

IN THE MATTER OF  
THE LICENSE OF  
ALFRED RAYMOND JOHNSON, D.O.

BEFORE THE  
TEXAS MEDICAL BOARD

MEDIATED AGREED ORDER

On the 9th day of April, 2010, came on to be heard before the Texas Medical Board (the "Board"), duly in session, the matter of the license of Alfred Raymond Johnson, D.O., ("Respondent").

On May 22, 2007, Respondent appeared in person, with counsel, Mike Sharp and Tony Cobos, at an Informal Show Compliance Proceeding and Settlement Conference in response to a letter of invitation from the staff of the Board. Mark Martyn and Scott M. Freshour represented Board staff. The Board's representatives were Lawrence Anderson, M.D., a member of the Board, and Noe Fernandez, a member of a District Review Committee.

The matter did not settle at the ISC, and the Board 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. Board members Allan Shulkin, M.D., and Annette Raggette, along with Board attorney Scott M. Freshour represented the Board during the mediation. Settlement was not reached as a result of the mediation. Respondent subsequently had a change of counsel to Tim Weitz. Thereafter, negotiations were renewed and resulted in this Mediated Agreed Order.

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 Mediated 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. F-8525. Respondent was originally issued this license to practice medicine in Texas on December 3, 1980. Respondent is licensed in Florida, Missouri, and Oklahoma.

3. Respondent is primarily engaged in the practice of environmental medicine, and internal medicine. Respondent is trained in the area of internal medicine. He is not board certified in internal medicine.

4. Respondent is 61 years of age.

5. Respondent has not previously been the subject of disciplinary action by the Board.

6. The issues before the Board concern Respondent's use of intra-dermal injections of extract of diesel and auto fumes to desensitize Patient No. 1 for reported allergies to vehicle exhaust and the lack of adequate documentation and laboratory results to clearly support the related diagnosis for use of intramuscular gamma globulin in Patient No. 2.

7. There was a lack of documented informed consent from Patient No. 1 for the treatment provided by the Respondent. Respondent did not document disclosure to Patient No. 1 of: (a) the concentration of the diesel fume extract in the formulation; (b) the components comprising the extract; (c) the fact that his treatment was experimental therapy; and, (d) the fact that the therapy is not FDA-approved.

8. Tests performed on the extracts used by Respondent showed that the amount of actual extract in the injections was less than parts per billion, but was detectable by gas chromatography and mass spectrometer.

9. There is limited evidence that there is any therapeutic benefit derived from the use of this therapy.

10. Respondent maintains that this extract was collected in accordance with the standard allergy extraction protocol. Respondent further maintains that this treatment was used only on a trial basis after the patient failed to respond to other treatments by Respondent and other physicians.

11. There has been no identifiable patient harm from Respondent's treatment.

12. Patient No. 2 has claimed to have been helped by use of the intramuscular gamma globulin.

13. Respondent does not agree with the adverse Findings of Fact and Conclusions of Law set forth herein. Respondent denies any violation of the Act. Respondent has cooperated in the investigation of the allegations related to this Agreed Order to avoid further lengthy and costly litigation. Respondent's cooperation, through consent to this Mediated 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 Mediated 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)(6) of the Act, as defined by Board Rule 190.9(1)(I), authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to obtain adequate informed consent from a patient.

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, specifically Board Rule 165, related to maintaining adequate medical records.

4. 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.

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

6. Section 164.002(d) of the Act provides that this Agreed Order is a settlement agreement under the Texas Rules of Evidence for purposes of civil litigation.

### ORDER

Based on the above Findings of Fact and Conclusions of Law, the Board ORDERS that Respondent is subject to the following terms and conditions:

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

1. Upon entry of this Order, Respondent shall begin utilizing the revised Informed Consent Form incorporated herein as Attachment A. The revised Informed Consent Form shall be provided to each and every patient who will undergo desensitization/antigen therapy for chemical sensitivity ("Therapy") by Respondent that is non-commercial, as defined by Ordering Paragraph No. 7 below.

2. For each and every patient who will undergo desensitization/antigen therapy for chemical sensitivity ("Therapy") by Respondent that is non-commercial, as defined by Ordering Paragraph No. 7 below, Respondent shall have each patient sign a copy of Attachment B, which is incorporated herein, and is an acknowledgment that the patient has received and was given a detailed disclosure regarding the content of the printed material described in Attachment A referenced in Ordering Paragraph No. 1 immediately above. Respondent must keep the signed acknowledgement in the medical record of each patient and an additional copy separate and apart from the medical records as required by Ordering Paragraph No. 4, below. This

acknowledgment is specifically applicable only to Respondent and his practice involving the Therapy noted herein, above.

