

LICENSE NO. E-1255

IN THE MATTER OF  
THE LICENSE OF  
RUSSELL R. ROBY, M.D.

BEFORE THE  
TEXAS MEDICAL BOARD

AGREED ORDER

On the 3RD day of JUNE, 2011, came on to be heard before the Texas Medical Board (the "Board"), duly in session, the matter of the license of Russell R. Roby, M.D. ("Respondent").

On February 24, 2010, Respondent appeared in person, with counsel Tony Cobos, at an Informal Show Compliance Proceeding and Settlement Conference in response to a letter of invitation from the staff of the Board. The Board's representatives were Allan Shulkin, M.D., and Julie Attebury, members of the Board ("Panel"). Scott M. Freshour represented Board staff.

Upon the recommendation of the Board's representatives and with the consent of Respondent, the Board makes the following Findings and Conclusions of Law and enters this Agreed Order.

BOARD CHARGES

Board Staff charged Respondent with multiple violations arising from several different investigations. The charges included failing to obtain proper informed consent, failing to adequately monitor a patient after giving sublingual drops, and altering medical records.

Respondent committed boundary violations with patients and employees. The Panel found no sexual boundary violations with employees; however, he had entered into a sexual relationship with a patient.

Board Staff charged that Respondent suffers from an impairment that could affect his ability to practice medicine.

Respondent was also charged with violating provisions of the 2007 Agreed Order.

### BOARD HISTORY

- A. Respondent has previously been the subject of disciplinary action by the Board.
1. Specifically, the Board entered an order on June 10, 1983, cancelling Respondent's medical license at his request.
  2. On December 1, 1984, the Board entered an order ("1984 Order") reinstating the Respondent's medical license and placing him on probation under certain terms and condition for a period of ten years: requiring that he not apply for his Federal Drug Enforcement Administration Controlled Substance Registration and Texas Controlled Substances Registration Certificate without Board approval; requiring that he participate in AA on a regular basis; requiring that he continue psychiatric treatment; and requiring that he not be found guilty of the intemperate use of alcohol and or habit forming drugs. On June 18, 1990, the 1984 Order terminated.
  3. On December 10, 2004, the Board entered an Agreed Order Order ("2004 Order") publically reprimanding the Respondent and imposing certain terms and conditions: requiring that his practice be monitored for twelve months; and requiring that he submit a revised informed consent form to the Board for approval. The action was based upon inadequate patient consent. The 2004 Order expired in December 2005.
  4. On August 24, 2007, the Board entered a Mediated Agreed Order ("2005 Order") imposing certain terms and conditions for a period of four years. The primary requirements of the 2005 Order required Respondent to provide certain disclosures in any and all infomercials, paid advertisements and commercials and all printed material released or distributed by himself or the Roby Institute; to maintain a signed acknowledgement that each patient received the written disclosure; to have a practice monitor; not treat any patient with thyroid therapy; to maintain a separate logbook of all antigen injections; to maintain copies of proposed clinical studies, research projects, IRB proposals, phase 1 and 2 studies/results, and any on-going or proposed research projects; and to pay an administrative penalty of \$15,000. The

action was based on inadequate patient consent, lack of disclosure to patients, and possible adverse reactions to certain therapies utilized by Respondent.

B. Upon the recommendation of the Board's representatives and with the consent of Respondent, the Board makes the following Findings and Conclusions of Law and enters this Agreed Order.

### FINDINGS

The Board finds the following:

A. General Findings:

1. Respondent received all notice required by law. All jurisdictional requirements have been satisfied. Respondent waives any defect in notice and any further right to notice or hearing under the Medical Practice Act, Title 3, Subtitle B, Texas Occupations Code (the "Act") or the Rules of the Board.
2. Respondent currently holds Texas Medical License No. E-1255. Respondent was originally licensed on January 19, 1974.
3. Respondent is primarily engaged in the practice of allergy and immunology. Respondent is not board certified.
4. Respondent is 69 years of age.

