Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
S. Khalid Hussain, M.D.,	
Petitioner,	DATE: June 11, 1992
- v. -	Docket No. C-330 Decision No. CR204
The Inspector General.	

DECISION

On October 4, 1990, the Inspector General (I.G.) notified Petitioner that he was being excluded from participating in Medicare and any State health care program[1] for a period of five years. The I.G. advised Petitioner that his exclusion was authorized by section 1156 of the Social Security Act (Act) because the I.G. agreed with the recommendation of the Peer Review Organization of New Jersey (NJPRO), which concluded that Petitioner had grossly and flagrantly violated his obligation under section 1156(b)(1)(B) to provide care to patients that meets professionally recognized standards of health care.[2] The

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[1] "State health care program" is defined by section 1128(h) of the Social Security Act to cover three types of federally financed programs, including Medicaid. I use the term "Medicaid" hereafter to refer to all State health care programs from which Petitioner was excluded.

[2] Section 1156(a) of the Act imposes on health care practitioners a number of duties, among them the duty to provide care of a quality that meets professionally recognized standards of health care. Section 1156(b) authorizes the Secretary of the Department of Health and Human Services to exclude practitioners who commit certain types of violations of their statutory obligations. Section 1156(b)(1)(A) authorizes the exclusion of practitioners who substantially violate their obligations in a substantial number of cases. Section 1156(b)(1)(B) authorizes the exclusion of practitioners who "grossly and flagrantly" violate their obligations on one or more occasions. In the

I.G. concluded that, while there was no specific evidence to support the conclusion that Petitioner was unwilling to comply with his obligations under section 1156 of the Act, Petitioner had demonstrated an inability to substantially comply with such obligations. The I.G. based his conclusion on Petitioner's treatment of seven patients, to whom I shall refer as Patients 268001, 8601866M, 854914, 86-0935, 277259, 8617854M, and 632365. The I.G. informed Petitioner that in arriving at the decision to exclude Petitioner for a period of five years, the I.G. had considered specific factors in accordance with 42 C.F.R. § 1004.90(d) (1989).[3]

In the notice letter, the I.G. informed Petitioner that he was entitled to a hearing before an administrative law judge (ALJ) to contest the I.G.'s determination to exclude him for five years. Petitioner timely requested a hearing, and the case was assigned to me for hearing and decision. I held hearings in Camden, New Jersey on September 13-14, 1991, and on November 14, 1991. I have considered the evidence and exhibits and the parties' briefs and arguments. I conclude that the evidence establishes that on three occasions Petitioner grossly and flagrantly violated his obligation to provide care which meets professionally recognized standards. I further conclude that Petitioner has demonstrated an inability to comply with his obligation. Therefore, the I.G. had the authority to exclude Petitioner under section 1156 of the Act. Although there is a remedial need for an exclusion in this case, a five-year exclusion would not serve a remedial purpose. Thus, the five-year exclusion imposed and directed by the I.G. is unreasonable. Accordingly, I modify the exclusion to an exclusion of three years.

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present case, the I.G. has alleged only that Petitioner's exclusion is authorized pursuant to section 1156(b)(1)(B).

[3] The I.G. must first determine that a violation (of Petitioner's obligation under the Act) has occurred. Once the I.G. has determined that a violation has occurred, he must consider the specific factors contained in 42 C.F.R. § 1004.90(d) in arriving at an appropriate sanction. The factors the I.G. is to consider are: (1) the recommendation of the Peer Review Organization (PRO); (2) the type of offense; (3) the severity of the offense; (4) the previous sanction record of the practitioner or other person; (5) the availability of alternative sources of services in the community; (6) any prior problems the Medicare carrier or intermediary has had with the practitioner or other person; (7) whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and (8) any other matters relevant to the particular case. 42 C.F.R. § 1004.90(d) (1989).

ISSUES

The issues in this case are whether:

1. the I.G. must prove his case by the preponderance of evidence or by clear and convincing evidence;

2. Petitioner grossly and flagrantly violated his obligation to provide health care which meets professionally recognized standards and demonstrated an unwillingness or inability to substantially comply with such obligation; and

3. the five year exclusion imposed and directed against Petitioner by the I.G. is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW[4]

Petitioner

1. Petitioner is a physician practicing in the specialty of neurological surgery, or neurosurgery, in Vineland, New Jersey. Tr. II/258-59.[5]

2. Neurosurgery is the surgical treatment of disorders and diseases of the brain, spine, spinal cord, and nerves. Tr. I/131-32.

3. Petitioner is licensed to practice medicine in the States of New Jersey and New York. Tr. II/262.

4. At the time of his exclusion, Petitioner was on the staffs of Newcomb Medical Center, Vineland, New Jersey; Millville Hospital,

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[4] I have used headings in organizing my Findings of Fact and Conclusions of Law (FFCLs). My headings are not FFCLs and they do not alter the meaning of my FFCLs.

[5] Citations to the record in this case are as follows:

Transcript	Tr. [volume]/[page]
Petitioner's Exhibit	P. Ex. [number]/[page]
I.G.'s Exhibit	I.G. Ex. [number]/[page]
Petitioner's Post-Hearing Brief	P. Br. [page]
I.G.'s Post-Hearing Brief	I.G. Br. [page]
Petitioner's Reply Brief	P. R. Br. [page]
I.G.'s Reply Brief	I.G. R. Br. [page]

Millville, New Jersey; Bridgeton Hospital, Bridgeton, New Jersey; and Elmer Community Hospital, Elmer, New Jersey. T. II/263.

5. Petitioner graduated first in his medical school class of approximately 250 students at Liaqat Medical College in Sind, Pakistan. Tr. II/260; P. Ex. 21.

6. Petitioner completed an internship at St. Elizabeth's Hospital in Chicago, Illinois. Tr. II/260; P. Ex. 21.

7. Petitioner completed a residency in general surgery at Long Island College Hospital in Brooklyn, New York. Tr. II/260-61; P. Ex. 21.

8. Petitioner completed a residency in neurosurgery at several New York hospitals during the period July 1975 to June 1980. Tr. II/260-61; P. Ex. 21.

9. Petitioner was certified by the American Board of Neurological Surgery in 1983. Tr. II/262; P. Ex. 21.

10. To become board certified in neurosurgery, a physician must successfully complete an accredited neurosurgical training program in the United States and must successfully complete a two part examination, encompassing a written and an oral component. Tr. I/48-49; Tr. II/262-63.

11. The process of board certification is intended to establish that a physician has mastered at least the minimum body of knowledge required of a neurosurgeon and is able to apply this knowledge on a clinical level. Tr. I/131.

Procedural History

12. By letter dated September 30, 1988, NJPRO notified Petitioner that it had concerns about Petitioner's management of seven identified cases. The letter informed Petitioner that the cases would be presented to the Quality Assurance Committee and that he could submit an explanation of his management of the cases. I.G. Ex. 1.

13. Petitioner provided written responses to NJPRO. I.G. Ex. 2.

14. By letter dated January 9, 1989, NJPRO informed Petitioner that his written responses failed to resolve its concerns. The letter stated that, based on his unacceptable responses, NJPRO would institute an intensified review of Petitioner's medical records of Medicare admissions occurring after January 1, 1988, for a three month period or 30 records. I.G. Ex. 3.

15. By letter dated August 9, 1989, NJPRO notified Petitioner that it had concluded that there was a reasonable basis to

determine that Petitioner had violated his obligation to assure that services provided to Medicare beneficiaries were of a quality that met professionally recognized standards of health care in six cases. I.G. Ex. 4.

16. Petitioner met with the Sanctions Committee of NJPRO on March 5, 1990. I.G. Ex. 6/1.

17. At the March 5, 1990, meeting, Petitioner was represented by counsel and offered the testimony of Dr. Najum Kazmi, a neurosurgeon practicing in New Jersey. I.G. Ex. 6/1, 177.

18. The Sanctions Committee was assisted at the March 5, 1990, meeting by Dr. Ira Kasoff, a neurosurgeon and consultant to NJPRO. I.G. Ex. 6.

19. Dr. Kasoff was not a voting member of the Sanctions Committee. I.G. Ex. 8/14.

20. At the conclusion of the March 5, 1990, meeting, the Sanctions Committee voted to recommend that Petitioner be excluded from participating in Medicare and State health care programs, based on its conclusion that Petitioner had grossly and flagrantly violated his obligation to provide health care that met professionally recognized standards and that he had demonstrated an unwillingness and inability to comply with his obligation. I.G. Ex. 6/179-80.

21. By letter dated February 15, 1990, NJPRO notified Petitioner that it had identified another instance in which it had reason to believe Petitioner had violated his obligation to provide health care that met professionally recognized standards. I.G. Ex. 5/1.

22. On April 30, 1990, Petitioner met with the Sanctions Committee of NJPRO regarding the case identified in the letter of February 15, 1990. I.G. Ex. 7/1.

23. Petitioner was represented by counsel at the April 30, 1990, meeting. I.G. Ex. 7/1.

24. At the conclusion of the April 30, 1990, meeting, the Sanctions Committee voted to recommend that Petitioner be excluded from participating in Medicare and State health care programs, based on its conclusion that Petitioner had grossly and flagrantly violated his obligation to provide health care that met professionally recognized standards and that he had demonstrated an unwillingness and inability to comply with his obligation. I.G. Ex. 7/56-58.

25. By letter dated October 4, 1990, the I.G. notified Petitioner that he was being excluded from participating in Medicare and State health care programs for a period of five

years. The I.G. agreed with NJPRO's conclusion, expressed in a letter dated June 19, 1990, that, in the seven cited cases, Petitioner had grossly and flagrantly violated his obligation to provide health care of a quality that met professionally recognized standards. The I.G. concluded that there was no specific evidence that Petitioner was unwilling to comply with his obligation, but it agreed with NJPRO that Petitioner had demonstrated an inability to comply. I.G. Exs. 8, 9.

Burden of Proof

26. Petitioner, as a practitioner who is dissatisfied with the determination made by NJPRO, has a right to a hearing. 42 U.S.C. § 1320c-4; Section 1155 of the Act.

27. Petitioner's right to a hearing is a right to a de novo hearing. Section 205(b) of the Act; Charles J. Barranco, M.D., DAB CR187 (1992).

28. Under the Administrative Procedure Act (APA), the standard to be used by an agency in making its determination on the evidence received at a hearing is preponderance of the evidence. Section 7 of the APA, 5 U.S.C. § 556.

29. The preponderance of the evidence standard, as provided in section 7 of the APA, 5 U.S.C. § 556, is applicable to adjudicatory proceedings. Section 5(b) of the APA, 5 U.S.C. § 554(c)(2).

30. The instant proceedings are adjudicatory in nature and are subject to the provisions of the APA. Sections 5 and 7 of the APA, 5 U.S.C. §§ 554, 556; see Steadman v. S.E.C., 450 U.S. 91, 95-98 (1981).

31. The appropriate standard of evidence in this case is preponderance of the evidence. Sections 5 and 7 of the APA, 5 U.S.C. §§ 554, 556; see Steadman.

Neurosurgical treatment of increased intracranial pressure

32. A craniectomy is a surgical procedure in which the surgeon makes a 3/8 inch diameter burr hole in the patient's skull with a particular drill bit. Tr. I/57.

33. A craniotomy is a surgical procedure in which the surgeon turns a bone flap, to create a "window" of some size in the patient's skull to perform a formal operation. Tr. I/57.

34. Both craniotomies and craniectomies are usually performed in an operating room under general anesthesia. Tr. I/57.

35. The terms infarct and stroke are synonymous. They indicate that a portion of the brain has been deprived of its blood supply. Tr. I/55.

36. Another category of stroke disease is characterized by hemorrhage, or bleeding into the brain. Tr. I/55.

37. Various diseases of the brain are accompanied by increases in intracranial pressure (ICP). Because the skull is a tight compartment, expanding lesions within the brain may be accompanied by increased ICP. Tr. I/58; Tr. II/269; P. Ex. 23/1.

38. Increased ICP may cause damage to a patient's brain because the swelling of the injured portion of the brain may put pressure on, or compress, previously undamaged portions of the brain. Increased ICP, if uncontrolled, can lead to death. Tr. II/269, Tr. III/36, 127.

39. The article Lehman, Intracranial Pressure Monitoring and Treatment: A Contemporary View, 19 Annals of Emergency Medicine 295 (1990)(Intracranial Pressure Monitoring), is authoritative medical literature. Tr. II/274; P. Ex. 23.

40. Intracranial Pressure Monitoring states that to alleviate the potential damage to the brain from swelling, most treatment measures have attempted to reduce the volume of cerebrospinal fluid (CSF), blood, or water in the brain without removing or manipulating viable brain tissue. P. Ex. 23/2.

41. The ventricles are structures deep in the brain, close to the midline, where CSF is produced. Tr. I/59.

42. A ventriculostomy is a procedure whereby a shunt or catheter is inserted into one of the ventricles of the brain in order to relieve pressure on the brain by draining excess CSF. Tr. I/59, 136.

43. The text Neurological Surgery (J. Youmans, M.D., 3d ed. 1990) (Youmans' Neurological Surgery), is an authoritative medical reference. Tr. II/271.

44. Youmans' Neurological Surgery states that severe brain infarction may be accompanied by swelling due to cerebral edema or hemorrhagic infarction and that the result may be increased ICP. P. Ex. 22/2.

45. Edema is another term for swelling of the brain. Tr. II/325.

46. Youmans' Neurological Surgery states that fatal outcome in massive cerebral or cerebellar infarction within the first week

can be directly related to acute brain swelling and its secondary effects. P. Ex. 22/3.

47. ICP monitoring (ICPM) was introduced in the early 1970's to measure the pressure within the confines of the skull. Tr. I/58.

48. Youmans' Neurological Surgery states that ICP monitoring of patients with severe brain swelling due to infarction has been beneficial in titrating medical measures and predicting the need for operative decompression. P. Ex. 22/3.

49. One method for recording and monitoring ICP is to insert a catheter into the ventricle, as for a ventriculostomy, and connect it to a transducer so that pressure waves transmitted through the CSF may be transformed into electrical impulses and plotted on a graph or converted to numerical values by digital means. Tr. I/59.

50. Employing a ventricular catheter as an ICPM device permits the treating physician to drain CSF as a therapeutic measure if ICP is elevated. Tr. I/137-38.

