BEFORE THE VIRGINIA BOARD OF MEDICINE

IN RE: LEILA HADDAD ZACKRISON, M.D.
License Number: 0101-045689
Case Numbers: 161559, 175503, 183943, 187023

ORDER OF SUMMARY SUSPENSION

Pursuant to Virginia Code § 54.1-2408.1(A), a quorum of the Board of Medicine ("Board") met by telephone conference call on September 12, 2019), after a good faith effort to convene a regular meeting of the Board had failed. The purpose of the meeting was to receive and act upon information indicating that Leila Haddad Zackrison, M.D., may have violated certain laws relating to the practice of medicine and surgery in the Commonwealth of Virginia, as more fully set forth in the attached "Notice of Formal Administrative Hearing and Statement of Allegations," which is attached hereto and incorporated by reference herein.

WHEREUPON, pursuant to its authority under Virginia Code § 54.1-2408.1(A), the Board concludes that a substantial danger to public health or safety warrants this action and ORDERS that the license of Leila Haddad Zackrison, M.D., to practice medicine and surgery in the Commonwealth of Virginia is SUSPENDED. It is further ORDERED that a hearing be convened within a reasonable time of the date of entry of this Order to receive and act upon evidence in this matter.

Pursuant to Virginia Code § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection or copying on request.

FOR THE BOARD

Jennifer L. Deutsch

For William L. Harp, M.D.
Executive Director
Virginia Board of Medicine

ENTERED : 9/12/19

BEFORE THE VIRGINIA BOARD OF MEDICINE

IN RE: **LEILA HADDAD ZACKRISON, M.D.**
License Number: **0101-045689**
Issue Date: **August 1, 1990**
Suspension Date: **September 12, 2019**
Case Numbers: **161559, 175503, 183943, 187023**

NOTICE OF FORMAL ADMINISTRATIVE HEARING AND STATEMENT OF ALLEGATIONS

You are hereby notified that a Formal Hearing has been scheduled before the Board of Medicine ("Board") regarding your license to practice medicine and surgery in the Commonwealth of Virginia.

TYPE OF PROCEEDING:	This is a formal administrative hearing before a panel of the Board.
DATE AND TIME:	**October 17, 2019** **11:00 A.M.**
PLACE:	Virginia Department of Health Professions Perimeter Center - 9960 Mayland Drive 2nd Floor - Virginia Conference Center Henrico, Virginia 23233

LEGAL AUTHORITY AND JURISDICTION:

1. This formal hearing is being held pursuant to Virginia Code §§ 2.2-4020, 2.2-4024(F), and 54.1-2400(11). This proceeding will be convened as a public meeting pursuant to Virginia Code § 2.2-3700.

2. At the conclusion of the proceeding, the Board is authorized to take any of the following actions:

- Exonerate you;
- Reprimand you;
- Require you to pay a monetary penalty;
- Place you on probation and/or under terms and conditions;
- Continue your license on suspension; or
- Revoke your license.

ABSENCE OF RESPONDENT AND RESPONDENT'S COUNSEL:

If you and/or your counsel fail to appear at the formal hearing, the Board may proceed to hear this matter in your absence and may take any of the actions outlined above.

RESPONDENT'S LEGAL RIGHTS:

You have the right to the information on which the Board will rely in making its decision, to be represented by counsel at this proceeding, to subpoena witnesses and/or documents, and to present relevant evidence on your behalf.

COMMONWEALTH'S EXHIBITS:

Enclosed is a copy of the Commonwealth's exhibits that will be distributed to the members of the Board for their review unless an objection is received within the timeframe specified in Section III below and sustained by the Panel Chair or acting Board officer. **These documents are enclosed only with the notice sent by UPS overnight mail. Please bring these documents with you to the formal hearing.**

FILING DEADLINES:

If you want to submit evidence or use expert witnesses, below are the deadlines for the submission of such evidence or your expert witness list. The deadlines for filing objections, if any, to the exhibits and expert witness list also follow.

I. Exhibit Submission	DEADLINE DATE
Respondent's Submission of Documents for Evidence (including expert witness reports) (Submit 15 copies to Jennie F. Wood, Discipline Case Manager)	**September 20, 2019**
Commonwealth's Deadline to Respond to Respondent's Submission (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 25, 2019**
Respondent's Deadline to Respond to Commonwealth's Objection (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 30, 2019**

II. Expert Witness Identification	DEADLINE DATE
Respondent's Expert Witnesses (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 20, 2019**
Commonwealth's Deadline to Object to Expert Witness (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 25, 2019**

The Board has engaged the services of Randall Fisher, M.D., and Melissa Russell, M.D., whose curriculum vitae and written reports are included in the exhibits enclosed with this letter. Dr. Fisher and

Dr. Russell will be present at the formal hearing to serve as experts on behalf of the Commonwealth unless an objection is received by September 20, 2019 and sustained by the Panel Chair or acting Board officer.

NOTE: If supplementation of expert witness lists is necessary, parties should transmit such supplement to the Board at least five (5) days in advance of the scheduled administrative proceeding. Objections to expert witnesses submitted on a supplemental list may be made prior to or at the hearing for consideration by the Panel Chair.

III. Objections to Commonwealth's Exhibits	**DEADLINE DATE**
Respondent's Objections to Commonwealth's Exhibits (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 20, 2019**
Commonwealth's Response to Respondent's Objections (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 25, 2019**

NOTE: If no objections have been received by September 20, 2019, the exhibits will be distributed to the Board members for their review.

IV. Motions/Continuance Requests	**DEADLINE DATE**
Respondent's Motions (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 20, 2019**
Commonwealth's Response to Motions (Submit, in writing, to Jennifer L. Deschenes, Deputy Executive Director)	**September 25, 2019**

STATEMENT OF ALLEGATIONS

The Board alleges that:

1. At all times relevant hereto, Leila Haddad Zackrison, M.D., was licensed to practice medicine and surgery in the Commonwealth of Virginia.

2. Leila Haddad Zackrison, M.D., violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in the care and treatment of Patient A, a female relative of Dr. Zackrison's, between approximately 2010 (when the patient was 14 years old) and 2015 (age 18). Specifically, Dr. Zackrison and/or her employees acting under her direction ordered medically unnecessary tests, made diagnoses without sufficient justification, and initiated and continued potentially harmful treatment (such as long-term oral and/or intravenous antibiotics, anti-fungal medications, and corticosteroids), without appropriately weighing possible side effects or adverse outcomes verses the likelihood of the treatments being effective. Further, in response to non-specific or transient symptoms such as fatigue, palpitations, near-syncope, headache, constipation, insomnia, concentration issues, excessive thirst, and loss of appetite in this pediatric patient, Dr. Zackrison and/or her employees ordered repeated tests for a variety of tick-borne illnesses (including Lyme disease, Rocky Mountain spotted fever, babesiosis, and anaplasmosis), parasitic or bacterial infections (including giardia, echinococcus, Chlamydophila, Mycoplasma, schistosomiasis, bartonella, Entamoeba histolytica, strongyloides, toxoplasma, and trichinella spiralis), and other rare/unlikely diseases or conditions (e.g., Q fever, murine typhus, actinomycosis, cysticercosis, brucellosis, WA1, heavy-metal poisoning, and toxic mold exposure). Upon review of negative or slightly abnormal test results, Dr. Zackrison and/or her employees diagnosed Patient A with, and aggressively treated her for, multiple simultaneous illnesses without regard to the likelihood of the disease process or whether the diagnoses made biological sense in relation to the symptom complex the patient was experiencing. For example:

a. Patient A was diagnosed with Lyme disease in or about April 2008 (at age 12[1]), apparently based on a positive Western blot (IgM +23 and +41). However, data suggests that of all people who test positive for those particular two IgM bands, only approximately 40 percent have Lyme disease, and a review of Patient A's chart from 2010 through 2015 indicates that she did not have acute or chronic/persistent Lyme disease. Moreover, after Patient A was diagnosed with Lyme disease, without medical justification, Dr. Zackrison and/or her employees ordered repeated serologic testing for Lyme (including on or about 4/2/10, 7/27/10, 11/12/10, 6/22/11, 12/16/11, 3/28/12, 5/11/12, 8/14/12, 10/8/12, 11/20/12, 2/4/13, 2/26/13, 5/13/13, 8/5/13, 11/12/13, 4/18/14, 6/5/14, 6/30/14, 8/8/14, 10/1/14, 3/10/15, 4/8/15, and 8/10/15[2]). Despite repeated negative tests, and without appropriately weighing the risks, Patient A was aggressively treated for an extended period for diagnoses of Lyme disease and/or "polymicrobial state."[3] For example, the patient was treated with Omnicef (cefdinir) for more than six months in 2011; Cipro (ciprofloxacin) in or about mid-2011; doxycycline from late 2012 through approximately late 2013, and late 2014 through early 2015; intravenous Rocephin (ceftriaxone) in or about February 2013, November 2013, and April 2014; and intravenous acyclovir, Vfend (voriconazole), and Invanz (ertapenem) in 2014.

b. It is unclear from Patient A's chart when she was first diagnosed with Rocky Mountain spotted fever ("RMSF"), and based on her persistently low-positive titer, it is possible that she

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[1] Of note, a hospital ED record from July 30, 2014 states that Patient A was being treated at Dr. Zackrison's practice for "medical issues which include history of Lyme, RMSF [Rocky Mountain spotted fever], babesiosis, possible DI [diabetes insipidus] and POTS [postural orthostatic tachycardia syndrome]. She first had symptoms at age 4 with migratory arthritides." Additionally, documentation from a pediatric cardiologist who saw Patient A in 2013 (at age 16) states that "She apparently has had chronic Lyme for 10 years."