B. Specific Board Findings:

5. Patient Care and informed Consent:
  - a. The Respondent treated one patient with sublingual drops. The patient suffered an adverse reaction.
  - b. The Respondent's informed consent did not disclose that anaphylaxis shock was could occur using this type of therapy.
  - c. The informed consent provided to the patient failed to disclose the treatment had not been FDA approved. The Respondent used a consent approved in the 2005 Order; however this 2005 consent was not sufficient as the more specific FDA language in the 2007 Order.

6. Improper Relationships:
  - a. The Respondent did enter into a sexual relationship with one patient.
  - b. The patient was also Respondent's employee, with whom he had had a long-term professional relationship prior to commencement of the personal or physician/patient relationship. After the physician/patient relation began Respondent improperly continued the business and personal relationship, including the investment in a South American business.
7. Impairment: The Respondent affirmed he suffers from bi-polar disorder, but there was no indication of impairment due this condition.
8. Violations of the 2007 Agreed Order:
  - a. The Panel found that Respondent violated the terms and conditions of the 2007 Agreed Order related to required disclosures described therein.
  - b. Respondent's informed consent forms and materials did not disclose: the treatments, therapies, and formulations used by Respondent were not FDA approved; the treatments, therapies, and formulations have not been tested for effectiveness; the Respondent did not disclose all the ingredients in his formulations, including designation of the "therapeutic" ingredients; statements in support of the effectiveness of the treatments, made by patients, were the subjective opinion of that patient; and Respondent failed to maintain signed acknowledgement of disclosures from the patients.

#### CONCLUSIONS OF LAW

Based on the above Findings, the Board concludes that:

1. The Board has jurisdiction over the subject matter and Respondent pursuant to the Act.
2. 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 §164.052 of the Act.
3. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board rule; to wit: Board Rule 165.1 requiring the maintenance of adequate medical records.

4. Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, as further defined by: Board Rule; Board Rule 190.8(1)(C), failure to use proper diligence in one's professional practice; and Board Rule 190.8(1)(K), prescription or administration of a drug in a manner not in compliance with Chapter 200 related to Complimentary and Alternative medicine.

5. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public, as further defined by Board Rule 190.8(2)(A), violating a Board Rule; and 190.8(2)(G), becoming financially or personally involved with a patient in an improper manner.

6. 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.

7. Section 164.002(a) of the Act authorizes the Board to resolve and make a disposition of this matter through an Agreed Order.

#### ORDER

Based on the above Findings and Conclusions of Law, the Board ORDERS that Respondent's Texas license is hereby subject to the following terms and conditions:

This Agreed Order shall constitute a PUBLIC REPRIMAND of Respondent, and Respondent is hereby reprimanded.

1. Within one year from the date of the entry of this Order, Respondent shall enroll in and successfully complete the professional boundaries course offered by University of California San Diego Physician Assessment and Clinical Education (PACE) program or an equivalent course approved in advance by the Executive Director. To obtain approval for a course other than PACE courses, Respondent shall submit in writing to the Compliance Division of the Board information on the course that includes description of the course content, faculty, course location, and dates of instruction. Respondent shall submit documentation of attendance and successful completion of this requirement to the Compliance Division of the Board on or before the expiration of the time limit set forth for completion of the course.

2. Within one year from the date of the entry of this Order, Respondent shall enroll in and successfully complete the medical recordkeeping course offered by the University of

California San Diego Physician Assessment and Clinical Education (PACE) program, or an equivalent course approved in advance by the Executive Director. To obtain approval for a course other than the PACE course, Respondent shall submit in writing to the Compliance Division of the Board information on the course, to include at least a reasonably detailed description of the course content, faculty, course location, and dates of instruction. Respondent shall submit documentation of attendance and successful completion of this requirement to the Compliance Division of the Board on or before the expiration of the time limit set forth for completion of the course.