51. Another method for recording and monitoring ICP is to place a hollow conical screw in a 1/4 inch drill hole in the patient's skull. The screw is attached to a transducer, pressure waves are transformed to electrical impulses and recorded in the same manner as with the ventricular catheter. Tr. I/58-59.

52. Insertion of the bolt or screw type of ICPM device is usually performed at bedside under local anesthetic. Tr. I/60.

53. A ventriculostomy or insertion of a ventricular catheter also can be performed under local anesthetic. Tr. I/61.

54. In the cases cited by the I.G., Petitioner performed ICP monitoring using the ventricular catheter method and not the bolt or screw method. Tr. I/136.

55. Dr. Samuel J. Hassenbusch, III is a staff member of the Department of Neurosurgery at the Cleveland Clinic Foundation (Cleveland Clinic). Dr. Hassenbusch obtained his M.D. and Ph.D. degrees from the Johns Hopkins University in Baltimore, Maryland, where he also served his internship and residency. Dr. Hassenbusch successfully completed the written examination phase of his board certification in neurosurgery in 1987. At the time he testified, Dr. Hassenbusch was awaiting a date for the administration of the oral examination phase of the board certification process. P. Ex. 19; Tr. III/6.

56. Dr. Hassenbusch is a qualified expert in neurosurgery. FFCL 55.

57. Dr. Hassenbusch testified that an estimated 30 to 50 percent of practicing neurosurgeons would perform ICPM in selected stroke patients or would consider it a reasonable alternative. Tr. III/47-48.

58. Dr. Hassenbusch testified that neurosurgeons at the Cleveland Clinic currently perform ICPM in selected stroke patients and that neurosurgeons at Johns Hopkins Hospital did so at the time he was in training there. Dr. Hassenbusch testified that ICPM was done at those institutions for therapeutic purposes, rather than for research. Tr. III/47-48, 126-27.

59. Both Dr. Hassenbusch and Dr. Kasoff testified that ICPM was done more frequently in the 1970's and 1980's than it is done currently. Tr. I/61-64; Tr. III/127.

60. The use of a ventricular catheter to relieve and monitor ICP is a reasonable procedure to perform in certain stroke cases where there are indications of increased ICP. Tr. II/271; Tr. III/48; FFCLs 50, 54, 57, 58.

61. To be within professionally recognized standards of care, a procedure need not be endorsed by the majority of the professional community; the procedure is within professionally recognized standards if it has substantial support within the professional community.

62. Insertion of a ventricular catheter for drainage and ICPM in a patient who is exhibiting clinical signs of increased ICP is within professionally recognized standards of neurosurgery. FFCL 60.

63. Clinical signs of increased ICP include decreased level of consciousness; lowered heart rate; elevated blood pressure; and impaired motor function, such as hemiparesis. Tr. II/288; Tr. III/165; I.G. Ex. 19/3-4.

64. Hemiparesis is a weakness on one side of the body. Tr. I/79.

65. The article, Ropper and Shafran, Brain Edema After Stroke, 41 Archives of Neurology 26 (1984) (Brain Edema After Stroke), is authoritative medical literature. Tr. III/143; 194.

66. The article Brain Edema After Stroke states that routine monitoring of ICP in patients with brain edema after stroke cannot be recommended. I.G. Ex. 20/4.

67. Dr. Ira Kasoff is a board certified neurosurgeon and clinical assistant professor at the Robert Wood Johnson School of Medicine at Rutgers University. Dr. Kasoff is a consultant to the NJPRO. Additionally, Dr. Kasoff was recently appointed a

consultant to the Super-PRO a national body, the function of which is to arbitrate conflicts that may arise between individuals and State PROs. Tr. I/48-53; I.G. Ex. 17.

68. Dr. Kasoff is a qualified expert in neurosurgery. FFCL 67.

69. Dr. Kasoff testified that the routine use of ICPM in the treatment of stroke patients is a violation of professionally recognized standards of neurosurgical care. Tr. I/63-64.

70. Dr. Kasoff's testimony that routine use of ICPM in stroke patients is a violation of professionally recognized standards of neurosurgical care is not inconsistent with Dr. Hassenbusch's testimony that use of ICPM in selected stroke patients is within professionally recognized standards of neurosurgical care. FFCLs 60, 62.

71. The I.G. proved that it is a violation of professionally recognized standards of neurosurgical care routinely to perform ICP monitoring on stroke patients. FFCLs 60, 61, 69, 70.

72. Dr. Kasoff testified that his review of the records in this case led him to conclude that Petitioner was prepared to use ICPM on a routine basis. Tr. III/196.

73. Dr. Kasoff acknowledged that he reached the conclusion that Petitioner was prepared to use ICPM on a routine basis without knowing how many similar patients Petitioner had treated during the relevant period. Tr. III/196.

74. During the period from July 1985 to July 1986, Petitioner treated over 100 patients for stroke, brain hemorrhage, and brain tumors. Tr. II/267.

75. Of the more than 100 patients suffering from stroke, brain hemorrhage, or brain tumor whom Petitioner treated from July 1985 to July 1986, only approximately seven or eight were treated by inserting an ICPM device and ventricular drain. Tr. II/268.

76. The I.G. did not prove that Petitioner routinely performed ICPM on his stroke patients. FFCLs 73-75.

77. Dr. Kasoff stated at the NJPRO meeting that the risk of mortality and morbidity associated with the use of general anesthesia is approximately one percent. I.G. Ex. 6/42.

78. Dr. Kasoff also testified that patients suffering from stroke disease may be placed at risk by the administration of general anesthesia because the inhalation anesthetic might cause blood to be diverted into the area of the brain that has experienced the stroke. This diversion, according to Dr. Kasoff,

could convert the stroke into a hemorrhage, resulting in greater brain damage to the patient. Tr. I/73.

79. The I.G. did not introduce any evidence as to the magnitude of the risk that a stroke patient would experience a cerebral hemorrhage as a result of receiving general anesthesia.

80. The only quantifiable evidence before me as to the magnitude of the risk presented by the administration of general anesthesia proves that the risk is approximately one percent. FFCLs 77-79.

81. Dr. Kasoff testified that there is a risk of infection associated with surgery and with insertion of an ICPM device. Tr. I/71.

82. The I.G. did not introduce any evidence quantifying the risk of infection associated with surgery to insert an ICPM device.

83. A gross and flagrant violation within the meaning of section 1156(b)(1)(B) of the Act is one that involves "an especially dangerous deviation from medical norms." Varadani v. Bowen, 824 F.2d 307, 312 (4th Cir. 1987).

84. Placing a patient who faces a near certain risk of death from his or her underlying disease process at a one percent risk of mortality from general anesthesia does not constitute an especially dangerous violation of medical norms because the patient is not placed at greater risk than that resulting from the underlying condition. FFCLs 80, 82, 83.

Patient 268001 (Case # 1)

85. Patient 268001 was an 81 year old male who was brought to the emergency room at Newcomb Hospital in Vineland, New Jersey, on August 23, 1985, after suffering a sudden weakness on the right side and becoming unconscious. I.G. Ex. 10/5.

86. In the emergency room, Patient 268001 was comatose and was not breathing effectively on his own. I.G. Ex. 10/5.

87. Patient 268001 was intubated in the emergency room. I.G. Ex. 10/5.

88. After examining the patient in the emergency room, Dr. Ilyas Rajput, the attending physician, listed his impressions as: 1) cerebrovascular accident with right hemiparesis; 2) increased blood pressure by history; and 3) history of irregular heart beats. I.G. Ex. 10/5.

89. Patient 268001 was admitted to the hospital and transferred to the Intensive Care Unit (ICU). I.G. Ex. 10/2.

90. On admission to the ICU, the patient was able to squeeze his left hand to commands and responded to his name by opening his eyes and turning his head toward the speaker. I.G. Ex. 10/57.

91. Petitioner saw the patient as a consultant on August 23, 1985. I.G. Ex. 10/18, 57.

92. On August 24, 1985, a computerized axial tomography (CAT) scan of the patient's head was performed. I.G. Ex. 10/97.

93. A CAT scan is similar to an x-ray except that it permits the physician to visualize soft tissue, in this case the brain, rather than just the bone. Tr. III/20.

94. According to the radiologist's report, the CAT scan revealed an area of decreased attenuation in the left temporal and parietal lobe consistent with a recent infarct with mass effect. The report also noted minimal compression of the left lateral ventricle. The radiologist's impression was that the patient had suffered an infarct involving the left temporal and parietal lobes. I.G. Ex. 10/97.

95. Dr. Hassenbusch testified that compression of the left lateral ventricle could indicate increased pressure within the brain. Tr. III/11.

96. On August 24, 1985, Dr. Rajput noted that Patient 268001 remained stuporous and occasionally responded to verbal commands. I.G. Ex. 10/18.

97. A nurse's note of 1500 hours (3:00 p.m.) August 24 reports the patient's neurological status as stuporous, pupils sluggish, right side flaccid, grips weakly with left hand. I.G. Ex. 10/58.

98. The nurse's note of 1500 hours August 24 further reports that at 1130 hours (11:30 a.m.) Patient 268001 became bradycardic with sinus arrest. I.G. Ex. 10/58.

99. Bradycardia means that the patient's heart rate was low. Tr. II/290.

100. In a note also dated August 24, 1985, Petitioner described Patient 268001's condition as unconscious, no verbal response; withdraws mainly to pain; pupils sluggish. Petitioner wrote that the patient's CAT scan showed shift and mass effect and concluded that, in view of the mass effect and decreased heart rate, Patient 268001 was probably experiencing increased ICP. I.G. Ex. 10/19; Tr. II/286.

101. Petitioner reported that he had discussed the patient's condition and treatment options with the patient's wife and that

the patient's family agreed to proceed with a ventriculostomy and ICPM. I.G. Ex. 10/19; Tr. II/286.

102. The patient was taken to the operating room for surgery at 1920 hours (7:20 p.m.), August 24, 1985. I.G. Ex. 10/59.

103. Petitioner performed a ventriculostomy on the patient under general anesthesia. I.G. Ex. 10/19.

104. There is no indication in the record as to what anesthetic agent or agents were administered to the patient.

105. In the operative record of the procedure, Petitioner stated that when the catheter entered the ventricle, fluid came out under pressure. I.G. Ex. 10/9.

106. In a note dated August 25, 1985, Dr. Robert D. Fazzaro, who was covering for Dr. Rajput (see I.G. Ex. 10/59), reported that the patient was more awake and that his heart rate was increased. I.G. Ex. 10/20.

107. Petitioner's note of August 25 also reported:"Patient is more awake. Started to follow verbal commands. Pre-op [patient] was completely unresponsive. His ICP WNL [within normal limits]. Pupils are reacting. Still has gaze preference to [left symbol]. . . . His HR [heart rate] is up. Started to move [right symbol] leg more." I.G. Ex. 10/21

108. Throughout the remainder of Patient 268001's stay at Newcomb Hospital, the physicians' notes reflect fairly consistently that the patient was more awake and was able to follow verbal commands. I.G. Ex. 10/21-34.

109. Petitioner removed the ICPM device on August 27, 1985. I.G. Ex. 10/22.

110. The values recorded for ICP were all within normal limits except for one notation that readings were "as high as 25 [mm/Hg] when pt [patient] is being suctioned." I.G. Ex. 10/64.

111. A consistent reading of greater than 15 mm/Hg indicates increased ICP. P. Ex. 23/6.

112. Efforts to wean Patient 268001 from the respirator were unsuccessful. I.G. Ex. 10/2.

113. At the family's request, Patient 268001 was transferred by ambulance to a Philadelphia hospital on September 11, 1985, so that he could be cared for by the family physician. I.G. Ex. 10/2.

114. Patient 268001 exhibited symptoms consistent with increased ICP. Those symptoms included a decrease in level of consciousness, an episode of bradycardia, or low heart rate, and right hemiparesis. The patient's CAT scan also suggested the possibility of increased ICP. FFCLs 63, 88, 94-100.

115. In light of Patient 268001's symptoms, it was reasonable for Petitioner to conclude that the patient might be suffering from increased ICP, and to perform surgery to insert a ventricular catheter for ICPM and drainage of CSF. FFCL 114.

116. Dr. Hassenbusch testified that performing the surgery under general anesthesia was an appropriate alternative because Patient 268001 was unable to follow verbal commands and thus might have been unable to cooperate if the procedure had been done under local anesthesia. Tr. III/14; 88-89; P. Ex. 18/1.

117. Dr. Joseph Arico, a board certified neurosurgeon, stated in a written report, prepared at Petitioner's request, that Petitioner's treatment approach was the best approach to both monitor and treat increased ICP. P. Ex. 1/1.

118. Dr. Hassenbusch testified that insertion of the ICPM device in Patient 268001 was within professionally recognized standards of neurosurgery. Tr. III/15.

119. The I.G. did not prove by a preponderance of the evidence that Petitioner violated his obligation to provide Patient 268001 with care that met professionally recognized standards of neurosurgery. FFCLs 114-118.

120. Because I have concluded that Petitioner did not violate his obligation to provide Patient 268001 with care that met professionally recognized standards of neurosurgery, I need not reach the question of whether Petitioner placed Patient 268001 in imminent danger or unnecessarily in a high risk situation. FFCLs 83, 119.

Patient 8601866M (Case # 2)

121. Patient 8601866M was a 74 year old female who was admitted to Millville Hospital in Millville, New Jersey, on January 17, 1986, after she suddenly developed confusion, slurred speech, and marked weakness of the left side. I.G. Ex. 11/4.

122. Patient 8601866M was seen in the emergency room by Dr. Fazzaro, who noted that her blood pressure was 240/110, that she was comatose with pupils pinpoint and nonreactive, and that she had severe left hemiparesis. Dr. Fazzaro's impression was that the patient had suffered a cerebrovascular accident (CVA), probable hemorrhage. I.G. Ex. 11/17.

123. Dr. Fazzaro ordered a CAT scan and requested a neurosurgical consultation on an emergency basis. I.G. Ex. 11/2.

124. The report of the CAT scan described a large hemorrhagic lesion throughout the right basal ganglia extending into the adjacent right frontotemporal and parietal lobes as well as into the right lateral ventricle. The report also noted significant right to left shift of the midline structures. I.G. Ex. 11/21.

