SOAH DOCKET NO. 503-07-2498
TEXAS MEDICAL LICENSE NO. D-6119

IN THE MATTER OF THE	
COMPLAINT AGAINST	BEFORE THE
KENNETH W. O'NEAL, M.D.	TEXAS MEDICAL BOARD

FINAL ORDER

During open meeting on April 11, 2008, at Austin, Texas, the Texas Medical Board ("Board") finds that after proper and timely notice was given, the above-styled case was heard by an Administrative Law Judge ("ALJ") of the State Office of Administrative Hearings ("SOAH"). ALJ Paul Keeper presided over the case, and prepared a Proposal For Decision ("PFD"), containing proposed Findings of Fact and Conclusions of Law. The PFD was properly served on all parties, and all parties were given an opportunity to file exceptions and replies as part of the record herein. No exceptions to the PFD were filed.

The Board, after review and due consideration of the PFD adopts the Findings of Fact and Conclusions of Law of the ALJ, with the exception of Conclusion of Law No. 128, which is a sanction recommendation, not a Conclusion of Law. However, the Board believes the proposed sanction of the ALJ is appropriate, and hereby adopts it as the sanction of the Board.

FINDINGS OF FACT

1. Kenneth W. O'Neal, M.D., Respondent, is a Texas physician and holds Texas Medical License No. D-6119, issued by the Texas Medical Board (Board) on August 27, 1969.

2. Respondent is a solo general practitioner who practiced medicine in Abilene, Texas, doing business as Southwest Medical/Abilene Integrative Clinic.

3. Respondent used alternative medicine in his practice.

4. In 2005, Respondent held medical privileges at eleven rural or community hospitals.

5. Respondent worked as a contract physician in rural emergency rooms.

6. Between May 21 and August 3, 2005, Respondent's patients included KS, AP, DT, and WB.

7. Between May 21 and August 3, 2005, each of KS, AP, DT, and WB died shortly after receiving from Respondent an intravenous vitamin solution or chelation therapy.

Patient KS

8. Patient KS was an eighty-three year-old female with a history of pernicious anemia, asthma, bronchitis, heart problems (including congestive heart failure), obesity, peptic ulcer disease, hiatal hernia, polynephritis, hypothyroidism, chronic vaginitis, colonic polyps, astigmatism, irregular bowels, and cataracts.

9. KS began seeing Respondent as her physician in February 2005.

10. At the time of her initial visit with Respondent, KS was taking Spiriva and Foradil inhalers and attending pulmonary rehabilitation three times a week.

11. Respondent saw KS on March 9, 2005, May 4, 2005 and May 12, 2005.

12. During KS' first two office visits, Respondent made no record about KS' extensive medical history, recorded no physical examination, made no diagnoses, made no comments on the records of other practitioners, made no comments on KS' abnormal echocardiograms or EKG, and recorded no treatment plans.

13. During KS' office visits in May 2005, Respondent failed to comment on KS' abnormal blood pressure of 167/91 or respiratory rate of 20.

14. Laboratory tests were ordered without differential diagnoses.

15. KS stopped taking her pulmonary medications for a week without a respiratory assessment.

16. Respondent started KS on lithium aspartate without explanation and without notation of the dosage.

17. Respondent prescribed a variety of vitamins and supplements (including hydrogen peroxide, mushroom extracts, licorice, and oil of oregano) without discussion of their purpose.

18. During KS' office visit on June 2, 2005, KS presented with an elevated temperature, poor oxygen saturation, a respiratory rate of 36, and a heart rate of 46.

19. During the office visit, Respondent administered an intravenous Myer's cocktail.

20. Respondent's Formulary included Myers Cocktail as a combination of vitamin C, B-complex, magnesium sulfate, calcium gluconate, pyridoxine, methylcobalamine, folic acid, B5, Isotonic Quintin [sic], and normal saline.

21. "Quintin" [correctly spelled "quinton"] is a reference to sea water taken from a specific depth from special places in the sea.

22. Upon Respondent's administration of the intravenous Myer's Cocktail, KS began having increased distress, altered level of consciousness, cyanosis, and increased difficulty breathing.

