## BEFORE THE ADMINISTRATIVE HEARING COMMISSION STATE OF MISSOURI SEP 1 7 2012

STATE BOARD OF REGISTRATION FOR THE HEALING ARTS	ADMINISTRATIVE HEARING COMMISSION
Petitioner,	
v.	Case No. 09-1693HA
CAROL A. RYSER, M.D.,	SEP 1 7 2012
Respondent.	ADMINISTRATIVE HEARING COMMISSION

## PETITIONER'S CORRECTED BRIEF IN SUPPORT OF PETITIONER'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

COMES NOW Respondent, the Missouri State Board of Registration for the Healing Arts ("the Board"), by and through undersigned counsel, and in support of its Proposed Findings of Fact and Conclusions of Law states the following:

#### BACKGROUND/INTRODUCTION

The State Board of Registration for the Healing Arts (hereinafter "the Board") is an agency of the state of Missouri, created and established pursuant to section 334.120 RSMo, for the purpose of executing and enforcing the provisions of Chapter 334, RSMo. Respondent, Carol A. Ryser, M.D., is licensed by the Board as a physician and surgeon, License Number R3788. This license was first issued on January 17, 1970. Dr. Ryser's license is current, and was current and active at all relevant times herein.

Respondent maintains an office at 5308 Longview Road, Kansas City, Missouri 64137, Health Centers of America (formerly Matrix Mid-America), which she established in 1975.

The Board filed its Complaint on December 24, 2009, which contains nine (9) separate counts involving allegations that Dr. Ryser's treatment of seven patients fell below the standard of care; allegations of repeated negligence; allegations that Dr. Ryser's treatment of the patients constituted misconduct, fraud, misrepresentation, dishonesty, unethical conduct or unprofessional conduct; allegations that Dr. Ryser obtained or attempted to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation and willfully and continually overcharged or overtreated patients; allegations that Dr. Ryser willfully and continually performed inappropriate or unnecessary treatment, diagnostic tests or medical or surgical services; allegations that Dr. Ryser delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform such responsibilities; and allegations that Dr. Ryser misrepresented that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine or device.

#### **EVIDENTIARY STANDARDS AND BURDENS**

The Board has the burden of proving that Dr. Ryser has committed conduct for which the law allows discipline. *Missouri Real Estate Comm'n v. Berger*, 764 S.W.2d 706, 711 (Mo. App. E.D. 1989). The Board must prove its contentions by a preponderance of the evidence. *State Board of Nursing v. Berry*, 32 S.W.3d 638, 642 (Mo. App., W.D. 2000). The standard of care must usually be established by expert testimony. *Tendai v. Missouri Bd. of Reg. for the Healing Arts*, 161S.W.3d 358, 368 (Mo. 2005); *Dine v. Williams*, 830 S.W.2d 453, 456 (Mo. App. W.D. 1992)

Here, the Board asserts that Dr. Ryser actions and conduct violated sections 334.100.2 (4), (4) (a), (4) (c), (4) (d), (4) (e), and (5) RSMo, which allow for discipline for the following:

2. The Board may cause a complaint to be filed with the administrative hearing commission as provided by Chapter 621, RSMo, against any holder of any certificate of

registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(4) Misconduct, fraud, misrepresentation, dishonesty, unethical conduct or unprofessional conduct in the performance of the functions or duties of any profession licensed or regulated by this chapter, including, but not limited to, the following:

\* \* \*

(a) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation; willfully and continually overcharging or overtreating patients; or charging for visits to the physician's office which did not occur unless the services were contracted for in advance, or for services which were not rendered or documented in the patient's records;

\* \* \*

(c) Willfully and continually performing inappropriate or unnecessary treatment, diagnostic tests or medical or surgical services;

\* \*

(d) Delegating professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform such responsibilities.

\* \* :

(e) Misrepresenting that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine or device;

\* \*

(5) Any conduct or practice which is or might be harmful or dangerous to the mental or physical health of a patient of the public; or incompetency, gross negligence or repeated negligence in the performance of the functions or duties of any profession licensed or regulated by this chapter. For the purposes of this subdivision, "repeated negligence" means the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member of the applicant's or licensee's profession;

Grounds for discipline such as "misconduct" and "fraud" require a willful or intentional act. *Missouri Bd. for Arch'ts, Prof'l Eng'rs & Land Surv'rs v. Duncan,* No. AR-84-0239, at 125 (Mo. Admin. Hearing Comm'n, Nov. 15, 1985), aff'd, 744 S.W.2d 524 (Mo. App., E.D. 1988); *State ex rel. Williams v. Purl,* 128 S.W. 196, 201 (Mo. 1910). However, the Commission has

previously held that grounds for discipline such as "unethical conduct" or "unprofessional conduct" may apply "to both unintentional conduct and intentional conduct." *Missouri Bd. of Reg. for the Healing Arts v. Swanson*, No. HA-99-1039, at 28 (Mo. Admin. Hearing Comm'n, Sept. 12, 2001) (Emphasis added).

The primary purpose of the statutes authorizing the Board to discipline a physician's license is to safeguard the public health and welfare. *State Bd. of Reg. for the Healing Arts v. Levine*, 808 S.W.2d 440, 442 (Mo. App. 1991). Because the statutes are remedial and not penal in nature, they should be construed liberally and with the purpose of suppressing the conduct undertaken to be remedied. *Bittiker v. State Bd. of Reg. for the Healing Arts*, 404 S.W.2d 402, 405 (Mo. App. W.D. 1966). It is the Board's contention that Ryser's conduct herein violates one or more provisions of § 334.100.2, RSMo and therefore cause exists for the Board to discipline her license.

I.

# Petitioner's qualified expert medical testimony that Respondent was repeatedly negligent in her care and treatment of the seven (7) patients set out in Petitioner's Complaint is effectively uncontroverted for failure of Respondent to have her expert medical witnesses define "negligence" as required by Missouri law and procedure

Petitioner presented expert medical testimony from Dr. Michael Cooperstock and Dr. Gordon Christensen establishing that Respondent was repeatedly negligent and violated established standards of care in her care and treatment of the seven (7) patients named in the Board's Complaint. (Petitioner's Exhibits 22a, 22d, 22e, 22g, 22h, Christensen depositions Volume I-V and Tr. XII pages 1577 to 1590; Testimony of Dr. Cooperstock, Tr. Volume 1, pages 60-138 and Volume II, pages146-300). Although Respondent presented testimony from three (3) expert witnesses and additionally gave expert testimony in her own defense, none of respondent's expert testimony regarding negligence and meeting the applicable standard of care

was properly qualified as required by a long line of Missouri case law, including *State Board of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 146 (Mo. banc 2003). *See also*, *Swope v. Printz*, 468 S.W.2d 34, 40 (Mo. 1971); Ladish v. *Gordon*, 879 S.W.2d 623, 634-35 (Mo. App. W.D. 1994) *Dine v. Williams*, 830 S.W.2d 453, 456 (Mo. App. W.D. 1992) (Entire record). These Missouri cases require that an expert medical witness at some point in his or her testimony specifically define their terms when testifying about medical negligence. At some point in his testimony, an expert witness must confirm that he is using the terms "negligence" and "standard of care" in accordance with the terms of the law, in this particular case, The Healing Arts Practice Act, Section 334.100.2(5), RSMo. 2000. Under Section 334.100.2(5), RSMo. 2000, "negligence" is defined as "the failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member(s) of the licensee's profession."

Although Dr. Sigal, Dr. Wormser, Dr. Cooperstock and Dr. Christensen defined "negligence" in accordance with the terms of Section 334.100.2(5)<sup>1</sup>, none of Respondent's experts were asked this question or gave this definition, although all repeatedly talked generally about "standards of care." (Entire record). Under the authority of the *McDonagh* and other applicable Missouri precedents, the testimony of Respondent's medical experts regarding the "standard of care," undefined, does not constitute substantial evidence that would support a finding of fact by the Commission. Petitioner's properly qualified expert testimony, given in the precise terms of the statute, to the effect that Respondent violated the applicable standards of care for all seven (7) patients, was effectively uncontroverted.

<sup>&</sup>lt;sup>1</sup> Testimony of Dr. Michael Cooperstock, Tr. Volume I, pages 105-106; Testimony of Dr. Gordon Christensen, Exhibit 22h, Deposition of Dr. Gordon Christensen, Volume V, April 30, 2012, page 93-94; Testimony of Dr. Leonard Sigal, Exhibit 1A, Sigal Deposition of 2/12/12, pages 4-5; Testimony of Dr. Gary Wormser, Exhibit 9a, page 184, line 8 to page 186, line 16.

The Western District Court of Appeals in Ladish v. Gordon, 879 S.W.2d 623, 634 (Mo.

App. W.D. 1994), discussed the requirement to define terms in a medical negligence case:

Dr. Gordon contends that plaintiff failed to make a submissible case because Dr. Weiss (plaintiff's expert witness) never gave any description or definition of the phrase "standard of care" used in his testimony. Under Missouri law, the term "negligence," as used in reference to health care providers, means the failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by members of defendant's profession. Gridley v. Johnson, 476 S.W.2d 475 (Mo. 1972). The use of the terms "accepted medical standards "and "standards of care" do not themselves satisfactorily articulate the appropriate legal standard. Care should be taken by counsel in every case, with every expert witness, to make sure the expert is properly oriented to the concept of negligence in the instance of a health care provider. \*\*\* It is necessary in each case that the fact finder be informed as to whether the witness, in offering opinions, is using the standard prescribed by law and not some other standard. Dine v. Williams, 830 S.W.2d 453, 456 (Mo. App. 1992). \*\*\* It is not necessary that the legal standard be recited in ritualistic fashion, but generally it must appear somewhere in the context of the expert's testimony that the proper objective legal standard is the standard being employed by this expert in his or her testimony. \*\*\* If attorneys and expert witnesses are allowed to become sloppy in the use of terms such as "accepted standards "and "standards of care" without specifying the meaning of those terms, experts will inevitably tend to rely on their own views of acceptable practice rather than applying the objective legal standard.

879 S.W.2d at 634.

#### The *McDonagh* decision states:

Because, in concluding that Dr. McDonagh did not violate section 334.100.2(5), the AHC relied on Dr. McDonagh's experts' testimony and because this testimony failed to establish whether the experts were using legal standards of care for "repeated negligence" set out in section 334.100.2(5), this Court must reverse and remand.\*\*\*Because the expert testimony upon which the AHC relied failed to furnish the appropriate legal standard of care, the circuit court's judgment is reversed, and the case is remanded.

#### 123 S.W.3d at 159 to 160.

In this case the requirement to define "negligence" is more than a mere technical requirement. This procedural requirement reaches to the heart of the dispute. The *McDonagh* court was dealing with a very similar case to the present case. Dr. McDonagh and his experts argued that because he followed the approved practice guidelines promulgated by the chelationists' organization, ACAM, he had met the requirements of a bona fide alternative minority standard of care. The Board argued that only a small fraction of physicians treating heart disease adhered to the ACAM guidelines. There, as here, it was argued that there were in fact two separate and equally valid standards of care. The Missouri Supreme Court found that the standard of care was neither "the most popular treatment" nor "blind acceptance of the views of a subgroup of treaters."

The relevant standard of care is neither a reformulation of the *Frye* general acceptance test, nor blind acceptance of the views of a subgroup of treaters. The relevant standard of care for discipline for repeated negligence is necessarily similar to that set out in the statute addressing that conduct, section 334.100.2(5). That standard, similar to Missouri's standard of proof of negligence in civil cases, "requires a showing whether the doctor showed the *'skill and learning ordinarily used under the same or similar circumstances by the member of [the doctor's] profession.'* (Emphasis provided by the Court). Rather the statute requires only what it says--that Dr. McDonagh use that degree of skill and learning used by members of the profession in similar circumstances.

123 S.W. 3d at 158.

So, basically, this Commission may not simply conclude that the majority, mainstream accepted standards for diagnosis and treatment of Lyme disease control, or that the ILADS Guidelines control, the Commission must decide whether a reasonable Missouri physician using ordinary skill and learning would have treated the seven patients in question as Respondent

treated them. If expert medical testimony were not admitted on this specific point, the Commission would be required to render a completely subjective opinion on what a reasonable physician would or would not have done with the care of these particular patients.

Petitioner's expert witnesses, Dr. Cooperstock and Dr. Christensen, supported by the expert opinions of Dr. Sigal and Dr. Wormser as to the science underlying the standard of care approaches to the diagnosis and treatment of Lyme disease, as represented by the IDSA Guidelines, have carefully explained the whys and wherefores of the generally accepted approach and why a physician using ordinary care and skill would not have diagnosed and treated Respondent's seven patients as Respondent did. (Petitioner's Exhibits 22a, 22d, 22e, 22g, 22h, Christensen depositions Volume I-V and Tr. XII pages 1577 to 1590; Testimony of Dr. Cooperstock, Tr. Volume 1, pages 60-138 and Volume II, pages146-300; Petitioner's Exhibit 1 and 2; Petitioner's Exhibits 9, 9a, 9b, and exhibits to 9b).

Petitioner's expert witnesses Dr. Michael Cooperstock and Dr. Gordon Christensen testified that Respondent repeatedly failed to use that degree of skill and learning ordinarily used by the members of the profession in similar circumstances in diagnosing and treating the seven (7) patients in question for purported Lyme disease. (Tr. Volume I, pages 112, 113, 122, 123, 130, 131, 136, 137, 138, 154, 156, 166, 167, 176, 179). No expert testimony presented by respondent directly contradicts that testimony (Entire record). Although Respondent's expert witnesses presented testimony of what the ILADS Guidelines provide and what they and some other individual physicians do in practice with regard to diagnosing and treating Lyme disease, there was no expert medical testimony to the effect that a reasonable Missouri physician would have followed the practices followed by Respondent in diagnosing and treating Lyme disease (Entire record). Therefore, Petitioner's expert testimony to the effect that Respondent repeatedly

failed to use that degree of skill and learning ordinarily used in the profession under similar circumstances is effectively uncontroverted.

A related point is that it appeared that Respondent and her expert medical witnesses were using a standard advocated by a few (300) so-called "Lyme Literate Physicians," who advocate the use of standards and procedures represented by the ILADS (International Lyme and Associated Diseases Society) Guidelines for the diagnosis and treatment of Lyme disease. Under the *McDonagh* decision, the Commission cannot judge the conduct of Respondent solely by the standards of those physicians who approach Lyme disease exactly like Respondent approaches Lyme disease. The Commission should judge the conduct by the standard of care of the broader group of those physicians who treat infectious diseases generally. Petitioner's expert medical witnesses testified as to the standard of care adopted by the vast majority of the physicians who treat infectious diseases in their approach to the diagnosis and treatment of Lyme disease. Respondent failed to introduce competent expert evidence that Respondent was not guilty of repeated negligence, as testified to by the Board's expert witnesses.

II.

The repeated and continual diagnosis of Lyme disease in patients whose only potential tick exposure was in Missouri and Kansas, states that are not endemic areas for Lyme disease, violated the applicable standard of cared for the diagnosis of Lyme disease and constituted repeated negligence under section 334.100.2(5) and also violated sections 334.100.2(4)(a) and (4)(c)

The evidence is overwhelming that Missouri and Kansas are not endemic areas for Lyme disease. (Entire record) (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 50, lines 10 to 21; page 51, lines 10 to 24). As the evidence demonstrated, Lyme disease is primarily a disease of the northeast coastal states and the upper Midwest states of Minnesota, Michigan and Wisconsin. (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 63, line 20 to page 64, line

19). Only a few cases of Lyme disease are reported each year in Missouri and Kansas and those reports may well be cases acquired by Missouri or Kansas residents in endemic areas. Exhibit 26 is a recent CDC map of the United States showing the areas where Lyme disease is reported. The northeast and the upper Midwest account for substantially all reported cases of Lyme disease. Missouri and Kansas show only a handful of reported cases.

Dr. Sigal and Dr. Wormser explained why there is no Lyme disease in this area. Lyme disease is spread through the bite of a tick, the *Ixodes scapularis* tick. (Exhibit 1, Deposition of Dr. Leonard Sigal, 2/2/2012, page 15, lines 1 to 11). "The tick bite is the only documented source of Lyme disease. There's no scientific evidence that any other means of infection exists." (Id. at 15, lines 7 to 11). Although some few *Ixodes scapularis* ticks have been reported in Missouri, Borrelia burgdorferi sensu stricto has never been cultured from a tick in Missouri, although scientists have been investigating Lyme disease in Missouri for many years. (Id. at Tr. Volume I, page 80, lines 1 to 10). It is thought that the *Ixodes scapularis* tick feeds on the white footed field mouse in the northeast and upper Midwest. (Id. at 49, lines 3, to 51, line 12). The mouse actually carries the Borrelia burgdorferi bacteria and the tick gets the bacteria from the mouse. (Id.) In the Midwest and southern states, the Ixodes scapularis tick has a different feeding pattern and feeds primarily on lizards called skinks, which do not carry the Borrelia burgdorferi bacteria. (Id. at 51, line 13 to 34). Therefore, Lyme disease is not prevalent in this area of the country. (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 41, lines 2 to 11). Although Respondent's expert witnesses questioned this theory, they presented no positive evidence to demonstrate that Ixodes scapularis ticks infected with Borrelia burgdorferi sensu stricto exist in Missouri or Kansas. In fact, Respondent's expert, Dr. Cameron, concedes that

there is no direct evidence that *Ixodes scapularis* in Missouri is infected with *Borrelia burgdorferi* sensu stricto. (Tr. Volume IX, page1301, line 2 to 6).

Dr. Sigal testified that although there are reported cases of Lyme disease in Missouri and Kansas, those cases were not acquired in Missouri or Kansas. (Exhibit 1, Deposition of Dr. Leonard Sigal 2/2/2012, page 48, lines 9 - 19). Lyme disease is a nationally reportable infectious disease, and where a case is reported does not necessarily mean it was acquired there. (Exhibit 1, Deposition of Dr. Leonard Sigal 10/24/2011, page 48 to 49). Dr. Wormser conducted numerous studies of Lyme disease in Missouri and provided at least five articles in support of his testimony that there is no well-documented case of *Borrelia burgdorferi* sensu stricto infection occurring in Missouri from a tick bite that occurred in Missouri. (Exhibits 1 to 5 of Petitioner's Exhibit 9, Wormser 1/3/2012, deposition).

The experts discussed the presence of Masters disease or STARI (Southern Tick Associated Rash Illness) in Missouri. (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 64, line 20 to page 65, line 13). Dr. Ed Masters of Cape Girardeau, Missouri, saw a number of patients before the turn of the century and felt that the erythema migrans rash he was seeing represented Lyme disease. (Id.). Further investigation by Dr. Masters and others led to the ultimate conclusion that the erythema migrans patients he was seeing did not have Lyme disease, as commonly understood, but rather, a new and separate disease ultimately called Masters disease or STARI. (Id. at page 64). STARI is a much less serious problem, consisting of only a rash that lasts a few days. Investigators have never discovered the cause of STARI but have associated the disease with the bite of the Lone Star tick (*Amblyomma americanum*). Dr. Masters eventually concluded that what he was seeing around Cape Girardeau was not in fact

Lyme disease and he published a paper to that effect. (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 231, lines 8 to 13).

The scientific evidence presented at the hearing clearly established that Missouri and Kansas are not endemic areas for Lyme disease. Dr. Wormser testified that there is no Lyme disease in Missouri or Kansas at all. (Exhibit 9, Deposition of Dr. Wormser, 9/5/2011, page 57, lines 2 to 10). Therefore, it is difficult to see where the seven (7) patients in the Complaint were supposed to have acquired Lyme disease. Although STARI or Masters disease has been shown to exist in Eastern Missouri, it has not been shown to exist in Western Missouri or Eastern Kansas. (Exhibit 1, Deposition of Dr. Leonard Sigal, 10/24/2011, page 48, line 20 to page 49 line 2). Even so, all STARI patients, by definition, have the EM rash. The only one of the seven (7) patients in question to have the EM rash was patient J.C. So STARI or Masters disease cannot be said to account for at least six (6) of the patients in the Complaint.

