HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-14-1342.MD
TEXAS MEDICAL LICENSE NO. D9377

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| IN THE MATTER OF THE | BEFORE THE |
| COMPLAINT AGAINST | |
| STANISLAW R. BURZYNSKI, M.D. | 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 and presided over by Administrative Law Judges (ALJ) Catherine Egan and Roy Scudday of the State Office of Administrative Hearings. The hearing on the merits convened on November 19-25, 2015, January 19, 2016, and May 3-12, 2016, in the William P. Clements Building, 300 West 15th St., Austin, Texas.[1] Attorneys Lee Bukstein, Amy Swanholm, Barbara Jordan, and Christopher Palazola represented Staff.[2] Attorneys Dan Cogdell, J. Dennis Hester, J. Gregory Myers, and Melanie Rubinsky represented Respondent. The ALJs issued a Proposal for Decision (PFD) on October 12, 2016, 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. Board Staff and Respondent both filed Exceptions and Replies to Exceptions. On December 21, 2016, the ALJs issued a letter regarding the Exceptions and Replies to Exceptions which amended the previously issued Findings of Fact and Conclusions of Law.

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

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[1] During the proceeding, Dr. Burzynski's cardiac health issues required a delay in reconvening the hearing from January 19 to May 2016. On May 3, 2016, ALJ Egan had to leave the hearing due to a family emergency. The parties elected to proceed with the hearing with the understanding that ALJ Egan would read the transcript for that portion of the hearing that she was unable to attend. ALJ Egan affirmed she read the May 3, 2016 transcript.

[2] Mr. Bukstein was Board Staff's lead counsel for this matter, but retired from the Texas Medical Board (Board) on January 19, 2016. Ms. Swanholm took over as Staff's lead counsel after his retirement.

## FINDINGS OF FACT

### *Factual Background*

1. Stanley Burzynski, M.D. (Respondent or Dr. Burzynski) is a physician who holds Texas Medical License No. D-9377 that was issued by the Texas Medical Board (Board) in 1973.

2. Respondent graduated from medical school in 1967, and received a biochemist doctorate in 1968 before immigrating to the United States in 1970.

3. Between 1970 and 1977, Respondent worked at Baylor College of Medicine doing cancer research.

4. In 1977, Respondent opened the Burzynski Clinic (Clinic), a private medical practice in Houston, Texas, to treat cancer patients.

5. Respondent is not a board-certified oncologist, although he has treated cancer patients for almost 40 years.

### *Procedural History*

6. Staff of the Board (Staff) filed the initial Complaint in this contested case on December 11, 2013, which was subsequently amended twice. The Second Amended Complaint (Complaint) filed on November 14, 2014, contains Staff's notice of the allegations against Respondent.

7. On August 21, 2014, Respondent filed a motion for summary disposition requesting that Staff's claims relating to alleged violations of federal regulations be dismissed.

8. Order No. 7 issued on September 10, 2014, granting Respondent's motion in part, held that Staff's alleged violations of non-criminal FDA-regulations pertaining to clinical studies of investigational new drugs are not subject to disciplinary action by the Board under 22 Texas Administrative Code (TAC) § 190.8(2)(R).

9. On September 24, 2015, Staff mailed the notice of hearing to Respondent. The notice of hearing contained a statement of the time, place, and nature of the hearing; 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 factual matters asserted.

10. Respondent received adequate notice of the hearing, including its time, place, and nature.

11. The hearing on the merits convened on November 19 through 20, and 23 through 25, 2015, January 19, and May 3 through 6, and 9 through 12, 2016, before Administrative Law Judges Catherine Egan and Roy G. Scudday in the William P. Clements Building, 300 West 15th St., Austin, Texas. Attorneys Lee Bukstein, Amy Swanholm, Barbara Jordan, and Christopher Palazola represented Staff. Attorneys Dan Cogdell, J. Dennis Hester, J. Gregory Myers, and Melanie Rubinsky represented Respondent. The record closed on August 15, 2016, with the filing of the parties' closing arguments and highlighted exhibits.

***The Clinic During the Relevant Period***

12. The Clinic employed about 150 people, including three board-certified oncologists (Drs. Jai Joshi, Jose Valladares, and Zanhua Yi), two internists (Drs. Robert Weaver and Gregory Burzynski), one family practitioner (Dr. Alejandro Marquis), and several research associates who were unlicensed foreign-trained doctors.

13. In the beginning of 1990, Respondent began providing gene-oriented treatment with personalized treatment to the Clinic's cancer patients. This purpose of this approach was to treat the cause of the cancer, abnormal genes, instead of the type of cancer.

14. Approximately 95% of the Clinic's cancer patients had terminal diagnoses, many of whom had tried other treatment protocols without success.

15. Each patient at the Clinic was assigned a team of health care providers that included an oncologist, either an internist or family practitioner, and a research associate, all of whom met with the patient and Respondent at the initial consultation to discuss the proposed treatment plan.

***Burzynski Research Institute/Institutional Review Board***

16. In 1993, the Federal Drug Administration (FDA) approved a clinical trial for the investigational drug antineoplaston (ANP) in the treatment of cancer patients. Over the years, Respondent has engaged in 65 prospective clinical trials and one retrospective clinical trial.