125. The radiologist's impression of the CAT scan was that Patient 8601866M had suffered a large hemorrhagic lesion on the right side of the brain with right to left shift, most likely representing a hemorrhagic infarction in the basal ganglia with extension into the ventricular system and adjacent brain. The radiologist stated that a neoplasm [tumor] with hemorrhage could not entirely be excluded. I.G. Ex. 11/21.

126. On January 17, 1986, Petitioner performed surgery to evacuate the hematoma. I.G. Ex. 11/17-18, 30.

127. Petitioner's operative record of the surgery describes a large intracerebral hematoma which extended from the surface of the brain, postero-medially to the basal ganglia. The hematoma was completely removed. I.G. Ex. 12/14.

128. After evacuating the hematoma, Petitioner inserted a catheter into the ventricle for monitoring and draining of intracranial pressure. I.G. Ex. 12/14.

129. The patient did not improve after surgery. She passed into a deep coma and was pronounced dead on January 20, 1986. I.G. Ex. 11/13, 20.

130. Dr. Fazzaro's expiration summary reflects his opinion that Patient 8601866M's only chance for survival was to perform surgery to evacuate the clot. I.G. Ex. 11/13.

131. Petitioner testified that Patient 8601866M had no chance for recovery without surgery, while with surgery, she might have had a 10 percent chance of recovery. Tr. II/296-97.

132. Dr. Hassenbusch testified that there was a 99 percent likelihood that Patient 8601866M would have died without surgery, whereas with surgery, he estimated her chances for survival at 3 to 10 percent. Tr. III/28-29.

133. Dr. Hassenbusch opined that the surgery to remove the hematoma was within professionally recognized standards of neurosurgical practice. Tr. III/25.

134. Dr. Arico stated in his written report, "had some aggressive treatment program not been undertaken, [the patient]

would have gone on to demise. Dr. Hussain's effort to decompress her was aggressive, but held out the only chance that this patient would have had for survival whatsoever." P. Ex. 1/2.

135. The unidentified neurologist who reviewed the case of Patient 8601866M for NJPRO concluded that, while the surgery held out little hope for recovery, "[o]ne certainly can't fault Dr. Hussain under the circumstances for trying to evacuate the hemorrhage." I.G. Ex. 4/8.

136. The unidentified neurosurgeon who reviewed the case of Patient 8601866M for NJPRO opined that the majority of neurosurgeons would consider the surgery unnecessary, although he conceded that there were those that would differ. I.G. Ex. 4/8.

137. Dr. Kasoff testified that there was no benefit to be gained by surgery to evacuate the hematoma because Patient 8601866M had descended into a very deep level of coma from which he would not anticipate recovery. Tr. I/89-90.

138. Dr. Kasoff testified that there are neurosurgeons who would consider surgery to remove the hematoma an appropriate alternative. Tr. I/161-62.

139. Dr. Kasoff testified that there were neurosurgeons who would proceed with surgery if there was the slightest chance that the surgical procedure could benefit the patient. Dr. Kasoff stated that, in his view, such surgery would be a "viable option." Tr. III/206.

140. By performing surgery to remove the hematoma from Patient 8601866M's brain, Petitioner did not violate his obligation to provide care that met professionally recognized standards of neurosurgery. FFCLs 133-136, 138, 139.

141. During the surgery to remove the hematoma, Petitioner also inserted a ventricular catheter for ICPM and drainage of cerebrospinal fluid. I.G. Ex. 11/14.

142. Petitioner testified that the primary purpose of performing the surgery was to evacuate the hematoma. Tr. II/300.

143. Petitioner testified that it is normal neurosurgical procedure to insert an ICP monitor after surgery to remove a hematoma. Tr. II/301-02.

144. Dr. Hassenbusch opined that placing the catheter was within accepted standards of neurosurgical care. Tr. III/26-27; P. Ex. 18/2.

145. Petitioner did not violate his obligation to provide care that met professionally recognized standards of neurosurgery by

placing a ventricular catheter in Patient 8601866M to monitor and regulate ICP. FFCLs 143, 144.

146. The only risk posed by the ICP monitor independent of the surgery to evacuate the hematoma is that of infection. Tr. I/71.

147. The I.G. presented no evidence as to the magnitude of this risk.

148. The I.G. failed to prove that the insertion of the ICP monitor placed the patient in imminent danger or unnecessarily in a high risk situation. FFCLs 144-147.

149. Even if insertion of a ventricular catheter for ICPM and drainage did represent a violation of Petitioner's obligation to provide care that met professionally recognized standards of neurosurgery, Petitioner did not commit a gross and flagrant violation of that obligation. FFCLs 146-148.

150. Petitioner testified that stroke patients who present a "fixed deficit," such as those suffering hemorrhages of the basal ganglia, are not helped by surgical means, because they have already damaged a particular part of the brain. Tr. II/268.

151. I understand Petitioner's testimony to mean that patients who have suffered irreversible brain damage due to strokes of the basal ganglia are not helped by surgical means.

152. The I.G. did not prove that Patient 8601866M had suffered irreversible brain damage at the time Petitioner performed surgery.

Patient 854914 (Case # 3)

153. Patient 854914 was an 80 year old male with a history of prior strokes (transient ischemic attacks or TIAs) and myocardial infarctions (heart attacks), who presented to the emergency room at Bridgeton Hospital in Bridgeton, New Jersey, on July 25, 1985, complaining of nausea and vomiting since the previous evening. Tr. I/91; I.G. Ex. 12/2.

154. Dr. Gladwyn Baptist, the attending physician, examined the patient in the emergency room. His neurological examination revealed minimal weakness over the left side but no significant sensory or motor deficits. Dr. Baptist listed his initial impressions as gastroenteritis with mild dehydration and indicated he intended to rule out the possibility of myocardial infarction. I.G. Ex. 12/2, 3.

155. Patient 854914 was admitted to Bridgeton Hospital on July 25, 1985, after abnormal electrocardiogram (EKG) findings and an episode of nausea in the emergency room. I.G. Ex. 12/2.

156. On July 29, 1985, Patient 854914 exhibited slurred speech and complained of mild chest and epigastric discomfort. I.G. Ex. 12/3.

157. On July 30, 1985, Patient 854914 became increasingly somnolent, his speech became further slurred, and his respiratory processes became depressed such that he required intubation. I.G. Ex. 12/3.

158. Dr. Sharan Rampal, a neurologist, was consulted and saw the patient on July 31, 1985. His initial impression indicated he was to rule out the possibility of a cerebellar infarct. I.G. Ex. 12/3.

159. A CAT scan was ordered. According to the discharge summary, the CAT scan showed a right parietal infarct encroaching on the occiput as well as acute right cerebellar infarction, with severe atrophy and moderate ventricular dilation. I.G. Ex. 12/3, 33.

160. On August 1, 1985, Dr. Rampal noted that Patient 854914 exhibited decerebrate posturing to deep pain and was unresponsive to verbal commands. Dr. Rampal's impression was that the patient was decerebrate secondary to cerebellar infarct and that the prognosis was grave. I.G. Ex. 12/35.

161. Decerebrate posturing refers to a position of the patient's arms and legs, in which the arms and legs are extended. The presence of decerebrate posturing indicates pressure upon or damage to the basic areas of the brain, specifically the brain stem and the mid-brain. Tr. III/32.

162. Dr. Rampal ordered Mannitol to reduce ICP and requested a repeat CAT scan. Tr. II/307; I.G. Ex. 12/5, 35.

163. Technical difficulties prevented a print of the follow-up CAT scan. However, the CAT scan was described in Dr. Rampal's notes as showing increased ventricular dilation suggesting obstructive hydrocephalus. Dr. Rampal noted that he would request urgent neurological evaluation for a possible shunt. Tr. I/171-72; Tr. II/35; I.G. Ex. 12/36.

164. The term shunt is a broad term for a device, usually similar to a catheter, which is used to drain fluid so that ICP can be reduced. The term shunt would include a ventriculostomy. Tr. II/305-06.

165. On August 2, 1985, Dr. Baptist described Patient 854914's condition as deteriorating, showing decerebrate posturing and unresponsiveness. Dr. Baptist also noted multiple CVAs with cerebral edema. I.G. Ex. 12/36.

166. Petitioner did not become involved with the treatment of Patient 854914 until he was consulted by Dr. Rampal on August 2, 1985. Tr. II/304.

167. On August 2, 1985, Petitioner performed a right frontal craniotomy, decompression, and ventriculostomy under general anesthesia and set up and calibrated an ICPM device on Patient 854914. I.G. Ex. 12/5, 37.

168. The ventriculostomy that Petitioner performed on Patient 854914 on August 2, 1985, was for the purpose of decompressing or draining the ventricular system. I.G. Ex. 12/83-84, 90.

169. Petitioner's contention that the procedure performed was a craniectomy, not a craniotomy, is not persuasive given the numerous references in the hospital records and in Petitioner's own notes, which refer to the procedure performed as a craniotomy. I.G. Ex. 12/3, 5, 37.

170. On August 3, 1985, Petitioner noted that Patient 854914 was comatose and decerebrating bilaterally, with withdrawal responses to deep painful stimuli. Petitioner also noted posterior fossa swelling and hydrocephalus, and indicated that if the patient failed to improve in the next two to three days he would consider a posterior fossa decompression. I.G. Ex. 12/38.

171. Dr. Rampal and Petitioner both indicated on August 3 and 4, 1985, that Patient 854914's neurological condition remained the same and stated that a repeat CAT scan would be performed. I.G. Ex. 12/40.

172. On August 6, 1985, Petitioner noted the patient was "unchanged" and noted a need for electroencephalogram (EEG) results. I.G. Ex. 12/41.

173. In a note also dated August 6, 1985, Dr. Baptist stated that the patient's prognosis was "very poor." I.G. Ex. 12/41.

174. Petitioner noted no change in Patient 854914's neurological status in his note of August 7, 1985. I.G. Ex. 12/43.

175. A repeat CAT scan done on or about August 8, 1985, showed increased mass effect, compression in the posterior fossa, and compression of the brain stem. I.G. Ex. 12/3; P. Ex. 20/31; Tr. III/34.

176. An EEG was performed on August 8, 1985, and revealed pronounced cortical (brain stem) function in Patient 854914. I.G. Ex. 12/45, 82.

177. On August 9, 1985, Petitioner performed a posterior fossa craniotomy, a posterior fossa decompression, and a

ventriculostomy on Patient 854914, using general anesthesia. I.G. Ex. 12/6, 45-46.

178. On August 13, 1985, Petitioner removed the ICPM device, noting that the patient's ICP was within normal limits. I.G. Ex. 12/49.

179. Patient 854914 did not improve after the surgery of August 9, 1985. Dr. Baptist noted that the prognosis appeared extremely poor. On August 16, 1985, the patient was extubated and allowed to expire with the consent of the family. I.G. Ex. 12/4.

180. A cerebellar stroke is a stroke which occurs in the part of the brain known as the cerebellum, and which may produce a mass effect on the brain stem. Tr. I/93.

181. In the case of cerebellar strokes, it is necessary and vital to decompress the cerebellum very quickly. Failure to do so may cause irreversible devastation to the brain stem and possibly death to the patient. Tr. I/93-94.

182. It was necessary and vital for Petitioner to act quickly to avoid total compromise of Patient 854914's brain stem function. FFCLs 159, 160, 170, 175, 181.

183. A posterior fossa decompression is an appropriate procedure to perform in the early stages of a cerebellar stroke (also called a cerebellar infarct). It serves to relieve intracranial pressure and alleviate mass effect, in turn protecting the vital brainstem. After the patient has suffered irreversible brainstem damage (a symptom of which may be decerebration) a posterior fossa decompression cannot remedy the condition. After a relatively short time, the brain stem is damaged and there is very little hope of the patient surviving. Tr. I/99-100, 173, 175.

184. The medically appropriate treatment for an acute cerebellar infarction with compression of the brainstem is prompt posterior fossa decompression. I.G. Ex. 4/9-10.

185. When Petitioner operated on Patient 854914 on August 2, 1985, he did not believe he was dealing with a cerebellar infarct; he believed the patient had acute hydrocephalus. I.G. Ex. 12/84-86.

186. Had Petitioner thought, on August 2, 1985, that he was dealing with a cerebellar infarct, he would have performed a posterior fossa decompression. I.G. Exs. 6/72-73; 12/87-88.

187. Petitioner's contention that the CAT scans of July 31 and August 1, 1985, showed only hydrocephalus is not credible, in light of the discharge report stating the July 31 CAT scan showed

a right parietal infarct encroaching on the occiput, as well as acute right cerebellar infarction, with severe atrophy and moderate ventricular dilation. I.G. Ex. 12/3, 33.

188. Petitioner became convinced, several days after the August 2, 1985, surgery, that he was dealing with a cerebellar infarct in Patient 854914. I.G. Ex. 12/90.

189. Despite Petitioner's realization that he was dealing with a cerebellar infarct in Patient 854914, he did not perform a posterior fossa decompression until August 9, 1985. FFCLs 177, 185, 186, 188.

190. Petitioner was satisfied with the quality of the CAT scan that was performed on August 1, 1985. I.G. Ex. 6/85.

191. It was the responsibility of Petitioner, when he was consulted in the case of Patient 854914, to ensure that all diagnostic procedures were performed that were necessary to diagnose the cause and severity of the patient's condition. I.G. Ex. 6/96, 98.

192. Petitioner noted that Patient 854914 was comatose and decerebrating on August 3, 1985. Petitioner also noted posterior fossa swelling and hydrocephalus in the patient on August 3. I.G. Ex. 12/38.

193. Petitioner did not perform a posterior fossa decompression on Patient 854914 until August 9, 1985, six days after he noted posterior fossa swelling and decerebration in the patient. I.G. Ex. 12/38.

194. When Petitioner performed a posterior fossa decompression on Patient 854914 on August 9, 1985, the patient's condition was unsalvageable and irreversible. To have been of any benefit in this case, a posterior fossa decompression would have to have been done by August 2, 1985. Tr. I/99-100, 173, 175.

195. Petitioner's performance of a posterior fossa decompression on Patient 854914 on August 9, 1985, was unnecessary. FFCLs 181-184, 193, 194.

196. Petitioner violated his obligation under the Act by failing to diagnose and treat Patient 854914 for an acute cerebellar infarction (stroke). FFCLs 181-195.

197. Petitioner violated his obligations under the Act by failing to recognize a cerebellar stroke in Patient 854914 and by failing promptly to perform a posterior fossa decompression to alleviate the compression of the patient's brain stem. FFCLs 181-196.