23. KS then became tachypenic and then lost consciousness.

24. EMS personnel found KS to be pulseless, apneic, and diaphoretic.

25. Cardiopulmonary resuscitation was initiated, and emergency services were called.

26. Upon the arrival of the Abilene Fire Department at Respondent's office, KS had no respirations and no pulse.

27. KS was transported to Hendrick Medical Center where she was pronounced dead at 1250 hours with the cause of death identified as cardiopulmonary arrest.

28. No autopsy was performed on KS

Patient AP

29. AP was eighty-five years old when she first began treatment with Respondent on August 6, 2003.

30. AP had a medical history of severe, symptomatic aortic stenosis, congestive heart failure, and severe hypertension.

31. Between 2003 and 2005, AP received numerous intravenous infusions of various mixtures from Respondent. These solutions included: Freamine; an Immune Boost Mixture (IBM) mixture which, according to Respondent's Formulary, contained vitamins, magnesium sulfate, selinium, zinc, and Isotonic Quinitin; and Myers Cocktail.

32. On August 3, 2005, AP presented to Respondent and received an intravenous infusion of Freamine, IR, Taurine, NaCHO3, and IBM.

33. Ten minutes into the infusion, AP reported itching and experienced a drop in blood pressure to 80/40.

34. At 1420, AP complained of severe back pain and emergency services were called.

35. AP was transported to Hendrick Memorial Hospital via the Abilene Fire Department.

36. When AP arrived at the hospital, she was experiencing shortness of breath, diaphoresis, and mid-sternal pain.

37. AP had suffered a cardiovascular incident after receiving alternative medicine intervention from Respondent.

38. AP died at 1612 hours, and no autopsy was performed.

Patient DT

39. DT was a fifty-two year-old male when he first began treatment with Respondent on December 15, 2004.

40. DT had a history of severe hypertension and hyperlipidemia.

41. Other than taking DT's vital signs, there is no documentation that Respondent completed a physical examination on DT.

42. From December 15, 2004 through July 2, 2005, Respondent administered to DT twenty-two treatments of intravenous vitamins.

43. The majority of these intravenous vitamin treatments were identified by Respondent as following Respondent's "Chelation Protocol."

44. Respondent made only four narrative entries in the medical record about DT's twenty-two intravenous infusions.

45. On June 2, 2005, DT presented to Respondent's clinic for chelation treatment.

46. Prior to starting the treatment, DT told Respondent's staff he was nauseated, but the chelation treatment was administered as planned.

47. At 1550, shortly after the administration of the solution, DT began to experience burning eyes and tongue, vomiting and diaphoresis.

48. DT was given Phenergan due to the vomiting.

49. At 1625 hours, DT's blood pressure was 152/88, with a pulse rate of 92 beats per minute.

50. At 1650 hours, DT's blood pressure was 167/90, with a pulse rate of 103 beats per minute.

51. DT continued to experience difficulty breathing.

52. At 1800 hours, emergency services were called to transport DT to the emergency room.

53. Respondent had attempted to manage DT's medical condition in his clinic for over two hours.

54. When the Abilene Fire Department arrived at Respondent's clinic, DT was in respiratory distress.

55. Emergency personnel were unable to get a blood pressure reading.

56. En route to Hendrick Medical Center, DT became unresponsive, and cardiopulmonary resuscitation was initiated.

57. DT arrived at Hendrick Medical Center in cardiopulmonary arrest.

58. Aggressive attempts to revive DT were unsuccessful and he was pronounced dead at 1853 hours.

59. The autopsy report identified DT's cause of death as "severe occlusive coronary atherosclerosis."

Patient WB

60. WB was a sixty-eight year old male with a long-standing history of atrial fibrillation, congestive heart failure, high blood pressure, enlarged prostate, and osteoarthritis.

61. Respondent initially saw WB on April 13, 2005.

62. Respondent's plan for treatment of WB was intravenous therapy.

63. On May 12, 2005, WB saw Respondent with worsening symptoms of congestive heart failure and increasing shortness of breath.

64. Respondent did not document any vital signs or a physical examination at this appointment.

65. On May 20, 2005, WB presented to Respondent with a temperature of 100 degrees, blood pressure 107/72, and pulse oximeter reading of 87%, on room air.

66. Respondent did not complete a physical examination on WB at this appointment.

67. Respondent administered intravenous chelation treatment to WB at this appointment.

68. WB died within twenty-four hours of receiving chelation therapy.

Respondent's Formulary

69. Respondent's Formulary is a six-page list of mixtures of substances for Respondent's treatment of particular symptoms, diseases, conditions, or body parts.

