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Before the
State Of Wisconsin
Medical Examining Board

In the Matter of Disciplinary Proceedings Against
Adegboyega H. Lawal, M.D., Respondent

FINAL DECISION AND ORDER

Order No. 0005272

Division of Legal Services and Compliance Case No. 13 MED 310

The State of Wisconsin, Medical Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, make the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Medical Examining Board.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated at Madison, Wisconsin on the 19th day of April, 2017.

Member
Medical Examining Board

Before The
State Of Wisconsin
DIVISION OF HEARINGS AND APPEALS

In the Matter of Disciplinary Proceedings Against
Adegboyega H. Lawal, M.D., Respondent

DHA Case No. SPS-15-0041
DLSC Case No. 13 MED 310

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

Adegboyega H. Lawal, M.D., by

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Leib Knott Gaynor
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PROCEDURAL HISTORY

On April 16, 2015, the Department of Safety and Professional Services (Department), Division of Legal Services and Compliance (Division), filed a formal Complaint against Respondent Adegboyega H. Lawal, M.D. (Respondent), alleging that Respondent engaged in unprofessional conduct with respect to a patient referred to in these proceedings as Patient A, by engaging in conduct which constituted a danger to the health, welfare or safety of the patient, in violation of Wis. Admin. Code § Med 10.02(2)(h); by failing to obtain informed consent from Patient A for the off-label use of gadolinium on her, in violation of Wis. Admin. Code § Med 10.02(2)(u); and by failing to document informed consent for the off-label use of gadolinium, in violation of Wis. Admin. Code § Med 10.02(2)(za). The Division alleged that as

a result of his treatment of Patient A, Respondent was subject to discipline pursuant to Wis. Stat. § 448.02(3).

On or about May 6, 2015, counsel for Respondent filed an Answer (captioned a Response) to the Complaint, denying any unprofessional conduct.

A telephone prehearing conference was scheduled for May 18, 2015, but at the request of Respondent's counsel, was postponed to June 10, 2015. At the June 10, 2015 prehearing conference, a hearing was scheduled for November 17, 2015. On September 25, 2015, counsel for the Division, with the agreement of Respondent's counsel, requested a suspension of the June 10, 2015 Scheduling Order, which resulted in cancellation of the hearing scheduled for November 17, 2015. A status conference was held on November 17, 2015, at which the hearing was re-scheduled to March 22-23, 2016. The hearing was subsequently rescheduled to May 11-12, 2016.

The contested case hearing was held on May 11-12, 2016, in Madison, Wisconsin. Exhibits were received from both parties. The Division presented five witnesses: two expert witnesses, Dr. James Conterato (by evidentiary deposition), and Dr. Vincent Mathews, Patient A (by evidentiary deposition), Attorney Arthur Thexton, and Respondent (adversely). Respondent called no witnesses other than himself.

Following post-hearing submissions from the parties, an order regarding evidentiary rulings and a briefing schedule was issued on May 27, 2016. On July 26, 2016, the Division, with Respondent's agreement, requested a three-day extension of time in which to file its submission. The request was granted, pursuant to which on July 28, 2016, the Division filed a Motion to Amend the Complaint, an Amended Complaint and its post-hearing brief. On August 29, 2016, counsel for Respondent filed a brief opposing the motion to amend the Complaint and requesting a new post-hearing briefing schedule.

By order dated September 6, 2016, the ALJ issued an order granting Respondent's request to postpone briefing until after a decision on the Division's motion to amend was issued. The order provided the Division an opportunity file a reply to Respondent's brief opposing the Division's motion to amend the Complaint. The Division filed its reply on September 21, 2016.

On October 21, 2016, the ALJ issued an Order partially granting the Division's motion to amend the Complaint and setting a new briefing schedule. The order granted the Division's motion to amend with respect to informed consent and documentation allegations, but denied the motion with respect to allegations that Respondent engaged in fraud, deceit and misrepresentation to the Board by his deposition and hearing testimony. The order provided the Division the opportunity to replace or supplement its July 28, 2016 post-hearing brief, and set deadlines for Respondent's response and the Divisions' reply.

On November 21, 2016, the Division filed its revised brief. On December 16, 2016, Respondent's counsel requested a three-week extension of time to file his post-hearing brief, from December 21, 2016 to January 13, 2017. In making the request, Respondent's counsel represented that the Division would only agree to a shorter extension request. The ALJ granted the full three-week extension, allowing Respondent's brief to be filed by January 13, 2017. Respondent's counsel did not submit his brief until the following day, Saturday, January 14, 2017, by email, which was considered filed Monday, January 16, 2017. On January 30, 2017,

the Division filed its reply brief and a motion to strike Respondent's brief due to the fact that it was not submitted until after the January 13, 2017 extended deadline. On January 31, 2017, the ALJ issued an order denying the motion to strike and accepting Respondent's brief as filed.

FINDINGS OF FACT

1. Respondent is licensed in the State of Wisconsin to practice medicine and surgery, having license number 43754-20, first issued on September 4, 2001. (Amended Complaint, ¶ 1; Amended Answer, ¶ 1)

2. Respondent has been practicing medicine for approximately 30 years, first in the United Kingdom and then in the United States. He is board certified in anesthesiology and has two board certifications in pain management, one from the American Board of Pain Medicine and the other from the American Society of Anesthesiologists. (Resp. Ex. 100; Hrg. Tr., pp. 495-496, 502-503)

3. At all times relevant to this proceeding, Respondent was employed as an anesthesiologist and pain management specialist. He practiced pain management 50 percent of the time and anesthesia 50 percent of the time. (Amended Complaint, ¶ 3; Amended Answer, ¶ 3; Resp. Ex. 100; Hrg. Tr., p. 498)

4. Respondent began practicing pain medicine at Aurora St. Luke's Medical Center in Milwaukee, Wisconsin (St. Luke's) in 2001, in partnership with approximately 14 other anesthesiologists. At the time of the hearing in this matter, Respondent was still employed at Aurora's pain clinic. (Resp. Ex. 100; Hrg. Tr., pp. 264-268)

5. On January 18, 2009, Patient A, a woman born in 1951, was admitted to St. Luke's for evaluation of recurrent back pain radiating into both legs. (Amended Complaint, ¶ 4; Amended Answer, ¶ 4; Hrg. Tr., p. 263)

6. A January 19, 2009 note in Patient A's medical chart written by another medical provider noted that Patient A was in "extreme pain," was moaning, had "burning" and "gnawing" pain, and exhibited facial behaviors or anguish. Patient A reported pain of 9 to 10 out of 10, with 10 as the most severe, and stated that the pain was like she was "lying on rocks." (Div. Ex. 19, pp. 16, 113; Hrg. Tr., pp. 516-517)

7. A previous provider had inserted a subcutaneous pain pump in Patient A's spine to infuse pain medications directly into her spinal canal, otherwise known for purposes of this proceeding as the intrathecal or subarachnoid space. Patient A was receiving four different pain medications through her pain pump at high dosages. (Amended Complaint, ¶ 5, Amended Answer, ¶ 5; Div. Ex. 9, pp. 21, 94, 109; Hrg. Tr., pp. 518-519)

8. According to a nursing note dated January 19, 2009, an MRI had been ordered by a neurosurgeon, but the MRI could not be performed for three days because the anesthesia Patient A required for the procedure would not be available until then. (Div. Ex. 19, p. 113; Hrg. Tr., p. 206)

9. On January 20, 2009, Respondent was asked by a colleague at St. Luke's to assess the integrity of Patient A's pain pump and look for possible leakage. Respondent was not

Patient A's regular treating physician. (Amended Complaint, ¶ 6; Amended Answer, ¶ 6; Hrg. Tr., pp. 268, 281)

10. Conducting such tests is routine for Respondent but is not routine for all pain doctors. By 2009, Respondent had conducted hundreds of pain pump installations and/or tests. (Hrg. Tr., pp. 282-283, 340-341)

11. In assessing a pain pump's integrity, a contrast material is injected, which allows one to track the contrast agent's path through the pump (including the catheter) into the intrathecal space. In order to track the contrast agent, a type of x-ray called fluoroscopy is used. (Hrg. Tr., pp. 132-134, 173-174, 281-282; Div. Ex. 9, pp. 21-22)

12. Typically, iodine is the contrast agent used for the procedure at issue. It is the only FDA-approved contrast agent for use in the intrathecal space. (Hrg. Tr., pp. 136-137; Div. Ex. 9, p. 23)

13. Patient A reported an allergy to iodine. Therefore, Respondent determined he should use gadolinium (in the form of Magnevist) as a contrast agent. (Amended Complaint, ¶ 8; Amended Answer, ¶ 8)

14. Prior to his treatment of Patient A, Respondent had never injected gadolinium intrathecally. However, Respondent had used gadolinium as a contrast agent in other procedures in the spine area approximately three to four times per week where patients had severe iodine allergies. (Hrg. Tr., pp. 341, 347, 504-505)

15. Respondent's use of gadolinium on Patient A was an off-label use, in that the FDA has not approved gadolinium for intrathecal use. Intravenous use of gadolinium is the only FDA-approved use of gadolinium. Gadolinium is the common contrast agent for an MRI, in which it is injected intravenously. Intrathecal use of gadolinium is infrequent. The most significant indication for injecting intrathecal gadolinium is for MR myelograms or cisternograms, which involve checking for leakage of fluid from the intrathecal space. (Hrg. Tr., pp. 128-131, 223)

16. Physicians frequently use medications off-label. Off-label use is guided by studies that demonstrate the efficacy, safety and appropriate dosing of the medication. The FDA does not necessarily oppose off-label use unless it is specifically found to be dangerous in certain ways, in which case there will be a black box warning about that drug. (Div. Ex. 9, pp. 72-73, 100-101; Hrg. Tr., pp. 195-196, 223)

17. Injecting gadolinium into a patient's intrathecal space is very different from administering the drug intravenously or around the spine structures. It carries a unique risk to the patient because the gadolinium travels to the patient's brain and the brain has no protection from the toxic effect of gadolinium. (Div. Ex. 9, pp. 29-30; Hrg. Tr., p. 149)

