BEFORE THE ARIZONA MEDICAL BOARD

In the Matter of **DAVID L. GREENE, M.D.** Holder of License No. **32747** For the Practice of Allopathic Medicine In the State of Arizona.	Board Case No. MD-06-1043A **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER** (Decree of Censure and Probation)

The Arizona Medical Board ("Board") considered this matter at its public meeting on August 9, 2007. David L. Greene, M.D., ("Respondent") appeared before the Board with legal counsel Paul J. Giancola for a formal interview pursuant to the authority vested in the Board by A.R.S. § 32-1451(H). The Board voted to issue the following Findings of Fact, Conclusions of Law and Order after due consideration of the facts and law applicable to this matter.

FINDINGS OF FACT

1. The Board is the duly constituted authority for the regulation and control of the practice of allopathic medicine in the State of Arizona.

2. Respondent is the holder of License No. 32747 for the practice of allopathic medicine in the State of Arizona.

3. The Board initiated case number MD-06-1043A after receiving a complaint regarding Respondent's care and treatment of a seventy-seven year-old female patient ("LO"). The complainant, a nurse, also informed the Board that she was aware of a significant number of additional poor patient outcomes. The Board reviewed six patient records in total and found deviations from the standard of care in five cases. Respondent met the standard of care in the sixth case. However, when viewed with the other five cases, all cases indicate poor surgical judgment with regard to indications for surgery and intraoperative decisions coupled with poor surgical technique.

Patient PH

4. Respondent initially evaluated PH, a seventy-one year-old female, on January 28, 2005 noting she had intense low back pain and severe right leg pain of four weeks duration. Respondent noted PH's past medical history of hypertension and physical findings of a weak and painful iliopsoas and diminished sensation of her right groin. Imaging studies demonstrated a large right paracentral disc herniation at T12-L1 and a significant right paracentral disc herniation at L2-L3. Respondent recommended a two level discectomy and a one level fusion at T12-L1. PH's MRI scan reported by another physician on January 17, 2005 noted multi-level disc protrusions T8 through T12 and multilevel spinal stenosis of the lumbar spine with left lateral disc bulge at L2-L3 and right lateral disc bulge at L3-L4.

5. Respondent's operative report of January 29, 2005 was dictated on February 1, 2005 and documents his T12-L1 and L2-L3 laminectomy/discectomy with a posterior spinal fusion T10 to L1 with pedicle screw fixation. Respondent noted no complications during the procedure and that PH's blood pressure remained stable. A Critical Care Specialist ("Dr. M") was consulted on January 29, 2005 and noted he saw PH for hypotension and oliguria. Dr. M. noted PH had surgical replacement of 1.4 liters of lactated ringors, 8.4 liters of normal saline and one liter of cell saver infusion (540 cc). PH's blood pressure was 86/42 and her pulse rate was 92. Dr. M diagnosed hypovolemic shock and oliguric renal insufficiency and recommended crystalloid resuscitation with mannitol diuresis. PH died on January 31, 2005.

6. A February 2, 2005 pathology report notes a final diagnosis of a laceration of the abdominal aorta, retroperitoneal hematoma and peritoneal effusion (2 liters), no evidence of myocardial infarction, bilateral pleural effusions (1 liter) each and bibasilar congestion. In Respondent's dictated report of a meeting with PH's family on February 5, 2005 he states he reviewed PH's abdominal CT scan with a general surgeon on January 31, 2005 noting the large retroperitoneal hematoma and decided to watch the hematoma conservatively and transfuse PH

"since in the vast majority of cases it is very very difficult to localize the source of the bleeding." Respondent noted passing out copies of the autopsy report and noting the laceration of the aorta.

7. Respondent's discharge summary dictated on February 8, 2005 notes PH's date of death of January 31, 2005 and a discharge diagnosis of disc herniation at T12-L1 and L2-L3, retroperitoneal hemorrhage, bilateral pleural effusion, myocardial infarction and death. Respondent documented PH's hemoglobin was 7.5 in the morning of January 31, 2005 and she was transfused with two units later that evening and it was 6.8 at about 6:30 p.m. and then 5. PH died at 10:20 that evening.