70. Respondent's Formulary's treatment groups are Freamine IVD, Insulin Resistant, (an unlabeled category), Injection, Chelation Protocol, Myer's Cocktail, IBM, Colchicine Treatment (IVP #1 and IVP#2), Osteoporosis IV, Super Detox IV, and four Protocols ("Anti Inflamatory" (sic), "Lungs and Sinuses," "Eyes and Brain," and "Allergies").

71. Respondent's Formulary did not contain or refer to any professional medical literature or research that supported the medical benefits of the intravenous treatments.

72. Respondent's Formulary did not identify specific medical conditions in which these treatments would be contraindicated in patients.

Chelation Therapy

73. Chelating therapy is ordinarily used for the treatment of heavy metal poisoning, particularly lead poisoning.

74. Respondent's Formulary provided for an intravenous drip or push of a combination of CaEDTA and other substances.

75. CaEDTA is sold as Versanate, calcium disodium ethylene diamine tetraacetic acid (EDTA).

76. The packaging for EDTA specifically warns against the administration by intravenous push. Instead, the manufacturer recommends infusion over a period of 8-12 hours and only for the treatment of acute lead toxicity.

77. The administration of EDTA is painful to the patient.

78. The manufacturer of EDTA warns that a side effect of the intravenous push administration of the drug may include death.

79. None of the four patients who were the subject of the Complaint filed by staff of the Board (Staff) had any history of lead intoxication.

Procedural History

80. On April 17, 2007, Staff filed a Request for Docketing Case in this matter with the State Office of Administrative Hearings (SOAH).

81. On April 19, 2007, Staff notified Respondent of the hearing on the merits.

82. On June 6, 2007, Staff submitted to counsel for Respondent attorney a set of discovery requests, including 123 separately numbered Requests for Admissions.

83. Staff's Requests for Admissions addressed substantially all of the factual assertions made by Staff against Respondent in the Complaint.

84. On June 13, 2007, counsel for Staff and counsel for Respondent participated in a telephonic prehearing conference.

85. On June 15, 2007, the ALJ issued a prehearing order resetting the hearing on the merits on March 10-19, 2008.

86. On June 29, 2007, Respondent (and not Respondent's counsel) responded to Staff's Requests for Admissions and did not admit or deny the truth of any of the requests, did not object to any of the requests, and did not assert that he could not admit or deny any of the matters stated.

87. On July 9, 2007, Respondent (and not Respondent's counsel) filed with SOAH a 58-page document entitled, "Declaration In the Nature of an Affidavit of Mistake and Withdrawal of Consent for Jurisdiction" (Respondent's Declaration) in which Respondent fired his attorney and sought to withdraw his consent to jurisdiction.

88. On July 11, 2007, Staff withdrew its agreement to mediate the case.

89. On July 24, 2007, Respondent's counsel filed a Motion to Withdraw as Respondent's attorney.

90. On July 27, 2007, the ALJ granted Respondent's counsel's Motion to Withdraw, and Respondent represented himself for the balance of the case.

91. On September 26, 2007, the ALJ ordered the withdrawal of the referral to mediation, scheduled for October 16, 2007, a second prehearing conference, and ordered the parties to provide a current telephone number for Respondent. Respondent failed to comply.

92. On October 16, 2007, the ALJ convened the prehearing conference with Staff, following which the ALJ issued an order reaffirming the date of the hearing on the merits and adopted a schedule for the receipt of motions for summary disposition from both parties.

93. On December 5, 2007, the ALJ extended the deadline for the submission of motions for summary disposition to January 18, 2008, set February 8, 2008, as the deadline for answers to motions for summary disposition, and set February 15, 2008, as the deadline for a hearing on all motions for summary disposition.

94. On December 13, 2007, Staff filed a Second Amended Complaint and submitted copies of its expert reports.

95. On January 2, 2008, Staff filed a Motion for Summary Disposition.

96. On January 10, 2008, Respondent filed a "Certificate of Service" as a vehicle for challenging the credibility of Staff's expert, Robert S. Baratz, M.D.

97. On January 25, 2008, the ALJ issued Order No. 13 notifying the parties that Respondent's pleading would be treated as a TEX. R. EVID. (TRE)104 motion and setting the hearing on the motion.

