

HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-06-2137
LICENSE NO. D-5986

IN THE MATTER OF THE
COMPLAINT AGAINST
LOUIS FERNAND FABRE, JR., 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 Louis Fernand Fabre, Jr, 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 D-5986, issued by the Board on August 27, 1969, 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 January 18, 2006, 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 performs medication clinical trials for pharmaceutical companies. On behalf of Zenith Goldline Pharmaceuticals, Respondent was the principal investigator for a clinical trial protocol for the medication Clozaril.

2. Clozaril is an anti-psychotic medication for severely ill schizophrenic patients who have failed to respond adequately to standard drug treatment for schizophrenia. Clozaril is not considered a "first-line" medication. Documentation regarding the use of this drug include warnings regarding the possible development of agranulocytosis, a medical condition where there is an insufficient number of white blood cells. Persons affected by agranulocytosis are susceptible to infections. Additional warnings for those using Clozaril include a risk of seizures and an increased risk of myocarditis. The risk of fatal myocarditis increases during the first month of treatment with Clozaril.

3. V.Z., a forty-seven year-old male (deceased), was referred to the Fabre Research Clinic by another patient for consideration to participate in the Clozaril study. V.Z. reported he was a Russian immigrant who had served in the Russian military. V.Z. reported having lived in

Houston since 1999. Ultimately, the identify of the patient as a Russian immigrant was questioned.

4. V.Z.'s initial screening, which determined his appropriateness for the study, was completed and V.Z. was diagnosed with schizophrenia by Respondent's employee, a licensed physician. This employee recorded that V.Z. had a "17 year history of auditory hallucinations and paranoid ideation." V.Z. reported having auditory hallucinations of many voices of men crying and a constant fear of violence directed toward him. In a questionnaire completed by the patient, V.Z. reported he had been hospitalized at the Keiv Military District Hospital in 1987, diagnosis and treatment unknown. Notwithstanding the patient's indications to the contrary, the patient's medical history at Respondent's clinic reflected no prior history of any known medical problems and no history of past or current medications. Respondent's employee documented that the patient had no history of hospitalization or medication. There is no indication in the record that Respondent attempted to verify V.Z.'s past medical history or obtain past medical records.

5. Based on the history given above, V.Z. was diagnosed with schizophrenia by Respondent's employee and deemed appropriate for participation in the Clozaril study. V.Z. contracted to be reimbursed \$900 for his participation in this study. As a participant, the patient was to be administered Clozaril in a monitored environment. Per research protocol, vital signs were taken twice daily and an adverse event log was kept on the patient.

6. A physical examination, dated April 8, 2002, was completed on the patient. It is difficult to ascertain who completed the examination or the credentials of the person completing the examination due to illegible hand-writing. It does appear that Respondent validated the physical examination via his signature; however, there is no indication Respondent examined the patient.

7. On April 8, 2002, the patient's initial screening indicated the patient had a blood pressure of 132/98 with a pulse of 60 beats per minute. The patient's baseline electrocardiogram was interpreted as normal.

8. On Day One of the study (April 11, 2002), the patient's blood pressure ranged from 110/78 to 143/74. The patient's heart rate ranged from 78 to 107 beats per minute.

9. On Day One of the study (April 11, 2002), the patient developed tachycardia with a pulse rate greater than 100 beats per minute.

10. On Day Ten of the study (April 20, 2002), the patient developed diarrhea.

11. On Day 11 of the study (April 21, 2002), the patient developed chills and a fever with a temperature of 101.2 degrees Fahrenheit.

12. Per drug study protocol, a complete blood count was drawn on Day Fourteen of the study, April 24, 2002. The laboratory values indicated the patient had elevated neutrophils. Respondent signed and dated the lab four days later. The medical record indicates no planned intervention. The Clozaril was continued as ordered.

13. On Day Sixteen of the study (April 26, 2002), the patient again developed diarrhea, and various treatment interventions, such as fluid replacement, were utilized. Respondent determined that the patient's diarrhea was "unrelated to the study drug," and Clozaril was continued. The patient's electrolytes were ordered, and one of Respondent's employees interpreted the lab results as not clinically significant, although the laboratory findings indicated low levels of Sodium, Chloride, Potassium, and Calcium. The patient's blood glucose and Creatinine were elevated.