18. Respondent testified that prior to meeting with Patient A, he reviewed Patient A's medical records and reviewed at least four articles in medical journals on the use of intrathecal gadolinium. According to Respondent, the four articles he reviewed consisted of two by the same authors (collectively, Safriel articles) – one from 2006 in *American Journal of Neuroradiology* entitled, "Gadolinium Use in Spine Procedures for Patients with Allergy to

Iodinated Contrast – Experience of 127 Procedures" (2006 Safriel article) and the other from 2008 in *Cardiovascular Interventional Radiology* entitled, "Gadolinium Use in Spine Pain Management Procedures for Patients with Contrast Allergies: Results in 527 Procedures" (2008 Safriel article); a 2002 article in *Investigative Radiology* entitled, "Intrathecal Gadolinium (Gadopentetate Dimeglumine) Enhanced Magnetic Resonance Myelography and Cisternography" (the Tali article); and a 2008 article in *Clinical Radiology* entitled, "Overdosage of intrathecal gadolinium and neurological response" (the Li article) (Div. Ex. 8, D2, D3, D4; Resp. Ex. 108, G; Hrg. Tr., pp. 434-436, 577-584)

19. The Tali article summarizes a study of 95 patients and concludes: "This cooperative study demonstrates the general safety and feasibility of low dose (0.5-1.0 mL/ml) intrathecal gadopentetate dimeglumine [*i.e.*, gadolinium] administration." (Div. Ex. 8, D3, p. 1; Hrg. Tr., pp. 157-160)

20. The 2006 Safriel article states: "A large multicenter study of 95 patients showed no deleterious effects of up to 5 mL of gadolinium compound (Magnevist...) injected into the lumbar subrachnoid space..." For this excerpt, the article cites the Tali article in a footnote. (Div. Ex. 8, D4, pp. 2, 4)

21. The 2008 Safriel article likewise states: "A large multicenter study of 95 patients showed no deleterious effects of up to 5 mL of gadolinium based contrast agent (Magnevist...) injected into the lumbar subarachnoid space." The Tali article is again cited in a footnote. (Resp. Ex. 108, G, pp. 5, 6)

22. These excerpts from the Safriel articles erroneously interpret the Tali article. The Tali article does not state that up to 5 mL of gadolinium injected intrathecally resulted in no deleterious effects. Rather, the Tali article concluded that between *.5 and 1 mL* resulted in no serious deleterious effects. (Hrg. Tr., pp. 215-216)

23. The 2008 Safriel article further states with respect to intrathecal injection of gadolinium, "In the limited series published thus far, low-dose intrathecal gadolinium-based contrast agent has not been associated with any significant adverse effects." (Resp. Ex. 108, G, p. 2)

24. The 2008 Safriel article also notes that one patient inadvertently had 3 mL of gadolinium injected into the intrathecal space "without sequelae" and that "[t]he patient was discharged after the usual follow-up (approximately 30 min) without complications and reported no adverse events to us or their [sic] primary physician." (Resp. Ex. 108, G, p. 3)

25. However, the 2008 Safriel article further documents a patient who had inadvertently had 1.4 mL of diluted Omniscan (*i.e.*, gadolinium) solution injected intrathecally. She experienced nausea followed by vomiting, became incoherent and hallucinatory, and had two grand mal seizures. The article documents another patient who inadvertently received 5 mL of Omniscan intrathecally and experienced headache, vomiting and a grand mal seizure. The article notes the possibility that the batch of Ominiscan used on both patients was defective. (Resp. Ex. 108, G, pp. 3-5; Hrg. Tr., pp. 154-157, 219, 228-229)

26. Respondent testified that his interpretation of the Safriel articles was that "up to 5 cc [or mL] was clearly tolerated." (Hrg. Tr., p. 435)

27. The 2008 Safriel article was retracted on June 26, 2009, which was after the events at issue in this case. (Resp. Ex. 108, G, p. 8; Hrg. Ex. 217) There is no indication in the record that the 2006 Safriel article was ever retracted.

28. The Li article documents a patient who inadvertently received a "high dose" of intrathecal gadolinium. The amount of gadolinium was approximately 15 mL, which the article described as "approximately 30 times the recommended dosage use in humans" and as "30 times over the usual dose used in humans." The patient immediately complained of headache, accompanying nausea, and vomiting and became comatose approximately one hour after the incident and had an outbreak of systemic seizures. (Div. Ex. 8, D2, pp. 1, 4; Hrg. Tr., pp. 151-153)

29. After meeting with Patient A on January 20, 2009, Respondent performed the test of Patient A's pain pump by injecting Magnevist 0.5 mmol gadoliniumopentetate dimeglumine/mL (i.e., gadolinium) as a contrast agent into Patient A's intrathecal space. (Complaint ¶ 8; Answer ¶ 8; Hrg. Tr., pp. 286, 292, 591)

30. After Respondent injected gadolinium into Patient A's intrathecal space, Patient A complained of headaches, developed hypertension, and became lethargic. She experienced involuntary flopping of her arms and legs. She was transferred to the ICU approximately four to five hours after the procedure. At some point after her transfer to the ICU, she was intubated and became comatose. (Div. Ex. 9 pp. 52-53; Hrg. Tr., pp. 164-165, 200-201 293-294, 297)

31. Several different consultants from neurosurgery, neurology, and pulmonary critical care medicine who were present during Patient A's hospitalization characterized Patient A as having an encephalopathy and being comatose. Encephalopathy is a diffuse dysfunction or malfunctioning of the brain such that the normal functions are no longer possible. Typically, patients with encephalopathy are either nonresponsive or poorly responsive and not in control of any of their faculties. (Div. Ex. 9, pp. 50-52)

32. Patient A was comatose until January 24, 2009, approximately four days after the procedure. She became agitated, and medical personnel continued to have her intubated for a few days after that because of her agitation. By January 26, 2009, she started to show full responsiveness. She was then extubated and believed to return to her baseline state. (Hrg. Tr., pp. 200-201)

33. On Respondent's post-procedure report dictated January 20, 2009, Respondent states, "I suspected [Patient A's] response was the result of increased intracranial pressure from the gadolinium dye introduced." (Div. Ex. 19, p. 296; Hrg. Tr., p. 294)

34. Respondent testified at hearing that he believed Patient A's symptoms could have been caused by withdrawal from medications, hypertensive encephalopathy or gadolinium neurotoxicity (*i.e.*, gadolinium-induced encephalopathy). (Hrg. Tr., pp. 439-440)

35. On January 21, 2009, Patient A underwent MRIs and a CT scan of her brain. The radiologists' reports showed evidence of gadolinium entering her brain. (Div. Ex. 19, pp. 196-201; Hrg. Tr., pp. 165-167)

36. A note dictated on January 25, 2009 by a cardiologist states that on January 22, 2009, for "unclear reasons," Patient A developed an encephalopathy. The note further states: "Severe bradycardia in a 57-year-old female who has an encephalopathy possibly hypertensive versus secondary to Gadolinium or other unknown etiology." A neurologist's note from January 21, 2009 states that Patient A is encephalopathic, with a question mark next to "cause." (Div. Ex. 19, pp. 31-32, 123; Hrg. Tr., pp. 208-210, 561-564)

37. The Division's two expert witnesses, Dr. James Conterato (an anesthesiologist and internist), and Dr. Vincent Mathews (a neuroradiologist), concluded after reviewing Patient A's medical records and relevant medical literature that Patient A's symptoms were consistent with gadolinium neurotoxicity as a result of intrathecal injection of gadolinium. (Hrg. Tr., pp. 165-170, 231-232; Div. Ex. 9, pp. 50-51)

38. Patient A's symptoms were similar to symptoms of patients described in medical literature who had received excessive amounts of intrathecal gadolinium. (Div. Ex. 9, p. 50-51; Div. Ex. 8, D3; Resp. Ex. 108)

39. On January 23, 2009, three days after the procedure at issue, a patient safety officer and the director of risk management from St. Luke's sent a memorandum to pain clinics captioned, "URGENT – INTERIM PROCEDURE FOR CONTRAST MEDIUM." The memorandum advised: "In light of a recent issue with neurotoxicity, all vials of MAGNEVIST (gadolinium) should be removed from the procedure cart and [are] to be stored in a separate secure area in the clinic. Any use in the pain clinics should have a consultation with an Interventional Radiologist." The memorandum further stated: "Anytime a patient presents with an allergy to iodine, the physician should consider the specific allergy symptoms and history and consider alternatives such as use of prophylactic allergy meds." That same day, a similar email was sent to St. Luke's medical staff from management. (Div. Exs. 12, 15)

40. After Respondent's treatment of Patient A, in either May of 2009 or May of 2010, Aurora changed its policy on the use of gadolinium to disallow its being injected into the intrathecal, intraspinal or epidural space unless the provider obtained an exception from the chief medical officer of the facility with support from the chief radiologist, based on specific indications for specific patients. (Div. Exs. 11, 14)

41. Respondent agreed that injecting 15 mL of undiluted gadolinium into a patient's intrathecal space "can create harm to the patient" and that "it is possible" that injecting 3 mL of gadolinium into a patient's intrathecal space could create a risk of harm. (Hrg. Tr., pp. 334-335)

15 vs. 3 mL[1] of Gadolinium

42. Respondent testified at hearing and at a prior deposition that he injected 3 mL of gadolinium diluted with 12 mL of a saline solution into Patient A's intrathecal space, for a total volume of 15 mL. (Hrg. Tr. pp. 427-428)

[1] The abbreviations "mL" and "cc" have the same meaning and were therefore used interchangeably throughout these proceedings. (Div. Ex. 9, pp. 38, 43)

43. Respondent's handwritten progress note in Patient A's medical records states: "Pump adequately linked to CSF via catheter, 15 cc Magnevist (Gadolinium) utilized.". (Div. Ex. 19, p. 125)

44. In a Pain Mangement Patient Assessment in Patient A's medical record, under a section entitled, "Procedure Medications" dated January 20, 2009, "15 cc" is written next to the typewritten "Magnevist" in what appears to be Respondent's handwriting. (Div. Ex. 19, p. 294; Hrg. Tr. pp. 300-305)

45. Respondent's handwritten note from January 20, 2009, immediately after Patient A's procedure, states:

> Dye Study
> 2 cc Aspirated
> 15 cc Gadolinium shows intact pump and catheter within subarachnoid space
> See full dictation

(Div. Ex. 19, p. 116; Hrg. Tr., pp. 284-286)

46. Respondent dictated more complete notes that same day, January 20, 2009, which state, among other things, that Respondent "introduced approximately 15 mL of Gadolinium dye." Respondent's detailed description of the procedure includes the following:

> I was able to aspirate 2 mL of clear fluid which will include fluid in the side port in the catheter and part of the cerebrospinal fluid. I was actually able to aspirate. If I wanted, I could aspirate more than 2 but I started at 2 mL. I then introduced gadolinium dye slowly. I introduced approximately 15 mL of Gadolinium dye. I was able to evaluate the area around the pump, I was not able to visualize any dye around the pump. I tracked from the pump the catheter and this was seen to go into the intrathecal space and I was able to find dye also within the cerebrospinal fluid into the subarachnoid space.