17. The Burzynski Research Institute (BRI), of which Respondent is the president and 80% owner of the shares, was created in 1983 to be involved in basic and clinical research on ANP and to sponsor FDA-approved clinical trials.

18. The Institutional Review Board (IRB) was also created in 1983 to supervise the ethical conduct of clinical studies by approving or disapproving clinical trial protocols; approving or disapproving patient participation in clinical trials pursuant to those protocols; collecting data on the toxicity and the response of the investigational agent; and evaluating data on the efficacy of the investigational agent.

19. Neither Respondent nor any of the Clinic's employees are members of the IRB.

***Standard of Care***

20. In September 2010, Patient A, a 67-year-old man, was given a preliminary diagnosis of Stage IV colon cancer with metastases to the liver. This type of cancer is uniformly fatal, with the medium survival rate being approximately five months.

21. Patient A declined the conventional cancer treatment of surgery and chemotherapy.

22. Patient A had an initial consultation at the Clinic on October 7, 2010.

23. Patient A was treated by the Clinic from October 2010 through October 2011, and died on November 4, 2011.

24. Patient B was a 56-year-old man from the Ukraine who was diagnosed on December 12, 2010, with glioblastoma, grade IV, a fast-growing, aggressive central nervous system tumor that forms on the supportive tissue of the brain.

25. Patient B had debulking surgery on December 20, 2010 to remove as much of the tumor as possible, but rejected the conventional treatment of radiation therapy and chemotherapy with Temodar (temozolomide).

26. On February 7, 2011, Patient B travelled from Germany to the Clinic with his personal physician, Dr. Demetri Brandt, to meet with Respondent.

27. After discussing various treatment options, Patient B and Dr. Brandt elected to follow Respondent's recommended treatment.

28. From February 7 through March 4, 2011, Patient B was treated at the Clinic with medications as directed by the Clinic's oncologist, Dr. Valladares, that included sodium phenylbutyrate (PB), Votrient, Avastin, and Tarceva.

29. On March 4, 2011, Patient B left the Clinic and went to Germany, where Dr. Brandt began treating Patient B with ANP.

30. On July 6 through 7, 2011, based on Respondent's recommendation, Patient B was

administered Afinitor, Sprycel, and Nexavar while under Dr. Brandt's care.

31. Dr. Brandt stopped treating Patient B with ANP at the end of September 2011. Patient B died on December 18, 2011.

32. In 1986, Patient C was a 42-year-old man who was diagnosed with Stage II A Nodular sclerosing Hodgkin's disease for which surgical and radiotherapy were successful.

33. On April 19, 2010, Patient C was diagnosed with cancer in his left lung.

34. Although Patient C's local oncologist recommended chemotherapy, Patient C chose to consult with the Clinic on May 11, 2010.

35. After the initial consultation among Patient C, Respondent, and Dr. Joshi, Patient C was treated at the Clinic from May 14 through 20, 2010, with a regimen of PB, Tarceva, Nexavar, Avastin, and Decadron (dexamethasone).

36. On May 20, 2010, Patient C left the Clinic and returned to his home, where he was under the care of his personal oncologist, Dr. Thomas Waits, who continued the treatment protocol begun at the Clinic until October 2011, when Dr. Waits chose to no longer continue the recommended treatments.

37. Patient D, a 28-year-old male, was diagnosed on May 13, 2010, with brain cancer (pleomorphic xanthoastrocytoma, grade II) for which he had a surgical resection.

38. Imaging studies taken on November 26, 2010, showed that Patient D had new lesions in his brain and spine.

39. On January 10, 2011, Patient D's oncologist recommended chemotherapy treatment with Temodar and radiation. This treatment was continued through April 6, 2011, until it was stopped because Patient D was experiencing adverse reactions to the treatment.

40. On June 7, 2011, Patient D visited the Clinic for a consultation.

41. On July 1, 2011, Patient D declined to follow Respondent's treatment recommendations and left the Clinic.

42. Patient D never received treatment at the Clinic.

43. Patient E, a 67-year-old male, had chromophobic type renal cell carcinoma (kidney cancer) with multiple recurrences.

44. On September 7, 2011, Patient E had an initial consultation at the Clinic.

45. At Respondent's recommendation, Patient E began treatment with the following medications: PB on September 8, 2011; Xgeva on September 13, 2011; Afinitor on September 14, 2011; and Sutent on September 15, 2011.

46. Patient E ceased treatments by the Clinic on October 16, 2011.

47. On September 21, 2009, Patient F, a 66-year-old male, was diagnosed with pancreatic cancer.

48. Although Patient F's local oncologist recommended chemotherapy treatment, Patient F and his wife chose to consult with Respondent and the treatment team at the Clinic on October 8, 2009.

49. Patient F was treated at the Clinic from October 8 through November 11, 2009, with a regimen of PB, Rapamune, Zolinza, Nexavar, Xeloda, and Avastin.

50. Patient F discontinued the treatment on November 11, 2009, due to financial constraints.

51. Patient G, a 26-year-old woman, was diagnosed on July 5, 2012, with suprasellar mass brain cancer and malignant astrocytoma of the optic nerve.