198. Petitioner violated his obligations under the Act when he failed to diagnose the cause of Patient 854914's hydrocephalus. FFCLs 185-188, 191, 194.

199. Petitioner's failure to obtain a repeat CAT scan to verify the nature of Patient 854914's condition was a violation of Petitioner's obligation under the Act. FFCLs 171, 175, 181-188, 190, 191.

200. Petitioner's failure timely to diagnose Patient 854914's condition placed the patient in imminent danger and unnecessarily in a high risk situation. FFCLs 181-189, 193-199.

201. Petitioner's failure promptly to perform a posterior fossa decompression, in light of clear evidence of compromised brain stem function and the deterioration of the patient, placed patient 854914 in imminent danger and unnecessarily in a high risk situation. FFCLs 177, 181-186, 193-199.

202. Petitioner's failure timely to obtain another CAT scan placed Patient 854914 in imminent danger and unnecessarily in a high risk situation. FFCLs 171, 175, 181-188, 190, 191, 199.

203. Petitioner committed gross and flagrant violations of his obligation under the Act when he failed timely to obtain a repeat CAT scan, failed timely to diagnose that Patient 854914 was suffering from a cerebellar infarct, and when he failed promptly to perform a posterior fossa decompression. FFCLs 200-202.

204. Petitioner failed to diagnose and treat Patient 854914's medical condition properly. FFCL 196, 197.

205. Petitioner's treatment of Patient 854914 manifests an inability promptly to diagnose and treat patients for cerebellar infarcts. FFCLs 181-193.

206. Petitioner demonstrated poor judgment in failing to order a repeat CAT scan. FFCLs 187, 191, 202.

207. Petitioner's treatment of Patient 85914 demonstrates a lack of appreciation for the need to act very quickly to diagnose a cerebellar infarct and to perform a posterior fossa decompression to prevent brain stem compression. FFCLs 182, 193, 197, 200, 201, 204.

208. Petitioner lacks knowledge vital to the prompt diagnosis and treatment of cerebellar strokes impacting on the brainstem. FFCLs 193-207.

209. Petitioner lacks the ability to comply with his obligation to provide care that meets professionally recognized standards,

because he lacks knowledge basic to the diagnosis and treatment of cerebellar stroke patients. FFCL 208.

Patient 86-0935 (Case # 4)

210. Patient 86-0935 was an 83 year old female, who was admitted to Elmer Community Hospital in Elmer, New Jersey on April 11, 1986, with complaints of confusion, unsteadiness, and fever. I.G. Ex. 13/4.

211. Dr. J. A. LaCavera, the admitting physician, found that Patient 86-0935 was able to move her upper and lower extremities fairly well and noted equal reflexes and no hemiparesis. His impression was a urinary tract infection, possible CVA, possible hypokalemia, and organic brain syndrome. I.G. Ex. 13/5.

212. Dr. LaCavera noted that, on April 11, 1986, the date of admission, the patient was unable to answer any questions, and was disoriented as to time, place, and year. I.G. Ex. 13/8.

213. On April 15, 1986, four days after her admission, a CAT scan was performed on Patient 86-0935. According to the radiologist's report, the CAT scan showed a high density area indicative of an acute hematoma and evidence of previous infarctions. The scan showed no shift in the midline structures of the brain. I.G. Ex. 13/31.

214. Petitioner was consulted and became involved with the treatment of Patient 86-0935 on April 16, 1986. I.G. Ex. 13/6.

215. Petitioner was not responsible for the unusual delay between Patient 86-0935's admission to the hospital on April 11, 1986, and the performance of the CAT scan on April 15, 1986. Tr. I/104; Tr. II/317.

216. Petitioner conducted an examination of Patient 86-0935 on April 16, 1986. Petitioner noted the patient's history and described her as stuporous, not following verbal commands. Tone was described as equal, symmetrical; however, Petitioner also noted a slight hemiparesis on the right side. Tr. II/318; I.G. Ex. 13/6.

217. Petitioner concluded on April 16, 1986, that Patient 86-0935's level of consciousness had decreased, that the hematoma was causing significant pressure on the brain, and that the patient was exhibiting a deterioration in her level of consciousness and weakness such that surgery was indicated. I.G. Ex. 13/10, Tr. II/319.

218. On April 17, 1986, Petitioner performed a surgical craniotomy on Patient 86-0935 under general anesthesia.

Petitioner evacuated the hematoma and inserted a catheter (drain) type of ICPM. I.G. Ex. 13/7, 10.

219. On April 18, 1986, Petitioner removed the ICPM device, without recording any ICP values in Patient 86-0395's chart. Tr. II/379-80.

220. Patient 86-0935 was released from the hospital to a nursing home, via ambulance, on April 29, 1986. Upon her release, she still exhibited confusion and disorientation and did not exhibit marked improvement. I.G. Ex. 13/90, 91.

221. In the instance of a small intracerebral hematoma, with no shift in the midline structures, the preferred form of treatment is conservative, namely to treat it with steroids and to let the body reabsorb it. Tr. I/180.

222. Surgery may be indicated for intracerebral hemorrhages where there is a deterioration in the neurological condition coupled with disordered motor function. Tr. I/180-181; Tr. III/165; P. Ex. 14.

223. Neurologic deterioration, by itself, is not an automatic signal to perform neurosurgery on a stroke patient. Tr. III/86.

224. Organic brain syndrome is a condition that is also known as Alzheimer's disease. I.G. Ex. 6/110-11; Tr. II/175.

225. Patient 86-0935 exhibited behavior patterns consistent with Alzheimer's disease. Tr. III/117.

226. Confusion is not necessarily indicative of a decreasing level of consciousness. Increasing somnolence, obtundation, or stupor are indicative of a decreasing level of consciousness. Tr. III/165.

227. A CAT scan showing no shift in midline structures is indicative of a small intracerebral hemorrhage. Tr. III/109.

228. Possible risks from postsurgical increases in intracranial pressure can be expected to occur, if at all, within three days following the surgery. Tr. I/111.

229. The nurse's notes in the record do not support Petitioner's conclusion that Patient 86-0935 was deteriorating neurologically. I.G. Ex. 13/52, 53; Tr. II/377-78.

230. The nurse's notes indicate that on the morning of April 16, 1986, Patient 86-0935 was aroused by verbal stimuli. I.G. Ex. 13/53.

231. Dr. LaCavera's notes do not support Petitioner's contention that patient 86-0935 was deteriorating neurologically. I.G. Ex. 13/8, 9.

232. Petitioner's notes in the patient's progress records that patient 86-0935 was deteriorating are inconsistent with Petitioner's consultation report, which does not mention that the patient was deteriorating or that surgery was a possible option. I.G. Ex. 13/6, 10.

233. Petitioner noted that the patient was basically unchanged neurologically upon her release, and that the patient still exhibited poor communication. I.G. Ex. 13/16.

234. Surgery to remove the hematoma was not indicated in the case of Patient 86-0935 because the patient had tolerated the small intracerebral hematoma for five days, because there was no shift in midline structures, and because the patient did not exhibit signs of neurological deterioration. FFCLs 217, 221-225, 227, 229, 231, 232.

235. Petitioner's insertion of an ICPM device and ventricular drain in Patient 86-0935 was not medically indicated, given that the patient did not exhibit signs of increased ICP. FFCLs 63, 219, 221, 222, 227, 234, 267.

236. Petitioner's insertion of an ICPM device and ventricular drain in Patient 86-0935 was a violation of Petitioner's obligations under the Act. FFCL 235.

237. Petitioner's removal of the ICPM device after only one day, when the patient was still at risk for swelling and edema, and without recording any pressure readings, was contrary to Petitioner's stated purpose in inserting the ICPM and was a violation of Petitioner's obligations under the Act. FFCLs 218, 219, 228, 235.

238. Petitioner subjected this patient unnecessarily to a high risk situation by performing surgery under general anesthesia, which was not medically indicated in this instance. FFCLs 218, 234.

239. Petitioner committed a gross and flagrant violation of his obligations under section 1156 by performing a surgical craniotomy and evacuation of hematoma under general anesthesia on Patient 86-0935. FFCL 238.

240. Petitioner failed to recognize that Patient 86-0935 was tolerating her small intracerebral hematoma and that surgical intervention to remove the hematoma was not medically indicated. FFCLs 221, 222, 227, 234, 238.

241. Petitioner inappropriately inserted an ICPM device and ventricular drain in Patient 86-0935, when the patient's hematoma was unlikely to cause increased ICP. FFCLs 213, 221, 222, 234, 235.

242. If Petitioner's purpose in inserting the ICPM device was to monitor any swelling caused by the surgery to remove the hematoma, Petitioner inappropriately removed the ICPM device from Patient 86-0935 when the patient remained at risk from edema and swelling of the brain secondary to the surgery. FFCLs 219, 237.

243. Petitioner's treatment of Patient 86-0935 demonstrates a lack of knowledge of the indications for surgical intervention, as opposed to medical management in cases of small intracerebral hemorrhages. FFCLs 234, 242.

Patient 277259 (Case # 5)

244. Patient 277259 was a 74 year old female who was admitted to Newcomb Medical Center on April 7, 1986, complaining of weakness in her left leg, difficulty walking, and a facial droop on the left side. I.G. Ex. 14/2.

245. Patient 277259 was examined by the admitting physician, Dr. Pasquale A. Ruggieri, a specialist in internal medicine and cardiology. Dr. Ruggieri's examination of the patient revealed a left central facial weakness associated with weakness of the left arm and left leg. Dr. Ruggieri's initial impression was a stroke in progress with left hemiparesis. I.G. Ex. 14/2.

246. Dr. Dirk E. Skinner, a neurologist, was called in for consultation on April 7, 1986. His impression was that Patient 277259 was suffering from a frontoparietal lesion, most likely a CVA, and indicated the the possibility of a tumor should be ruled out. Tr. II/322; I.G. Ex. 14/2, 6.

247. A CAT scan performed on April 8, 1986, on Patient 277259 revealed a tumor in the right frontal lobe attached to the falx with large edema surrounding the tumor and a shift in the midline structures. Tr. I/12; Tr. II/323; I.G. Ex. 14/16.

248. The falx is the membrane which connects the two hemispheres of the brain. Tr. II/324-25.

249. Petitioner was called for a neurosurgical consultation on April 8, 1986. His consultation noted that the patient was lethargic, not following verbal commands, and had vomited. Petitioner concluded that the patient was deteriorating from awake to lethargic in 1-2 hours and that it would be wise to monitor ICP and stabilize and then consider surgery for removal of the lesion. I.G. Ex. 14/7.

250. Petitioner discussed his recommendation for surgery with the family of Patient 277259 and noted that the family was indecisive about pursuing a surgical option. I.G. Ex. 14/11.

251. Petitioner informed the patient's family of the risks of delay. On the morning of April 9, 1986, Patient 277259's husband and daughter decided to proceed with treatment. I.G. Ex. 14/11.

252. On April 9, 1986, Petitioner performed a surgical craniectomy and inserted a ventricular catheter for drainage and an ICPM device. Upon insertion of the ventricular catheter, fluid came out under pressure. I.G. Ex. 14/4.

253. Petitioner performed the ventriculostomy for the dual purposes of monitoring Patient 277259's ICP and for relieving the patient's increased ICP. I.G. Ex. 14/3, 12, 26.

254. After the surgery, Dr. Ruggieri noted that the patient was neurologically stable, and Dr. Skinner noted that the patient was awake and alert. I.G. Ex. 14/14.

255. During the two days following the surgery of April 9, 1986, Patient 277259's ICP ranged from 8 to 20 mm/Hg, with several readings of 15 or above, indicative of increased ICP. P. Ex. 23/6; I.G. Ex. 14/24-26; FFCL 111.

256. Petitioner ordered anti-swelling medications to be administered to Patient 277259 after the April 9 surgery. I.G. Ex. 14/19-20.

257. Petitioner tentatively scheduled Patient 277259 for surgery to remove the tumor on April 11, 1986. I.G. Ex. 14/14, 24.

258. Patient 277259's daughter was a nurse at St. Luke's Hospital in New York City. The daughter contacted a neurosurgeon at St. Luke's and made arrangements to have the patient transferred there. The patient was transferred to St. Luke's on April 11, 1986. I.G. Ex. 14/3, 14

259. Petitioner was unable to perform surgery to remove Patient 277259's brain tumor because the patient was transferred to another hospital. FFCLs 257, 258.

260. Petitioner testified that the neurosurgeon in New York, to whose care Patient 277259 was transferred, concurred with Petitioner's plan to stabilize the patient by inserting the ventricular catheter for drainage and ICPM. Tr. II/330-31.

261. Advances and Technical Standards in Neurosurgery, (H. Krayenbuhl ed.) (Advances and Technical Standards in Neurosurgery) is an authoritative reference on neurosurgical procedure. Tr. I/190; P. Ex. 24.

262. Advances and Technical Standards in Neurosurgery endorses the practice of inserting an ICPM device into a patient several days before surgery to remove a brain tumor to lower and monitor the patient's ICP. P. Ex. 24/2.

263. Dr. Maurice M. Davidson, a board certified neurosurgeon who prepared a written report at Petitioner's request, stated that it was appropriate neurosurgical practice to lower ICP for several days prior to surgery to remove certain brain tumors and that this would be enhanced by ICPM. P. Ex. 15.

264. Dr. Hassenbusch testified that an ICPM device may be indicated in brain tumor cases where the patient experiences severe brain swelling. Tr. III/123.

265. ICPM of patients with certain types of brain tumors is within professionally accepted standards of neurosurgery. FFCLs 262-264.

266. Petitioner's decision to insert an ICPM device and ventricular catheter was based on his determination that Patient 277259 was deteriorating due to increased ICP. Petitioner determined that Patient 277259 was deteriorating based on her decreased level of consciousness, her vomiting, and her increased left hemiparesis. I.G. Ex. 14/11.

267. Decreasing level of consciousness, vomiting, and increased hemiparesis are clinical signs that a patient may be experiencing increased ICP. Tr. I/180-181; Tr. III/165; FFCL 63.

