IN THE MATTER OF	*	**BEFORE THE**
DANIEL A. JALLER, M.D.	*	**MARYLAND STATE**
Respondent	*	**BOARD OF PHYSICIANS**
License Number: D33138		**Case Number: 2014-0184**

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CHARGES UNDER THE MARYLAND MEDICAL PRACTICE ACT

Disciplinary Panel B of the Maryland State Board of Physicians (the "Board") hereby charges Daniel A. Jaller, M.D., (the "Respondent"), license number D33138, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("H.O.") §§ 14-101 *et seq.* (2014 Repl. Vol.).

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

> **§ 14-404. Denials, reprimands, probations, suspensions, and revocations – Grounds.**
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> (a) *In general.* Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary panel of the Board, 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:
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> ...
>
> (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[.]

ALLEGATIONS OF FACT[1]

Disciplinary Panel B of the Board bases its charges on the following facts that it has reason to believe are true:

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[1] The statements of the Respondent's conduct herein are intended to provide the Respondent with notice of the alleged charges. They are not intended as, and do not necessarily represent, a complete description of the evidence, either documentary or testimonial, to be offered against the Respondent.

1. At all times relevant hereto, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was originally licensed to practice medicine in Maryland on December 23, 1985. His license is scheduled to expire on September 30, 2016. The Respondent holds an inactive license in Pennsylvania.

2. The Respondent was board-certified in Family Medicine from July 10, 1987 through December 31, 2013. The Respondent is no longer board-certified.

3. At all times relevant, the Respondent maintained an office of the practice of medicine in Montgomery County, Maryland.

4. On August 26, 2009, the Board issued to the Respondent an Advisory Letter that notified the Respondent that the Board had investigated a complaint regarding his treatment of patients diagnosed with Lyme disease. The Respondent was further notified that the Board had closed the case; however, he was provided with a summary of the peer reviewers' concerns. Those concerns included but were not limited to: the Respondent's failure to consider alternate diagnoses when the patient failed to improve after treatment; failure to provide justification for frequent changes in medications prescribed and prolonged treatment with antibiotics despite the lack of effectiveness of such treatment.

5. On or about September 4, 2013, the Board received a Clinical Privileges Action Report ("Report") from an insurance company in which the Board was informed that the Respondent had voluntarily surrendered his participation in the company while under investigation. The Report further advised that review of the Respondent's care of six patients with Lyme disease deviated from the accepted

standard of care.

6. The Board initiated an investigation of the Respondent's medical practice which included review of patient records by two peer reviewers who are board-certified in infectious disease, the Respondent's written summaries of his care and response to the peer reviewers' reports.

7. In an undated letter that accompanied the Respondent's transmission of the patient records, the Respondent presented "introductory remarks" to his summaries of care. In his remarks, the Respondent differentiated between the "mainstream" and "alternate" paradigm. The alternate paradigm, to which the Respondent subscribes, is supported by the International Lyme and Associated Diseases Society ("ILADS"); the mainstream paradigm is advocated by the Infectious Disease Society of America ("IDSA"). The Respondent noted that standard mainstream therapy, a short course of antimicrobial medications,[2] is usually effective if Lyme disease is caught early; however, late stage or "chronic" Lyme disease requires a different approach. In accordance with ILADS tenets, chronic Lyme disease is "nearly always viewed as a polymicrobial disease and other tickborne pathogens frequently play an important role in the overall disease syndrome." The Respondent continued:

> The corollary of this is that certain, specific symptoms, may be clinically suggestive of a particular co-infection. For example, babesiosis[3] is frequently associated with recurring flu-like symptoms, night sweats and air hunger. Bartonellosis[4] is frequently

[2] Antimicrobial denotes a class of medication of which antibiotics are a subset. Both kill or inhibit the growth of other microorganisms. Antibiotics do not include antimicrobial substances that are synthetic, semi-synthetic, or those that come from plants or animals. In contrast, antimicrobials include all agents that act against all types of organisms: bacteria (antibacterial); viruses (antiviral); fungi (antifungal) and protozoa (antiprotozoal). The Respondent prescribes a variety of antibiotics and antimicrobials.
[3] Babesiosis is a tick-borne infectious disease.
[4] Bartonellosis is an infectious bacterial disease.

> associated with tendon pain (like shin splints and plantar fasciitis), specific rashes and psychiatric symptoms. As a whole, co-infections make the disease more severe and more difficult to treat.