In his reports to the Kansas Board of Healing Arts, Dr. Christensen had this to say about Lyme disease in Missouri and Kansas:

Note: There was no documentation that he patient (S.K.) had visited an endemic area for Lyme disease; there was no documentation that the patient had an erythema migrans rash. In my opinion, the history did not include any information persuasive of Lyme disease.

Comment: It is true that erythema migrans rashes occur in Kansas and Missouri and surrounding states after the bite of the tick 

Amblyomma americanum which unlike Ixodes scapularis is not known to carry Lyme disease. Indeed, Borrelia burgdorferi sensu

stricto--the cause of Lyme disease--has never been recovered from a Missouri patient. It is possible that erythema migrans rash that occurs in Missouri and is known as Masters' disease is due to an organism similar to *Borrelia burgdorferi* sensu stricto, but this is unproven speculation. It is possible that many patients with Masters' disease do not recall or never had an erythema migrans rash, but this too, is entirely speculative.

Cases are reported through the various health departments of each state and then are reported to the CDC. (Wormser deposition January 3, 2012, page 251) The CDC statistics reflect where the Lyme disease was reported not where it was acquired. Petitioner's trial exhibit 9A (i.e., Wormser deposition, January 3, 2012, page 250-251) "If you acquire Lyme disease in another state, and you go back to Missouri, and the doctor diagnoses you with Lyme disease, they will report it out of Missouri. So it will count on Missouri's statistics, not on the state where you presumably acquired it." Id.

Lyme disease is a nationally reportable infectious disease; therefore, Lyme disease is a reportable infectious disease in Missouri. (Exhibit 13 to Petitioners Exhibit 9, Wormser deposition January 3, 2012, page 3 of DHSS Lyme disease Position Paper). However, Respondent makes the illogical leap that because it is reportable in Missouri, it therefore can be acquired in Missouri.

The Missouri Department of Health and Senior Services, in its Lyme disease Position

Paper, discusses the issue of Lyme disease in Missouri, stating that "[T]here have been patients

with symptoms (including EM rashes) similar to those in other areas of the United States, but B.

Burgdorferi has not yet been isolated from any patients in Missouri." (Exhibit 13 to Petitioners Exhibit 9, Wormser deposition January 3, 2012, page 3 of DHSS Lyme disease Position Paper).

Furthermore, the Missouri Department of Health and Senior Services ("DHSS"), in its Communicable Disease Investigation Reference Manual page 2, Exhibit 14 to Petitioner's trial exhibit 9(i.e. exhibit 14 to Dr. Wormser's January 3, 2012 deposition) states "Most North American cases of Lyme disease occur in the northeastern, mid-Atlantic, and north-central U.S. Lyme bacteria have never been isolated from any of Missouri's EM cases. Nevertheless, "bull's eye" rashes similar to those caused by B. Burgdorferi are diagnosed in Missouri and other south-central U.S. states. Unlike true Lyme disease, "Lyme-like" rashes are not linked to any arthritic, neurological, or other long-term symptoms". Furthermore, on the issue of "Status of Lyme disease in Missouri", the DHSS states "there are currently no counties in Missouri that meet the Centers for Disease Control and Prevention's (CDC) Lyme disease (infection with *Borrelia burgdorferi*) 2008 public health surveillance case definition for "disease endemic to county". (emphasis in original) (Exhibit 14 to Petitioner's Exhibit 9, Wormser deposition January 3, 2012, page 5).

The CDC annually reports the total Lyme disease cases by state. (Exhibit 7 to Petitioner's Exhibit 9, Wormser deposition 1/3/12). In Missouri, the CDC reported 70 cases in 2003, 25 cases in 2004, 15 cases in 2005, 5 cases in 2006, 10 cases in 2007, and 6 cases in 2008. In Kansas, the CDC reported 4 cases in 2003, 3 cases in 2004, 3 cases in 2005, 4 cases in 2006, 8 cases in 2007, and 16 cases in 2008. In Connecticut, for example, the reported numbers were 1403 cases in 2003, 1348 cases in 2004, 1810 cases in 2005, 1788 cases in 2006, 3085 cases in 2007, and 2738 cases in 2008. The dramatic difference in reported cases between Connecticut and Missouri is telling; 6 cases reported in Missouri for 2008 and 2738 cases reported in

Connecticut for 2008. With only 6 reported cases in 2008, it is logical to assume that most, if not all of these cases were acquired outside of Missouri. Logic would suggest that if *Borrelia burgdorferi* infection were prevalent or endemic in Missouri, the reported numbers would be much higher. These statistics support the proposition that there is little to no support for the presence of *Borrelia burgdorferi* infection in Missouri.

There is no competent evidence that rebuts the Board's evidence that *Borrelia* burgdorferi has not been isolated in patients with EM rashes in Missouri nor has Borrelia burgdorferi been isolated in any Ixodes scapularis tick from Missouri. Petitioner has provided significant support for the fact that Lyme disease, Borrelia burgdorferi infection, does not exist in Missouri. The CDC reports, Missouri Health and Senior Services, Drs, Wormser, Sigal, Cooperstock and Christensen. Respondents have not been able to provide any competent evidence showing that the Ixodes scapularis in Missouri or Kansas is infected with Bb.

Respondent's repeated and continual diagnosis of Lyme disease in patients who have not experienced a tick bite in an area that is endemic for Lyme disease violated the standard of care for Lyme disease diagnosis and constituted repeated negligence under Section 334.100.2(5), RSMo., violated Section 334.100.2(4)(a) "willfully and continually overcharging or overtreating patients", and also violate Section 334.100.2(4)(c) "willfully and continually performing inappropriate or unnecessary treatment, diagnostic tests or medical services" in that *Borrelia burgdorferi* has not been isolated in patients with EM rashes in Missouri or Kansas nor has *Borrelia burgdorferi* been isolated in any *Ixodes scapularis* tick from Missouri or Kansas.

#### III.

Respondent repeatedly represented to B.L., D.L., K.K., and S.K. that Lyme disease is sexually transmitted, which fell below the standard of care in diagnosing Lyme disease because Lyme disease is a vector borne illness transmitted by the bite of a tick and is not

### sexually transmitted nor transferred via other bodily fluids, and therefore constituted repeated negligence under section 334.100.2(5)

Each expert, whether for petitioner or respondent, unanimously and unequivocally agrees Lyme disease is a tick-borne illness. (Tr. Volume I, page 79, lines 5 to 10; Petitioner's Exhibit 9, deposition of Dr. Wormser, 9/5/2011, page 30, lines 2 to 4; Tr., Volume V, page 568, lines 3 to 5; Petitioner's Exhibit 22a, deposition of Dr. Christensen, page 64, lines 17 to 18; Petitioner's Exhibit 1, deposition of Dr. Sigal, page 15, lines 1 to 17; Tr., Volume XI, page 1344, lines 6 to 18; Respondent's Exhibit T, Deposition of Dr. Francis, page 14 lines 5 to 16; Tr. Volume IV, page 412, line 7 to page 413, line 10).

The ILADS Guidelines, the guidelines Respondent relies on for diagnosis and treatment, clearly states in the first sentence "[L]yme disease is transmitted by the bite of a tick." (Respondent's Exhibit B, page 1). Respondent inappropriately diagnosed and treated patients based on the notion that Lyme disease is sexually transmitted instead of transmitted only through the bite of a tick.

None of the experts have conceded that there is any reliable diagnostic information showing Lyme disease is sexually transmitted. Respondent's experts even acknowledge there is no reliable evidence indicating sexual transmission of Lyme disease. Dr. Cameron states there is "no evidence that Lyme disease or the *Borrelia burgdorferi* infection is sexually transmitted." (Tr. Volume XI, page 1315, lines 16 to 19). Dr. Harris believes one has to establish likelihood of exposure to a tick bite before diagnosis. (Tr. Volume III, page 413 lines 6 to 9). Dr. Horowitz states "sexual transmission [of Lyme disease] is a hypothesis." (Tr. Volume V, page 704, lines 5 to 11). Some experts even explicitly indicate Lyme disease is not sexually transmitted. (Tr. Volume I, page 137, line 12; Petitioner's Exhibit 9, deposition of Dr. Wormser 9/5/2011, page 61, lines 2 to 3). Sexual transmission of Lyme disease has been repeatedly investigated

epidemiologically by a variety of researchers through the Centers for Disease Control (CDC), and no supporting data or evidence has been found. (Tr. Volume II, page 287, line 18 to page 288, line 3). Sexual transmission of Lyme disease is not in the ILADS guidelines, nor does the IDSA claim there is sexual transmission of Lyme disease. (Tr. Volume V, page 704, lines 5 to 11; Exhibit 1, deposition of Dr. Sigal 10/24/2011, page 20, lines 23-25).

Respondent claims to never have diagnosed the patients involved in the case at bar based on sexually transmitted Lyme disease. (Tr. Volume VIII, page 1020, lines 4 to 8; Tr. Volume XI, page 1455, line 24 to page 1456, line 2). Respondent claims she is commonly asked if Lyme disease is sexually transmitted, and respondent tells the patients there was one research study with about 40 patients that shows through culturing semen and vaginal secretion there was transmission of the spirochete, but that has not been corroborated. (Tr. Volume VIII, page 1020, lines 9 to 18). Respondent claims that she told patients that most of the infections if they existed in two or three people were coming from patients being contemporaneously exposed in the same proximity so it possible that more than one person could be bitten by infected ticks. (Tr. Volume VIII, page 1021, line 23 to page 1022, line 5).

However, Dr. Karen Beatham, a long time employee of Respondent, witnessed Respondent telling patients that Lyme disease can be transmitted through sex, blood, urine, and saliva while working at Health Centers of America. (Petitioner's Exhibit 21, deposition of Dr. Karen Beatham 12/12/2011, page 23, line 22 to page 24, line 1). Dr. Ryser taught Dr. Beatham that Lyme disease can be transferred through sex, urine, blood, and saliva. (Petitioner's Exhibit 21, deposition of Dr. Karen Beatham 12/12/2011, page 21, lines 7 to 17). In fact, Respondent talked with Dr. Beatham numerous times about Lyme disease's transmission through sex, blood, urine, and saliva. (Exhibit 21, Deposition of Dr. Karen Beatham 12/12/2011, page 22, line 2).

Moreover, Diana Smith, R.N., the nurse employed by Respondent, has been in a room with Respondent telling a patient *Borrelia burgdorferi* was found in sperm and therefore can be sexually transmitted. (Petitioner's Exhibit 20, deposition of Diana Smith, R.N., page 47, lines 11 to 14). It is no coincidence when two employees of the Health Centers of America, under the direct supervision of Respondent, separately make accounts of Respondent advising patients that Lyme disease is sexually transmitted.

Respondent inappropriately initiated unnecessary Lyme disease diagnosis and treatment on S.K. from the uncorroborated fact that Lyme disease is sexually transmitted. Respondent told S.K. to abstain from sexual intercourse or use protection because Lyme disease was sexually transmitted. (Tr. Volume IX, page 1353, lines 2 to 6). This information was disclosed after S.K.'s husband, K.K., had been diagnosed with Lyme disease. (Tr. Volume IX, page 1354, lines 3 to 6). S.K. had not read or learned any time prior to Respondent's disclosure that Lyme disease was sexually transmitted. (Deposition Exhibit 6 to Petitioner's Hearing Exhibit 13, page 56, lines 8 to 25). Respondent told S.K. she should probably be tested because of the sexual transmission, leading S.K. to agree out of fear. (Tr. Volume IX, page 1354, lines 10 to 25). Respondent recommended S.K. not have children, bringing S.K. to tears and completely devastating S.K. who wanted to have a child. (Deposition Exhibit 6 to Petitioner's Hearing Exhibit 13, page 58, lines 1 to 10; Petitioner's Exhibit 13, deposition of S.K. 10/12/2011, page 99, lines 15 to 16). S.K. has no doubt in her mind that Respondent made clear the fact Lyme disease was sexually transmitted. (Tr. Volume IX, page 1353, lines 7 to 16). Respondent inappropriately initiated Lyme disease diagnosis and treatment on S.K. based on the uncorroborated fact Lyme disease is sexually transmitted resulting in extreme hardship to both S.K. and K.K.

Respondent inappropriately initiated unnecessary Lyme disease diagnosis and treatment on D.L. from the uncorroborated fact that Lyme disease is sexually transmitted. Respondent told D.L. that husband and wife could infect each other through sexual intercourse, kissing, or being around each other. (Petitioner's Exhibit 16, deposition of D.L. 12/21/2010, page 23, line 5 to 10). Respondent further advised D.L. that even though D.L. or D.L.'s wife could be treated, D.L. and his wife could reinfect each other if both were not treated for Lyme disease. (Petitioner's Exhibit 16, deposition of D.L. 12/21/2010, page 23, lines 19 to 23). Respondent's records on 2/9/2004 state that D.L. was "here due to wife's diagnosis of Lymes [sic], and wanted to be tested." (Petitioner's Exhibit 7, Medical Records of D.L., page 2326). D.L. only wanted to be tested after being told Lyme disease is sexually transmitted and Respondent telling D.L. that he should be tested. (Petitioner's Exhibit 16, deposition of D.L. 12/21/2010, page 97, lines 1 to 17). Respondent inappropriately diagnosed and treated D.L. for Lyme disease based on the uncorroborated fact that Lyme disease is sexually transmitted.

All of the experts agree that Lyme disease is transferred via a tick bite. No expert testified that there is any scientific information indicating Lyme disease is sexually transmitted. Respondent denies advising patients to get tested for Lyme disease due to sexual transmission, yet Respondent's employees witnessed Respondent clearly advising patients that Lyme disease is sexually transmitted. Moreover, patients in S.K. and D.L. were told to get tested because Lyme disease is sexually transmitted between spouses, and as a result were erroneously diagnosed by Respondent. Respondent fell below the standard of care when erroneously testing and diagnosing patients based on the sexual transmission of Lyme disease.

Lyme disease is a vector born infection and necessarily requires a tick bite for its diagnosis. Each expert, whether testifying on behalf of petitioner or respondent, unanimously

and unequivocally agrees Lyme disease is a tick-borne illness. (Tr. Volume I, page 79, lines 5 to 10; Petitioner's Exhibit 9, deposition of Dr. Wormser, 9/5/2011, page 30, lines 2 to 4; Tr., Volume V, page 568, lines 3 to 5; Petitioner's Exhibit 22a, deposition of Dr. Christensen, page 64, lines 17 to 18; Petitioner's Exhibit 1, deposition of Dr. Sigal, page 15, lines 1 to 17; Tr., Volume XI, page 1344, lines 6 to 18; Respondent's Exhibit T, Deposition of Dr. Francis, page 14 lines 5 to 16). The ILADS Guidelines, the guidelines Respondent relies on for diagnosis, clearly states in the first sentence "Lyme disease is transmitted by the bite of a tick." (Respondent's Exhibit B, ILADS Guidelines, page 1).

Respondent's repeated and continual diagnosis of Lyme disease in patients based on the sexual transmission of the organism violated the standard of care for Lyme disease diagnosis and constituted repeated negligence under Section 334.100.2(5), RSMo., violated Section 334.100.2(4)(a) "willfully and continually overcharging or overtreating patients", and also violate Section 334.100.2(4)(c) "willfully and continually performing inappropriate or unnecessary treatment, diagnostic tests or medical services", in that Lyme disease is strictly a vector borne infection and not sexually transmitted.

IV.

The repeated and continual use by Respondent of the Bowen Labs Q-RiBb test for Lyme disease blood testing violated the applicable standard of care for Lyme disease testing and constituted repeated negligence under Section 334.100.2(5), RSMo 2000, and also violated Section 334.100.2(4)(c), "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests"

For several years, Respondent admittedly sent blood samples from patients to the Bowen Labs, a Florida laboratory headed by Dr. Jo Anne Whitaker (Tr. Volume XI, page 1493, lines 23 to 25). The Bowen Q-RiBb test supposedly was able to identify actual *Borrelia burgdorferi* spirochetes in the blood of a patient infected with Lyme disease. The Bowen Q-RiBb test was at

no time approved by the FDA, the CAP, or by any other recognized certifying agency. (Tr. Volume XI, page 1505, line 13 to page 1506, line 217). At all times relevant here, Respondent was admittedly aware of the appropriate certifications that would guarantee that a particular lab test was effective. Respondent was likewise aware that it was the physician's responsibility under the applicable standard of care to make certain that ordered lab tests for her patients was certified as effective. (Tr. Volume XI, page 1509, lines 6 to 10). Respondent never knew of any peer reviewed literature documenting the effectiveness of the Bowen Q-RiBb test for Lyme disease (Tr. Volume XI, page 1498, line 231 to page 1500, line 1). Respondent was aware for all patients mentioned in Petitioner's Complaint that Bowen Labs Q-RiBb test report included the qualification that the test was for research purposes only and was not to be used for clinical diagnosis (Tr. Volume XI, page 1497, lines 15 to 19). Nonetheless, Respondent had her patients pay a \$250 "donation" to the Bowen Labs for the Bowen Q-RiBb test and used the results of such testing, which was universally positive for Lyme disease, to assure her patients that they indeed had Lyme disease (Tr. Volume XI, page 1498, lines 12 to 16).

Although Respondent was at great lengths to testify that the diagnosis of Lyme disease was a "clinical diagnosis" and that the Bowen testing was not relied upon to make a diagnosis of Lyme disease, she nonetheless used the results of the Bowen Q-RiBb test to convince her patients that they had Lyme disease (Tr. Volume IX, page 1365, lines 10 to 14). Patient S.K. testified in person to the effect that Respondent sat her down with the results of the Bowen Q-RiBb test and spent considerable time explaining that her results were positive for Lyme disease. (Tr. Volume IX, page 1364, line 22 to page 1365, line 25). Although patient S.K.'s test report stated on its face that it was "positive" for Lyme disease, Respondent testified that with a titer of only 1:8, she considered the result negative for Lyme disease and did not rely on the test (Tr.

Volume IV, page 504, lines 4 to 21). However, both patient S.K. and Respondent testified that Respondent showed patient S.K. the results of the test, even to the point of showing her the pictures of the supposed spirochetes in the photos returned with the test report (Tr. Volume IX, page 1365, lines 3 to 22). If Respondent considered the report negative as she claimed, did not rely on the results of the test, and did not in fact diagnose patient S.K. with Lyme disease as she claimed, then why would she spend time going over the results of the test and photos of the supposed "spirochetes" in such detail? Respondent's testimony that she went over the test results with patient S.K., as patient S.K. testified, in fact supports patient S.K. 's trial testimony that Respondent used the "positive" Bowen test to convince patient S.K. that she had Lyme disease and needed treatment (Tr. Volume XI, page 1513, line 19 to page 1514, line 7).

Patient B.L. testified in her deposition that Respondent told her that her positive Bowen test was "cutting edge" technology. (Exhibit 15, Vol. 2, Deposition of Brenda Lampton, page 326, lines 15-21). Ryser never mentioned to patient B.L. that the Bowen test was unaccredited. (Id. at 327, lines 17-19). Patient B.L. in fact had two separate Bowen tests, with the result on the second test being worse than the first. (Id. at 328, lines 14-18). Patient B.L. testified that Respondent told her that the second, worse Bowen test showed that she needed further intravenous antibiotic treatment. (Id. at 388, lines 18-24). Dr. Ryser suggested that patient D.L. take the Bowen test. (Exhibit 16, Volume 1, Deposition of D.L., page 41, lines 4-20). Patient D.L. was under the impression that the Bowen test was the exclusive means by which Respondent would diagnose Lyme disease. (Id. at 45, lines 13-24). Patient D.L. testified that Dr. Ryser called the Bowen test the "gold standard" for Lyme disease testing and the test she would trust. (Id. at 45, lines 1-3). D.L. testified that Respondent said that the result of the

Bowen test proved that his wife, B.L., had Lyme disease. (Exhibit 17, Deposition of D.L., Volume 2, page 221, lines 19-23).

