IN THE MATTER OF \* BEFORE THE MARYLAND

HOPE ALISON MCINTYRE, M.D. \* STATE BOARD

RESPONDENT \* OF PHYSICIANS

LICENSE NO.: D46096 \* CASE NO.: 2014-0735 B

\* \* \* \* \* \* \* \* \* \*

# **CONSENT ORDER**

On November 6, 2015, Disciplinary Panel B of the Maryland State Board of Physicians (the "Board") charged Hope Alison McIntyre, M.D. (the "Respondent"), License No. D46096, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occupations II ("Health Occ. II") §§14-401 et seq. (2014 Repl. Vol.).

The pertinent provisions of the Act under Health Occ. §14-404(a) provide as follows:

# §14-404. Denials, reprimands, probations, suspensions, and revocations—Grounds.

- (a) In general. Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:
- (22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State;
- (40) Fails to keep adequate medical records as determined by appropriate peer review[.]

On December 16, 2015, Disciplinary Panel B was convened as a Disciplinary Committee for Case Resolution ("DCCR") in this matter. Based on negotiations occurring as a result of the DCCR, Respondent agreed to enter into this Consent Order, consisting of Findings of Fact, Conclusions of Law, and Order.

### **FINDINGS OF FACT**

Disciplinary Panel B makes the following findings of fact:

# I. Background

- 1. At all times relevant hereto, Respondent was and is licensed to practice medicine in Maryland. Respondent was originally licensed to practice medicine in Maryland in 1994 under license number D46096. She has continuously renewed her license. Respondent last renewed her license in or around September 2015, which will expire on September 30, 2017.
- 2. Since 2010, Respondent has practiced family medicine as a solo practitioner, specializing in the treatment of Lyme and Tick-Bourne Diseases (TBDs) in adults and children, in Towson, Maryland.
- 3. Respondent was initially granted board-certification in Family Medicine by the American Board of Family Medicine on July 8, 1994. She was re-certified on July 14, 2000 and August 4, 2007, which will expire on December 31, 2017. Respondent does not hold a sub-specialty certification in infectious disease.

# II. Complaint

- 4. On March 24, 2014, the Board received a complaint from a health insurance company stating that Respondent may be inappropriately prescribing medication to a patient, Patient 4,<sup>1</sup> for the treatment of Lyme disease.<sup>2</sup>
- 5. On or about June 5, 2014, the Board received an amended complaint from the insurance company including Patient 4's name and medical records. The

<sup>&</sup>lt;sup>1</sup> Names of individuals and facilities are not used in this document in order to preserve confidentiality. Respondent has been provided with a Confidential Identification List with the names of the individuals and facilities and the corresponding identifier.

<sup>&</sup>lt;sup>2</sup> Lyme disease is an infectious disease caused by bacteria of the *Borrelia* type. The most common sign of infection is an expanding area of redness that begins at the site of a tick bite about a week after it has occurred. Other early symptoms may include fever, headache, and feeling tired. If untreated, symptoms may include loss of the ability to move one or both sides of the face, joint pains, severe headaches with neck stiffness, or heart palpitations. Months to years later, repeated episodes of joint pain and swelling may occur. Despite appropriate treatment, about 10 to 20% of people also develop joint pains, have memory problems, and feel tired much of the time.

insurance company reported the following:

- a. The insurance company's Medical Director reviewed available records and engaged in peer to peer review with Respondent regarding diagnosis and treatment of Patient 4.
- b. The Medical Director concluded that based on national guidelines on the treatment of Lyme disease, the medications prescribed by Respondent for this diagnosis do not fit evidence based recommendations for the treatment of Lyme disease. The Medical Director also concluded that there was no evidence to support the diagnosis of Babesiosis.<sup>3</sup>

# III. <u>Investigation</u>

- 6. In June 2014, the Board issued subpoenas for patient drug surveys to three national chain pharmacies in the vicinity of Respondent's practice.
- 7. On or around August 26, 2014, the Board issued a subpoena to Respondent for the medical records of six named patients, including the patient about whom the complaint was based, Patient 4. Respondent was also asked to submit written summaries of her care of each of the six patients.
- 8. On or around September 11, 2014, the Board sent the six medical records and summaries of care as received from Respondent to Permidion, to send to two physicians, both board-certified in Internal Medicine with subspecialty certification in Infectious Disease, to conduct an independent peer review of the six treatment records.
- 9. On or about February 11, 2015, the Board received the peer review reports. The peer reviewers concurred that with regard to the six patients reviewed, Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records with regard to all six patients.
- 10. On or about February 13, 2015, the Board sent copies of the peer review reports to Respondent with the names of the reviewers redacted, requesting a

<sup>&</sup>lt;sup>3</sup> Babesiosis is a disease caused by microscopic parasites that infect red blood cells and are spread by certain ticks. Many people infected with *Babesia microti* feel fine and do not have any symptoms. Some people develop flu-like symptoms, such as fever, chills, sweats, headache, body aches, loss of appetite, nausea, or fatigue.

Supplemental Response.

