

BEFORE THE  
NORTH CAROLINA MEDICAL BOARD

In re: )  
 )  
Wendell Lewis Randall, M.D., )                    CONSENT ORDER  
 )  
Respondent. )

This matter is before the North Carolina Medical Board ("Board") on information regarding Wendell Lewis Randall, M.D. ("Dr. Randall"). Dr. Randall admits and the Board finds and concludes that:

STATUTORY AUTHORITY

The Board is a body duly organized under the laws of North Carolina and is the proper party to bring this proceeding under the authority granted it in Article 1 of Chapter 90 of the North Carolina General Statutes and the rules and regulations promulgated thereto.

FINDINGS OF FACT

Dr. Randall is a physician licensed by the Board on or about September 19, 1992, license number 36016.

During the times relevant herein, Dr. Randall practiced medicine in Wilkesboro, North Carolina.

In November 2013, Dr. Randall served as the supervising physician for Nurse Practitioner Laura Jane Deleruyelle ("Ms. Deleruyelle"). Dr. Randall practiced at Holistic Medical Clinic

of the Carolinas, LLC ("Holistic Medical") in Wilkesboro from the Spring of 2014 to January, 2015.

In or about November 2013, the sole member (owner) of Holistic Medical was Ronald Cohn, D.C. Dr. Cohn is a licensed chiropractor but not a licensed physician, although he does display a medical degree from an off-shore medical school in his office. Ms. Deleruyelle was supervised by Wendell Lewis Randall, M.D. ("Dr. Randall").

Holistic Medical engaged in the practice of medicine through Dr. Randall and Ms. Deleruyelle. As a general rule, it is unlawful for a private, non-physician owned, for-profit business, such as Holistic Medical, to provide services that constitute the practice of medicine. When a private, non-physician owned, for-profit business provides professional services that constitute the practice of medicine as defined by N.C. Gen. Stat. 90-1.1(a)(5), then such business is deemed to be engaged in what is called the unlawful "corporate practice of medicine." It is unethical for a physician, nurse practitioner or physician assistant to aid and abet the unlawful corporate practice of medicine.

Dr. Cohn controlled and dictated the operation of Holistic Medical and at times, according to Ms. Deleruyelle and Dr. Randall, attempted to influence how medicine was practiced there. Furthermore, Ms. Delleruyelle and Dr. Randall report

that Dr. Cohn controlled all of the patient records and, at times, altered them at his will over the objections of Ms. Deleruyelle and Dr. Randall.

The Board reviewed several of Ms. Deleruyelle's medical charts as provided to the Board by Holistic Medical and presumably Dr. Cohn. Ms. Deleruyelle and Dr. Randall report that they were not involved with the transmittal of the requested records. The records were reviewed by an infectious disease specialist and an integrative medicine practitioner. From these reviews, the Board obtained evidence, from which it could conclude, that substandard care was being provided at Holistic Medical.

For instance, as to Patient A, the Board has evidence that shows that Ms. Deleruyelle administered testosterone replacement therapy to Patient A under the "Wiley Protocol". The Wiley Protocol involves administering a topical testosterone and DHEA (a precursor to adrenal and gonadal steroidal hormones). Dosing follows a seasonal rhythm, highest in the fall and lowest in the winter, or can mimic a partner's monthly cycle ("lunar WP"). There is no evidence that such a cyclical pattern changes the benefits or risks of testosterone replacement therapy in men. The Wiley Protocol is considered substandard practice, as the actual standard of care in North Carolina for testosterone replacement therapy involves static dosing of topical or

parenteral testosterone. Ms. Deleruyelle states and the record shows that she did not administer dosing based on a seasonal rhythm, but did start therapy per the "lunar WP." After starting dosing based on the "lunar WP," Ms. Deleruyelle states, and the record shows, she administered static dosing thereafter with changes consistent with lab results. The Board takes note that Dr. Randall was not Ms. Deleruyelle's supervising physician during most of Patient A's treatment by Ms. Deleruyelle, and only became her supervising physician during the last few months of Patient A's care that the Board reviewed.