14. On Day Twenty-two of the study (May 2, 2002), the patient's electrolytes were abnormal, and Respondent discontinued the Clozaril. An electrocardiogram revealed sinus tachycardia and abnormalities that suggested significantly compromised cardiac health. Respondent determined that the patient's sinus tachycardia was possibly related to the drug study.

15. The patient's final dose of Clozaril was at 8:10 a.m. on May 2, 2002.

16. On Day Twenty-three of the study (May 3, 2002), the patient was found unresponsive. Cardiopulmonary resuscitation was initiated; however, the patient expired. Autopsy results found the cause of death to be myocarditis, a known risk of the medication Clozaril.

17. A chronological review of the patient's vital signs taken during the study show that the patient's pulse rate was greater than 100 beats per minute from Day 1 of the study until the patient's death on Day 23 of the study. There is no documentation in the medical record that Respondent or his staff were concerned about the patient's tachycardia. No additional evaluations or assessments were completed.

18. Respondent's direct observation and assessment of the patient were limited. As documented in the medical record, Respondent validated assessments or observations by staff

members via his signature in the record; however, Respondent does not document any first-hand assessments or observations of the patient. Respondent's only hand-written Progress Note occurred on May 3, 2002, and that document details only the fact that the patient was found unresponsive and the patient ultimately died. Respondent documented it was probable that the patient had suffered a myocardial infarction that was not related to the medication Clozaril.

19. Outside of the initial evaluation done by an employee physician that determined V.Z. appropriate for the clinical study and Respondent's limited documentation in the medical record, the majority of care and decision making for the patient was made by registered nurses and an unlicensed person with medical training from Mexico. The patient's medical record indicated that Respondent did not adequately supervise these individuals to whom he delegated duties as evidence by Respondent's lack of documentation in the medical record and lack of first-hand, direct assessment of the patient.

20. The Food and Drug Administration investigated Fabre Research Clinics, Inc. in October 2002, to evaluate their research activities and to assure that the rights, safety, and welfare of human subjects was being protected. Allegations against Fabre Research Clinics, Inc. included that the Clinic had failed to conduct clinical trials in accordance with federal law and had failed to protect the rights, safety, and welfare of the subjects and that Respondent had failed to adequately supervise the clinical investigation and had submitted false information in his reports regarding adverse events during the drug study. The Food and Drug Administration sent Respondent a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain dated January 19, 2005.

21. Respondent violated the standard of care by failing to adequately evaluate the patient for inclusion in the study because it is questionable if the patient met the criteria for a diagnosis of schizophrenia; for lack of response to the patient's deteriorating medical condition, and failing to adequately supervise delegates under Respondent's authority.

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 164.052(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.
2. 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 manner consistent with public health and welfare.
3. Sections 164.052(a)(5) and 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's prescribing or administering a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.
4. Section 164.053(a)(8) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to supervise adequately the activities of those acting under Respondent's supervision.
5. Section 164.053(a)(9) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent delegating professional medical responsibility or acts to a person whom Respondent knew or had reason to know

was not qualified by training, experience, or licensure to perform the responsibility or acts.

6. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 165, which requires the maintenance of adequate medical records.
7. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 190.8(1)(A), failure to treat a patient according to the generally accepted standard of care.
8. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 190.8(1)(B), negligence in performing medical services.
9. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 190.8(1)(C), failure to use diligence in one's professional practice.
10. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Board Rule 190.8(1)(D), failure to safeguard against potential complications.
11. Section 164.051(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of Section 164.052.

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 sets forth statutory requirements for the amount and basis of 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 factor present in this case includes the severity of patient harm.

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: *Nancy Leshikar*

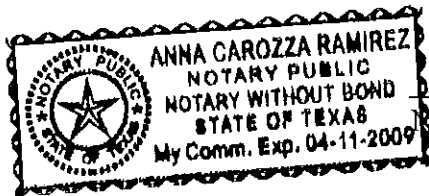
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THE STATE OF TEXAS

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COUNTY OF TRAVIS

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



Anna Carozza Ramirez
Notary Public, State of Texas

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

Jerry Walker
Jerry Walker
Deputy Executive Director
Texas Medical Board