- 11. On or about March 4, 2015, the Board received Respondent's Supplemental Response which was subsequently reviewed by the two peer reviewers, prior to the issuance of Charges.
- 12. In response to the Peer Review Reports, Respondent presented introductory remarks prior to remarking on each individual patient. In her remarks, Respondent stated that she does not rely on only one set of guidelines in treating her patients with Lyme disease. She noted that she finds the Infectious Disease Society of America ("IDSA") recommendations helpful but she also relies on the International Lyme and Associated Diseases Society ("ILADS") guidelines. Respondent also referenced as a resource, "Advanced Topics in Lyme Disease" by Joseph J. Burrascano, Jr., M.D., a board member of ILADS. Respondent noted that she has completed two ILADS training preceptorships in 2006 and 2010. In 2014, Respondent gave a presentation at the ILADS conference entitled "Multi-Drug Combination Therapy for Babesiosis: a Study of 56 Patients." Respondent stated that the diagnosis of Lyme disease and the diagnosis of Babesiosis, the most common co-infection of Lyme disease, are made clinically; therefore, she considers chronic antibiotic treatment with probiotics in patients with persistent symptoms.

# IV. General Allegations of Violation of Health Occ. § 14-404(a)(22) & (40)

- 13. According to the two independent peer reviewers, Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patients 1 through 6 in that she:
  - a. Failed to provide clinical and/or laboratory justification for the intermittent diagnoses of Lyme, Bartonella, or Babesia;
  - b. Failed to adequately document objective assessments, including physical examinations and laboratory findings that would provide a rationale for, or

- support the treatment plan of antibiotics for Lyme, Bartonella or Babesia for prolonged periods of time;
- c. Failed to document a rationale for her periodic changes in diagnoses;
- d. Failed to document a rationale for the selection of, frequent changes in, and duration of antibiotic medications she prescribed;
- e. Failed to justify pursing treatment with antibiotics for a duration despite the lack of effectiveness of such treatment;
- f. Performed repetitive laboratory assessments; and
- g. Failed to obtain meaningful informed consent in that the information presented in the consent form is confusing, misleading, omits discussion of certain risks, and biased toward ILADS guidelines.

# V. Patient Specific Findings under Health Occ. § 14-404(a) (22) & (40)

#### Patient 1

14. On or about May 28, 2013, Patient 1, then a 49 year old female, presented for the first time to Respondent. According to Respondent's case summary which Respondent prepared after she was notified that she was under investigation:

- a. Patient 1's symptoms include recurrent yeast infections, abdominal pain, urinary frequency, insomnia, rib pain, knee pain and swelling, proximal interphalangeal (PIP) joint swelling and pain, air hunger, trouble thinking, and swollen hands in the morning.
- a. Patient 1 has had symptoms for 10 years and had some improvement with previous Lyme disease treatment but has never been treated for Babesiosis as she was allergic to Mepron<sup>4</sup>—"the drug choice for Babesiosis."
- c. Patient 1 has a history of significant hypothyroidism, endometrial ablation in 2009, significant Lumbar spine infusion in July of 2012, and gastritis in April 2013.
- d. Respondent "suspected Babesiosis due to [Patient 1's] symptoms and previous testing."
- 15. Patient 1 completed a two-page symptom check list and a multiple page

<sup>4</sup> Mepron (atovaquone) is a quinone antimicrobial drug for oral administration and is used to treat pneumocystis pneumonia and toxoplasmosis. Mepron is also used in cases where patients are allergic to other medications or when other therapies have been ineffective.

medical history. Respondent documented Patient 1's medical history on a "Lyme Treatment Flow sheet," on the medical history form that was completed by Patient 1, and in a clinical note. Respondent documented a physical examination on the medical history form that was completed by Patient 1 and also on a separate "Physical Examination" form. On the initial visit, Respondent did not document a diagnosis or assessment, although Respondent noted "cc" (chief complaint) as "Babesiosis and Lyme disease."

- 16. On May 28, 2013, Patient 1 signed an "Informed Consent for Treatment of Persistent Lyme Disease" form and an "Informed Consent for Coartem<sup>6</sup> Therapy for Babesiosis" form.
- 17. Respondent prescribed Diflucan<sup>7</sup> (200 mg/daily) for 14 days for oral thrush and Omeprazole<sup>8</sup> (20 mg/twice daily) for Patient 1's stomach. Respondent also prescribed Coartemand Doxycycline.<sup>9</sup>
- 18. On June 24, 2013, Respondent assessed Babesiosis. Respondent prescribed Doxycycline (150 mg/twice daily), Artemether/Lumefantrine<sup>10</sup> (Coartem) (2

<sup>&</sup>lt;sup>5</sup> Respondent uses the same or similar forms for all of the patients reviewed.

<sup>&</sup>lt;sup>6</sup> Coartem contains a combination of artemether and lumefantrine. Artemether and lumefantrine are anti-malaria medications that interfere with the growth of parasites in the red blood cells of the human body. Malaria is caused by parasites that enter the body through the bite of a mosquito.

<sup>&</sup>lt;sup>7</sup> Diflucan (fluconazole) is an antifungal medicine used to treat a variety of fungal and yeast infections.

<sup>&</sup>lt;sup>8</sup> Omeprazole is a proton pump inhibitor used to decrease the amount of acid produced in the stomach.