(Div. Ex. 19, p. 296; Hrg. Tr., pp. 284-293)

47. Respondent reviewed the transcription of his dictated notes and electronically signed the dictated transcription on January 23, 2009. (Div. Ex. 19, p. 297; Hrg. Tr., p. 287)

48. On January 21, 2009, Respondent discussed the case with neurologist Dr. Bhupendra Khatri. In Respondent's post-procedure note referencing the conference with Dr. Khatri, Respondent again charted that the patient had been injected with 15 mL of intrathecal gadolinium. The note specifically states, "[P]ump adequately linked to CSF via catheter, 15 cc Magnevist (Gadolinium) utilized." (Ex. 19, p. 125; Hrg. Tr., pp. 324-325)

49. A neurology note dated January 21, 2009, prepared by a neurologist, either Dr. Khatri or a Dr. Patrick, also reflects that Patient A had been injected with 15 mL of intrathecal gadolinium. The note states: "Received 15 ml. of GAD (Magnevist) intrathecally yesterday. Immediately c/o headache . . . unresponsive/comatose today . . . Encephalopathic/cause?. . ." (Hrg. Ex. 19, p. 123; Hrg. Tr., pp. 322-324, 563-564)

50. In describing the gadolinium injected into Patient A, neither Respondent nor any other medical provider mentions a quantity of 3 mL, nor is there any mention of dilution, saline, volume or concentration.

51. Respondent testified at hearing that "[i]t is important to document what you used: the volume, the dose, the concentration." He testified that he documented "the volume injected of the solution," but did not document "how it was mixed." When asked if it was important to accurately document the exact amount of gadolinium used, he testified, "I documented the exact volume of gadolinium that I used." (Hrg. Tr., pp. 320-321)

52. When asked why he wrote 15 mL or cc of gadolinium in his charts, Respondent testified, "The reason was usually when I use gadolinium, I would write it as a volume. When I use Magnevist, I write it as a volume. I have done hundreds and hundreds of procedures, and it was more or less like routine. I just write the volume, and I move on." (Hrg. Tr., p. 557)

53. The Division's expert witnesses, Dr. Mathews and Dr. Conterato, interpreted Respondent's notes to mean that Respondent injected 15 mL of undiluted gadolinium into Patient A. (Hrg. Tr., pp. 147, 173; Div. Ex. 9, p. 39)

54. Mathews opined that Respondent's testimony that he diluted 3 mL of gadolinium with 12 mL of saline was inconsistent with Respondent's notes indicating that he could track the contrast agent. He testified that if Respondent had diluted 3 mL of gadolinium with 12 mL of saline, he would not have been able to see the contrast track from the pump through the catheter and into the intrathecal space using fluoroscopy, as reflected in Respondent's notes. Mathews opined, "[I]f you want to see gadolinium under fluoroscopy, you would not want to dilute it. But if you wanted to inject it intrathecally, you would have to dilute it. So it's sort of a conundrum." (Hrg. Tr., pp. 174-176, 179)

55. Aurora's billing records for Patient A for January 20, 2009 indicate that 15 mL of gadolinium was used, stating: "CONTRAST GADO BASED PER ML (QTY of 0000015)," with an amount billed of $930. (Div. Ex. 3, p. 8[2]; Hrg. Tr., p. 442)

56. Testimony from Attorney Arthur Thexton supports the conclusion that Respondent used 15 mL of undiluted gadolinium. Thexton was an attorney at the Department[3] assigned to this matter during its investigative stage. Thexton testified that his role at the investigative stage was not only to be an advocate for the Department but also to oversee investigations and to close those cases for which there was insufficient evidence or where prosecutorial discretion should be exercised. He testified that half of all Department investigations are closed. (Hrg. Tr., pp. 460-461, 472)

57. During the course of the investigation of this matter, on August 22, 2014, Thexton interviewed Respondent by telephone with Respondent's attorney on the line. Thexton testified at hearing that the purpose of the conversation was to have some questions answered which Patient A's chart did not fully answer. He had explained to Respondent's attorney why he wanted to interview Respondent. (Div. Ex. 16; Hrg. Tr., pp. 408, 461-462)

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[2] This excerpt appears on page 8 of the Division's Exhibit 3; however, the page number at the top of the document is page 6.

[3] Thexton retired from the Department in January of 2015. (Hrg. Tr., p. 460)

58. Following his conversation with Respondent, Thexton memorialized the conversation in an email to Dr. Timothy Swan, a case advisor from the Wisconsin Medical Examining Board. Thexton testified that the email reflected all of the information from Respondent he thought to be important to the case and that there was nothing important to the case that he did not record. (Div. Ex. 16; Hrg. Tr., pp. 446, 464-465, 480)

59. Thexton's email states, in relevant part:

> [Respondent] practices with four other physicians, and all of them use gadolinium when iodine cannot be used. He believes this is the standard of care in pain medicine. . . .
>
> [Respondent] does check the level of allergy in patients, and this patient said she had a large reaction.
>
> It is sometimes necessary to adjust the fluoroscope when using gadolinium, because it is a poor contrast agent[], compared to iodine. . . .
>
> [Respondent] believes that gadolinium comes in one strength, and that there is no choice available to the physician. The brand name is Magnevist. It cannot be diluted, and he has never seen it diluted. Because it is a relatively weak contrast solution, diluting it would make it impossible to actually see anything. The way this works is that the vial is opened in front of him and then placed in a sterile well, in the field. He then personally puts a syringe in the file [sic], and draws it up. Most patients get 2 to 5 cc's, and he draws up two or 3 cm^3 at a time. This patient received 15 cm^3, because he was asked to look all along the catheter, from the abdomen to the intrathecal space, and not just at the tip. Secondly, the patient was morbidly obese, and it was harder to see. Given the outcome, he would never use this amount again.

(Div. Ex. 16, pp. 1-2)

60. Thexton testified that he asked Respondent about dilution because either Dr. Conterato or Dr. Swan had informed him that gadolinium should be diluted when going into the intrathecal space as opposed to being injected intravenously. He testified, "So I asked him specifically about dilution and whether it had been diluted for this patient and if he ever had diluted it. . . ." In response, Respondent informed Thexton that it was a "very weak contrast agent and that in order for it to show up on the fluoroscope, you have to have enough there. And if you diluted it further, then it would be so weak that you couldn't see it with the equipment." (Hrg. Tr., pp. 466-467)

61. Thexton testified that because Respondent stated he never diluted Magnevist and has never seen it diluted, Thexton inferred that Respondent did not do it for Patient A either. (Hrg. Tr., p. 467)

62. Thexton testified that if Respondent had told him that he diluted the gadolinium for Patient A, Thexton would have written that down. He testified: "I would have written that down because that would have been critically important and I would have recognized it immediately as

critically important. I mean, this woman was in a coma for several days; and so this was critically important to the investigation." (Hrg. Tr., pp. 467-468)

63. When asked if the conversation with Respondent was about this case and Patient A, Thexton responded, "Certainly." (Hrg. Tr., p. 468)

64. When asked if, based on the conversation with Respondent, it was his understanding that Respondent had told him that he injected 15 ccs (*i.e.*, mLs) of gadolinium into Patient A, Thexton testified, "Correct. 15 CCs of undiluted Magnevist into the catheter." (Hrg. Tr., p. 469)[4]

65. In response to the allegation contained in the Division's original April 8, 2015 Complaint that Respondent "injected 15 mL of gadolinium into the pain pump's catheter," Respondent's counsel, in his May 5, 2015 Answer, asserted: "Respondent was informed by the patient that she was allergic to iodine-based contrast, thus necessitating the appropriate use of gadolinium as a contrast agent. *Respondent denies knowledge of the precise amount injected in the pain pump's catheter.*" (Emphasis added) No modification was made to the Answer until after the hearing, when the Division filed an Amended Complaint. (Complaint ¶ 8; Answer ¶ 8; Amended Answer; Hrg. Tr., pp. 425, 428-429)

66. In response to the allegation contained in the Division's original Complaint that "[t]he generally accepted safe dose of intrathecal gadolinium is 1.5 mL," counsel for Respondent did not assert that up to 5 mL was tolerated according to medical literature. Rather, he answered: "Respondent denies this statement as vague and an inaccurate assertion of 'fact.' Respondent affirmatively asserts that there was no 'generally accepted safe dose' for the usage undertaken on January 20, 2009, nor is there such a standard now. Affirmatively allege and state that the quantity of contrast to be used in the circumstance is a matter of medical judgment" based on various factors. (Complaint, ¶ 9; Answer, ¶ 9)[5]

67. Respondent testified that prior to his treatment of Patient A, he informed her that she could suffer seizures as a result of the procedure he would perform on her. (Hrg. Tr., p. 359)

68. The facts set forth above establish by a preponderance of evidence that Respondent injected 15 mL of undiluted gadolinium into Patient A's intrathecal space.