98. On January 31, 2008, Respondent filed a Motion for Continuance in which he sought an extension of all deadlines, including a continuance of the hearing on the merits, so that he could engage an attorney.

99. On February 1, 2008, the ALJ issued Order No. 14 that: (1) granted Respondent's Motion for Continuance in part by extending to February 14, 2008, the deadline for Respondent's responses to discovery; (2) set a telephone hearing on February 13, 2008, to consider the balance of Respondent's Motion for Continuance; and (3) ordered Respondent (for a second time in this case) to file with the ALJ by February 12, 2008, a telephone number at which Respondent could be contacted for a telephone hearing. The order provided that Respondent's failure to comply would result in the denial of Respondent's motion.

100. On February 8, 2008, Respondent filed with the ALJ a copy of Respondent's written notice to the Board of his "order" to cancel his medical license "effective immediately." The date of Respondent's notice to the Board was February 4, 2008.

101. On February 12, 2008, Respondent failed to provide to the ALJ his telephone number, as required by Order No. 14.

102. On February 13, 2008, the ALJ convened the hearing on Respondent's Motion for Continuance at which Staff appeared and Respondent failed to appear. The ALJ denied the motion.

103. On February 14, 2008, Respondent failed to file his responses to Staff's Requests for Admission, Respondent's second failure to meet a deadline for this action.

104. On February 15, 2008, the ALJ convened the hearing on Respondent's TRE 104 motion at which Staff appeared and Respondent failed to appear. The ALJ denied the motion.

105. On February 15, 2008, the ALJ convened the hearing on Staff's Motion for Summary Disposition at which Staff appeared and Respondent failed to appear. The ALJ granted the motion.

CONCLUSIONS OF LAW

106. The Texas State Board of Medical Examiners (Board) has jurisdiction to discipline its licensees. Texas Medical Practices Act, TEX. OCC. CODE ANN. chs. 151-165.

107. The State Office of Administrative Hearings (SOAH) has jurisdiction to hear this matter and issue a proposal for decision, including findings of fact and conclusions of law. TEX. GOV'T CODE ANN. ch. 2003.

108. A party to a contested hearing may obtain discovery through requests for "admission of facts and the genuineness or identity of documents or things." 1 TEX. ADMIN. CODE (TAC) § 155.31(d) (SOAH Rule 155.31(d)).

109. A party responding to a request for admissions may admit or deny the request or may state that the party cannot truthfully admit or deny the matter. SOAH Rule 155.31(d)(2)(A).

110. A denial must be specific, and a statement that the party cannot admit or deny must give the reasons for the party's inability to respond. SOAH Rule 155.31(d)(2)(A).

111. If a responding party neither denies a request for admission nor states that the party cannot admit or deny the request, then the matter "is admitted without necessity of an order of the judge." SOAH Rule 155.31(d)(2)(A).

112. If a matter is admitted, then the admission may be used as a discovery product by a party "for the purpose of the pending action . . . ." SOAH Rule 155.31(d)(2)(B).

113. Respondent's actions were legally insufficient to serve as denials or objections to the requests. SOAH Rule 155.31(d)(2)(A).

114. As a matter of law, Respondent admitted to each of Staff's requests for admission. SOAH Rule 155.31(d)(2)(A).

115. Staff's witness, Robert S. Baratz, M.D., is credible and possessed the necessary credentials to present expert opinions in this proceeding. TEX. R. EVID. 104; *Gammill v.*

Jack Williams Chevrolet, Inc., 972 S.W.2d 713, 726-27 (Tex. 1998) (citing *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997)).

116. An ALJ may dispose of a pending action by granting a motion for summary disposition and issuing a PFD. SOAH Rule 155.57(a).

117. In considering a motion for summary disposition, the ALJ need not hold an evidentiary hearing if the admissions or evidence of record show that: (1) there is no genuine issue as to any material fact and (2) a party is entitled to a decision in its favor as a matter of law. SOAH Rule 155.57(a).

118. Respondent received adequate and timely notice of the hearing on the Motion for Summary Disposition filed by staff of the Board (Staff). TEX. GOV'T CODE ANN. §§ 2001.051 and 2001.052.