[2] A flow sheet in Patient A's chart also indicates she was tested for Lyme on or about 7/16/07, 4/2/08, 6/6/08, 8/8/08, 10/2/08, 12/30/08, 6/11/09, 7/8/09, 10/2/09, and 11/11/09.

[3] At various locations in Patient A's chart, the term "polymicrobial state" is applied to combinations of allegedly coexisting infections, including but not limited to Lyme, RMSF, Rickettsia bacteria, Typhus/murine typhus, "tick-borne diseases," anaplasma, C. pneumonia, Bartonella, babesia, candida/yeast, Q fever, Legionella, and WA1 (a variant of babesia).

had an asymptomatic or marginally symptomatic infection with Rickettsia rickettsiae. Once Dr. Zackrison or her staff made this diagnosis for Patient A, however, there was no justification for repeated serological testing for RMSF (including on or about 4/2/10, 6/4/10, 7/27/10, 10/22/10, 1/4/11, 5/4/11, 6/22/11, 12/16/11, 3/28/12, 5/11/12, 8/14/12, 10/8/12, 11/19/12, 2/4/13, 2/26/13, 5/13/13, 8/5/13, 4/18/14, 6/5/14, 6/30/14, 8/8/14, 10/1/14, 1/16/15, 2/24/15, and 4/8/15[4]). Moreover, assuming the diagnosis was correct, Patient A was incorrectly treated; even in severe cases of acute RMSF, treatment consists of timely administration of seven to ten days of doxycycline, while individuals who have a positive IgG titer but are not showing symptoms referable to RMSF -- such as Patient A -- do not require therapy at all. However, on multiple occasions between 2010 and 2014, Patient A was aggressively treated with multiple medications for diagnoses of RMSF and/or "polymicrobial state."[5] For example, she was prescribed Lariam (mefloquine) in 2010; albendazole, mebendazole, Biltericide (praziquantel), and Ketek (telithromycin) in 2011 and 2012; Alinia (nitazoxanide) in or about 2011 through 2014; Coartem from 2012 through 2014; doxycycline in or about 2012 through 2015; unspecified "IV antibiotics" in 2013, and Vfend in 2014.

c. Between 2010 and 2015, Patient A lacked a documented history suggestive of anaplasmosis, yet she was repeatedly tested for this tick-borne disease (including on or about 6/22/11, 12/16/11, 5/11/12, 8/14/12, 11/19/12, 2/4/13, 5/13/13, 8/5/13, 11/12/13, 4/18/14, 6/5/14, 8/8/14, and 4/8/15). While some of the tests were positive, given that Patient A was asymptomatic or only marginally symptomatic for anaplasmosis, no treatment was required. However, on multiple occasions between 2011 and 2015, as detailed above in Allegations 2(a) and 2(b), Patient A was aggressively treated with

[4] Patient A's chart also indicates she was tested for RMSF on 4/2/08, 8/8/08, 6/11/09, and 10/2/09.

[5] See footnote 3 above.

antibiotics for diagnoses of "multiple tick-borne diseases" and/or "polymicrobial state," both of which were defined or explained in the patient's chart as including anaplasma/anaplasmosis.

d. To treat these multiple diagnoses (including but not limited to tick-borne diseases, "polymicrobial state," yeast/fungal overgrowth, and "detox dysfunction"), without making an appropriate risk/benefit assessment Dr. Zackrison and/or her employees ordered antibiotics and antifungals, vitamins/supplements, and/or hydration to be administered intravenously to Patient A. As the frequency of such treatment increased, Dr. Zackrison or her staff ordered surgical placement of indwelling catheters (including in or about March 2013 (at age 16); mid-September 2013 through October 2014; November/December 2014; and April through September 2015[6]), although the patient's chart does not indicate that she was unable to take medication or hydration orally. Thereafter, Patient A required monitoring for deep vein thrombosis with frequent blood work and ultrasounds (including ultrasounds on 3/22/13 (confirmed DVT, requiring removal of peripherally inserted central catheter ("PICC") from left arm and prescription of anticoagulants), 4/1/13 (follow-up scan from DVT), 6/7/13 (same), 11/8/13 (ultrasound of right arm for possible DVT), unspecified date in April 2014 (same), 6/5/14 (same), and 10/6/14 (ultrasound of right arm for possible DVT followed by replacement of midline catheter due to complaints of poor functioning)). After Patient A had been receiving IV infusions at home with parental assistance for some time, she began self-administration, and in November 2014 she was authorized by Dr. Zackrison to self-administer IV hydration at school if she felt ill and a family member was unable to pick her up. Of note, a nurse practitioner who treated Patient A while working at Dr. Zackrison's practice between late 2010 and early 2015 stated to the Board's investigator that she did not believe Patient A was chronically ill. Lastly, notes in her chart indicate that the patient herself did not always support the IV treatments. For example, another provider who treated Patient A at the practice e-mailed Dr. Zackrison

[6] The patient's chart also indicates she had a PICC in her left arm from approximately June through November 2009, when she was 12 years old.

on or about January 13, 2011 (when the patient was 14), saying that the provider "hope[d] she would have begun IVs" already, and Dr. Zackrison replied: "She is dragging her feet again." Likewise, when a representative of the company providing supplies for home infusions e-mailed Dr. Zackrison on or about June 24, 2014 (when the patient was 17) asking if the company should deliver more Invanz and hydration that week, Dr. Zackrison replied: "She is has [sic] become less compliant. Pls do not send any further supplies including hydration at this time."

e. On multiple occasions, Dr. Zackrison and/or her employees acting under her direction ordered excessive testing, tests without an appropriate medical indication, and/or tests which did not reasonably serve a clinical purpose in the treatment of Patient A. For example:

- Patient A was tested for HHV-6 (human herpesvirus) antibodies on multiple occasions (including on or about 6/22/11, 11/19/12, 2/26/13, and 8/10/15[7]). There is no medical indication for ordering this test, let alone multiple times, in a teenaged patient; almost all children over the age of five would have been previously infected and therefore would test positive for this antibody, as HHV-6 is ubiquitous and infects almost all children by that age. Further, there is no specific treatment for an active HHV-6 infection, and the symptoms (fever, rash) generally subside in 3 to 5 days.

- On or about June 5, 2014, Patient A was tested for coxsackie virus ("hand, foot, and mouth disease"). This is a mild, common enterovirus for which there is no specific treatment.

- At an office visit on June 27, 2014, a nurse practitioner at Dr. Zackrison's practice ordered the following tests for Patient A: comprehensive metabolic panel, serum osmolality, 24h urine total sodium, 24h urine osmolality, and 24h total uric acid (osmolality, NA, K+, CA). Three days later, without examining Patient A, Dr. Zackrison ordered approximately 65 lab tests[8] for

[7] Patient A's chart also indicates she was tested for HHV-6 on or about 12/30/08 and 6/11/09. The same test was also ordered on 5/27/11, although the lab was unable to complete it due to gross hemolysis, requiring a redrawing of blood.

[8] Specifically: angio-tension converting enzyme, anti-thyroid antibodies, ASO, Streptozyme, DNAase, CA Ionized, intact PTH (frozen specimen) fasting, C4a, CBC with differential and platelets, fasting insulin, ACTH hormone, FSH/LH, prolactin, insulin growth factor-1 (IgF-1), 17 hydroxyprogesterone, 17 beta estradiol, progesterone, pregnenolone, DHEA-S, estrone, estradiol, estriol androstenedione, hemoglobin A1C, H. pylori, iron/TIBC, ferritin, G6PD, total serum copper, ceruloplasmin, methylmalonic acid (MMA), PA-intrins. fact. block antibody & gastric parietal cell antibody, TAT, prothrombin fragment, free testosterone, total testosterone, sex-hormone binding globulin, zinc, selenium, L-carnitine, 25 hydroxy vit. D, Candida AB & AG (antigen), NH3, AL, PB, urine CHO, plasma renin & aldosterone, 24h urine creatinine clearance and serum creatinine, 24h urine porphyrines [sic], 24h urine total calcium, total oxalate, 24h total uric acid (spot urine, osmolality, NA, K+, Cl), antiphospholipid antibody list (cardiolipin AB (IgA, IgM, IgG), PTT, lupus coagulant), serum osmolality, comprehensive metabolic panel, phosphorus, magnesium RBC level, GGT, LDH, total & direct bilirubin, and Rocky Mountain spotted fever.