With regard to treatment, the Respondent wrote: "[t]he alternate model takes advantage of an expanded arsenal of antimicrobial agents not allowed in the standard model. The chronic, persisting infection models frequently calls for the use of combination therapy for synergy and other specific effects." The ILADS approach accepts that long-term antimicrobial/antibiotic therapy might be beneficial because Lyme spirochetes[5] persist after "standard" antibiotic therapy has been administered.

8. ILADS and ISDA diagnostic criteria also differ. The ISDA criteria is based on specific serologic results and overall clinical picture to confirm a diagnosis of Lyme disease. ILADS, according to the Respondent, "considers laboratory tests [to be] inaccurate and many patients with Lyme disease are sero-negative." With regard to patients' symptoms, the Respondent stated, "[m]any patients present with unusual and atypical symptoms and may be diagnosed with another disorder incorrectly. Alternatively, a patient may be diagnosed correctly, for example, fibromyalgia or chronic fatigue syndrome, but the concurrent diagnosis of tickborne disease may provide a mechanism for understanding underlying causality."

9. Based upon their review of the Respondent's records, including his introductory remarks and summaries of care, the peer reviewers concurred that the Respondent failed to meet the standard of quality care for all six of the patients

[5] A spirochete is a gram-negative, motile, spiral-shaped type of bacterium that causes diseases including Lyme disease.

whose care was reviewed. A summary of the peer reviewers' findings and patient-specific findings are set forth below.

SUMMARY OF PRACTICE DEFICIENCIES

10. The review of the Respondent's practice focused on his treatment of patients who are diagnosed with Lyme disease, a vector-borne (tick-borne) infectious disease, and whom the Respondent diagnosed with co-infections such as babesiosis and/or bartonellosis.

11. The Respondent diagnoses were based on multiple negative or indeterminate blood tests, and in some instances, notwithstanding the absence of objective evidence of infection in the patient's history (i.e. no documented inquiry about tick bites).

12. The Respondent made clinical diagnoses of multiple chronic infections based on symptoms mostly of a subjective nature that are likely attributable to other diagnoses. The Respondent diagnosed each patient described herein who presented with non-specific symptoms including but not limited to: fatigue; pain; sleep disturbances; brain fog and similar symptoms with chronic Lyme disease. He also typically diagnosed the patients with co-infections such as babesiosis and/or bartonellosis. The Respondent typically established the diagnoses on the patient's first visit, notwithstanding the vague or non-specific nature of the presenting symptoms. The Respondent consistently failed to construct or consider an initial differential diagnosis.

13. The Respondent failed to refer patients to specialists to address symptoms such as depression, neuropathy and/or chronic fatigue, despite having documented

the severe or disabling nature of those symptoms.

14. Based on his diagnoses of bacterial infectious disease(s), the Respondent prescribed antimicrobial treatment for months and often years. The Respondent prescribed multiple antimicrobials (up to seven different agents at a time) and frequently changed the type of antimicrobial agent used without documenting his treatment rationale.

15. The Respondent frequently prescribed intravenous ("IV") administration of antimicrobials for drugs despite the availability of bioequivalent oral formulations and without documentation that the patient was unable to absorb the drug orally. The Respondent prescribed IV drugs for months at a time, exposing the patient to undue risks of complications of long-term central venous catheter usage, such as deep venous thrombosis (see Patients A and D, below), as well as adverse drug reactions and increased resistance to antimicrobial drugs.

16. To patients to whom the Respondent prescribed Plaquenil, an antimalarial medication, the Respondent failed to conduct or refer patients for routine ophthalmological evaluation for Plaquenil toxicity.

17. The Respondent provided to his patients an informed consent form regarding his treatment of Lyme disease. The patient's informed consent, however, does not mitigate the Respondent's prolonged antimicrobial treatment in the absence of objective evidence supporting his infectious disease diagnoses.

PATIENT-SPECIFIC ALLEGATIONS

Patient A[6]

18. Patient A, a male in his early teens, initially presented to the Respondent in July 2009 with complaints of persistent fatigue, joint and muscle pains, night sweats and weakness. The Respondent documented that Patient A's symptoms began one week after Patient A had found three tick bites behind his knees and ankle a couple of days after playing in the woods.

19. The Respondent documented that Patient A had been seen by another physician who had initially prescribed an antibiotic, doxycycline, for six weeks and then had prescribed an increased dosage of doxycycline for an additional four weeks when Patient A's symptoms persisted.

20. The Respondent did not document that Patient A had developed a rash after been bitten by the ticks.[7]

21. In his summary of care, the Respondent noted that when Patient A had remained symptomatic, his family wanted to "investigate an approach based on the chronic infection paradigm" because Patient A's father had "suffered with chronic Lyme disease and babesiosis for a long time."