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[4] Respondent testified that when he told Thexton that he did not dilute gadolinium, he believed they were discussing what Respondent normally did with his other patients in the spine, and that they were not discussing Patient A. Respondent testified that he told Thexton that he used 15 cc of Magnevist on Patient A and that he did not state whether it was diluted or not. (Hrg. Tr., pp. 411-414, 423-424, 489) I credit Thexton's testimony that Respondent stated that he never diluted gadolinium because it is a weak contrast agent and that he used 15 mL of gadolinium on Patient A because he needed to look all along the catheter, from the abdomen to the intrathecal space, and because the patient was morbidly obese, making it harder to see. I also credit Thexton's testimony that the conversation about dilution of gadolinium included whether it was diluted for Patient A, particularly given that Thexton had previously been informed that gadolinium needed to be diluted when used intrathecally and knew that the amount of gadolinium injected was critical to the investigation. My view of the respective testimony is not changed by the settlement offer sent from Thexton to Respondent's counsel (Resp. Ex. 115; Div. Ex. 23) upon which Respondent's counsel relied at hearing to attempt to show that Thexton misinterpreted the conversation.

[5] In support of its assertion that 15 mL of gadolinium was injected, the Division also relies on a letter to the Division from Respondent's counsel dated September 6, 2013. However, this letter was not made part of the record and therefore may not be considered. (Hrg. Tr., pp. 609-610)

Expert Testimony Regarding Amount of Gadolinium Injected

69. James Conterato, M.D., is board-certified in anesthesiology and in internal medicine and has practiced medicine for 37 years. He practiced interventional pain management from 1991-1999, has implanted pain pumps and has performed assessments of pain pumps. He performed a training fellowship from 2005-2006 at Mayo Clinic in regional anesthesia and acute pain medicine. He serves as a staff anesthesiologist at the Marshfield Clinic in Marshfield, Wisconsin, as medical director of Ambulatory Surgical Center, as medical director of the Regional Anesthesia and Acute Pain Service, and the co-director of Perioperative Surgical Home. (Div. Ex. 7; Div. Ex. 9, pp. 6-16)

70. When asked why he was qualified to render opinions on whether Respondent comported with minimal competency standards for a pain physician, Conterato stated that many of the procedures that Respondent routinely performs he (Conterato) has performed in the past, including implantation of pumps, implantation of spinal cord stimulators, assessment of pump function, and side arm injections. (Div. Ex. 9, pp. 15-16)

71. Vincent Mathews, M.D., is a neuroradiologist with over 25 years of experience. He is board-certified in diagnostic radiology and neuroradiology from the American Board of Radiology. As a radiologist, Dr. Mathews has injected gadolinium both intravenously and intrathecally. In his work as a neuroradiologist, Mathews has been involved in procedures where patients have had gadolinium injected into their intrathecal space in the context of myelograms and cisternograms, although it is not a common procedure. Mathews currently uses gadolinium intrathecally four to five times per year, although in the past, he did so 10-12 times per year. Mathews has also read MRIs with gadolinium injected thousands of times. (Div. Ex. 5; Hrg. Tr., pp. 121-126, 129-131, 199, 223)

72. Mathews does not work with pain pumps and is not a pain management specialist. However, as a neuroradiologist, Mathews has performed some procedures that are considered pain management procedures, including epidural steroid injections, nerve root blocks, and occasionally, facet injections. He has also tested the integrity of catheter tubing into the intrathecal space of patients, although not for catheter tubing related to a pain pump. Using intrathecal gadolinium is a procedure that is performed by a variety of medical specialists, including neuroradiology and pain management physicians. (Hrg. Tr., pp. 131-133, 203)

73. When asked why he (a neurologist) believes he is qualified to render opinions on whether Lawal comported with minimum competency standards for a pain physician, Mathews stated that the use of intrathecal gadolinium is a procedure performed by a variety of specialties, including neuroradiology and pain management physicians. He stated that specialties frequently use the same tools, the same drugs, the same techniques and sometimes the exact same procedures. He explained that there is an overlap for many procedures and that pain management is done by anesthesiologists, neuroradiologists, psychiatrists and some other physicians. He believed he was qualified to speak to the minimal competency standards of pain management in limited areas, which include intrathecal use of gadolinium, querying a patient about her patient allergies and whether other specialties should be consulted. (Hrg. Tr., pp. 133-134, 232)

74. Both experts reviewed Patient A's medical chart, Respondent's deposition testimony and relevant medical literature that existed at the time of Patient A's treatment in order to render

expert testimony to a reasonable degree of medical certainty regarding Respondent's care and treatment of Patient A. (Div. Ex. 9, pp. 17-19; Hrg. Tr., p. 135)

75. In reaching an opinion, Conterato performed a literature search in an attempt to mirror what the minimally competent pain physician may have conducted in 2009. He went on to Pub Med, which is the collection of all published medical literature in the world available to any physician, and conducted a search using the words "intrathecal" and "gadolinium." The result was a large number of studies discussing the safe intrathecal use of gadolinium. Conterato's review of the medical literature included the two Safriel articles, the Tali article and the Li article, all of which Respondent claimed to have reviewed. Conterato testified that no minimally competent physician contemplating the use of gadolinium in 2009 would have reviewed the literature results and injected either 15 or 3 mL of gadolinium intrathecally because the recognized upper safe limit was 1 mL. (Div. Ex. 9, pp. 37-38, 45-49, 106-111, 148-150)

76. Conterato testified to a reasonable degree of medical certainty that in treating Patient A, Respondent did not meet minimal standards of competency for a pain physician or radiologist[6] because the amount of gadolinium administered significantly exceeded the recommended top dose for intrathecal injection as shown throughout the existing medical literature at the time. Conterato testified that in 2009, "[u]niversally, on every continent, the upper safe limit of safety was 1 milliliter of undiluted Gadoloinium."[7] (Div. Ex. 9, pp. 19, 30-31, 35-36)

77. Conterato testified that a minimally competent pain physician practicing in 2009 should know that:

- The upper safe limit for injecting gadolinium into a patient's intrathecal space is 1 mL.
- Injecting gadolinium in excess of 1 mL into a patient's intrathecal space has a known toxic effect. These effects could include brain changes and resultant complications including headache and nausea, frank grand mal seizures, loss of consciousness, encephalopathy and coma.

(Div. Ex. 9, pp. 19, 35-37)

78. Conterato opined that a minimally competent physician who had never used gadolinium intrathecally needed to consult the literature for guidance as to how gadolinium was used in this off-label manner or consult with a physician who had experience utilizing gadolinium in this way. (Div. Ex. 9, p. 29)

79. Conterato opined to a reasonable degree of medical certainty that Respondent's use of gadolinium in Patient A created an unacceptable risk to Patient A because it was in excess of

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[6] Conterato testified that pain physicians and radiologists were the physicians most likely to use the materials at issue in this case. (Div. Ex. 9, p. 19)

[7] Respondent points out that Dr. Swan stated in an email to Attorney Thexton that the studies indicate safety of intrathecal gadolinium of up to 1.5 mL (rather than 1 mL). Respondent also notes that the Division's original Complaint (which has been superseded by its Amended Complaint) alleged that "[t]he general accepted safe dose of intrathecal gadolinium is 1.5 mL." (Respondent's Brief, p. 21; Div. Ex. 16, p. 1; Div. Ex. 9, p. 144; Hrg. Tr., p. 223) This information is of little relevance, however, in light of the conclusion reached in this case that Respondent injected 15 mL of gadolinium into Patient A's intrathecal space.

what was recommended and relevant medical literature showed that amounts exceeding 1 mL created a major risk to the patient of creating an encephalopathy. He stated that either 15 mL or 3 mL would have created that unacceptable risk. (Div. Ex. 9, p. 54)

80. Mathews similarly opined to a reasonable degree of medical certainty that Respondent's treatment of Patient A failed to comport with minimal competency standards because in 2009, any physician, including one in the specialty of pain management, exercising minimal competency standards, would conclude based on the available medical literature that the safe upper limit dose of intrathecal gadolinium is 1 mL. He further opined that by exceeding the upper safe limit of 1 mL, Respondent created an unusual and unacceptable risk of danger to Patient A. He testified that the minimally competent physician, after reviewing the relevant medical literature, would not undertake injection of either 3 mL or 15 mL of gadolinium into a patient's intrathecal space. (Hrg. Tr., pp. 135-136, 146-148, 153, 162-163, 171-173)

81. In addressing the excerpt from the Safriel articles indicating that up to 5 mL of gadolinium may safely be injected intrathecally, Conterato testified that a minimally competent physician practicing pain management could not rely on any passage in the medical literature to support injecting either 15 or 3 mL of gadolinium intrathecally. He further testified that in determining what the safe dose is, the minimum expectation would be that a physician would not rely on one passage that was referred to in a discussion. (Div. Ex 9, pp. 149-154)

82. Mathews also testified that Respondent should not have relied on the excerpts from the Safriel articles suggesting that up to 5 mL of gadolinium was acceptable. Mathews stated that a practitioner reviewing the Safriel articles should have checked the original source (*i.e.*, the Tali article, which Respondent claimed to have reviewed) and would need to realize that there was an error in the statements contained in the Safriel articles. (Hrg. Tr., pp. 164, 216, 229)

Informed Consent

83. A preoperative record in Patient A's chart states: "Risks/benefits/alternatives to the procedure have been discussed with the patient, informed consent has been obtained." Respondent signed it. (Div. Ex. 19, p. 294; Hrg. Tr., pp. 306, 566)

84. Patient A testified that she signed multiple permission forms for the procedure. She first stated that Respondent gave her a permission for procedure form to sign but then stated she believed it was a nurse who gave her forms to sign. (Div. Ex. 10, pp. 26-27; Hrg. Tr., pp. 82-83, 90-91)

85. Respondent testified that there is an informed consent form that is signed for procedures at St. Luke's and that a physician cannot do a procedure at St. Luke's without a signed consent form. He testified that both the patient and physician sign it and it is placed in the chart and contains the alternatives, risks, and benefits discussed with the patient. He testified that the form would have been completed on the date of the procedure, prior to the procedure. Respondent testified, "I can't say 100 percent. But what we did then was to have a signed consent, but I can't say 100 percent." He stated that he did not have a specific memory of doing so with Patient A but that it was typically done. (Hrg. Tr., pp. 343-344, 566-567)