Respondent's 2009 letter to the Board about patient S.K. also supports patient S.K.'s testimony in that Respondent cites the "positive" Bowen test as a basis for her diagnosis and treatment of patient S.K. for Lyme disease (Tr. Volume XI, page 1535, line 14 to page 1537, line 23). Although Respondent claimed that the 2009 letter contained mistakes and that she in fact did not diagnose patient S.K. with Lyme disease or treat her for Lyme disease, an identical 2007 letter to the Kansas Board about patient S.K. contained the exact same "mistakes" (Tr. Volume XI, page 1570, lines 1 to 8).

It is clear that Respondent used the Bowen Q-RiBb test results to convince patients that they had Lyme disease. It is also clear that Respondent knew that the Bowen Q-RiBb test was, to say the least, highly questionable. Respondent admitted on cross-examination that the Bowen founder, Dr. Jo Anne Whitaker had told her that there had never been a negative Bowen Q-RiBb test for Lyme disease in the history of the laboratory (Tr. Volume XI, page 1503, lines 4 to 12). Although Respondent testified that she told Dr. Whitaker that she had received negative Q-RiBb tests, Respondent ultimately admitted that she had never gotten back a blood test denominated as negative by Bowen labs (Tr. Volume XI, page 1504, line 22 to page 1505, line 12). Respondent claimed that she considered any Q-RiBb test with a titer of 1:8 or less as negative or not clinically significant (Tr. Volume XI, page 1503, line 19 to page 1504, line 3). Respondent admitted that she was aware that Dr. Jo Anne Whitaker had been forced to defend the admitted fact that Bowen Labs had never had a negative blood test for Lyme disease (Tr. Volume XI, page 1503, lines 4 to 18).

In fact there is no defense to the criticism of the Bowen Labs Q-RiBb test on the grounds that the lab never at any time had a negative test. As Petitioner's experts explained, such a situation would have clearly indicated that the Bowen Q-RiBb test was essentially worthless as a test for Lyme disease (Ex. 1, Deposition of Dr. Leonard Sigal, 2/2/2012, page 35, line 14 to 36 line 18) (Tr. Volume I, page 109, line 22 to page 113, line 5). The lack of a test denominated as negative by the Bowen Labs should have been a big red flag for Respondent if she had been truly interested in her patients' best interests.

Dr. Jo Anne Whitaker lost her medical license over her Bowen labs activities in 2005. (Exhibit 24). About this point, Bowen Labs started asking for "donations" to do a Q-RiBb test and started qualifying the results of the test by stating that it was for "research purposes only" and was not to be used for clinical diagnosis. (Tr. Volume XI, page 1497, lines 15 to 19). On February 3, 2005, the state of Florida revoked the Florida license of the Bowen Research and Training Institute, Inc., as the Q-RiBb Lyme disease test had never been demonstrated to be valid by the usual scientific criteria used to validate testing. (Exhibit 25).

The standard of care at all times relevant to this case was the two-tier testing by the ELISA and Western Blot tests (Ex 1, Deposition of Dr. Leonard Sigal, 2/2/2012, page 31, line 2 to page 34, line 2). Conveniently, Respondent and other "Lyme Literate Physicians" believe that a positive Western Blot test can be relied on but that a negative Western Blot test should be ignored because it supposedly misses too many true cases of Lyme disease (Tr. Volume XI, page 1496, lines 8 to 13). Respondent does occasionally use the IGeneX Laboratories in California, which uses the less strict three-band standard for a positive Western Blot test, instead of the generally approved standard of care five-band standard (Tr. Volume I, page 293, line 12 to page 294, line 24). In the patients in the Complaint who got Western Blot tests, not one of them tested

positive under the accepted five-band standard (Entire record). Petitioner submits that Respondent shops around for tests that will help convince her patients that her "clinical diagnosis" of Lyme disease is correct and justify her expensive course of antibiotic treatments.

The CDC promulgates a surveillance/case definition (Respondent's Exhibit O) and the CDC recommends a two tier approach for serologic testing. Respondent can't seem to separate these two (See, Petitioner's Exhibit 9A, Wormser deposition 1/3/12, page 213, line 11, to page 215, line 23), but a review of the CDC's publications makes it very clear that the CDC provides a case definition that is that used when reporting cases of Lyme disease to health departments. The surveillance case definition does clearly indicate that the case definition was developed for national reporting of Lyme disease; it is not intended to be used in clinical diagnosis. This case definition is promulgated annually (see Respondent's trial exhibit O) and there is the notation that the definition was developed for reporting purposes.

However, separate and distinct from this case definition for surveillance purposes, the CDC published recommendations for serologic testing entitled "Notice to Readers Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme disease" *Exhibit 1 to Petitioners Exhibit 9B (i.e. exhibit 1 to Dr. Wormser's January 31, 2012 deposition).* The CDC, the Food and Drug Administration National Institutes for Health, the Council of State and Territorial Epidemiologists, the National Committee for Clinical Laboratory Standards and the Association of State and Territorial Public Health Laboratory Directors presented recommendations for serologic test performance and interpretation for serodiagnosis of Lyme disease, which resulted in the two tier approach that the CDC recommends for diagnosing Lyme disease. *Petitioners Exhibit 9B, page 6, line 11 to page 8, line 8(i.e. Dr. Wormser's January 31, 2012 deposition).* The two tier approach being the Elisa

followed by the Western-blot, with specific criteria for the numbers of bands required for a seropositive diagnosis. *Id.* 

All of Petitioner's expert medical witnesses confirmed that the two-tier testing standard of ELISA and Western Blot constitute the standard of care for testing for Lyme disease. (Ex. 1, Deposition of Dr. Leonard Sigal, 2/2/2012, page 31, line 2 to page 34, line 2). Dr. Sigal testified at length about the Bowen Q-RiBb test for Lyme disease. (Id., page 34, line 2 to page 47, line 5). Dr. Sigal testified that the Bowen Q-RiBb test for Lyme disease was approved by no authoritative certifying agency and was a worthless test (Id.). Dr. Sigal called the supposed scientific explanation for the Bowen Q-RiBb test "science fiction." (Id. at page 39, line 15 to 25). "... [i]f everybody is positive, then there's something wrong with the assay." (Id. at page 43, lines 3 to 5). Dr. Michael Cooperstock testified that the use of the unapproved Bowen Q-RiBb test for Lyme disease blood testing in lieu of the ELISA/Western Blot testing would not meet the applicable standard of care for testing patients for Lyme disease. (Tr. Volume I, page 112, line 2 to page 113, line 20; Tr. Volume I, page 156, lines 11 to 21.)

- Q. I suppose your testimony about the Bowen Labs test would apply to all the patients that had the test, is that correct?
- A. It is.
- Q. And with regard to all these patients, including this lady, BL, would you believe that the usage of this particular test at that particular time by Dr. Ryser would constitute a violation of the standard of care if she used it to help diagnose this Lyme disease situation?

A. Yes.

(Id.)

Dr. Christensen had these comments about the use of the Bowen test by Dr. Ryser:

This is not an acceptable approach. The approach is being done in a research laboratory, not a clinical laboratory. The approach uses reagents which are not approved and the approach uses a test, which — for which we have no information, no background that this is anything to do with it. There's no information regarding standards, positive, negative, no information regarding reproducibility and, furthermore, the laboratory test itself says that this is a research tool. It's not intended, they say, for — to make clinical decisions, but it's being used to make clinical decisions. From my standpoint, my experience having been Chief of Staff of University of Missouri Hospital, teaching medical school for 30 years, this is highly inappropriate, off-the-chart inappropriate.

(Petitioner's Exhibit 22e, Deposition of Dr. Gordon Christensen, Volume 3, 3/14/2012, page 354, lines 6 to 20). Dr. Christensen testified that a clinician has an obligation to use accredited testing. (Petitioner's Exhibit 22c, Deposition of Dr. Gordon Christensen, Volume 1, 3/14/2012, page 219, lines 1 to 10).

Dr. Christensen was asked to review the care provided by Respondent to a number of patients by the Kansas Board of Healing Arts. Among these patients were the Lamptons and the Klausners. Dr. Christensen wrote four (4) separate reports to the Kansas Board on Brenda and David Lampton and on Keith and Sheri Klausner, respectively. These reports were marked as Exhibits 14 (K.K.), 15 (B.L.), 16 (S.K.), and 17 (D.L.) to Dr. Christensen's deposition. (Exhibit

22a through 22i). Dr. Christensen stated in his report to the Kansas Board on S.K that the use of the Bowen Q-RiBb test by Respondent constituted negligence. In paragraph 18 on page 22 Dr. Christensen stated the following:

I note in her letter to the Kansas Board of Healing Arts, that Dr. Ryser claimed:
"Note that the Bowen test was approved by Medicare this year, 2007, for testing
of Lyme disease and pays for the test. It is the ONLY test for Lyme disease that
Medicare pays for."

[Comment: This statement is wrong. I have to think that Dr. Ryser knew it was wrong because she asked the Klausners to make a \$250 "donation" to the Bowen Research Institute for the testing. The Bowen Institute had to ask for donations instead of billing for their services because in 2003 the Bowen Institute lost their "CLIA" certification. CLIA refers to the Clinical Laboratory Improvement Amendments (CLIA) by which the Centers for Medicare & Medicaid Services ("Medicare) certifies laboratories to receive payment for their services. Clinical laboratories, such as Quest Diagnostics, that perform the standard two step diagnostic procedure for Lyme disease and are accredited by CLIA (as well as by the American College or (sic) Pathology) are able to bill Medicare and receive payment for their services.]

Dr. Christensen went on to state that "Dr. Ryser appears to have purposefully and falsely stated the laboratory credentials of the Bowen Research and Training Institute." (Id. at page 25).

Dr. Sigal testified that a clinician has the responsibility to use tests that are appropriate and that have a demonstrated utility in diagnosis.

So a physician has a moral responsibility to choose the appropriate kind of tests to either confirm or not confirm a diagnosis of any sort. And the use of tests that are not scientifically based, that are not confirmed by scientific literature, that -- or for that matter where the clinician doesn't understand the test sufficiently to understand the sensitivity and specificity of the assay (test) are, and that's improper and that's below the standard of care anyplace, regardless of how you define it. To use a test that is clearly marked "for research use only" and to put it forward as a diagnostic test, is clearly below the standard of care under any circumstances.

(Tr. Volume I, page 119, line 17 to page 120, line 6).

Respondent repeatedly violated the standard of care by continually asking her patients to provide a \$250 "donation" to pay for the Bowen Q-RiBb test for Lyme disease, a test approved by nobody. It is worth noting that none of Respondent's three expert medical witnesses really tried to defend her use of the Bowen Q-RiBb Lyme disease test. This no doubt because there is no defense. In addition, Respondent violated Section 334.100.2(4) (c) by continually using an inappropriate and unnecessary diagnostic test. Respondent is subject to discipline under Section 334.100.2(4) (c) and (5).

V.

The repeated and continual use by Respondent of unnecessary testing on patients under a general practice of over-testing violated the standard of care and constituted repeated negligence under sections 334.100.2(5), and also violated sections 334.100.2(4),(4)(c), and (4)(a)

Conducting more tests on a patient than is necessary to make an effective diagnosis is not in the best interest of the patient. Over-testing is not only time consuming, it is also very expensive for the patient. Often times over-testing can lead to misdiagnoses and stress on the patient that is not needed. In this particular case, over-testing by Dr. Ryser caused misdiagnoses

in each of the seven patients as well as a treatment regime that was physically and financially burdensome.

#### (a) Misdiagnoses as a Result of Over-testing

Dr. Ryser's testing regime included several unnecessary and very expensive tests on the patients involved in this case. This general practice of over-testing led to false diagnoses and complex medication protocols that were unnecessary in treatment of patients. Section 334.100.2(4) (c) prohibits a physician from "willfully and continually performing inappropriate or unnecessary treatment, diagnostic tests or medical or surgical services". In connection with patient J.C., Dr. Cooperstock testified that Dr. Ryser "launched on an enormous, enormously complex set of tests, many of which I had never even heard of before, and most of which I to this day don't know what they mean or how they could have been interpreted to help him" (Petitioner's Exhibit 22, deposition of Dr. Cooperstock 11/8/2011, page 95, lines 12 to 16). Dr. Cooperstock also testified that none of the seven patients analyzed in this case actually had Lyme disease despite Dr. Ryser's diagnosis. With regard to testing methods, Dr. Cooperstock testified that Dr. Ryser "performed a very large battery of tests, unusual and of uncertain value." (Petitioner's Exhibit 22, deposition of Dr. Cooperstock, page 156 lines 3 to 5). Dr. Cooperstock was not the only doctor critical of Dr. Ryser's testing methods. Dr. Christensen also testified that none of the patients in this case actually had Lyme disease and that Dr. Ryser's testing methods are excessive and unhelpful. (Petitioner's exhibits 22a, 22d, 22e, 22g, 22h, Volumes I-V of Christensen depositions).

Along with his belief that Dr. Ryser misdiagnosed her patients, Dr. Christensen also testified that the testing Dr. Ryser performed was invalid and not generally accepted in the medical community. He testified that "Dr. Ryser depended on the laboratory results from an

unaccredited research laboratory" (Deposition Exhibit 16 to Petitioner's Exhibit 22h, Christensen deposition, Volume V, 12/21/20, page 17, para 4b) and that "to discard accepted laboratories and use this one in preference, which is unproven and self-declared to be research, and, and which has the very, the unusual or strange thing of asking patients to donate money for services that are provided is just, is just, the appearance is very, very suspect. The appearance is, is bogus. The appearance is that, that this is fraudulent". (Petitioner's Exhibit 22g, Deposition of Dr. Christensen 4/11/2011, page 24, line 22 to page 25 line 5). Furthermore, Dr. Ryser's testing methods were unsupported in these patients. Dr. Christensen testified that "in situations like that it is not considered appropriate to use unproven methodologies, laboratory testing, to take care of the patient because you have no basis". (Id. at 25). The use of unsupported testing shows a lack of capable patient care on the part of Dr. Ryser.

#### (b) Physical Harm Caused by Over-testing

Over-testing here led to a medication routine that resulted in physical harm to the patients. Patient B.L. had to have her gallbladder removed because of damage done to it by unnecessary Lyme disease testing and treatment with the drug Ceftriaxone. (Id. at page 159 lines 7 to 25). Treating an ailment that is not indicated in the patient with high doses of medication can lead to a multitude of problems as seen in this case. Dr. Christensen testified that use of these unconventional tests is dangerous because they can give a false or misleading impression of the health of the patient (Id. at page 80, lines 5 to 11). This can lead a physician to start medication that is unwarranted and possibly harmful to the patient. S.K. testified that her husband's condition became worse with the IV treatments as opposed to better, causing K.K. to barely be able to care for himself. (Tr. Volume IX, page 1369, lines, 1 to 14). As mentioned previously, Section 334.100.2(4) (c) prohibits physicians from utilizing and prescribing

unnecessary treatments. Several experts in this case testified that none of the seven patients involved in this case actually had Lyme disease making the IV treatments received by K.K. unnecessary. (Tr. Volume I, page 166, lines 20-22).

#### (c) Financial Burden and Stress Caused by Over-testing

Harm from over-testing does not only come in the form of physical symptoms and misdiagnoses. Many of the patients involved in this case suffered from high stress levels due to intense treatment routines given as a result of over-testing. S.K. argues her divorce from K.K. was motivated by stresses relating to K.K.'s supposed Lyme disease treatment (Tr. Volume IX, page 1370, lines 2 to 3). Because K.K.'s condition worsened with treatment, K.K. required around the clock care putting a lot of stress on S.K. S.K. also testified that the family spent around \$80,000 on treatments for K.K. (Tr. Volume IX, page 1371, line 23). The financial burden put a lot of pressure on the family that was unnecessary and could have been avoided. Many of the patients in this case had insurance that was not willing to pay for the Bowen testing done by Dr. Ryser and wrote checks for the testing themselves. (Tr. Volume IX, page 1362 line 9). Dr. Ryser also required patients to purchase medications from her office, which were quite expensive and could sometimes have been obtained elsewhere. (Tr. Volume XI, page 1483, lines 9 to 23).

Respondent repeatedly violated the standard of care by continually using unnecessary testing under a general practice of over-testing. In addition, Respondent violated Section 334.100.2(4), (4) (a), and (4) (c) by continually using an inappropriate and unnecessary diagnostic test. Respondent is subject to discipline under Section 334.100.2(4) (c) and (5).

#### The repeated and continual diagnosis of Lyme disease by Respondent using vague, nonspecific, overly broad, subjective criteria violated the standard of care for diagnosing Lyme disease and constituted repeated negligence under section 334.100.2 (5), and also violated sections 334.100.2(4), (4)(c), and (4)(a)

Lyme disease as an illness shares many symptoms with other illnesses but at its root it is an "infection with this organism *Borrelia burgdorferi*." (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/1, page 14, lines 20 to 21.) The key to accurately diagnosing Lyme disease is the detailed patient history taken by the clinician so those symptoms can be evaluated in the proper context.

"The infection is diagnosed by history and physical examination, which is to say a competent clinician asking the appropriate questions, doing a competent physical examination ... [and thinking] before one does anything else." (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 16, lines 14 to 21.)

When taking and evaluating a patient's history there are three objective criteria which should be present to consider a diagnosis of Lyme disease. The clinician would look for presence in a "Lyme endemic area", a tick bite, and the existence of symptoms associated with Lyme disease. Objectively, a patient should meet the three criteria for a Lyme disease diagnosis.

First, a patient must have been in a "Lyme endemic area". A patient who does not live in nor recently traveled in an endemic area is much less likely to have contracted Lyme disease, and a clinician would pursue different possible diagnoses before considering Lyme disease. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 83, lines 20 to 25.) A Lyme endemic area requires the prevalence of the carrier species tick, at the right stage of development, with the right physical environment and an infected food source. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 49, line 3 to page 53, line 11).

The infecting organism is transmitted to humans through tick bites from the *Ixodes* ticks, of which there are several species. In the northeastern and northern Midwestern United States the *Ixodes scapularis* is prevalent, much like *Ixodes pacificus*, in the western United States. The ticks thrive in moist environments with undergrowth and tree litter, known as "duff". (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 49, line 25 to page 50, line 3.) In the northeastern United States the forest floor is sufficiently moist for *Ixodes scapularis* ticks to survive. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 50, lines 2 to 3.) However, the mere presence of Ixodes *scapularis* or *pacificus* ticks does not create an endemic area.

The carrier species ticks are not born infected with *Borrelia burgdorferi*. It acquires the infection when its first food choice is a carrier of the *Borrelia burgdorferi* organism. Ticks require blood meals. In northeastern United States and in the upper Midwest, the young *scapularis* tick feeds on the white-footed field mouse. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 50, lines 16 to 18.) This particular breed of mouse is a known carrier of *Borrelia burgdorferi*. A tick feeding on an infected mouse consumes the organism along with its blood meal. The organism is then transmitted via tick bite to the tick's next meal source. (*Id.* at lines 18 to 21.)

When *Ixodes scapularis* ticks do not feed on infected mammals, they do not acquire nor subsequently transmit the organism. In southern regions of the United States, the *Ixodes scapularis* tick does not have access to the white-footed field mouse. (*Id.* at page 51, lines 13 to 24). It feeds primarily on skinks which are not carriers of *Borrelia burgdorferi*. *Id.* The result is very little Lyme disease in Georgia, South Carolina, Florida, Alabama, and Mississippi. *Id.* The *Ixodes scapularis* ticks in these southern regions therefore are not sources of Lyme disease

infection. The drier environmental conditions found in Missouri and Kansas put the states in the same regional classification as those southern states. Neither state hosts the infected first food source.