52. Patient G underwent surgery on August 3, 2012, and was treated by her local oncologist with Avastin on August 24, 2012.

53. Patient G's oncologist recommended that, after surgery, she be treated with radiation therapy and Temodar, but explained the radiation would probably cause her to go blind.

54. Patient G consulted with the Clinic on August 31, 2012.

55. Patient G was ineligible to participate in a clinical trial for ANP because she had previously received chemotherapy.

56. On September 6, 2012, the FDA and IRB approved Patient G for a single-patient protocol to receive ANP.

57. From September 12 to November 26, 2012 Patient G was treated with ANP, but the treatment was discontinued because Patient G experienced consistent problems of edema in her legs.

58. In December 2012, Patient G began conventional cancer treatment in her home town with radiation, Temodar, and Avastin. The patient's records indicate that she experienced edema, severe headaches, and other severe side effects, including a hospital admission with sepsis, while on conventional treatment.

59. There is insufficient evidence to establish that Respondent violated the standard of care by:

(a) failing to make Patients A through G aware of the potential toxicities of the combination of drugs;

(b) failing to provide adequate medical rationale for treatment of Patients A through G with ANP, PB, and/or the combined use of drugs;

(c) failing to provide adequate medical rationale for the evaluation, diagnosis, and treatment of Patients A through G; or

(d) with the exception of informed consent regarding the below-described treatment of Patient E, providing inadequate medical documentation for Patients A through G.

60. There is insufficient evidence that Respondent violated the standard of care in the treatment of Patients A, B, C, D, F, or G.

61. In a private practice setting, informed consent forms for each drug being used concurrently to treat cancer meet the standard of care where the risks of combining the drugs are unknown.

62. Prior to his treatment at the Clinic, Patient E had experienced toxicity with Votrient that had similar tyrosine kinase parameters as Sutent.

63. Between September 13 and 15, 2011, Patient E began treatment at the Clinic with PB, Xgeva, Afinitor, and Sutent.

64. According to the Clinic's informed consent form for Afinitor that was reviewed with Patient E, the "purpose of treatment" section stated that Afinitor was a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with Sutent.

65. Patient E was treated with Afinitor at the Clinic before he was treated with Sutent, after which the drugs were administered together, as directed by Respondent.

66. Administering Afinitor to Patient E before treating with Sutent, and then administering them together, was a deviation from the procedure indicated in the Afinitor informed consent form that Patient E signed.

67. There is no documentation in Patient E's medical records showing that Respondent explained, or had explained, to Patient E that the treatment protocol would deviate from

that set out in the Afinitor informed consent form.

68. Patient E did not have an opportunity to give his informed consent to using these two drugs, Afinitor and Sutent, in a manner different from that disclosed on the Afinitor informed consent form that he signed.

69. Because Respondent did not provide Patient E with a written explanation for the deviation in the treatment protocol set out in the Afinitor informed consent form, Patient E did not give his informed consent for being treated with Afinitor before Sutent or for the simultaneous use of both drugs.

70. Respondent's failure to ensure that Patient E received adequate information to explain that his treatment with Afinitor would be different from that disclosed in the informed consent form violated the standard of care.

***Inadequate Delegation and Improper Use Of Unlicensed Practitioners***

71. Respondent's son, Dr. Gregory Burzynski, is a board-certified internist licensed by the Board in January 2011.

72. Dr. Gregory Burzynski was responsible for treating internal medical problems that arose while a patient received cancer treatments at the Clinic.

73. Dr. Alejandro Marquis is a family physician licensed by the Board who worked at the Clinic from 2006 until 2014.

74. Dr. Gregory Burzynski and Dr. Marquis were responsible for assisting the treating oncologists in monitoring and communicating with Clinic patients, ensuring the Clinic received requested laboratory tests and scans in a timely manner, and managing any side effects a patient experienced from the drugs prescribed by the treating oncologists.

75. Dr. Gregory Burzynski and Dr. Marquis were qualified by training, experience, and licensure to perform the medical services they provided at the Clinic.

76. Respondent was responsible for the supervision of the Clinic's research associates, including Tolib Rakhmanov, Mohammed Khan, Larisa Tikhomirova, Sheryll Acelar, and Lourdes DeLeon.

***Tolib Rakhmanov***

77. RA Rakhmanov is an unlicensed foreign-trained doctor who worked at the Clinic as a research associate from 2006 to July 2016.

78. RA Rakhmanov's job duties at the Clinic included collecting the patient's medical history,

obtaining the patient's prior medical records, reviewing the informed consent forms with patients who elected to be treated at the Clinic, and communicating with the patient and the patient's local oncologist once the patient returned home.

79. RA Rakhmanov did not conduct the patient's physical examinations or diagnose and treat patients.

80. In a medical setting, by taking patient histories, signing orders, reviewing laboratory results, communicating with the patients' local oncologists as "Dr. Rakhmanov," wearing a white lab coat with a name tag identifying himself as "Dr. Rakhmanov," being addressed at the Clinic as "Dr. Rakhmanov," and signing Clinic forms, including informed consent forms, as a physician, RA Rakhmanov represented himself to the public as a licensed physician authorized to practice medicine.