268. The admission note of April 7, 1986, describes Patient 277259 as exhibiting some left side weakness. The nurse's notes of April 8, 1986, indicate severe left side weakness and an episode of vomiting. I.G. Ex. 14/28

269. The nurse's notes confirm Petitioner's observation that Patient 277259 was deteriorating. FFCLs 267, 268.

270. Petitioner's decision to insert an ICPM device to stabilize and monitor Patient 277259 was within professionally accepted standards of neurosurgery. FFCLs 265-269.

271. The I.G. did not prove by a preponderance of the evidence that Petitioner failed to consider removal of Patient 277259's brain tumor. FFCLs 250, 257, 258, 259.

272. The I.G. did not prove by a preponderance of the evidence that Petitioner violated his obligation under the Act to provide care to Patient 277259 in accordance with generally recognized standards of neurosurgery. FFCL 271.

273. Because I have concluded that Petitioner did not violate his obligation to provide Patient 277259 with care that met professionally recognized standards of neurosurgery, I need not reach the question of whether Petitioner placed Patient 277259 in imminent danger or unnecessarily in a high risk situation. FFCL 272.

Patient 8617854M (Case # 6)

274. Patient 8617854M was a 70 year old male who was admitted to Millville Hospital on June 21, 1986, following weakness and paralysis of the left extremities. I.G. Ex. 15/3-4, 15.

275. Patient 8617854M had previously had a myocardial infarction and arteriosclerotic disease. I.G. Ex. 15/3.

276. Dr. Dominic Diorio, a medical internist, was both the admitting and attending physician for Patient 8617854M. On admission, Dr. Diorio noted that Patient 861754M was able to converse when spoken to and noted no problems other than weakness of the left arm and left leg and lethargy. Dr. Diorio's initial impression was a CVA involving the right hemisphere with left sided manifestations. I.G. Ex. 15/3, 15.

277. Dr. Diorio ordered an EEG and a CAT scan on June 21, 1986. The EEG and CAT scan were not performed until June 23, 1986. I.G. Ex. 15/6, 33.

278. According to the radiologist's report, the CAT scan revealed a large acute infarction in the right parietal and temporal lobes. The radiologist noted mass effect with a shift of the lateral ventricles. I.G. Ex. 15/33.

279. A shift of the lateral ventricles of the brain indicates a shift in the midline of the brain.

280. The EEG performed on June 23 showed an abnormal disturbance of the right hemisphere. I.G. Ex. 15/29.

281. On June 24, 1986, Patient 8617854M developed respiratory complications and had to be transferred to the ICU and intubated. I.G. Exs. 15/15, 25.

282. On June 24, 1986, Dr. Skinner, a neurologist, saw Patient 8617854M as a consultant. I.G. Ex. 15/21.

283. On June 26, 1986, Dr. Skinner noted that Patient 8617854M was exhibiting increased stupor. I.G. Ex. 15/16.

284. On June 27, 1986, the patient was having respiratory difficulties and Dr. Diorio noted the need for a neurosurgical consultation for an ICPM device. I.G. Ex. 15/16.

285. Petitioner was first consulted regarding Patient 8617854M on June 27, 1986. On examination, Petitioner found the patient comatose and decerebrate to pain. I.G. Exs. 6/163, 15/18, 22.

286. Petitioner's impression was that Patient 8617854M was suffering from brain edema with closed right ventricle, mass effect, and increased ICP. I.G. Exs. 6/164, 15/22.

287. Petitioner recommended that Patient 8617854M undergo a ventriculostomy and monitoring of ICP. Tr. II/336-38; I.G. Exs. 6/164, 15/22.

288. On June 27, 1986, Petitioner performed a right frontal craniectomy and a ventriculostomy, and inserted an ICPM device to monitor ICP. I.G. Ex. 15/17-18, 24-25, 28.

289. During the procedure, Petitioner noted the patient's brain was edematous with increased pressure. Petitioner noted that cerebrospinal fluid came out of the ventricular catheter under pressure. Tr. III/58; P. Ex. 1/3, 16; I.G. Ex. 15/28.

290. Petitioner testified at the NJPRO proceedings that no general anesthesia was used when he performed surgery on Patient 8617854M. He further testified that, because the patient was comatose at the time of the surgery, only oxygen was administered. I.G. Ex. 6/166.

291. Generally, anesthesia is not administered when performing surgery on comatose patients, because there is no need to anesthetize a comatose patient since that patient cannot experience pain. Tr. II/340-43.

292. The I.G. offered insufficient evidence from which I could reasonably conclude, by a preponderance of the evidence, that Petitioner used anything other than oxygen when he performed surgery on Patient 8617854M. I.G. Ex. 15/17.

293. I am unable to conclude from the evidence in the record that Patient 8617854M had, at the time of surgery, lost all signs of cerebral activity and suffered herniation of the brain. I.G. Exs. 6/163-64, 15/16, 22-23.

294. Petitioner's examination of Patient 8617854M on June 28, 1986, one day after surgery, revealed no brain function. I.G. Ex. 15/18.

295. EEGs performed on June 30 and July 1, 1986, confirmed the absence of brain function. I.G. Ex. 15/19-20, 30-31.

296. After consultation with the family and the Ethics Committee, the physicians removed Patient 8617854M from life

support systems on July 1, 1986, and the patient died. I.G. Ex. 15/20, 24-25.

297. Petitioner's rationale for performing surgery on Patient 8617854M was that the patient had suffered rapid deterioration due to massive brain swelling and edema. Petitioner thought that drainage of CSF and ICPM might improve the patient's condition. I.G. Ex. 6/164.

298. Patient 8617854M was severely compromised and close to brain death when Petitioner undertook surgical intervention. The surgical procedure undertaken by Petitioner on Patient 8617854M at best increased the patient's chances of survival by 5 to 10 percent. Tr. II/346.

299. The surgical procedure undertaken by Petitioner on Patient 8617854M represented the patient's only and best hope for survival. Tr. III/59-61; P. Exs. 1/3; 16/2.

300. I am unable to conclude that Petitioner subjected Patient 8617854M to an unnecessary high risk from general anesthesia, because the I.G. has failed to show by a preponderance of the evidence that general anesthesia was used. FFCLs 290-292.

301. I am unable to conclude that Petitioner subjected Patient 8618754M to an unnecessary operative procedure, because that procedure was a reasonable treatment to alleviate the condition of the patient, and because it represented the patient's only hope of survival. FFCLs 297-299.

302. I am unable to conclude that Petitioner's use of ICPM in Patient 8618754M was an unnecessary operative procedure, because the ICPM device was also used to reduce ICP, and because reduction of ICP was clinically indicated. FFCLs 286, 288, 289.

303. The I.G. failed to prove by a preponderance of the evidence that Petitioner violated his obligation to provide services to Patient 8618754M in accordance with professionally recognized standards of neurosurgery. FFCLs 299-302.

304. Because I have concluded that Petitioner did not violate his obligation to provide Patient 8618754M with care that met professionally recognized standards of neurosurgery, I need not reach the question of whether Petitioner placed Patient 8618754M in imminent danger or unnecessarily in a high risk situation. FFCL 303.

Patient 632365 (Case # 7)

305. Patient 632365 was an 84 year old female who was brought to the emergency room of Millville Hospital on August 5, 1989 after

being found unresponsive on the floor of her home. I.G. Ex. 16/4-5; Tr. II/346-48.

306. On August 4, 1989, the day prior to her admission, Patient 632365 had complained of a cold and headache and overall weakness, but had been ambulating, feeding herself, and doing well. I.G. Exs. 7/13, 16/4, 5; Tr. II/346-48.

307. Petitioner was the admitting physician. On admission, he initially diagnosed Patient 632365 as having a left CVA, and indicated he would test to rule out the possibility of an intracranial hemorrhage. I.G. Ex. 16/4-5.

308. In the emergency room, Patient 632365 received a number of diagnostic procedures, including a chest x-ray, an EKG, and blood chemistry tests. I.G. Ex. 16/28, 33-34, 57-58.

309. The chest x-ray showed the patient's heart as enlarged with pulmonary venous congestion present. I.G. Ex. 16/28.

310. Enlarged heart and pulmonary venous congestion are symptomatic of congestive heart failure. I.G. Ex. 16/28.

311. Both the chest x-ray and the radiologist's report confirm that Patient 632365 had congestive heart failure. A written declaration by Dr. Joseph C. Spagnuolo, who is board certified in internal medicine, also confirms this diagnosis. I.G. Exs. 16/28, 19/9, 13.

312. Petitioner testified to the NJPRO that the radiologist orally reported that Patient 632365's chest x-ray did not reveal any acute condition. I.G. Ex. 7/26.

313. Even if Petitioner received an oral report from the radiologist indicating that the chest x-ray did not show anything acute, Petitioner had a duty to inquire further or to order a follow-up chest x-ray when he received a written report from the radiologist that indicated that Patient 632365 was suffering from congestive heart failure. I.G. Exs. 7/26, 16/28.

314. The EKG performed on Patient 632365 was normal. I.G. Ex. 16/33, 34; Tr. II/352.

315. On the date of admission, August 5, 1986, Patient 632365's blood chemistry tests revealed that her creatine phosphokinase (CPK) level was 525, and her MB isoenzyme level was 20. I.G. Exs. 16/57-58; 19/10.

316. CPK level is normal within a range of 60-270 units per liter; MB isoenzyme is normal below 15 units per liter. I.G. Exs. 16/57-58; 19/10.

317. It is frequently a signal of cardiac damage when MB isoenzyme is approximately four percent or greater of total CPK. The initial test result for MB isoenzyme in Patient 632365 indicated a MB isoenzyme level of 20, which was four percent of the total CPK level of 525. I.G. Ex. 19/10.

318. The test result which revealed a CPK level of 525 and an MB isoenzyme level of 20 noted that the result was not obtained by the electrophoresis method and stated that the results might not have the same predictive value as results obtained with the electrophoresis method. I.G. Ex. 16/57.

319. Electrophoresis is a very accurate method of chemically analyzing blood. Tr. III/68.

320. The CPK test was repeated August 5, 1986, using the electrophoresis method. The results were as follows: CPK level was 61; MB isoenzyme level was 0. The pathologist who read this report interpreted it as normal. Tr. III/68; I.G. Ex. 16/56.

321. On the date of admission, August 5, 1986, Patient 632365's blood chemistry tests revealed that her serum sodium level was 122 milliequivalents per liter.

322. A patient's serum sodium level is normal within a range of 136-153 milliequivalents per liter. I.G. Exs. 16/57, 19/10.

323. Petitioner recognized that Patient 632365's serum sodium was relatively low, but did not consider that it required correction. I.G. Ex. 7/17.

324. Patient 632365's serum sodium level was 127 milliequivalents per liter on August 9, 1989. Patient 632365's serum sodium was 117 milliequivalents per liter on August 24, 1989. I.G. Ex. 16/57.

325. A decreased serum sodium level can be indicative of an increase in water as a percentage of body weight, which can be a complication in cases of congestive heart failure. Increased body water content can alter a person's mental status and serve to mimic the symptoms of neurological deterioration. I.G. Ex. 19/10-11.

326. A serum sodium level that is below the normal range is medically unrelated to an intracerebral hematoma. I.G. Ex. 19/9.

327. In the face of an abnormal serum sodium level, normal medical practice is to repeat the test for serum sodium at least every 24 hours until the serum sodium level is within normal limits. I.G. Ex. 19/10-11.

328. In the face of a decreased serum sodium level, proper medical treatment usually consists of diuretics or restriction of fluids, but the specific problem should be isolated before any treatment is begun. I.G. Ex. 19/10-11.

329. Petitioner did not believe that Patient 632365 showed any signs of cardiac symptoms. I.G. Ex. 7/24.

330. If a patient exhibits cardiac symptoms, it is Petitioner's practice to consult an internist or cardiologist to co-manage the patient. I.G. Ex. 7/28.

331. If Petitioner had recognized that Patient 632365 was exhibiting any symptoms of a serious cardiac condition, he would have immediately consulted a cardiologist or internist to assist him. I.G. Ex. 7/53.

332. Petitioner did not recognize that Patient 632365 was exhibiting cardiac symptoms and needed to be treated accordingly. FFCLs 309-312, 315-317, 321-330.

333. Petitioner violated his obligations under the Act to provide care in accordance with professionally recognized standards when he failed to recognize the chest x-ray was symptomatic of congestive heart failure and further failed to treat the patient according to the symptoms shown to be present by the x-ray. FFCLs 309-312, 329-332.

334. Petitioner violated his obligation under the Act to provide care within professionally recognized standards when he failed to repeat the serum sodium test until August 9, when he failed to repeat the serum sodium test every 24 hours, and when he failed to isolate the cause of and treat Patient 632365's abnormally decreased serum sodium levels. FFCLs 321-332.

335. A CAT scan performed on Patient 632365 on August 7, 1989, showed a normal head without any evidence of intracerebral hematoma. I.G. Ex. 16/37; P. Ex. 20/103-4.

336. Patient 632365 was initially placed in ICU on August 5, 1989, but was transferred to neurological service within one or two days. I.G. Ex. 7/14.

337. A diagnosis of cerebrovascular event or intracerebral hematoma or hemorrhage is medically inconsistent with a CAT scan that shows a normal head. I.G. Ex. 16/37; Tr. III/62-64.

338. On August 9 and 10, 1989, Patient 632365 was alert, but shaky and complained of neck pain, stiffness, and discomfort. X-rays of the patient's cervical spine showed degenerative disease with encroachment on the neural foramina. Tr. II/350; I.G. Ex. 16/17.

339. Based on the results of the x-rays of the cervical spine and his examination of Patient 632365, Petitioner diagnosed her symptoms as being caused by an arthritic condition known as cervical spondylosis. Petitioner began the patient on a course of physical therapy that commenced on or about August 14, 1989. Tr. II/350-51; Tr. II/151; I.G. Ex. 7/15, 16/19.

340. On August 15, 1989, Petitioner noted no neurological deficits in Patient 632365's condition. I.G. Ex. 16/19.

341. Cervical x-rays taken of Patient 632365 on August 16, 1989, confirmed Petitioner's initial findings of degenerative joint disease of the cervical spine. I.G. Ex. 16/30.

342. From the period of August 16 through August 23, 1989, Petitioner noted that Patient 632365's symptoms of pain and weakness persisted and noted that the patient appeared confused at times. I.G. Ex. 16/20-22.

343. On August 23, 1989, Petitioner recommended that Patient 632365 undergo a myelogram to rule out the possibility of compression of the spinal cord. I.G. Ex. 16/22.