3. Within one year following the date of the entry of this Order, Respondent shall take and pass with a score of 75 or above the Medical Jurisprudence Examination ("JP Exam") given by the Texas Medical Board. Respondent is allowed three attempts to successfully pass each of these examinations.

Respondent's failure to take and pass the JP Exam within three attempts within one year following the date of the entry of this Order shall constitute a violation of this Agreed Order. After a committee of the Board or a panel of Board representatives (Board Representatives), has considered the information related to Respondent's violation of this provision and has determined that Respondent has not fulfilled the requirements of this provision, Respondent's medical license shall be **IMMEDIATELY SUSPENDED** pursuant to correspondence to Respondent from the Executive Director or Secretary-Treasurer of the Board indicating that Board Representatives have considered the information related to Respondent's violation of this provision and have determined that Respondent has not fulfilled the requirements of this provision. Although Respondent shall be invited to provide information or testimony to the Board Representatives, Respondent specifically waives any administrative due process under the Medical Practice Act, or the Administrative Procedure Act, for the Board Representatives to consider this information. **THIS SUSPENSION SHALL BE EFFECTIVE WITHOUT THE NEED FOR A HEARING AT THE STATE OFFICE OF ADMINISTRATIVE HEARINGS OR OTHER ADMINISTRATIVE DUE PROCESS UNDER THE MEDICAL PRACTICE ACT OR THE ADMINISTRATIVE PROCEDURE ACT, AND RESPONDENT SPECIFICALLY WAIVES ANY SUCH HEARING OR DUE PROCESS AND ALL RIGHTS OF APPEAL.** Respondent shall be notified of any suspension by certified mail, return receipt requested to Respondent's last known address on file with the Board. If

Respondent's license is suspended on such a basis, the suspension shall remain until such time as Respondent takes and passes the JP Exam and subsequently appears before the Board in person and provides sufficient evidence which, in the discretion of the Board, is adequate to show that Respondent possesses the skills and knowledge to safely practice in Texas and is otherwise physically and mentally competent to resume the practice in this state

4. Within one year from the date of the entry of this Order, Respondent shall obtain continuing medical education ("CME") approved for Category I credits by the American Medical Association, as follows: eight hours in the topic of ethics. The courses must be attended in person and shall be approved in writing in advance by the Compliance Division of the Board. To obtain approval for the courses, Respondent shall submit in writing to the Compliance Division of the Board information on the course, to include at least a reasonably detailed description of the course content and faculty, as well as the course location and dates of instruction. Respondent shall submit documentation of attendance and successful completion of this requirement to the Compliance Division of the Board on or before the expiration of the time limit set forth for completion of the course. These requirements are in addition to the minimum CME requirements for licensure renewal, and the requirement in Ordering Paragraph Nos. 1 and 2 above

5. Respondent shall continue his treatment concerning his bi-polar disorder. Respondent shall furnish a letter from his treating physician on an annual basis regarding his bi-polar treatment and status, and his continued ability to practice medicine safely. The annual report period shall be one year from the date of the entry of this order, and

6. Respondent shall within 30 days of the entry of this Order submit all of his written media, commercials, advertisement, consent forms, and other materials for review to the Compliance Division of the Board, to demonstrate they are in strict compliance with the provisions of the 2007 Agreed Order as it relates to disclosures.

7. Respondent shall pay an administrative penalty in the amount of \$3,000 within 60 days of the date of the entry of this Order. The administrative penalty shall be paid in a single payment by cashier's check or money order payable to the Texas Medical Board and shall be submitted to the Board for routing so as to be remitted to the Comptroller of Texas for deposit in the general revenue fund. Respondent's failure to pay the administrative penalty as ordered shall

constitute grounds for further disciplinary action by the Board, and may result in a referral by the Executive Director of the Board for collection by the Office of the Attorney General.