119. The Board has the authority to take disciplinary action against a physician for failing to practice medicine in an acceptable professional manner consistent with public health and welfare. TEX. OCC. CODE ANN. § 164.051(a)(6); 22 TAC § 190.8(1).

120. The Board has the authority to take disciplinary action against a physician for engaging in unprofessional or dishonorable conduct that is likely to deceive or defraud the public. TEX. OCC. CODE ANN. § 164.052(a)(5).

121. The Board has the authority to take disciplinary action against a physician for 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. TEX. OCC. CODE ANN. § 164.053(a)(5).

122. The Board has the authority to take disciplinary action against a physician for failing to maintain an adequate medical record for each patient that is complete, contemporaneous and legible. TEX. OCC. CODE ANN. § 164.051(a)(3); 22 TEX. ADMIN. CODE (TAC) § 165.1(a).

123. Respondent violated the standard of care in his treatment of KS as follows: he failed to perform an adequate physical examination; he failed to provide a diagnosis to support medical treatment; he failed to appropriately document services provided; he failed to justify the use of a non-FDA approved drug; he failed to provide appropriate medical care; he failed to appropriately treat KS's respiratory distress; he failed to timely notify emergency services (EMS); he failed to provide medically necessary information to EMS; he failed to document the medical necessity for intravenous infusions; and he failed to properly monitor KS while KS received intravenous therapy.

124. Respondent violated the standard of care in his treatment of AP as follows: he failed to complete a physical examination; he failed to appropriately document services provided; he failed to appropriately treat and diagnose AP; he failed to obtain appropriate consent for therapy; he failed to justify the use of a non- FDA approved drug; he failed to assess if AP was an appropriate candidate for intravenous infusions.

125. Respondent violated the standard of care in his treatment of DT as follows: he failed to perform an adequate physical examination on DT; he failed to adequately treat DT's

hypertension and hyperlipidemia; he failed to appropriately document services provided; he failed to justify the use of a non-FDA approved drug; he failed to recognize DT's life-threatening reaction to the Myers Cocktail that was administered by Respondent. Respondent also violated the standard of care when he delayed transporting DT to the emergency room for over two hours even though DT was critically ill.

126. Respondent violated the standard of care in his treatment of WB as follows: he failed to complete an adequate physical examination; he failed to appropriately document services provided; he failed to diagnosis WB prior to providing intravenous treatment; he failed to address WB's pulmonary and cardiovascular issues; he failed to justify the use of a non-FDA approved drug; he failed to consider that WB was an appropriate candidate for intravenous treatment; and he failed to document justification to administer intravenous fluids in a congestive heart failure patient.

127. Respondent failed to meet the standard of care with his intravenous treatments he provided to KS, DT, and WB. The intravenous treatments were not indicated for use in these patients because: (a) none of the patients had any valid evidence of lead toxicity, (b) none of the patients had any condition requiring the use of chelation agents, and (c) none of the patients had any demonstrated vitamin or mineral deficiencies.

128. Based on the Findings of Fact and Conclusions of Law, the Board should revoke Respondent's license to practice medicine in the State of Texas.

*Conclusion of Law No. 128 of the PFD is not adopted as a Conclusion of Law, but rather it is considered to be a sanction recommendation. The Board may however, consider the recommendation pursuant to Board Rule 190.2. **The Board has determined consistent with its statutory authority that the recommended sanction of the ALJ is an appropriate sanction in this case.**

ORDER

The Board hereby adopts the Findings of Fact and Conclusions of Law as proposed by the ALJ. except Conclusion of Law No. 128, which is a sanction recommendation. However, the Board finds that the recommendation for sanctions delineated in the PFD is sufficient to protect the public interest; therefore, the Board adopts the ALJ's recommended sanction, and ORDERS that:

1. Respondent's Texas medical license is hereby REVOKED.
2. The Board finds this revocation is reasonably supported by evidence adduced at trial and found in the record.
3. In accordance with TEX. OCC. CODE ANN §2001.177 and Board Rule §187.39(c), should Respondent appeal this Final Order, the Respondent shall be responsible for

payment of all costs of preparation of the original or certified copy of the record of the agency proceedings.

SIGNED AND ENTERED by the presiding officer of the Texas Medical Board on this 11th day of April, 2008.

Larry Price DO

Larry Price, D.O., Vice President
Texas Medical Board