22. The Respondent documented that Patient A had decreased bilateral facial sensation, bilateral motor weakness and "severe" decreased sensation in his extremities.

23. At Patient A's first visit, the Respondent prescribed multiple antimicrobials:

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[6] The names of patients and other individuals are confidential. The Respondent may obtain the names from the Administrative Prosecutor.

[7] Lyme disease is often, but not always, characterized by the appearance of a bulls-eye shaped skin lesion (erythema migrans) at the site of the tick bite.

amoxicillin; charithromycin (Biaxin) and hydroxychloroquine (Plaquenil).

24. The Respondent ordered several blood tests at Patient A's first visit. The tests included several for Lyme disease including Lyme Western blot, Lyme C6 peptide, Lyme IgM and IgG Western blot, all of which were negative.[8]

25. The Respondent also ordered a wet mount blood smear test the result of which was "scarce elongated pleomorphic motile extracelluar organisms were observed."

26. On August 12, 2009, Patient A returned to the Respondent. The Respondent documented that Patient A presented with symptoms similar to those he had presented at the July visit. The Respondent also noted that Patient A had "severe cognitive problems" (which the Respondent did not describe), shortness of breath, dizziness and mood swings. The Respondent documented that Patient A had "bacteria in blood."

27. The Respondent changed Patient A's antibiotic/antimicrobial regimen to: cefdinir (Omnicef); azithromycin (Zithromax), rifampin and atovoqone/proguanil HCL (Malarone).

28. Patient A next presented almost two years later, on June 20, 2011, after having being hit in the head by a hockey puck and sustaining a concussion. The Respondent noted that at Patient A's 2009 visits, he was "seronegative for Lyme, blood smear showed bacteremia. On a clinical basis he was treated for both Lyme and babesiosis [with antibiotics]."

29. At the June 2011 visit, the Respondent diagnosed Patient A with Lyme disease and prescribed amoxicillin and Zithromax.

[8] One IgG band out of 14 was positive, but at the weakest reaction.

30. On August 9, 2011, the Respondent documented that Patient A felt very depressed and experienced suicidal ideations when he stopped taking Lyrica[9] which his (Patient A's) father had provided to him.

31. Thereafter, the Respondent periodically added depression to Patient A's diagnoses and prescribed anti-depression, anti-anxiety and anti-psychotic medications including Wellbutrin, Xanax and Ability.

32. On November 10, 2011, the Respondent added babesiosis, bartonellosis and Postural Orthostatic Tachycardia Syndrome ("POTS")[10] to Patient A's diagnoses. In his summary of care, the Respondent described Patient A's POTS as having developed "in relation to Lyme disease, a not infrequent occurrence."

33. In the Respondent's summary of care, he described Patient A's bartonellosis as "intractable" and stated that he confirmed the diagnoses by "new red striae [on Patient A's] back," the presence of which was "essentially pathognomonic."[11] The Respondent sometimes referred to the striae as "stretch marks."

34. At the November 10, 2011 visit and continuing through January 13, 2012, the Respondent prescribed ceftriaxone to be administered intravenously daily for 30 days.

35. From November 2011 through November 2012, the Respondent prescribed to Patient A various IV antibiotics, often two at a time. The IV antibiotics were administered through a peripherally inserted central catheter ("PICC")[12] line in Patient A's left arm.

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[9] An anticonvulsant used to treat seizures, fibromyalgia and other types of pain.
[10] A condition in which a change from a supine position to an upright position causes an abnormally large increase in heart rate.
[11] A sign or symptom that is so characteristic of a disease that it can be used to make a diagnosis.
[12] A form of intravenous access that can be used over a long period of time.

36. On November 13, 2012, the Respondent documented that a deep venous thrombosis ("DVT") had developed at the site of Patient A's PICC. To treat this issue, the Respondent prescribed Coumadin and Lovenox, both of which are anti-coagulants. [13]

37. In May 2012, the Respondent documented that Patient A had developed candida espophagitis[14], a complication of long-term antibiotic therapy.

38. During Patient A's course of treatment, through February 3, 2014, Patient A presented with waxing and waning symptoms, including joint pain, neuropathy, neurocognitive problems including depression/suicidal ideation and fatigue. The Respondent attributed these symptoms to Lyme disease, bartonellosis and babesiosis. The Respondent treated Patient A with various combinations of oral and injectable antimicrobials. For example, in July 2012, the Respondent prescribed six different agents; the oral medications included: fluconazole (antifungal); valacyclovir (antiviral); Nystatin (antifungal) and atovoquone/proguanil HCl (antimalarial). The IV agents were rifampin and azithromycin.