8. The standard of care requires a physician to recognize a complication of surgery, diagnose it expeditiously and treat it appropriately with exploration or, at a minimum, contrast vascular studies.

9. Respondent deviated from the standard of care by failing to expeditiously diagnose and manage PH's laceration of the aorta despite PH's continued need for transfusions and a large retroperitoneal bleed.

10. PH died of hypovolemic shock as a result of an iatrogenic laceration of the aorta that Respondent did not detect for two days despite dropping blood pressures and hemoglobins.

Patient RD

11. RD, a fifty-one year-old male, was seen by a physician on June 8, 2004 complaining of low back pain and pain radiating down the left leg. RD saw another physician ("Dr. E") on September 30, 2004. Dr. E noted RD's left leg pain and an MRI scan with an eccentric disc at L5-S1 on the left and subsequently recommended epidural steroid injections. On November 4, 2004 another physician's electrodiagnostic studies suggested bilateral chronic lumbar radiculopathy at L5-S1. On December 10, 2004 Dr. E noted RD had minimal leg pain and primarily back pain and suggested he seek a second opinion with an orthopedic surgeon.

12. Respondent evaluated RD on January 1, 2005 noting RD's left low back pain and left leg pain. Respondent noted RD was 5'7", 170 pounds with tenderness of the left low back and positive straight leg raising of forty degrees on the left. Respondent recommended a complete discectomy with interbody fusion and posterior fusion of L5-S1.

13. Respondent performed the procedures on February 2, 2005 documenting transforaminal lumbar interbody fusion of L5-S1 with posterior pedicle screw fixation and fusion with autograft, BMP and fluoroscopy. There is no documentation in the records that Respondent verified screw fixation under fluoroscopy. Respondent noted RD could dorsiflex and plantar flex his toes in the recovery room. Respondent's post-surgery notes document RD's lower right extremity pain on February 3, 2005 with no left leg pain. His subsequent notes of February 4, and 5 document continued right lower extremity pain with complaints of weakness of the right foot on February 5 and a right foot drop.

14. Respondent's progress note of February 6, 2005 documents no left leg pain, but right leg pain and weakness of dorsiflexion and plantar flexion of the right foot. Respondent ordered an AFO. RD underwent a CT scan on February 7, 2005 – five days post-surgery. Respondent documented the CT scan as demonstrating mal-position of the S-1 right screw with violation of the medical pedicle. Respondent returned RD to surgery on February 8, 2005. Respondent's operative report documents his hardware revision of L5-S1 on the right for a mal-positioned right S-1 pedicle screw and notes he found the screw abutting the nerve root, which was swollen, but appeared intact.

15. RD was admitted to another facility on February 11, 2005 for severe right low back pain and right leg pain. RD was discharged on February 19, 2005 on Elavil, Neurontin, Zanaflex, Valium, Oxycontin and Oxycodone for pain control. Respondent's February 25, 2005 office record noted RD was two weeks post-op with weakness of the S-1 root on the right. Respondent placed him on Neurontin. A March 22, 2005 EMG/NCV from another physician documents RD had

chronic denervation at L4-S1 on the right and S1 on the left. Respondent's April 5, 2005 office record noted the hardware in good position, but that RD did not have any significant dorsiflexion or plantar flexion.

16. The standard of care requires a physician performing a discectomy, interbody fusion and postero-lateral fusion with pedicle screw instrumentation to document the positions of the pedicle screws with fluoroscopy to prevent nerve or dural injury.

17. Respondent deviated from the standard of care by failing to document with intraoperative fluoroscopy the position of the right S-1 pedicle screw.

18. RD developed severe right leg pain with foot drop.

Patient JD

19. Respondent initially revaluated JD, a thirty-five year-old male, on April 7, 2005. JD presented with a history of mid-back pain after a motor vehicle accident. JD complained of increased pain with increased activity and that he had difficulty sleeping. Respondent noted JD had pain over the lower thoracic spine and that x-rays demonstrated an apparent old compression fracture of T-8. JD had a past history of tumor resection from beneath his left scapula in 1999. Respondent recommended an MRI.

