

LICENSE NO. E-1255

IN THE MATTER OF THE

BEFORE THE

COMPLAINT AGAINST

RUSSELL R. ROBY, M.D.

TEXAS MEDICAL BOARD

MEDIATED AGREED ORDER

On December 15, 2005, Respondent appeared in person, with counsel Mike Sharp and Tony Cobos, at an Informal Show Compliance Proceeding and Settlement Conference ("ISC") in response to a letter of invitation from the staff of the Board. Nancy Leshikar represented Board staff. The Board's representatives were Melinda S. Fredricks, a member of the Board and Allan Shulkin, M.D., a member of the District Review Committee.

Respondent presented for a second ISC in January 2007. The complaint concerned treatment of certain patients with endocrine conditions and Respondent's use of sublingual drops in these patients. Scott M. Freshour represented Board Staff.

These matters did not settle, and Mr. Freshour filed a formal complaint at the State Office of Administrative Hearings ("SOAH"). Prior to this matter going to trial the parties agreed to attempt mediation. During the mediation a tentative settlement was reached.

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

FINDINGS OF FACT

The Board finds that:

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 issued this license to practice medicine in Texas on January 19, 1974. Respondent is not licensed to practice in any other state.

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

4. Respondent is 66 years of age.

5. Respondent has previously been the subject of disciplinary action by the Board. Respondent canceled his Texas license in 1983.

6. In December 1984, Respondent's Texas medical license was reinstated and placed Respondent on probation for a period of 10 years under certain terms and conditions including limits of his DEA authority.

7. In 1989, the 1984 Order was modified to require Respondent's to keep more thorough and accurate medical charts, and to complete 20 hours of Continuing Medical Education ("CME") in allergy and immunology.

8. In December of 2004, Respondent received a one-year order imposing a public reprimand, requiring a chart monitor, and requiring a revised informed consent form for use by Respondent.

9. The terms of that order were met and the order expired in December of 2005.

10. Respondent advertises through the internet and in television infomercials.

11. In that advertising, Respondent discusses a process he utilizes on patients referred to as "hormone neutralization," a process in which oral syringes are used to place a liquid dilution containing hormones under the patients' tongues.

12. The infomercials describe the use of the neutralization therapy on patients with various medical complaints ranging from viral colds, Temporal Mandibular Joint Dysfunction (TMJ), neck, back, elbow, and hip pain. Many of the patients testified to significantly reduced symptoms within five seconds of the sublingual drops.

13. 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.

14. Respondent claims that this therapy is successful in treating symptoms such as pain, weight gain, fatigue, loss of sex drive, short-term memory loss, migraines, asthma, and depression.

15. Respondent treated several patients with thyroid medication, and/or adrenal medication without adequate indication for such therapy based on laboratory testing.

16. In addition, a number of thyroid patients were treated with sublingual drops, without adequate indications or rationale for the treatment in the medical records.

17. Respondent medical records do not disclose the content of the sublingual drops used, but rather uses terms such as Vial 1, Vial 2 and/or Kit 1.

18. Respondent has cooperated in the investigation of the allegations related to this Agreed Order. Respondent's cooperation, through consent to this Agreed Order, pursuant to the provisions of Section 164.002 the Act, will save money and resources for the State of Texas. To avoid further investigation, hearings, and the expense and inconvenience of litigation, Respondent agrees to the entry of this Agreed Order and to comply with its terms and conditions.

CONCLUSIONS OF LAW

Based on the above Findings of Fact, 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 Section 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 rule adopted under this Act, to wit; Board Rule 164.3 that 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; 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; or makes a representation that is designed to take advantage of the fears or emotions of a particularly susceptible type of patient.

