

HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-06-2136
LICENSE NO. E-1255

IN THE MATTER OF THE
COMPLAINT AGAINST
RUSSELL R. ROBY, M.D.

BEFORE THE
TEXAS MEDICAL BOARD

COMPLAINT

TO THE HONORABLE TEXAS MEDICAL BOARD AND THE HONORABLE
ADMINISTRATIVE LAW JUDGE TO BE ASSIGNED:

COMES NOW, the Staff of the Texas Medical Board (the "Board"), and files this Complaint against Russell R. Roby, M.D., ("Respondent"), based on Respondent's alleged violations of the Medical Practice Act ("the Act"), TEX. OCC. CODE ANN., Title 3, Subtitle B, Chapters 151 – 165 (Vernon's 2004 & Supp. 2005), and would show the following:

I. INTRODUCTION

The filing of this Complaint and the relief requested are necessary to protect the health and public interest of the citizens of the State of Texas, as provided in Section 151.003 of the Act.

II. LEGAL AUTHORITY AND JURISDICTION

Respondent is a Texas physician and holds Texas medical license number E-1255, issued by the Board on January 19, 1974, which was in full force and effect at all times material and relevant to this Complaint. All jurisdictional requirements have been satisfied.

III. PROCEDURAL BACKGROUND

1. The Board received information that Respondent may have violated the Act and,

based on that information, conducted an investigation. The investigation compiled evidence that support allegations of a violation.

2. Respondent was invited to attend an Informal Show Compliance Proceeding and Settlement Conference ("ISC"), held on December 15, 2005, which was conducted in accordance with §2001.054(c), GOV'T CODE and §164.004 of the Act. The Board representatives, including at least one physician ("Panel"), reviewed and considered evidence from the investigation, as well as any information presented by Respondent. The Panel determined that Respondent had not shown compliance with all requirements of the Act.

3. In an attempt to resolve this matter informally, the Panel offered Respondent a proposed Agreed Order, setting forth certain terms and conditions. Respondent failed and/or refused to agree to the proposed settlement offer and no agreement to settle this matter has been reached by the parties.

IV. FACTUAL ALLEGATIONS

Board Staff has received information and on that information believes that Respondent has violated the Act. Based on such information and belief, Board Staff alleges:

1. Respondent is primarily engaged in the practice of allergy and immunology. Respondent is not board certified.

2. Respondent treats patients using "hormone neutralization" therapy. This therapy involves a process in which oral syringes are used to place a liquid solution containing a dilution of hormones under patients' tongues. Respondent states that "neutralization" of progesterone with homeopathic concentrations leads to relief of pain, fatigue, viral colds, Temporomandibular Joint Dysfunction (TMJ), depression, migraine, asthma, loss of sex drive, and numerous other disorders.

3. Respondent states that pain relief from his sublingual drops occurs faster than the circulation time required for the solution he uses to get to the brain or body part. Respondent fails to explain, demonstrate or substantiate how pain relief from the hormone neutralization occurs faster than the circulation required to get to the brain or body part.

4. Respondent does not perform controlled skin or patch tests to demonstrate functional sensitivity reactions. Respondent does not measure IgE antibodies, the type of antibodies

typically associated with allergic disorders. Respondent states that in his therapy, he measures IgG and IgM antibodies to progesterone. Respondent does not, however, state what the antibodies he studies actually do.

5. One type of dilution Respondent uses in the hormone neutralization therapy is a dilution of progesterone, which Respondent states is a 10 to the 30th dilution. A one molar solution contains six times 10 to the 23rd molecules. A 30-fold dilution may not contain any progesterone molecules in any given tenth of a milliliter.

6. Respondent has no evidence that there are any other medical practitioners in Texas or in the United States who utilize or espouse the effectiveness of the progesterone neutralization therapy he uses.

7. The only study supporting Respondent's hormone neutralization therapy is a study coauthored by Respondent. The research upon which Respondent bases his therapy has not been published in any professional journal, has not been peer reviewed, has not been replicated by any other researcher, and was not the subject of a double blind placebo controlled study to control the placebo effect and investigator influence.

8. The Respondent has not demonstrated that the expected beneficial outcome resulting from the application of the hormone neutralization therapy is supported by scientific evidence and does not solely rely on the placebo effect, nor can Respondent demonstrate the medical, scientific, or other theoretical principles connected with his treatment. His sole support is his study that itself is couched in terms of possibilities and is admittedly the first study of its kind.

9. Respondent has submitted his study that supports his hormone neutralization therapy to the *Journal of Reproductive Immunology* for publication and has presented this paper as an *abstract* at two professional meetings. Neither action meets the criteria for peer review.

10. There is no scientific evidence that Respondent's hormone neutralization therapy has any medical validity.

11. Respondent's use of sublingual drops based on a dilution of progesterone to the 30th power effectively results in a treatment that is non-therapeutic in nature.

