COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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August 11, 2014

Leila Haddad Zackrison, M.D.
Optimal Health Dimensions
3930 Pender Drive, Suite 280
Fairfax, Virginia 22030

UPS OVERNIGHT MAIL

RE: License No.: 0101-045689

Dear Dr. Zackrison:

In accordance with Sections 54.1-105, 54.1-110, 54.1-2400, 2.2-4020, and 2.2-4021 of the Code of Virginia (1950), as amended ("Code"), you are hereby given notice that the Virginia Board of Medicine ("Board") will convene a formal administrative hearing to receive and act upon evidence that you may have violated certain laws governing the practice of medicine in Virginia, as set forth in the attached Statement of Particulars.

The formal administrative hearing will be held in accordance with the provisions of Section 54.1-2400(11) of the Code, before a panel of the Board, with a member of the Board presiding. You have been scheduled to appear before the Board on **Saturday, October, 18, 2014, at 9:00 a.m., in the offices of the Department of Health Professions, 9960 Mayland Drive, 2nd floor, Henrico, Virginia**. Your presence is required thirty (30) minutes in advance of the appointed time. Please be seated in the waiting room and you will be called when the Board is ready to meet with you.

You have the following rights, among others: to be accompanied by and represented by counsel, to submit oral and documentary evidence and rebuttal proofs, to conduct such cross-examination as may elicit a full and fair disclosure of the facts, and to have the proceedings completed and a decision made with dispatch. Should you wish to subpoena witnesses, requests for subpoenas must be made, in writing, in accordance with the enclosed Instructions for Requesting Subpoenas.

Please carefully read the following paragraphs, which contain date-sensitive and important information regarding this proceeding.

COMMONWEALTH'S EVIDENCE

You have the right to the information that will be used by the Board in reaching a decision regarding this matter; therefore, I enclose the Commonwealth's evidence. Please note that these documents are enclosed only with the original notice sent by UPS overnight mail. These materials have been provided this date to your counsel, R. Harrison Pledger, Jr., Esquire.

Should you wish to file objections to the Commonwealth's evidence, you must send your written objections to me, at the address on this letterhead, no later than **September 19, 2014**. If you have not filed any objections by **September 19, 2014**, the exhibits will be distributed to the Board members for their review prior to your hearing, and will be considered by the Board as evidence when it deliberates upon your case. If you do file objections, the Commonwealth has until **September 25, 2014,** to file a response to the objections, in writing and addressed to me at the Board office. The Chair of the proceeding will rule on the motion.

RESPONDENT'S EVIDENCE

Further, should you wish for the Board to consider additional information relative to this proceeding, you must submit fifteen (15) copies of any such documents to Jennie Wood, Discipline Case Manager, Virginia Board of Medicine, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, by **September 16, 2014.** You may not submit your documents by facsimile or e-mail.

The Commonwealth must file any objections to your submissions in writing, addressed to me at the Board office, no later than **September 22, 2014**. If no objections have been received by **September 22, 2014**, the evidence will be distributed to the Board members for their review, and will be considered by the Board as evidence when it deliberates upon your case. If the Commonwealth raises objections, you have until **September 25, 2014,** to file your response to the objections, in writing and addressed to me at the Board office. The Chair of the proceeding will rule on the motion.

OTHER PRE-HEARING MOTIONS

If you or Senior Assistant Attorney General James Schliessmann wish to make any pre-hearing motions regarding matters other than the exhibits, including offers of settlement, each of you is directed to file motions, in writing, addressed to me at the Board office by **September 16, 2014**. Responses to motions filed must be submitted by **September 22, 2014**. The Chair of the proceeding will rule on the motion.

REQUEST FOR A CONTINUANCE

Absent exigent circumstances, such as personal or family illness, a request for a continuance after **September 25, 2014,** will not be considered.

Relevant sections of the Administrative Process Act, which govern proceedings of this nature, as well as laws relating to the practice of medicine and other healing arts in Virginia

cited in this notice can be found at http://leg1.state.va.us. To access this information, please click on *Code of Virginia* for laws and *Virginia Administrative Code* for regulations.

Please indicate, by letter to this office, your intention to be present.