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.
5. 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.
6. 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 of Fact and Conclusions of Law, the Board ORDERS that Respondent shall be subject to the following terms and conditions for four years:

1. Respondent shall be required to provide the following in any and all infomercials/ paid advertisements/commercials (collectively called "infomercials" for purposes of this order):
 - a. At the start of all infomercials a full page screen message stating that sublingual drops/therapy being used by Dr. Roby are not FDA approved, and that this therapy is experimental. A continuous ticker at bottom of infomercials, explaining that sublingual drops/therapy being used by Dr. Roby are not FDA approved, and that this therapy is alternative/complementary.
 - b. When interviewing physicians, or presenting endorsement of physicians or other professionals, disclose that the physician/professional being interviewed or providing the endorsement is part of Dr. Roby's practice, if applicable, or is being paid/compensated for the appearance or endorsement.
 - c. Between each testimonial of each patient insert full page disclosure- Stating that there is inadequate medical/scientific research that using these drops reverses chronic conditions such as bone on bone pain, and that pain relief is not the same as curing a disease/condition.
 - d. Between each testimonial of each patient insert full page disclosure that states the pain scale used is subjective, and all relief claimed by patients is subjective

opinion/statement of the patient's perception, and is not verified by any objective testing.

- e. Disclose that the patient testimonials are actual interviews/office visits in which the patient has signed a HIPPA release, or in the alternative that the patient encounter is being staged to recreate the events of the actual visits that previously occurred.
- f. All disclaimers in a-e above shall be stated verbally at the start of the infomercial and at each time any disclosure is displayed during the course of the infomercial.

These requirements must be included in any and all new infomercials before their releasing or airing. Respondent shall be required to add these disclosures to all existing infomercials within 90 days of the signing of this order by the president of the board.

2. In all printed material released or distributed by Respondent and/or the Roby Institute shall include the following:

- a. A disclaimer that formulations prescribed by you and/or the Roby Institute physicians are not FDA approved.
- b. A disclaimer that formulations prescribed by you and/or the Roby Institute physicians, have never been tested for by the FDA for determination of the actual contents or the medical effectiveness of the formulations.
- c. A statement that formulations prescribed by you and/or the Roby Institute physicians are considered alternative/complementary treatment.
- d. Provide handout to each patient before prescribing, administering, or providing sublingual drops that contains a disclosure sheet(s) listing the formulation content by ingredient percentages from the most to least for each and every kit or vial offered by the you and/or the Roby Institute. This listing shall include a clear designation of the "therapeutic" ingredient(s) in the formulation.
- e. Disclose in bold print that any express or implied statement as to favorable outcomes from sublingual drops used in hormone allergy treatments or treatments based on "hormone neutralization" are based on the subjective statement/opinion of patient, and have not been verified by any type of objective testing.

These disclaimers/statements must be included in all printed materials within 90 days of the signing of this order by the president of the board.

3. Respondent must have patient sign and keep in the medical record a copy of an acknowledgment that the patient received and was given detailed disclosure regarding the content of the printed material described #2 immediately above.

4. Respondent's practice shall be monitored from date of the date of the assignment of a Board Compliance Officer, by a physician ("monitor"), in accordance with §164.001(b)(7) of the Act. The Compliance Division of the Board shall designate the monitor and may change the monitor at any

time for any reason. The monitor shall have expertise in a similar specialty area as Respondent, including alternative/complementary experience. The Compliance Division shall provide a copy of this Order to the monitor, together with other information necessary to assist the monitor.

- A. As requested by the Compliance Division, Respondent shall prepare and provide complete legible copies of selected patient medical and billing records ("selected records"). The Compliance Division shall select records for at least 30 patients seen by Respondent during each three-month period following the last day of the month of entry of this Order ("reporting period"). The Compliance Division may select records for more than 30 patients, up to 10% of the patients seen during a reporting period. If Respondent fails to see at least 30 patients during any three-month period, the term of this Order shall be extended until Respondent can submit a sufficient number of records for a monitor to review.
- B. The monitor shall perform the following duties:
 - a. Personally review the selected records.
 - b. Prepare written reports documenting any perceived deficiencies and any recommendations to improve Respondent's practice of medicine or assist in the ongoing monitoring process. Reports shall be submitted as requested by the Compliance Division; and
 - c. Perform any other duty that the Compliance Division determines will assist the effective monitoring of Respondent's practice.