<sup>&</sup>lt;sup>9</sup> Doxycycline is used to treat bacterial infections, including pneumonia and other respiratory tract infections; Lyme disease; acne; infections of skin, genital, and urinary systems; and anthrax (after inhalational exposure). It is also used to prevent malaria. Doxycycline is in a class of medications called tetracycline antibiotics. It works by preventing the growth and spread of bacteria. Antibiotics will not work for colds, flu, or other viral infections

<sup>&</sup>lt;sup>10</sup> The combination of artemether and lumefantrine is Coartem, an anti-malarial agent that is used to treat certain kinds of malaria infections.

tabs/twice daily). Respondent also prescribed Levothyroxine<sup>11</sup> (75mg) and Clotrimazole<sup>12</sup> (Dissolve 1 in mouth 5 x's/day for 30 days).

- 19. On August 5, 2013, Respondent assessed Babesiosis. Respondent documented that Patient 1 had two episodes of vertigo over the previous week, but improvement in energy. Respondent instructed Patient 1 to continue Clotrimazole (2x/day as needed) and Doxycycline (150)mg/twice daily). increase Artemether/Lumefantrine (Coartem) (3 tabs/twice daily), and add Meclizine<sup>13</sup> (150mg/twice daily).
- 20. On September 12, 2013, Respondent assessed Lyme disease and Babesiosis. Respondent instructed Patient 1 to continue Doxycycline (150 mg/twice daily), increase Artemether/Lumefantrine (Coartem) (4 tabs/twice daily), and start Zolpidem<sup>14</sup> (10 mg).
- 21. On October 7, 2013, Patient 1 presented with nausea and stomach pains. Respondent assessed only Lyme disease. Respondent documented that Patient 1 was "out on FMLA for depression," seen in Emergency Room (ER) on September 18, 2013 for chest pains. Respondent documented that Patient 1's pain level had improved from prior 6-9/10 to current 4/10. Respondent instructed Patient 1 to continue Omeprazole (20mg/twice daily) for one month and liver supplements, to stop Doxycycline, to take Artemether/Lumefantrine (Coartem) alone for 5 days (4 tabs/twice daily), and to add Minocycline 15 (50 mg/twice daily for two weeks).

<sup>&</sup>lt;sup>11</sup> Levothyroxine is used to treat low thyroid activity and to treat or suppress different types of goiters.

<sup>&</sup>lt;sup>12</sup> Clotrimazole is an antifungal medicine used to treat a variety of fungal and yeast infections.

<sup>&</sup>lt;sup>13</sup> Meclizine is an antihistamine used to treat motion sickness and vertigo.

<sup>&</sup>lt;sup>14</sup> Zolpidem (Ambien) is a sedative often used to treat insomnia.

<sup>&</sup>lt;sup>15</sup> Minocycline is a broad-spectrum tetracycline antibiotic and is used to treat infections such as urinary tract infections, acne and chlamydia.

- 22. On November 5, 2013, Respondent documented that Patient 1 did not respond to the Babesia treatment and assessed Patient 1 with Lyme disease and GERD (gatroesophageal reflux disease). Respondent changed Patient 1's medications to Amoxicillin, <sup>16</sup> Azithromycin, <sup>17</sup> and Probenecid. <sup>18</sup>
- 23. On November 14, 2013, Patient 1 called Respondent stating that she still has problems with yeast and wanted to wait a week or two before starting new medications because she was still having nausea and stomach pain. Respondent recommended Diflucan 200 mg. daily.
- 24. Patient 1 did not return to Respondent's office following the November 5, 2013 visit.
- 25. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to maintain adequate medical records in regard to her care and treatment of Patient 1 for reasons including but not limited to that she:
  - a. Diagnosed Babesiosis without sufficient laboratory or clinical evidence of the disease, and without a rationale clearly stated in the record;
  - b. Failed to document rationale for the selection of, frequent changes in, and duration of antibiotic medications she prescribed;
  - c. Treated Patient 1 with Coartem for six months although Respondent's consent form states that Patient 1 should expect only 6 to 12 weeks treatment; and
  - d. Failed to obtain meaningful informed consent in that the information presented in the consent form confusing, misleading, omits discussion of certain risks, and biased toward ILADS guidelines.

26. On or about May 18, 2010, Patient 2 presented for the first time to

<sup>&</sup>lt;sup>16</sup> Amoxicillin is an antibiotic used to treat a variety of bacterial infections.

<sup>&</sup>lt;sup>17</sup> Azithromycin is an antibiotic used to treat a variety of bacterial infections.

<sup>&</sup>lt;sup>18</sup> Probenecid is a uricosuric drug used to treat chronic gout and gouty arthritis.

Respondent. According to Respondent's case summary:

- a. Patient 2, then a 41 year old female, initially complained of muscle stiffness and pain, joint pain in back, hips and shoulders, trouble thinking, Achilles tendonitis, and fatigue worsening for 12 years. Respondent found a multinodular goiter on Patient 2.
- b. Patient 2 had a history significant for recurrent sinusitis, allergic rhinitis, hypercholesterolemia, Psoriasis, and GERD.
- c. Patient 2 had a positive Lyme disease test at Labcorp on August 29, 2009, and reported improving with antibiotics.
- 27. Respondent diagnosed Patient 2 with "Lyme [disease] by positive testing, positive exposure, symptoms, and response to treatment. Respondent also diagnosed Patient 2 with Bartonella<sup>19</sup> by symptoms.
- 28. On May 18, 2010, Patient 2 signed Respondent's "Informed Consent for Treatment of Persistent Lyme Disease" form.
- 29. Respondent instructed Patient 2 to continue Minocycline (100 mg/twice a day), add Bactrim DS<sup>20</sup> (one tablet/twice a day), and after two weeks, stop Bactrim DS "if things are going well," and add Flagyl<sup>21</sup> (375 mg/once a day).
- 30. On June 17, 2010, Patient 2 presented with a rash from the Bactrim, worsened Psoriasis, joint, muscle, back and knee pain, and worsening Lyme disease symptoms. Respondent assessed Lyme disease "worsening symptoms off Ceftin" and thyroid nodule. Respondent dropped the diagnosis of Bartonella. Respondent instructed Patient 2 to alternate Flagyl (375 mg/3 times a day) and Minocycline (100 mg/twice a day) one week on and one week off, and add Ceftin<sup>22</sup> (500 mg/twice a day).