In May 2013, Patient B presented to Ms. Deleruyelle with complaints of musculoskeletal and other problems. Ms. Deleruyelle diagnosed Patient B with Lyme disease despite the fact that Patient B tested negative for the disease. According to Ms. Deleruyelle, Patient B, by means of oral history, presented a history of a tick bite in 2010 with erythema migrans.

The standard of care in North Carolina for a suspected case of Lyme disease is for a patient to undergo an EIA or ELISA (enzyme-linked immunosorbent assay) test to detect the patient's response to Lyme disease. An ELISA test is very sensitive and nearly everyone with Lyme disease will test positive under ELISA. However, other conditions besides Lyme disease may also trigger a positive ELISA result. Therefore, to confirm a

diagnosis of Lyme disease, the practitioner will administer what is called a Western Blot test. A patient with both a positive ELISA and Western Blot test will have a confirmed diagnosis of Lyme disease.

With regard to Patient B, Ms. Deleruyelle only administered a Western Blot test for which Patient B tested negative for Lyme disease.

Despite these findings, Ms. Deleruyelle treated Patient B for Lyme disease with intravenous doses of Rocephin® (ceftriaxone) and non-evidence based, non-standard therapies such as IV glutathione, hyperbaric oxygen, lymphatic massage, and infrared therapy.

Patient B also suffered from Amyotrophic Lateral Sclerosis ("ALS") or Lou Gehrig's disease. Ms. Deleruyelle provided palliative care to Patient B and there is evidence of appreciation from the family for the palliative care which was received.

Patient C presented to Ms. Deleruyelle with complaints of low libido. Ms. Deleruyelle treated Patient C with testosterone replacement therapy pursuant to Wiley Protocol without seasonal adjustment. Patient C's records, as provided to the Board, do not indicate laboratory evidence of hypogonadism. After testosterone replacement therapy was initiated, Patient C began to experience elevated PSA levels. Ms. Deleruyelle referred

Patient C to an urologist but Patient C declined the urological consult. Ms. Deleruyelle did not discontinue or terminate testosterone replacement therapy when Patient C refused the urological consult. In addition, the Holistic Medical consent form that Patient C signed did not cover what would happen if Patient C did refuse to follow recommended tests and referrals.

Patient D is a patient of Holistic Medical who received the Wiley Protocol as administered by Ms. Deleruyelle without seasonal adjustment. Patient D's treatment resulted in elevated levels of testosterone that exceeded the therapeutic target. When Patient D's PSA levels increased and Ms. Deleruyelle performed a prostate exam that was abnormal, she referred Patient D for a urological consultation. Patient D refused the referral and Dr. Cohn would not allow his dismissal. Notwithstanding the elevated PSA levels, the abnormal prostate exam and Patient D's decision not to obtain a urological consult, Ms. Deleruyelle continued to provide testosterone replacement therapy. The Holistic Medical consent form that Patient D signed did not cover what would happen if Patient D did refuse to follow recommended tests and referrals.

As the supervising physician for Ms. Deleruyelle, Dr. Randall is responsible for the care that she provides to their patients. Pursuant to 21 NCAC 32M .0101(10), a primary supervising physician is "the licensed physician who shall

provide on-going supervision, collaboration, consultation and evaluation of the medical acts performed by the nurse practitioner as defined in the collaborative practice agreement...The primary supervising physician shall assure both Boards that the nurse practitioner is qualified to perform those medical acts described in the collaborative practice agreement." Accordingly, Dr. Randall is responsible to the Board for the care that Ms. Deleruyelle provided to Patients A through D.

#### CONCLUSIONS OF LAW

Dr. Randall's conduct, specifically his aiding and abetting the unlicensed corporate practice of medicine as described above, constitutes a violation of a law involving the practice of medicine within the meaning of N.C. Gen. Stat. § 90-14(a)(7) which is grounds under that section of the North Carolina General Statutes for the Board to annul, suspend, revoke, condition, or limit Dr. Randall's license to practice medicine or to deny any application he may make in the future.