5. The Compliance Division shall provide to Respondent a copy of any deficiencies or recommendations submitted by the monitor. Respondent shall implement the recommendations as directed by the Compliance Division.

6. The monitor shall be the agent of the Board, but shall be compensated by the Respondent through the Board. Such compensation and any costs incurred by the monitor shall be paid by Respondent to the Board and remitted by the Board to the monitor. Respondent shall not charge the compensation and costs paid to the monitor to any patient.

7. Respondent shall within one year from the entry of this order attend the following CME course, Intensive Course in Medical Record Keeping sponsored by the PACE Program. The classes shall be attended in person. These hours are in addition to the annual minimum requirements.

Respondent shall submit documentation of attendance and completion of this course within 60 days of completion.

8. Respondent shall within one year from the entry of this order attend six hours of medical ethics. The hours shall be attended in person. These hours are in addition to the annual minimum requirements. Respondent shall submit documentation of attendance and completion of this course within 60 days of completion.

9. Respondent shall not treat any patient with thyroid therapy.

10. The Respondent shall maintain separate from the medical records, a separate logbook for each patient of all antigen injections given to that patient. This logbook shall include the date given, the type of injection, the strength of the injection, and the basis for the injection/desensitization.

11. Respondent shall provide copies of all proposed clinical studies, research projects, IRB proposals, phase 1 and 2 studies/results, and any on-going or proposed research projects.

12. Respondent shall pay an administrative penalty in the amount of \$ 15,000 within 180 days 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 Director of Compliance for 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.

13. Respondent shall be permitted to supervise and delegate prescriptive authority to physician assistants and advanced practice nurses and to supervise surgical assistants.

14. The time period of this Order shall be extended for any period of time that (a) Respondent subsequently resides or practices outside the State of Texas, (b) Respondent's license is subsequently canceled for nonpayment of licensure fees, or (c) this Order is stayed or enjoined by Court Order. If Respondent leaves Texas to live or practice elsewhere, Respondent shall immediately notify the Board in writing of the dates of Respondent's departure from and subsequent return to Texas. 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 extended Order. Respondent shall pay all fees for reinstatement or renewal of a license covering the period of extension.

15. Respondent shall comply with all the provisions of the Act and other statutes regulating the

Respondent's practice.

16. 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.

18. Respondent shall inform the Board in writing of any change of Respondent's mailing or practice address within ten days of the address change. This information shall be submitted to the Permits Department and the Director of Compliance for 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.

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

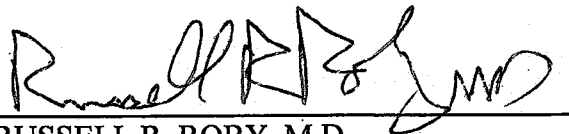
19. The above-referenced conditions shall continue in full force and effect without opportunity for amendment, except for clear error in drafting, for 12 months following entry of this Order. If, after the passage of the 12-month period, Respondent wishes to seek amendment or termination of these conditions, 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.

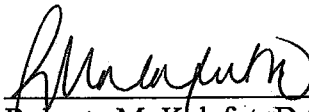
I, RUSSELL R. ROBY, M.D., HAVE READ AND UNDERSTAND THE FOREGOING AGREED ORDER. I UNDERSTAND THAT BY SIGNING, I WAIVE CERTAIN RIGHTS. I SIGN IT VOLUNTARILY. I UNDERSTAND THIS AGREED ORDER CONTAINS THE ENTIRE AGREEMENT AND THERE IS NO OTHER AGREEMENT OF ANY KIND, VERBAL, WRITTEN OR OTHERWISE.

DATED: 7-17, 2007.



RUSSELL R. ROBY, M.D.
Respondent

SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this 24th day of August, 2007.



Roberta M. Kalafut, D.O., President
Texas Medical Board