Counsel Bureau of Professional Medical Conduct

APPENDIX II

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TERMS OF PROBATION

- Respondent shall conduct himself/herself in all ways in a manner befitting his/her professional status, and shall conform fully to the moral and professional standards of conduct and obligations imposed by law and by his/her profession. Respondent acknowledges that if s/he commits professional misconduct as enumerated in New York State Education Law §6530 or §6531, those acts shall be deemed to be a violation of probation and that an action may be taken against Respondent's license pursuant to New York State Public Health Law §230(19).
- 2. Respondent shall submit written notification to the New York State Department of Health, addressed to the Director, Office of Professional Medical Conduct (OPMC), Hedley Park Place, 433 River Street Suite 303, Troy, New York 12180-2299; said notice is to include a full description of any employment and practice, professional and residential addresses and telephone numbers within or without New York State, and any and all investigations, charges, convictions or disciplinary actions by any local, state or federal agency, institution or facility, within thirty days of each action.
- 3. Respondent shall fully cooperate with and respond in a timely manner to requests from OPMC to provide written periodic verification of Respondent's compliance with the terms of this Order. Respondent shall personally meet with a person designated by the Director of OPMC as requested by the Director.
- 4. Any civil penalty not paid by the date prescribed herein shall be subject to all provisions of law relating to debt collection by New York State. This includes but is not limited to the imposition of interest, late payment charges and collection fees; referral to the New York State Department of Taxation and Finance for collection; and non-renewal of permits or licenses [Tax Law section 171(27)]; State Finance Law section 18; CPLR section 5001; Executive Law Section 32]
- 5. The period of probation shall be tolled during periods in which Respondent is not engaged in the active practice of medicine in New York State. Respondent shall notify the Director of OPMC, in writing, if Respondent is not currently engaged in or intends to leave the active practice of medicine in New York State for a period of thirty (30) consecutive days or more. Respondent shall then notify the Director again prior to any change in that status. The period of probation shall resume and any terms of probation which were not fulfilled shall be fulfilled upon Respondent's return to practice in New York State.
- 6. Respondent's professional performance may be reviewed by the Director of OPMC. This review may include, but shall not be limited to, a review of office records, patient records and/or hospital charts, interviews with or periodic visits with Respondent and his/her staff at practice locations or OPMC offices.
- 7. Respondent shall maintain legible and complete medical records that accurately reflect the evaluation and treatment of patients. The medical records shall contain all information required by State rules and regulations regarding controlled substances.
- 8. Respondent shall practice medicine only when monitored by a licensed physician board certified in infectious diseases ("practice monitor") proposed by Respondent and subject to the written approval of the Director of OPMC.

- 9. Respondent shall make available to the monitor any and all records or access to the practice requested by the monitor, including on-site observation. The practice monitor shall visit Respondent's medical practice at each and every location, on a random unannounced basis at least monthly and shall examine a selection of no less than five (5) records maintained by Respondent, including patient records, prescribing information and office records. The review will determine whether the Respondent's medical practice is conducted in accordance with the generally accepted standards of professional medical care. Any perceived deviation of accepted standards of medical care or refusal to cooperate with the monitor shall be reported within 24 hours to OPMC.
- 10. Respondent shall be solely responsible for all expenses associated with monitoring, including fees, if any, to the monitoring physician.
- 11. Respondent shall cause the practice monitor to report quarterly, in writing, to the Director of OPMC.
- 12. Respondent shall maintain medical malpractice insurance coverage with limits no less than \$2 million per occurrence and \$6 million per policy year, in accordance with Section 230(180(b) of the Public Health Law. Proof of coverage shall be submitted to the director of OPMC prior to Respondent's practice after the effective date of this Order.
- 13. Respondent shall comply with all terms, conditions, restrictions, limitations and penalties to which he or she is subject pursuant to the Order and shall assume and bear all costs related to compliance. Upon receipt of evidence of noncompliance with, or any violation of these terms, the Director of OPMC and/or the Board may initiate a violation of probation proceeding and/or any such other proceeding against Respondent as may be authorized pursuant to the law.