12. Respondent advertises his hormone neutralization therapy discussed herein through the internet and in television infomercials.

13. In infomercials used by Respondent, Respondent filmed the use of the neutralization therapy on patients with various medical complaints ranging from viral colds, Temporo-

Mandibular Joint Dysfunction (TMJ), and neck, back, elbow, and hip pain. In one infomercial, Respondent related the experience of a patient scheduled for a knee replacement. Respondent represented that the orthopedic surgeon who was to perform the surgery had indicated to the patient that the cartilage in the knee was essentially gone from the knee joint, resulting in a "bone-on-bone" condition. Respondent indicated that because of the use of the hormone neutralization therapy, the patient's pain had disappeared and there was no need for surgery.

14. The testimonials of those appearing in the infomercials and the statements of Respondent strongly imply, and in some instances directly state, a causal relationship between the receipt of the sublingual dilutions used in the hormone neutralization therapy used by Respondent and relief of a variety of symptoms.

15. Based on the lack of any medical or scientific validity to, or scientific acceptance of, the effectiveness of Respondent's hormone neutralization therapy, Respondent's advertising contains misrepresentations of material facts.

16. Based on the lack of any medical or scientific validity to, or scientific acceptance of, the effectiveness of Respondent's hormone neutralization therapy, Respondent's advertising contains implied false claims of material facts.

17. Based on the lack of any medical or scientific validity to, or scientific acceptance of, the effectiveness of Respondent's hormone neutralization therapy, Respondent's advertising omits material facts.

18. Based on the lack of any medical or scientific validity to, or scientific acceptance of, the effectiveness of Respondent's hormone neutralization therapy, Respondent's advertising makes a representation likely to create an unjustified expectation about the results of a health care service or procedure.

19. The Respondent's resumé presented in the website was confusing and did not accurately or completely describe the Respondent's professional and educational credentials. Respondent's advertising does not indicate where, or in what manner, Respondent gathered his alleged allergy immunology experience in 1974 or in the period 1980 through 1981. Although Respondent is not a member of the American Academy of Environmental Medicine, his advertising indicates that he is. Respondent's advertising references his holding of a position in pediatrics; however, there is no agency listed and no specific definition of what such position actually is or was. Respondent makes vague references to his admission for Ph.D. candidacy and

publications, yet there is no specific information upon which one could check or base an informed decision as to the exact credentials of Respondent.

20. Respondent's advertising causes confusion or misunderstanding as to the credentials, education, or licensure of a health care professional.

21. Respondent's advertising makes claims that Respondent has a unique skill without substantiation of such a claim.

22. Respondent's advertising is designed to take advantage of the fears or emotions of a particularly susceptible type of patient, including patients who have experienced pain not easily treated with other types of medications.

V. APPLICABLE STATUTES, RULES, AND AGENCY POLICY

Respondent's conduct, as described above, constitutes grounds for the Board to revoke or suspend Respondent's Texas medical license or to impose any other authorized means of discipline upon the Respondent. The following statutes, rules, and agency policy are applicable to this matter:

A. Procedures for the Conduct of this Hearing:

1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.

2. 22 TEX. ADMIN. CODE, Chapter 187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.

3. 1 TEX. ADMIN. CODE §155.3(c) provides that the procedural rules of the state agency on behalf of which the hearing is conducted govern procedural matters that relate to the hearing as required by law, to wit: Section 164.007(a) of the Act, as cited above.

4. 1 TEX. ADMIN. CODE, CHAPTER 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.

B. Violations Warranting Disciplinary Action:

1. Section 164.051(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's commission of an act prohibited under Section 164.052 of the Act.

2. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a rule adopted under this Act.

3. Board Rule 164.3 provides that no physician shall disseminate or cause the dissemination of any advertisement that is in any way false, deceptive, or misleading. An advertisement shall be deemed by the Board to be false, deceptive, or misleading if it, among other things: contains material false claims or misrepresentations of material facts which cannot be substantiated; contains material implied false claims or implied misrepresentations of material fact; omits material facts; makes a representation likely to create an unjustified expectation about the results of a health care service or procedure; causes confusion or misunderstanding as to the credentials, education, or licensure of a health care professional; makes a representation that is designed to take advantage of the fears or emotions of a particularly susceptible type of patient; or claims that a physician has a unique skill without substantiation of such claim.

4. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public, as defined by Board Rule 190.8(2)(I) regarding the use of false, misleading, or deceptive advertising.

5. Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's use of an advertising statement that is false, misleading or deceptive.

C. Sanctions That May Be Imposed:

1. Section 164.001 of the Act authorizes the Board to impose a range of disciplinary actions against a person for violation of the Act or a Board rule. Such sanctions include: revocation, suspension, probation, public reprimand, limitation or restriction on practice,

counseling or treatment, required educational or counseling programs, monitored practice, public service, and an administrative penalty.