3. Upon approval of this Agreed Order, Respondent shall separately track or otherwise segregate charts involving Respondent's use of the Therapy noted herein, above, so as to be able to track outcome trends, identify recurrent side effects and complications, and provide ready access to these charts in the event of a future related investigation of the Board.

4. From the date of this Agreed Order, separate from individual patient records and in addition to, Respondent shall maintain complete legible copies of all patient Informed Consent Forms and signed acknowledgments completed by patients receiving antigen/desensitization therapy for chemical sensitivities (Therapy). These additional copies shall be made available to the Compliance Division upon request to verify compliance with the requirements of Ordering Paragraph Nos. 1 and 2 above related to content and patient acknowledgment of the revised Informed Consent Form.

5. Respondent shall maintain medical records on all patients in a manner consistent with the Act and the Board's rules as may be amended or changed from time-to-time. The record on each patient shall contain: the medical rationale for all diagnostic testing ordered; the interpretation of diagnostic testing performed; and any subsequent diagnosis and treatment modalities provided, if any, including the use of the Therapy and/or a decision not to provide treatment.

6. Within one year of the entry of this Order the Respondent shall be required to obtain at least 10 hours of Category I Continuing Medical Education (CME) in the area of allergy/immunology and at least 8 hours of Category I Continuing Medical Education (CME) in the area of medical record keeping. The classes shall be attended in person. The CME credits shall be approved as Category I CME credits by the American Medical Association or the American Osteopathic Medical Association. The CME credits required herein are in addition to the bi-annual minimum requirements for licensure. Respondent shall submit documentation of

attendance and completion of these hours on or before the anniversary date of the date of the entry of this Order.

7. Additionally, within two years from the date of the entry of this Order, Respondent shall enroll in and successfully complete at least a 14-hour Certification Board Review Course in Allergy and Immunology. This review course shall be in addition to the bi-annual minimum requirements for licensure. Respondent shall submit documentation of attendance and completion of these hours on or before the second anniversary date of the date of the entry of this Order.

8. The 18 hours of Category I CME referenced in ordering paragraph number 6, above, and the 14-hour Certification Board Review Course in Allergy and Immunology referenced in ordering paragraph number 7, above, shall be approved in writing in advance by the Compliance Division of the Board. To obtain approval, Respondent shall submit in writing to the Compliance Division of the Board information on the course or courses to include at least a reasonably detailed description of the course content and faculty as well as the course location and dates of instruction.

9. Respondent shall, within 60 days of the date of the entry of this Order, submit a list of Therapy that Respondent utilizes in his medical practice. This list shall designate those extracts used in Therapy that are commercially available, and those that are non-commercial. Commercially available for purpose of this provision shall mean: extracts that are produced in a licensed production facility, and extracts are FDA approved specifically for use as an allergy injection to treat chemical sensitivity. For commercially available extracts the list shall include the name and address of the manufacturer of the extract, and any brochure/catalog provided by a manufacturer and/or distributor of the extract.

10. Respondent shall include in every patient's medical record who receives the Therapy that is non-commercial, a notation by name or otherwise which allows for immediate cross-referencing to the corresponding written protocol of Respondent regarding the antigen formulation used and the revised Informed Consent as required in ordering Paragraph No. 1 above. The written protocol shall be maintained in Respondent's office and be available for review by Respondent's staff, patients, and Board staff. The written protocol provided by

Respondent shall at a minimum include: a written description of the source material (where the material is from, who collected the material, how it was collected, shipping labels/information, producer of the material, and the country or point of origin of the material if applicable); the type of process used to obtain the final product provided to the patient; the solvents/methods used to extract the antigens from the collecting filters/median; the purification processes; and, the quality control standards used in the extracting and formulation processes.

11. Respondent shall pay an administrative penalty in the amount of \$4,500 within 90 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.

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

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

14. 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.

15. 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.

16. 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).

17. 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.

16. 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 the entry of the 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, ALFRED RAYMOND JOHNSON, D.O., 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: 3/1, 2010.