<sup>&</sup>lt;sup>19</sup> Bartonella bacteria cause several diseases in humans. The three most common are cat scratch disease (B. henselae), trench fever (B. Quintana), and Carrion's disease (B. bacilliformis), which is diagnosed with a combination of symptoms and laboratory tests, such as peripheral smears and polymerase chain reactions (PCR).

<sup>&</sup>lt;sup>20</sup> Bactrim DS is a synthetic antibacterial combination used to treat bacterial infections.

<sup>&</sup>lt;sup>21</sup> Flagyl (metronidazole) is an antibiotic used to treat certain parasitic and bacterial infections.

<sup>&</sup>lt;sup>22</sup> Ceftin (Cefuroxime Axetil) is an antibiotic used to treat a variety of bacterial infections.

- 31. On August 12, 2010, Respondent assessed Lyme disease. Respondent instructed Patient 2 to continue medication as previously instructed: Ceftin (500 mg/twice a day) and alternating Flagyl (375 mg/3 times a day) and Minocycline (100 mg/twice a day) one week on and one week off.
- 32. On November 2, 2010, Respondent assessed Lyme disease. Respondent instructed Patient 2 to stop Ceftin and Flagyl, continue Minocycline (100 mg/twice a day), and add Rifampin<sup>23</sup> (300 mg/once per day). Respondent instructed Patient 2 to increase Rifampin to twice a day if doing better after one month.
- 33. On January 4, 2011, Respondent diagnosed Patient 2 with Lyme disease and added the diagnosis of Bartonella. Respondent instructed Patient 2 to continue Minocycline (100 mg/twice a day) and Rifampin (300 mg/once per day) and "actually try Doxy[cycline]" (100 mg/twice a day).
- 34. In 2011, Respondent saw Patient 2 for five additional visits, approximately every other month. On each of these additional visits, Respondent diagnosed Patient 2 with Lyme disease, again dropping the diagnosis of Bartonella after the January 4, 2011 visit. Respondent did not explain the status of, treatment of, or possible resolution of the previously diagnosed Bartonella infection.
- 35. In 2012, Respondent saw Patient 2 for five visits, approximately every other month and continued to prescribe antibiotics. On February 7, 2012, Respondent diagnosed Lyme disease. On April 3, 2012, Respondent diagnosed Lyme disease and Bartonella "by symptoms." On June 7, 2012, Respondent diagnosed Lyme disease and Bartonella. On August 7, 2012, Respondent diagnosed Lyme disease only. On October 9, 2012, Respondent diagnosed Lyme disease only.
  - 36. On February 28, 2013, Respondent assessed "Babesia duncani."

<sup>&</sup>lt;sup>23</sup> Rifampin is an antibiotic used to treat bacterial infections.

Respondent initiated a "Coartem Protocol" consisting of Doxycycline DR 150 mg. 1 tablet twice a day and Coartem 2 tabs 2 times a day for 6 days and repeat for 7 days. Respondent mailed to Patient 2 an "Informed Consent for Coartem Therapy for Babesiosis" form.<sup>24</sup>

- 37. In 2013, Respondent saw Patient 2 for seven additional visits and continued to prescribe Coartem and antibiotics.
- 38. In 2014, Respondent saw Patient 2 for two visits and continued to prescribe Coartem and antibiotics.
- 39. On February 24, 2014, Patient 2 signed an "Informed Consent for Coartem Therapy for Babesiosis" form.
- 40. Respondent last saw Patient 2 on April 17, 2014. Respondent prescribed Coartem. Respondent scheduled Patient 2 for follow-up in June 2014 but Patient 2 did not return.
- 41. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patient 2 for reasons including but not limited to that she:
  - a. Failed to provide a rationale based on clinical and/or laboratory justification for the intermittent diagnosis and treatment of Bartonella infection:
  - b. Failed to provide a rationale based on clinical and/or laboratory justification for diagnosis of Lyme disease;
  - Failed to adequately document objective assessments, including physical examinations and laboratory findings that would provide the rationale for, or support the treatment plan of antibiotics for Bartonella and Lyme disease;
  - d. Failed to document a rationale for the selection of, frequent changes in, and duration of antibiotic medications she prescribed;

<sup>&</sup>lt;sup>24</sup> Patient 2 did not sign the form until February 24, 2014.

- e. Treated Patient 2 with Coartem for over a year although Respondent's consent form states that Patient 2 should expect only 6 to 12 weeks treatment; and
- f. Failed to obtain meaningful informed consent in that the information presented in the consent form is confusing, misleading, omits discussion of certain risks, and biased toward ILADS guidelines.