Sincerely,

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

Enclosures:
Commonwealth's Exhibits 1-6 (5 volumes)
Statement of Particulars
Attachment I
Instructions for Requesting Subpoenas

cc: James Schliessmann, Senior Assistant Attorney General (*with enclosures*)
Erin Barrett, Assistant Attorney General, Board Counsel
Tracy E. Robinson, Adjudication Specialist, APD
Lorraine McGehee, Deputy Director, APD
R. Harrison Pledger, Jr., Esquire (*with enclosures*)
Jacques G. Simon, Esquire
Sharron Squires, R.N., Senior Investigator (139030)

VIRGINIA:

BEFORE THE BOARD OF MEDICINE

IN RE: LEILA HADDAD ZACKRISON, M.D.
License No.: 0101-045689

STATEMENT OF PARTICULARS

The Virginia Board of Medicine ("Board") alleges that Dr. Zackrison may have violated Sections 54.1-2915.A(3)[1], (13), and (16) of the Code of Virginia (1950), as amended ("Code"), in the care and treatment of Patient A from 2003 through 2007. Specifically:

1. In or about May 2003, Dr. Zackrison diagnosed Patient A with reactive arthritis/spondyloarthropathy. The patient was HLA B27 negative, making this diagnosis less likely, although it would not exclude this diagnosis. However, the clinical presentation and lack of radiographic findings such as sacroiliitis are not supportive of a diagnosis of chronic reactive arthritis.

2. In or about August 2003, Dr. Zackrison diagnosed Patient A with systemic vasculitis, although the patient's records lacked physical exam findings suggestive of vasculitis, and inflammatory parameters (erythrocyte sedimentation rate and C-reactive protein) were noted to be normal on several occasions.

3. In or about February 2005, Dr. Zackrison diagnosed Patient A with calcium pyrophosphate dihydrate ("CPPD") disease/pseudogout and prescribed colchicine to treat the condition, although the basis of the diagnosis in the patient's medical records is unclear. Medical records do not include radiographic documentation

[1] Prior to July 1, 2003, Section 54.1-2915.A(3) was codified as Section 54.1-2915.A(4) as written to include gross ignorance or carelessness in the practice, or gross malpractice. After July 1, 2003, it was rewritten to include intentional or negligent conduct in the practice that causes or is likely to cause injury to the

of chondrocalcinosis, synovial fluid crystal analysis, or subjective report of episodic joint swelling suggestive of pseudogout.

4. In regards to Dr. Zackrison's diagnosis and treatment of Patient A for Lyme disease beginning in or about October 2003:

a. Dr. Zackrison diagnosed Patient A with Lyme disease although medical records do not note a history of symptoms/signs compatible with the diagnosis, such as erythema migrans skin lesions, arthritis of the large weight bearing joints, carditis, Bell's palsy, acute radiculopathy, or lymphocytic meningitis.

b. Dr. Zackrison diagnosed the patient with Lyme disease, although numerous serologic tests for Lyme infection, including Western blot and ELISA, were negative.

c. After initial lab tests (Western blot and ELISA) were negative, Dr. Zackrison ordered repeat tests on approximately 16 occasions, with each result being negative. Moreover, on approximately nine occasions Dr. Zackrison ordered polymerase chain reaction ("PCR") tests on urine, although this test is not approved by the U.S. Food and Drug Administration to diagnose Lyme disease.

d. On two occasions for durations of approximately three months each (November 6, 2003 to February 13, 2004; and July 28, 2006 to November 2, 2006), Dr. Zackrison treated Patient A with long-term antibiotic therapy

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patients.

(ceftriaxone). However, Patient A did not meet Infectious Diseases Society of America ("IDSA") Guidelines-established criteria for diagnosis of Lyme disease, and prolonged courses of ceftriaxone have not been demonstrated to be beneficial. This type of treatment placed Patient A at risk for infection from a PICC line as well as antibiotic side-effects. Moreover, ceftriaxone therapy was administered to the patient in pulsed dosing, five days a week, in contradiction of IDSA Guideline evidence-based recommendations.

e. Dr. Zackrison appeared to base the duration of antibiotic treatment for the patient's diagnosis of Lyme disease on normalization of antibody titers, although the presence of IgG antibodies does not distinguish between active infection and prior exposures, and it is very common for protective IgG antibodies to persist for many years following vaccination or recovery from an infection.