39. In his summary of care, the Respondent stated: "laboratory tests have been non-diagnostic and [Patient A's] diagnoses have largely been clinical in nature...The best clinical evidence in this case was and has been a dramatic rash which appeared on [Patient A's] back. He has rows of horizontal striae which is *(sic)* been purplish, now these are finally clearing out. This rash matches textbook

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[13] In his summary of care, the Respondent first mentioned that Patient A was taking Coumadin in an entry dated March 26, 2013, adding that it was recommended by a hematologist. The Respondent did not document in Patient A's chart such a recommendation.

[14] A yeast infection of the esophagus.

images of known cases of bartonellosis." The Respondent further noted that the 2009 wet mount blood study "suggest[ed] the possibility of something like bartonella."

40. In his summary of care, the Respondent noted that Patient A's "illness snowballed downhill after a head injury." The Respondent described this as a well-known "clinical phenomena" to those in the field; that is, "an unrelated injury or illness can cause Lyme disease syndrome to spiral out of control." The Respondent evaluated his treatment of Patient A as "fabulously successful."

41. The Respondent failed to meet the standard of quality care in his treatment of Patient A for reasons including, but not limited to the following:

a. The Respondent diagnosed Patient A with Lyme disease in 2011 without considering alternative diagnoses;

b. The Respondent diagnosed Patient A with Lyme disease, bartonellosis and babesiosis based on non-specific symptoms and repeated negative laboratory testing;

c. The Respondent failed to refer Patient A for consultations with specialists even when describing Patient A's symptoms as "severe" or "disabling." For example and not in limitation, the Respondent failed to refer Patient A for: a psychiatric consultation when Patient A presented with depression and suicidal ideation; a dermatological consultation when Patient A presented with a rash that formed a basis for long-term anti-microbial treatment; and a neurological consultation to monitor Patient A's neuropathy and provide guidance for Patient A's neurological symptoms

or a cardiology consultation after diagnosing him with POTS.[15]

d. The Respondent overprescribed long-term, combination antimicrobial agents for years without evidence of active infection(s) and without progressive benefit to Patient A;

e. In the absence of documented medical justification, the Respondent prescribed IV medications when oral formulations of these drugs give equivalent serum levels. The Respondent exposed Patient A to the risks of a central venous catheter device;

f. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed to Patient A;

g. The Respondent's long-term IV therapy caused Patient A to suffer a DVT which required treatment with anti-coagulants, and candida espophagitis;

h. The Respondent exposed Patient a to the risk of prolonged antimicrobial treatment.

i. The wet mount test is not a standard or specific diagnostic test for Bartonella.

Patient B

42. Patient B, a male in his forties, initially presented to the Respondent in June 2009. Patient B reported a past history of "chronic Lyme disease" for which he had received extensive antimicrobial treatment. Patient B's symptoms were both somatic and psychological and included: fatigue; insomnia; palpitations;

[15] The Respondent noted that two other physicians concurred with a diagnosis of Lyme disease for Patient A and one physician concurred with the Respondent's diagnosis of POTS. There are no reports from these physicians in Patient A's chart.

headaches; brain fog; mood swings; anxiety and musculoskeletal pain. Patient B also reported sensations of bugs crawling on his skin (formications) and was concerned he had a parasitic infection.

43. Prior to seeking treatment from the Respondent, Patient B had been diagnosed with babesiosis based on a 1999 blood test.

44. The Respondent ordered frequent testing for Lyme disease and babesiosis, the results for the vast majority of which were either negative or indeterminate.[16] Despite these results, the Respondent continued to prescribe multiple antimicrobial agents over Patient B's course of treatment. For example, in his summary of care, the Respondent discussed a Lyme Western blot[17] study conducted on October 5, 2011. Although the results of the test were indeterminate for the IgG and IgM bands that were detected, the Respondent stated that this test, among others, constituted "laboratory support for tick-borne infection." With regard to the October 2011 Western blot test, the Respondent determined that Patient B's "'seropositivity' only occurred after long-term antibiotic therapy" and continued to prescribe antimicrobial treatment for over two more years. The Respondent concluded that "[l]aboratory testing is problematic in the management of this disease and for the most part the diagnosis is made on clinical grounds."

45. The Respondent diagnosed and treated Patient B for babesiosis although

[16]Of the blood tests ordered by the Respondent, only one was reported as positive. On October 5, 2011, Patient B's WA1 IgG antibody was 1:256 (reference range = ≥1:256 Antibody detected).
[17]A test that measures a patient's antibody response to infection. Levels of two antibodies (immunoglobulins), IgM and IgG, indicate current infection (IgM) and either current infection or past exposure/infection (IgG).

serology did not support such a diagnosis. In April 2011, a PCR[18] blood test was negative for Babesia. In May 2011, the Respondent noted that "the original symptoms pegged to Babesia are the same has *(sic)* today" and later prescribed additional antimicrobials to Patient B.

