BEFORE THE ADMINISTRATIVE HEARING COMMISSION
STATE OF MISSOURI

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

PETITIONER'S MOTION *IN LIMINE* AND OBJECTION TO EXPERT TESTIMONY UNDER SECTION 490.065, RSMO 2000 TO EXCLUDE TESTIMONY OF RESPONDENT'S EXPERT WITNESSES AND LITERATURE REGARDING PURPORTED ALTERNATIVE STANDARDS OF CARE FOR DIAGNOSIS AND TREATMENT OF LYME DISEASE

COMES NOW Petitioner, through counsel undersigned and hereby moves under Section 490.065, RSMo 2000, that the Commission exclude certain expert testimony as to an alternative standard of care for the diagnosis and treatment of Lyme disease as expected from Respondent's identified expert witnesses, Drs. Richard Horowitz, Daniel Cameron, and Steven Harris, on the grounds that such testimony is not based on valid science and is not otherwise admissible under Section 490.065, RSMo 2000. Petitioner also expects that Respondent herself will attempt to offer expert testimony on certain issues related to an alternative standard of care and Petitioner would include under this motion Respondent's own expected testimony in addition to the testimony of Drs. Horowitz, Cameron, and Harris. If such expert testimony is not scientifically valid within the meaning of Section 490.065.1 and the case law interpreting that statute, then such expert testimony is not relevant and admissible, in that it would not assist the trier of fact. Petitioner hereby objects *in limine* to such testimony and evidence.

As a practical matter, and as done in the similar *McDonagh*[1] case at the AHC, Petitioner hereby makes its record under Section 490.065, expecting that the Commission will hear and preserve the testimony in question in the record under the provisions of Section 536.070(7), RSMo 2000, and that these evidentiary issues will be taken and decided with the case.

SUGGESTIONS IN SUPPORT

Under Section 490.065, RSMo 2000, the Commissioner functions as the gatekeeper with regard to the admission of novel scientific evidence. Respondent has identified three expert witnesses whom Respondent intends to call at hearing. Although each of these experts is a qualified physician, each expert witness will ostensibly attempt to establish that, although Respondent's diagnosis and treatment of Lyme disease routinely deviates from the generally accepted standards of care for the diagnosis and treatment of Lyme disease, there is an alternative standard of care for the diagnosis and treatment of Lyme disease. The purported alternative standard of care proposed by Respondent and her identified expert witnesses is based on practice guidelines for the diagnosis and treatment of Lyme disease promulgated by the International Lyme and Associated Diseases Society (ILADS). ILADS is an association of people interested in Lyme disease made up of patients, activists and some physicians who treat Lyme disease. ILADS is generally a trade organization governed by a small group of physicians who, like Respondent, make their living by providing patients with questionable, experimental and unproven diagnoses and treatments for Lyme disease for profit.

ILADS has promulgated practice guidelines for the diagnosis and treatment of Lyme disease that is not based on and does not comport with the teachings of valid science. Respondent purports to practice within the ILADS practice guidelines. However, in several key

[1] *State Board of Registration for Healing Arts v. McDonagh,* 123 S.W.3d 146 (Mo. banc 2003).

respects, Respondent's routine practices are not consistent with either the generally accepted standards of care for the diagnosis and treatment of Lyme disease, as represented by the practice guidelines issued by the Infectious Diseases Society of America (IDSA), or with the ILADS guidelines.

As the evidence will establish, the standards of care for the diagnosis and treatment of Lyme disease that are generally accepted by physicians who treat infectious diseases are represented by the practice guidelines for Lyme disease issued by the IDSA. These guidelines are based on valid science as published in well-established, peer reviewed medical and scientific journals. On the other hand, the ILADS practice guidelines are not based on valid science as published in well-established, peer reviewed medical and scientific journals and, in fact, conflict with the teachings of valid, well-established medical and scientific thinking.