"In general the *Borrelia burgdorferi* infection rate of *Ixodes scapularis* ticks throughout the South is extremely different from Northeast and Wisconsin and Minnesota, those North Central states." (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 85, line 24 to page 86, line 5.)

Another difference between endemic and non-endemic areas is the actual tick behavior. There are four stages of tick development: egg, larval, nymphal and adult. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 31, lines 6 to 9.) Studies have shown that larval and nymphal stage ticks behave differently in the northeastern regions compared to the southern regions. (Petitioner's Exhibit 9, Dr. Wormser Deposition page 31, line 23 to page 32, line 3.) In the northeast, these tiny larval and nymphal stage ticks are considered "frequent biters". When drag cloths were pulled through tick-infested undergrowth, more young ticks would latch onto the cloth in the northeast compared to the same experiment in the south. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 32, lines 4 to 12.)

In southern regions including Missouri (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 34, lines 24 to 25) larval and adult stage *Ixodes scapularis* ticks are easily collected, but the nymphal stage tick is more difficult because it does not bite as frequently as the northern variety. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 33, lines 11 to 14.) This results in significantly different rate of infection in the southern regions. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 35, line 11-21.)

The combination of the carrier tick species, an infected meal source and more frequent biting rate create a Lyme endemic area. A known tick bite from such a region is a red flag for the clinician during the diagnostic process.

According to the Center for Disease Control (CDC), 95 percent of the reported cases of Lyme disease come from just 12 states. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 63, line 23 to page 64, line 2.) In non-endemic areas, a reported case "in all likelihood, those are imported [;] [t]hose are people who have been traveling and come back, and they were bitten by a tick when they were in wherever and come back and manifested the disease while in Kansas. I'm not aware of there being any indigenous cases of Lyme disease." (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 48, lines 13 to 19.) "My opinion is that there's no *Borrelia burgdorferi* Lyme disease in Missouri that occurs in Missouri as a result of a tick bite in Missouri." (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 51, lines 14 to 17.) Unless a patient has had some physical connection to an endemic geographic area, the physician's first diagnostic triage should not include Lyme. "The epidemiology influences the likelihood of it being *Borrelia burgdorferi* infection." (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 83, line 25 to page 84, line 3.)

The second factor in the patient history which would guide a clinician to consider a Lyme diagnosis is the patient must have suffered a tick bite from his or her exposure to a Lyme endemic area. "If you don't have exposure to ticks you're not getting Lyme disease." (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 72, lines 9 to 10.) "It's not transmitted by other insect[s]. It's not transmitted sexually." (Wormser Petitioner's Exhibit 9, Dr. Wormser Deposition, page 72, lines 14 to 15.)

The organism is spread by tick bite. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 15, lines 7 to 8.) The ticks that spread the organism are *Ixodes scapularis* in the northeast and northern Midwest and *Ixodes pacificus* in the western United States. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 15, lines 1 to 6.) A patient can be infected when a tick previously infected attaches to the patient for a blood meal. During feeding, the tick will regurgitate excess water into the subject's skin. (Petitioner's Exhibit 1, Dr. Sigal's Deposition, 10/24/11, page 15, lines 12 to 17). The regurgitated water can carry with it the *Borrelia burgdorferi* organism, which then infects the new host. *Id.* 

The duration of the bite is an important sub-factor. Again, in the northeast, *Ixodes scapularis* is a frequent biter and its food source is a source of infection. An infected tick removed during the first 24 hours after biting has a near zero rate of transmission of the infection. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 44, lines 4 to 6.) The *Borrelia burgdorferi* infection is mostly transmitted after the tick has been attached for 72 hours. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 44, lines 3 to 4.) The transmission is not immediate upon the bite. (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 43, lines 19 to 21.)

Another significant factor is the size of the ticks. In the northeastern United States, the frequent biters are the ticks in the nymphal and larval stages. These ticks are tiny and difficult to see. "The larvae are the sign [sic] of a pinhead, the nymphs are the size of a poppy seed, and the adults are the size of a sesame seed." (TR., page 412, lines 15 to 17.) The difficulty spotting an attached tick increases the likelihood that it will remain attached for more than 24 hours and possibly infect its host. Older larger ticks are not only less likely to attach, they are more likely to be spotted and removed prior to transmitting the infection.

In California, the primary source of infection is *Ixodes pacificus* ticks in the nymphal stages, which are "poppy seed size." (TR., page 514, lines 15 to 17.) "So they could be easily missed for a freckle." (TR., page 507, line 20 to 508, line 1.)

The third factor in the diagnostic process is the symptoms experienced by the patient. Specific symptoms, within the historical context of a tick bite from a Lyme endemic region might be indicative of Lyme disease. The same symptoms, in a different context would suggest a different probable diagnosis. "The epidemiology is different in different parts of the country. In other words, if you go to Alaska, it pretty much doesn't matter what you have, it's probably not Lyme disease. So that your skepticism for that diagnosis would be much different that a person with the same clinical manifestation in New York." (Petitioner's Exhibit 9, Dr. Wormser Deposition, page 83, lines 12 to 19.)

Likewise, a patient with a bulls-eye rash in Missouri is suggestive of STARI, but in Westchester, it is presumed to be Lyme disease. (Petitioner's Exhibit 9, 9/5/11 Wormser Deposition, page 84, lines 12 to 18.) "This rash didn't follow the bite of a deer tick (*Ixodes scapularis*) It followed the bite of the Lone Star tick, when a tick bite was recalled." (Petitioner's Exhibit 9, Wormser Deposition, 9/5/11, page 69, lines 12 to 13 and lines 18 to 21.)

This is a limited set of specific symptoms, not an over-inclusive list of general symptoms. (Petitioner's Exhibit 9, Wormser Deposition, 9/5/11, page 94, lines 14 to 17.) Those symptoms appear in roughly three stages, though the time lapse from the first stage through the last stage can vary anywhere from months to years. (Petitioner's Exhibit 1, Sigal Deposition, 10/24/11., page 16, lines 13 to 14.)

Early Lyme disease manifests as "early localized diseases, skin disease, can be associated with a little bit of fever, with some aches and pains, headache." (Petitioner's Exhibit 1, Sigal Deposition, 10/24/11, page 16, lines 4 to 7.)

Some studies show that "70 percent of Lyme disease patients present with *erythema* migrans; isn't that true? Yes." (TR. Vol. IV, page 500, lines 13 to 16.) "The most common clinical manifestation of *Borrelia burgdorferi* is a characteristic skin lesion that's called *erythema migrans* and it's a red expanding skin lesion that occurs at the site of the tick bite and it can occur elsewhere as well if the *Borrelia* spreads through the bloodstream to other parts of the skin." (Petitioner's Exhibit 9, Wormser Deposition, 9/5/11 page 66, lines 2 to 9.)

Other clinical manifestations include 7<sup>th</sup> nerve palsy due to Lyme disease, radiculopathy, meningitis, and atrioventricular block, and Lyme arthritis. (Petitioner's Exhibit 9, Wormser Deposition, 9/5/11, page 66, line 22 to page 67, line 17; Petitioner's Exhibit 1, Sigal Deposition, 10/24/11, page 16, lines 7 to 12.) "One of the symptoms of any stage of Lyme disease can be joint pain. But late Lyme disease, the most common manifestation of that, is an actual swollen joint, it's very conspicuous." (Petitioner's Exhibit 9, Wormser Deposition, page 67, line 22 to page 68, line 2.)

Most patients diagnosed can be cured with a standard round of oral antibiotics. (Petitioner's Exhibit 9, Wormser Deposition, page 108, lines 6 to 11.) Some symptoms that accompany the typical rash such as fatigue may take longer to resolve but more treatment does not yield faster results. (Petitioner's Exhibit 9, Wormser Deposition, page 109, lines 19 to 22.) *Borrelia burgdorferi* is extremely susceptible to antibiotics and is usually resolved with a single course. (Petitioner's Exhibit 9, Wormser Deposition, page 108, lines 6 to 11; Petitioner's Exhibit

1, Sigal deposition 10/24/11, page 63, lines 8-18; Petitioner's Exhibit 1, Sigal deposition 10/24/11, page 14, line 18 - page 17, line 14.)

Respondent repeatedly violated that standard of care by diagnosing patients with Lyme disease using vague, non-specific, overly broad, subjective criteria, which constituted repeated negligence under section 334.100.2 (5), and also violated sections 334.100.2(4), (4)(c), and (4)(a).

#### VII.

Respondent repeatedly and continually prescribed antibiotics for more than the standard seven to ten days and well beyond the outside limit of four weeks, which violated the applicable standard of care and constituted repeated negligence under section 334.100.2(5)

Dr. Sigal testified that the current standard of care for the treatment of Lyme disease, at least early localized, is amoxicillin and doxycycline. (Petitioner's Exhibit 1, Sigal deposition 10/24/11, page 17-19). Furthermore, he went on to specify:

If a patient has meningitis or severe carditis, we typically treat with intravenous antibiotics. The most commonly used is ceftriaxone, c-e-f-t-r-i-x-o-n-e, it's marketed as Rocephin...And that's given two weeks, 2 grams a day for two weeks, very effective. For patients with Lyme arthritis that does not respond to oral antibiotics, which should be the first approach, we give two weeks of Rocephin. Occasionally, on rare occasions you need to give four weeks, but it's two weeks. Patients with Lyme central nervous system disorders will receive intravenous antibiotics, as well, and that's typically two weeks, sometimes four weeks. But there's no evidence to suggest that longer duration therapy is warranted...There's no reason to suggest that longer duration therapy is warranted. There's no reason to believe that one should cycle antibiotics, using one for a month and another for a month and another for a month. And there's no evidence to suggest that long-term therapy is warranted. That's a mythology.

Id.

There is no evidence that long term antibiotics are more effective. The erythema migrans rash will vanish within days and if there is carditis, it should improve within days. Lyme arthritis may get better within a few days but it could take months to improve. Central nervous

system disorders of the late variety can take months or years to see improvement. However, the continued use of long-term antibiotics will not affect these persistent symptoms and therefore does not warrant continued antibiotics. (Petitioner's Exhibit 1, Sigal deposition 10/24/11, pages 55 to 59). Dr. Sigal explains, "If I treated you for 12 months you'd be fine. You'd also have 12 months' worth of toxicities, 12 months' worth of side effects, 12 months' worth of expense. If I treat you for one month and 11 months of just follow up and you're fine, then you have one month worth of treatment, et cetera, et cetera, et cetera. In fact, the one month was sufficient. There's no reason to treat for 12 months, because the outcome will be the same." Id.

Dr. Sigal further testified that there is no scientific evidence to support that there is any benefit to longer term, months of antibiotic use. In fact, he testified that there was a study out of Tufts and treated patients with "chronic Lyme disease" with three months of antibiotics and saw no difference in outcomes. Id. There are significant side effects to the use of long term antibiotics, including toxicities that can be trivial, like a rash, but some can be life threatening, such as continual diarrhea, liver toxicity, bone marrow toxicity. (Petitioner's Exhibit 1, Sigal deposition 10/24/11, pages 55 to 59). This is especially a problem when clinicians use combinations of antibiotics where the toxicities overlap. Id.

Dr. Wormser testified that most patients can be cured with a ten to 28-day course of antibiotics depending on the clinical manifestations. (Petitioners Exhibit 9, Wormser deposition 9/5/11, page 108). Dr. Wormser further testified that persistent symptoms due not warrant continued antibiotic treatment as it will not make those symptoms disappear any quicker. Id.

Respondent continually justifies her use of long term antibiotics by relying on the theory of persistent infection, commonly referred to as Chronic Lyme disease. Dr. Sigal testified that there are patients that will have long term symptoms by that are not caused by chronic infection

with *Borrelia burgdorferi*. (Petitioners Exhibit 1, Sigal deposition, 10/24/11, page 129 to 132). Antibiotics will not resolve those persistent symptoms. Id.

Dr. Sigal further warns of basing treatment guidelines on anecdote:

In the medical literature when you talk about an individual case where we did this and we found that, that's an anecdote. That's not a scientific statement of anything. Because, again, the patient could have gotten better had you given them two or three weeks of antibiotics and waited an additional 11 and a half months. There's no way to know.

Q. So a physician's caseload is anecdotal, is that what you're telling me?

A. Any individual case is an anecdote. If, on the other hand, you set up a study where you have a set of inclusion and exclusion criteria, you bring the patients into the study. You then double-blind treat this way versus this way. "Double-blind" means neither the patient knows, nor the clinician, the evaluator. You do that. At the end of a certain period of time you then evaluate the patients. If you see a difference between the two groups, now you've got -- and if it's a statistically significant difference, now what you've got is scientific evidence that one treatment does something different from the other. But saying that I have 500 patients in my clinic, and I've done this, this, this, this and this, these 500 patients, and the people who got this seemed to have done better, that's just 500 anecdotes, that's not the scientific method.

Id.

Respondent prescribed J.C. at least two months of antibiotics, A.S. at least one year of antibiotics, K.K. at least four months of antibiotics, S.K. at least one month of antibiotics, B.L. at least nine months of antibiotics, D.L. at least one month of antibiotics, and J.F. at least a year of antibiotics. (Respondent's Exhibits, 2C, 3B, 4B, 5B, 6B, 7B, and 8B). Respondent repeatedly prescribed unnecessary and harmful antibiotics, when the scientific evidence is very clear that the standard of care in treatment is seven to ten days and up to four weeks when justified.

Respondent repeated violated that standard of care by treating patients with long term antibiotics, repeatedly exposing the patients to harm from unnecessary toxins related to long term antibiotic, which constituted repeated negligence under section 334.100.2 (5), and also violated sections 334.100.2(4), (4)(c), and (4)(a).

### VIII.

# Respondent was repeatedly negligent in her care and treatment of the seven (7) patients named in Petitioner's Complaint.

## (a) Patient J.C.

Dr. Cooperstock evaluated J.C. following his treatment with Dr. Ryser. Dr. Cooperstock testified that Patient J.C. did not have any classic findings associated with Lyme disease, except the history of an erythema migrans rash. (Tr. Volume 1, page 94, lines 7 to 25). While working on his grandfather's farm in Stillwell, KS, JC experience a rash that spread. He went to a clinic in Overland Park that diagnosed erythema migrans and prescribed ten days of doxycycline and the rash soon cleared. (Petitioner's Exhibit 10 – J.C. 1/13/11 deposition, page 7, line 3 to page 7, line 9; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 16, line 8 to page 16, line 14).

J.C. was taken to see Dr. Ryser by his father as a precautionary measure after his father became concerned about the possibility of J.C. having contracted Lyme disease and that the ten (10) days of doxycycline was not going to be sufficient. J.C. and his father were told that several symptoms noted in his history were caused by Lyme disease, even though some of the symptoms were present even before J.C. acquired his rash in 2008. (Petitioner's Exhibit 10 – J.C. 1/13/11 deposition, page 48, line 5 to page 51, line 4; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page131, line 4 to page 132, line 23).

Based on these vague and subjective symptoms Dr. Ryser ordered at least fifty-two (52) laboratory tests on J.C., over half of which are not approved by the FDA. (Tr. Volume VI, page 876, line 10 to page 893, line 6; Respondent's Exhibit 2C, page 76-77). Dr. Ryser relied on the results of the IGeneX Western Blot, which was not positive by CDC guidelines and diagnosed J.C. with Lyme disease, despite the fact that he had already been treated with doxycycline.

Respondent tends to use questionable guidelines in interpreting test results. For instance, Dr. Ryser reported that J.C.'s clotting activation result as abnormal, despite the fact that the lab results clearing indicate that there is not a reference range for patients under 18 years old. (Tr. Volume VI, page 907, line 21 to page 909, line3; Respondent's Exhibit 2C, page 49).

Respondent subjected J.C. to multiple antibiotics explaining that one antibiotic breaks the bacteria out of the cyst form and the other antibiotic kills it. (Petitioner's Exhibit 11, R.C. 11/22/10 deposition, page 39, line 16 to page 40, line 3). However, Dr. Sigal testified that there is no evidence to support using multiple antibiotics, long term antibiotics or cycling antibiotics. Petitioner's Exhibit 1, Sigal deposition, 10/24/11, pages 18 to 19). Dr. Christensen testified that *Borrelia burgdorferi* does not hide in a cyst form requiring multiple antibiotics. (Tr., Volume XII, page 1580, line 18 to page 1584, line 16).

Dr. Ryser prescribed antibiotics for J.C., which lead to fatigue and aches, muscle pain, and joint pain, which Dr. Ryser stated were Herxheimer reactions from the killing of toxins in J.C.'s body. Dr. Cooperstock testified that Respondent was negligent and violated the applicable standards of care by diagnosing and treating J.C. for Lyme disease. (Tr., Volume 1, page 107). The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in diagnosing and treating J.C. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient J.C. Patient J.C. may have been bitten by a tick in Kansas and was treated with a ten day course of doxycycline. Despite this, Respondent further treated J.C. with three months of unnecessary antibiotics when further treatment was not indicated. Treating a patient for a disease that has already been treated and cured amounts to negligence and violates the applicable

standards of care. Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests". Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients. Respondent delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience, or licensure to perform such responsibilities, violating section 334.100.2(4) (d).

## (b) Patient A.S.

A.S. presented to Dr. Ryser primarily with mental health issues and had no physical complaints. (Tr. Volume VII, page 934, lines 19 to 22; Petitioner's Exhibit 3, page 884). Dr. Ryser ordered the Bowen Q-RiBb test twice, the first at the initial visit on January 26, 2005 and then again on June 9, 2005. The serial dilution values were 1:16 and 1:32 respectively, both reported as positive. (Petitioner's Exhibit 3, pages 679 and 680). However, Dr. Ryser asserts that she never diagnosed or treated A.S. for Lyme disease, instead diagnosing with Beta strep and Babesia. (Tr. Volume VII, page 952, lines 1 to page 954, line 5; Id. at page 946, lines 23 to 25). Dr. Ryser testified that she did not diagnose A.S. with Lyme disease but kept it in the differential so that it would remain in focus. (Tr. Volume VII, page 952, lines 1 to page 954, line 1; Tr. Volume VII, page 973, line 5 to page 975, line 9). Dr. Ryser testified that A.S. had migratory joint pain, but A.S. did not have all of the physical symptoms that they normally see and that is why she thought Strep was a better diagnosis. *Id.* A.S. testified that Dr. Ryser told her that she had Lyme disease and treated it with Mepron (Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 34, lines 2 to 23).

Although she insists she did not diagnose or treat for Lyme disease, the records support the fact that she did. On 1/19/05, the date of A.S.'s initial exam, Diana Smith completed a Bowen Labs "Lyme disease Questionnaire" regarding A.S., which noted that A.S. had not been diagnosed with Lyme disease. (Respondent's Exhibit 3B, page350). This form was completed upon requesting the first Bowen test. *Id.* On 6/9/05, Diana Smith completed another Bowen Labs "Lyme disease Questionnaire" regarding A.S., which noted that A.S. had been diagnosed with Lyme disease, based on the Bowen test and that the Lyme disease was treated with Mepron and Zithromax. This form was completed upon requesting the second Bowen test. (Respondent's Exhibit 3B, page 337 and 338). And on 8/18/05, Diana Smith completed another Bowen Labs "Lyme disease Questionnaire" regarding A.S., which noted that A.S. had been diagnosed with Lyme disease, based on the Bowen test and that the Lyme disease was treated with Mepron and Zithromax. This form was completed upon requesting the third Bowen test. (Petitioner's Exhibit 3, page 928).

Both Dr. Horowitz and Cameron testified that Dr. Ryser diagnosed and treated A.S. with chronic Lyme disease and Babesia. (Tr. Volume 5, page 656, line 22 to page 657, line 4;Tr. Volume 9, page 1283 line 7, to page 1284, line 6). Dr. Christensen testified that Babesia is an infection transmitted by ticks; "wildly" uncommon in MO; only three cases ever reported in Mo. (Petitioner's Exhibit 22d, Christensen deposition Volume II 3/3/11, page 219, line 22 to page 220, line 11; Petitioner's Exhibit 22e, Christensen deposition Volume III 3/14/11, page 338, line 21 to 23).