81. Respondent supervised RA Rakhmanov, delegated medical acts to RA Rakhmanov, and permitted him to be misrepresented as a person authorized to practice medicine.

82. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Rakhmanov to ensure that he did not misrepresent his licensure, either directly or indirectly, and he failed to do so.

83. Although RA Rakhmanov misrepresented that he was authorized to practice medicine, he only performed medical acts that he was qualified to perform and under a physician's supervision.

84. There is insufficient evidence to show that RA Rakhmanov engaged in the practice of medicine.

85. Respondent did not aid and abet RA Rakhmanov in the unlicensed practice of medicine.

***Mohammed Khan***

86. RA Khan, an unlicensed foreign-trained doctor, has been employed by the Clinic as a research associate since 1997.

87. Respondent was RA Khan's supervisor.

88. RA Khan worked as the Clinic's radiology technician and was not directly involved with the Clinic's patients.

89. RA Khan did not misrepresent to the public that he was authorized to practice medicine.

90. The Clinic does not take its own radiology scans, and when outside radiology films arrived at the Clinic, RA Kahn collected them, downloaded them into the computer, and

then showed them to the treating physicians.

91. Although RA Khan took tumor measurements from scans he downloaded into the computer, Respondent remeasured the tumors to verify the measurements.

92. Respondent dictated to RA Khan what he wanted included in the radiology reports so that RA Khan could prepare Respondent's written report.

93. The Clinic's physicians relied on their own review of the radiologic imaging and the official radiology report to make treatment decisions.

94. Respondent did not improperly delegate medical acts to RA Khan and did not aid and abet RA Khan in the unlicensed practice of medicine.

***Larisa Tikhomirova***

95. Larisa Tikhomirova, an unlicensed foreign-trained doctor, worked at the Clinic as a research associate from July 2009 to May 2012.

96. On February 7, 15, and 17, 2011, RA Tikhomirova signed Patient B's informed consents as the "Physician performing consent." She was identified on Patient B's laboratory results as a physician, and signed Clinic forms as the patient's physician, including a February 7, 2011 prescription for supplements and radiology orders issued on February 7 and March 4, 2011.

97. RA Tikhomirova signed the October 8, 2009 informed consent for Patient F's pretreatment evaluation statement as the physician, and initialed the Clinic's form entitled "Food Supplements" authorizing Patient F to have certain supplements.

98. Between October 9 through 15, 2009, RA Tikhomirova signed Patient F's informed consent forms for the drugs used in his treatment as the "Physician performing consent."

99. RA Tikhomirova misrepresented to Patients B and F that she was a physician authorized to practice medicine.

100. Respondent supervised and delegated medical acts to RA Tikhomirova and permitted her to be misrepresented to the public as a person authorized to practice medicine.

101. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Tikhomirova to ensure that she did not misrepresent her licensure, either directly or indirectly, and he failed to do so.

102. The medical acts that RA Tikhomirova performed were done under the supervision of a licensed physician.

103. Although RA Tikhomirova misrepresented to the public that she was authorized to practice medicine, there is insufficient evidence to establish that RA Tikhomirova was unqualified to perform the medical acts delegated to her by Respondent and the other licensed physicians.

104. There is insufficient evidence to show that RA Tikhomirova engaged in the practice of medicine.

105. Respondent did not aid and abet RA Tikhomirova in the unlicensed practice of medicine.

***Sheryll Acelar***

106. Sheryll Acelar, an unlicensed foreign-trained doctor, worked at the Clinic as a research associate from 2010 to 2014. At the Clinic, she was wore a white lab coat with a name tag identifying her as "Dr. Acelar," and was addressed by the Clinic staff as "Dr. Acelar."

107. RA Acelar's job duties included taking the patient histories, communicating with the patient, keeping records for Clinic physicians, ensuring that laboratory results were delivered to Clinic physicians, monitoring phone calls, and relaying messages about a patient's symptomatology in regards to the prescribed medications.

108. RA Acelar reviewed the informed consent forms for Patients C and G, including the Pretreatment Evaluation and for the drugs Avastin and PB, and then initialed the forms as a physician.

109. When RA Acelar communicated with Patient C's local oncologist, Dr. Waits, she identified herself as "Dr. Acelar."

110. Dr. Waits reasonably believed RA Acelar was the contact physician at the Clinic for Patient C, addressed her as "Dr. Acelar," and referred to her in written correspondence as "Sheryl Acelar, M.D."

111. On December 9, 2010, RA Acelar issued treatment orders in response to an email requesting permission to reduce the medication dosage that Patient C was receiving. She issued the treatment order to adjust this dosage without input from a licensed physician.

112. RA Acelar authorized Patient G's local oncologist to decrease her Decadron dosage and instructed the physician to put the patient back on ANP as soon as possible without instructions from a licensed physician to do so.

113. RA Acelar misrepresented to the public that she was authorized to practice medicine by signing informed consent forms as the patient's physician, issuing orders, adjusting dosages, and calling herself "Dr. Acelar."

114. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Acelar to ensure that she did not misrepresent her licensure, either directly or indirectly.

