

SOAH DOCKET NO. 503-12-8054.MD
LICENSE NO. E-1255

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

BEFORE THE
TEXAS MEDICAL BOARD

FINAL ORDER

During an open meeting at Austin, Texas, the Texas Medical Board (Board) finds that the above-styled case was assigned to Administrative Law Judge Joanne Summerhays (ALJ) of the State Office of Administrative Hearings, who presided over the hearing on the merits, which was held January 7, 2015. The ALJ issued a Proposal for Decision (PFD) on February 12, 2015, that contained findings of fact and conclusions of law. The PFD was properly served on all parties, and all parties were given an opportunity to file exceptions and replies as part of the record herein. No exceptions were filed.

The Board, after review and due consideration of the PFD, adopts the Findings of Fact and Conclusions of Law of the ALJ.

I. FINDINGS OF FACT

1. Russell Roby, M.D., is licensed as a physician by the Texas Medical Board (Board) under License No. E-1255, which was originally issued on January 19, 1974.
2. On December 3, 2014, the Board's staff (Staff) filed the notice of hearing in this matter. The notice contained a statement of the legal authority and jurisdiction under which the hearing was to be held, a reference to the particular sections of the statutes and rules involved, and a short, plain statement of the matters asserted.
3. Dr. Roby received adequate notice of the hearing, including its time, place, and nature.
4. The hearing convened before Administrative Law Judge Joanne Summerhays on January 7, 2015, at the State Office of Administrative Hearings (SOAH), William P. Clements State Office Building, 300 West 15th Street, Fourth Floor, Austin, Texas. Attorneys Trina Richardson and Chris Palazola represented Staff. Dr. Roby appeared *pro se*. The record closed on January 22, 2015, upon the receipt of the written transcript.

5. On August 24, 2007, the Board and Dr. Roby entered into a Mediated Agreed Order (2007 Order) disciplining Dr. Roby's license.
6. One of the provisions of the 2007 Order required Dr. Roby's practice to be monitored by a physician (Monitor) on a quarterly basis. Dr. Roby was required to implement any recommendations made by the Monitor.
7. The Monitor provided Dr. Roby with a report dated June 2011, which contained recommendations for Dr. Roby to implement regarding his records and patient treatment. The same recommendations were included in another Monitor's report dated December 2011.
8. In addition, the 2007 Order required that Respondent include a disclaimer (Disclaimer) on all printed material released or distributed by him or the Roby Institute. The Disclaimer required, among other terms, a statement that the "formulations prescribed by Dr. Roby and/or the Roby Institute physicians have never been tested by the FDA for determination of the actual contents or the medical effectiveness of the formulations."
9. Dr. Roby failed to comply with the provisions of the 2007 Order, in that he did not comply with the recommendations of the Monitor and he did not include the disclaimer on all printed materials released or distributed by him or the Roby Institute.

Aggravating factors

10. Dr. Roby has been subject to previous disciplinary actions by the Board:
 - a) On April 10, 1983, the Board entered an Order of Temporary Suspension of Medical License.
 - b) On June 10, 1983, the Board entered an Order of the Board, which canceled Dr. Roby's medical license at his request.
 - c) On December 1, 1984, the Board entered an Order of the Board (1984 Order), which reinstated Dr. Roby's license and placed him on probation for a period of ten years.
 - d) On July 28, 1989, Board entered an order modifying the 1984 Order by requiring Dr. Roby to adhere to additional requirements, based on findings that Dr. Roby's medical recordkeeping and recording of test results were inaccurate, and that he failed to properly treat one patient.
 - e) The 1984 Order, as modified, terminated on June 18, 1990.
 - f) On December 10, 2004, the Board entered an Agreed Order publicly reprimanding Dr. Roby and requiring him to have a practice monitor for 12 months and implementation of a revised informed consent form. The

action was based upon Dr. Roby's failure to obtain informed consent from one patient. This order expired in December of 2005.

g) On June 3, 2011, the Board entered an Agreed Order publicly reprimanding Dr. Roby and imposing the terms and conditions including continuing education, treatment of mental disorders, and an administrative penalty. The Board Order recited that the action was based upon Dr. Roby's failure to obtain informed consent, his unprofessional conduct, and his violation of the 2007 Order.

11. Dr. Roby engaged in a prior similar violation, *i.e.*, violating the 2007 Order.
12. Dr. Roby knowingly failed to include the Disclaimer on all materials distributed by him or the Roby Institute.

Mitigating Factors

13. In addition to the 2007 Order, Dr. Roby signed two other agreed orders, one in 2004 and one in 2011, as described above. In addition, he admitted the violations of the 2007 Order alleged in this case.
14. Dr. Roby fulfilled the requirements of two previous orders, resulting in their expiration or termination by the Board.

II. CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter. Tex. Occ. Code (Code) Title 3, Subchapter B.
2. SOAH has jurisdiction over the hearing in this proceeding, including the authority to issue a proposal for decision with proposed findings of fact and conclusions of law. Tex. Gov't Code ch. 2003.
3. Notice of the hearing on the merits was provided as required by the Texas Medical Practice Act and by the Administrative Procedure Act. Code § 164.007(a); Tex. Gov't Code §§ 2001.051, .052.
4. Staff had the burden of showing by a preponderance of the evidence that Dr. Roby is subject to disciplinary action by the Board and any aggravating factors the Board may consider in determining the appropriate sanction against Dr. Roby. 1 Tex. Admin. Code § 155.427.
5. Dr. Roby had the burden of showing by a preponderance of the evidence any mitigating factors the Board may consider in determining the appropriate sanction against Dr. Roby. 1 Tex. Admin. Code § 155.427.

6. The Board is authorized to take disciplinary action against a licensed physician who violates a Board rule or sections 164.051 through 164.054 of the Code. Code § 164.001(a), (b).
7. The Board may take disciplinary action against a person if the person engages in unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public. Code §§ 164.051(a)(1), .052(a)(5).
8. Unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public includes the failure to comply with a Board order. 22 Tex. Admin. Code § 190.8(2)(A).
9. By failing to comply with the 2007 Order, Dr. Roby engaged in unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public. Code § 164.052(a)(5); 22 Tex. Admin. Code § 190.8(2)(A).
10. The Board may consider as aggravating factors that may warrant more severe or restrictive action: previous disciplinary actions, prior similar violation, and knowing violation. 22 Tex. Admin. Code § 190.15(a).
11. The Board may consider as mitigating factors that may warrant less severe or restrictive action: rehabilitative potential, acknowledgement of wrong doing, and entry into agreed orders. 22 Tex. Admin. Code §§ 190.14(1), (9), .15(b).

ORDER

The Board hereby adopts the Findings of Fact and Conclusions of Law as proposed by the ALJ and ORDERS the following:

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 used by Respondent are not FDA approved, and that this therapy is experimental. The infomercials must have a continuous ticker across the bottom explaining that sublingual drops/therapy being used by Respondent are not FDA approved, and that this therapy is alternative /complimentary.
 - b. When interviewing physicians, or presenting endorsements of physicians or other professionals, Respondent must 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/endorsement.
 - c. Between each testimonial of each patient insert a 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 stating that relieving pain is not the same as curing a disease/condition.

- d. Between each testimonial of each patient insert a full page disclosure that states the pain scale used is subjective, and relief claimed by each patient is a subjective opinion/statement of the patient's perception, and is not verified by any objective testing.
- e. Disclose that the patient testimonial is an 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 found in a-e of this Ordering Paragraph, shall be stated verbally at the start of the infomercials and each time any disclosure is displayed during the course of the infomercial.

These requirements must be included in any and all new infomercials before being released, aired, or presented to the public. 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. All printed material released or distributed by Respondent and/or the Roby Institute shall include the following:
 - a. A disclaimer that formulations prescribed by Respondent and/or the Roby Institute physicians are not FDA approved.
 - b. A disclaimer that formulations prescribed by Respondent 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 Respondent and/or the Roby Institute physicians are considered alternative/complimentary treatments.
 - d. Provide a 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 Respondent 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 the individual 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 each patient sign and Respondent must 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 in Ordering Paragraph 2.
4. In addition to patient medical records, Respondent shall maintain a separate logbook of all antigen injections given to each individual patient. This logbook shall include the date the antigen was given to the patient, the type of injection/administrations, the strength of the antigen, and the basis/rationale for the antigen.
5. Respondent shall provide the Board with copies of all proposed clinical studies, research projects, IRB proposals, phase 1 and 2 studies/results, and any ongoing or proposed research projects.
6. Respondent shall not treat any patient with thyroid therapy.
7. Respondent shall continue his treatment for his bipolar disorder. Within 60 days from the date of the entry of this Order, Respondent shall furnish a letter (status letter) from his treating physician regarding Respondent's bipolar treatment and status, and his continued ability to practice medicine safely. Status letters shall then be provided to the Board on an annual basis.
8. Respondent shall be subject to consecutive monitoring cycles, (defined below). Respondent's practice shall be monitored 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. 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 five 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 five patients, up to 10 percent of the patients seen during a reporting period. If Respondent fails to see at least five 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:
 - i. Personally review the selected records;
 - ii. 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
 - iii. Perform any other duty that the Compliance Division determines will assist the effective monitoring of Respondent's practice.
- c. 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. If the chart monitor recommends that Respondent restrict or suspend his or her practice of medicine, Respondent shall be required to personally appear before a panel of Board representatives, upon written request mailed to Respondent's last known address on file with the Board at least 10 calendar days before the requested appearance date. Such appearance shall be for the purpose of consideration of the chart monitor's recommendations of restriction or suspension and held in accordance with 22 TEX. ADMIN. CODE, §187.44. Based upon the panel's findings and recommendations, the Board may modify this Order so that Respondent's practice is restricted or suspended, in accordance with the chart monitor's recommendations, or take any other action that may be appropriate to resolve the issues presented.
- d. 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 patients.