A.S. was charge hundreds of dollars for the treatment of Lyme disease. (Petitioner's Exhibit 3, page 857, 679 to 711; Respondent's Exhibit 3B, pages 332 and 333). A.S. was eventually seen by a psychiatrist, who diagnosed bipolar disorder, and her symptoms improved

with therapy and treatment for the bipolar disorder. (Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 72, line 8 to page 73, line 7).

Dr. Cooperstock testified that Respondent was negligent and violated the applicable standard of care by diagnosing patient A.S. with Lyme disease and treating her with antibiotics when she did not have Lyme disease. (Transcript Volume 1, pages 118 to 122). He testified that the constellation of symptoms that A.S. presented with were not particularly suggestive of Lyme disease and that she had never been in an area that was endemic for Lyme disease. *Id.* He also testified that he found no evidence of Babesia as well. *Id.* The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in diagnosing and treating A.S. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient A.S. Patient S.K. never had Lyme disease. Respondent denies that she ever diagnosed and treated A.S. with Lyme disease, but treated her for Babesia. Despite her denials, it is clear that Respondent purported to treat patient A.S. for Lyme disease. In treating a patient for a disease that they did not have clearly amounts to negligence and violates the applicable standards of care. Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients.

## (c) Patient K.K.

K.K. presented to Respondent with a previous diagnosis and treatment for rheumatoid arthritis. Dr. Ryser told K.K. that the rheumatoid arthritis he was experiencing was attributable to his Lyme disease. (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 82, line 16 to page 85, line 24)

Dr. Ryser testified that the basis of the diagnosis of Lyme disease was Bell's palsy, first testifying that K.K. had marked yes on the initial questionnaire that he had Bell's palsy, then upon reviewing the records noted that was not accurate. (Tr. Volume VIII, page 1074, line 17 to page 1075, line 5). Dr. Ryser also testified that the Bell's palsy was not observed at the initial exam, but that it was observed later. (Tr. Volume VIII, page 1074, line 17 to page 1075, line 25). Dr. Ryser testified then that K.K. had marked that he had Bell's palsy on the questionnaire of symptoms. The questionnaire that K.K. completed indicated "No" to the question of Bell's palsy. (Tr. Volume VIII, page 1118, line 3 to page 1118, line 16; Petitioner's Exhibit 4, page 2019 to 2022).

Drs. Horowitz, Cameron, and Harris testified that K.K. had Bell's palsy, justifying the diagnosis of Lyme disease. (Tr. Volume V, page 659; Tr. Volume IX, page 1292; Tr. Volume IV, page 462). There is no notation in K.K.'s history and physical, diagnosis code sheet or any other section of Dr. Ryser's medical records that K.K. reported he had Bell's palsy or that Dr. Ryser observed Bell's palsy. (Dr. Ryser's Exhibit 4B).

Dr. Ryser testified that the tests for Lyme disease came back negative, but explained that the tests came back negative because K.K. was on Prednisone. (Tr. Volume VIII, page 1084, line 2 to page 1084, line 25). She testified that the tests were negative because "you need to be off any kind of major anti-inflammatory or Prednisone probably three months before we do it".

*Id.* However, if Dr. Ryser knew the tests were going to come back negative then Respondent necessarily ran unnecessary tests.

Dr. Ryser told K.K. that to confirm the diagnosis of Lyme disease he needed to take the Bowen Laboratory Q-RiBb test. (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 94, line 10 to page 95, line 3) Dr. Ryser admitted that the test was not FDA approved, but that she would use it to confirm her suspicion that he in fact had Lyme disease. (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 94, line 15 to page 95, line 3). Dr. Ryser told K.K. that she believed he had Lyme disease and the Bowen test was the only accurate test for Lyme disease. *Id.* Dr. Ryser informed K.K. that the Bowen Laboratory results were positive for Lyme disease, stating that his test score was the highest that she had ever seen. (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 91, line 10 to page 92, line23). The Bowen lab results carried the disclaimer "this research test was developed and its performance characteristics determined by the Bowen Research and Training Institute, Inc., a non-profit organization strictly supported by donations.

The Q-RiBb© test has not been approve by the U.S. Food and Drug Administration. This information is to be used as a reference only. This testing is for research use only and is not intended for the use in diagnosis and / or treatment. All data is reserved for research analysis". (Petitioner's Exhibit 4, page 2105) Bowen Research and Training Institute was not licensed in 2006, and the AHCA, the agency that licenses clinical laboratories in Florida, denied Bowen's application for licensure in 2006. JoAnne Whitaker, the President and Director of Bowen had voluntarily relinquished Bowen's license to operate Bowen as a clinical laboratory. (Petitioner's Exhibit 24; Petitioner's Exhibit 25).

Relying on the Bowen test result, on 1/17/05, Dr. Ryser ordered IV antibiotics Rocephin and supplements, which were to treat the Lyme disease that Dr. Ryser had diagnosed. (Tr. Volume VIII, page 1095, line 12 to page 1096, line 5; Petitioner's Exhibit 4, pages 2009 to 2014). During the time he was given treatment by Dr. Ryser, K.K. experienced such periods of fatigue and exhaustion that he was unable to work and had to retire from the FAA. K.K. did not

experience any problems with fatigue prior to being treated by Dr. Ryser. (Petitioner's Exhibit 23, K.K. deposition 2/4/08, page 55, line 8 to page 57, line 1). At one point during his treatment, K.K.'s legs were swollen and his breathing slowed to around four (4) breaths per minute, and when he spoke to Dr. Ryser he was told that he would get a diuretic the following day when he came in for his IV treatment. (Petitioner's Exhibit 13, S.K. deposition 10/12/11, page 64, line 16 to page 71, line 22). Concerned, he spoke to another physician who told him to go directly to the emergency room, which he did. *Id.* At the hospital K.K. was told that he was negative for Lyme disease. *Id.* 

Dr. Christensen testified that Dr. Ryser's care and treatment was well below the standard of care because she diagnosed a patient with an illness who had no complaints and who had by Dr. Ryser's own physical history and laboratory evaluation no evidence of disease. (Exhibit 14 to Petitioner's Exhibit 22h, Christensen Deposition, Volume V, page 12) Dr. Ryser used lab results to diagnose a disease from a lab that was not approved for this purpose. *Id.* Dr. Ryser prescribed potentially injurious therapeutics for an extended period of time for a disease that did not exist. *Id.* The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in diagnosing and treating K.K. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient K.K. Respondent based her diagnosis of Lyme disease of vague subjective symptoms and use the "positive" Bowen Q-RiBb test to convince K.K. that he had Lyme disease and required extensive IV antibiotic treatment. Despite her denials, it is clear that Respondent told K.K. and S.K. that Lyme disease is sexually transmitted. K.K. did not have Lyme disease, but suffered from rheumatoid arthritis. Treating a patient for a disease that they did not have clearly

amounts to negligence and violates the applicable standards of care. Furthermore, Respondent treated K.K. with antibiotics for over four months, far exceeding the standard of care in treating Lyme disease. Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients. Respondent delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience, or licensure to perform such responsibilities, violating section 334.100.2(4) (d).

## (d) Patient S.K.

Respondent repeatedly insisted at the hearing that she did not diagnose patient S.K. with Lyme disease and did not treat her for Lyme disease (Tr. Volume XI, page 1559, line 14 to page 1561, line 10). She testified that she gave patient S.K. doxycycline, standard treatment for Lyme disease, but that the doxycycline was actually prescribed to treat mycoplasma, another type of infection (Id.). One wonders then why her expert witnesses would testify that not only did she diagnose and treat patient S.K. for Lyme disease but that she met the "standard of care" in all respects in doing so. Dr. Steven Harris reviewed Respondent's patient chart for patient S.K. and concluded that her diagnosis and treatment of Lyme disease met the "standard of care." (Tr. Volume IV, page 486, line 20 to page 487, line 1). Likewise, Dr. Richard Horowitz reviewed the patient charts and found that Respondent had diagnosed patient S.K. with "chronic Lyme disease" and that her diagnosis and treatment with doxycycline met the "standard of care." (Tr. Volume V, page 661, line 8 to page 664, line 9) Dr. Horowitz testified that "doxycycline is a

classical drug that's used for Lyme disease . . . " (Tr. Volume V, page 661, line 8 to page 664, line 9). Just to make the confusion unanimous, Dr. Daniel Cameron testified that Respondent met the "standard of care" in her diagnosis and treatment of Lyme disease in patient S.K., based on his review of the records. (Tr. Volume IX, page 1295, line 20 to page 1297, line 5).

Respondent also insisted that she considered the Bowen test for patient S.K. showing a 1:8 dilution as negative even though Bowen had denominated the test as "positive" for Lyme disease (Tr. Volume XI, page 1520, lines 2 to 11) (Tr. Volume XI, page 1504, lines 4 to 21). Exhibit 28 is Dr. Ryser's 2009 letter to the Board regarding patient S.K. in which she indicates that she diagnosed S.K. with Lyme disease, treated her for Lyme disease with doxycycline, and used the Bowen Q-RiBb test in making the diagnosis.

Dr. Cooperstock and Dr. Christensen testified that Respondent was negligent and violated the applicable standards of care, as defined in Section 334.100.2(5), by diagnosing patient S.K. with Lyme disease and treating her with doxycycline for Lyme disease when she did not have Lyme disease (Tr. Volume I, page 130, lines 17 to 22) (Tr. Volume I, page 131, lines 1 to 7) (Deposition Exhibit 16 to Petitioner's Exhibit 22h). The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in her care and treatment of patient S.K. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I., above. Additionally, one would have to conclude based on Exhibit 28 that Respondent's credibility is extremely questionable. Although Respondent insisted that she did not diagnose patient S.K. with Lyme disease, or treat her for Lyme disease, or use the Bowen "positive" test for Lyme disease, her own experts in reviewing the patient chart thought that she indeed diagnosed patient S.K. with Lyme disease and appropriately treated her with doxycycline.

Patient S.K. testified live at the hearing and disputed Dr. Ryser's testimony. Patient S.K. credibly testified that Dr. Ryser told her that the Bowen test proved that she had Lyme disease. (Tr. Volume IX, page 1361, lines 10 to 20). Patient S.K. also testified that Dr. Ryser told her that she had Lyme disease and that she was prescribing doxycycline for her supposed Lyme disease. (Tr. Volume IX, page 1363, lines 18 to 25). Patient S.K. testified that Respondent was already treating her husband for about two months when Respondent told her that Lyme disease can be sexually transmitted. (Tr. Volume IX, page 1353, lines 7 to 25). Based on this advice, patient S.K. believed that there was a possibility that she herself had Lyme disease. (Tr. Volume IX, page 1354, lines 7 to 9). Respondent told patient S.K. that she probably should be tested. (Tr. Volume IX, page 1354, lines 10 to 21). Respondent told patient S.K. that the Bowen test was the most reliable test for Lyme disease and that she wanted to do that. (Tr. Volume IX, page 1361, lines 10 to 20). Respondent did not indicate to patient S.K. that the Bowen test had not been approved by any certifying organization. (Tr. Volume IX, page 1361, lines 21 to 24).

Significantly, Respondent did not begin to treat patient S.K. for Lyme disease until the results of the Bowen test came back. (Tr. Volume IX, page 1363, lines 10 to 15). Patient S.K. met with Respondent and went over the results of the test, which Respondent indicated proved that patient S.K. in fact, had Lyme disease. (Tr. Volume IX, page 1364, line 22 to page 1365, line 25). Patient S.K. testified that Respondent showed her pictures of "spirochetes" which she told patient S.K. were in fact Lyme spirochetes in their "cyst form." (Tr. Volume IX, page 1365, lines 10 to 13). Respondent told patient S.K. that the doxycycline she prescribed for her was to get rid of the Lyme disease. (Tr. Volume IX, page 1363, lines 20 to 23). It appeared to patient S.K. that Respondent's diagnosis of Lyme disease was largely based on the results of the Bowen test. (Tr. Volume IX, page 1365, lines 20 to 22). Patient S.K. and her husband were charged in

the neighborhood of \$80,000 for the antibiotics he took all those months. (Tr. Volume IX, page 1371, lines 18 to 23).

In his report to the Kansas Board of Healing Arts, Exhibit 16, Dr. Christensen discussed patient S.K.'s purported symptoms of Lyme disease.

a. The list of "Lyme symptoms" made no sense to me. The list consisted primarily of unrelated diagnoses, most of which to my knowledge had never been associated with Lyme disease. The list included some symptoms, many of which were poorly defined, as well as even more poorly defined (non-medical) colloquial terms.

(Deposition Exhibit 16 to Petitioner's Exhibit 22h, Christensen Deposition, Volume V, 12/21/2010, page 21, para 17a.) Dr. Christensen further stated:

Note: There was no documentation that the patient had visited an endemic area for Lyme disease; there was no documentation that the patient had an erythema migrans rash. In my opinion, the history did not include any information persuasive of Lyme disease.

(Deposition Exhibit 16 to Petitioner's Exhibit 22h, Christensen Deposition, Volume V, 12/21/2010, page 16, para 7).

Both Dr. Cooperstock and Dr. Christensen testified that patient S.K. never had Lyme disease. (Tr. Volume I, page 130, lines 17 to 22). Respondent convinced her that she did by falsely claiming that Lyme disease can be sexually transmitted from husband to wife, despite the complete absence of scientific evidence to support such a claim. Respondent then knowingly used an unapproved, unaccredited, and worthless Bowen lab test to convince patient S.K. that she had Lyme disease. Respondent then treated patient S.K. with the antibiotic doxycycline for a

disease that she never had. Patient S.K. had a few diverse and unrelated physical complaints that Respondent claimed were due to Lyme disease, none of which Dr. Cooperstock or Dr. Christensen believed were indicative of Lyme disease. Furthermore, as the evidence overwhelmingly established, there is no indigenous Lyme disease in Missouri or Kansas. (Entire record). Dr. Cooperstock and Dr. Christensen both testified that Respondent treated patient S.K. for a disease that she never in fact had. (Tr. Volume I, page 131, lines 1 to 7).

Perhaps realizing the futility of trying to defend her diagnosis and treatment of Lyme disease in patient S.K., Respondent at the hearing tried to claim that she never in fact diagnosed Lyme disease or treated patient S.K. for Lyme disease. Her own words in Exhibit 28, written to the Board to defend her care and treatment of patient S.K., put the lie to her testimony.

Respondent was negligent and violated the applicable standards of care in her treatment of patient S.K. Patient S.K. never had Lyme disease. Despite her denials, it is clear that Respondent purported to treat patient S.K. for Lyme disease. Treating a patient for a disease that they did not have clearly amounts to negligence and violates the applicable standards of care. Dr. Christensen in his testimony stated that Respondent's treatment of patient S.K. amounted to gross negligence. Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients.

## (e) Patient B.L.

B.L. presented to Dr. Ryser with a previous diagnosis of fibromyalgia. (Petitioner's Exhibit 6 page 2511;Petitioner's Exhibit 14, B.L. deposition 12/15/10, page 24, line 2 to line 7, page 40, line 1 to line 5, page 44 line 12 to 16). Dr. Ryser testified that she thought that fibromyalgia was a manifestation of the "cyst form" of *Borrelia burgdorferi*. (Tr. Volume XI, page 1443, line 2 to line 11).

B.L.'s presenting symptoms included achy joints, sore muscles, headaches, fatigue, photosensitivity, fevers, swollen glands, and sleep problems. (Petitioner's Exhibit 6, page 2386). Dr. Ryser's nurse, Diana Smith, performed an initial exam and informed B.L. that she could tell just by looking at her that she had Lyme disease. (Petitioners Exhibit 15, B.L. deposition 10/11/11, page 209, lines 1-5). B.L. testified that in the whole time she was treated by her, Dr. Ryser never once performed a medical exam on her; Dr. Ryser never touched her one time. (Petitioners Exhibit 15, B.L. deposition 10/11/11, page 208, line 20 to page 209, line 25).

Dr. Ryser ordered blood tests and told B.L. that the Bowen Laboratory test was the way to diagnose Lyme disease, and that the Bowen Q-RiBb was on the cutting edge. (Petitioner's Exhibit 15, B.L. deposition 10/11/11, page 326, line 12 to page 327, line 8). Dr. Ryser also ordered Bartonella, Babesia, and Lyme Western Blot and Elisa tests on 11/19/03, which were all negative. The Bowen Q-RiBb test of 11/11/03 was reported back positive with a serial dilution value of 1:8. Dr. Ryser testified that she evaluates the Bowen result of serial dilution value of 1:8 as negative. However, Dr. Ryser testified that despite the test results, she made a clinical diagnosis of Lyme disease because of B.L.'s history of tick bites, not feeling well, chronic flulike symptoms, psychiatric symptoms and chronic pain. (Tr. Volume XI, page 1436 to 1438). On 12/19/03, a PICC line was started because Dr. Ryser prescribed IV antibiotic treatment for B.L. (Tr. Volume XI, page 1435, line 23, to page 1436, line 9).

Dr. Ryser prescribed B.L. antibiotics, rotating between IV and oral from January 2004 to September 2004. (Respondent's Exhibit 6B, pages 51 to 65; Tr. Volume XI, page 1439, line 14 to page 1442, line 25). Dr. Ryser routinely rotates antibiotics every 4 to 6 weeks. (Tr. Volume XI, page 1442, line 4 to 25). Dr. Sigal testified that there is no evidence to support cycling antibiotics. (Petitioner's Exhibit 1, page 19).

After several rounds of antibiotics, B.L. felt achy, was in pain, was having issues with her memory and cognitive functions, and her stomach started to swell. (Petitioner's Exhibit 15, B.L. deposition 10/11/11, page 271, lines 4-8). After being referred to a specialist, B.L. had to have her gallbladder removed. Dr. Ryser referred B.L. to a specialist for her stomach, and indicated that the IV treatment may have caused sludge in her gallbladder, necessitating removal. (*Id.* at page 266, line 22 to page 275, line 13).

Dr. Ryser charge B.L. several thousand dollars for treatment for herself and her husband, D.L. (Petitioner's Exhibit 17, page 282, 11 to page 284, line 4).

Dr. Christensen testified that Dr. Ryser's care and treatment of B.L. was well below the standard of care because she had a classic presentation for fibromyalgia and had carried that diagnosis for many years and without justification discarded this diagnosis, even though she confirmed the diagnosis herself. Dr. Ryser pursued ill defined conditions including Lyme disease. Dr. Christensen criticized Dr. Ryser's "shotgun" approach to laboratory diagnosis, in that she ordered tests that had little relevance and from labs with dubious credentials. (Exhibit 15 to Petitioner's Exhibit 22h, Christensen Deposition, Volume V, 12/21/2010, page 16 and 17).

In his report to the Kansas Board of Healing Arts, Exhibit 16 to Petitioner's Exhibit 22h, Dr. Christensen further criticized Dr. Ryser's care of B.L. because she ignored results, for instance:

- a. She diagnosed the patient as having "PANDAS" even thought the patient was a middle aged adult and the test was negative.
- b. She prescribed intravenous "antioxidant" therapy even though the tests she ordered showed normal antioxidant content.
- c. She ignored the testing for Lyme disease that she had obtained from Medical Diagnostic Laboratories, testing which show no evidence of Lyme disease. Instead she used the results of the Bowen Research Institutes, but then she appeared to have ignored the implications of the increased value reported by the Bowen Lyme disease test, a value that increased despite extensive antimicrobial therapy.

Id.

Dr. Christensen testified that Dr. Ryser's care of B.L. demonstrated gross negligence. (Exhibit 15 to Petitioner's Exhibit 22h, Christensen Deposition, Volume V, 12/21/2010, page 16 and 17). The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in her care and treatment of patient S.K. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I, above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient B.L. Patient B.L. never had Lyme disease. Treating a patient for a disease that they did not have clearly amounts to negligence and violates the applicable standards of care.

Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients.

Respondent delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience, or licensure to perform such responsibilities, violating section 334.100.2(4) (d).

## (f) Patient D.L.

In February, 2004, D.L. became a patient of Dr. Ryser because Respondent diagnosed and treated his wife with Lyme disease. Dr. Ryser informed D.L. and B.L. that Lyme disease is passed through saliva, blood, semen, tears, and is often times passed between spouses.

(Petitioner's Exhibit16, D.L. deposition Vol. 1 12/20/10, page 19, line 11 to page 23, line 10).

Dr. Ryser testified that she ran a Lyme test based on the presence of mood changes, chest pain, blood pressure issues, slight tremors, increased weight, and migratory joint pain. She testified that he didn't have very many symptoms. (Tr. Volume VII, page 1000, line 18 to page 1001, line 30). D.L. had previously been tested for Lyme disease by another physician who used the Western Blot test, which came back negative for Lyme disease. (Petitioner's Exhibit16, D.L. deposition Vol. 1 12/20/10, page 26, line 16 to page 28, line 25). Dr. Ryser informed D.L. that the Western Blot test was inaccurate and inconclusive, and that the Bowen test was needed to diagnose Lyme disease. Dr. Ryser told D.L. that the Bowen test was the 'gold standard' of Lyme tests and that it needed to be performed to prove that D.L. had Lyme disease. (*Id.* at page 31, line 5 to page 32, line 25 and page 41, line 4 to page 45, line 10).

Dr. Ryser ordered a Bowen test, which returned with a serial dilution value of 1:32 that was reported as positive. (Petitioner's Exhibit 7, page 2371). Dr. Ryser relied on the Bowen test to diagnose D.L. and informed him that he had tested positive for Lyme disease, and he was started on oral antibiotics.(Petitioner's Exhibit 7, page 2325; (Petitioner's Exhibit 16, D.L. deposition Vol. 1 12/20/10, page 55, line 11 to 18; Tr. Volume VII, page 1006, line 11 to 14).

Dr. Ryser testified that D.L. had a complete remission of his joint pain with the doxycycline, noting that the 7/14/04 office note indicated that he felt good, there were no problems, no visual problems, and that he didn't think he was irritable anymore. (Tr. Volume

VII, page 1007, line16 to page 1008, line 2). However, another Bowen Q-RiBb was ordered on August 23, 2004, which was returned with a serial dilution value of 1:128 that was reported as positive, higher that his previous test. (Petitioner's Exhibit 7, page2364).

Dr. Christensen testified that Dr. Ryser's care and treatment of D.L. was well below the standard of care because she appeared to frighten D.L. into being tested for Lyme disease by erroneously telling him that the disease was sexually transmitted. (Exhibit 17 to Petitioner's Exhibit 22h Christensen Deposition, Volume, page 12). She diagnosed D.L. with an illness when he had no complaints and who had by Dr. Ryser's own physical and laboratory evaluation no evidence of disease. *Id.* Dr. Ryser used lab results to diagnose a disease from a lab that was not approved for this purpose. *Id.* Dr. Ryser prescribed potentially injurious therapeutics for an extended period of time for a disease that did not exist. *Id.* Dr. Christensen testified that Dr. Ryser's care of D.L. demonstrated gross negligence. *Id.* The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in her care and treatment of patient S.K. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I, above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient D.L. Patient D.L. never had Lyme disease. Treating a patient for a disease that they did not have clearly amounts to negligence and violates the applicable standards of care. Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients.

# (g) Patient J.F.

J.F. initially complained of pain, fatigue, red flush skin, shaking, hallucinations and memory loss and Dr. Ryser testified that hallucinations are a symptom of Lyme disease. (Tr. Volume VIII, page 1142, line 18 to page 1143, line 8). Dr. Ryser told J.F. that if she were not treated she would die and that Lyme disease is not curable. (Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 43, line 15 to page 44, line 1; Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 31, line 20 to page 32, line 20). Dr. Christensen testified that Lyme disease does not have chronic aspects to it and it does not lead to fatal conditions. (Petitioner's Exhibit 22e, Christensen deposition Volume III 3/14/11, page 340, line 20-25).

The initial intake examination was done by Dr. Ryser's nurse, Diana Smith. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21). Dr. Ryser did not examine the patient until the follow up visit, two weeks after the initial exam, at which time she reviewed test results. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21). Laboratory tests were ordered after the initial visit with Diana Smith, before Dr. Ryser examined J.F. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21; Respondent's Exhibit 8B, pages 972 to 973).

The diagnosis code sheet was filled out by Diana Smith although Dr. Ryser did not examine the patient until the follow up visit on August 15, 2006. (Petitioner's Exhibit 8, page 1671). Diana Smith made the following diagnoses at the initial visit on 7/24/06- Lymes (sic) disease, Fibromyalgia, hypercoagulation, constipation, irritable bowel syndrome, iodine deficiency, Bells palsy, beta strep, upper respiratory infection, chronic fatigue syndrome rheumatoid arthritis, disease of CNS, insomnia, migraine, poly neuropathy, tremors, nutritional deficiency, levido reticularis and Vit. B deficiency. (Petitioner's Exhibit 8, page 1671).

Dr. Ryser testified that J.F. experienced Bell's palsy and that was observed at the initial exam. (Tr. Volume VIII, page 1148, line 15 to page 1149, line 4She testified that there was droopiness of the left eye and testified at the hearing that there was a picture in the medical records, but did not identify the location in her medical records. Id. The medical records contain pictures of J.F. that were taken on 2/8/07 and 6/24/08, neither is from the initial exam on July 24, 2006 nor do they show drooping of the left eye. (Respondent's Exhibit 8B, pages 151 and 167-170). J.F. noted on her "Lyme disease Questionnaire" under the Bell's palsy symptom that her left eyelid droops. (Respondent's Exhibit 8B, page 163). Bell's palsy is neurologic condition in which the facial muscles become paralyzed. "Bell's palsy" refers to idiopathic 7<sup>th</sup> nerve palsy. When the likely cause of the 7<sup>th</sup> nerve palsy is known, it is referred to as 7<sup>th</sup> nerve palsy due to Lyme disease. (Petitioner's Exhibit 22e, Christensen deposition Volume III 3/14/12, page 320, line 13 to line 19; Petitioner's Exhibit 9, Wormser deposition 9/5/11, page 66, line 16 to line 24). Dr. Sigal described 7<sup>th</sup> nerve palsy due to Lyme disease as "you can see facial droop, which is to say the seventh cranial nerve is damaged in Lyme disease and you've got a person whose one side of the face doesn't work, can't raise the mouth, can't wrinkle the forehead, that's another thing, can't make a smile." (Petitioner's Exhibit 1, Sigal deposition 10/24/11, page 24, line 17 to line 22).

The IGeneX lab Western Blot of 7/26/06 reported back as negative. (Respondent's Exhibit 8B, pages 307 to 309). The Bowen Q-RiBb of 7/26/06 reported back positive with a serial dilution value of 1:64. The Bowen Babesia test on July 26, 2006 came back negative. (Respondent's Exhibit 8B, pages 304 to 306). Dr. Ryser relied on the Bowen test, telling J.F. that she thought the Bowen test was the "gold standard" in Lyme testing. (Petitioner's Exhibit 18, J.F. deposition 10/12/11, page 71, line 25 to page 72, line 11). Upon receiving the results of

the lab tests, J.F. was told that she had tested positive for Lyme disease. (Petitioner's Exhibit 18, J.F. deposition 10/12/11, page 68, line 10 to page 70, line 16).

J.F. received IV antibiotic treatment from approximately September 2006 until approximately September 2007. (Respondent's Exhibit 8B page 878 to 895). J.F. weighed 131 pounds at her initial physical exam on July 24, 2006 and 108 on May 14, 2007(Respondent's Exhibit 8B, page 32 and 85). During treatment with Dr. Ryser, J.F. experienced frequent instability, shakiness, and fainting spells. (Respondent's Exhibit 8B, pages 338 to 341). On 8/16/07 J.F. was at Dr. Ryser's office when she became unstable and fell and hit her head. (Respondent's Exhibit 8B, pages 338 to 341). J.F. went to the St. Joseph Medical Center Emergency Room. (*Id* at pages 338 to 387).

During the treatment, J.F. was abusing prescription medications, and Dr. Ryser was aware of the abuse issues. (Tr. Volume XI, page 1418, line 18 to page 1419, line 9).Dr. Ryser continued to prescribe controlled substances knowing that J.F. was abusing prescription medications and having issues while receiving treatment. *Id*.

Dr. Ryser treated J.F. with over 300 days of treatment charging J.F. at least \$1188.35 for treatment of Lyme disease. (Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 38, line 1 to 8; respondent's Exhibit 8B page 878 to 895; Respondent Exhibit 8B, page 533 to 536).

Dr. Cooperstock testified that J.F. did not have Lyme disease and Respondent's diagnosis and treatment of J.F. for Lyme disease was negligent and violated the standard of care. He testified that J.F. had a lot of symptoms that were hard to place anywhere but not related to Lyme disease. (Tr. Volume II, page 176, line 18 to 23). Dr. Cooperstock testified that relying on the Bowen test to diagnose Lyme disease fell below the applicable standard of care. (Tr. Volume II, page 179, line 15 to 17). Dr. Cooperstock testified that Dr. Ryser treated J.F. extensively with

IV antibiotics and the reason for the medications is not clear from the medical records. (Tr. Volume II, page 177, line 4 to page 178, line 11). Dr. Cooperstock testified that the standard for treating chronic fatigue syndrome and fibromyalgia and Dr. Ryser was not providing treatment for either. (Tr. Volume II, page 174 to 179). The *pro forma* testimony of Drs. Harris, Horowitz, and Cameron that Respondent in her care and treatment of patient J.F. met some undefined "standard of care" does not constitute substantial evidence, as fully discussed in part I., above.

Respondent was negligent and violated the applicable standards of care in her treatment of patient J.F. Patient J.F. never had Lyme disease. In treating a patient for a disease that they did not have clearly amounts to negligence and violates the applicable standards of care.

Respondent is subject to discipline under Section 334.100.2(5) for negligence, conduct that is or might be harmful or dangerous to the mental and physical health of the patient, gross negligence and incompetency, and 4(c) for "willfully (sic) and continually performing inappropriate and unnecessary diagnostic tests" in her use of the Bowen test. Respondent violated section 334.100.2(4) and (4) (a) for willfully and continually overcharging or overtreating patients.

Respondent delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience, or licensure to perform such responsibilities, violating section 334.100.2(4) (d).

### **CONCLUSION**

The Board has the burden of proving that Respondent has committed conduct for which the law allows discipline. The Board believes that the evidence in the record demonstrates beyond a preponderance of the evidence that cause exists for the Board to impose discipline against Respondent's medical license. The Board has offered expert testimony, medical records, and other testimony to support its allegations that the diagnosis and treatment of J.C., A.S., K.K.,

S.K., B.L., D.L., and J.F. violated the standard of care with regards to these patients and that on more than one occasion she has failed to meet the applicable standard of care by failing to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of her profession. Respondent's actions and treatment of the patients therefore constitutes "repeated negligence". The Board has offered expert testimony, records and other testimony in support of its claims that Respondent willfully and continually performed inappropriate and unnecessary diagnostic tests, treatment, and medical service, which constitutes misconduct, fraud, misrepresentation, dishonesty, unethical conduct and unprofessional conduct in the performance of the functions or duties of the medical and surgical profession. The Board has also offered evidence that Respondent has overtreated these patients. The Board has also offered testimony and records supporting its claims that Respondent delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform such responsibilities. Based on the record, there is sufficient basis for the Commission to find cause for discipline under sections 334.100.2(4), (4) (a), (4) (c), (4) (d), (4) (e), and (5), RSMo.

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# **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the \_\_\_\_\_\_ of September, 2012, a true and correct copy of the foregoing *Petitioner's Corrected Brief in Support of Findings of Fact and Conclusions of Law* was emailed to:

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## ATTORNEYS FOR THE RESPONDENT

**ATTORNEY FOR PETITIONER** 

# BEFORE THE ADMINISTRATIVE HEARING COMMISSION STATE OF MISSOURI

STATE BOARD OF REGISTRATION FOR THE HEALING ARTS	)	
Petitioner,	)	
v.	) Case No. 09-1693H	A
CAROL A. RYSER, M.D.,	)	
Respondent	)	

# PETITIONER'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

COMES NOW Petitioner, the Missouri State Board of Registration for the Healing Arts (the "Board"), through counsel undersigned, and hereby requests the Commission enter the following findings of fact and conclusions of law:

## FINDINGS OF FACT

- 1. The Missouri State Board of Registration for the Healing Arts ("the Board") is an agency of the State of Missouri created and established pursuant to § 334.120, RSMo., for the purpose of executing and enforcing provisions of Chapter 334, RSMo. (*Petitioner's Complaint*, ¶ 1)
- 2. Respondent, Carol A. Ryser, M.D. ("Dr. Ryser"), is licensed by the Board as a physician and surgeon, and her license, Number R378, was first issued on January 17, 1970 and is current, and was current and active at all relevant times herein. (*Petitioner's Complaint*, ¶ 2; *Respondent's Responsive Pleading*, ¶ 2)

## COUNT I - J.C.

- 3. Patient J.C. was a seventeen (17) year-old male who first presented to Dr. Ryser in September, 2008, with concerns after a possible tick exposure. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 16, line 20 to page 23, line 11; Petitioner's Exhibit 10 J.C. 1/13/11 deposition, page 8, line 18 to page 8, line 21).
- 4. After working at his grandfather's farm in Stilwell, Kansas in July 2008, J.C. experienced a rash on his torso that spread up to his armpit. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 11, line 1 to page 14, line 12; Petitioner's Exhibit 10 J.C. 1/13/11 deposition, page 7, line 3 to page 7, line 9).
- 5. J.C. went to a clinic in Overland Park, K.S., where he was treated with ten (10) days of doxycycline and the rash cleared. (Tr. Volume VI, page 869, line 3 to page 869, line 8; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 16, line 8 to page 16, line 14).
- 6. The physicians in Overland Park diagnosed erythema migrans. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 14, line 25 to page 15, line 11; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 18, line 15 to page 18, line 22).
- 7. J.C. was taken to see Dr. Ryser by his father as a precautionary measure after his father became concerned about the possibility of J.C. having contracted Lyme disease and that the ten (10) days of doxycycline was not going to be sufficient. (*Petitioner's Exhibit 10 J.C.* 1/13/11 deposition, page 8, line 22 to page 10, line 25; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 16, line 20 to page 18, line 14).
- 8. Dr. Ryser assumed that J.C. had been previously diagnosed with Lyme disease.

  (Tr. Volume VI, page 869, lines 1 to 23).
- 9. At the first office visit, J.C. was initially seen by Dr. Ryser's nurse Diana Smith, who did an initial intake and examination of J.C. At the time of the exam, J.C.'s rash was gone,

and he was experiencing no new symptoms from the date of the rash on his stomach.

(Petitioner's Exhibit 10 – J.C. 1/13/11 deposition, page 19, line 12 to page 20, line 18).

- 10. J.C. and his father were told that several symptoms noted in his history were caused by Lyme disease, even though some of the symptoms were present even before J.C. received his rash in 2008. (Petitioner's Exhibit 10 J.C. 1/13/11 deposition, page 48, line 5 to page 51, line 4; Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 131, line 4 to page 132, line 23).
- 11. Dr. Ryser held herself out to J.C. and his family as an authority in the field of treating Lyme disease. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 146, line 3 to page 146, line 11; Petitioner's Exhibit 10 J.C. 1/13/11 deposition, page 71, line 6 to page 71, line 19).
- 12. Dr. Ryser prescribed antibiotics and supplements after the first visit with J.C. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 134, line 17 to page 134, line 20).
- 13. Dr. Ryser ordered blood work and J.C. testified that "quite a bit of blood was drawn", "maybe around 40 vials of blood were drawn". (*Petitioner's Exhibit 10 J.C. 1/13/11 deposition, page 15, line 7 to page 15, line 16*).
- 14. At J.C.'s first appointment Dr. Ryser ordered at least fifty-two (52) laboratory tests on J.C. (Tr. Volume VI, page 876, line 10 to page 893, line 6; Respondent's Exhibit 2C, page 76-77).
- 15. Thirty three (33) of the 52 lab tests ordered at that first appointment were marked on the "Reference Lab Orders" form. (*Respondent's Exhibit 2C*, page 77).

- 16. Dr. Ryser testified that the Reference Lab tests are not FDA approved and recognizes that FDA approved tests go through more testing and the company has spent more money validating the tests. (*Tr. Volume VI*, page 887, line 17 to 888, line 20).
- 17. Dr. Ryser ran a syphilis and a Hepatitis C test on J.C. She testified that it is her standard practice to run a syphilis and Hepatitis C on every patient because many of the guidelines and states, but neither Missouri or Kansas, require a negative syphilis and Hepatitis C before making a Lyme diagnosis. (*Tr. Volume VI*, page 889, line 12 to 25).
- 18. Neither the ILADS nor the IDSA guidelines discuss that a negative syphilis and Hepatitis C test must precede a Lyme diagnosis. (Respondent's exhibits B and C).
- 19. Dr. Ryser testified that she ran the H. Pylori test because J.C. experienced indigestion, stomach pain and bloating. (Tr. Volume VI, page 890, line 3 to line 10).
- 20. J.C. did not mark bloating or stomach pain on the initial intake form. (Respondent's Exhibit 2C, page 25).
- 21. Dr. Ryser did not indicate bloating or stomach pain in the review of symptoms. (Respondent's Exhibit 2C, page 7).
- 22. Dr. Ryser testified that she ran the glucose and insulin tests because J.C. was fatigued after he ate, not being able to wait to eat, and craving sugar. (Tr. Volume VI, page 879, line 19 to page 880, line 3).
- 23. The review of symptoms in the medical record indicates that J.C. craves sugar, bread, chocolate and fast food. The review of symptoms also indicate that J.C. "can go long without eating", and does not indicate that J.C. gets fatigued after eating. (Respondent's Exhibit 2C, page 7).

- J.C. returned to see Dr. Ryser on or about November 2008. At this return visit,

  J.C. was informed that he had Lyme disease, as confirmed by some of the blood tests that Dr.

  Ryser had ordered. Dr. Ryser relied on the IGeneX Western Blot, which was read as positive for

  Lyme disease by the IGeneX lab standards. (Tr. Volume VI, page 895, line 20 to page 896, line

  4; Petitioner's Exhibit 10, J.C. deposition 1/13/11, page 22, line 11 to 16; Petitioner's Exhibit

  11-R.C.11/22/10 deposition, page 106, line 8 to page 106, line 24; Petitioner's Exhibit 10 –

  J.C. 1/13/11 deposition, page 66, line 15 to page 66, line 23).
- 25. The Lyme Immunofluorescence Assay (IFA) run through IGeneX reported an indeterminate result of 1:40. (Respondent's Exhibit 2C, page 50).
- 26. The IGeneX Western Blot IgG and IgM readings did not meet the requirements for a positive diagnosis according to the Center for Disease Control (CDC) criteria.

  (Respondent's Exhibit 2C, page 51 and 52)
- The CDC recommends "that an IgM immunoblot be considered positive if two of the following three bands are present: 24 kDa (OspC) \*, 39 kDa (BmpA), and 41 kDa (Fla) (1). It was further recommended that an that IgG immunoblot be considered positive if five of the following 10 bands are present: 18 kDa, 21 kDa (OspC) \*, 28 kDa, 30 kDa, 39 kDa (BmpA), 41 kDa (Fla), 45 kDa, 58 kDa (not GroEL), 66 kDa, and 93 kDa (2)." (Exhibit 1 to Petitioners Exhibit 9B, Dr. Wormser's January 31, 2012 deposition).
- 28. Dr. Ryser reported the clotting activation result as abnormal. (Tr. Volume VI, page 907, line 21 to page 909, line 3).
- 29. The lab result for the clotting activation test indicates that there is not a reference range for patients under 18 years old. (Respondent's Exhibit 2C, page 49).