86. No informed consent forms are in Patient A's health care records.

Informed Consent Regarding Iodine vs. Gadolinium

87. Patient A testified that she believed she had an iodine allergy because approximately 20 years before the procedure at issue, she had iodine injected into her arm and experienced hives and itching and was gasping for air. (Div. Ex. 10, pp. 12-13)

88. Mathews stated his opinion to a reasonable degree of medical certainty that a pain physician exercising minimal competency standards should query patients regarding iodine allergies before considering intrathecal gadolinium. Mathews stated that Respondent was required to determine what the symptoms were, what the circumstances of the administration were, how and when it was given, and to determine if it truly was an allergic reaction. He stated that patients are often confused about their allergies to medicines and when physicians inquire further, they sometimes find out that the patients do not really have an allergic reaction. (Hrg. Tr., pp. 137, 189)

89. Conterato also testified that minimal standards of competency required that Respondent determine the specific nature of Patient A's iodine allergy before using an alternative contrast agent such as gadolinium. He testified that it would be important to know what the iodine reaction was and the route by which the iodine had been given. He further testified that if Respondent held this discussion with Patient A, he failed to document the discussion in her medical chart. (Div. Ex. 9, pp. 25-27)

90. Conterato and Mathews opined that a physician comporting with minimal competency standards would determine what the contrast reaction was and when it occurred because several decades earlier a more potent form of iodine was commonly used. Since that time, a less concentrated form of iodine has been developed which does not invoke severe allergic reactions in patients who report iodine allergies. (Div. Ex. 9, p. 26; Hrg. Tr., pp. 140-141)

91. Conterato and Mathews testified that to meet minimal competency standards, Respondent should have discussed options for preventing or reducing a reaction to iodine, such as premedicating, although Mathews further stated that the patient should also be informed that there could still be a risk of a reaction. (Div. Ex. 9, pp. 58-59, 67-68; Hrg. Tr., pp. 142-146)

92. Mathews questioned the nature of Patient A's reaction to iodine because she testified that she had undergone CT myelograms, which involve iodine, and she evidently did not have a problem with iodine during the myelograms. (Hrg. Tr., pp. 225-227)

93. Respondent testified that while receiving the referral for Patient A, he discussed Patient A with the referring physician. He then reviewed Patient A's chart prior to seeing Patient A. It was clearly documented in many parts of her chart that Patient A had an iodine allergy. (Hrg. Tr., pp. 275, 348-349, 515)

94. Patient A's medical chart includes her handwritten statement that she is allergic to four different medications, which she listed. "IVP DYE" was capitalized and underlined, whereas the other three listed medications were not. Patient A put asterisks on both sides of the listed medications. IVP stands for intravenous pyelogram and typically involves iodine. (Div. Ex. 19, pp. 173, 284, Hrg. Tr., pp. 539-540, 586, 602)

95. An ambulance transport document dated January 18, 2009 lists allergies to four medications, including IVP dye. (Div Ex. 19, p. 9; Hrg. Tr., p. 515)

96. A note from another provider dated January 19, 2009 lists dye as an allergy. (Div. Ex. 19, p. 113)

97. A note from another provider dated January 20, 2009 likewise lists allergies to four medications, including IVP dye. (Div. Ex 19, p. 294, Hrg Tr., pp. 298-299)

98. Respondent testified that when he met with Patient A, she told him she had an iodine allergy and that her reaction to iodine had consisted of hives and respiratory problems. Respondent testified that Patient A stated she was fearful with respect to iodine and that she refused an iodine-based contrast and said she did not want iodine under any circumstance. He testified that she told him, "'No. You can't use iodine on me'" and "'I was told never to have it. I have breathing problems.'" (Hrg. Tr., pp. 277, 347, 538-539)

99. Respondent's notes do not identify Patient A's specific reactions or that he queried Patient A as to when or how the iodine allergy manifested itself. (Div. Ex. 19; Hrg. Tr., pp. 141-142, 279-281, 348-349, 353, 585-586)

100. Respondent testified he had no reason to doubt the iodine allergy based on Patient A's chart and his conversations with her. Based on his review of the chart and his conversation with Patient A, Respondent decided against using iodine. (Hrg. Tr., pp. 276-277, 280-281, 436)

101. Respondent's post-procedure notes, dictated the same day of the procedure, state, "[Patient A] is allergic to iodine within her system. I, therefore explained to her that I will be using gadolinium." (Div. Ex. 19, pp. 296-297; Hrg. Tr., p. 279)

102. Patient A testified that she was asked about her allergy to iodine by the nurse and that she told the nurse she had a reaction to it. She stated that she met with Respondent for the first time on the day of the procedure for only approximately ten minutes. She could not recall the details of her conversation with Respondent but did not believe she told Respondent about her iodine allergy and did not think he asked her about it. She testified that she understood she would not be receiving iodine but did not recall whether he told her he would use gadolinium. (Div. Ex. 10, pp. 14-17, 47; Hrg. Tr., pp. 79-81, 87)

103. Patient A further testified that Respondent was pleasant and open to her, a kind man, and gave her all the time she needed to ask questions of him. She testified that if Respondent had suggested using iodine for the procedure, she would not have been comfortable with that. (Div. Ex. 10, pp. 45-46, 49; Hrg. Tr., pp. 89-91)

104. Patient A's testimony was taken in a nursing home over seven years after the procedure. When asked her address, she could not remember it. When asked for the names of her children, she had problems remembering some of their last names. (Div. Ex. 10, pp. 6, 32; Hrg. Tr., pp. 78, 84-85)

105. Respondent disagreed with Patient A that he only met with her for 10 minutes before performing the procedure; however, he did not recall exactly how much time he spent with her. (Hrg. Tr., pp. 274-275)

106. Mathews testified that he would not have felt comfortable using iodine as a contrast agent on Patient A based on the information he had, that he would need more information, and that if a patient is not comfortable using iodine as a contrast agent, a physician should defer to the patient. (Hrg. Tr., p. 225-226)

Informed Consent Regarding Alternate Medical Modes of Treatment

107. Mathews testified to a reasonable degree of medical certainty that an alternative to Respondent's procedure may have been to inject gadolinium of less than 1 mL diluted with up to 10 mL of saline into the intrathecal space and then do a spine MRI or a T1 radio spine MR to ensure that the gadolinium entered the thecal sac and determine whether the pump was functioning properly. However, he acknowledged he would probably not be able to see a micro-perforation in a catheter using an MRI. He also acknowledged that an MRI may not have been feasible due to the fact that anesthesia was not available for three days. (Hrg. Tr., pp. 188-189, 205-207, 229)

108. Patient A testified that Respondent did not discuss with her options other than the procedure he performed on her. He did not tell her that surgery, MRI scan or CT myelograms were alternative options. (Div. Ex. 10, pp. 22-24; Hrg. Tr., pp. 82)

109. Respondent testified that he considered MRI, but an MRI had already been ordered and would not be completed for three days and would not have given him the answer to the question. He believed that three days was a long time for Patient A to wait given her pain. In addition, he testified that Patient A had significant metal in her spine from prior surgical procedures and that the resulting metallic artifacts would interfere with an MRI. He also stated that an MRI study would focus only on the spine and would not detect leakage along the flow of the catheter outside the spine. (Hrg. Tr., pp. 347, 520-522)

110. Respondent testified that he also considered a CT scan, which was ruled out because the procedure uses a substantial amount of iodine and Patient A stated that "she did not want iodine under any circumstance." In addition, like an MRI, the CT scan would show the spine but may not detect a perforation in the catheter outside the spine. (Hrg. Tr., pp. 347, 526)

111. Respondent stated he considered surgery for Patient A to remove the old pump and replace it with a new one but determined that the risks far outweighed the benefits because she had a previous reaction to anesthesia which included a hard time breathing after back surgery; was diabetic and morbidly obese; and had severe pain, hypertension, cardiovascular problems, reflux disease, and sleep apnea requiring a CPAP and BiPap machine. Therefore, as an anesthesiologist, he saw her as being very high risk for anesthesia and surgery. (Div. Ex. 19, pp. 16-17; Hrg. Tr., pp. 346-347, 527-530)

112. Mathews agreed that "there were not many good options available for dealing with [Patient A]" and that "[s]he kind of put the caretakers in a bind" with her complicated presentation. (Hrg. Tr., p. 211)

Informed Consent Regarding the Substantial Risks Posed by the Amount of Gadolinium Injected

113. Patient A testified that Respondent did not inform her that she could suffer nerve damage, paralysis, seizures, respiratory complications, coma or death as a result of Respondent's injection of gadolinium. (Div. Ex. 10, pp. 22-24; Hrg. Tr.. p. 82)

114. Respondent testified that he informed Patient A that she could suffer seizures as a result of the procedure he would perform on her. (Hrg. Tr., p. 359)

115. Respondent testified that a form delineating risks and benefits was signed by himself and Patient A and that he informed Patient A of the possibility that she could suffer seizures. Patient A testified that she signed informed consent forms. Informed consent forms are not part of Patient A's health care record. (See Findings of Fact 66, 84-85, above)

116. Conterato testified to a reasonable degree of medical certainty that Respondent should have explained to Patient A that the amount of gadolinium he was using was in a range that would have a more than reasonable chance of causing toxicity. (Div. Ex. 9, p. 58)

Maintaining Accurate, Complete and Timely Health Care Records for Patient A

117. Respondent agrees that accurate documentation of pertinent information is important because it helps protect patients. (Hrg. Tr., pp. 317-318)

118. Respondent's notes do not reflect when or how Patient A's iodine allergy manifested itself nor do they show that he looked at or discussed with Patient A the option of pretreating her iodine allergy with medication. (Hrg. Tr., pp. 141-142, 145-146)

119. Conterato testified that the nature of the reaction to gadolinium should have been delineated and a decision made about whether to pursue other avenues and that Respondent did not document that he did this. (Div. Ex. 9, p. 56-57)

120. Mathews testified that he was not surprised that Respondent's medical notes did not include a lot of information regarding Patient A's iodine allergy and he did not have strong criticisms of that. (Hrg. Tr., p. 224)

121. Respondent's notes do not show what other options he considered other than intrathecal injection of gadolinium. Respondent testified that most doctors do not chart all options considered. (Hrg. Tr., p. 346)

122. Conterato testified that he saw no documentation of informed consent other than what Respondent dictated in his note and that therefore Respondent's documentation was inadequate. (Div. Ex. 9, p. 57)

DISCUSSION

Burden of Proof

The burden of proof in disciplinary proceedings is on the Division to show by a preponderance of the evidence that the events constituting the alleged violations occurred. Wis.