5. In regards to Dr. Zackrison's diagnosis and treatment of Patient A for salmonella, salmonellosis, and/or reactive arthritis due to chronic salmonellosis beginning in or about May 2003:

a. Dr. Zackrison diagnosed the patient with salmonella without any positive cultures of blood, stool, or urine to support the diagnosis. Although the patient had multiple positive serologic screens for salmonella, such tests cannot distinguish between past and present infection.

b. Despite the lack of usefulness of serologic tests for salmonellosis, Dr. Zackrison ordered such tests on approximately nine occasions.

c. Although Patient A lacked any culture-confirmed evidence of salmonella infection, Dr. Zackrison treated her with ciprofloxacin for approximately five months (May 5, 2004 to October 18, 2004).

6. In regards to Dr. Zackrison's diagnosis and treatment of Patient A for babesiosis and/or reactive arthritis due to babesiosis beginning in or about January 2004:

a. Dr. Zackrison diagnosed the patient with babesiosis without positive identification of the parasite on thin blood smears and in the absence of suggestive clinical signs and symptoms of the disease, such as history of tick exposure in an endemic area for babesiosis or history of blood transfusion, and presentation of the patient with fever, hemolytic anemia, or thrombocytopenia, as well as nonspecific symptoms such as headache, chills, myalgias, and arthralgias.

b. Dr. Zackrison apparently diagnosed the patient with babesiosis based on a positive Babesia microti PCR on one occasion, a positive Babesia microti IgG on two occasions, and a persistently positive WA1 IgG. However, on multiple occasions the patient had negative Babesia microti PCR results, raising the issue of a false positive or contaminated specimen. Moreover, serologic tests cannot distinguish past from current infection. Finally, Dr. Zackrison did not consult with or refer the patient to an infectious diseases specialist who would be more acquainted with the reliability and significance of such assay results.

c. After ordering an initial blood test for Babesia antibodies, Dr.

Zackrison ordered repeat tests on approximately 17 occasions, although the patient never had positive identification of the parasite on thin blood smears and she no longer had exposure to potential infection from Babesia during the time she was under Dr. Zackrison's care.

d. Even if the diagnosis of babesiosis had been correct, Dr. Zackrison incorrectly and excessively treated Patient A with antibiotics for this disease. Standard treatment for babesiosis lasts 7 to 10 days, unless continued parasitemia on blood smears is documented. However, without such test results, Dr. Zackrison treated the patient with antibiotics during the following approximate date ranges:

Medication	Date(s)
Biaxin	2/16/04 to 5/5/04 2/3/06 to 6/20/06 5/21/07
Atovaquone	2/16/04 to 5/5/04 3/3/05 to 5/21/07
Ketek	4/13/05 to 5/13/05
Clindamycin	4/21/06 to 9/15/06
Azithromycin	6/20/06 to 7/25/06 (intravenous) 4/21/06 to 5/21/07 (oral)

7. In or about February 2006, Dr. Zackrison diagnosed Patient A with suspected Bartonella infection, although repeated testing for Bartonella was negative. Furthermore, Dr. Zackrison failed to consult with or refer the patient to an infectious diseases specialist regarding her lab results.

8. On or about October 13, 2003, Dr. Zackrison diagnosed Patient A with "candida yeast infection of stool/gut," although no supporting information such as culture reports substantiated this diagnosis. Moreover, although Dr. Zackrison lacked

culture evidence of candida infection, she treated the patient with fluconazole for a one-year period (October 13, 2003 to October 18, 2004).

9. Although an established diagnosis of one or more active infections was not supported in the patient's medical records, as discussed in the allegations above, Dr. Zackrison treated Patient A with antibiotics for multiple conditions on an approximate continuous basis from approximately late 2003 to mid-2007. During this time period, there was no consistent documentation in the medical record supporting sustained improvement in the patient's physical or cognitive function. Moreover, the records lack a treatment plan to document improvement, to reevaluate the success of therapy and to help guide its duration, and to reconsider the appropriateness of Dr. Zackrison's initial diagnoses for Patient A.

Please see Attachment I for the identity of the patient listed above.

FOR THE BOARD

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

DATE: 8/11/2014