- 30. J.C.'s father testified that Dr. Ryser explained that the bacteria would go into a cyst form and therefore she prescribed one antibiotic in the morning "to break it out of its cyst form" and then another antibiotic "in the evening to actually kill the virus (sic)". (Petitioner's Exhibit 11, R.C. 11/22/10 deposition, page 39, line 16 to page 40, line 3).
- 31. Dr. Ryser recommended J.C. undergo treatment for Lyme disease that included antibiotics and supplements. (Petitioner's Exhibit 11, R.C. 11/22/10 deposition, page 39, line 14 to page 43, line 6).
- 32. During treatment, J.C. experienced fatigue and aches, muscle pain, and joint pain, which Dr. Ryser stated were Herxheimer reactions from the killing of toxins in J.C.'s body. (Petitioner's Exhibit 10, J.C. deposition, 1/13/11, page 23, line 22 to page 24, line 6; Id. at page 101, line 3 to line 14).
- 33. During the treatment J.C.'s attendance at school declined, his school work was effected, he was exhausted sleeping 13 to 14 hours a day, and he was having trouble thinking. He did not feel like himself. (*Petitioner's Exhibit 10, J.C. deposition, 1/13/11, page 29, line 9 to page 29, line 25*).
- 34. J.C. was taken to another physician for a second opinion, who reviewed J.C.'s case as well as Dr. Ryser's paperwork. The new physician ordered new blood work which came back negative for Lyme disease. (*Petitioner's Exhibit 10, J.C. deposition, 1/13/11, page 85, line 24 to page 89, line 23; Id. at page 92, line 12 to page 93, line 1)*.
- 35. J.C. discontinued seeing Dr. Ryser and stopped receiving treatment from her.

  After stopping the treatment, J.C. was able to put back on the weight he lost during the treatment and saw an increase in his energy levels. (Petitioner's Exhibit 11, R.C. 11/22/10 deposition, page 166, line 22 to page 170, line 8).

36. Dr. Ryser charged J.C. and his family approximately \$2500 for the diagnosis and treatment of Lyme disease. (Petitioner's Exhibit 11-R.C.11/22/10 deposition, page 45, line 16 to page 46, line 23).

# **COUNT II - A.S.**

- 37. Patient A.S., a thirty-eight (38) year-old female, first started seeing Dr. Ryser on or about January of 2005. (Tr. Volume VII, page 933, line 22 to 24; Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 7, lines 16 to 21).
- 38. A.S.'s presenting issues were all mental health and had no physical complaints.

  (Tr. Volume VII, page 934, lines 19 to 22; Petitioner's Exhibit 3, page 884).
- 39. Dr. Ryser testified that she initially diagnosed A.S. with Beta strep and at the follow up visit diagnosed A.S. with Babesiosis based on a positive Geimsa Wright smear test. (Tr. Volume VII, page 952, line 1 to page 954, line 5; Id. at page 946, lines 23 to 25).
- 40. Dr. Ryser testified that she did not diagnose A.S. with Lyme disease but kept it in the differential so that it would remain in focus. Dr. Ryser testified that A.S. had migratory joint pain, but A.S. did not have all of the physical symptoms that they normally see and that is why she thought Strep was a better diagnosis. (Tr. Volume VII, page 952, line 1 to page 954, line 1; Tr. Volume VII, page 973, line 5 to page 975, line 9).
- 41. Dr. Ryser testified that she treated A.S. for Babesia which supported treating the psychiatric symptoms, Beta Strep, and nutritional deficiencies, but she did not treat Lyme disease. (Tr. Volume VII, page 980, line 14 to page 981, line 21.)
- 42. Dr. Ryser ordered the Bowen QRiBb test twice, the first at the initial visit on January 26, 2005 and then again on June 9, 2005. The serial dilution values were 1:16 and 1:32 respectively, both reported as positive. (*Petitioner's Exhibit 3, pages 679 and 680*).

- 43. A.S. testified that Dr. Ryser diagnosed her with Lyme and treated it with Mepron (Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 34, lines 2 to 23).
- 44. Dr. Ryser testified that A.S. suffered from migratory joint pain, but the medical records reflect multiple joints, "joint pain right shoulder (tennis), right knee and big toe joints" but does not indicate that it is migratory. (Tr. Volume VII, page 941 line 17 to page 942 line 8 and page 975, lines 10 to 16; Petitioner's Exhibit 3, page 885).
- 45. Dr. Ryser told A.S. that her psychiatric symptoms were caused by Lyme disease and that by treating the Lyme disease she was treating the psychiatric symptoms. (*Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 38, lines 9 to 15*).
- 46. At A.S.'s second visit with Dr. Ryser on 3/10/05, Dr. Ryser listed Lyme disease, Babesia, Beta strep, and hyper coagulation as the top diagnoses. (*Petitioner's Exhibit 3, page 883*).
- 47. On 1/19/05, the date of A.S.'s initial exam, Diana Smith completed a Bowen Labs "Lyme Disease Questionnaire" regarding A.S., which noted that A.S. had not been diagnosed with Lyme disease. This form was completed upon requesting the first Bowen test.

  (Respondent's Exhibit 3B, page 350).
- 48. On 6/9/05, Diana Smith completed a Bowen Labs "Lyme Disease Questionnaire" regarding A.S., which noted that A.S. had been diagnosed with Lyme disease, based on the Bowen test and that the Lyme disease was treated with Mepron and Zithromax. This form was completed upon requesting the second Bowen test. (Respondent's Exhibit 3B, page 337 and 338).
- 49. On 8/18/05, Diana Smith completed a Bowen Labs "Lyme Disease Questionnaire" regarding A.S., which noted that A.S. had been diagnosed with Lyme disease,

based on the Bowen test and that the Lyme disease was treated with Mepron and Zithromax.

This form was completed upon requesting the third Bowen test. (Petitioner's Exhibit 3, page 928).

- 50. The result of the 8/18/05 Bowen Babesia smear returned negative and Dr. Ryser noted in the 8/25/05 office note under the diagnosis list that Babesia was negative. (Petitioner's Exhibit 3, page 877).
- 51. On 8/25/05 Dr. Ryser noted in the office note that "Babesia is gone. Discussed at length treatment of Borrreliosis and will still be treated further". (*Petitioner's Exhibit 3, page* 877).
- 52. On 9/28/05, 10/12/05, 11/1/05 and 12/14/05, Dr. Ryser wrote in the office note that Lyme was the top diagnosis. (*Petitioner's Exhibit 3, pages 873, 872, 871, and 867*).
- 53. Dr. Ryser's expert, Dr. Horowitz, testified that Dr. Ryser diagnosed and treated A.S. with chronic Lyme disease and Babesia. (*Tr. Volume 5, page 656, line 22 to page 657, line 4*).
- 54. Dr. Ryser's expert, Dr. Cameron, testified that Dr. Ryser diagnosed and treated A.S. with Lyme disease. (*Tr. Volume 9, page 1283 line 7, to page 1284, line 6*).
- 55. Dr. Christensen testified that Babesia is an infection transmitted by ticks; wildly uncommon in Missouri; only three cases ever reported in Missouri. (Petitioner's Exhibit 22d, Christensen deposition Volume II 3/3/11, page 219, line 22 to page 220, line 11; Petitioner's Exhibit 22e, Christensen deposition Volume III 3/14/11, page 338, lines 21 to 23).
- 56. In or around March of 2006, Dr. Ryser proposed that A.S. should start using IV antibiotic treatment, since her symptoms were not getting better and were in fact increasing. Dr. Ryser recommended that A.S. undergo 84 days of IV antibiotic treatment, at a cost of \$890 per

day, for a total of \$75,000. A.S. was told that her insurance would not cover any of the expense, and that she would be responsible for \$41,000, with \$5,000 due at the start of the IV therapy.

(Petitioner's Exhibit 3, page 698).

- 57. A.S. paid \$250 on 1/26/05 and 6/9/05, and 8/18/95 for the Bowen QRiBb test.

  A.S. paid hundreds of dollars to Dr. Ryser for the treatment of Lyme disease. (Petitioner's Exhibit 3, page 857, 679 to 711; Respondent's Exhibit 3B, pages 332 and 333).
- 58. A.S., after not feeling any improvement, saw a separate physician who suggested that she receive a second opinion from a specialist with regards to the Lyme disease diagnosis. Blood tests were ordered to confirm the Lyme disease diagnosis, and the tests results were negative for Lyme disease. A.S. stopped the medical treatment prescribed by Dr. Ryser. (Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 60, line 20 to page 66, line 12).
- 59. Upon discontinuing treatment with Dr. Ryser, A.S. was also seen by a psychiatrist, who diagnosed bipolar disorder, and her symptoms improved with therapy and treatment for the bipolar disorder. (Petitioner's Exhibit 12, A.S. deposition, 2/14/11, page 72, line 8 to page 73, line 7).

## COUNT III - K.K.

- 60. Patient K.K. first started seeing Dr. Ryser on or about November of 2004. (Tr. Volume VIII, page 1061, line 24 to page 1062, line 21; Petitioner's Exhibit 4, page 1981).
- 61. K.K. had been previously diagnosed with and treated for rheumatoid arthritis.

  (Tr. Volume VIII, page 1064, line 1 to page 1066, line 21; Petitioner's Exhibit 4, page 2041).
- 62. Dr. Ryser told K.K. that the rheumatoid arthritis he was experiencing was attributable to his Lyme disease. (*Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 82, line 16 to page 85, line 24*)

- 63. K.K. was initially seen by Dr. Ryser's nurse, Diana Smith, who performed the initial examination, and informed K.K. that she thought he had Lyme disease based on his blotchy skin and the fact that he had floaters in his eyes. (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 82, line 16 to page 85, line 24; Petitioner's Exhibit 23B, K.K.6/30/08 deposition, page 152, line 1 to page 152, line 16).
- 64. Dr. Ryser testified that the basis of the diagnosis of Lyme disease was Bell 's palsy, first testifying that K.K. had marked yes on the initial questionnaire that he had Bell 's palsy, then upon reviewing the records noted that was not accurate. Dr. Ryser also testified that the Bell's palsy was not observed at the initial exam but that it was observed later. (Tr. Volume VIII, page 1074, line 17 to page 1075, line 25).
- 65. Dr. Ryser testified then that K.K. had marked that he had Bell 's palsy on the questionnaire of symptoms. The questionnaire that K.K. completed indicated "No" to the question of Bell 's palsy. (Tr. Volume VIII, page 1118, line 3 to page 1118, line 16; Petitioner's Exhibit 4, page 2019).
- 66. Dr. Ryser sent a letter of medical necessity to GEHA, K.K.'s insurance company, indicating that K.K. experienced Bell 's palsy. (*Petitioner's Exhibit 4, pages 1903 to 1908*).
- 67. Dr. Horowitz testified that K.K. had severe Bell's palsy, justifying the diagnosis of Lyme disease. (*Tr. Volume V, page 659*).
- 68. Dr. Cameron testified that K.K. had Bell's palsy justifying the diagnosis of Lyme disease. (*Tr. Volume IX, page 1292*).
- 69. Dr. Harris testified that K.K. had Bell's palsy, justifying the diagnosis of Lyme disease. (Tr. Volume IV, page 462).

- 70. K.K. noted in the intake form questionnaire that he had no history of Bell's palsy. (Petitioner's Exhibit 4, pages 2019 to 2022).
- 71. There is no notation in K.K.'s history and physical, diagnosis code sheet or any other section of Dr. Ryser's medical records that K.K. reported he had Bell's palsy or that Dr. Ryser observed Bell's palsy. (Dr. Ryser's Exhibit 4B).
- 72. Dr. Ryser testified that the tests for Lyme disease came back negative, but explained that the tests came back negative because K.K. was on Prednisone. She testified that the tests were negative because "you need to be off any kind of major anti-inflammatory or Prednisone probably three months before we do it". (Tr. Volume VIII, page 1084, line 2 to page 1084, line 25).
- 73. After the initial examination by Diana Smith, R.N., K.K. met with Dr. Ryser, who stated that to confirm the diagnosis of Lyme disease he needed to take the Bowen Laboratory Q-RiBb test. (*Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 94, line 10 to page 95, line 3*)
- 74. Dr. Ryser admitted that the test was not FDA approved, but that she would use it to confirm her suspicion that he in fact had Lyme disease. Dr. Ryser told K.K. that she believed he had Lyme disease and the Bowen test was the only accurate test for Lyme disease.

# (Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 94, line 15 to page 95, line 3)

- 75. Dr. Ryser informed K.K. that the Bowen Laboratory results were positive for Lyme disease, stating that his test score was the highest that she had ever seen. (*Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 91, line 10 to page 92, line23*)
- 76. K.K.'s Bowen QRiBb test results from 12/1/2004 were reported as positive with a serial dilution value of 1:128. (*Petitioner's Exhibit 4, pages 2105 to 2107*)

- 77. Bowen lab results carried the disclaimer "this research test was developed and its performance characteristics determined by the Bowen Research and Training Institute, Inc., a non-profit organization strictly supported by donations. The Q-RiBb© test has not been approve by the U.S. Food and Drug Administration. This information is to be used as a reference only. This testing is for research use only and is not intended for the use in diagnosis and / or treatment. All data is reserved for research analysis". (Petitioner's Exhibit 4, page 2105)
- 78. Bowen Research and Training Institute was not licensed in 2006, and the AHCA, the agency that licenses clinical laboratories in Florida, denied Bowen's application for licensure in 2006. JoAnne Whitaker, the President and Director of Bowen had voluntarily relinquished Bowen's license to operate Bowen as a clinical laboratory. (Petitioner's Exhibit 24; Petitioner's Exhibit 25).
- 79. Prior to seeing Dr. Ryser, K.K. had been tested for Lyme disease using the Western Blot, which was negative. Dr. Ryser informed K.K. that the test was not accurate and that they needed to perform a special test for Lyme disease. (*Petitioner's Exhibit 23; K.K.2/4/08 deposition, page 87, line 9 to page 87, line 23*)
- 80. The CDC recommends a two tier approach to serologic testing for Lyme disease, which involves the Elisa followed by the Western-blot. (Petitioner's Exhibit 1, Sigal deposition 10/24/11, page 31, line 2 to page 34, line 2; Petitioner's Exhibit 9A, Wormser deposition 1/3/12, page 213, line 20 to page 214, line 2).
- 81. On 1/17/05, K.K. started on IV antibiotics Rocephin and supplements, which were to treat the Lyme disease that Dr. Ryser had diagnosed. (*Tr. Volume VIII*, page 1095, line 12 to page 1096, line 5; Petitioner's Exhibit 4, pages 2009 to 2014).

- 82. The IV infusion treatment was estimated to cost \$53,496 for two months. After estimates of insurance payments, estimated adjustments, and \$1000 already paid, the balance due by K.K. after two months of treatment would be \$11,435. (Petitioner's Exhibit 4, page 1923).
- 83. During the time he was given treatment by Dr. Ryser, K.K. experienced such periods of fatigue and exhaustion that he was unable to work and had to retire from the FAA. K.K. did not experience any problems with fatigue prior to being treated by Dr. Ryser. (Petitioner's Exhibit 23, K.K. deposition 2/4/08, page 55, line 8 to page 57, line 1).
- 84. At one point during his treatment, K.K.'s legs were swollen and his breathing slowed to around four (4) breaths per minute, and when he spoke to Dr. Ryser he was told that he would get a diuretic the following day when he came in for his IV treatment. Concerned, he spoke to another physician who told him to go directly to the emergency room, which he did. At the hospital, K.K. was told that he was negative for Lyme disease, and he never returned to see Dr. Ryser for treatment. (*Petitioner's Exhibit 13, S.K. deposition 10/12/11, page 64, line 16 to page 71, line 22*).
- 85. Upon stopping the treatment prescribed by Dr. Ryser, K.K. slowly recovered some of his cognitive function, energy, and he stated that he began to feel more normal. (Petitioner's Exhibit 23B, K.K. deposition 6/30/08, page 116, line 20 to page 177, line 21).
- 86. Dr. Ryser testified that K.K. was using cocaine and that this drug use was negatively impacting his treatments, slowing down his recovery. (Tr. Volume VIII, page 1109, line 19 to page 1110, line 11).
- 87. There is no mention of cocaine use in Dr. Ryser's medical records for K.K. (Dr. Ryser's Exhibit 4B).

## **COUNT IV - S.K.**

- 88. Patient S.K. was s the wife of K.K. (Tr. Volume VIII, page 1024, line 6 to 10).
- 89. Dr. Ryser told S.K. that Lyme disease is spread through saliva, blood, and can be transmitted through sexual contact, and that she should be tested since Dr. Ryser had already diagnosed K.K. with Lyme disease. Dr. Ryser told S.K., who was contemplating getting pregnant, that she should not attempt to get pregnant due to the fact that the disease could spread to the unborn child. Dr. Ryser's view is that Lyme disease is spread through saliva, blood, or can be sexually transmitted. (*Petitioner's Exhibit 13, S.K. deposition 10/12/11, page 20, line 2 to page 21, line 24*).
- 90. Dr. Beatham testified that Dr. Ryser has said that Lyme disease is sexually transmitted and has heard her tell patients this. (Petitioner's exhibit 21, Beatham deposition 12/12/11, page 21, lines 7 to 17 and page 23, line 22 to page 24, line 2.)
- 91. Diana Smith testified that Dr. Dr. Ryser has said that Lyme disease is sexually transmitted and has heard her tell patients this. (Petitioners exhibit 20, Smith deposition 12/8/11, page 47, line 8 to 23).
- 92. On 3/18/05, S.K. became a patient of Dr. Ryser. (*Tr. Volume VIII*, page 1024, line 2 to 5).
- 93. Dr. Ryser testified that S.K. had minimal symptoms, hemanginomas and a lacy rash, and livedo reticularis. (*Tr. Volume VIII*, page 1032, line 25 to page 1033, line 3).
- 94. Dr. Ryser ordered a Bowen test, which returned with a serial dilution value of 1:8 that was reported as positive. (Tr. Volume VIII, page 1036, lines 1 to 3 and page 1049, lines 16 to 22; Petitioners exhibit 5, pages 2217-2219)

- 95. Dr. Ryser used the Bowen test to confirm a Lyme disease diagnosis for S.K. and started her on oral antibiotics and supplements. (Petitioner's Exhibit 13, S.K. deposition 10/12/11, page 90, line 24 to 92, line 12).
- 96. Dr. Ryser testifies that she never treated S.K. for Lyme disease; rather, she treated Mycoplasma, hypothyroid, chronic fatigue, vitamin deficiency, and irritable bowel (*Tr. Volume VIII*, page 1056, lines 17 to 25, and page 1049, line 23 to page 1050, line 15).
- 97. When K.K. was taken to the hospital for emergency treatment, tests were run on S.K. also that verified that she also did not have Lyme disease. (Petitioner's Exhibit 13, S.K. deposition 10/12/11, page 95, line 20 to page 96, line 3).
- 98. In response to a January 26, 2009 subpoena from the Board, Dr. Ryser wrote a letter to the Board with a narrative summary of her treatment of S.K. On page 4 of the letter, Dr. Ryser indicates "Test results for patient: Tested Positive for Lyme disease". On page 5 of the letter, Dr. Ryser indicates that the diagnoses for S.K. included Chronic Fatigue Syndrome, Irritable Bowel Syndrome, major depression, anxiety and Lyme disease. There is no mention of Mycoplasma in this letter. On page 6, Dr. Ryser notes that the "patient was treated with the following Doxycycline for Lyme disease." (*Petitioner's Exhibit 28*).