Stat. § 440.20(3); *see also* Wis. Admin. Code § HA 1.17(2). To prove by a preponderance of the evidence means that it is "more likely than not" that the examined action occurred. *See State v. Rodriguez*, 2007 WI App. 252, ¶ 18, 306 Wis. 2d. 129, 743 N.W.2d 460, citing *United States v. Saulter*, 60 F.3d 270, 280 (7th Cir. 1995).

Violations

Intrathecal Injection of Gadolinium

The parties dispute how much gadolinium Respondent injected into Patient A's intrathecal space, with Respondent asserting that he injected 3 mL of gadolinium (along with 12 mL of saline solution) and the Division asserting that he injected 15 mL of undiluted gadolinium. The Division also asserts that even if Respondent used only 3 mL of gadolinium, injection of such an amount would nevertheless constitute unprofessional conduct. As summarized below, a preponderance of the credible evidence demonstrates that Respondent injected 15 mL of undiluted gadolinium into Patient A's intrathecal space. Therefore, it need not be decided whether injecting 3 mL would have been unprofessional conduct.

Respondent testified at hearing and at a deposition approximately three months before hearing that he injected 3 mL of gadolinium diluted with 12 mL of a saline solution into Patient A's intrathecal space, for a total volume of 15 mL. Other evidence establishes that it is more likely than not that Respondent actually injected 15 mL of undiluted gadolinium into Patient A's intrathecal space. As described in the findings of fact above, on several occasions, Respondent wrote in Patient A's chart that he injected 15 mL or cc's of "gadolinium" (or "Magnevist") intrathecally, with no mention of dilution or saline, and no indication that the 15 mL was a solution consisting of gadolinium and some other substance. These notes cannot be attributed to some type of hasty short-hand made during his treatment of Patient A. Respondent's post-procedure notes which were dictated the day of the procedure and signed three days later include a very specific and relatively lengthy description of the procedure, noting such details as that Respondent "was able to aspirate 2 mL of clear fluid which will include fluid in the side port in the catheter and part of the cerebrospinal fluid," that "[i]f [he] wanted, [he] could aspirate more than 2 but [he] started at 2 mL," that he "introduced gadolinium dye slowly," and that he "introduced approximately 15 mL of Gadolinium dye." It is extremely difficult to believe that Respondent would have neglected to chart -- even after having time to review his notes -- the very significant fact that the 15 mL consisted of only 3 mL of gadolinium and 12 mL of saline, particularly given that other seemingly less significant details are provided, that when Respondent signed his notes three days after the procedure, Patient A was in a coma, and that Respondent himself acknowledged that "[i]t is important to document what you used: the volume, the dose, the concentration."

Moreover, other medical providers familiar with the case, such as the neurologist, also noted in Patient A's chart that Patient A had been injected with 15 mL of gadolinium. In addition, the Division's two experts, long-time physicians presumably with experience in interpreting other physicians' chart notes, interpreted Respondent's notes to mean that 15 mL of undiluted gadolinium was injected. Dr. Mathews also credibly noted that if Respondent had diluted 3 mL of gadolinium with 12 mL of saline, he would not have been able to see the contrast track from the pump through the catheter and into the intrathecal space using fluoroscopy, as reflected in Respondent's notes. This conclusion is consistent with what Attorney Thexton

reported that Respondent had told him – that gadolinium was a weak contrast agent and that he needed to use a significant amount of it (15 mL) to be able to see it track in Patient A.

Further, in his initial Answer to the Division's initial Complaint, Respondent never once asserted that he had injected only 3 mL of gadolinium or that he reviewed medical literature and that the literature reflected that such an amount was medically acceptable. In response to the allegation contained in the Division's original April 8, 2015 Complaint that Respondent "injected 15 mL of gadolinium into the pain pump's catheter," Respondent asserted: "*Respondent denies knowledge of the precise amount injected in the pain pump's catheter.*" (Emphasis added.) No explanation has been provided in this proceeding as to why Respondent made such a response if the amount he injected was only 3 mL, and if he believed, based on his medical review of the literature, that this amount was medically sound.

Also, in response to the allegation contained in the Division's original Complaint that "[t]he generally accepted safe dose of intrathecal gadolinium is 1.5 mL," Respondent did not assert that up to 5 mL was tolerated according to medical literature. Rather, he answered: "Respondent denies this statement as vague and an inaccurate assertion of 'fact.' Respondent affirmatively asserts that there was no 'generally accepted safe dose' for the usage undertaken on January 20, 2009, nor is there such a standard now. Affirmatively allege and state that the quantity of contrast to be used in the circumstance is a matter of medical judgment" based on various factors.

The conclusion that Respondent injected 15 mL of undiluted gadolinium is also consistent with Aurora's billing records for Patient A for January 20, 2009, which state: "CONTRAST GADO BASED PER ML (QTY of 0000015)," with an amount billed of $930.

Injection of 15 mL of undiluted gadolinium is also consistent with the testimony Attorney Thexton who credibly testified that Respondent told him during his investigation of this matter in 2014 that Magnevist, the brand name for gadolinium, "cannot be diluted, and he has never seen it diluted," that (consistent with Mathews' testimony) "it is a relatively weak contrast solution, diluting it would make it impossible to actually see anything," that most patients receive 2 to 5 cc's but "[t]his patient received 15 cm^3, because he was asked to look all along the catheter, from the abdomen to the intrathecal space, and not just at the tip" and because "the patient was morbidly obese" which made it "harder to see." Thexton credibly testified that his understanding, based on the conversation with Respondent, was that Respondent injected "15 CCs of undiluted Magnevist into the catheter." Thexton also credibly testified that Respondent informed him that given the outcome, he would never use this amount again.

Respondent's position is also undermined by his own testimony that he informed Patient A that she could suffer seizures as a result of the procedure. If Respondent had injected only 3 mL of gadolinium based on his review of medical literature which he interpreted as supporting that up to 5 mL was tolerated, then it makes little sense that he would inform Patient A that she could suffer seizures based on his injection of 3 mL of gadolinium.

Respondent's position is also undermined by his statement that he wrote 15 mL of gadolinium in his charts because during his hundreds of procedures using gadolinium, it was his routine to just write down the volume. As set forth above, Respondent indicated to Thexton that he does not dilute Magnevist and that this was the first time he used it intrathecally. Thus, the

"volume" Respondent refers to would presumably consist entirely of Magnevist, as it did with respect to Patient A.

Having concluded that Respondent injected 15 mL of undiluted gadolinium into Patient A's intrathecal space, the next question is whether such conduct constituted unprofessional conduct under Wis. Admin. Code § Med 10.02(2)(h), as alleged by the Division. Wisconsin Admin. Code § Med 10.02(2)(h) defines unprofessional conduct to include "[a]ny practice or conduct which tends to constitute a danger to the health, welfare, or safety of patient or public." In interpreting this language, the Wisconsin Supreme Court has stated that "unprofessional conduct" is conduct which does not meet the level of minimal competence using accepted medical standards and which poses an unacceptable risk to the health, welfare or safety of the patients. *Gilbert v. Medical Examining Board*, 119 Wis. 2d 168, 196, 349 N.W.2d 68 (1984).

The overwhelming evidence establishes that Respondent's injection of this amount constituted unprofessional conduct. The Division's experts both testified that intrathecal injection of 15 mL of gadolinium does not meet levels of minimal competence for a pain physician and creates an unacceptable risk to the patient's health. During his testimony, Respondent never indicated that intrathecal injection of 15 mL was safe or acceptable, or even that he believed it was, nor is such an argument made in his post-hearing brief. Instead, Respondent indicated that based on his review of the literature, he believed that up to 5 mL was tolerated and that he therefore injected 3 mL of gadolinium with 12 mL of saline solution. This testimony was not credited, in light of the more substantial evidence undermining it.

None of the medical literature upon which Respondent states he relied demonstrates that 15 mL may safely be injected. In fact, the literature demonstrates the opposite. The Li article, which Respondent states he reviewed prior to meeting with Patient A, documents a patient who inadvertently received a "high dose" of intrathecal gadolinium. The amount of gadolinium was approximately 15 mL, the amount injected here, which the article describes on two occasions as "30 times" the recommended dosage use in humans. The patient immediately complained of headache, accompanying nausea, and vomiting. She became comatose approximately one hour after the incident and had an outbreak of systemic seizures. These symptoms are remarkably similar to Patient A's symptoms. The 2008 Safriel article, which Respondent also states that he reviewed, documents a patient who inadvertently received 5 mL of gadolinium intrathecally and experienced headache, vomiting and a grand mal seizure. And even if Respondent is correct that excerpts in both the 2006 and 2008 Safriel articles support the safety of up to 5 mL of intrathecal gadolinium, none of the literature supports the safety of 15 mL.

Respondent also argues that the Division has failed to demonstrate the existence of an accepted standard of care for Patient A in these circumstances. In so arguing, Respondent relies heavily on a dissenting opinion in *Seifert v. Balink*, 2017 WI 2, 372 Wis. 2d 525, 888 N.W.2d 816, for the proposition that the standard must be commonly accessible by those practicing in the relevant field. (Respondent's Brief, pp. 14, 16) Even assuming that views expressed in a dissenting opinion were law or that the principles asserted are true, they do not assist Respondent here. Respondent argues that the situation involving Patient A was highly unique and required Respondent to resort to medical literature. He then states, "Where the conclusion can only be reached through interpretation of multiple studies it simply cannot be 'commonly accessible.'" (*Id.*, p. 17) This argument is misplaced, however, as the studies in the record lead overwhelmingly to the conclusion that injection of 15 mL is unsafe and could result in such

consequences as coma and seizures, and none of the studies remotely suggest that injection of 15 mL was safe. Under Respondent's analysis, it appears that a physician in Respondent's situation could inject any amount of gadolinium with impunity.