115. Respondent permitted RA Acelar to misrepresent to the public that she was a person authorized to practice medicine.

116. RA Acelar was unqualified by licensure to make adjustments to a patient's treatment.

117. Respondent failed to adequately supervise RA Acelar by permitting her to sign medical records in the space designated for the physician's signature and allowing her to make treatment decisions regarding Patients C and G.

118. Respondent aided and abetted RA Acelar in the unlicensed practice of medicine.

***Lourdes DeLeon***

119. Lourdes DeLeon, an unlicensed foreign-trained doctor, has worked as a research associate at the Clinic since 2005.

120. RA DeLeon wore a white lab coat with a name tag identifying her as "Dr. DeLeon," and signed consent forms and orders in the space designated for the physician's signature, but she told Patient E and other patients when she first met them that she was not licensed in the United States.

121. There is insufficient evidence that RA DeLeon misrepresented to the public that she was a person authorized to practice medicine. There is insufficient evidence to establish that RA DeLeon was unqualified to perform the medical acts that were delegated to her by Respondent and the other Clinic physicians.

122. Respondent did not fail to supervise RA DeLeon, did not improperly delegate medical acts to her, and did not aid and abet her in the unlicensed practice of medicine.

***Informed Consent***

123. The Clinic's pretreatment evaluation statements given to Patients A through C and E through G represented that the patient would "be asked to sign a treatment specific consent form indicating that [he] understands that particular treatment and that [he] wished to receive that treatment regimen."

124. After the treatment plans were established, Respondent failed to ensure Patients A through C and E through G received a more specific informed consent regarding the treatment plan to review and sign.

125. On February 9, 2011, Patient B received treatment with Avastin, before he signed the informed consent form for Avastin on February 17, 2011.

126. On October 14, 2009, Patient F began treatment with Avastin, but the informed consent form was signed on October 15, 2009.

127. Respondent did not ensure that Patients B and F reviewed and signed the informed consent form for Avastin prior to having administered Avastin to them.

128. After Patient C had returned home to Indiana, he was treated by his local oncologist, Dr. Waits.

129. While under Dr. Waits care, Patient C's medication was changed.

130. The evidence is insufficient to show that it was Respondent's responsibility to secure informed consent forms for new drugs administered to Patient C while he was in the care of Dr. Waits.

***Off-labeled Use of FDA-Approved Drugs***

131. There is insufficient evidence to show that Respondent violated the Texas Occupations Code (Code) or any Board rule by identifying in the informed consents what uses of a drug had FDA approval rather than stating that he was using the drug "off-label."

***Alternative Therapy or Clinical Trials***

132. The FDA is the regulatory agency with the authority to grant an application for a clinical trial and to make sure that the clinical trial is performed in compliance with the approved protocols and the FDA regulations.

133. The FDA approved the informed consent forms used by Respondent in the FDA-approved clinical trials.

134. Any issues regarding the Clinic's consent forms used for clinical trials have been remedied through the proper process and Respondent, BRI, and the FDA. The FDA's correspondence does not, without additional evidence, establish a violation of the Code or the Board rules.

***Disclosure of Ownership Interest in Pharmacies and Laboratory***

135. Respondent is the sole owner of Southern Family Pharmacy and SRB Pharmacy (the pharmacies).

136. Southern Family Pharmacy was located in the same building as the Clinic.

137. Patients who received care from Respondent had their medication prescriptions filled at the pharmacies.

138. Patients who were prescribed PB and ANP could only have their prescriptions filled at the pharmacies.

139. Respondent did not disclose to his patients his ownership interests in the pharmacies.

140. The failure of Respondent to disclose his ownership interest in Southern Family Pharmacy, which was located in the Clinic building, was unprofessional conduct.

141. The SR Burzynski Lab, owned by Respondent, conducted laboratory analyses of samples taken for patients treated by Respondent and Respondent's subordinates.

142. It is clear from the name SR Burzynski Lab that Respondent had some ownership interest in it.

143. The failure of Respondent to disclose his ownership interest in the laboratory was not unprofessional conduct.

***Improper Charges and Retainer Demands***

144. There is insufficient evidence to establish any improper charges were made by Respondent to Patients A, D, and F.

145. On February 7, 2011, Respondent charged Patient B $350 for prolonged physician services and $500 for prolonged service without contact.

146. On February 10, 2011, Respondent charged Patient B $125 for a visit with Dr. Gregory Burzynski.

147. On February 28 and March 2, 2011, Respondent charged Patient B $60 each for group health education.

148. Respondent failed to document adequate support for the above-described charges to Patient B.

149. Respondent charged Patient C $125 for each phone evaluation/maintenance held on June 23, July 2, July 13, July 27, August 10, August 17, August 23, September 27, and December 14, 2010, and August 31, 2011.

150. Respondent failed to document adequate support for the above-described charges to Patient C.

151. On September 10 and 11, 2011, Patient E was charged $95 each for after-hours medical services, and on September 16, 2011, Patient E was charged $100 for an office visit.