20. The MRI report of April 29, 2005 demonstrated a superior end plate compression fracture deformity of T8 demonstrating mild wedging with bright signal intensity suggesting a sub-acute fracture and apparent hemangioma of the superior posterior body of T-9. A bone scan reported on June 21, 2005 demonstrated focal activity of T-8 suggesting an acute or sub-acute compression fracture. A CT scan of the thoracic spine demonstrated a mild compression deformity of the superior endplate of T-8 and two ossific densities of T-9.

21. Respondent again evaluated JD on June 16, 2005, noted the radiographic studies and normal laboratory work-up and recommended a biopsy. On July 6, 2005 Respondent performed a trans-pedicular biopsy of T-8 and T-9. Respondent's office note of July 13, 2005

records JD had a biopsy of T-8 and T-9 with no evidence of infection or malignancy and he recommended a kyphoplasty with bone graft for JD's apparent persistently painful fractures.

22. On July 25, 2005 Respondent performed a Percutaneous Kyphoplasty T-8 and T-9 with allograft and fluoroscopy control. In his report, Respondent noted that placement of his dilator and working cannula at T-8 was difficult and required three attempts. Respondent then used the drill and fan curette to prepare for the placement of the allograft. Respondent repeated this same procedure at T-9. On awaking, JD had no sensation below T-9. A subsequent MRI demonstrated an epidural hematoma.

23. Respondent returned JD to surgery on this same day for a laminectomy of T-8 and T-9 with evacuation of an epidural hematoma and dural repair. Respondent noted at surgery there was a dural tear and a significant irreparable spinal cord injury. Another physician evaluated JD in neurologic consultation and noted JD had decreased sensation below T-8, no motor strength in the lower extremities, and no reflexes in the lower extremities. It was his impression that JD had traumatic cord myelopathy. JD was transferred to another facility for rehabilitation on July 29, 2005.

24. The standard of care requires a physician to perform a kyphoplasty for osteoporotic compression fractures or relatively recent history of traumatic compression fractures.

25. Respondent deviated from the standard of care by performing kyphoplasty on a thirty-five year-old patient who had neither osteoporotic compression fractures nor relatively recent history of traumatic compression fractures.

26. JD is a paraplegic as a result of the spinal cord injury.

Patient LO

27. Respondent initially evaluated LO on October 5, 2005. LO had back and lower extremity pain in the right more than the left that had increased over the prior few years. LO had tried physical therapy and chiropractic care and was taking Fiorcet, Percocet, Methocabamol,

Neurontin, Atenolol, Amytryptiline and Lovastatin. Respondent's examination of LO revealed level shoulders and iliac crests, tenderness of the lumbar spine and no neurological deficit. LO's x-rays revealed degenerative scoliosis of the lumbar spine of forty degrees with a lateral listhesis at L3-L4. An MRI scan revealed lumbar spinal stenosis of L3-L4 and L4-L5. Respondent recommended a laminectomy of L3-L4 and L4-L5, a fusion with pedicle instrumentation from T11 to S1 and interbody fusions. A Persantine myocardial perfusion study interpreted by another physician on November 16, 2005 was an abnormal study with antero-apical ischemia. On November 17, 2005 this physician cleared LO as a low risk surgical candidate for spine surgery.

28. Respondent's preoperative evaluation notes of January 1, 2006 document he reviewed the procedure and the risks and complications of the procedure with LO and noted her laboratory results (after LO donated blood for an auto-transfusion) as slightly anemic, Hb-10.1 and Hct of 29.5. Respondent's operative report of January 6, 2006 notes he placed pedicle screws from T11-S1, performed a laminectomy at L3-L5 and an interbody cage at L3-L4. After more than four hours of surgery Respondent was preparing the L4-L5 disc space for an interbody cage and encountered significant bleeding. Respondent packed the area and LO's blood pressure diminished precipitously. Respondent removed the right sided screws, closed the wound with staples, turned the patient and began resuscitation as LO arrested. LO was stabilized and Respondent obtained a vascular surgery consult. Another physician ("Dr. R") was called to the operating room to perform an exploratory laparotomy. As Dr. R started the procedure, LO arrested again. Dr. R quickly exposed the retroperitoneal area and found a retroperitoneal hemorrhage (estimated at 400 cc) from an inferior vena cava injury. Dr. R controlled the bleeding with direct pressure as resuscitative attempts continued, but the attempts were unsuccessful and LO died. Dr. R dissected the area post-mortem and noted a posterior perforation of the vena cava. In his operative report, Respondent noted he violated the disc space.