35 assessed problems.[9] Of note, at the related office visit with the nurse practitioner, Patient A had reported that on most days her joint/muscle pain was at a level of 1 to 2 out 10, and she rated her fatigue on most days as 2 out of 10. Similarly, on September 23, 2014, a lab order for Patient A completed by Dr. Zackrison requested approximately 25 tests for 25 assessed problems.

- On at least six occasions (on or about 6/22/11, 12/16/11, 11/19/12, 6/30/14, 1/16/15, and 2/24/15), Patent A was tested for H. pylori antibodies, although her differential diagnosis/assessment did not include peptic ulcers. Further, urea breath tests and stool antigen tests are more accurate than serologic tests to detect an active infection with H. pylori.

- Patient A had blood tests for candida albicans antibodies on at least 11 occasions (on or about 10/22/10, 12/16/11, 8/14/12, 11/19/12, 2/26/13, 6/5/14, 6/30/14, 8/8/14, 1/16/15, 6/3/15, and 8/10/15). This test is not useful, as healthy individuals may test positive, and the most accurate method of testing for candida is by blood culture, not serologic antibody testing.

- On October 8, 2014, Patient A had rectal/fecal swabs taken to be tested for candida albicans and Actinomyces israelii, organisms that commonly are found in the digestive tract. At the time, Patient A did not have clinical symptoms of actinomycosis or invasive candidiasis, so no testing was warranted. Further, the most accurate method of testing for candidiasis is by blood culture, and actinomyces is identified by microscopy and culture of sputum, pus, or a biopsy specimen, not from a fecal sample.

3. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in the care and treatment of Patient B, a 13-year-old female, in that between approximately September 2016 and November 2017, she ordered tests, made diagnoses, and initiated and continued potentially harmful treatment, such as long-term oral and intravenous antibiotics and steroids, without sufficient justification and without appropriately weighing possible side effects or adverse outcomes of such treatment verses the likelihood of the treatment being effective. Patient B's chart from Dr. Zackrison's practice includes the following non-specific symptoms: fatigue, palpitations, malaise, headache, weight loss, and several episodes of collapsing or fainting. In response, Dr. Zackrison recommended or ordered numerous tests,

[9] Specifically: abdominal pain, abnormal stool, adrenal glands disorder, anemia–iron deficiency unspecified, babesiosis, calcium metabolism disorders, candidiasis–thrush/vulva, chest pain/cough, chronic-fatigue syndrome, circulating anticoagulants, coagulation abnormality, constipation, dehydration, dysautonomia, enteritis–regional, fibromyalgia/chronic fatigue syndrome, fracture (closed), gastritis/gastroenteritis NOS, headache, hormonal imbalance/endocrine, hypomagnesemia, hypophosphatasia, hypothyroidism, L-carnitine deficiency, lymph nodes enlarged, malaise and fatigue, myalgia (unspecified), neutropenia (leucopenia), palpitation, paresthesia, polyarthritis inflammatory, renal insufficiency, RMSF, sleep disturbance/sleep apnea, thrombocytopenia, and weakness (muscle).

including blood work on approximately 15 occasions and urine tests five times over a 15-month period; stool tests; multiple cardiology studies, including a 30-day heart monitor, despite prior negative workups; a brain MRI and 72-hour continuous EEG, despite negative neurological workups; and a lumbar puncture/spinal tap. Upon receipt of negative or slightly abnormal test results, Dr. Zackrison diagnosed the patient with and aggressively treated her for multiple simultaneous illnesses[10] without regard to the likelihood of the disease process or whether the diagnoses made biological sense in relation to the symptom complex the patient was experiencing. For example:

a. Without referring Patient B to an appropriate specialist, Dr. Zackrison incorrectly diagnosed and treated her for Addison's disease, adrenal insufficiency, "adrenal fatigue," and/or "adrenal hypoperfusion." Adrenal insufficiency is diagnosed based on low morning cortisol levels, with confirmatory adrenocorticotropic hormone (ACTH) stimulation testing showing a peak cortisol level below 18 mcg/dL or insufficient rise from baseline cortisol. Tests of morning salivary cortisol levels are not recommended as a primary diagnostic tool due to low sensitivity and specificity. Without ordering and reviewing appropriate testing, on May 4, 2017, Dr. Zackrison diagnosed Patient B with adrenal insufficiency. The patient's chart lacked a documented ACTH level, the serum samples submitted for lab testing (collected on or about 7/27/17, 8/31/17, 10/13/17, and 11/14/17) were not obtained in the morning, and the patient's morning salivary cortisol level (from a sample submitted on 4/11/17) was within the normal range. After making this incorrect diagnosis, beginning on or about September 12, 2017, Dr. Zackrison unnecessarily prescribed hydrocortisone at doses ranging from 20mg to 30mg per day. Further, without directly communicating with the patient's ENT surgeon or the OR anesthesiologist, based on the

[10] This includes rare and unlikely diseases (e.g., bacteremia – anaerobics, pseudomembranous pharyngitis, and PANDAS); diseases for which Dr. Zackrison lacked confirmatory test results (e.g., Lyme disease, Bartonella, babesiosis, streptococcus, thrush, inflammatory arthritis, juvenile rheumatoid arthritis (juvenile idiopathic arthritis), undifferentiated connective tissue disease, sinus arrhythmia, dysautonomia, Ehlers-Danlos Syndrome, mast cell activation syndrome, Crohn's disease, and adrenal insufficiency); and conditions that are not accepted medical diagnoses (e.g., gut infections, "strep syndrome," "suspect parasites," "increased microbial burden," and "presumed bacteremia").

incorrect Addison's disease diagnosis, on October 16, 2017, Dr. Zackrison provided Patient B with a prescription for a stress dose of intravenous hydrocortisone to be administered during the patient's tonsillectomy, scheduled for October 28, 2017.

b. Patient B was diagnosed with and treated for Lyme disease, Bartonella/ bartonellosis, and "tick-borne diseases" absent an appropriate medical indication. Specifically, at her first office visit, Dr. Zackrison documented a history of a tick bite, but she did not note where or when this occurred, nor did she document whether the patient experienced symptoms indicative of Lyme disease (e.g.. erythema migrans rash, facial palsy, or joint swelling) following the tick bite. Additionally, in Patient B's chart Dr. Zackrison referred to Bartonella as a tick-borne disease and often paired it with the Lyme diagnosis; however, no study in the United States has shown that Bartonella can be transmitted to humans by ticks. Despite a lack of clinical symptoms and numerous negative antibody titers for Lyme disease (e.g., results from samples collected on or about 9/30/16, 12/15/16, 3/20/17, 7/26/17, 7/27/17, 8/31/17, and 10/13/17) and Bartonella (e.g., results from samples collected on or about 3/20/17, 5/11/17, and 7/26/17), Dr. Zackrison treated these conditions with long-term antibiotics (cefuroxime and rifampin), vitamins/supplements (including intravenous infusions administered at the practice from approximately March through June 2017), and a multitude of homeopathic substances. Of note, in a written statement provided to the Board's investigator in late 2017, Dr. Zackrison explained that Patient B's Lyme diagnosis was "proven by PCR on the tonsils." However, in addition to the PCR test being conducted after the patient had been treated with antibiotics for many months, this test was useless because B. burgdorferi is not a pathogen in the tonsil or the throat, and there are no vetted polymerase chain reaction tests for B. burgdorferi in tonsillar tissue.

c. At Patient B's first office visit, on September 15, 2016, Dr. Zackrison documented suspecting a streptococcus infection, which she listed as a possible "trigger" or "root cause" of the 13-

year-old's nonspecific complaints. Without a reasonable basis, at Patient B's second office visit (September 29, 2016), Dr. Zackrison diagnosed "strep syndrome" and Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections ("PANDAS"). "Strep syndrome" is not an accepted medical diagnosis, and PANDAS is a rare condition for which Patient B did not exhibit relevant symptoms (i.e., no history of abruptly showing signs of an obsessive compulsive and/or tic disorder shortly following a known strep infection). Following such diagnoses, on multiple occasions Dr. Zackrison ordered serum testing[11] for streptococcus (including on or about 12/15/16, 4/25/17, 5/31/17, 6/26/17, 7/27/17, 8/31/17, and 10/13/17) and she continued to treat the patient for a diagnosis of "systemic" strep,[12] although streptococcal infection generally is not diagnosed via serology. Further, even if Patient B had been properly diagnosed with streptococcus, the antibiotics regimen prescribed was incorrect. For example, on January 2, 2017, Dr. Zackrison documented her plan to use "conventional therapy" for strep infection; however, she did not prescribe a standard course of treatment for strep, i.e., a single antibiotic for a total duration of ten days. Instead, Dr. Zackrison prescribed the following unconventional and unproven antibiotics regimen (which she noted "also covers Lyme"): cefuroxime 250mg/5cc suspension to be taken 1 cc QD for one day, 1cc BID for 2 days, 2cc BID for 2 days, 3cc BID for 3 days, then 5cc BID until finishing the medication, at which time the patient was to switch to cefuroxime capsules, 500mg BID for 3 weeks, then increasing to 1,000mg BID for an unspecified duration. While taking the cefuroxime, Patient B also was instructed to increase her vancomycin dose from 125mg BID to 250mg BID.