344. A myelogram is an injection of medical dye into the spinal cord to note any irregularities or deformities.

345. On August 24, 1989, Patient 632365 suffered cardiac arrest and went into an irreversible coma. It was determined that the patient was brain dead. Patient 632365 died on August 30, 1989. Tr. II/151-52, Tr. III/65; I.G. Exs. 7/16-17, 16/22-26.

346. Petitioner placed Patient 632365 in imminent danger and unnecessarily in a high risk situation by failing to recognize, diagnose, and treat her cardiac symptoms. FFCLs 332-334.

347. Petitioner placed Patient 632365 in imminent danger and unnecessarily in a high risk situation by failing to consult an internist or cardiologist. FFCLs 330-332.

348. Petitioner placed Patient 632365 in imminent danger and unnecessarily in a high risk situation by failing to order or administer conclusive follow up tests of serum sodium levels and chest x-rays, where initial tests had indicated that the patient was experiencing cardiac difficulties. FFCLs 333, 334.

349. Petitioner grossly and flagrantly violated his obligation under the Act to provide medical care in accordance with professionally recognized standards by failing to recognize, diagnose, or treat Patient 632365's cardiac symptoms. FFCL 346.

350. Petitioner grossly and flagrantly violated his obligation under the Act to provide medical care in accordance with

professionally recognized standards by failing to consult an internist or cardiologist regarding Patient 632365. FFCL 347.

351. Petitioner grossly and flagrantly violated his obligation under the Act to provide medical care in accordance with professionally recognized standards by failing to order or administer conclusive follow up tests for Patient 632365's electrolytic abnormalities and by failing to properly monitor or treat the patient's electrolytic abnormalities. FFCL 348.

352. Petitioner's treatment of Patient 632365 demonstrates a lack of knowledge of the clinical signs and symptoms that may indicate the presence of cardiac damage or disease. FFCLs 346, 349.

353. Petitioner's treatment of Patient 632365 demonstrates a lack of appreciation of specific cardiac signs or symptoms that would indicate the need to consult with an internist or cardiologist in the management of a patient. FFCLs 347, 350.

354. Petitioner has demonstrated an inability to recognize, diagnose, and treat cardiac symptoms. FFCLs 351, 352.

355. Petitioner has demonstrated an inability to know when to consult with an internist or cardiologist in the management of a patient. FFCL 353.

Willingness and Ability to Comply

356. Petitioner has demonstrated an inability to comply with his obligations under the Act. FFCLs 204, 205, 207, 208, 209, 240, 243, 353-355.

357. Petitioner has demonstrated a willingness to comply with his obligations under the Act. Tr. II/359-62.

Length of Exclusion

358. The I.G. has demonstrated by a preponderance of the evidence that Petitioner has violated his obligation to provide health care in accordance with professionally recognized medical standards with regard to Patient 632365 (Case # 7). FFCLs 333, 334.

359. The I.G. has demonstrated by a preponderance of the evidence that Petitioner violated his obligation to provide health care in accordance with professionally recognized standards of neurosurgery with regard to Patient 854914 and Patient 86-0935 (Cases # 3 and # 4). FFCLs 196-199, 236, 237.

360. The I.G. has demonstrated by a preponderance of the evidence that Petitioner violated his obligation to provide

health care in accordance with professionally recognized standards of medical care with regard to Patient 632365 (Case # 7). FFCLs 333, 334.

361. The I.G. has demonstrated by a preponderance of the evidence that Petitioner has committed gross and flagrant violations of his obligation within the meaning of section 1156(b)(1)(B) of the Act with regard to Patients 854914, 86-0935, and 632365 (Cases # 3, # 4 and # 7). FFCLs 203, 239, 349-351.

362. The I.G. has failed to demonstrate by a preponderance of the evidence that Petitioner violated his obligation to provide health care in accordance with professionally recognized standards of neurosurgery with regard to Patients 268001, 8601866M, 277259, and 8617584M (Cases # 1, # 2, # 5, and # 6). FFCLs 119, 140, 145, 272, 303.

363. Under Section 1156 of the Act, the Secretary of the Department of Health and Human Services (Secretary) may exclude a physician from participating in Medicare and Medicaid where the Secretary determines, based on a recommendation by a PRO, that the physician has grossly and flagrantly violated the obligation to provide health care of a quality which meets professionally recognized standards of care and has demonstrated an inability or unwillingness to substantially comply with the obligation to provide such care. Social Security Act, sections 1156 (a)(2), (b)(1).

364. A "gross and flagrant violation" is defined as the violation of an obligation to provide care in one or more instances which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in a high risk situation. 42 C.F.R. § 1004.1(b) (1989).

365. The I.G. proved that Petitioner committed gross and flagrant violations of his obligation to provide health care in accordance with professionally recognized standards of care. FFCLs 203, 239, 349-351.

366. Although Petitioner has demonstrated a willingness to meet his obligations under the Act, he has not demonstrated the ability to do so. FFCLs 356, 357.

367. The I.G. had the authority to exclude Petitioner from participating in Medicare and Medicaid. FFCLs 20, 24, 25, 360, 363-366.

368. The purpose of section 1156 of the Act is remedial.

369. Section 1156 is intended to enable the Secretary to protect federally funded health care programs and their beneficiaries and

recipients from health care providers who have demonstrated by their conduct that they are not trustworthy. Evelyn Reyes, M.D., DAB CR131 at 37 (1991)

370. The medical records in this case exhibit poor documentation by Petitioner. I.G. Ex. 6/179; Tr. III/161-162.

371. Petitioner has engaged in conduct that endangered the health and safety of program beneficiaries. FFCL 365.

372. Petitioner has demonstrated by his gross and flagrant violations that he is not trustworthy to treat program beneficiaries and recipients. FFCLs 356, 357, 365, 366.

373. The I.G. excluded Petitioner from participating in Medicare and Medicaid for a period of five years. I.G. Ex. 9; FFCL 25.

374. The I.G. has not proven that there exists a remedial purpose to exclude Petitioner for five years.

375. The remedial purpose of section 1156 will be served by excluding Petitioner from participating in Medicare and Medicaid for three years.

RATIONALE

1. The I.G. must prove his case by the preponderance of evidence.

Petitioner contends that the sanction imposed by the I.G. must be sustained by clear and convincing evidence. Petitioner acknowledges that preponderance of the evidence is the standard of proof to be applied in adjudicatory proceedings before an administrative agency if those proceedings are governed by § 7(c) of the Administrative Procedure Act (APA). 5 U.S.C. § 556(d); Steadman v. S.E.C., 450 U.S. 91, 95-98 (1981); P. Br. 31. However, Petitioner argues that the preponderance of the evidence standard as articulated by section 7(c) of the APA does not apply to this case. The appropriate standard for me to apply, according to Petitioner, is that of clear and convincing evidence. Petitioner cites Woodby v. Immigration Serv., 385 U.S. 273 (1966), in support of his contention.

In Woodby, the Court held that while deportation was not a criminal sanction, it did amount to a "drastic deprivation" of rights, and therefore a higher standard of proof than the mere preponderance standard was appropriate and necessary. Id. at 286. Petitioner acknowledges that Steadman is a more recent articulation of the Court's view than Woodby. Petitioner also acknowledges that, in Steadman, the Court rejected the argument that the agency should have applied a clear and convincing standard of proof because of the severity of the sanction.

However, Petitioner reasons that because the Court did not explicitly overrule Woodby in the Steadman decision, it left open the issue of whether the clear and convincing standard could be applied to cases where: 1) Congress has not spoken as to the standard of proof in Medicare exclusion hearings and 2) the sanction involves important individual interests. P.Br. 32-33.

The I.G. argues that the appropriate standard of proof to apply in this case is the preponderance of the evidence standard. The I.G. states that in Steadman, the Court explicitly rejected the application of the clear and convincing standard in administrative hearings involving civil sanctions. Moreover, the I.G. argues that Petitioner's potential exclusion in this case is a civil sanction and is therefore distinguishable from Woodby, because it does not involve Petitioner's personal liberty or infringe on any of Petitioner's protected property rights or entitlements[6]. I.G. R. Br. 2-3. Lastly, the I.G. argues that the new exclusion regulations published on January 29, 1992 (new regulations), unequivocally state that the I.G. bears the burden of persuasion by preponderance of the evidence; whereas the respondent bears the burden of proof as to any affirmative defenses or mitigating circumstances. 57 Fed. Reg. 3298, 3352-53 (1992)(to be codified at 42 C.F.R. § 1005.15).

I hold that preponderance of the evidence is the correct standard to be applied in the case before me. Petitioner's right to an administrative hearing in this case is contained in section 1155 of the Act, codified at 42 U.S.C. § 1320c-4, which provides in relevant part:

> . . . any practitioner or provider, who is dissatisfied with a determination made by a contracting peer review organization in conducting its review responsibilities under this part, shall be entitled to a reconsideration of such determination by the reviewing organization. Where the reconsideration is adverse to the beneficiary and where the matter in controversy is $200 or more, such beneficiary

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[6] I do not agree with the I.G.'s assertion that Petitioner's expectation of continued participation in the Medicare program is not a property right. In Charles J. Barranco, M.D., DAB CR187 at 23 (1992), I noted that "Petitioner's expectation of continued participation as a program provider is a property interest protected by the due process clause of the Fifth Amendment," citing Ram v. Heckler, 792 F.2d 444, 447 (4th Cir. 1986). Petitioner's property interest ensures that he will be afforded due process of law. However, Petitioner's property interest in being a program provider is distinguishable from the rights of individual liberty that are manifest in a deportation proceeding.

> shall be entitled to a hearing by the Secretary (to the same extent provided in section 205(b).

Section 205(b) of the Act provides that Petitioners subject to exclusions imposed by the I.G. are entitled to de novo hearings. Charles J. Barranco, M.D., DAB CR187 at 16 (1992). The Act does not specify the standard of review to be used in adjudications of Peer Review Organization (PRO) review cases before the Departmental Appeals Board (DAB). Section 5 of the APA, 5 U.S.C. § 554, "applies in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing." Section 5(b) of the APA, 5 U.S.C. § 554(c)(2), makes the provisions of section 7, 5 U.S.C. § 556, applicable to adjudicatory proceedings. Steadman at 96-97. The standard to be used by the agency in making its decision is the preponderance of the evidence. Section 7 of the APA, 5 U.S.C. § 556; Steadman at 100-01; Fischer and Porter Co. v. U.S. Int'l Trade Comm'n, 831 F.2d 1574, 1580-81 (1987).

Petitioner's reliance on Woodby is misplaced, as Woodby was a decision of very narrow application. Specifically, the Court adopted the clear and convincing standard in Woodby because:

> deportation proceedings were not subject to the APA, and the Immigration and Nationality Act (INA) did not prescribe a standard of proof, only the judicial scope of review. . . . The language, purpose and history of these sections of the INA differ in language, purpose, and legislative history of § 7(c).

Steadman at 102, n.22.

The Woodby decision is not controlling here, where the administrative hearings of the DAB are subject to the APA. Moreover, while Steadman did not explicitly overrule Woodby, it is a more recent decision and one closely analogous to the situation before me. Moreover, Woodby applied only to proceedings that were outside the scope of the APA, and not proceedings, such as this one, that are subject to the APA's procedures.

The I.G. correctly asserts that the new regulations resolve this matter by stating the I.G. bears the burden of persuasion by preponderance of the evidence. 57 Fed. Reg. at 3352-53. However, I cannot conclude the new regulations are binding on me where their effective date is after the date the I.G. made his determination to exclude Petitioner. Behrooz Bassim, M.D., DAB 1333 at 5-9 (1992). While I do not believe the new provision changes the burden of proof from the standard used in the past, I am reluctant to use the new regulations as support for that rationale.

Additional support for the application of the preponderance of the evidence standard to exclusion cases is found in Michael Burditt, DAB CR35 (1989), aff'd DAB 1167 (1990). In Burditt, ALJ Charles Stratton stated that the applicable standard for the burden of proof in a section 1867 "anti-dumping" case, where no specific statutory guidance existed, was "preponderance of the evidence." Burditt, DAB CR35 at 30. This preponderance of the evidence standard was reiterated by an appellate panel of the DAB in affirming Judge Stratton's decision. Burditt, DAB 1167 at 8.

In Evelyn Reyes, M.D., DAB CR131 (1991), ALJ Steven Kessel used a preponderance of the evidence standard both in determining that a petitioner had grossly and flagrantly violated her obligation under section 1156 to provide health care that met professionally recognized standards, and in determining that the petitioner in that case was unable to comply with her obligation under the Act. Reyes was not challenged on appeal.

Based on the Supreme Court's decision in Steadman and the inapplicability of Woodby, as well as the guidance contained in the APA and in DAB decisions, I find that the correct standard to be applied in the case before me is one of preponderance of the evidence. In the following sections of this decision, I conclude that the I.G. has proven by a preponderance of the evidence that Petitioner grossly and flagrantly violated his obligation to provide care which met professionally recognized standards under section 1156 in three instances. I further conclude that the I.G. proved by a preponderance of the evidence that Petitioner is unable substantially to comply with his section 1156 obligation and that Petitioner's exclusion is remedially necessary to protect Medicare beneficiaries.

2. Petitioner grossly and flagrantly violated his obligation under section 1156 to provide professionally recognized standards of health care in three instances.

Section 1156 of the Act imposes on physicians and other health care providers an obligation, among other things, to provide services "of a quality which meets professionally recognized standards of health care." Section 1156(b)(1)(B) authorizes the Secretary to exclude from participation in Medicare and Medicaid practitioners who have been determined by a Peer Review Organization (PRO) to have "grossly and flagrantly" violated their obligation in one or more instances. To justify an exclusion, the Secretary must further conclude that the practitioner has demonstrated an unwillingness or inability substantially to comply with his or her obligation under the Act. In analyzing whether the I.G., as the Secretary's delegate, was authorized to exclude Petitioner, I first discuss the general nature of Petitioner's obligation to provide care that meets professionally recognized standards, and the definition of a

gross and flagrant violation of that obligation. I next proceed to an analysis of the specific instances in which the I.G. alleges that Petitioner committed gross and flagrant violations of his statutory obligation.