The Supreme Court of Missouri in *State Board of Registration for Healing Arts v. McDonagh,* 123 S.W.3d 146 (Mo. banc 2003), held that § 490.065, RSMo 2000, provides the standard for admission of expert testimony in civil actions and administrative proceedings. The court of appeals, in *Goddard v. State*, 144 S.W.3d 848, 852 (Mo. App. S.D. 2004), held that the test for admissibility of scientific evidence in these cases is prescribed by § 490.065.1, rather than § 490.065.3. Section 490.065.1 provides:

> In any civil action, if scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.

The Court reasoned that § 490.065.1 provides the test because the "overarching subject" of § 490.065.1, just as FRE 702, "is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission." *Goddard*, 144 S.W.3d at 853

(quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993)). The Court continued that, in passing upon the admissibility of scientific evidence, the trial judge acts as a gatekeeper, requiring the court to look to *Daubert* and its progeny for guidance in determining scientific validity—i.e., whether a theory or technique is "scientific knowledge" that will assist the trier of fact.

Likewise, the Supreme Court of Missouri, in *McDonagh,* 123 S.W.3d at 155 (citation omitted), wrote the following:

> Few cases have interpreted section 490.065. To the extent that section 490.065 mirrors FRE 702 and FRE 703, as interpreted and applied in *Daubert* and its progeny, the cases interpreting those federal rules provide relevant and 4–101 useful guidance in interpreting and applying section 490.065. To the extent that the two approaches differ, however, the standard set out in section 490.065 must govern.

Accordingly, the factors a court should consider under the *Daubert* decision include whether:

- the theory or technique can be or has been tested using "scientific methodology";
- the theory or technique has been subjected to peer review and publication;
- the technique has a known or potential rate of error; and
- the theory or technique meets the *Frye* test of general acceptance in the particular field.

Daubert, 509 U.S. 579 at 593–94.

The trial judge's function in determining the scientific validity of a technique or process is different than the judge's responsibility in regard to the admissibility of expert opinion testimony. The latter is governed by § 490.065.3, which provides:

> The facts or data in a particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing and must be of a type reasonably relied upon by experts in the field in forming opinions or inferences upon the subject and must be otherwise reasonably reliable.

Therefore, under Missouri law, the trial judge, or here the Commissioner, acts as a gatekeeper, requiring the court to look to *Daubert* and its progeny for guidance in determining scientific validity—i.e., whether a theory or technique is "scientific knowledge" that will assist the trier of fact. If a theory or technique does not rise to the level of "scientific knowledge," then testimony as to such theory or technique cannot assist the trier of fact by definition. As well established under the *Daubert* line of case law, "scientific knowledge" must be based on the scientific method.

In the present case, as in the *McDonagh* case, there are really two separate questions involved in the opinions of the experts. The expert witnesses in this case are going to be testifying about the applicable standard of care or standards of care that should be applied to the resolve issues in the case of the seven (7) patients in question. The underlying issue is whether a given expert should be permitted to testify in support of a given standard of care in the light of the status of scientific knowledge underlying the purported standard of care at the time of the care and treatment in question. One issue is procedural and the other is a matter of substantive law. If, as Petitioner believes the evidence will develop, Respondent's experts cannot demonstrate that the purported standards of care they are advocating for were developed based on valid scientific evidence, then the testimony of those experts should be denied admission into the record. If that were the ultimate outcome, then the testimony of Petitioner's expert medical witnesses to the effect that Respondent's care and treatment of some or all of the seven (7) patients in question failed to meet the applicable standards of care in multiple respects would be uncontroverted and findings of fact supporting Petitioner's allegations as contained in its Complaint should be entered by the Commission.