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[11] On or about September 29, 2016, Dr. Zackrison also ordered a rectal swab that was tested for streptococcus, among other pathogens. This PCR test is not FDA approved, and the lab report noted that the test is used to "analyze samples for most commonly found bacteria in wound or ear, nose, and throat samples." Dr. Zackrison wrote on the laboratory order form that the specimen source was a rectal wound, although in the patient's chart she referred to the test as a "rectal swab," and the patient was not documented as having a rectal wound. The swab was negative for all tested bacteria.

[12] At various times the diagnosis was listed in the patient's chart as "? strep flush," "strep/working dx PANDAS," "intestinal strep," "strep infection," "strep flare – systemic," "strep rash," "strep flare with joint flare," "PANDAS flare," and "systemic strep (PANDAS)."

d. Without appropriately weighing possible side effects or adverse outcomes in a pediatric patient verses the likelihood of the treatment being effective, Dr. Zackrison prescribed antibiotics/antivirals to Patient B continuously for over a year, as follows:

- Vancomycin from approximately October 2016 to November 2017;
- Cefuroxime from approximately January to March 2017, in July 2017, and in October 2017;
- Azithromycin in July and October 2017;
- Rifampin from approximately March to August 2017;
- Clindamycin in June 2017, and from approximately July to October 2017;
- Acyclovir in November 2017; and
- Intravenous Rocephin in or about late October to November 2017 (the patient was noted to have a hep-lock placed on or about October 31, 2017, for home administration).

Long-term use of antibiotics can result in gastric distress and opportunistic infections (such as C. difficile) and contributes to antibiotic resistance, and intravenous catheters carry a risk of line infection, bacteremia, and more rarely, sepsis.

4. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in the care and treatment of Patient B between late 2016 and late 2017. Specifically, while treating this pediatric patient for, among other things, sleep disturbance, unexplained weight loss/anorexia, severe fatigue, and recurrent fainting spells apparently triggered by anxiety, Dr. Zackrison failed to refer her for psychiatric or behavioral health care and/or failed to coordinate care with any such provider concurrently treating the patient, despite knowledge of the following:

- The patient, who was 13 years old as of her first visit with Dr. Zackrison, had treated with a psychologist in the past.

- At Patient B's second office visit, on September 29, 2016, Dr. Zackrison diagnosed her with PANDAS, whose symptoms can include OCD, motor or vocal tics, mood changes, anxiety attacks, and separation anxiety.

- On or about November 8, 2016, during a telephone call with a cardiologist and neurologist involved in the care of Patient B, Dr. Zackrison stated that she believed the patient's symptoms had "emotional overlays." Dr. Zackrison also told the other providers that Patient B had been diagnosed with obsessive-compulsive disorder by a psychiatrist, but there is no such documentation in Patient B's chart at Dr. Zackrison's practice. In her notes from the call, Dr. Zackrison documented the other providers' concerns that "non[e] of [the patient's] reported

[fainting/collapsing] events ever witnessed by medical professionals" and that she "needs to be seen by behavioral health."

- In an e-mail sent to Patient B's mother on or about May 1, 2017, Dr. Zackrison stated that the intravenous treatments the patient had been receiving at the practice were "keeping her from having a full mental melt down [sic]."

- At an office visit on May 4, 2017, Dr. Zackrison documented that the patient was having hallucinations of "Blk shapes" and "being watched." She further noted: "attracted to more violent + Disturbing 'criminal' mindset."

- At an office visit on June 6, 2017, Dr. Zackrison's assessment of Patient B included "? Hallucinations."

- At an office visit on July 26, 2017, Dr. Zackrison noted the patient, who had just turned 14, was "belligerent" and "loud," that she had "social anxiety, chronic persistent," and that she reported feeling "isolated." (During much of the time Patient B was being treated at the practice, she received home-bound educational instruction or attended school for only part of the day due to her health status, which included extreme fatigue, complaints of severe joint pain, and being bed-bound.)

- At an office visit on September 5, 2017, Dr. Zackrison documented, "very poor historian[,] hesitant[,] non specific[,] whispers[,] less belligerent."

- At an office visit on September 12, 2017, Dr. Zackrison noted that the patient was a poor historian, and that it was "Not clear if she is reporting paranoid ideation." That day, Dr. Zackrison wrote a note for Patient B's school, stating that the patient "is dealing with significant medical illnesses that cause both physical + mental symptoms + dysfunction. We will cont. to attempt school based education."

- At an office visit on October 16, 2017, Dr. Zackrison documented "violent thoughts recent." She further noted the patient was a "very poor historian, reports violent thoughts [without] action, not suicidal, not homicidal." Dr. Zackrison also noted, "it's very hard to get her to be specific + detailed in her complaints even after more questions. Still not sure where her jnt pain is for example." (Regarding joint pain, Dr. Zackrison had diagnosed juvenile rheumatoid arthritis at the patient's second office visit, and at the third office visit she had assessed "suspected" Ehlers-Danlos syndrome.)

- At multiple office visits (including 5/4/17, 7/26/17, 9/5/17, 9/12/17, and 10/16/17) Dr. Zackrison noted compliance issues with the complex treatment regimen, which included severe dietary restrictions (no dairy/casein, eggs, gluten, or sugar) and numerous medications and supplements. At the patient's September 12, 2017 office visit, Dr. Zackrison documented "pill fatigue – diff[iculty] swallowing or doesn't feel well or overwhelmed."[13]

[13] At the prior office visit, on September 5, 2017, Patient B had been taking or was prescribed clindamycin, vancomycin, and compound progesterone, as well as multiple supplements/homeopathic substances, including vitamins B12 and D3,

5. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in that, on or about October 25, 2017, when contacted by Patient B's mother regarding the patient continuing to experience insomnia after taking two tablets of Benadryl and 20mg of melatonin, Dr. Zackrison did not advise about the abnormally high melatonin dose,[14] and instead replied: "Try one of the Flexeril's you have on hand – one at dinner." Nothing in the patient's chart indicates that Dr. Zackrison had prescribed Flexeril to her, or that Patient B recently had been prescribed Flexeril by another provider.

6. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in the care and treatment of Patient C, a 13-year-old female, between September 2017 and April 2018, in that she ordered unnecessary tests, made diagnoses without sufficient justification, and initiated and continued potentially harmful treatment -- such as long-term oral and/or intravenous antibiotics (e.g., cefdinir, azithromycin, vancomycin, ceftriaxone, doxycycline, and amoxicillin) and anti-fungal or anti-parasitic medications (e.g., Mepron and Coartem) -- without an appropriate indication and without ensuring that the potential benefits of the treatment outweighed the risks. For example:

a. Over an eight-month period, Dr. Zackrison diagnosed Patient C with, and treated her for, numerous diseases and conditions that are unlikely to simultaneously coexist in a single patient and which lacked an appropriate medical basis. For example:

- At the patient's third office visit, on October 5, 2017, Dr. Zackrison diagnosed dysbiosis/bacteroides, apparently based on a non-approved fecal PCR test from a sample collected on September 21, 2017. Bacteroides infection is typically diagnosed by isolation of the organism in culture from blood or another normally sterile body fluid; as bacteroides is a normal inhabitant of the gut, its identification in stool is not proof of infection. Moreover, the relevant lab report specifically states that the results "are intended for Research Use Only" and "are not intended for the diagnosis, treatment, or prevention of disease."

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multivitamins, magnesium malate, ashwagandha, Cytozyme-AD, Liver Rocket, Seriphos, Women's Phase I, Moducare, B Activ, golden pearls, thunder pearls, lightning pearls, peace pearls, Liver Protect, and Selectrolytes. Some of these were to be taken multiple times per day (e.g., the patient was instructed to take clindamycin BID, vitamin B12 BID, and ashwagandha 2 tabs BID).

[14] Dr. Zackrison had recommended melatonin to Patient B at an office visit on March 20, 2017, but she did not document a dosing recommendation.

- On October 5, 2017, Dr. Zackrison diagnosed babesiosis apparently based on an IgG test for Babesia microti from a sample collected on September 21, 2017. Babesiosis generally is diagnosed by blood smear examination, not a serum antibody test. (Of note, elsewhere in the lengthy progress notes for the same office visit, Dr. Zackrison described this as a "clinical" diagnosis.)

