FILED

JUN 30 2015

KS State Board of Healing Arts

BEFORE THE BOARD OF HEALING ARTS
OF THE STATE OF KANSAS

In the Matter of	)	
MARTIN LEE, M.D.	)	
	)	**KSBHA Docket No. 15-HA00099**
Kansas License No. 04-20164	)	
(Application for Reinstatement)	)	
	)	

FINAL ORDER GRANTING LIMITED LICENSE

NOW on this 12th day of June 2015, comes before the Kansas State Board of Healing Arts ("Board") the application for reinstatement filed by Martin Lee, M.D. ("Applicant") for an for reinstatement of his license to practice medicine and surgery in the State of Kansas. Applicant appears in person *pro se*. Jessica Bryson, Associate Litigation Counsel appears on behalf of the Respondent Board.

Pursuant to the authority granted to the Board by the Kansas Healing Arts Act, K.S.A. 65-2801, *et seq*., and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq*., the Board hereby enters this Final Order in the above-captioned matter. After reviewing the agency record, hearing the statements and arguments of the parties, and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

1. Applicant was originally licensed to practice medicine and surgery in the State of Kansas on July 1, 1983. His license was canceled for nonrenewal on June 30, 1997.

2. On approximately September 11, 2014, Applicant submitted an application for reinstatement of his Kansas medical license. Such application was complete and filed with the Board on April 22, 2015.

3. Applicant's practice specialties are hematology and oncology. Applicant is board certified in oncology and internal medicine. Between 1994 and 2006, he actively practiced full-time at the Cancer Center at Park Nicollet Clinic. During that time, Applicant served on the Clinical Board of Governors, as the Medical Director of Oncology Research, and as the Chairman of the Institutional Review Board.

4. From approximately 2006 through May of 2011, Applicant actively practiced part-time while he also worked in pharmaceutical research. Applicant has not actively practiced medicine and surgery since May of 2011, but has continued to be employed in pharmaceutical research. Applicant currently works for PRA Health Sciences in Lenexa, Kansas, where he serves as Vice President of Investigator Relations.

5. Applicant desires to reinstate his Kansas medical license so that he will be able to oversee clinical research trials of medications within his present employment and possibly re-enter clinical oncology practice in the future.

6. As evidence in support of reinstatement of his medical license, Applicant points to his current Minnesota licensure and CME maintenance; his board certifications; and his limited time out of practice compared to his overall practice time (4-year absence, 24 years total practice; 19 years full-time). Applicant also asserts he is competent to practice because of his continued connection to active practice through his pharmaceutical research work by staying abreast of patterns of care; frequently discussing treatment paradigms; educating physicians about side effects of trial medications; and being involved at national specialty society meetings in hematology and oncology.

7. On behalf of the Board's Disciplinary Panel, Associate Disciplinary Counsel opposes reinstatement of Applicant's medical license. The Response in Opposition filed by Associate Litigation Counsel first alleges that, because of Applicant's absence from active practice for over two years, the Board should require "additional testing, training or education as the Board may deem necessary to establish the licensee's present ability to practice with reasonable skill and safety" pursuant to K.S.A. 65-2809(e).

8. Associate Litigation Counsel proposes that the Board require additional testing in the form of a comprehensive, re-entry to practice evaluation at the Center for Personalized Education for Physicians ("CPEP") to assess Applicant's current knowledge, skill and clinical judgment and make recommendations for further education and training, if needed.

9. The Response in Opposition further alleges that Applicant's four-year absence from active practice constitutes professional incompetency pursuant to K.S.A. 65-2836(b), as further defined by K.S.A. 65-2837(a), in that his absence amounts to "other behavior which demonstrates a manifest incapacity or incompetence to practice the healing arts."

10. The Board concludes that the determination of whether an applicant's absence from active practice constitutes professional incompetency depends on several factors, including but not limited to the Applicant's particular qualifications, specialty area, practice experience, length of absence from practice, and maintenance of medical knowledge and skill.

11. The prior Board case cited by Associate Litigation Counsel during oral argument involved a twelve-year absence from practice which was found to create a presumption of clinical incompetence which the applicant in that case failed to overcome. In the present matter, Applicant has only been absent from practice for four years and presented evidence of his continued involvement with clinical practice and maintenance of his continuing education.

Additionally, Applicant's intended practice area, conducting clinical research trials of medications in healthy volunteers, is a limited scope of practice.

12. The Board concludes that Applicant's four-year absence from active practice does not constitute professional incompetency, but does raise concerns about Applicant's ability to practice should Applicant decide to re-enter oncology practice outside of conducting clinical research trials with healthy volunteers. The Board concludes that these concerns would best be addressed through the comprehensive re-entry evaluation process at CPEP.

13. Based on the evidence presented, K.S.A. 65-2809(e) affords discretion to the Board to determine whether "additional testing, training or education" is necessary, and to what degree. It also permits the Board to tailor a testing, training or education requirement, or combination thereof, which in the Board's opinion will ensure Applicant's "present ability to practice with reasonable skill and safety."