Petitioner has identified three (3) retained expert witnesses and those witnesses have been deposed. Petitioner has identified Richard Horowitz, M.D., Daniel Cameron, M.D., and Steven Harris, M.D., as expert witnesses to be called at trial. Respondent has provided the following "General description of testimony" for these expert witnesses:

> "Each one of the experts will opine with respect to each one of the allegations contained in the complaint and pertaining to each one of the seven patient charts relevant to the complaint. The experts will testify with respect to the applicable standard of care regarding each one of the patients delineated in the complaint as recognized by the medical community which practices medicine in a manner similar to the one practiced by the Respondent. The experts are expected to testify also with respect to relevant deposition testimony further to be obtained from Petitioner's experts." (Emphasis added).

Respondent's description of the expected testimony of her expert witnesses demonstrates the basic problem with such expected testimony. "The experts will testify with respect to the applicable standard of care regarding each one of the patients delineated in the complaint as recognized by the medical community which practices medicine in a manner similar to the one practiced by the Respondent." As set out in the *McDonagh* opinion, the Missouri Supreme Court in a similar case specifically held that the standard of care is not to be determined by whether a method of practice or treatment is recognized by the small group of treaters who have adopted and approved the method of practice or treatment. Obviously, the physicians who accept the treatment accept the treatment.

> But, to limit the relevant "field" to only those doctors who have already expressed their view that the therapy is question is appropriate would make the inquiry into acceptance in the field pointless, for, by definition, only those who had accepted the therapy would be asked for their opinion. *** The relevant field must be determined not by the approach a particular doctor chooses to take, but by the standards in the field in which the doctor has chosen to practice.

McDonagh, supra, at 156. The relevant field to consider is that group of physicians overall who treat the particular problem in question. Petitioner would submit that the relevant group in the present case is "all physicians who treat infectious diseases."

The evidence will demonstrate that the treatment methods utilized by Respondent are not generally accepted by the universe of physicians who treat infectious diseases. Indeed, the evidence will show that physicians who treat infectious diseases as a whole overwhelmingly reject the theories and treatment protocols represented by the ILADS practice guidelines for Lyme disease. The only physicians who accept the ILAD treatment protocols are essentially those physicians who purport to diagnose Lyme disease and "chronic Lyme disease" on the basis of random, non-specific patient complaints supported in some cases by unapproved and scientifically questionable testing procedures and who make a practice of prescribing lengthy courses of antibiotics for suspected "chronic Lyme disease." And who do those things for profit. All three of Respondent's identified expert witnesses essentially fall into that described category.

EXAMINATION BY MR. SIMON:
Q. Doctor, by reviewing the medical records of the seven patients, did you reach a conclusion with a reasonable degree of medical certainty as to whether or not Dr. Ryser met the medical standard of care in the diagnosis and treatment of each one of these patients?
A. Yes.

Q. What was that conclusion?
A. Considering that there is no one standard of care and she chose to use more of the ILADS guidelines than the IDSA guidelines, which I personally have found that IDSA guidelines do not help or work on

people, she chose to use a more expanded view of Lyme disease, which I have found to be clinically useful and, therefore, she was within the medical legal boundaries of how she was practicing, because she was using one of the standards of care that is out there.
MR. SIMON: No further questions.

(Deposition of Dr. Richard Horowitz, page 113, line 17 to page 114).

The deposition of Dr. Horowitz squarely presents the question for decision in the present case. Is the purported standard of care for diagnosing and treating Lyme disease as represented by the ILADS practice guidelines a standard of care generally accepted by the universe of physicians who treat infectious diseases? A related question would be whether the ILADS treatment guidelines for Lyme disease represent a treatment protocol based on valid science?

Respondent's experts purport to identify an alternative standard of care. However, none of Respondent's experts have testified to the standard of care as generally accepted in the appropriate field. Respondent's experts have testified that a small number of physicians follow the ILADS practice guidelines for the diagnosis and treatment of Lyme disease. However, none of Respondent's experts have testified that the universe of physicians who treat infectious diseases, the relevant professional field, generally accept the ILADS practice guidelines for the diagnosis and treatment of Lyme disease as constituting a *bona fide* alternative standard of care for the diagnosis and treatment of Lyme disease. Indeed, the evidence will show that the universe of physicians who treat infectious diseases wholeheartedly and virtually unanimously reject the ILADS practice guidelines for the diagnosis and treatment of Lyme disease. No

generally accepted, peer reviewed literature supports the fundamental premises upon which the ILADS practice guidelines for the diagnosis and treatment of Lyme disease are based.