29. The estimated blood loss from the procedure was listed as 800 cc. The anesthesia record reflects LO was given 3000cc of normal saline, 1900 cc of lactated Ringors', nine units of packed cells (2250cc) and one unit of platelets (total 7250cc) during the four and one-half hour procedure and code. Stat blood work obtained during the code was recorded as an Hct of 16 an Hb of 5.4. Another stat blood work at 13:40 is recorded as Hct of 19 and HB of 6.5.

30. Respondent maintained the aortic laceration was not iatrogenic during the surgery because LO would have died on the table. According to Respondent, an aortic tear of 1.7 centimeters during a procedure would be fatal at that time. However, the autopsy report notes the abdominal aorta laceration corresponding to L2-L3 – the area where he performed the surgery.

31. The standard of care requires a physician performing surgery on the spine to identify excessive bleeding intra-operatively with a decreased blood pressure as a possible vascular injury; to terminate the procedure and obtain a vascular surgery consult.

32. Respondent deviated from the standard of care when, after he lacerated the vena cava, he delayed the corrective measures by removing the pedicle screws prior to closure and turning LO for abdominal exploration.

33. The standard of care requires a physician to consider the patient's age, evaluation, prior treatment failures, co-morbidities and the extent of the planned surgery before proceeding with an extensive elective surgery.

34. Respondent deviated from the standard of care by showing poor surgical judgment in deciding to proceed with LO's aggressive elective surgery knowing she was a seventy-seven year-old patient with a documented history of cardiac disease and pre-operative anemia.

35. LO arrested and could not be successfully resuscitated during the procedure after an intra-operative complication – laceration of the inferior vena cava.

Patient GG

36. Respondent evaluated GG, a seventy-three year-old male patient, who presented with a history of chronic back pain secondary to arachnoiditis from multiple back surgeries in the remote past. GG had been more comfortable with a prior spinal cord stimulator that had stopped functioning. Respondent recommended a new spinal cord stimulator.

37. Respondent performed the procedure on June 13, 2006 and documented the hardware removal, T-11 laminectomy, implantation of a new spinal cord stimulator, and creation of a new battery pocket. On June 20, 2006 GG had problems with delayed healing of the battery pocket and Respondent recommended wet to dry dressings. Respondent performed a second procedure on June 26, 2006 and documented his irrigation and debridement of the lumbar spine and creation of a new battery pocket of the buttock. Respondent cultured the wound and washed the battery and leads with Betadine and re-implanted them.

38. Respondent saw GG on July 6, 2006 with erythema about the spinal incision. On July 18, 2006 Respondent noted purulent drainage from the battery pouch area. On September 9, 2006 Respondent documented problems with the battery not charging, but noted the wound was okay. On September 7, 12, and 21, 2006 Respondent documented continued drainage from the battery pouch area. Respondent started GG on Cipro. On November 10, 2006 another physician removed the spinal cord stimulator and battery and debrided the upper and lower back wounds. On February 5, 2007 Respondent performed irrigation and debridement of thoracic and lumbar spine wounds and a 21 cm scar revision.

39. The standard of care if an infection develops post-surgery requires it be debrided and that hardware from the area of prior infection or potential infection not be re-implanted.

40. Respondent deviated from the standard of care by re-implanting hardware from a potentially infected area.

41. GG required additional surgery as a result of the subsequent infection of all the hardware areas and could have developed an epidural abscess with tracking of the infection along the leads.

Patient DB

42. Respondent evaluated DB, a fifty-three year-old male patient, in 2006 for severe cervical spondylosis and spinal cord compression. Respondent performed surgery on August 10, 2006 and documented an anterior cervical discectomy and fusion of C3-C7 with plate and screws. Post-operatively DB developed a cervical hematoma resulting in respiratory compromise that required emergent intubation and a return to surgery on August 11, 2006 at which time Respondent evacuated a cervical wound hematoma. Respondent's office records of October 17, 2006 document a screw backing out of the distal plate. On January 20, 2007 Respondent performed a procedure to remove the loose screw. On February 9, 2007 Respondent documented DB was doing well, but may need a posterior fusion.