Neither section 1156 of the Act nor the applicable regulations define the term "professionally recognized standards of health care."[7] Petitioner argues that this standard is equivalent to a common law malpractice standard. P. Br. 34. I do not agree. As the I.G. points out, medical malpractice is a common law tort, intended to compensate patients who suffer injury caused by a physician's failure to meet a duty of care. See I.G. R. Br. 4. By contrast, section 1156 is intended to protect Medicare beneficiaries from the risk of harm by identifying practitioners whose care fails to meet the standards of practice of their professions. See Reyes at 37. Thus, the different purposes of section 1156 and the common law of medical malpractice argue against a wholesale importation of medical malpractice standards into litigation arising under section 1156.

Moreover, while I have stated that the present case is not governed by the new regulations, I find persuasive support for my conclusion that "professionally recognized standards of health care" are not synonymous with a medical malpractice standard in the preamble to those regulations. The preamble rejects the suggestion of a commenter that the regulations adopt a medical malpractice standard, stating:

> [T]he proposed definition of "professionally recognized standards of health care" does not provide a litmus test which can easily be applied in every case. It would be very difficult to formulate a wholly objective standard in the

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[7] The new regulations promulgated and effective on January 29, 1992, define the term "professionally recognized standards of health care" to mean:

> Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is at issue, recognize as applying to those peers practicing or providing care within a State.

57 Fed. Reg. at 3330 (to be codified at 42 C.F.R. § 1001.2). The parties do not argue that the new regulations are applicable to this case. P. R. Br. 3; I.G. R. Br. 6. Moreover, I have previously held in Barranco that the new regulations are not applicable to cases which were pending before an administrative law judge prior to their effective date. An appellate panel concurred with that holding in Bassim. See discussion supra p.40.

> area of medical practice, where a certain amount of subjectivity in judgment is inevitable.

57 Fed. Reg. at 3301.

The perspective of the preamble is consistent with that of Varadani v. Bowen, 824 F.2d 307 (4th Cir. 1987). In holding that "professionally recognized standards of health care" was not unconstitutionally vague, the Court of Appeals for the Fourth Circuit stated:

> The definition of adequate medical care cannot be boiled down to a precise mathematical formula; it must be grounded in what, from time to time, other health professionals consider to be acceptable standards of health care.

Id. at 312.

From the court's decision in Varadani, I infer that "professionally recognized standards of health care" describes treatment which the professional peers of a physician would regard as acceptable.

My interpretation of the standard would not require unanimity of opinion among physicians as to the acceptability of a given treatment. Petitioner cites a decision which is persuasive as to this point. In the case of Scheuler v. Strelinger, 204 A.2d 577 (1964), the Supreme Court of New Jersey stated:

> [W]hen a surgeon selects one of two courses, . . . either one of which has substantial support as proper practice by the medical profession, a claim of malpractice cannot be predicated solely on the course pursued.

204 A.2d 577 at 585.

While the case addresses medical malpractice, it illustrates an important point -- in many instances, it may be impossible to identify one course of treatment as the only acceptable standard. For purposes of this case, I conclude that a physician does not violate his obligation to provide health care that meets professionally recognized standards if the physician pursues a course of treatment that has substantial support as proper practice among his or her professional peers. The parties agree, and I hold that the relevant professional peers in this case are neurosurgeons practicing in the United States.

Just as "professionally recognized standards" are not defined by statute, section 1156 also does not define the term "gross and flagrant violation." However, that term has been defined by regulation to mean a violation "which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or

places the beneficiary unnecessarily in high-risk situations." 42 C.F.R. § 1004.1(b) (1989).

The I.G. asserts that Petitioner grossly and flagrantly violated his obligation to provide services which meet professionally recognized standards of health care in each of the seven cases cited. The I.G. has made substantially similar arguments in a number of the cases. For this reason, I discuss these common arguments as a preliminary matter before proceeding to the specific facts of each case.

As to the first six patients, the I.G. contends, among other things, that Petitioner committed gross and flagrant violations by performing surgery under general anesthesia for ventriculostomy and ICPM. These cases primarily involved patients suffering from either stroke or cerebral hemorrhage. The terms infarct and stroke are synonymous. They indicate that a portion of the brain has been deprived of its blood supply. Tr. I/55.

Neurological Surgery (J. Youmans, M.D. 3d ed. 1900) (Youmans' Neurological Surgery), an authoritative medical reference, states that severe brain infarction may be accompanied by swelling due to cerebral edema or hemorrhagic infarction and that the result may be increased ICP. P. Ex. 22/2. Increased ICP occurs because the skull is a tight compartment which limits the range in which a brain lesion can expand. Tr. I/58; Tr. II/269; P. Ex. 23/1. Increased ICP may cause damage to a patient's brain because the swelling of the injured portion of the brain may put pressure on, or compress, previously undamaged portions of the brain. Tr. II/269. Youmans' Neurological Surgery states that fatal outcome in massive cerebral or cerebellar infarction within the first week can be directly related to acute brain swelling and its secondary effects. P. Ex. 22/3.

The article Lehman, Intracranial Pressure Monitoring and Treatment: A Contemporary View, 19 Annals of Emergency Medicine 295 (1990)(Intracranial Pressure Monitoring), states that to alleviate the potential damage to the brain from swelling, most treatment measures have attempted to reduce the volume of cerebrospinal fluid (CSF), blood, or water in the brain without removing or manipulating viable brain tissue. P. Ex. 23/2. One method of alleviating potential damage to the brain from swelling is to perform a ventriculostomy. A ventriculostomy is a procedure whereby a shunt or catheter is inserted into one of the ventricles of the brain in order to relieve pressure on the brain by draining excess CSF. Tr. I/59, 136. The ventricles are structures deep in the brain, close to the midline, where CSF is produced. Tr. I/59.

ICPM was introduced in the early 1970's to measure the pressure within the confines of the skull. Tr. I/58. One method for

recording and monitoring ICP is to insert a catheter into the ventricle of the brain, as in a ventriculostomy, and connect it to a transducer so that pressure waves transmitted through the CSF may be transformed into electrical impulses and plotted on a graph or converted to numerical values by digital means. Tr. I/59. Employing a ventricular catheter as an ICPM device permits the treating physician to drain CSF as a therapeutic measure to control and relieve elevated ICP. Tr. I/137-38.

Another method for recording and monitoring ICP is to place a hollow conical screw in a 1/4 inch drill hole in the patient's skull. The screw is attached to a transducer, pressure waves are transformed to electrical impulses and recorded in the same manner as with the ventricular catheter. Tr. I/58-59. Insertion of the bolt or screw type of ICPM device is usually performed at bedside under local anesthetic. Tr. I/60. A ventriculostomy or insertion of a ventricular catheter also can be performed under local anesthetic. Tr. I/61. In the cases cited by the I.G., Petitioner performed ICPM using the ventricular catheter method and not the bolt or screw method.

The I.G.'s expert, Dr. Ira Kasoff, a board-certified neurosurgeon and consultant to NJPRO, testified that the routine use of ICPM in the treatment of stroke patients violates professionally recognized standards of neurosurgical care. Dr. Kasoff's view is supported by the article Ropper and Shafran, Brain Edema After Stroke, 41 Archives of Neurology 26 (1984), which states:

> Routine monitoring of ICP in this situation [brain edema after stroke], however, cannot be recommended at this time since it has not yet been demonstrated that treatment based on ICP measurement improves outcome, only that persistently raised ICP is associated with brain death.

I.G. Ex. 20/4 (emphasis added).

Based on this evidence, I conclude that performing ICPM in stroke patients on a routine basis is a violation of the obligation to provide health care which meets professionally recognized standards.

The I.G. appears to argue, in his post-hearing brief, that any use of ICPM in stroke patients is not an accepted medical practice. I.G. Br. 15. I interpret this as an assertion that ICPM is never indicated in the treatment of stroke patients. This assertion is not supported by the record. Even the I.G.'s expert, Dr. Kasoff, acknowledged that ICPM could be done in selected stroke cases. However, he testified that this was not the practice in the neurosurgical community in New Jersey. Tr. III/197.

Petitioner introduced the expert testimony of Dr. Samuel Hassenbusch, a neurosurgeon practicing at the Cleveland Clinic,[8] who testified that a significant percentage of neurosurgeons (30 to 50 percent according to his estimate) would do the procedure in selected stroke cases, or would consider it a reasonable alternative. Tr. III/47-48. Dr. Hassenbusch's testimony that ICPM in certain stroke cases meets professionally recognized standards of care is supported by several learned treatises offered by Petitioner, including the aforementioned Youmans' Neurological Surgery, which Petitioner testified is the only text recommended in all neurosurgery training programs. Tr. II/271; see also P. Ex. 22; P. Ex. 23.

At the meeting of the NJPRO, Dr. Kasoff conceded that the author of the chapter in Youmans' Neurological Surgery chapter cited by Petitioner is a reputable neurosurgeon. I.G. Ex. 6/157. However, Dr. Kasoff noted that the author practiced at the Mayo Clinic and asserted that standards of care practiced at the Mayo Clinic may not be appropriate in private practice. Id. at 157-58.[9] Dr. Kasoff stated that physicians at academic or research institutions such as the Mayo clinic are employing ICPM in stroke cases only when conducting research intended for publication. I.G. Ex. 6/157-58. The testimony of Petitioner's expert, Dr. Hassenbusch, directly contradicts Dr. Kasoff's assertion. Dr. Hassenbusch testified that ICPM of selected stroke patients is currently being done at the Cleveland Clinic and that it was also

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[8] Dr. Hassenbusch's Curriculum Vitae indicates that he completed Part I of his board certification in neurosurgery (written examination) in March 1987. P. Ex. 19/2. Dr. Hassenbusch testified that he is eligible for Part II of the board certification (oral examination), but had not yet completed it as of the hearing date. Tr. III/6. I found both Dr. Hassenbusch and Dr. Kasoff well qualified and authoritative witnesses as to the practice of neurosurgery.

[9] If I were to follow the implications of Dr. Kasoff's testimony to their logical conclusion, I would have to conclude that a procedure which is performed by neurosurgeons at some of the leading health care institutions in the United States does not meet professionally recognized standards because the procedure is not routinely performed in private practice at local community hospitals. Such a result would have the effect of setting professionally recognized standards at the level of care rendered at local community hospitals without regard to the fact that standards of practice at local hospitals may be different from those at large teaching hospitals due to factors unrelated to the safety or efficacy of the practice at issue. Constraints such as lack of funds, unavailability of technology, or a lag in dissemination of information may explain why a given practice or procedure has not become standard in local hospitals.

done at Johns Hopkins Hospital, where he served his residency. He specifically stated that ICPM was being performed at those institutions for therapeutic rather than research purposes. Tr. III/127. Dr. Hassenbusch and Dr. Kasoff both testified that ICPM was done more frequently in the 1970's and 1980's than it is done currently. Tr. I/61-64, Tr. III/127.

Petitioner has introduced authoritative treatises and the testimony of an expert witness in support of his contention that ICPM is accepted by the neurosurgical community in the treatment of selected stroke patients. Based on this evidence, I find that the use of ICPM in a patient diagnosed with stroke disease is not a per se violation of professionally recognized standards of neurosurgery. For this reason, I must determine, as to each individual case, whether Petitioner's insertion of a catheter for ICPM violated his obligation to provide treatment which comports with professionally recognized standards.

Petitioner does not dispute that routine ICPM of stroke patients violates professionally recognized standards of neurosurgery. Instead, he argues that the cases cited by the I.G., in fact, represent the nonroutine use of ICPM in selected patients who, in addition to having suffered some brain insult such as a stroke or hemorrhage, showed clinical signs for increased ICP. Petitioner testified that he does not routinely insert ICP monitors in stroke patients. According to Petitioner's estimate, he treated over 100 patients for stroke, brain hemorrhage, or hematoma, and brain tumors during the period 1985 to 1986. Tr. II/267-68. Of those cases, Petitioner estimated that he used ICPM in seven or eight. Id. I find that Petitioner did not routinely use ICPM in treating his stroke patients.

I have concluded as a general matter that Petitioner did not violate his section 1156 obligations by routinely performing ICPM of stroke patients. I must next consider, as to each individual case, whether Petitioner's insertion of an ICPM device violated his obligation to provide care in accordance with professionally recognized standards. However, even a finding that the treatment provided failed to meet professionally recognized standards, without more, will not justify an exclusion. An exclusion under section 1156(b)(1)(B) is only justified if Petitioner's failure to comply with professionally recognized standards was gross and flagrant -- that is, if it placed the patient in imminent danger or unnecessarily in a high risk situation -- and if he is unwilling or unable substantially to comply with such obligation.[10]

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[10] I will discuss my findings regarding Petitioner's unwillingness or inability to substantially meet his obligation under section 1156 of the Act in a separate section of my decision which can be found at pages 89-93.

The I.G.'s contention that Petitioner's treatment placed the patients in imminent danger and unnecessarily in high risk situations generally stems from the view that in these cases the surgical procedure to insert an ICPM device was unjustified. Thus, according to the I.G., the usual risks of surgery, such as the risk of death from anesthesia, or the risk of infection, were unnecessary in these cases. The I.G. contends that Petitioner performed surgery in cases where there was either no clinical indication or deterioration that would justify surgical intervention or where the patient was so devastated that surgery offered no meaningful chance of recovery.

Petitioner contends that, in his judgment, the patients did deteriorate or show clinical signs of increased ICP. Petitioner testified, and the I.G.'s experts confirm, that the clinical indications for increased ICP include: decreased level of consciousness; lowered heart rate; elevated blood pressure; and impaired motor function, such as hemiparesis. Tr. II/288; Tr. III/165; I.G. Ex. 19/3-4. Thus, in the cases involving ICPM alone, a determination that Petitioner violated his obligation to provide care that meets professionally recognized standards of neurosurgery initially turns on the question of whether the medical records support Petitioner's clinical judgment that the patients suffered neurological deterioration consistent with increased ICP. Assuming the records reflect no neurological deterioration or deterioration to a degree that does not warrant ICPM, then a determination that a gross and flagrant violation occurred must be based on a showing that the patient was in imminent danger or placed unnecessarily in a high risk situation by the use of ICPM.

The I.G. alleges that Petitioner grossly and flagrantly violated his section 1156 obligations in several cases where Petitioner performed surgery to insert ICPM devices for drainage and monitoring in patients who had suffered very serious strokes or hemorrhages and were at grave risk of dying from the brain injury regardless of whether they underwent surgery. In these cases, the I.G. asserts that the surgical procedures placed the patients unnecessarily in high risk situations because, in the I.G.'s view, the patients were unnecessarily exposed to the risks inherent in the use of general anesthesia and to the risks of infection associated with surgery.