Generally Accepted Principles for the Diagnosis and Treatment of Lyme Disease Among Physicians Who Treat Infectious Diseases

(1) It is generally accepted by physicians who treat infectious diseases that Lyme disease is caused exclusively by the bite of an Ixodes Scapularis tick that has been previously infected with Borrelia Burgdorferi bacteria.

(2) It is generally accepted that only certain areas on the East Coast and in the North Central states have such infected ticks and that Missouri and Kansas have had no identifiable and confirmed cases of classical Lyme disease, as per the generally accepted definition of that disease as being an infection with Borrelia Burgdorferi bacteria.

(3) It is generally accepted that Lyme disease is not transmitted between humans by sexual contact.

(4) It is generally accepted that the ELISA test followed up by a Western Blot test, if the ELISA test is positive, are the appropriate standard of care confirmatory tests for the identification of the presence in a human of Borrelia Burgdorferi bacteria and to confirm a diagnosis of Lyme Disease.

(5) It is generally accepted that "Chronic Lyme disease," defined as a persistent infection with Borrelia Burgdorferi bacteria that is unresponsive to a short course of commonly-used antibiotics, does not exist as such.

(6) It is generally accepted that acute Lyme disease should be treated with a short course of appropriate antibiotics for no more than thirty (30) days.

(6a) It is generally accepted that the Borrelia Burgdorferi bacteria is sensitive to several widely used and readily available antibiotics and that the use of such antibiotics for a short course of treatment of no more than thirty (30) days should be effective to kill the bacteria.

(7) It is generally accepted that lengthy courses of antibiotics are ineffective against symptoms of Lyme disease unaccompanied by active infection with Borrelia Burgdorferi bacteria.

(8) It is generally accepted that lengthy courses of treatment with antibiotics can carry serious health risks and side effects.

(9) It is generally accepted that only FDA and institutionally approved tests for the presence of Borrelia Burgdorferi should be used to confirm a diagnosis of Lyme disease.

(10) It is generally accepted that the Bowen Labs Q-RiBb test for Borrelia Burgdorferi bacteria has never been proven to be effective to identify the presence of Borrelia Burgdorferi bacteria.

(11) The applicable standards of care would require that a reasonable Missouri physician observe and follow the generally accepted principles for the diagnosis and treatment of Lyme disease as set out in paragraphs (1) through (10), above, in the course of his/her practice.

(12) The above stated principles related to the diagnosis and treatment of Lyme disease are based on valid science and supported by generally accepted, peer reviewed medical and scientific literature.

(13) There is no valid science in the form of generally accepted, peer reviewed literature, to support the claim that Borrelia Burgdorferi bacteria can assume different forms and "hide" inside cells, thereby avoiding the effects of standard antibiotics.

(14) There is no valid science in the form of generally accepted, peer reviewed literature, to support the claim that Borrelia Burgdorferi bacteria can be transmitted by fleas, ticks other than the Ixodes Scapularis, birds, or other birds, animals or insects.

(15) There is no valid science in the form of generally accepted, peer reviewed literature, to support the claim that Borrelia Burgdorferi bacteria can be transmitted from one person to another by sexual contact.

(16) There is no valid science in the form of generally accepted, peer reviewed literature, to support the claim that the presence of the Borrelia Burgdorferi bacteria or human antibodies to Borrelia Burgdorferi bacteria can be detected in human blood or serum by the Bowen Labs Q-RIBR test.