#### COUNT V - B.L.

- 99. Patient B.L. first saw Dr. Ryser on or around November 2003. (Tr. Volume XI, page 1421, line 1 to 4; Petitioner's Exhibit 6, page 2386).
- 100. B.L. had previously been diagnosed with fibromyalgia. (Petitioner's Exhibit 6 page 2511; Petitioner's Exhibit 14, B.L. deposition 12/15/10, page 24, line 2 to line 7, page 40, line 1 to line 5, page 44 lines 12 to 16).

- 101. B.L.'s presenting symptoms were achy joints, sore muscles, headaches, fatigue, photosensitivity, fevers, swollen glands, and sleep problems. (*Petitioner's Exhibit 15, B.L.* deposition 10/11/11, page 204, line 12 to page 205, line 4; Petitioner's Exhibit 6, page 2386).
- 102. Dr. Ryser's nurse, Diana Smith, performed an initial exam and informed B.L. that she could tell just by looking at her that she had Lyme disease. (*Petitioner's Exhibit 15, B.L.* deposition 10/11/11, page 208, line 20 to page 209, line 5).
- 103. B.L. testified that in the whole time she was treated by her, Dr. Ryser never once performed a medical exam on her; Dr. Ryser never touched her one time. (Petitioners Exhibit 15, B.L. deposition 10/11/11, page 209, line 15 to page 209, line 25).
- 104. Dr. Ryser ordered blood tests and told B.L. that the Bowen Laboratory test was the way to diagnose Lyme disease, and that the Bowen QRiBb was on the cutting edge.

  (Petitioner's Exhibit 15, B.L. deposition 10/11/11, page 326, line 12 to page 327, line 8).
- 105. The Bartonella, Babesia, and Lyme Western Blot and Elisa of 11/19/03 were all negative. (Respondent's Exhibit 6B, page 210).
- 106. The Bowen QRiBb of 11/11/03 reported back positive with a serial dilution value of 1:8. (Respondent's Exhibit 6B, page 202).
- 107. Dr. Ryser testified that she evaluates the Bowen result of serial dilution value of 1:8 as negative. (Tr. Volume XI, page 1438, line 5 to page 1439, line 8).
- 108. Dr. Ryser testified that despite the test results, she made a clinical diagnosis of Lyme disease because of B.L.'s history of tick bites, not feeling well, chronic flu-like symptoms, psychiatric symptoms and chronic pain. (*Tr. Volume XI*, page 1436, line 10 to 25).
- 109. On 12/19/03, a PICC line was started because Dr. Ryser prescribed IV antibiotic treatment for B.L. (*Tr. Volume XI*, page 1435, line 23, to page 1436, line 9).

- 110. Dr. Ryser prescribed B.L. antibiotics rotating between IV and oral from January 2004 to September 2004. (Respondent's Exhibit 6B, pages 51 to 65; Tr. Volume XI, page 1439, line 14 to page 1442, line 25)
- 111. Dr. Ryser routinely rotates antibiotics every 4 to 6 weeks. (Tr. Volume XI, page 1442, line 4 to 25).
- 112. Dr. Ryser testified that she thought that fibromyalgia was a manifestation of the "cyst form" of Borrelia Burgdorferi. (*Tr. Volume XI*, page 1443, line 2 to line 11).
- 113. After several rounds of antibiotics, B.L. felt achy, was in pain, was having issues with her memory and cognitive functions, and her stomach started to swell. After being referred to a specialist, B.L. had to have her gallbladder removed. Dr. Ryser referred B.L. to a specialist for her stomach, and indicated that the IV treatment may have caused sludge in her gallbladder, necessitating removal. (*Petitioner's Exhibit 15, B.L. deposition 10/11/11, page 266, line 22 to page 275, line 13*).
- 114. Dr. Ryser also informed B.L. that Lyme disease could be transferred through saliva, blood, and could be sexually transmitted. (*Petitioner's Exhibit 15, B.L. deposition* 10/11/11, 325, line 17 to page 326, line 9).
- 115. B.L. was charged \$250 for the Bowen test performed on November 12, 2003 and the Bowen test performed on August 31, 2004. (Respondent's Exhibit 6B, pages 201 and 173).
- 116. B.L. paid Dr. Ryser several thousand dollars for treatment for herself and her husband, D.L. (Petitioner's Exhibit 17, page 282, 11 to page 284, line 4).

## COUNT VI - D.L.

117. Patient D.L. is the husband of B.L. (Tr. Volume VII, page 983, line 9 to 10).

- 118. In February, 2004, D.L. became a patient of Dr. Ryser because his wife was diagnosed with Lyme disease. D.L. testified that Dr. Ryser stated that Lyme disease is passed through saliva, blood, semen, tears, and is often times passed between spouses. (Petitioner's Exhibit 16, D.L. deposition Vol. 1 12/20/10, page 19, line 11 to page 23, line 10).
- 119. Dr. Ryser testified that she never told D.L. or B.L. that Lyme disease is sexually transmitted. (Tr. Volume VII, page 983, line 10 to page 988, line 23).
- 120. Dr. Ryser said that she ran a Lyme test based on the presence of mood changes, chest pain, blood pressure issues, slight tremors, increased weight and migratory joint pain. She testified that he didn't have very many symptoms. (*Tr. Volume VII*, page 1000, line 18 to page 1001, line 30).
- the Western Blot test, which came back negative for Lyme disease. Dr. Ryser informed D.L. that the Western Blot test was inaccurate and inconclusive, and that the Bowen test was needed to diagnose Lyme disease. Dr. Ryser told D.L. that the Bowen test was the 'gold standard' of Lyme tests and that it needed to be performed to prove that D.L. had Lyme disease. (Petitioner's Exhibit 16, D.L. deposition Vol. 1 12/20/10, page 31, line 5 to page 32, line 25 and page 41, line 4 to page 45, line 10).
- 122. At the initial visit, Dr. Ryser ordered a Bowen test, which returned with a serial dilution value of 1:32 that was reported as positive. (*Petitioner's Exhibit 7, page 2371*).
- 123. Dr. Ryser relied on the Bowen test to diagnose D.L. and informed him that he had tested positive for Lyme disease, and he was started on oral antibiotics. (*Petitioner's Exhibit 7*, page 2325; *Petitioner's Exhibit 16*, D.L. deposition Vol. 1 12/20/10, page 55, line 11 to 18; Tr. Volume VII, page 1006, line 11 to 14).

- Doxycycline, noting that the 7/14/04 office note indicated that he felt good, there were no problems, no visual problems, and that he didn't think he was irritable anymore. (Tr. Volume VII, page 1007, line 16 to page 1008, line 2).
- 125. Another Bowen QRiBb was ordered on August 23, 2004, which returned with a serial dilution value of 1:128 that was reported as positive. (*Petitioner's Exhibit 7*, *page 2364*).
- 126. D.L. stopped seeing Dr. Ryser when other doctors told him and B.L. that she likely never had Lyme disease and if she did it would have been treated ten times over already.

  (Petitioner's Exhibit16, D.L. deposition Vol. 1 12/20/10, page 257, line 8 to page 262, line 25).
- 127. D.L. paid \$250 for the Bowen QRiBb test on February 6, 2004 and August 31, 2004. (Petitioner's Exhibit 7, pages 2370 and 2363).

## **COUNT VII - J.F.**

- 128. Patient J.F. first started seeing Dr. Ryser in July of 2006. (Tr. Volume VIII, page 1137, line 12 to 14; Petitioner's Exhibit 8, page 1659).
- 129. J.F. initially complained of pain, fatigue, red flush skin, shaking, hallucinations and memory loss. (*Petitioner's Exhibit 8, page 1659; Petitioner's Exhibit 18, J.F. deposition* 10/21/11, page 10, line 24 to page 11, line 11; Tr. Volume VIII, page 1137, line 21 to page 1142, line 17).
- 130. Dr. Ryser testified that hallucinations are a symptom of Lyme disease. (Tr. Volume VIII, page 1142, line 18 to page 1143, line 8).
- 131. Dr. Ryser told J.F. that if she were not treated she would die and that Lyme disease is not curable. (Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 43, line 15 to

- page 44, line 1; Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 31, line 20 to page 32, line 20).
- 132. Lyme disease does not have chronic aspects to it and it does not lead to fatal conditions. (Petitioner's Exhibit 22e, Christensen deposition Volume III 3/14/11, page 340, line 20-25).
- 133. The initial intake examination was done by Dr. Ryser's nurse, Diana Smith. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21).
- 134. Dr. Ryser did not examine the patient until the follow up visit, two weeks after the initial exam, at which time she reviewed test results. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21).
- 135. Laboratory tests were order after the initial visit with Diana Smith, before Dr. Ryser examined J.F. (Petitioner's Exhibit 18, J.F. deposition 10/21/22, page 15, line 20 to page 17, line 21; Respondent's Exhibit 8B, pages 972 to 973).
- 136. The diagnosis code sheet was filled out by Diana Smith although Dr. Ryser did not examine the patient until the follow up visit on August 15, 2006. (*Petitioner's Exhibit 8*, page 1671).
- 137. Diana Smith made the following diagnoses at the initial visit on 7/24/06- Lymes (sic) disease, Fibromyalgia, hypercoagulation, constipation, irritable bowel syndrome, iodine deficiency, Bells palsy, beta strep, upper respiratory infection, chronic fatigue syndrome rheumatoid arthritis, disease of CNS, insomnia, migraine, poly neuropathy, tremors, nutritional deficiency, levido reticularis and Vit. B deficiency. (*Petitioner's Exhibit 8, page 1671*).
- 138. Diana Smith ordered the following labs at the initial visit on 7/24/06- c-reactive protein, candidiasis, CBC, comprehensive metabolic panel, fasting glucose and insulin, genetic

coagulation panel, two hour glucose and insulin, parovirus (sic) antibody, h-pylori, nasal culture, lipid profile, hormone panel, soluable (sic) interleukin receptor, thyroid panel, urine analysis, reverse T3, Bowen Lyme test, heavy metal urine and stool, salivary cortisol, and CDSA 2.0. (Petitioner's Exhibit 8, page 1671).

- 139. Dr. Ryser did not sign off on the physical examination that Diana Smith performed at the initial appointment. (*Petitioner's Exhibit 8, page 1659 to 1670*).
- 140. Dr. Ryser signed prescriptions and orders for tests before she examined J.F. at the follow up visit on 8/15/06. (Respondent's Exhibit 8B, page 462 to 467).
- 141. Dr. Ryser testified that J.F. experienced Bell's palsy and that was observed at the initial exam. She testified that there was droopiness of the left eye and said there was a picture in the medical records, but did not identify the location in her medical records. (Tr. Volume VIII, page 1148, line 15 to page 1149, line 4).
- 142. There are two dates when pictures were taken of J.F.; 2/8/07 and 6/24/08, neither is from the initial exam on July 24, 2006 nor do they show drooping of the left eye.

  (Respondent's Exhibit 8B, pages 151 and 167-170).
- 143. J.F. noted on her "Lyme Disease Questionnaire" under the Bell's palsy symptom that her left eyelid droops. (*Respondent's Exhibit 8B*, page 163).
- 144. Diana Smith diagnosed Bells palsy and noted in the physical exam a slight drooping of the left eye and mouth. There is no picture of J.F. on July 24, 2006 in her medical records. (Respondent's Exhibit 8B, pages 35 and 32).
- 145. Bell's palsy is a neurologic condition in which the facial muscles become paralyzed. "Bell's palsy" refers to idiopathic 7<sup>th</sup> nerve palsy. When the likely cause of the 7<sup>th</sup> nerve palsy is known, it is referred to as 7<sup>th</sup> nerve palsy due to Lyme disease. (*Petitioner's*

- Exhibit 22e, Christensen deposition Volume III 3/14/12, page 320, line 13 to line 19; Petitioner's Exhibit 9, Wormser deposition 9/5/11, page 66, line 16 to line 24).
- 146. Dr. Sigal described 7<sup>th</sup> nerve palsy due to Lyme disease as "you can see facial droop, which is to say the seventh cranial nerve is damaged in Lyme disease and you've got a person whose one side of the face doesn't work, can't raise the mouth, can't wrinkle the forehead, that's another thing, can't make a smile." (Petitioner's Exhibit 1, Sigal deposition 10/24/11, page 24, line 17 to line 22).
- 147. The IGeneX lab Western Blot of 7/26/06 reported back as negative. (Respondent's Exhibit 8B, pages 307 to 309).
- 148. The Bowen QRiBb of 7/26/06 reported back positive with a serial dilution value of 1:64. The Bowen Babesia test on July 26, 2006 came back negative. (Respondent's Exhibit 8B, pages 304 to 306).
- 149. Upon receiving the results of the lab tests, J.F. was told that she had tested positive for Lyme disease. (Petitioner's Exhibit 18, J.F. deposition 10/12/11, page 68, line 10 to page 70, line 16).
- 150. Dr. Ryser told J.F. that she thought the Bowen test was the "gold standard" in Lyme testing. (Petitioner's Exhibit 18, J.F. deposition 10/12/11, page 71, line 25 to page 72, line 11).
- 151. Dr Ryser ran a Babesia test through Fry Labs; the sample was collected on 5/29/07 and the results were reported on 5/31/07. (Respondent's Exhibit 8B, pages 214 and 215).

- 152. The Fry Clinical Laboratories reported that "Babesia microti IgG Ab" was negative and the smear indicates "moderate number of protozoan forms". (Respondent's Exhibit 8B, pages 214 and 215).
- 153. Dr. Ryser testified that she started J.F. on Mepron for Babesia because she tested positive through Fry Labs. (Tr. Volume XI, page 1404, line 12 to page 1407, line 1).
- 154. Dr. Ryser started J.F. on Mepron on 5/14/07, before she tested for Babesia. (Respondent's Exhibit 8B, page 138).
- 155. Dr. Ryser testified that J.F. did not seek out Respondent specifically for an assessment of Lyme disease. (*Tr. Volume VIII*, page 1144, lines 5 to 12).
- 156. J.F. completed a "Lyme Disease Questionnaire" on July 3, 2006, prior to her initial visit to Dr. Ryser's office. (Respondent's Exhibit 8B, pages 163 to 164).
- 157. J.F. received IV antibiotic treatment from approximately September 2006 until approximately September 2007. (*Respondent's Exhibit 8B page 878 to 895*).
- 158. J.F. weighed 131 pounds at her initial physical exam on July 24, 2006. (Respondent's Exhibit 8B, page 32).
- 159. On May 14, 2007, J.F. weighed 108 pounds. (Respondent's Exhibit 8B, page 85).
- 160. During treatment with Dr. Ryser, J.F. experienced frequent instability, shakiness, and fainting spells. On 8/16/07 J.F. was at Dr. Ryser's office when she became unstable and fell and hit her head. J.F. went to the St. Joseph Medical Center Emergency Room. (Respondent's Exhibit 8B, pages 338 to 387).
- 161. During the treatment, J.F. was abusing prescription medications, and Dr. Ryser was aware of the abuse issues. Dr. Ryser continued to prescribe controlled substances knowing

- that J.F. was abusing prescription medications, and having issues while receiving treatment. (Tr. Volume XI, page 1418, line 18 to page 1419, line 9).
- 162. Dr. Ryser treated J.F. with over 300 days of treatment (Petitioner's Exhibit 18, J.F. deposition 10/21/11, page 38, line 1 to 8; respondent's Exhibit 8B page 878 to 895).
- 163. Between 11/4/06 and 5/15/07, J.F. paid \$1188.35 for prescriptions ordered by Dr. Ryser. (Respondent Exhibit 8B, page 533 to 536).
- 164. Dr. Ryser collected \$450 from J.F. on 5/25/07 for lab fees. (Respondent's Exhibit 8B, page 968).

#### **CONCLUSIONS OF LAW**

- 165. Section 334.100.2, RSMo 2007, provides the following as grounds for discipline:
  - 2. The Board may cause a complaint to be filed with the administrative hearing commission as provided by Chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(4) Misconduct, fraud, misrepresentation, dishonesty, unethical conduct or unprofessional conduct in the performance of the functions or duties of any profession licensed or regulated by this chapter, including, but not limited to, the following:

\* \* \*

(a) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation; willfully and continually overcharging or overtreating patients; or charging for visits to the physician's office which did not occur unless the services were contracted for in advance, or for services which were not rendered or documented in the patient's records;

\* \* \*

(c) Willfully and continually performing inappropriate or unnecessary treatment, diagnostic tests or medical or surgical services;

\* \* \*

(d) Delegating professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform such responsibilities.

\* \* \*

(e) Misrepresenting that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine or osteopathic value;

\* \* \*

- (5) Any conduct or practice which is or might be harmful or dangerous to the mental or physical health of a patient of the public; or incompetency, gross negligence or repeated negligence in the performance of the functions or duties of any profession licensed or regulated by this chapter. For the purposes of this subdivision, "repeated negligence" means the failure, on more than one occasion, to use that degree of skill and learning ordinarily used under the same or similar circumstances by the member of the applicant's or licensee's profession;
- 166. Dr. Ryser's conduct toward patients J.C., A.S., K.K., S.K., B.L., D.L., and J.F., as described above, constitutes misconduct and was inappropriate, unprofessional and unethical. Dr. Ryser's conduct was or might have been harmful or dangerous to the mental or physical health of patients J.C., A.S., K.K., S.K., B.L., D.L., and J.F.
- 167. Dr. Ryser's treatment of J.C., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes

incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of J.C.

- 168. Dr. Ryser's treatment of A.S., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of A.S.,
- 169. Dr. Ryser's treatment of K.K., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of K.K.
- 170. Dr. Ryser's treatment of S.K., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of S.K.
- 171. Dr. Ryser's treatment of B.L., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of B.L.
- 172. Dr. Ryser's treatment of D.L., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of D.L.

- 173. Dr. Ryser's treatment of J.F., as described above, constitutes misconduct and was inappropriate, unprofessional, and unethical. Dr. Ryser's conduct further constitutes incompetence, repeated negligence, gross negligence, and was or might have been harmful or dangerous to the mental or physical health of J.F.
- 174. Dr. Ryser has engaged in a pattern and practice of misstating, misrepresenting, and exaggerating the prevalence of Lyme disease in Missouri and Kansas.
- 175. Dr. Ryser has engaged in a pattern and practice of misstating and misrepresenting lab results prior to performing unnecessary and excessive treatment for Lyme disease.
- 176. Dr. Ryser has engaged in a pattern and practice of misstating and misrepresenting how Lyme disease is transmitted.
- 177. Dr. Ryser has failed to evaluate all diagnoses when treating patients with vague, subjective symptoms.
- 178. Dr. Ryser has willfully and continually overtreated patients in violation of § 334.100.2(4)(a), RSMo.
- 179. Dr. Ryser delegated professional responsibilities to a person who is not qualified by training, skill, competency, age, experience or licensure to perform such responsibilities in violation of § 334.100.2(4)(d).
- 180. Dr. Ryser has willfully and continually performed inappropriate and unnecessary diagnostic tests, treatment, and medical services in violation of § 334.100.2(4)(c), RSMo.
- 181. Such conduct constitutes misconduct, fraud, misrepresentation, dishonesty, unethical conduct and unprofessional conduct in the performance of the functions or duties of the medical and surgical profession.

- 182. In her treatment of patients J.C., A.S., K.K., S.K., B.L., D.L., and J.F., Dr. Ryser has failed, on more than one occasion, to meet the applicable standard of care by failing to use that degree of skill and learning ordinarily used under the same or similar circumstances by the members of her profession. Dr. Ryser's actions and treatment of the patients above therefore constitutes "repeated negligence" within the meaning of § 334.100.2(5), RSMo.
- 183. For the foregoing reasons, Dr. Ryser's medical license is subject to discipline pursuant to § 334.100.2(4), (4)(a), (4)(c), (4)(d), (4)(e), and (5), RSMo.

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on the day of August, 2012, a true and correct copy of the foregoing Petitioner's Proposed Findings of Fact and Conclusions of Law was mailed and faxed to:

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