46. During Patient B's course of treatment (through November 2013), the Respondent documented waxing and waning symptoms, which he noted were triggered by stressful situations such as marital separation and the death of Patient B's father.

47. In his summary of care, the Respondent noted that in early 2011, he considered whether Patient B's recurring symptoms were attributable to infections other than Lyme disease, such as babesiosis and bartonella. Thereafter, the Respondent prescribed varying antimicrobials to treat these infections as well as Lyme disease.

48. Almost continuously during Patient B's four year course of treatment, the Respondent prescribed over 20 different antimicrobials in multiple combinations. They included antiparasitic, antibacterial and antifungal agents. In his summary of care, the Respondent acknowledged that "there were months during which [Patient B] did not improve despite myriad variations of antimicrobial agents."

49. The Respondent failed to meet the standard of quality care in his treatment of Patient B for reasons including but not limited to:

    a. The Respondent failed to conduct an adequate initial evaluation of Patient B. The Respondent failed to explore aspects of Patient B's history including: tick bite history; pet or animal exposure/bites/scratches;

[18] Polymerase Chain Reaction ("PCR") detects microbial pathogens in clinical specimens.

possible immunosuppression; rash history and status of spleen;

b. The Respondent failed to consider diagnoses other than infectious diseases despite blood tests that were not consistent with active infection;

c. The Respondent failed to consider referring Patient B for psychiatric evaluation despite having documented several neuropsychiatric issues including depression, anxiety and fixed ideation;[19]

d. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed;

e. The Respondent exposed Patient B to the risk of prolonged antimicrobial treatment in the absence of medical justification.

Patient C

50. Patient C, then a female in her mid-forties, presented to the Respondent in October 2003. Patient C initially presented with seasonal allergies.

51. In September 2005, Patient C presented after being diagnosed with Bell's palsy. The Respondent documented that Patient C had a "h/o [history of] tick bites," but did not otherwise describe the history. The Respondent noted a plan to rule out Lyme disease and prescribed doxycycline, an antibiotic.

52. On December 30, 2010, Patient C presented with a recurrence of Bell's palsy. The Respondent diagnosed her with Lyme disease and prescribed a 30-day

[19] In his summary of care, the Respondent noted that, "[a]lthough not documented, [Patient B] would not consider seeing a mental health professional (for stress and anxiety) because of cultural biases." This is one of several instances in which the Respondent reported past interactions with patients that he failed to document in the patient's record. As a further example, the Respondent noted in his summary of care that in November 2013, Patient B had "started hydrogen peroxide (therapy) and I warned him that this is dangerous." Review of Patient B's chart reveals a note that he had started hydrogen peroxide; however, the Respondent failed to document that he had warned Patient B of its danger.

course of doxycycline.

53. On March 1, 2011, Patient C presented with continuing headaches, brain fog and left ear pain. The Respondent noted that these symptoms had persisted after a 2004 tick bite and added "suspected babesiosis" to Patient C's diagnoses. He prescribed Biaxin and Placquenil. In his summary of care, the Respondent stated that he prescribed these antimicrobials because they are "synergistic because Plaquenil lowers intercellular pH making macrolides[20] more effective."

54. In May 2011, Patient C complained of sweating badly. The Respondent noted that Patient C recalled multiple tick bites. The Respondent added babesiosis to Patient C diagnoses although a March 2011 blood test was negative for Babesia.

55. From 2011 through November 2013, Patient C tested negative for Lyme disease and babesiosis on all blood tests ordered by the Respondent. During this time, the Respondent prescribed over ten different antimicrobials in multiple combinations. For example, on December 13, 2011, the Respondent prescribed seven antimicrobials at once to Patient C, after noting that Patient C was complaining of nausea and vomiting.

56. The Respondent failed to meet the standard of quality care in his treatment of Patient C for reasons including, but not limited to, the following:

    a. The Respondent failed to conduct an adequate initial evaluation of Patient C. The Respondent failed to explore aspects of Patient C's history including: tick bite history; pet or animal exposure/bites/scratches; possible immunosuppression; rash history and status of spleen;

    b. The Respondent failed to consider diagnoses other than infectious

[20] A class of antimicrobials with a broad spectrum of activity against gram-positive bacteria.

diseases despite blood tests that were not consistent with active infection;

c. The Respondent failed to investigate possible causes of Patient C's recurrent Bell's palsy;

d. The Respondent's combination of Plaquenil with Biaxin for synergy purposes exposed Patient C to potential adverse side effects without proven benefit;

e. The Respondent based his diagnoses of Lyme disease and babesiosis on non-specific symptom complexes without evidence of support from laboratory testing or significant benefit from long-term multiple antimicrobial agents and frequently changed antimicrobial therapy;

f. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed;

g. The Respondent exposed Patient C to the risk of prolonged antimicrobial treatment.