Respondent also asserts that the appropriate standard is the standard of minimal competence of a "reasonable anesthesiologist practicing in the field of pain management." (*Id.*, p. 16) He appears to believe that because Mathews and Conterato, unlike Respondent, are not anesthesiologists practicing in the field of pain management, the proper standards were not applied in this case. He notes that Mathews, a neurologist, does not work with pain pumps or hold himself out as a pain management specialist, and that Conterato, although an anesthesiologist, is not a pain management specialist.

However, the critical procedure at issue in this case is the injection of intrathecal gadolinium, a procedure which Respondent had never conducted prior to this case and which Mathews had conducted on numerous occasions as a neuroradiologist. In addition, Mathews has used gadolinium intravenously, has performed procedures that are considered pain management procedures, and has tested the integrity of catheter tubing into the intrathecal space of patients. Conterato, like Respondent, is an anesthesiologist, and has substantial experience in pain management. He practiced interventional pain management from 1991-1999, had implanted pain pumps and had performed assessments of pain pumps. He performed a training fellowship from 2005-2006 at Mayo Clinic in regional anesthesia and acute pain medicine.

Moreover, Respondent provides no support for the suggestion that expert opinions may only be credited if they come from those who practice in the exact same subspecialty as the physician whose conduct is being examined. As explained by Mathews, injection of intrathecal gadolinium is a procedure performed by a variety of specialties, including neuroradiology and pain management physicians. Specialties frequently use the same tools, drugs, techniques and sometimes the exact same procedures. In addition, pain management may be done by several different specialists, including anesthesiologists, neuroradiologists, and psychiatrists.

Further, Respondent has not shown that improper standards were applied. Both experts testified regarding whether Respondent complied with minimum competency standards. A reasonable inference is that they were referring to Respondent in his specialty practice. The experts also frequently testified regarding whether Respondent's conduct complied with minimal standards for a pain physician. Conterato also referred to minimal standards for a pain physician or a radiologist because he believed that pain physicians and radiologists are the physicians most likely to use gadolinium. Finally, the standard being applied in this decision is whether Respondent complied with minimal competency standards for a pain management physician.[8]

The bottom line is that the only evidence addressing intrathecal injection of 15 mL of gadolinium showed that it was extremely unsafe and fell below the standard of minimal competency for a pain physician, and the record contains no evidence at all (and no persuasive argument from Respondent) that intrathecal injection of 15 mL of gadolinium was reasonable.

The evidence also demonstrates that Respondent's conduct created an unacceptable risk to Patient A's health. Both of the Division's experts testified to a reasonable degree of medical

[8] During the relevant time period, Respondent practiced anesthesia 50 percent of the time and pain management 50 percent of the time. His treatment of Patient A was in his capacity as a pain management specialist.

certainty that Respondent's treatment of Patient A created an unacceptable risk of harm to her. Although Respondent argues that Patient A's coma and other symptoms could have been caused by factors other than injection of gadolinium and points out that some physicians reviewing Patient A's situation expressed some question about what caused Patient A's encephalopathy, the Division's burden is to show that Respondent's conduct created an unacceptable risk of harm, not that his conduct actually harmed the patient. The Division's experts testified that Patient A's symptoms were consistent with gadolinium neurotoxicity. Her symptoms were remarkably similar to the symptoms of gadolinium neurotoxicity described in the medical literature, including headache, seizure-like activities (involuntary flopping of arms and legs), encephalopathy and coma. As reflected in their notes, other physicians reviewing the situation at St. Luke's also considered gadolinium as a potential cause of Patient A's symptoms. Respondent himself testified that Patient A's encephalopathy could have resulted from his injection of gadolinium. In addition, St. Luke's changed its policies immediately after Patient A's trauma to limit access to gadolinium "[i]n light of a recent issue with neurotoxicity," and established a strict protocol for its intrathecal use.

As shown above, the preponderance of evidence establishes that Respondent injected 15 mL of gadolinium into Patient A's intrathecal space and that this conduct fell below the standard of minimal competence for a pain physician and created an unacceptable risk of harm to Patient A, thereby constituting unprofessional conduct under Wis. Admin. Code § Med 10.02(2)(h).

Informed Consent[9]

"Unprofessional conduct" is defined to include "[f]ailure to inform a patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments." Wis. Admin. Code § Med 10.02(2)(u). *See also* Wis. Stat. § 448.30 (imposing same requirements).

The Division asserts that Respondent failed to obtain informed consent because he did not obtain adequate information about Patient's A's reported allergy to iodine before using gadolinium and did not consider pretreating Patient A so that he could use iodine rather than gadolinium; did not adequately inform Patient A of reasonable alternatives, such as surgery, an MRI scan or a CT myelogram; and did not inform Patient A of the adverse consequences that she could suffer as a result of intrathecal injection of gadolinium in excess of 1 mL. For the reasons set forth below, the Division has failed to show by a preponderance of evidence that Respondent violated informed consent requirements.

A preoperative record in Patient A's chart states: "Risks/benefits/alternatives to the procedure have been discussed with the patient, informed consent has been obtained." Respondent signed it. Patient A testified that she signed multiple permission forms for the procedure. Her testimony was equivocal about whether it was a nurse or Respondent who had her sign them. Respondent also testified that St. Luke's required an informed consent form which contains the alternatives, risks, and benefits discussed with the patient and he was fairly confident he and Patient A had signed it. There are no informed consent forms in Patient A's

[9] In his post-hearing brief, Respondent again challenges what he perceives as the Division's addition of new allegations of informed consent and documentation. These arguments have been addressed in the ALJ's post-hearing ruling on the Division's motion to amend the Complaint and will not be addressed again here.

medical chart. Therefore, although the testimony of the two witnesses establishes by a preponderance of evidence that an informed consent form was signed, there is no indication of what specific information the form contained.

With regard to the Divisions' specific claim that Respondent failed to discuss options available for using iodine instead of gadolinium, there is no dispute that Patient A's iodine allergy was well-established in her medical record. At one place, Patient A herself emphasized her iodine allergy by writing it in capital letters and underlining it. Patient A herself testified that her reaction to iodine included hives and gasping for air. She stated she was fearful of iodine and that if Respondent had suggested using iodine for the procedure, she would not have been comfortable with that. She indicated that Respondent was kind and gave her all the time she needed to ask questions of him.

Respondent testified that when he met with Patient A, she told him she had an iodine allergy and that her reaction to iodine had consisted of hives and respiratory problems, although Respondent did not chart these responses. Respondent testified that Patient A stated she was fearful with respect to iodine and that she refused an iodine-based contrast and said she did not want iodine under any circumstance. He testified that she told him, "'No. You can't use iodine on me'" and "'I was told never to have it. I have breathing problems.'" Respondent testified he had no reason to doubt the iodine allergy based on her chart and his conversations with her. Respondent's notes, dictated the same day of the procedure, state, "[Patient A] is allergic to iodine within her system. I, therefore explained to her that I will be using gadolinium." The Division emphasizes that Patient A's testimony differs from Respondent's in that she stated she believed she discussed her iodine allergy with nurses rather than Respondent, and did not believe he asked her about her iodine allergy. She also testified that she understood she would not be receiving iodine but did not recall whether he told her he would use gadolinium.

The Division has not met its burden of establishing that Respondent engaged in unprofessional conduct by failing to sufficiently query Patient A regarding her iodine allergy or failing to consider and discuss with her how iodine could safely be used. Respondent testified that he discussed Patient A's iodine allergy with her and that Patient A refused iodine. His notes record that due to her iodine allergy, he explained he would use gadolinium. Patient A's testimony was less certain on whether they discussed her allergy or whether she only discussed it with nursing staff, and her testimony reflects some fairly significant memory issues. Patient A was adamant about not using iodine. Mathews testified that given the information he had, he would not feel comfortable using iodine on Patient A and that such a decision is ultimately the patient's choice. Given these facts, the Division has not met its burden of establishing a violation of Wis. Admin. Code § Med 10.02(2)(u) or Wis. Stat. § 448.30 with regard to the use of iodine.

The Division also argues that Respondent violated informed consent provisions by failing to discuss or consider other options to gadolinium. Although the Division is rather vague as to what it believes the other viable options were (other than using iodine, addressed above), presumably, it is arguing that or an MRI, a CT scan or surgery presented viable options. The Division has not met its burden of establishing that these were viable options which Respondent was required to discuss with Patient A to obtain her informed consent.

Mathews acknowledged that "there were not many good options available for dealing with [Patient A]" and that "[s]he kind of put the caretakers in a bind" with her complicated presentation.

Respondent testified that he considered an MRI, but an MRI had already been ordered and would not be completed for three days and would not have given him the answer to the question. He believed that three days was a long time for Patient A to wait given her pain. In addition, he testified that Patient A had significant metal in her spine from prior surgical procedures and that the resulting metallic artifacts would interfere with an MRI. He also stated that an MRI study would focus only on the spine and would not detect leakage along the flow of the catheter outside the spine. Mathews acknowledged Respondent would probably not be able to see a micro-perforation in a catheter using an MRI. He also acknowledged that an MRI may not have been feasible due to the fact that anesthesia was not available for three days.

Respondent testified that he also considered a CT scan, which was ruled out because the procedure uses a substantial amount of iodine, and Patient A stated that "she did not want iodine under any circumstance." In addition, Respondent stated that, like an MRI, the CT scan would show the spine and may not detect a perforation in the catheter outside the spine.

Respondent stated he considered surgery for Patient A to remove the old pump and replace it with a new one but he determined that the risks far outweighed the benefits because she had had a previous reaction to anesthesia which included a hard time breathing after back surgery. She was also diabetic, morbidly obese and had severe pain, hypertension, cardiovascular problems, reflux disease, and sleep apnea requiring a CPAP and BiPap machine. Therefore, as an anesthesiologist, he saw her as being very high risk for anesthesia and surgery.