152. Respondent failed to document adequate support for the above-described charges to Patient E.

153. On September 16, and 23, 2012, Patient G was charged $95 each for after-hours medical services.

154. CPT Code No. 96416 requires that a nurse or other licensed health provider be continuously present when ANP is given to the patient through a pump.

155. On September 12, 2012, the medical records document that Patient G was charged $170 for a first infusion and $395 for a second infusion even though the records do not identify a health professional who was present during these two infusions.

156. From September 13 through 22, 2012, Patient G received infusions of ANP at the Clinic for which she was charged $395 under CPT Code 96416 even though the records do not identify a health professional who was present during the infusions.

157. Respondent improperly billed Patient G for infusion charges under CPT Code 96416 even though no nurse or other licensed health provider was documented as being continuously present when the ANP infusions were given to Patient G through a pump.

158. On September 29 through October 19, October 23 through 27, November 1, and November 5 through 14, 2012, Patient G self-administered the ANP infusions at home; they were not administered by a health professional at the Clinic.

159. Patient G was improperly charged $395 for each of the self-administered infusions under CPT Code 96416.

160. On September 12, 2012, Patient G was counseled by someone at the Clinic about birth control and appropriate diet while on ANP treatment, for which she was charged $60.

161. Patient G's Daily Worksheets documented that she attended ANP training from September 3 through 21, 2012, for which she was charged $60 per day of training.

162. These charges were coded as CPT Code 99078, the code to use when patients receive education from a physician in a group setting.

163. Respondent failed to document adequate support to show that a physician provided training to Patient G in a group setting.

164. Respondent failed to document adequate support for the above-described charges to Patient G.

165. The failure to document support for the above-described charges resulted in inadequate medical records for Patients B, C, E, and G.

***Deceptive Marketing and Advertising***

166. There is insufficient evidence to establish that Respondent used advertising statements that were false, misleading, or deceptive.

***Ethical and Professional Responsibilities In Clinical Trials***

167. Respondent was the principal investigator at the Clinic for all FDA-approved clinical trials.

168. Patients A through F were not participating in FDA-approved clinical trials.

169. Patient B was not treated with ANP at the Clinic.

170. There is insufficient evidence to show that Respondent failed to protect Patient G by failing to report adverse events from ANP treatments.

171. There is insufficient evidence to show that Respondent failed to protect Patient I in the clinical trial by failing to report Patient I's adverse events in compliance with the BT-10 protocol approved by the FDA.

172. There is insufficient evidence to show that Respondent inaccurately measured Patient I's tumor response to treatment in accordance with the BT-10 protocol approved by the FDA.

173. Respondent's classification of Patient J's response to treatment as "stable disease" (SD) was in compliance with Protocol BT-10.

174. The evidence is insufficient to establish that Respondent measured Patient J's lesions inaccurately or misrepresented the tumor's progression to the child's parents.

175. There is insufficient evidence to establish that Respondent misdiagnosed Patient N's cancer or that Respondent inaccurately reported the results of Patient N's imaging studies.

176. There is insufficient evidence to show that Patients O and P participated in a clinical study or that they received ANP.

177. There is insufficient evidence to establish that Respondent misrepresented Patient S's response to ANP or skewed the results of the tumor measurements.

178. There is insufficient evidence to show that the Clinic failed to properly train Patient T's parents on how to use the pump or that Respondent misrepresented Patient T's response to ANP by skewing the results of the tumor measurements.

179. Respondent inaccurately reported Patient Q's tumor measurements, causing the classification of the tumor's response to treatment to be in error and inaccurately reported the severity of Patient AA's adverse event.

180. There is insufficient evidence to establish that Respondent was required to report overdoses caused by operator errors or that he failed to report adverse events that occurred as required by the clinical study.

181. Respondent did not disclose in the informed consent forms given to patients in FDA-approved clinical trials the additional costs related to ANP treatment, but he did disclose this information before initiating treatment in the billing agreement signed by each patient.

182. Respondent did not engage in unprofessional and unethical conduct by disclosing before treatment the additional costs of participating in an ANP clinical trial in a treatment billing agreement rather than in the informed consent form.

183. There is insufficient evidence to establish that Respondent failed to adequately train his subordinates about adverse events and the need to document and report them to a licensed physician.

184. There is insufficient evidence to show that Respondent failed to train and retrain patients, their families, or the Clinic staff on proper pump use for ANP infusions.

185. Respondent considered and reported the impact of Patient G's taking of corticosteroids on her treatment.

186. There is insufficient evidence to establish that Respondent failed to isolate the impact of corticosteroid use on Patient G's tumor.

187. Respondent informed Patient G of the additional costs that she might incur in her cancer treatment before she began receiving the treatment.

188. Except for Finding of Fact No. 179, the credible evidence failed to show that Respondent violated his ethical duty and responsibilities as a clinical investigator.

***Aggravating and Mitigating Factors***

189. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients suffered actual harm to their health by a violation of the standard of care or having inadequate records.

190. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were actually harmed by his failure to ensure that RAs Rakhmanov, Tikhomirova, and Acelar did not directly or indirectly represent to the public that they were authorized to practice medicine.

191. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were actually harmed by his allowing RA Acelar to practice medicine without a license.

192. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were economically harmed by his failure to disclose his ownership interest in the pharmacies.

193. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were economically harmed by his failure to have adequate medical records to support Clinic charges.

194. Based on the above-stated findings of fact, Respondent failed to obtain timely and/or adequate informed consent for more than one patient.

195. Based on the above-stated findings of fact, unless corrected for the future, the following actions by Respondent could represent potential harm to the public: (1) failing to ensure that research associates did not directly or indirectly represent to the public that they were authorized to practice medicine, (2) allowing a research associate to practice medicine without a license; (3) failing to disclose his ownership interest in the pharmacies; and (4) failing to have adequate medical records to support Clinic charges.

196. On August 31, 1994, the Board suspended Respondent's license for a period of ten years, but probated the suspension. The basis of the action was that Respondent had treated patients with ANP in violation of the laws in effect at that time and had made false advertisements about ANP.

197. Based on the above stated Findings of Fact, Respondent did not treat patients with ANP in violation of the laws in effect during the relevant time period and did not make false advertisements about ANP during the relevant time period. Accordingly, Respondent has not been disciplined by the Board for prior similar violations.

198. For almost 40 years, Respondent has devoted himself to treating terminally ill cancer patients who have either rejected conventional cancer treatments or had tried conventional treatments without success. Some of Respondent's treatments have become more accepted and mainstream.

199. If Respondent is unable to continue practicing medicine, critically ill cancer patients being treated with ANP under FDA-approved clinical trials or a special exception will no longer

have access to this treatment.

200. Respondent's continued practice in treating advanced cancer patients is a present value to the cancer community.

201. Respondent's treatments have saved the lives of cancer patients, both adults and children, who were not expected to live.

## CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Code title 3, subtitle B.

2. The State Office of Administrative Hearings 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, pursuant to Texas Government Code ch. 2003.

3. Respondent was adequately and timely apprised of the hearing and the factual allegations against him. Tex. Gov't Code §§ 2001.051-.052.

4. Staff had the burden of proving the elements of its case by a preponderance of the evidence, while Respondent had the burden of proving the elements of any claimed exemption under the law. 1 TAC § 155.427.

5. The Board has authority to take disciplinary action against a licensee who violates the statutes or rules regarding physicians, or has failed to practice medicine in an acceptable professional manner consistent with public health and welfare. Code § 164.051(3), (6).

6. Non-criminal FDA regulations pertaining to clinical studies of investigational new drugs are not subject to disciplinary action by the Board under 22 TAC § 190.8(2)(R).

7. Respondent is subject to sanction for failing to document the risk factors of, or explain the deviation from, the prescribed treatment plan, and to give Patient E the opportunity to give his informed consent to the simultaneous use of two specific drugs, in violation of 22 TAC §§ 165.1(a)(5), (7) and 190.8(1)(I).

8. Respondent is subject to sanction for failing to supervise RAs Rakhmanov, Tikhomirova, and Acelar to ensure that they did not represent to the public that they were authorized to practice medicine, in violation of Code §§ 164.052(a)(5) and 164.053(a)(8), (9).

9. Respondent is subject to sanction for aiding and abetting RA Acelar in the unlicensed practice of medicine, in violation of Code §§ 164.052(17) and 164.053(a)(9).

10. Respondent is subject to sanction for failing to give Patients A through C and E through

G a more specific informed consent form regarding the treatment plan to review and sign, and for failing to timely obtain informed consent for Avastin from Patients B and F, in violation of 22 TAC §§ 190.8(1)(G), (H) and (I) and 200.3(2).

11. Respondent is subject to sanction for failing to disclose his ownership interest in Southern Family Pharmacy, which was located in the Clinic building, to his patients in violation of 22 TAC § 190.8(2)(H).

12. Respondent is subject to sanction for failing to maintain adequate medical records to support charges to Patients B, C, and E, in violation of 22 TAC § 165.1(a)(9).

13. Respondent is subject to sanction for failing to maintain adequate medical records to support charges to Patient G, in violation of 22 TAC §§ 165.1(a)(9) and 190.8(2)(J).

14. Respondent is subject to sanction for inaccurately reporting Patient Q's tumor measurements, causing the classification of the tumor's response to treatment to be in error, in violation of 22 TAC § 200.3(7)(A).

## ORDER

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

1. Respondent's Texas license is hereby SUSPENDED for a period of five years; however, the suspension is STAYED and Respondent is placed on PROBATION under the following terms and conditions.

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

3. Respondent shall be subject to the following terms and conditions for 12 consecutive monitoring cycles, (defined below). Respondent's billing practice shall be monitored by a billing monitor (monitor), in accordance with the Act. The Compliance Division of the Board shall designate the monitor and may change the monitor at any time for any reason. 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 billing records, along with any medical records necessary to the review ("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 percent 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:

1) Personally review the selected records;

2) Prepare written reports documenting any perceived deficiencies and any recommendations to improve Respondent's billing practice or assist in the ongoing monitoring process. Reports shall be submitted as requested by the Compliance Division; and

3) 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 Respondent fails to implement any such recommendations, 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. Based upon the panel's findings and recommendations, the Board may modify this Order 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.