- On October 5, 2017, Dr. Zackrison diagnosed the patient with borreliosis (a/k/a Lyme disease) and "suspect[ed] bartonellosis" (described elsewhere in that day's progress note as "suspect[ed] Bartonella bacteroides (intestinal)"). Test results from a blood sample collected on or about September 21, 2017 had been negative for Lyme and Bartonella henselae.

- On October 5, 2017, Dr. Zackrison diagnosed the patient with "suspected" intestinal parasites. This diagnosis was without basis; a PCR stool test from a sample collected on September 21, 2017 showed no evidence of parasitic infection.

- On October 5, 2017, Dr. Zackrison diagnosed the patient with "sinusitis/mold?" although she did not document symptoms suggestive of either sinusitis or a mold infection at that office visit. Without a reasonable basis, at the patient's seventh office visit, on January 31, 2018, Dr. Zackrison noted they would "soon" begin "empiric antimold Tx," and on Patient C's ninth office visit, on March 23, 2018, Dr. Zackrison noted "suspect mold infections" absent evidence of such.

- At the patient's fourth office visit, on October 18, 2017, Dr. Zackrison diagnosed a strep infection. The diagnosis apparently was based on a positive streptozyme titer from a sample collected on September 21, 2017, which would be expected to remain positive for months following a simple, non-invasive streptococcal infection such as strep throat.

b. At Patient C's first office visit, on September 20, 2017, Dr. Zackrison documented "joint deformities consistent with" juvenile idiopathic arthritis ("JIA"), a diagnosis originally made in March 2017 by providers at a local children's hospital. However, on or about March 22, 2018, Dr. Zackrison improperly diagnosed Patient C with Lyme septic arthritis. This diagnosis apparently was based on Patient C's report at her first office visit of receiving a tick bite on her right arm during a trip to New York three months before, although the patient's family told Dr. Zackrison that Patient C did not have a rash and experienced no change in symptoms following the tick bite. In addition to a lack of early symptoms of Lyme disease following the tick bite, testing of three blood samples (collected on or about 9/21/17, 12/11/17, and 1/31/18) was not indicative of Lyme septic arthritis. (The 1/31/18 sample exhibited

two positive bands (+41 and +23) on IgM Western Blot, but these bands have been shown to be the most common false-positive results, and Patient C's sample from that day lacked five positive IgG bands, which would be expected in a patient with Lyme arthritis.) Moreover, the patient did not undergo joint fluid analysis, as would be needed to diagnose and properly treat septic arthritis. At an office visit on March 23, 2018, Dr. Zackrison clarified that the patient had a "clinical diagnosis" of Lyme arthritis, and that despite the patient's parents' request to stop antibiotics, she "must" be treated with antibiotics for this diagnosis.[15] At multiple office visits Dr. Zackrison appropriately recommended that the patient's JIA be treated with disease-modifying anti-rheumatic drugs ("DMARDs") and/or biologic response modifiers ("biologics," e.g., Remicade or Humira), but when the patient's parents refused, she continued to treat Patient C with long-term antibiotics for an apparent working diagnosis of joint pain caused by Lyme and/or other "persistent" tick-borne diseases without appropriate evidence for such.

c. The treatment provided to Patient C demonstrates an incorrect understanding of the disease process of JIA. Specifically, at the patient's first office visit, Dr. Zackrison listed a diagnosis of inflammatory polyarthritis with extensive synovitis and joint deformities consistent with JIA, but explained to the patient and her family that she aimed to treat the "root causes" of this condition, which she documented as infections (strep, parasite, mold, viruses), increased toxins (petrochemicals and mold toxins), and "increased heavy metal burden." Likewise, at the patient's third office visit, on October 5, 2017, Dr. Zackrison documented explaining that while Patient C was diagnosed with JIA under "conventional medicine" standards, under "conventional + functional medicine" her symptoms were explained in part by infections -- further defined by Dr. Zackrison as viral, bacterial (suspected intestinal Bartonella bacteroides), fungal (suspected), parasites, and tick-borne diseases (including babesia and

[15] Before this office visit, Patient C had been administered IV Rocephin daily and was taking oral Zithromax every other day, as prescribed on March 5, 2018.

Lyme). In fact, the "root causes" identified by Dr. Zackrison have not definitively been demonstrated as being associated with JIA.

d. Between September 2017 and March 2018, Dr. Zackrison failed to properly diagnose, monitor, and respond to Patient C's significant weight loss and low weight. Specifically, as of her first appointment with Dr. Zackrison (September 20, 2017), Patient C had lost approximately 40 pounds over the prior six months (down to approximately 60 lbs. from 101 lbs. in March 2017), and Dr. Zackrison diagnosed failure to thrive/significant weight loss. At that office visit, Dr. Zackrison documented explaining that the patient's weight loss was caused by vaccine mercury; in fact, vaccine mercury does not cause weight loss, and there is no mercury or thimerosal in Gardasil, the HPV vaccine to which the patient's parents attributed Patient C's ill health. During Patient C's treatment at the practice, her weight was only documented at four out of nine office visits, and it was not taken during the approximately 32 occasions at which she presented to receive IV supplements or medication. At her first office visit, the patient's parents reported that she was on a restricted diet (low-sugar, all organic, and "strict" gluten-free for the prior two weeks), but rather than referring Patient C to a dietician or requesting a food diary, Dr. Zackrison recommended eliminating all sugar and to "read up on casein free" without a valid medical basis. (Dr. Zackrison had ordered a "Food Inflammation Test," but she had not received the results when she instructed the patient on dietary changes, and the lab report from the testing notes that the testing has not been cleared by the FDA.) Similarly, on March 20, 2018, after reviewing results from additional serologic testing for IgG antibodies related to cow milk, wheat, egg yolk and egg white exposure,[16] Dr. Zackrison recommended that Patient C continue to "stay off eggs and dairy," although she could begin eating sprouted grains. While maintaining the patient on a restricted diet based on non-verified tests, Dr. Zackrison attempted to have a PICC or gastronomy tube placed "in hopes to start TPN

[16] This test was ordered from a different lab than the "Food Inflammation Test" from September 2017, but the lab report similarly notes that it "was performed using a kit that has not been cleared or approved by the FDA."

[total parenteral nutrition]"; however, she failed to recommend other options after the pediatric gastroenterologist (to whom Patient C was referred by her pediatrician) declined because the patient did not have demonstrated malabsorption issues or evidence of an improperly functioning gut. During this time, based on Dr. Zackrison's orders or instructions the patient was taking approximately 38 pills per day, in addition to 140ml of "therapeutic" oils as well as over the counter supplements.

7. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(1), (3), (13), (16), (18) and 18 VAC 85-20-26(C) of the Regulations Governing the Practice of Medicine ("Regulations") in the care and treatment of Patients A and C. Specifically, Dr. Zackrison and/or her subordinate employees acting under her direction intentionally provided inaccurate and/or incomplete information to outside medical providers concurrently treating the patients. For example:

a. In or about early March 2013, a provider at Dr. Zackrison's practice referred Patient A to a radiology practice for placement of a PICC with a history of connective tissue disease and adenopathy. Said PICC was inserted on March 13, 2013. Prior to the placement of the PICC, Patient A's most recent office visit at Dr. Zackrison's practice was on December 5, 2012, when she was seen by a nurse practitioner, and progress notes from that date do not mention connective tissue disease or adenopathy. Additionally, Patient A's pediatrician, who began treating her in 2007, never documented diagnoses of connective tissue disease or adenopathy.

b. On or about August 26, 2013, a provider at Dr. Zackrison's practice referred Patient A to a radiology practice for placement of a new PICC due to a history of encephalitis. Said PICC was inserted on September 13, 2013. Other than the September 2013 PICC order, the only documentation in the patient's chart (for the period from 2010 through 2015) mentioning encephalitis is a printout labelled "Diagnosis History," which indicates Patient A was diagnosed with or treated for Japanese encephalitis on August 14, 2012, and was diagnosed with or treated for encephalitis/myelitis/encephalomyelitis NOS

on August 20, 2013; however, progress notes from August 14, 2012 and August 5, 2013 do not include such diagnoses. Moreover, there is no indication in the patient's chart in 2012 that she recently had traveled to Asia or the Western Pacific, where the virus causing Japanese encephalitis is contracted. Further, Patient A's pediatrician never documented a diagnosis of encephalitis, nor was a history of encephalitis reported to specialists seen by Patient A during this time.

c. On or about March 6, 2018, Dr. Zackrison signed an order for IV home infusion of Rocephin for Patient C for a diagnosis of sepsis, although the patient had not been diagnosed with sepsis at her most recent office visit.

8. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), (16) and (18) and 18 VAC 85-20-28(A)(1) of the Regulations in the care and treatment of Patient D, a 35-year-old male, in or about late 2012 and early 2013, by improperly diagnosing and treating multiple simultaneous infections or disorders for which the patient tested negative and/or that are unlikely to coexist in a single patient who reported being in "excellent" general health. Specifically:

a. On October 11, 2012 (Patient D's fifth office visit at the practice, but his first with Dr. Zackrison), Dr. Zackrison told him he was "unhealthy" and prescribed Omnicef for a diagnosis of Lyme disease, "suspect chronic status," despite being aware of significant evidence indicating that he did not have Lyme disease. For example, after being bitten by ticks in mid-May 2012, Patient D did not exhibit an erythema migrans rash, facial palsy, or joint swelling. Additionally, following his first office visit, the practice sent the ticks (which Patient D had saved) to be analyzed, and the lab identified them as lone star ticks, which do not carry or spread Lyme, and a PCR test on the ticks was negative for Lyme. Moreover, multiple blood tests (from samples collected on or about 6/7/12, 6/26/12, and 9/28/12) were negative for Lyme based on CDC criteria. Finally, the nurse practitioner who treated Patient D at his first four office visits had not diagnosed Lyme disease during that time. At the office visit with Dr. Zackrison,

she apparently made a "clinical" diagnosis of "chronic" Lyme disease and/or based her diagnosis on test results that did not meet CDC criteria, without informing Patient D of such.

b. In addition to incorrectly diagnosing Patient D with Lyme disease, at the same office visit Dr. Zackrison diagnosed multiple infections (including acute anaplasmosis, acute ehrlichia, mycoplasmosis,[17] legionellosis, "suspect chronic" babesiosis, "questionable" bartonellosis, and "polymicrobial state") as well as PANDAS, "CFS [chronic fatigue syndrome] with viral overload[18] vs. encephalopathy/encephalitis," and cranial neuritis. In response she prescribed medication and supplements, recommended that the patient "start IV nutrients/support" to be administered at the practice, and ordered approximately 27 lab tests[19] for 20 diagnoses,[20] although the patient had undergone four rounds of blood work over the prior four months in addition to urinalysis and stool testing on two occasions. Dr. Zackrison made these diagnoses and prescribed azithromycin and Coartem without sufficient evidence. Prior to his office visit with Dr. Zackrison, Patient D had taken several courses of antibiotics as prescribed by the nurse practitioner (doxycycline for approximately three months and Levaquin for two weeks), making it unlikely that he had multiple acute infections. Tests for babesia (from blood samples collected on 6/7/12, 6/26/12, and 9/28/12) and bartonella (sample collected on 6/26/12)

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[17] Patient D subsequently told another provider that Dr. Zackrison had informed him that mycoplasmosis "is chronic and often misdiagnosed as an allergy. This may be why I have to clear my throat a lot."

[18] Described in progress notes as including HSV 1, EBV, and [HH]V6.

[19] Specifically: C1Q, C3a, C4a, CBC with differential and platelets, HS-CRP (cardiac), homocysteine, methylmalonic acid (MMA), IgE PCN-G + PCN-VK, antiphospholipid antibody list (cardiolipin, AB (IGA, IGM, IGG), PTT, Lupus anticoagulant), hepatitis list (includes multiple subparts which are difficult to read on form), complete metabolic panel (basic metabolic + TP, ALB, bili, CA/CA++, akl phos, protein, AST, ALT), phosphorus, lyric acid, magnesium RBC level, legionella titer IgG/IgM, CA ionized, intact PTH (frozen specimen) fasting, C-telopeptide, 25 hydroxy Vit D, urine cytology, urine creatinine clearance and serum creatinine, 24h urine protein electrophoresis, 24h urine total protein, 24h urine total calcium, total oxalate, urine N-telopeptide (second void of the morning) (osteomark), and chemistry panel – phosphorus.

[20] Specifically: Abdominal pain, abnormal kidney or renal function, abnormal weight loss, babesiosis, circulating anticoagulants, coagulation anomaly, fatigue (general weakness) (identified twice), gastritis/gastroduodenitis NOS, hormonal imbalance/endocrine (identified twice), hypomagnesemia (identified twice), L carnitine deficiency, lymph nodes enlarged, malabsorption, malaise and fatigue (identified twice), myalgia unspecified, peripheral neuropathy, paresthesia, flushing, CTD - diffuse/unspecified, and hyperglycemia/hypoglycemia.

were negative, and his chart did not contain a test for ehrlichia. Additionally, lone star ticks do not transmit babesia, and babesia is identified by peripheral blood smear examination, not the immunoglobulin testing ordered by Dr. Zackrison. The patient was not exhibiting symptoms of pneumonia consistent with an acute mycoplasma or legionella infection, nor was he exhibiting symptoms of acute anaplasmosis. Further, PANDAS is a rare condition that is not generally diagnosed in adults, and Patient D did not provide a history consistent with PANDAS in childhood (i.e., sudden development of OCD or tic symptoms following a known strep infection). Finally, two practitioners who subsequently examined Patient D disagreed with Dr. Zackrison's diagnoses and treatment plan, as follows:

- On November 5, 2012 (less than one month after he saw Dr. Zackrison), Patient D was examined by a physician assistant at an infectious disease practice. After taking his history and reviewing test results that he brought from Dr. Zackrison's practice, the physician assistant explained to Patient D that his tests were either negative or had been performed at non-standard laboratories, and therefore "should be interpreted with caution." Given that the patient had never felt very ill, she said that he did not need to take the medications prescribed by Dr. Zackrison. Further, the physician assistant did not recommend additional testing.

- On March 20, 2013, Patient D had an office visit with an infectious disease specialist at Johns Hopkins, who examined him and reviewed his prior test results. The specialist noted that the Lyme tests had been negative, and that some of the tests ordered by Dr. Zackrison had been performed at a specific lab in which he did not have confidence. The specialist also informed Patient D that many of the positive blood tests referenced by Dr. Zackrison "merely represent past exposure to bacteria and/or latency of normal viruses of the human condition" (e.g., HSV1, EBV, CMV), or lack relevance because the patient had no signs of active infection or inflammatory processes (e.g., Legionella, WA1). Finally, the specialist told Patient D that the "style of practice that Dr. Zackrison follows is not evidence-based and tends towards a liberal diagnosis of multiple simultaneous infections in long-term therapy." The specialist provided recommendations for several other health conditions going forward, but he did not concur with Dr. Zackrison's primary diagnoses (including tick-borne diseases and other infectious agents) or related treatment plan for Patient D.

c. Dr. Zackrison subsequently admitted to Patient D that her practice does not follow the standard of care applicable to Virginia physicians. After consulting with other providers and his health insurance company, Patient D exchanged several e-mail messages with staff members at Dr. Zackrison's

practice, requesting a refund of some of the fees he paid for what he concluded was unnecessary testing and incorrect treatment. In an reply sent to Patient D on or about January 4, 2013, Dr. Zackrison stated:

> It is my desire to address your concerns. …To get an accurate feedback on our evaluations and recommendations you will need to see providers for a 2nd opinion that understand, are trained in, and practice functional medicine as is practiced in my office. Physicians who are additionally experts in the complexity of tick-borne diseases. There are 2 standards of care currently being practiced in medicine: the average provider who does not usually treat cause, but only symptoms[,] which leads to poor outcomes when dealing w/ diseases that are complex and chronic[,] as compared to advanced thinkers that treat causes leading to significantly improved outcomes. The two physicians you consulted for 2nd opinions are from the average standard of care. The 2nd standard is much higher in that we seek to treat your symptoms and the condition that causes them, proactively seeking a better outcome for you and all our patients.

9. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), (16) and (18) and 18 VAC 85-20-28(A)(1) and 18 VAC 85-20-40(A)-(C) of the Regulations in the care and treatment of Patients A-D between 2010 and 2018. Specifically, Dr. Zackrison ordered or recommended numerous vitamins, minerals, and food supplements (including homeopathic substances) to be taken topically, orally, and /or intravenously without consistently documenting the rationale for such and without having a reasonable expectation that their use would result in favorable patient outcomes or provide a greater benefit than would be achieved without such use. For example:

- On July 26, 2017, Dr. Zackrison instructed Patient B to take the following supplements without specifying the specific conditions for which they were indicated and/or the results expected from their use:
  - Golden Pearls – 1 QD, working up to 2 BID
  - ashwagandha – TID
  - CytoTyme-AD – 1 Q AM
  - Cytozyme-SP – 1 QD
  - fish oil – increase to BID
  - methyl B-12 – BID
  - Moon Pearls – "put name on waiting list"
  - Women's Phase I – BID
  - Peace Pearls – 2 BID

- On October 18, 2017, Dr. Zackrison instructed Patient C to take the following supplements without specifying the specific conditions for which they were indicated and/or the results expected from their use:

- Nrfz Activator – 2 TID
- Serretia – 1 QD
- Bio Allay – 2 BID
- Kapp Arrest – 2 TID
- Liposomal curcumin – TID
- Frankincense/bergamot – 8-10 drops each, QID
- Pro DHA 2000 – BID
- Algo med – 2 TID
- Iron bisglycinate – BID
- Buffered Vit C 500mg – BID
- CBD/Hemp oil – no dose specified

- On October 11, 2012, Dr. Zackrison instructed Patient D to take daily methyl B-12 10,000mcg (PO 2 qAM and 2 qPM, under tongue), taurine 500mg (2 BID), milk thistle (1 BID), CoQ Power (1 PO qAM), and Pro Omega (2 TID), to continue to drink "medical shakes," and to "start IV nutrients/support" at her practice, without specifying the specific conditions for which these substances were indicated and/or the results expected from their use.