8. The time period of this Order shall be extended for any period of time that: (a) Respondent subsequently practices exclusively outside the State of Texas; (b) Respondent's license is subsequently cancelled for nonpayment of licensure fees; (c) this Order is stayed or enjoined by Court Order; or (d) for any period of time longer than 60 consecutive days that Respondent does not actively practice medicine. If Respondent leaves Texas to practice elsewhere or ceases active practice for more than 60 consecutive days, Respondent shall immediately notify the Board in writing. Upon Respondent's return to active practice or return to practice in Texas, Respondent shall notify the Board in writing. When the period of extension ends, Respondent shall be required to comply with the terms of this Order for the period of time remaining on the Order. Respondent shall pay all fees for reinstatement or renewal of a license covering the period of extension or tolling.

9. Respondent shall comply with all the provisions of the Act and other statutes regulating the Respondent's practice.

10. Respondent shall fully cooperate with the Board and the Board staff, including Board attorneys, investigators, compliance officers, consultants, and other employees or agents of the Board in any way involved in investigation, review, or monitoring associated with Respondent's compliance with this Order. Failure to fully cooperate shall constitute a violation of this order and a basis for disciplinary action against Respondent pursuant to the Act.

11. Respondent shall inform the Board in writing of any change of Respondent's office or mailing address within 10 days of the address change. This information shall be submitted to the Registration Department and the Compliance Department of the Board. Failure to provide such information in a timely manner shall constitute a basis for disciplinary action by the Board against Respondent pursuant to the Act. Respondent agrees that 10 days notice of a Probationer Show Compliance Proceeding to address any allegation of non-compliance of this Agreed Order is adequate and reasonable notice prior to the initiation of formal disciplinary action. Respondent waives the 30-day notice requirement provided by §164.003(b)(2) of the Medical Practice Act and agrees to 10 days notice, as provided in 22 Texas Administrative Code §187.44(4).



12. Respondent shall not be permitted to delegate prescriptive authority to a physician assistant or advanced nurse practitioner.

13. Any violation of the terms, conditions, or requirements of this Order by Respondent shall constitute unprofessional conduct likely to deceive or defraud the public, or to injure the public, and shall constitute a basis for disciplinary action by the Board against Respondent pursuant to the Act.

14. The above-referenced conditions shall continue in full force and effect, without opportunity for amendment, except for a clear error in drafting, for one year following the date of entry of this Order. If, after the passage of one-year period, Respondent wishes to seek amendment or termination of these conditions, Respondent may petition the Board in writing. The Board may inquire into the request and may, in its sole discretion, grant or deny the petition without further appeal or review. Petitions for modifying or terminating may be filed only once a year thereafter.


**RESPONDENT WAIVES ANY FURTHER HEARINGS OR APPEALS TO THE BOARD OR TO ANY COURT IN REGARD TO ALL TERMS AND CONDITIONS OF THIS AGREED ORDER. RESPONDENT AGREES THAT THIS IS A FINAL ORDER.**

**THIS ORDER IS A PUBLIC RECORD.**

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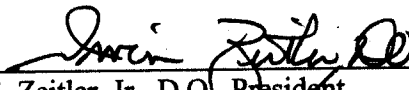
I, RUSSELL R. ROBY, M.D., HAVE READ AND UNDERSTAND THE FOREGOING AGREED ORDER. I UNDERSTAND THAT BY SIGNING, I WAIVE CERTAIN RIGHTS. I SIGN IT VOLUNTARILY. I UNDERSTAND THIS AGREED ORDER CONTAINS THE ENTIRE AGREEMENT AND THERE IS NO OTHER AGREEMENT OF ANY KIND, VERBAL, WRITTEN OR OTHERWISE.

DATED: 5-17, 2011.

A handwritten signature in black ink, appearing to read "Russell R. Roby MD", written over a horizontal line.

RUSSELL R. ROBY, M.D.  
Respondent

SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this  
3rd day of JUNE, 2011.

  
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Irvin E. Zeitler, Jr., D.O. President  
Texas Medical Board