- 42. On or about February 4, 2010, Patient 3, then a 36 year old female, presented for the first time to Respondent. Patient 3 had been seen in 2008 and 2009 by another physician in Respondent's office. According to Respondent's case summary:
  - a. Patient 3 presented with a history of Lyme disease diagnosed in 2002, persistent joint pain and fatigue. In 2008, Patient 3 was diagnosed with rheumatoid arthritis (RA) and Sjogren's disease.<sup>25</sup>
  - b. Patient 3 complained of joint pains, fatigue, dry mouth, low grade fever, and neck stiffness.
- 43. Previously, on August 26, 2008, Patient 3 signed an "Informed Consent for Treatment of Persistent Lyme Disease" form.<sup>26</sup>
- 44. Respondent diagnosed Patient 3 with "Lyme disease by symptoms and testing (in 2008) with resultant Sjogren's ? (possibly)" (possible) RA." Patient 3 had been treated by a rheumatologist with prednisone. Respondent treated Patient 3 with Mepron, Azithromycin, and Plaquenil.<sup>27</sup>
- 45. On April 1, 2010, Respondent diagnosed Patient 3 with Lyme, Bartonella "by symptoms." Respondent documented that Mepron made Patient 3 sick.

  Respondent treated Patient 3 with Azithromycin, Plaquenil, and Bactrim DS.

<sup>&</sup>lt;sup>25</sup> Sjogren's disease is an immune system disorder characterized by fatigue and joint pain as well as dry eyes and dry mouth.

<sup>&</sup>lt;sup>26</sup> The informed consent form is identical to the informed consent for form that Respondent uses.

<sup>&</sup>lt;sup>27</sup> Plaquenil (Hydroxychloroquine) is used to treat or prevent malaria and the symptoms of rheumatoid arthritis.

- 46. On May 24, 2010, Respondent assessed "Lyme disease, RA, severe fatigue suspect chronic EBV<sup>28</sup> infection." Respondent prescribed antibiotics and Plaquenil. Respondent documented that Patient 3 should make an appointment with a rheumatologist and provided a name and number.
- 47. On July 29, 2010, Respondent assessed "Lyme and Reactivated mono." Respondent prescribed Synthyroid and changed antibiotics.
- 48. On September 21, 2010, Respondent assessed "RA/Sjogrens, ? (possibly) Lyme induced." Respondent prescribed antibiotics, Celebrex, and began treatment with Coartem.
- 49. On November 9, 2010, Respondent assessed "RA, Lyme disease and ? (possibly) Babesia (has night sweats.)"
  - 50. On December 13, 2010, Respondent assessed Lyme disease and RA.
- 51. In March 2011, Respondent recommended that Patient 3 see a different rheumatologist for "disease modifiers."
- 52. In May 2011, Respondent documented that Patient 3 had seen the rheumatologist who informed Patient 3 that she did not have Lyme disease and recommended Arava.<sup>29</sup> Respondent assessed Lyme and possible Babesia. Respondent prescribed antibiotics, Plaquenil and Lortab.
  - 53. Respondent saw Patient 3 in June, July and August, 2011.
- 54. In September 2011, started treatment with Coartem and recommended Patient 3 return to her rheumatologist for "disease modifiers for RA."

<sup>&</sup>lt;sup>28</sup> Epstein-Barr Virus (EBV), also called human herpes virus 4 (HHV-4), is one of eight viruses in the herpes family, and is one of the most common viruses in humans. It is best known as the cause of infectious mononucleosis (glandular fever)

<sup>&</sup>lt;sup>29</sup> Arava is a medication for rheumatoid arthritis.

- 55. From 2011 to June 2014, Respondent saw Patient 3 five to eight times per year and continued to treat Patient 3 with various antibiotics, Paquenil, Prednisone, and supplements for RA, Lyme disease, Bartonella, chronic EBV, and Babesia.
- 56. In May 2013, Respondent initiated Coartem treatment which Respondent continued to prescribed intermittently.
- 57. Patient 3's last visit with Respondent, prior to Respondent providing Patient 3's medical records to the Board, was on June 26, 2014.
- 58. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patient 3 for reasons including but not limited to that she:
  - a. Failed to provide clinical and/or laboratory justification for diagnosis of Lyme disease, Bartonella, chronic EBV, and Babesia;
  - b. Failed to document a rationale for the selection of, frequent changes in, and duration of antibiotic medications she prescribed;
  - c. Failed to provide a rationale for pursing treatment with antibiotics for over four years despite the lack of effectiveness of such treatment;
  - d. Failed to adequately document objective assessments, including physical examinations and laboratory findings that would provide the rationale for or support the prolonged treatment plan of antibiotics for Lyme disease, Bartonella, chronic EBV, and Babesiosis; and
  - e. Failed to obtain meaningful informed consent in that the information presented in the form is confusing, misleading, omits discussion of certain risks, and biased toward ILADS guidelines.

- 59. On or about March 22, 2012, Respondent saw Patient 4, a 42 year old male, for the first time. According to Respondent's case summary:
  - Patient 4 presented with a history of back surgery in 2007 and 2008 and chronic back pain. Patient 4 has a history of hypercholesterolemia and GERD.
  - b. Patient 4 was hospitalized in 2005 for an insect bite accompanied with high fever and neutropenia, which resolved with IV antibiotics. In 2010,

Patient 4 was treated for another insect bite, which was also resolved with IV antibiotics.