The Board has evidence from the records provided by Holistic Medical that Dr. Randall's conduct, specifically with regard to the oversight and evaluation of the care provided by Ms. Deleruyelle, could constitute a violation of a law involving the practice of medicine within the meaning of N.C. Gen. Stat. § 90-14(a)(7) which is grounds under that section of the North Carolina General Statutes for the Board to annul, suspend,

revoke, condition, or limit Dr. Randall's license to practice medicine or to deny any application he may make in the future.

The Board has evidence from records provided by Holistic Medical which could constitute, that Dr. Randall's conduct, specifically his responsibility for the care Ms. Deleruyelle provided to Patient A through D, was unprofessional conduct, including, but not limited to, departure from, or the failure to conform to, the standards of acceptable and prevailing medical practice, within the meaning of N.C. Gen. Stat. § 90-14(a)(6) which is grounds under that section of the North Carolina General Statutes for the Board to annul, suspend, revoke, condition, or limit Dr. Randall's license to practice medicine or to deny any application he may make in the future.

#### PROCEDURAL STIPULATIONS

Dr. Randall acknowledges and agrees that the Board has jurisdiction over him and over the subject matter of this case.

Dr. Randall knowingly waives his right to any hearing and to any judicial review or appeal in this case.

Dr. Randall acknowledges that he has read and understands this Consent Order and enters into it voluntarily.

Dr. Randall would like to resolve this matter without the need for more formal proceedings.

Whereas the Board has determined that it is in the public interest to resolve this case as set forth below.



ORDER

NOW, THEREFORE, with Dr. Randall's consent, it is ORDERED that:

1. Dr. Randall be and hereby is REPRIMANDED for the preceding conduct.

2. Dr. Randall shall completely discontinue any association with Holistic Medical Clinic of the Carolinas, PLLC and Mr. Cohn.

3. Dr. Randall shall notify the Board in writing of any change in his residence and practice addresses within ten (10) days of the change.

4. Dr. Randall shall obey all laws. Likewise, Dr. Randall shall obey all rules and regulations involving the practice of medicine.

5. Dr. Randall shall meet with the Board or members of the Board for an investigative interview at such times as requested by the Board.

6. If Dr. Randall fails to comply with any of the terms of this Consent Order, that failure shall constitute unprofessional conduct within the meaning of N.C. Gen. Stat. § 90-14(a)(6) and shall be grounds, after any required notice and hearing, for the Board to annul, revoke, suspend or limit his license or to deny any application he might then have pending or might make in the future for a license.

7. Dr. Randall hereby waives any requirement under any law or rule that this Consent Order be served on him.

8. This Consent Order shall take effect immediately upon its execution by both Dr. Randall and the Board and it shall continue in effect until specifically ordered otherwise by the Board.

9. Upon execution by Dr. Randall and the Board, this Consent Order shall become a public record within the meaning of Chapter 132 of the North Carolina General Statutes and shall be subject to public inspection and dissemination pursuant to the provisions thereof. Additionally, it will be reported to persons, entities, agencies and clearinghouses as required and permitted by law.

By Order of the North Carolina Medical Board this the 19<sup>th</sup> day of February, 2015.

NORTH CAROLINA MEDICAL BOARD

By: Cheryl L. Walker-McGill  
Cheryl L. Walker-McGill, M.D.  
President

Consented to this the 19<sup>th</sup> day of February, 2015.

*[Handwritten signature]*

Wendell Lewis Randall, M.D.

State of North Carolina

County of Wake

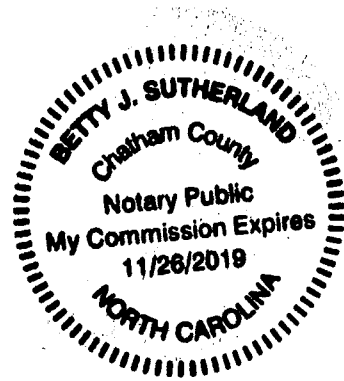
I, Betty J. Sutherland, a Notary Public for the above named State and County, do hereby certify that Wendell Lewis Randall, M.D. personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal

this the 19<sup>th</sup> day of February, 2015.

Betty J. Sutherland  
Notary Public

(SEAL)



My Commission expires: 11/26/19