Patient D

57. Patient D, a female in her fifties, initially presented to the Respondent in September 2008 complaining of neck pain. Patient D's medical history included obsessive compulsive disorder, ADD and depression. The Respondent noted a possible diagnosis of bipolar disorder and on Patient D's second visit ordered a psychological evaluation based on the patient's "multiple psy[chological]. issues."

58. Patient D returned to the Respondent's care on November 17, 2011 with

"a plethora of symptoms" including: heart palpitations; memory issues; chronic shoulder and scapular pain; numbness and tingling of her upper extremities and burning sensations. The Respondent documented that Patient D claimed she had had these symptoms since 2000 with recurring episodes. The Respondent diagnosed Patient D with fibromyalgia and myositis and ordered laboratory tests, including those for tick-borne illnesses.

59. In November 2011, Patient D tested positive for the WA1 IgG antibody (Babesia duncani or B. duncani), but otherwise negative for Lyme disease. The Respondent noted "+ results for Lyme disease."

60. The WA1 is a serological test with high rates of false positivity. The Respondent did not ask Patient D whether she had traveled to the Pacific northwest, an endemic area for B. duncani, as a risk factor for this disease nor did he order additional laboratory studies such as a smear or PCR to discern the validity of his diagnosis.

61. On January 29, 2012, Patient D's third visit, the Respondent documented that Patient D did not recall having had a tick bite, but noted that she had a dog and was an "outdoors person." He added Lyme disease and babesiosis to Patient D's diagnoses, which also included memory loss, mild cognitive impairment and hypothyroidism.

62. Beginning in January 2012 and continuing throughout Patient D's course of treatment (December 2012), the Respondent treated Patient D with multiple antimicrobials even after she tested negative for WA1 in May

2012 and did not test positive for Lyme disease on subsequent lab studies. The Respondent diagnosed Patient D at various times with Lyme disease, babesiosis and encephalopathy, unspecified.

63. On October 8, 2012, Patient D's TSH (thyroid stimulating hormone) level was noted on a lab study to be high (39.290; reference range = 0.450 – 4.50). This result would indicate hypothyroidism as a possible factor responsible for the worsening of her chronic symptoms. The Respondent, although noting that Patient D's thyroid conditions had been difficult to control and earlier prescribing Synthroid, continued to focus on infection as the operative force driving her chronic symptoms.

64. In his summary of care, the Respondent noted that "[i]n the case of tertiary never diagnosed Lyme disease with multisystem complaints, I assume that the sprirochetal organisms are widely disseminated. This suggests that aggressive antibiotic therapy may be required." During Patient D's course of treatment, through December 2012, the Respondent continuously prescribed multiple oral and IV antimicrobials (a total of 10 different agents).

65. The Respondent often documented that Patient D's spine and neck pain was severe. On May 3, 2012, noted that Patient D was "writhing in pain." The Respondent added opioids such as Dilaudid[21] to Patient D's medication regimen but failed to order radiologic studies at any time during her treatment and persisted in attributing her symptoms to bacterial infection.

[21] A Schedule II Controlled Dangerous Substance.

66. Similarly, the Respondent prescribed a variety of medications to treat Patient D's psychiatric symptoms (Klonopin, Adderall, Neurontin, Xanax), but failed to refer her to for psychiatric treatment.

67. On June 29, 2012, the Respondent diagnosed Patient D with a DVT at the site of her PICC. The Respondent initially prescribed Lovenox and later switched to Coumadin. The Respondent continued to prescribe IV antimicrobials through September 2012 despite the DVT. He restarted IV medications in October 2012 after Patient D advised that her symptoms returned.

68. On December 11, 2012, Patient D's last visit, the Respondent noted that because her symptoms quickly return when IV medications are stopped, "treatment for Babesia with Mepron[22] may be very helpful. She has clearly tested positive for B. duncani with an elevated titer."

69. Beginning in May 2012, the Respondent noted that Patient D's liver function tests ("LFTs") were abnormally high. This concern persisted throughout Patient D's course of treatment. On October 12, 2012, the Respondent noted that Patient D's LFTs had improved when she stopped drinking alcohol. He further noted "[a]ctually doing better just taking Mepron." The Respondent noted in his summary of care for Patient E, however, that Mepron has been associated with elevated LFT.