- c. Previously, in September 2011, Patient 4 began having severe tremors of his legs and left arm, with severe fatigue sweats, short- term memory loss, orthostatic hypotension, daily headaches, sound sensitivity, electrical shock-like pains, anxiety, reddish discoloration of hands and feet, hips, ankles and hands.
- 60. Respondent assessed Patient 4 with Lyme disease, Bartonella, Babesia, and Ehrlichia.<sup>30</sup> Respondent treated Patient 4 with Minocycline and Levofloxacin.<sup>31</sup>
- 61. On March 22, 2012, Patient 4 signed an "Informed Consent for Treatment of Persistent Lyme Disease" form.
- 62. In 2012, Respondent saw Patient 4 for seven additional visits, approximately every month. On April 23, 2012, Respondent assessed Lyme disease and Bartonella by symptoms. On May 24, 2012, Respondent assessed Lyme disease, insomnia, and Bartonella. On July 5, 2012, Respondent assessed Lyme disease and Bartonella. Respondent added Babesia (by symptoms) as another assessment. On August 28, and September 27, 2012 Respondent assessed only Lyme disease. On October 23, 2012, Respondent assessed Lyme disease and Bartonella. On December 6, 2012, Respondent assessed Lyme disease and Babesia by symptoms. Respondent initiated treatment with Doxycycline plus Coartem. Respondent did not document an explanation for her periodic changes in diagnoses from intermittently adding then dropping Babesia, Bartonella and Ehrlichia without documenting whether the prior diagnosis was ongoing or resolved.
- 63. On February 14, 2013, Patient 4 signed an "Informed Consent for Coartem Therapy for Babesiosis" form.

<sup>&</sup>lt;sup>30</sup> Ehrlichia is a genus of *rickettsiales* bacteria. They are transmitted by ticks. Several species can cause infection (Ehrlichiosis) in humans

<sup>&</sup>lt;sup>31</sup> Levofloxacin is a quinolone antibiotic that treats infections and is given to people who have been exposed to anthrax.

- 64. From 2013 to August 2014, Respondent saw Patient 4 for nine to eleven visits per year and continued to treat Patient 4 with various antibiotics and Coartem for Lyme disease, Bartonella, and Babesia infection.
- 65. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patient 4 for reasons including but not limited to that she:
  - a. Failed to provide clinical and/or laboratory justification for the intermittent diagnoses of Lyme, Bartonella, chronic EBV, and Babesia;
  - b. Failed to adequately document objective assessments, including physical examinations and laboratory findings that would provide a rationale for, or support the treatment plan of antibiotics for Babesiosis, Bartonella and Lyme disease for prolonged periods of time;
  - c. Failed to document a rationale for her periodic changes in diagnoses;
  - d. Failed to provide rationale for frequent changes in medications prescribed;
  - e. Failed to justify pursing treatment with antibiotics for over two years despite the lack of effectiveness of such treatment; and
  - f. Failed to obtain meaningful informed consent in that the information presented in the consent form is confusing, misleading, omits discussion of certain risks, and biased toward ILADS guidelines.

- 66. On or about August 8, 2011, Respondent saw Patient 5, then a 44 year old female, for the first time for "Lyme consult." According to Respondent's case summary:
  - a. Patient 5 presented with a past medical history of significant breast cancer and mastectomy in 2004 and a thyroid nodule.
  - b. Patient 5 had a tick bite with a rash, hair loss and respiratory illness that was treated with Doxycycline in 2009.
  - c. Patient 5 had another tick bite in May of 2011, after which she developed a fever and a rash. Doxycycline was not helpful.
  - d. Patient 5 complained of a headache, shaking sensation, fatigue, hair loss, and tachycardia.

- 67. Respondent assessed Patient 5 with "suspected" Bartonella with Lyme and possible Babesia due to respiratory illness and hot flashes.
  - 68. Respondent prescribed Doxycycline, Levaquin, and Doryx. 32
- 69. On August 8, 2011, Patient 5 signed an "Informed Consent for Treatment of Persistent Lyme Disease" form and an "Intravenous Treatment Consent Form."
- 70. On September 22, 2011, Respondent assessed Lyme and Bartonella by symptoms. Respondent dropped the diagnosis of Babesia. Respondent prescribed Rifampin, Bactrim DS, and Cipro 250 mg.
- 71. On October 27, 2011, Respondent assessed Lyme and "Bartonella by symptoms." Respondent prescribed Diflucan, Terazol cream, Ambien, Zithromax, Doryx, and Rifampin.
- 72. On December 8, 2011, Respondent assessed Lyme disease and chronic sinusitis. Respondent dropped the diagnosis of Bartonella. Respondent instructed Patient 5 to stop Rifampin and Zithromax. Respondent prescribed Doryx and Cipro.
- 73. From January 2012 to July 2014, Respondent saw Patient 5 six to ten times per year and continued to treat Patient 5 with various antibiotics for Lyme disease. Respondent recommended probiotics. On some visits, but not all, Respondent added the assessments of Bartonella and Babesia infection.
- 74. On January 29, 2013, Respondent initiated Coartem and Doxycycline treatment. After March 4, 2013, Respondent discontinued the assessment of Lyme and solely assessed Babesia Duncani. Respondent added Malarone<sup>33</sup> 250/100, as well as antibiotics and stopped other medications. On December 12, 2013, Respondent added

<sup>&</sup>lt;sup>32</sup> Doryx is an antibiotic used to treat various infections and anthrax after possible exposure.