Conclusion

Petitioner hereby moves under Section 490.065, RSMo 2000, that the Commission exclude certain expert testimony as to an alternative standard of care for the diagnosis and treatment of Lyme disease as expected from Respondent's identified expert witnesses, Drs. Richard Horowitz, Daniel Cameron, Steven Harris and Respondent herself, on the grounds that such testimony is not based on valid science and is not otherwise admissible under Section 490.065, RSMo 2000. If such expert testimony is not scientifically valid within the meaning of Section 490.065.1 and the case law interpreting that statute, then such expert testimony is not relevant and admissible, in that it would not assist the trier of fact. Petitioner hereby objects *in limine* to such testimony and evidence.

The following principles form the underlying basis for the ILADS treatment guidelines for the diagnosis and treatment of Lyme disease and/or the underlying basis for Respondent's

own individual practices as they may differ from those promulgated in the ILADS practice guidelines.

(13) Borrelia Burgdorferi bacteria can assume different forms and "hide" inside cells, thereby avoiding detection by standard of care confirmatory testing by the ELISA test and the Western Blot test and also avoiding the effects of standard antibiotics.

(14) Borrelia Burgdorferi bacteria can be transmitted by fleas, ticks other than the Ixodes Scapularis, birds, or other birds, animals or insects.

(15) Borrelia Burgdorferi bacteria can be transmitted from one person to another by sexual contact.

(16) The presence of the Borrelia Burgdorferi bacteria or human antibodies to Borrelia Burgdorferi bacteria can be detected in human blood or serum by the Bowen Labs Q-RIBR test.

() Lyme disease, the infection of a human being by the Borrelia Burgdorferi bacteria, can be acquired in the states of Missouri or Kansas;

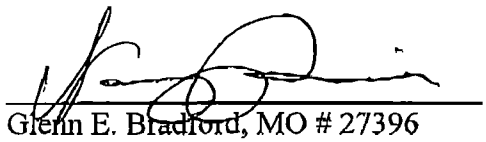
() "Chronic Lyme disease," defined as a persistent infection with Borrelia Burgdorferi bacteria that is unresponsive to a short course of commonly-used antibiotics, exists as such.

The Commission should find that the above-stated principles advocated by Respondent and her expert witnesses are not based on valid science and, as such, are inadmissible under the provisions of Section 490.065.1, RSMo 2000. In addition, the Commission should find that the testimony of Petitioner's expert witnesses to the effect that Respondent's care of the seven (7) patients identified in Petitioner's Complaint violated the applicable standards of care as outlined by Petitioner's experts is admissible. The standards of care advocated by Petitioner's expert witnesses represent the generally accepted standards of care among the universe of physicians who treat infectious diseases.

An Alternative Standard of Care

The *McDonagh* opinion recognized that there may in fact be more than one applicable standard of care approach to treatment. The example used by the McDonagh majority opinion was that one physician might treat a heart problem with angioplasty or a by-pass operation, where another physician might choose to use a drug instead. *McDonagh*, at 123 S.W.3d at 159. As the Court noted, both methods of treatment would meet the generally accepted standard of care that a physician applying ordinary skill and learning would use in the same or similar circumstances. However, here the ILADS practice guidelines are not generally accepted by the overwhelming majority of physicians who treat infectious diseases and the generally accepted approach, as represented by the IDSA practice guideline are in fact fundamentally inconsistent with the ILADS approaches to the various aspects of diagnosis and treatment of Lyme disease. A physician using ordinary skill and learning would not use the ILADS guidelines for the treatment of Lyme disease as that would be flying in the face of valid science.

WHEREFORE, Petitioner prays that the Commission hold and rule under the provisions of Section 490.065.1, RSMo 2000, that the testimony of Drs. Horowitz, Cameron, Harris, as well as the testimony of Respondent as to a purported alternative standard of care for the treatment of Lyme disease is not based on valid science and as such is inadmissible upon the issues made out by the pleadings herein, and that Petitioner's objection thereto be sustained.



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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 23rd day of April, 2012, a true and correct copy of the foregoing Petitioner's Motion to Compel was faxed to:

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