Of note, information in the charts of Patients B and D indicates that Dr. Zackrison's practice was selling many of these substances to her patients.

10. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), and (16) in the care and treatment of Patients A-D in that Dr. Zackrison and/or her subordinate employees acting under her direction ordered medically unproven testing and/or ordered or recommended diagnostic or treatment modalities that are outside of evidence-based medicine and whose risks are not outweighed by potential benefits. For example:

- Without objective evidence that Patient A had heavy-metal poisoning, on several occasions providers at the practice recommended that the patient undergo chelation (including on or about 3/28/12, 9/20/12, 12/5/12, and 11/12/13).

- On multiple occasions (including on or about 5/3/11, 5/17/11, 12/17/11, 3/15/12, 3/28/12, 10/3/12, and 4/10/14) providers at the practice recommended that Patient A undergo "muscle testing" or be tested with Asyra, an electrodermal device that allegedly measures galvanic skin response to provide information regarding the health of internal organs, as well as allergies and recommendations for substances to use or take to "rebalance" the body (similar to claims made by "muscle testing" in "applied kinesiology").

- On multiple occasions (including on or about 10/8/10, 11/12/10, 11/17/10, 1/4/11, 11/17/11, 12/16/11, 3/28/12, and 4/24/12) providers at Dr. Zackrison's practice recommended that Patient A undergo liver or gallbladder "detoxification," "flushing," or "cleansing."

- At an office visit on July 28, 2011, Patient A (age 14) was instructed to utilize weekly coffee enemas to kill "Parasites & atypical bacteria."

- At an office visit on October 11, 2012, Dr. Zackrison instructed Patient D to "Please start IV nutrients/support" by "speak[ing] with IV staff," although there was no indication the patient was unable to take vitamins or supplements orally.

- On or about July 5, 2017, Dr. Zackrison instructed Patient B to undergo testing with ZYTO, an electrodermal device in use at her practice whose proponents made similar claims to those made by proponents of the Asyra device described above. That same day, Dr. Zackrison recommended that Patient B begin homeopathy treatment relating to the "Top 88 foods" that the ZYTO device allegedly identified as affecting her. Similarly, on or about December 11, 2017 and March 6, 2018, Dr. Zackrison recommended that Patient C undergo testing with ZYTO.

- On December 11, 2017, Patient C was instructed to "Cont[inue] Long distance energy work."

- On or about October 25, 2016, Dr. Zackrison instructed Patient B to treat her headaches with a specific brand and formula of essential oil, which she recommended the patient apply to the top of her forehead, the "knobs" on the back of her head, the back of her neck, and "along inner wrists." At the same appointment, Dr. Zackrison recommended another essential oil from the same brand to treat nausea.

11. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(3), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in that her records for Patients A-D, dating between 2010 and 2018, are inaccurate and/or incomplete. Specifically:

a. It is difficult or impossible to determine comprehensive treatment plans, including estimated duration of each recommended treatment modality, and when or if the treatment plans changed based on test results and/or how the patients responded to specific treatment modalities.

b. It is difficult or impossible to readily determine patient medication regimens from their charts. Specifically, the charts lack flow sheets and do not contain copies of all prescriptions. Additionally, progress notes do not consistently list medications and supplements prescribed at each office visit, nor do they consistently and accurately document the doses prescribed or recommended. Lastly, the

diagnosis or symptom for which each medication or supplement was prescribed/recommended frequently cannot be discerned from progress notes. For example:

- When asked to "Please list your medications & supplements" at office visits between 2010 and 2015, Patient A often left that portion of the form blank, wrote in a question mark, or wrote that the provider should ask a parent for the information. The providers treating the patient did not consistently complete such information, and the chart lacked a flow sheet by which it could be determined all medications and supplements the patient was taking (orally or intravenously) as of each office visit.

- In an e-mail to her staff dated March 22, 2012, Dr. Zackrison requested that the following prescriptions be ordered by mail for Patient A: #120 Coartem 20/120mg (3 BID), #60 mebendazole 100mg (TID), and #120 albendazole 200mg (2 BID), although the most recent progress note, from an office visit with a nurse practitioner on January 5, 2012, does not include such a treatment regimen. Progress notes from a subsequent office visit, on April 24, 2012, include a "Rotation schedule based upon tolerance" for treatment of "Polymicrobial state" which listed five medications (biltracide [sic], Alinia (nitazoxanide), Coartem, albendazole, mebendazole, and Tindamax (tinidazole)), but did not include any dosing information, including the length of each "rotation."

- On or about April 14, 2015, Dr. Zackrison e-mailed a member of her staff to inquire about "the status of the compounded vaginal Vanco Rx I wrote in March" for Patient A. Staff responded that it had been delivered to the patient's home on March 7th. Patient A did not have a documented examination at the practice in February or March 2015, and her file does not otherwise contain information about this prescription or its indication.

- Dr. Zackrison documented recommending melatonin to Patients B (on 3/20/17) and C (on 3/6/18), but she did not document the dose recommended to these underweight pediatric patients.

- On November 7, 2017, Dr. Zackrison prescribed to Patient C #14 Zithromax plus one refill (1 PO QD), #60 vancomycin plus one refill (1 PO BID), and #60 Augmentin 500mg plus one refill (1 PO BID) without clearly documenting related rationales. Progress notes from that day include the following diagnoses: PsA sine psoriasis, juvenile idiopathic arthritis, marked synovitis, failure to thrive, multiple food sensitivities, ANCA [anti-neutrophil cytoplasmic antibody] + UCTD [undifferentiated connective tissue disease], APL Abs [antiphospholipid antibodies], persistent tick-borne diseases, strep, detox dysfunction, pain management; 100% disabled, along with "Strong Hx of Toxin Burden Ppt illness ie Gardasil" and "microbial burden" (which was explained as including Babesia and strep).

- On multiple occasions, progress notes indicate that intravenous treatment had been recommended or that patients were receiving intravenous infusions, but the dates of such treatments were not consistently documented in patient charts, nor were the substances being infused or recommended for infusion consistently or clearly documented. For example:

- Progress notes for office visits on 9/29/16 and 10/25/16 indicate that Dr. Zackrison recommended intravenous "nutrients," "detoxing," and/or "natural antimicrobials" to Patient B, but no additional information was included in such notes.

- Records for Patients A (e.g., 11/12/13, 7/8/14, and 9/14/15), B (e.g., 3/20/17, 4/7/17, and 5/4/17) and C (e.g., 12/11/17, 2/23/18, and 3/5/18) indicate they were receiving infusions of "Miss" or "MISS" without detailing what substances were contained in the IV solution. (Of note, Patients B and C both reported adverse reactions to these treatments.)

- At an office visit on 11/7/17, the plan for Patient C included "Start IV detoxing," but this was not further defined in the progress note.

- At an office visit on October 11, 2012, Dr. Zackrison instructed Patient D to "Please start IV nutrients/support" by "speak[ing] with IV staff," but progress notes do not indicate a rationale, doctor-recommended infusion schedule, or information on what substances were recommended for infusion.

c. Dr. Zackrison provided patients with medication dosing instructions that differed from dosing instructions provided to the pharmacy on the corresponding written scripts. For example:

Patient	Date	Script - Medication & Dose	Dosing Instructions to Patient
B	11/22/16	#60 Vancomycin 125mg – 1 PO BID	1 a day x 2 wks [then increase to] 1 twice a day
	1/2/17	cefuroxime 250mg/5cc liquid +2RF - 5cc BID	1cc QD x 1 day; 1cc BID x 2 days; 2cc BID x 2 days; 3cc BID x 3 days; 5cc BID - "finish and switch to capsules."
	1/2/17	#120 cefuroxime 500mg – 2 PO BID	1 PO BID for three weeks, then increase to 2 PO BID[21]
	3/20/17	#60 rifampin 150mg - 1 PO BID	1 QD for 7 days, then increase to 1 PO BID
	7/5/17	#20 Zithromax 500mg – 1 PO QD	"Start in 5 days 1 a day x 5 ds ½ a day x 5 ds ½ 3x/wk @ Dinner"

[21] At the patient's next appointment (2/13/17), Dr. Zackrison instructed the patient to take cefuroxime 250mg tablets as follows: 2 in the morning and 3 in the evening for 7 days, increasing to 3 in the morning and 3 in the evening for 7 days, increasing to 3 in the morning and 4 in the evening for 7 days, then increasing to 4 in the morning and 4 in the evening (or 500mg 2 tabs BID). There was no corresponding script in the chart for 250mg tablets of cefuroxime on this date, and the progress note does not indicate how many dosage units were prescribed. After the appointment, the patient's mother e-mailed Dr. Zackrison for clarification, saying, "There was some confusion today about how many mg of Cefuroxime [Patient B] has been taking. I checked the previous notes and prescriptions and [she] has been taking 1000mg 2 times per day since February 5th, as per your instructions. This is probably why she is having headaches. The plan we established at today's appointment was to build her up to this dose of Cefuroxime over the next three weeks, but we are already there."