- e. A "monitoring cycle" begins when the Compliance Division selects patient records for review, and concludes when Respondent receives the monitor's report for that group of records and has made payment for the costs of that monitoring cycle.

Respondent shall personally appear before the Board, a committee of the Board, or a panel of Board representatives, upon written request mailed to Respondent's last known address on file with the Board at least 10 calendar days before the requested appearance date. Such appearances shall be for the purpose of reporting on and addressing issues related to Respondent's compliance with the terms and conditions of this Order.

9. 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 Special Purpose Examination (SPEX) as promulgated by the Federation of State Medical Boards of the United States. Respondent is allowed three attempts to successfully pass this examination.

Respondent's failure to take and pass the SPEX 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 in effect until such time as Respondent takes and passes the SPEX 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.

10. Within one year from the date of the entry of this Order, Respondent shall enroll in and successfully complete at least 12 hours of continuing medical education (CME) approved for Category I credits by the American Medical Association in endocrinology, approved in writing in advance by the Executive Director or a designee. To obtain approval for the course, Respondent shall submit in writing to the Compliance Department 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 Department on or before the expiration of the time limit set forth for completion of the course. The CME requirements set forth in this paragraph shall be in addition to all other CME required for licensure maintenance.

11. Respondent's failure to substantially comply with any terms of this Order shall constitute a violation of this order. If the Board representatives at a Probationer Show Compliance proceeding determine that Respondent is in violation of the Order, pursuant to this provision, the Board representatives may direct the Executive Director to immediately **SUSPEND** Respondent's medical license. **THIS SUSPENSION SHALL BE EFFECTIVE IMMEDIATELY WITHOUT THE NEED FOR A FORMAL**

HEARING BEFORE THE BOARD, A PANEL OF THE BOARD, OR THE STATE OFFICE OF ADMINISTRATIVE HEARINGS OR OTHER ADMINISTRATIVE DUE PROCESS UNDER THE MEDICAL PRACTICE ACT OR THE ADMINISTRATIVE PROCEDURE ACT. RESPONDENT WAIVES ANY SUCH HEARING OR ANY SUCH DUE PROCESS AND ALL RIGHTS OF APPEAL IN REGARD TO THE SUSPENSION.

12. If Respondent's license is suspended under this provision, a Board representative shall file a formal complaint under Section 164.005 of the Medical Practice Act as soon as practicable, alleging the violations of this Order under this provision and seeking such disciplinary action as may be appropriate. The formal complaint may also include allegations of other violations of this Order and other violations of the Medical Practice Act. The parties may resolve the issues by an agreed order, either before or after the filing of a formal complaint. **RESPONDENT DOES NOT WAIVE AND SPECIFICALLY RESERVES THE RIGHT TO A HEARING BEFORE THE STATE OFFICE OF ADMINISTRATIVE HEARINGS, WITH ALL RIGHTS PROVIDED BY THE MEDICAL PRACTICE ACT OR THE ADMINISTRATIVE PROCEDURE ACT AND THE RIGHT TO SEEK JUDICIAL REVIEW OF THE FINAL ORDER.**
13. This Order supersedes all previous Board orders.
14. At all times while Respondent is under the terms of this Order, Respondent shall give a copy of this Order to all hospitals, nursing homes, treatment facilities, and other health care entities where Respondent has privileges, has pending an application for privileges, applies for privileges, or otherwise practices. Within 30 days of being first contacted by the Compliance Division of the Board following entry of this Order, Respondent shall provide to the Compliance Division of the Board documentation, including proof of delivery, that the Order was delivered to all such facilities.

15. Respondent shall not be permitted to supervise and delegate prescriptive authority to physician assistants and advanced practice nurses and to supervise surgical assistants.
16. 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.
17. Respondent shall comply with all the provisions of the Act and other statutes regulating the Respondent's practice.
18. 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.
19. 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

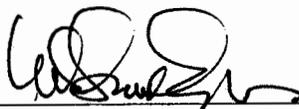
prior to the initiation of formal disciplinary action. Respondent waives the 30-day notice requirement provided by §164.003(b)(2) of the Medical Practice Act and agrees to 10 days' notice, as provided in 22 Texas Administrative Code §187.44(4).

20. 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.
21. The above-referenced conditions shall continue in full force and effect without opportunity for amendment, except for clear error in drafting, for one year following the date of the entry of this Order. If, after the passage of the 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.

THIS ORDER IS A PUBLIC RECORD.

SIGNATURE PAGE TO FOLLOW

SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this
10th day of April, 2015.



Michael Arambula, M.D., Pharm. D., President
Texas Medical Board