4. Within 30 days from the date of the entry of this Order, Respondent shall enroll in the ethics course offered by Colorado Physicians Education Program (CPEP) and successfully complete the CPEP ethics course within one year of the entry of this Order. Respondent shall submit documentation of attendance and successful completion of this requirement to the Compliance Division of the Board within 30 days of enrollment and 30 days of completion of the course.

5. Within 30 days from the date of the entry of this Order, Respondent shall submit all informed consent forms in use at his Clinic to the Medical Director of the Board for review. The informed consent forms must comply with Board statutes and rules, and include at a minimum the following information:

a. the specific treatment plan that each patient will be receiving; for any changes made to the treatment plan, Respondent, the patient's treating physicians at Respondent's clinic and the patient together must sign an updated consent form containing the amended treatment plan;

b. a statement listing the potential known and unknown risks and benefits of the treatment plan, a statement affirming that Respondent, the patient's treating physicians at Respondent's clinic, and the patient have discussed the potential risks and benefits of the treatment plan together, and signatures from all treating physicians at Respondent's clinic and the patient;

c. whether the medications and/or combinations of medications the patient will be receiving are approved by the FDA and/or will be administered in a manner that is approved by the FDA;

d. whether the treatment plan includes medications that are considered by the medical community to be chemotherapy drugs;

e. for those treatment plans where drugs will be used for a complimentary or alternative purpose, including the administration of sodium phenylbutyrate in nonstandard combinations with anti-cancer and chemotherapy drugs, Respondent shall include a written disclaimer in all caps stating that the therapeutic value of the therapy, if any, has not been established or proven and is subject to dispute;

f. the patient's complete financial obligations to Respondent's clinic, including any initial fees, monthly fees, a means for patients to dispute any charges,

Respondent's policy regarding payment from 3rd parties, nonprofits, and fundraising groups, and Respondent's policy for refunding any excess payments or improper charges;

g. a statement which clearly states what, if any, of Respondent's treatment plan could be covered by the patient's insurance;

Upon review and approval of the informed consent form, Respondent shall be required to present this form to each and every patient receiving medical care, or being evaluated at Respondent's clinic and obtain the patient's consent and signature prior to the prescription of any drugs or the billing of and receipt of any payment from the patient. This consent form shall be in addition to individual drug-specific consent forms. If the patient or patient's guardian does not speak English or is a non-native English speaker, this consent form shall be translated into and executed in the patient or guardian's native language. Respondent shall not bill any patient or patient representative for the cost of translation. Respondent, the patient's treating physicians at Respondent's clinic, and the patient shall all review, sign, and date the consent form together. This consent process may not be delegated to an unlicensed individual or anyone who is not a treating physician.

Respondent must provide a copy of the signed consent form to each patient, keep the signed consent form in the medical record of each patient, and keep an additional copy of the signed informed consent form in a separate file. The separate file, and any medical records as needed, shall be made available to the compliance division upon request to verify compliance with this ordering provision.

6. Within 30 days from the entry of this Order, Respondent shall submit an ownership interest disclosure form to the Board's Executive Director for review. This form shall disclose all associated facilities, laboratories, and pharmacies that Respondent and any physician employed by Respondent's clinic has an ownership interest in, as required by 22 Texas Administrative Code Section 190.8(2)(H).

Upon review and approval by the Board's Executive Director, Respondent or the patient's treating physician at Respondent's clinic shall present this form to each and every patient receiving medical care at Respondent's clinic, sign the form, and obtain the patient's signature prior to the billing of and receipt of any payment from the patient and prior to referral

to any entity in which Respondent and any treating physician at Respondent's clinic has an ownership interest.

This ownership interest disclosure form must be updated with the Board within 30 days of any change in ownership interest of any entity.

7. Within two years from the date of the entry of this Order, Respondent shall enroll in and successfully complete at least 72 hours of continuing medical education (CME) approved for Category I credits by the American Medical Association or the American Osteopathic Association in the following categories: 15 hours on the topic of informed consent, 14 hours on the topic of medical recordkeeping, 14 hours on the topic of risk management, 15 hours in supervision and delegation, 14 hours on the topic of patient communication, approved in writing in advance by the Board. 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.

8. 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 this examination. 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 Order.

9. Respondent shall pay an administrative penalty in the amount of $40,000 **(forty thousand dollars and no cents** within 60 days of the date of the entry of this Order. The administrative penalty shall be paid 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.

10. Respondent shall pay restitution in the amount of $20,000.00 **(twenty thousand dollars and no cents)** within 60 days of the date of the entry of this Order. The restitution shall be paid in a single payment by cashier's check or money order payable to the legal heirs of Patient G. Respondent's failure to pay restitution 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.

11. At all times while under 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 applied for privileges, applies for privileges, or otherwise practices. Within thirty days of 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.

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

13. 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.

14. 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 45-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).

15. 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.

16. The above-referenced conditions shall continue in full force and effect, without opportunity for amendment except for error in drafting, for two years following the date of entry of this Order. If, after the passage of two year period, Respondent wishes to seek amendment 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.

SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this 3rd day of March, 2017.

Sherif Zaafran, M.D., President
Texas Medical Board