14. In order to assure the Board he is up-to-date in his clinical knowledge regarding his intended practice area, Applicant offers to complete the course entitled, "Good Clinical Practice (GCP) for Clinical Trials with Investigational Drugs and Medical Devices- U.S. FDA focus" that is offered by the Collaborative Institutional Training Initiative (CITI) at the University of Miami. Completion of the course is worth six Category 1 continuing medical education credits.

15. In lieu of having a re-entry evaluation at CPEP to evaluate his clinical competence in oncology practice, Applicant further offers to voluntarily accept a license that is limited to his present research setting. During the hearing in this matter, Applicant affirmed his voluntary consent to a limited license.

16. The Board concludes that Applicant is competent to practice medicine and surgery with reasonable skill and safety within the limited scope of practice inherent in conducting normal healthy volunteer clinical trials and human abuse liability studies for the purposes of pharmaceutical research.

17. The Board concludes that Applicant should be granted a license to practice medicine and surgery that is limited to the scope of practice inherent in conducting normal healthy volunteer clinical trials and human abuse liability studies. Applicant should also be required to complete the "Good Clinical Practice (GCP) for Clinical Trials with Investigational Drugs and Medical Devices- U.S. FDA focus" course that is offered by the Collaborative Institutional Training Initiative (CITI).

18. The Board further concludes that if Applicant requests termination of the limitations on his license in order to expand his scope of practice, the Board shall require Applicant to obtain a re-entry evaluation by CPEP to assess his present clinical competency and provide evidence to the Board demonstrating he is able to practice with reasonable skill and safety to patients.

IT IS THEREFORE ORDERED, BY THE KANSAS STATE BOARD OF HEALING ARTS that Applicant is hereby GRANTED a license to practice medicine and surgery in the State of Kansas which is voluntarily LIMITED to the scope of practice inherent in conducting normal healthy volunteer clinical trials and human abuse liability studies for the purpose of pharmaceutical research. The voluntary LIMITATION is not based on disciplinary grounds, but was agreed to by Applicant in lieu of additional testing, training or education.

IT IS FURTHER ORDERED that Applicant shall complete the "Good Clinical Practice (GCP) for Clinical Trials with Investigational Drugs and Medical Devices- U.S. FDA focus" course that is offered by the Collaborative Institutional Training Initiative (CITI). On or before October 1, 2015, Applicant shall submit documentary proof of successful completion to: Compliance Coordinator, Kansas State Board of Healing Arts, 800 SW Jackson Street, Lower Level, Suite A, Topeka, Kansas 66612.

IT IS FURTHER ORDERED that if Applicant files a request to modify or terminate the limitation on his license in order to expand his scope of practice, Applicant shall be required to obtain a re-entry evaluation by CPEP to assess his present clinical competency beyond his current limited scope of practice. Applicant shall bear the evidentiary burden of proof to demonstrate his ability to practice with reasonable skill and safety to patients in any expanded scope of practice.

IT IS SO ORDERED THIS 30 DAY OF JUNE, 2015, IN THE CITY OF TOPEKA, COUNTY OF SHAWNEE, STATE OF KANSAS.

Confidential

Kathleen Selzler Lippert, Executive Director
Kansas State Board of Healing Arts

NOTICE OF RIGHTS

PLEASE TAKE NOTICE that this is a Final Order. A Final Order is effective upon service, and service of a Final Order is complete upon mailing. Pursuant to K.S.A. 77-529, Applicant may petition the Board for Reconsideration of a Final Order within fifteen (15) days following service of the Final Order. Additionally, a party to an agency proceeding may seek judicial review of a Final Order by filing a petition in the District Court, as authorized by K.S.A. 77-601, *et seq*. Reconsideration of a Final Order is not a prerequisite to judicial review. A petition for judicial review is not timely unless filed within **30 days** following service of the Final Order. A copy of any petition for judicial review must be served upon Kathleen Selzler Lippert, Executive Director, Kansas State Board of Healing Arts, 800 SW Jackson, Lower Level-Suite A, Topeka, KS 66612.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that a true and correct copy of the above and foregoing **FINAL ORDER GRANTING LIMITED LICENSE** was served on this 30th day of June, 2015, by depositing the same in the United States Mail, first-class, postage prepaid, and addressed to:

Martin Lee, M.D.
Confidential

Lenexa, Kansas 66220

And a copy was delivered to:

Jessica Bryson, Associate Litigation Counsel
Kansas State Board of Healing Arts
800 SW Jackson, Lower Level-Suite A
Topeka, Kansas 66612

Katy Lenahan, Licensing Administrator
Kansas State Board of Healing Arts
800 SW Jackson, Lower Level-Suite A
Topeka, Kansas 66612

And the original was filed with the office of the Executive Director.

for [signature]
Cathy Brown, Executive Assistant