70. In his summary of care for Patient D, the Respondent concluded his remarks as follows: "Certainly she had other problems: depression, hypothyroidism, excessive use of alcohol at certain points in time. But this

[22] An antiprotozoal medication.

cannot take away from the diagnosis of tickborne illness and these other diagnoses cannot account for her symptoms."

71. The Respondent failed to meet the standard of quality care in his treatment of Patient D for reasons including, but not limited to, the following:

a. The Respondent failed to conduct an adequate initial evaluation of Patient D. The Respondent failed to explore aspects of Patient C's history including: tick bite history; pet or animal exposure/bites/scratches; possible immunosuppression; rash history and status of spleen;

b. The Respondent failed to consider diagnoses other than infectious diseases despite blood tests that were not consistent with active infection;

c. The Respondent based his diagnoses of Lyme disease and babesiosis on non-specific symptom complexes without evidence of support from laboratory testing or significant benefit from long-term multiple antimicrobial agents and frequently changed antimicrobial therapy;

d. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed;

e. The Respondent failed to refer Patient D for psychiatric treatment;

f. The Respondent prescribed IV medications in an ambulatory setting when oral formulations of these drugs provide equivalent serum levels without subjecting a patient to the risks of a central venous catheter device;

g. The Respondent's long-term IV therapy caused Patient D to suffer a DVT which required treatment with anti-coagulants;

h. The Respondent exposed Patient D to the risk of prolonged antimicrobial treatment.

Patient E

72. Patient E, a female in her forties, initially presented to the Respondent in July 2009 with a petechial rash on her arms and legs that the Respondent noted "comes and goes." The Respondent further noted that Patient E complained of feet and face twitches, "sweats" and joint pain.

73. Although not documented in the Respondent's notes, in his summary of care he noted that Patient E had been treated for two and one half years by Physician A (whose website indicates that he is a member of ILADS) for an "established diagnosis of Lyme disease/tickborne disease." The Respondent did not indicate the dates of treatment or the type of treatment Patient E had previously undergone.

74. The Respondent also documented in his summary of care that he had reviewed Patient E's laboratory tests when she initially presented. The Respondent stated that a January 31, 2007 test result "revealed a very high titer, greater than 1:320 for Babesia microti. This demonstrates tick borne infection from Ixodes scapularis, the tick which transmits Lyme disease."[23]

75. With the exception on a single low positive Babesia microti IgG result in 2012, which suggests either a false positive or remote infection, Patient E's laboratory results in 2010 and 2011 for Babesis microti were negative, as were multiple laboratory results for Lyme disease. On September 8, 2010, the Respondent

[23] The results of the 2007 Babesia microti panel revealed a negative IgM and a positive IgG result. This indicates exposure and resolution of babesiosis at some time before the blood test.

noted that Patient E had "elevated Bartonella tests." His comment was based on the results of a wet mount showed "ample Bartonella."[24] Patient E tested negative for Bartonella antibodies on a May 2012 laboratory study.

76. Despite the lack of objective evidence that would suggest active infection, the Respondent diagnosed Patient E with Lyme disease, bartonellosis and babesiosis and treated her for more than three years with antimicrobial therapy that failed to yield clear benefit and which was ongoing as of 2012.

77. Review of the record reveals that the Respondent prescribed 20 different antimicrobials during Patient E's course of treatment, often in combination of three or four agents at a time. The Respondent frequently failed to document his treatment rationale for stopping or starting specific medications.

78. The Respondent failed to meet the standard of quality care in his treatment of Patient E for reasons including, but not limited to, the following:

a. The Respondent failed to conduct an adequate initial evaluation of Patient E. The Respondent failed to explore aspects of Patient E's history including: tick bite history; pet or animal exposure/bites/scratches; possible immunosuppression; rash history and status of spleen;

b. The Respondent failed to consider diagnoses other than infectious diseases despite blood tests that were not consistent with active infection;

c. The Respondent based his diagnoses of Lyme disease and babesiosis on non-specific symptom complexes without evidence of support from laboratory testing or significant benefit from long-term multiple

[24] The wet mount laboratory result was not present in Patient E's chart. On this date, the Respondent noted that Patient E's sweats might due to babesiosis or menopause. This is one of few instances when the Respondent entertained a diagnosis for a patient's symptoms other than bacterial infection.

antimicrobial agents and frequently changed antimicrobial therapy;

d. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed;

e. The wet mount test used by the Respondent is not a standard diagnostic test for Bartonella;

f. The Respondent exposed Patient E to the risk of prolonged antimicrobial treatment.