43. A patient with severe cervical spondylosis and spinal cord compression is a candidate for surgical decompression and fusion. The standard of care requires the surgery be accomplished with care and all bleeding controlled and a post-surgical drain utilized to prevent hematoma formation. Although Respondent met the standard of care in this case, it is concerning when viewed with the cases above.

Complications in the Last Sixteen Months

44. Respondent maintained that over the past year and one-half he has not had any major technical complications; no surgical complications such as vessel injuries, bowel injuries, nerve root injuries, paraplegia, quadriplegia, and no deaths secondary to technical complications; he had one cervical hematoma in a patient who did not disclose he was a drinker; and one patient who, immediately post-op of an uneventful L5-S1 fusion began having increasing numbness and tingling and motor weakness in her lower extremities. Respondent maintained he returned the

patient to surgery and there was no evidence of hematoma and within eight hours from the index procedure, the patient was normal neurologic function.

Finding of Immediate Effectiveness

45. It is necessary for this decision to take immediate effect to protect the public health and safety. A.A.C. R4-16-102(B).

CONCLUSIONS OF LAW

1. The Arizona Medical Board possesses jurisdiction over the subject matter hereof and over Respondent.

2. The Board has received substantial evidence supporting the Findings of Fact described above and said findings constitute unprofessional conduct or other grounds for the Board to take disciplinary action.

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1401(27)(q) ("[a]ny conduct or practice that is or might be harmful or dangerous to the health of the patient or the public"); and A.R.S. § 32-1401(27)(ll) ("[c]onduct that the board determines is gross negligence, repeated negligence or negligence resulting in harm to or the death of a patient.").

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law,

IT IS HEREBY ORDERED:

1. Respondent is issued a Decree of Censure for multiple mishandled surgical complications and poor clinical judgment.

2. Respondent is placed on probation for two years with the following terms and conditions:

a. Respondent shall maintain a log of all operative procedures he performs. The log shall include the identity of the patient; the indications for the procedure performed; the outcome of

the procedure; and any complications experienced. Respondent shall submit the log to the Board each month.

b. Respondent is subject to periodic chart reviews by Board Staff. Respondent shall cooperate fully with Board Staff and provide the charts when requested.

c. Respondent must notify all hospitals, surgery centers, etc., where he is on staff or has privileges to immediately report any complications to the Board. Respondent is responsible for ensuring the reports are filed.

d. Respondent must report to the Board within five calendar days any malpractice cases that are filed or any actions taken against his privileges by any facility.

e. Respondent shall obey all federal, state, and local laws and all rules governing the practice of medicine in Arizona.

f. Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all conditions of probation. The declarations must be submitted on or before the 15th of March, June, September, and December each year beginning on December 15, 2007.

3. In the event Respondent should leave Arizona to reside or practice outside the State or for any reason should Respondent stop practicing medicine in Arizona, Respondent shall notify the Executive Director in writing within ten days of departure and return or the dates of non-practice within Arizona. Non-practice is defined as any period of time exceeding thirty days during which Respondent is not engaging in the practice of medicine. Periods of temporary or permanent residence or practice outside Arizona or of non-practice within Arizona, will not apply to the reduction of the probationary period.

RIGHT TO APPEAL TO SUPERIOR COURT

Respondent is hereby notified that this Order is the final administrative decision of the Board and that Respondent has exhausted his administrative remedies. Respondent is advised

that an appeal to Superior Court in Maricopa County may be taken from this decision pursuant to Title 12, Chapter 7, Article 6.

DATED this 16th day of August 2007.

THE ARIZONA MEDICAL BOARD

By _____
TIMOTHY C. MILLER, J.D.
Executive Director

ORIGINAL of the foregoing filed this 16th day of August, 2007 with:

Arizona Medical Board
9545 East Doubletree Ranch Road
Scottsdale, Arizona 85258

Executed copy of the foregoing mailed by U.S. Mail this 16th day of August, 2007, to:

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David L. Greene, M.D.
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