2. Chapter 165, Subchapter A of the Act and 22 TEX. ADMIN. CODE § 190.16 sets forth statutory and Board rule requirements, respectively, for the amount of, and basis for, an administrative penalty.

3. 22 TEX. ADMIN. CODE § 187.39 authorizes the Board to assess, in addition to any penalty imposed, costs of the investigation and administrative hearing in the case of a default judgment or upon adjudication that Respondent is in violation of the Act after a trial on the merits.

4. 22 TEX. ADMIN. CODE Chapter 190 provides disciplinary guidelines intended to provide guidance and a framework of analysis for administrative law judges in the making of recommendations in contested licensure and disciplinary matters and to provide guidance as to the types of conduct that constitute violations of the Act or Board rules. The Chapter 190 guidelines also include a list of aggravating factors that need to be considered in making a sanction recommendation. The aggravating factors present in this case include harm to one or more patients, the severity of the harm to patients, economic harm to the patient, the severity of economic harm to patients, extensive prior disciplinary history at the Board, and relevant circumstances increasing the seriousness of the misconduct.

VI. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS NOTICE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHIN 20 DAYS OF THE DATE NOTICE OF SERVICE WAS MAILED, A DEFAULT JUDGMENT MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS INCLUDING THE REVOCATION OF YOUR LICENSE. IF YOU FILE A WRITTEN ANSWER, BUT THEN FAIL TO ATTEND THE HEARING, A DEFAULT JUDGMENT MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS INCLUDING THE REVOCATION OF YOUR LICENSE. A COPY OF ANY RESPONSE YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS STATE BOARD OF MEDICAL EXAMINERS.

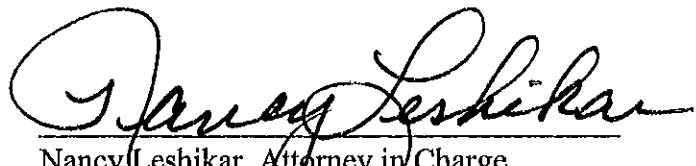
PURSUANT TO 22 TEX. ADMIN. CODE § 187.27(a)(2), A WRITTEN ANSWER SHALL SPECIFICALLY ADMIT OR DENY EACH FACTUAL ALLEGATION MADE AGAINST THE RESPONDENT.

WHEREFORE, PREMISES CONSIDERED, Board Staff requests that an administrative law judge employed by the State Office of Administrative Hearings conduct a contested case hearing on the merits of the Complaint, in accordance with Section 164.007(a) of the Act. Upon final hearing, Board Staff requests that the Honorable Administrative Law Judge issue a Proposal for Decision ("PFD") that reflects Respondent's violation of the Act as set forth in this Complaint. Following issuance of the PFD, Board Staff requests that the Board, pursuant to § 164.001 and § 165.003 of the Act and Board Rules 187.30, 187.39, 190.8, 190.14, 190.15 and 190.16, enter an Order imposing any and all sanctions or disciplinary measures necessary to protect health and public welfare, including the imposition on Respondent of SOAH hearing costs and an administrative penalty.

Respectfully submitted,

TEXAS MEDICAL BOARD

By:



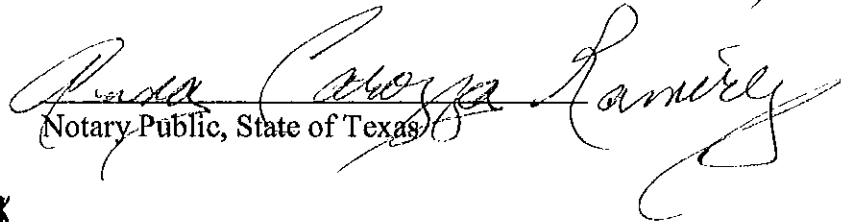
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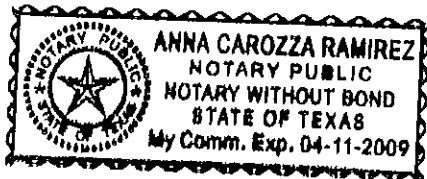
THE STATE OF TEXAS

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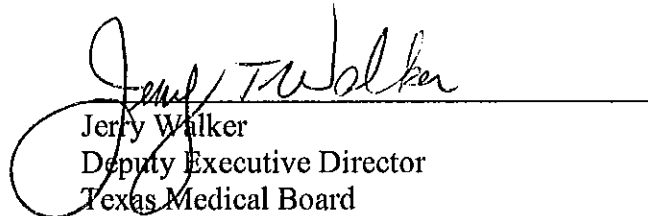
COUNTY OF TRAVIS

SUBSCRIBED AND SWORN to before me by the said Nancy Leshikar on April 24,
2006.


Notary Public, State of Texas



Filed with the Texas Medical Board on April 26, 2006.


Jerry Walker
Deputy Executive Director
Texas Medical Board