Patient F

79. Patient F, a female in her thirties, initially presented to the Respondent on March 8, 2012. According to the Respondent's summary of care, Patient E had been "very ill for about 10 years with a mystery diagnosis. Another physician recently diagnosed Lyme disease and started her on herbal therapy." The Respondent further stated that Patient E presented with symptoms of a "multi-system illness" and wanted to confirm whether she had Lyme disease.

80. In his March 8, 2012 note the Respondent documented that Patient F had been treated by a neurologist for complex seizures a few years earlier. Her symptoms included: facial numbness; frontal headaches; swollen neck gland; neck and back pain; flu-like symptoms and formications.

81. In his note of Patient F's initial visit, the Respondent documented, "[n]o tick bites. Lives in rural area. Gardens. Has spent a lot of time outdoors." The Respondent further noted that Patient E had developed joint pain over the last three years and that a "workup, including Lyme was negative." The Respondent

ordered laboratory studies of Lyme disease and diagnosed Patient E with "[m]ultiple other symptoms compatible multisystem illness such as chronic Lyme disease."

82. Initial and subsequent laboratory testing for tick-borne illnesses that were ordered by the Respondent were negative.

83. On Patient F's second office visit, March 16, 2012, the Respondent diagnosed her with "possible Lyme disease and babesiosis" and prescribed doxycycline, an antibiotic.

84. On later visits, the Respondent prescribed Patient F with bartonellosis and babesiosis in the absence of evidence of active infection.

85. During Patient F's course of treatment (through January 2013), the Respondent 11 different anti-microbial agents, often in combination. Several of these agents were administered intravenously for months at a time in an ambulatory setting when oral formulations of these drugs give equivalent serum levels.

86. On November 19, 2912, the Respondent diagnosed Patient F with common variable immunodeficiency ("CVIDS") based on a mild depression of some immune globulin levels. The Respondent prescribed IV immunoglobulins. The Respondent, however, failed to inquire whether Patient F had recurrent bacterial sinusitis or pneumonia that typically are the indications for immunoglobulin supplementation. The Respondent also failed to explore the cause of Patient F's low normal immunoglobulin results. Specifically, he did not administer a provocative vaccine (e.g., pneumococcal polysaccharide immunization) to determine if Patient F had a lack of response to new antigens.

87. The Respondent failed to meet the standard of quality care in his treatment of Patient F for reasons including, but not limited to, the following:

a. The Respondent failed to conduct an adequate initial evaluation of Patient F. The Respondent failed to explore aspects of Patient F's history including: tick bite history; pet or animal exposure/bites/scratches; possible immunosuppression; rash history and status of spleen;

b. The Respondent failed to consider diagnoses other than infectious diseases despite blood tests that were not consistent with active infection;

c. The Respondent based his diagnoses of Lyme disease, bartonellosis and babesiosis on non-specific symptom complexes without evidence of support from laboratory testing or significant benefit from long-term multiple antimicrobial agents and frequently changed antimicrobial therapy;

d. The Respondent exposed Patient F to the risk of prolonged antimicrobial treatment;

e. The Respondent failed to document adequately his rationale for starting, stopping, combining and changing the dosages of the antimicrobials and other medications he prescribed;

f. In the absence of documented medical justification, the Respondent prescribed IV medications when oral formulations of these drugs give equivalent serum levels. The Respondent exposed Patient F to the risks of a central venous catheter device.

88. The Respondent's conduct, in whole or in part, constitutes failure to meet the

standard of quality care, in violation of H.O. § 14-404(a)(22).

NOTICE OF POSSIBLE SANCTIONS

If, after a hearing, a disciplinary panel of the Board finds that there are grounds for action under H.O. § 14-404(a)(22), the disciplinary panel may impose disciplinary sanctions against the Respondent's license, including revocation, suspension, or reprimand and may place the Respondent on probation, and/or may impose a monetary fine.

NOTICE OF DISCIPLINARY CONFERENCE FOR CASE RESOLUTION AND HEARING

A Disciplinary Conference for Case Resolution ("DCCR") in this matter has been scheduled for **Wednesday, June 24, 2015 at 9:00 a.m.** at the offices of the Maryland Board of Physicians, 4201 Patterson Avenue, Baltimore, Maryland 21215.

The nature and purpose of the DCCR are described in the attached letter to the Respondent. If this case is not resolved at the DCCR, an evidentiary hearing will be scheduled.

BRIAN E. FROSH
ATTORNEY GENERAL

April 22, 2015
Date

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