It is the Division's burden to show that Respondent violated informed consent provisions. It did not present sufficient evidence to demonstrate this, particularly in light of Respondent's evidence to the contrary. While in hindsight, any of these alternatives were almost certainly better than injecting 15 mL of gadolinium into Patient A's intrathecal space, fairness dictates that Respondent's failure to discuss or choose alternatives be evaluated from the perspective of him not understanding the extreme danger of injecting 15 mL of gadolinium.[10] A violation has been found for Respondent's use of 15 mL. It would be illogical and excessive to find violations for his failure to discuss or choose these alternatives to a procedure he evidently did not believe to be dangerous. By this same rationale, to the extent the Division asserts that Respondent violated informed consent provisions by failing to inform Patient A of the substantial risks posed by the amount of gadolinium he was injecting, the Division has not met its burden of establishing a violation. I cannot conclude that the informed consent provisions require a physician to essentially inform a patient that the physician will violate the standard of care in treating the patient where the evidence does not show that the physician knew that his treatment would endanger the patient.

Documentation

Unprofessional conduct is also defined to include "[f]ailure by a physician . . . to maintain patient health care records consistent with the requirements of ch. Med 21." Wis. Admin. Code § Med 10.02(2)(za). Wisconsin Admin. Code § Med 21.03(2) states:

[10] I do not credit Respondent's testimony that he informed Patient A she could suffer seizures.

A patient health care record prepared by a physician . . . shall contain the following clinical health care information which applies to the patient's medical condition:

(a) Pertinent patient history.
(b) Pertinent objective findings related to examination and test results.
(c) Assessment of diagnosis.
(d) Plan of treatment for the patient.

The Division's main argument with respect to record keeping is that Respondent should have included in Patient A's health care records the exact concentration of gadolinium introduced. This argument appears to be dependent on a conclusion that Respondent injected 3 mL of gadolinium along with 12 mL of saline solution, rather than the 15 mL of gadolinium that Respondent documented. Because I conclude that Respondent injected the precise amount of gadolinium he documented and billed for – 15 mL – there is no merit to the argument that Respondent's documentation of gadolinium concentration violated Wis. Admin. Code §§ Med 10.02(2)(za) and 21.03(2).

The Division also argues that Respondent's documentation of Patient A's iodine allergy was legally insufficient. The Division has failed to meet its burden of establishing a violation, particularly in light of the opinion of its own expert, Mathews, that it was unsurprising that Respondent's medical notes did not include a lot of information regarding Patient A's iodine allergy and that he did not have strong criticisms of that.

In light of this tribunal's conclusion that Respondent did not violate informed consent provisions regarding consideration and discussion of options such as an MRI, CT scan or surgery and the lack of evidence establishing that a physician must document all procedures considered and rejected, the Division has failed to meet its burden of establishing inadequate documentation with respect to these alternatives.

Discipline

The three purposes of discipline are: (1) to promote the rehabilitation of the licensee; (2) to protect the public from other instances of misconduct; and (3) to deter other licensees from engaging in similar conduct. *State v. Aldrich,* 71 Wis. 2d 206, 237 N.W.2d 689 (1976).

The Division requests that Respondent's license be suspended for a minimum of 14 days and that he be required to complete remedial education courses on the topic of ethics, informed consent and documentation. Respondent argues that no discipline should be imposed, that Respondent attempted to do what was best for a patient who had no other options, and that "this case is at most an argument that a pain management physician failed to detect the error in two peer-reviewed publications." (Respondent's Brief, p. 25) Respondent's last assertion is negated by this tribunal's conclusion that Respondent injected 15 mL of gadolinium, an amount which no medical literature in the record supports. Respondent also asserts that the Division's recommended discipline seeks to punish Respondent for exercising his right to a hearing in this matter. In support of this latter assertion, Respondent points to the fact that the Board case advisor, Dr. Swan, in his initial review of this matter, recommended "a letter of warning

(minimum) or reprimand with education (maximum)" and (Div. Ex. 16, p. 1) and that the Division later proposed a stipulated resolution along similar lines (Div. Ex. 23).[11]

Based on the factors in *Aldrich* and the record in this case, I conclude that a one-week suspension of Respondent's license is warranted. This discipline promotes Respondent's rehabilitation and serves to protect the public in that Respondent will hopefully understand and learn from his grave error in injecting 15 mL of gadolinium into Patient A's intrathecal space. A mere reprimand or warning does not sufficiently address Respondent's rehabilitation, the protection of the public or deterrence. Injecting 15 mL of gadolinium fell well below minimal standards of competency and placed Patient A in extreme and unacceptable danger. However, the suspension imposed is less than that requested by the Division because the Division failed to prove its informed consent and documentation violations. Moreover, the educational hours requested by the Division are not imposed as two of the courses address violations not found in this case and the other, on ethics, does not address the underlying allegations in the Amended Complaint. The discipline imposed also takes into account the fact that Respondent has been practicing medicine for approximately 30 years with no previous disciplinary action and there is no indication in the record that Respondent intended to violate the standard of care.

Costs

The Division has the authority to assess costs pursuant to Wis. Stat. § 440.22. With respect to imposition of costs, factors which may be considered include: (1) the number of counts charged, contested and proven; (2) the nature and seriousness of the misconduct; (3) the level of discipline sought by the prosecutor; (4) the cooperation of the respondent; (5) any prior discipline; and (6) the fact that the Department is a program revenue agency, funded by other licensees. *See In the Matter of Disciplinary Proceedings against Elizabeth Buenzli-Fritz, D.C.*, Order No. LS0802183CHI (Aug. 14, 2008). It is not mandatory that all or any of these factors be considered, and it is within the Department's discretion to determine what weight, if any, to give any factors considered.

Respondent argues that no costs should be imposed, stating that he should not be penalized for defending himself, that this case involved at most medical judgment and the interpretation of complicated medical literature, that he has been cooperative in these proceedings, and that at or following hearing, the Division withdrew several counts alleged and amended its Complaint in several other respects.

The Division requests that full costs be imposed in this case, relying primarily on the multiple counts of unprofessional conduct alleged and on the premise that others in his profession should not have to bear the costs of Respondent's wrongdoing.

I conclude that Respondent should be required to pay 50 percent of the costs of these proceedings. Respondent is correct that the Division made several significant changes to its Complaint at or after hearing, withdrawing some allegations and defining other allegations more precisely. Most, if not all, of these changes could have taken place earlier in the process and prior to hearing, through a motion to amend the Complaint. No good reason was offered for why

[11] Although I do not usually consider pre-hearing settlement discussions or offers, both parties have waived objections to consideration of this information, the Division by introduction of these exhibits, and Respondent by his reliance on them.

this did not occur, and although no violations of due process resulted, the Division's failure to hone its case earlier undoubtedly increased the costs of this proceeding. Moreover, after substantial discussion at hearing and in post-hearing briefing, this tribunal denied the Division's request to amend its Complaint to allege deceitful conduct by Respondent, and although the Division was allowed to amend its Complaint with respect to its informed consent and documentation allegations, the Division failed to prove those counts. The ALJ also denied the Division's motion to strike the Respondent's post-hearing brief which the Division filed, despite previous extensions being provided to the Division, because Respondent's brief was three additional days late after Respondent had been granted an extension.

However, with respect to the count proven, Respondent's conduct reflects an extremely serious lapse of medical judgment that resulted in very significant consequences for Patient A, including being in a coma for several days. Nothing in the record supports injection of 15 mL of gadolinium, approximately 30 times above the maximum dosage according to the Division's experts and well over the maximum dosage according to the medical literature. However, there was no evidence of intentional misconduct, and Respondent has no prior discipline in his 30 years of practice. Regarding the level of discipline sought by the Division, I note that the Division recommended a two-week suspension along with educational requirements. Although any suspension is serious, the two weeks recommended is well below the maximum which could be imposed, which is revocation, and is half of what is imposed here. With respect to Respondent's cooperation, he has been generally cooperative throughout these very lengthy proceedings, although it cannot be ignored that his testimony regarding the amount of gadolinium he injected was not found to be credible in light of the other more substantial and convincing evidence undermining it. In imposing these costs, I must also consider the fact that any costs not borne by Respondent will be borne by those in his profession who have not engaged in such misconduct.

CONCLUSIONS OF LAW

1. The Division established by a preponderance of evidence that Respondent engaged in unprofessional conduct under Wis. Admin. Code § Med 10.02(2)(h) because his injection of 15 mL of gadolinium into Patient A's intrathecal space fell below the standards of minimal competence for a pain physician and posed an unacceptable risk of harm to Patient A.

2. The Division failed to establish by a preponderance of evidence that Respondent violated informed consent provisions of Wis. Admin. Code § Med 10.02(2)(u) or Wis. Stat. § 448.30.

3. The Division failed to establish by a preponderance of evidence that Respondent violated the documentation provisions of Wis. Admin. Code §§ Med 10.02(2)(za) and Med 21.03(2).

4. A one-week suspension of Respondent's license to practice medicine and surgery is warranted under the facts of this case and the criteria set forth in *Aldrich.*

5. Respondent is required to pay 50 percent of the costs of this proceeding pursuant to Wis. Stat. § 440.22.

ORDER

For the reasons set forth above, IT IS HEREBY ORDERED that:

1. Respondent's license to practice medicine and surgery is suspended for one week, commencing the date the Wisconsin Medical Examining Board signs the Final Decision and Order in this matter.

2. Respondent shall pay 50 percent of the recoverable costs in this matter in an amount to be established pursuant to Wis. Admin. Code § SPS 2.18. After the amount is established, payment shall be made by certified check or money order payable to the Wisconsin Department of Safety and Professional Services and sent to:

Department Monitor
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

Dated at Madison, Wisconsin on March 8, 2017.

STATE OF WISCONSIN
DIVISION OF HEARINGS AND APPEALS
5005 University Avenue, Suite 201
Madison, Wisconsin 53705
Telephone: (608) 266-7709
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By: _____
Jennifer H. Nashold
Administrative Law Judge