	7/5/17	#60 Vancomycin 250mg – 1 PO BID	"1 a day"
	7/26/17	#60 Vancomycin 250mg – 1 PO BID	"Continue Vanco 250[mg] 1 a day"
	10/16/17	#20 Zithromax 500mg – 1 PO QD	"1 every other day"
C	10/18/17	#300cc Mepron 7.5mg/5cc liquid – 5cc PO BID	"See previous titration schedule." At the prior office visit (10/5/17) the patient was instructed as follows: ½ tsp every other day x 10 days; 1 tsp every other day x 10 days; 1 tsp 2x a day every other day x 10 days. (The chart does not include a script for the 10/5/17 prescription.)
	11/7/17	#60 doxycycline 100mg +1RF – 1 PO BID	"Start doxycycline 100mg 1 @ dinner w/ lots food Before + after taking Doxy 3x/wk."
	12/11/17	#300cc Mepron 750mg/5cc liquid - 5cc PO BID	1 tsp every other day
	12/11/17	#60 Omnicef 300mg BID	1 at dinner x 5 days, increasing to 1 twice a day
	1/31/18	#20 Zithromax 600mg – 1 PO QD	Zithromax 600mg ½ a day @ Dinner #30
	3/6/18	#80 Coartem 20/120 – 2 PO BID	1 every other day
D	10/11/12	#24 Coartem 20/120mg – 3 PO BID	One tablet twice a week for the first week, increasing to two tablets together twice a week for the second week, then on the third week increasing to two tablets together three times a week.[22]

d. The charts for Patients A, B, and C are incomplete or contain erroneous information. For example:

- Patient A's chart does not contain reports or other documentation from the use of the Asyra device, which apparently was conducted on March 28, 2012. (The results appear to be referenced in the patient's chart.)

- On or about May 13, 2013, Dr. Zackrison ordered radiology studies of Patient A's left elbow and thumb for "Cellulitis/fasciitis L elbow pain eval for effusion" and "Trauma to L thumb w/ pain + swelling + [decreased] ROM." However, Patient A had not had an office visit with examination at the practice since April 8, 2013, and such symptoms were not noted on that progress note.

[22] On October 31, 2012, Patient D e-mailed Dr. Zackrison to ask what he should do after he mistakenly continued the first week's dosing instructions for two weeks.

- Per Dr. Zackrison's letter to the Board's investigator dated October 21, 2015, Patient A had a PICC placed in March 2013 "for the purpose of infusing IV antibiotics and IV fluids. The rationale behind the upgrade to IV antibiotics was a medical judgment [by a nurse practitioner at the practice]. The patient failed several attempts at oral antibiotic treatments." However, prior to placement of the PICC, Patient A had not presented for an office visit for approximately three months, and progress notes from the previous office visit (December 5, 2012), do not address the need for a PICC. Additionally, the patient's chart does not include an order related to this PICC placement.

- Per Dr. Zackrison's letter to the Board's investigator dated October 21, 2015, Patient A was evaluated for a possible DVT in April 2014 in relation to her PICC; however, the patient's chart does not include a related radiology report.

- Patient B's chart does not contain reports or other documentation from the use of the ZYTO device, which apparently was conducted on or about July 5, 2017. (Dr. Zackrison referenced such results in the patient's chart.)

- On or about October 31, 2017, Patient B's mother e-mailed Dr. Zackrison to report that her daughter was "unable to tolerate the oral antibiotics. … Her throat [after recent tonsillectomy] is still too sore and swollen to swallow the pills." Dr. Zackrison instructed staff to "set up a phone consult URGENTLY with NP (consider bringing in for IM or IV Rocephin QD x4)." Staff replied to Dr. Zackrison that the patient would be coming in that day for administration of IV Rocephin and "going home with a hep lock to do IV at home as well." However, the IV Rocephin dosing was not specified, the patient's chart does not include documentation from the in-office infusion performed that day, nor does the chart include instructions on whether the patient was advised to discontinue her oral antibiotics while taking IV Rocephin. (As of her last office visit two weeks prior, Patient B was prescribed oral cefuroxime (liquid and pills), vancomycin, and Zithromax (liquid and pills).)

- On or about November 8, 2016, in relation to a telephone call with a cardiologist and neurologist involved in the care of Patient B, Dr. Zackrison told the other providers that Patient B had met with a psychiatrist and been diagnosed with obsessive-compulsive disorder; however, there is no documentation of such a diagnosis by an outside provider in Patient B's chart or any evidence of coordination of care by Dr. Zackrison with such a provider.

- On or about March 23, 2018 Dr. Zackrison referred Patient C for x-rays, but there is no copy of the referral slip in the patient's chart.

- Patient C's weight was only documented at four out of nine office visits, although this pediatric patient had been diagnosed with failure to thrive and low weight. Additionally, the weight documented at her first office visit (9/20/17), may be incorrect, as both her weight and height were recorded as the same number (60.2). Further, in her written statement to the Board's investigator dated April 20, 2018, Dr. Zackrison noted that the weight recorded at the patient's fourth office visit (10/18/17) -- which would have represented significant weight gain -- might be incorrect, as "Mom was supporting her on the scale; not sure this is accurate."

- In or about November 2017 Dr. Zackrison or a member of her staff at her direction ordered placement of a PICC for Patient C. Said PICC was placed by an outside practice on or about November 21, 20017, but the patient's chart lacks a copy of such order. Additionally, on March 22, 2018 during a telephone call with Patient C's pediatrician, Dr. Zackrison stated that she "has had confirmatory xrays for placement" of Patient C's PICC, but no such documentation is found in Patient C's chart.

12. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(1), (16), and (18) and 18 VAC 85-20-300(B) of the Regulations in that she made false and deceptive statements relating to the practice of medicine. Specifically:

a. On April 1, 2016, Dr. Zackrison provided false information during questioning under oath in a legal matter involving her care of Patient D, as follows:

> Q: "Are you board certified?"
> A [Dr. Zackrison]: "Yes."
> Q: "In what fields?"
> A [Dr. Zackrison]: "In both internal medicine and rheumatology."
> ...
> Q: Well, you're board certified as a rheumatologist.
> A [Dr. Zackrison]: Correct.

Dr. Zackrison's board certification in internal medicine had expired approximately four years earlier, and her board certification in rheumatology expired approximately two years earlier.

b. On or about September 22, 2016, Dr. Zackrison provided false information on her Board of Medicine Practitioner Profile (located at www.vahealthprovider.com). Specifically, her profile stated that she became Board Certified in "Internal Medicine: Rheumatology" in 2016. In fact, she became board certified in this specialty in 1994, which expired in or about 2014. The false information remained on her profile at least as of November 23, 2016.

c. In or about late November or early December 2017, Dr. Zackrison provided false information to the Board's investigator. Specifically, Dr. Zackrison submitted a CV which stated: "Board Certified – Diplomat, American Board of Internal Medicine. September 1991. Recertified – Diplomat,

American Board of Internal Medicine. 2012," thus giving the impression that she held active board certification in internal medicine, although her certification had expired approximately five years earlier.

13. Dr. Zackrison violated Virginia Code § 54.1-2915(A)(16) and (18), as further defined by Virginia Code § 54.1-111(A)(7), and 18 VAC 85-20-105 of the Regulations, in that on December 4, 2017 and December 5, 2017, she willfully refused to provide information as requested by the Board's investigator pursuant to an investigation.

14. Dr. Zackrison is in violation of Virginia Code § 54.1-2915(A)(4) in that she is incompetent to practice medicine with safety to patients and the public, lacks sound medical judgment, and has failed to conform to the standard of care of evidence-based medicine, as demonstrated by the Order of the Board entered February 25, 2015, and Allegations #2 through #13 above.

See Confidential Attachment for the names of the patients referenced above.

William L. Harp, M.D.
Executive Director
Virginia Board of Medicine

9/12/19
Date