<sup>&</sup>lt;sup>33</sup> Malarone (atovaquone and proguanil) is an antiprotozoal and antimalarial and is used to treat or prevent malaria.

the assessment of Lyme, discontinued it on January 13, 2014, and then added it again on April 14, 2014. On May 12, 2014, Respondent dropped the assessment of Lyme, continued the assessment of Babesia, and added "chronic pain syndrome – nerve pain/pulsing sensation."

- 75. On January 29, 2013, Patient 5 signed an "Informed Consent for Coartem Therapy for Babesios" form.
- 76. On July 29, 2014, Patient 5's last visit prior to Respondent submitting Patient 5's medical records to the Board, Respondent assessed Lyme disease and Babesiosis. Respondent recommended a trial off medications and if symptoms returned, to resume Coartem and Primaquine.<sup>34</sup>
- 77. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patient 5 for reasons including but not limited to that she:
  - a. Failed to consider alternative diagnoses such as chronic fatigue syndrome, fibromyalgia, depression and anxiety;
  - b. Failed to provide clinical and/or laboratory justification for the intermittent diagnoses of Lyme, Bartonella, chronic EBV, and Babesia;
  - c. Failed to document a rationale for periodic changes in diagnoses;
  - Failed to provide rationale for treatment with antibiotics in spite of negative or inconclusive tests, and frequent changes in medications prescribed;
  - e. Failed to justify pursing treatment with antibiotics for over four years despite the lack of effectiveness of such treatment;
  - f. Treated Patient 5 for Babesiosis with Coartem for ten months although Respondent's consent form states that Patient 5 should expect only 6 to 12 weeks treatment; and
  - g. Failed to obtain meaningful informed consent in that the information presented in the consent form is confusing, misleading, omits certain risks, and biased toward ILADS guidelines.

<sup>&</sup>lt;sup>34</sup> Primaquine is a medication used in the treatment of malaria and Pneumocystis pneumonia.

- 78. On October 22, 2013, Patient 6, then a 20 year old male, presented to Respondent for "Lyme's symtoms." According to Respondent's case summary:
  - a. Patient 6's symptoms include anxiety, insomnia, inability to concentrate, headache, and depression.
  - b. Patient 6 has a history of anxiety, insomnia, headaches, and "brain fog" as a teenager. He has a history of Lyme disease as a child. When Patient 6 was 6 years old, a tick was found imbedded, then he developed a rash 2 weeks later with a positive test one month later.
  - c. Patient 6's depression and insomnia were being treated with Sertraline<sup>35</sup> (50 mg) and Zolpidem<sup>36</sup> (10 mg hs) by another provider but Patient 6 reported not taking the medications consistently.
- 79. Respondent did not document an assessment or diagnosis on the initial visit. Respondent instructed Patient 6 to take Sertraline as prescribed and started Patient 6 on Amoxicillin (875 mg/twice a day), Azithromycin (1/2 tablet daily), and Ambien (10 mg/as needed).
- 80. On October 22, 2103, Patient 6 signed an "Informed Consent for Treatment of Persistent Lyme Disease" form.
- 81. On November 26, 2013, Respondent documented Patient 6 as less anxious and able to think slightly more clearly. Respondent assessed Lyme disease. Respondent instructed Patient 6 to continue Amoxicillin, Azithromycin, and Ambien, and added Probenecid (500 mg/twice daily).
- 82. On December 30, 2013, Respondent documented that Patient 6 had itchy red spots on arms and legs after only 3 days on the Probenecid. Patient 6 reported that "brain fog" was 75% better, but he still experienced disrupted sleep. Patient 6 stopped Sertraline on his own decision. Respondent instructed Patient 6 to add Lexapro 10 mg

<sup>&</sup>lt;sup>35</sup>Sertraline (Zoloft) is an antidepressant of the selective serotonin reuptake inhibitor (SSRI) class.

<sup>&</sup>lt;sup>36</sup>Zolpidem (Ambien) is a sedative used for the short-term treatment of insomnia by helping the person to fall asleep.

(1/2 tab/day for 8 days, then 1 tab/day), increase Amoxicillin to (2 tabs/day), and continue Azithromycin and Ambien. Patient 6 stopped the Lexapro on his own decision.

- 83. On January 28, 2014, Respondent diagnosed Patient 6 with Lyme disease and depression. Respondent instructed Patient 6 to add Wellbutrin XL (150mg/once per day for a week, then twice per day) and Mepron (1 teaspoon/twice a day) after 10 days, and continue Amoxicillin, Azithromycin, and Ambien. Patient 6 stopped taking Lexapro because he felt "too flat" and sleepy.
- 84. On March 31, 2014, Patient 6's mother called to cancel his follow-up appointment which had been scheduled for April 1, 2014.
- 85. Respondent failed to meet appropriate standards for the delivery of quality medical care and failed to keep adequate medical records in regard to her care and treatment of Patient 6 for reasons including but not limited to that she:
  - a. Failed to provide clinical and/or laboratory justification for the diagnosis of Lyme disease;
  - b. Failed to provide rationale for frequent changes in medications prescribed;
  - c. Failed to document the indication for treating Patient 6 with Mepron (Atovaquone) in the absence of a diagnosis of Babesiosis;
  - Failed to consider alternative causes of Patient 6's symptoms of anxiety, insomnia, headache, depression after Patient 6 did not respond to antibiotics; and
  - e. Failed to obtain meaningful informed consent in that the information presented in the consent form is confusing, misleading, omits certain risks, and is biased toward ILADS guidelines.