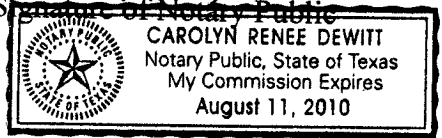
*Alfred R. Johnson D.O.*  
ALFRED RAYMOND JOHNSON, D.O.  
Respondent

STATE OF TEXAS  
COUNTY OF DALLAS

§  
§  
§

SWORN TO AND ACKNOWLEDGED BEFORE ME, the undersigned Notary Public, on this 1st day of MARCH, 2010.

(Notary Seal)

*Carolyn Renee Dewitt*  
Signature of Notary Public  


SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this 9th day of April, 2010.

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

ATTACHMENT A

**PATIENT INFORMED CONSENT**  
**NON-COMMERCIAL DESENSITIZATION/ANTIGEN**  
**THERAPY FOR CHEMICAL SENSITIVITY**

By the affixing of my signature below, I hereby acknowledge on behalf of myself as the patient or as the authorized guardian of the patient, that \_\_\_\_\_ has been advised and understands that the therapy being offered and being accepted is desensitization/antigen therapy for chemical sensitivity ("Therapy"). It is further acknowledged and understood that the Therapy is non-commercial. In addition, I have been advised of the following information about the Therapy

- (1) The Therapy being offered is not FDA approved, and is considered experimental medicine;
- (2) The medical/scientific proof of effectiveness/therapeutic value of the Therapy is disputed;
- (3) The formulations prescribed or administered are not FDA approved;
- (4) The formulations prescribed or administered have never been tested by the FDA for determination of the actual contents or the medical effectiveness;
- (5) The formulations prescribed or administered may contain material listed by the EPA as hazardous substances, and are known to be possible carcinogens;
- (6) The Therapy may contain a toxin, carcinogen, potential toxin or hazardous substance; however, the amount of the hazardous substance and/or carcinogen is less than the human exposure level listed by the EPA, and/or the Agency for Toxic Substance Registration & Disease Registry; and,
- (7) The ingredients of the Therapy are attached to show the formulation's content by individual ingredient percentages (both active and inactive) from the most to least for each and every antigen, intra-dermal injection, formulation, kit or vial for the Therapy to be administered or prescribed for the treatment of "chemical sensitivity." See attached.

\_\_\_\_\_  
Signature of Patient or Guardian

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Typed or Printed Name

\_\_\_\_\_  
Typed or Printed Name

\_\_\_\_\_  
Date

**THE TREATMENT/ANITGEN THERAPY BEING UTILIZED AND DESCRIBED IN THIS DISCLOSURE STATEMENT IS NOT ENDORSED, APPROVED, ACCEPTED, RECOMMENDED OR SUPPORTED BY THE TEXAS MEDICAL BOARD.**

ATTACHMENT B

**PATIENT ACKNOWLEDGMENT OF RECEIPT OF DISCLOSURE:  
INFORMED CONSENT FOR NON-COMMERCIAL  
DESENSITIZATION/ANTIGEN THERAPY FOR  
CHEMICAL SENSITIVITY**

By the affixing of my signature below, I hereby acknowledge on behalf of myself as the patient or as the authorized guardian of the patient, that \_\_\_\_\_, was given and received a detailed disclosure in an informed consent document regarding non-commercial desensitization/antigen therapy for chemical sensitivity ("Therapy").

It is further acknowledged and confirmed that the disclosure was in writing and included the content and ingredients of the Therapy as well as statements that the Therapy and formulation being offered are not FDA approved, and are considered experimental medicine. The disclosure also included statements that the medical/scientific proof of effectiveness/therapeutic value of the Therapy is disputed, and that the formulations prescribed or administered have never been tested by the FDA for determination of the actual contents or the medical effectiveness. It was further disclosed in writing that the formulations prescribed or administered may contain material listed by the EPA as hazardous substances, and may contain toxins or possible carcinogens.

The disclosure included the following disclaimer in bold typeface:

**"THE TREATMENT/ANITGEN THERAPY BEING UTILIZED AND DESCRIBED IN THIS DISCLOSURE STATEMENT IS NOT ENDORSED, APPROVED, ACCEPTED, RECOMMENDED OR SUPPORTED BY THE TEXAS MEDICAL BOARD. "**

By signing below it is acknowledged that through these disclosures and the disclaimer, informed consent was obtained in a separately signed and more detailed document.

\_\_\_\_\_  
Signature of Patient or Guardian

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Typed or Printed Name

\_\_\_\_\_  
Typed or Printed Name

\_\_\_\_\_  
Date