#### **CONCLUSIONS OF LAW**

Based on the foregoing Findings of Fact, Disciplinary Panel B of the Board concludes as a matter of law that Respondent violated Health Occ. § 14-404(a) 22) (fails to meets standards of quality medical care); and (a)(40) (inadequate medical record

keeping.)

# **ORDER**

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

**ORDERED** that Respondent is Reprimanded; and it is further

**ORDERED** that effective the date of this Consent Order, Respondent is placed on **PROBATION** for a minimum of one (1) year subject to the following terms and conditions:

- 1. Within thirty (30) days from the date of the Consent Order, Respondent shall revise, and submit for Board approval, her office forms entitled "Informed Consent for Treatment of Persistent Lyme Disease" and "Informed Consent for Coartem Therapy for Babesiosis." Respondent shall "re-consent" all of her existing patients and continue to use the Board-approved form for all subsequent patients;
- 2. Within three (3) months of the date of this Order, Respondent shall enroll in, and within nine (9) months of the date of this Order, Respondent shall successfully complete, a Board-approved course in medical documentation. The course will not count toward fulfilling the continuing education requirements that Respondent must fulfill in order to renew her license to practice medicine;
- 3. Within six (6) months after the completion of the course on medical documentation, Respondent's practice shall be subject either to peer review by an appropriate peer review entity, or a chart review by a Board designee, to be determined at the discretion of the Board. The review shall focus on whether Respondent has corrected the deficiencies as stated in the Charges of November 6, 2015;
- 4. An unsatisfactory peer review by an appropriate peer review entity shall be deemed a violation of probation, as described below;
- 5. Respondent shall be responsible for all costs associated with fulfilling the terms and conditions of this Consent Order:
- 6. Respondent shall practice according to the Maryland Medical Practice Act and in accordance with all applicable laws, statutes, and regulations pertaining to the practice of medicine. Failure to do so shall constitute a violation of this Consent Order;
- 7. The Respondent shall not petition the Board for early termination of the terms and conditions of this Consent Order;

8. Any violation of the terms or conditions of this Consent Order may be deemed a violation of this Consent Order; and be it further

ORDERED, if Respondent violates any of the terms and conditions of probation, a disciplinary panel of the Board, in its discretion, after notice and an opportunity for a show cause hearing before a disciplinary panel of the Board, or opportunity for an evidentiary hearing before an Administrative Law Judge at the Office of Administrative Hearings if there is a genuine dispute as to the underlying material facts, may impose sanctions which it may have imposed in this case, including probationary terms and conditions, reprimand, suspension, revocation and/or monetary penalty, said violation of the terms and conditions being proved by a preponderance of the evidence; and be it further

ORDERED that after a minimum of one (1) year, and after the conclusion of a satisfactory peer review or chart review, Respondent may petition for termination of probation, but only if Respondent has satisfactorily complied with all conditions of this Consent Order, and if there are no pending complaints regarding Respondent before the Board. Her probation will be terminated through an order of Panel B; and be it further

ORDERED that the Consent Order is a public document pursuant to Md. Code

Ann., Gen. Prov. §§ 4-101 et seq. (2014)

01/01/2016

01/07/2016

Christine A. Farrelly, Executive Director Maryland State Board of Physicians

# CONSENT

- I, Hope Alison Mcintryre, M.D., License No. D46096, by affixing my signature, acknowledge that:
  - 1. I have consulted with counsel, Alan Dumoff, Esquire, and knowingly and voluntarily elect to enter into this Consent Order. By this Consent and for the purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its terms and conditions.

- 2. I am aware that I am entitled to a formal evidentiary hearing, pursuant to Md. Code Ann., Health Occ. II § 14-405 (2014 Repl. Vol.) and Md. Code Ann., State Gov't. II §§ 10-201 et seq. (2014 Repl. Vol.).
- I acknowledge the validity and enforceability of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I am waiving those procedural and substantive protections.
- I voluntarily enter into and agree to abide by the terms and conditions set forth herein as a resolution of the Charges against me. I waive any right to contest the Findings of Fact and Conclusions of Law and I waive my right to a full evidentiary hearing, as set forth above, and my right to appeal any adverse ruling of a Disciplinary Panel of the Board that might have followed any such hearing, and any right to appeal this Consent Order.
- 5. I sign this Consent Order voluntarily, without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order.

Mann

My commission expires 12/28/2018

I HEREBY CERTIFY that on this 5th day of January, 2018
I HEREBY CERTIFY that on this 5th day of January, 2018
hofore me a Notoni Dublic of the Otto
before me, a Notary Public of the State and County aforesaid, personally appeared
Hope McIntyre, M.D, License number D46096, and gave oath in due form of law that the

foregoing Consent Order was her voluntary act and deed.

AS WITNESS, my hand and Notary Seal.

KATHRYN D. RUDISILL

Kathy D. Rudisill

1/2/2016

Notary Public Carroll County Maryland

My Commission Expires Dec. 28, 2018