Dr. Kasoff stated at the PRO meeting that the risk of mortality and morbidity associated with the use of general anesthesia is approximately one percent. I.G. Ex. 6/42. At the hearing before me, Dr. Kasoff also testified that patients suffering from stroke disease may be placed at risk by the administration of general anesthesia because the inhalation anesthetic might cause blood to be diverted into the area of the brain that has experienced the stroke. Tr. I/73. This diversion, according to Dr. Kasoff,

could convert the stroke into a hemorrhage, resulting in greater brain damage to the patient. Id. Dr. Kasoff did not testify, and the I.G. did not introduce any other evidence, as to the magnitude of this risk. Thus, the only quantifiable evidence before me as to the magnitude of the risk presented by the administration of general anesthesia indicates that the risk is approximately one percent. Similarly, although Dr. Kasoff testified that there is a risk of infection associated with surgery and with insertion of an ICPM device, the I.G. did not introduce any evidence quantifying these risks.

The court in the Varadani case explained that a gross and flagrant violation involves "an especially dangerous deviation from medical norms." 824 F.2d at 312. I conclude that placing a patient who already faces a near certain risk of death from his or her underlying disease process at a one percent risk of mortality from general anesthesia does not constitute an especially dangerous deviation from medical norms. I reach this conclusion because the patient in such a case is not placed at greater risk than that he or she already faces as a result of the underlying condition.[11]

As a preliminary matter, I have concluded that Petitioner did not violate his obligation to provide care that met professionally recognized standards of neurosurgery by routinely monitoring ICP in stroke patients. I have also concluded that administering general anesthesia to a severely compromised patient does not place the patient in imminent danger or in an unnecessarily high risk situation within the meaning of the regulation. With these general observations as background, I now turn to an examination of the individual cases in which the I.G. alleges that Petitioner committed gross and flagrant violations of his obligation to provide services that met professionally recognized standards of health care. As to each case, I first analyze the question of

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[11] I would reach this conclusion even in a case where I concluded that the surgery was unnecessary. My conclusion that the patient is not placed unnecessarily in a high risk situation does not mean that I would condone unnecessary surgery simply because it is performed on a critically ill patient. Section 1156(b)(1)(A) authorizes the Secretary to exclude practitioners who, among other things, violate their obligations in a substantial number of cases by providing services that are not medically necessary, without regard to whether patients are placed unnecessarily in high risk situations. In the present case, however, the I.G. did not seek to exclude Petitioner pursuant to section 1156(b)(1)(A), but instead relied on section 1156(b)(1)(B) which, with 42 C.F.R. § 1004.1, requires a finding that the patient was placed in imminent danger or unnecessarily in a high risk situation.

whether Petitioner violated his obligation to provide care of the requisite quality. Where I find such an obligation, I proceed to determine whether the violation placed the patient in imminent danger or unnecessarily in a high risk situation, that is, whether the violation was gross and flagrant.

a. Petitioner's treatment of Patient 268001 (Case # 1) did not violate section 1156 of the Act.

Patient 268001 was an 81 year old male who was admitted to Newcomb Hospital in Vineland, New Jersey, on August 23, 1985. The patient had apparently suffered a sudden weakness on the right side and became unconscious. He was comatose on admission and was intubated in the emergency room because he was not breathing effectively on his own. I.G. Ex. 10/5. On admission, Dr. Rajput, the attending physician, listed his impressions as: 1) cerebrovascular accident (CVA) with right hemiparesis; 2) increased blood pressure by history; and 3) history of irregular heart beats. Id. The patient was transferred to the intensive care unti (ICU).

The nurse's notes on admission to the ICU indicate that the patient's level of consciousness was somewhat improved. The nurse noted that the patient was able to squeeze his left hand to commands and responded to his name by opening his eyes and turning his head toward the speaker. I.G. Ex. 10/57. Petitioner saw the patient as a consultant on August 23. I.G. Ex. 10/18, 57.

On August 24, 1985, Dr. Rajput noted that the patient remained stuporous and occasionally responded to verbal commands. I.G. Ex. 10/18. On that date, a computerized axial tomography (CAT) scan of the patient's head was performed. I.G. Ex. 10/97. A CAT scan is similar to an x-ray except that it permits the physician to visualize soft tissue, such as the brain, rather than just the bone. Tr. III/20. According to the radiologist's report, the CAT scan revealed an area of decreased attenuation in the left temporal and parietal lobe consistent with a recent infarct with mass effect. I.G. Ex. 10/97. The report also noted minimal compression of the left lateral ventricle. The radiologist's impression was that the patient had suffered an infarct involving the left temporal and parietal lobes. Id.

The nurse's note of 1500 hours (3:00 p.m.) August 24 reported the patient's neurological status as stuporous, pupils sluggish, right side flaccid, grips weakly with left hand. I.G. Ex. 10/58. That note further reported as to the patient's cardiovascular status that at 1130 hours (11:30 a.m.), the patient had become bradycardic with sinus arrest. Id. Bradycardia means that the patient had decreased heart rate. Tr. II/290.

In a later note, also dated August 24, Petitioner stated that the patient was deteriorating neurologically. He described the patient as unconscious, no verbal response, withdraws mainly to pain, pupils sluggish. Petitioner indicated the CAT scan showed shift and mass effect. Petitioner believed that, in view of the mass effect and decreased heart rate, there was a probability of increased ICP. Petitioner discussed the patient's condition and possible treatment options with his wife and family. They agreed to allow Petitioner to proceed with a ventriculostomy and ICPM. I.G. Ex. 10/19; Tr. II/286.

The patient was taken to the operating room for surgery at 1920 hours (7:20 p.m.), August 24. I.G. Ex. 10/59. Petitioner performed a ventriculostomy on the patient under general anesthesia. I.G. Ex. 10/19. There is no indication in the record as to what anesthetic agent or agents were administered to the patient. In the operative record of the procedure, Petitioner stated that when the catheter entered the ventricle, fluid came out under pressure. I.G. Ex. 10/9.

In a note dated August 25, 1985, Dr. Robert Fazzaro, who was substituting for Dr. Rajput (see I.G. Ex. 10/59), reported that the patient was more awake and that his heart rate was increased. I.G. Ex. 10/20. Petitioner's note of August 25 also reported: "Patient is more awake. Started to follow verbal commands. Pre-op pt [patient] was completely unresponsive. His ICP WNL [within normal limits]. Pupils are reacting. Still has gaze preference to [left symbol]. . .His HR [heart rate] is up. Started to move [right symbol] leg more." I.G. Ex. 10/21

Thereafter, the physicians' notes reflect fairly consistently that the patient was more awake and was able to follow verbal commands. I.G. Ex. 10/21-34. Petitioner removed the ICPM device on August 27. I.G. Ex. 10/22. The values recorded for ICP were all within normal limits except for one notation that readings were "as high as 25 when pt is being suctioned." I.G. Ex. 10/64. There were no further significant changes in the patient's neurological condition. Efforts to wean him from the respirator were unsuccessful. At the family's request, the patient was transferred by ambulance to a Philadelphia hospital on September 11, 1985, so that he could be cared for by the family physician.

In its letter of June 19, 1990, NJPRO notified Petitioner that it had concluded that he had grossly and flagrantly violated his obligation to provide care that met professionally recognized standards in his treatment of Patient 268001 in the following respects: 1) inappropriate use of an intracranial pressure monitoring devise [sic] to treat a stroke; 2) subjecting the patient to the risks and hazards of general anesthesia; 3) increasing the risk of infection by subjecting the patient to an unnecessary invasive operative procedure: i.e., the insertion of

an intracranial pressure monitoring catheter; and 4) inappropriate management of a stroke. I.G. Ex. 8/1.

In determining to exclude Petitioner, the I.G. accepted NJPRO's conclusion that the conduct cited represented a gross and flagrant abuse of Petitioner's obligations under section 1156 of the Act. I.G. Ex. 9/2.

The I.G. argues that Petitioner grossly and flagrantly violated his obligations to this patient by performing a ventriculostomy and ICPM when the patient was diagnosed with an acute stroke. I have concluded above that it is not a per se violation of Petitioner's obligations to perform ICPM in stroke cases. However, the I.G. contends that ICPM of this patient was unjustified, because this case involved an acute stroke without any clinical signs of increased ICP. Such clinical signs would include a decreased level of consciousness; lowered heart rate; elevated blood pressure; and impaired motor function, such as hemiparesis. Tr. II/288; Tr. III/165; I.G. Ex. 19/3-4. I conclude that there were clinical signs from which Petitioner could reasonably have concluded that Patient 268001 may have been experiencing increased ICP. For this reason, I conclude that the I.G. failed to prove that Petitioner violated his obligation to provide care that met professionally recognized standards of neurosurgery to Patient 268001.

Dr. Kasoff testified that, in his view, the patient did not deteriorate further beyond his condition on admission, which was described as comatose and unable to breathe on his own. Therefore, Dr. Kasoff concluded that Petitioner's pre-operative note, which described the patient as deteriorating, was not supported by the record. Tr. I/148-149. I disagree. It is true that the patient was described as unconscious on admission and that he was placed on a respirator. However, the nurse's notes on the patient's condition on admission to the ICU indicate that he had regained some level of consciousness. For example, he opened his eyes and turned his head in response to his name. Further, while Dr. Rajput's note of August 24 describes the patient as "stuporous," he also notes that the patient was occasionally able to follow verbal commands. In contrast, Petitioner's note of August 24 describes the patient as unconscious and "no verbal response."

Additionally, the nurse's notes describe an episode of bradycardia, or low heart rate, on August 24. Finally, from the time of admission, the patient had been experiencing right hemiparesis. Thus, the record contains evidence that three clinical parameters for increased ICP were present in this case, namely: decreasing level of consciousness, lowered heart rate, and motor dysfunction. Moreover, according to Dr. Hassenbusch, the CAT scan report, which described compression of the left

lateral ventricle, also raised the possibility of increased ICP. Tr. III/11.

Petitioner's operative report indicates that CSF came out under pressure when the catheter entered the ventricle. Dr. Hassenbusch testified that this was an indication that the patient was, in fact, experiencing increased ICP. Tr. III/12. Dr. Hassenbusch also testified that performing the surgery under general anesthesia was a reasonable alternative, because performing a burr hole under local anesthetic requires a cooperative patient. Patient 268001 was experiencing altered mental status and was unable to follow verbal commands, and thus may have been unable to cooperate. Tr. III/14; 88-89; P. Ex. 18/1. Finally, the patient's status seems to have improved somewhat after the surgery. The physicians' notes from August 25 through September 11, when the patient was transferred, generally indicate that the patient was more awake and responsive. Based on this evidence, I conclude that the I.G. failed to prove that by performing a ventriculostomy and ICPM on Patient 268001, Petitioner violated his obligation to provide care that met professionally recognized standards of neurosurgery.

Because I have concluded that the I.G. did not prove that Petitioner violated his obligation to provide treatment that met professionally recognized standards, I do not reach the question of whether the treatment placed the patient in imminent danger or placed him unnecessarily in a high risk situation.

b. Petitioner's treatment of Patient 8601866M (Case # 2) did not violate section 1156 of the Act.

Patient 8601866M was a 74 year old female who was admitted to Millville Hospital in Millville, New Jersey, on January 17, 1986. Apparently, she had been in excellent health until she suddenly became confused and rapidly developed slurred speech and marked weakness of the left side. I.G. Ex. 11/4. The patient was seen in the emergency room by Dr. Fazzaro, who noted that her blood pressure was 240/110, that she was comatose with pupils pinpoint and nonreactive, and that she had severe left hemiparesis. I.G. Ex. 11/17. Dr. Fazzaro's impression was that the patient had suffered a CVA, probable hemorrhage. Id. Dr. Fazzaro ordered a CAT scan and requested a neurosurgical consult on an emergency basis. I.G. Ex. 11/2.

The report of the CAT scan describes a large hemorrhagic lesion throughout the right basal ganglia extending into the adjacent right frontotemporal and parietal lobes, as well as into the right lateral ventricle. I.G. Ex. 11/21. The report also notes significant right to left shift of the midline structures. Id. The radiologist's impression was:

> Large hemorrhagic lesion on the right side of the brain with right to left shift, most likely representing a hemorrhagic infarction in the basal ganglia with extension into the ventricular system and adjacent brain. A neoplasm [tumor] with hemorrhage cannot entirely be excluded.

Id.

Dr. Fazzaro's expiration note states, "It was felt that [the patient's] only chance was for evacuation of clot." I.G. Ex. 11/13. Therefore, on the same day, January 17, Petitioner performed surgery to evacuate the hematoma. Petitioner's operative record of the surgery describes a large intracerebral hematoma which extended from the surface of the brain, posteromedially to the basal ganglia. I.G. Ex. 12/14. The hematoma was completely removed. Id. After evacuating the hematoma, Petitioner inserted a catheter into the ventricle for ICPM and drainage of CSF (ventriculostomy). Id. The patient did not improve after surgery. I.G. Ex. 11/13. She passed into a deep coma and was pronounced dead on January 20, 1986. I.G. Ex. 11/13, 20.

The I.G. and NJPRO concluded that Petitioner grossly and flagrantly violated his obligation to provide health care that met professionally recognized standards by: 1) subjecting the patient to unnecessary intracranial operative procedures, i.e., the evacuation of a clot and insertion of an ICPM catheter; 2) failing to acknowledge the poor prognosis of the patient and proceeding with an operative procedure; and 3) subjecting an already moribund and compromised patient to the risks and hazards of general anesthesia and operative procedure. I.G. Exs. 8/2; 9/2.

The essence of the I.G.'s argument as to this patient is that the extent of the hemorrhage which she suffered was so great that there was little hope of her recovery. For this reason, the I.G. argues, Petitioner violated his section 1156 obligations by intervening surgically, rather than simply rendering supportive care. The I.G.'s expert, Dr. Kasoff, testified that the patient had descended into a very deep level of coma, from which he would not anticipate recovery. Tr. I/89. He stated that there was no benefit to be gained by evacuating the hematoma and that ICPM in such a case was "irrelevant." Tr. I/90-91. Dr. Kasoff testified that the accepted course of treatment in such a case would be supportive medical management. Tr. I/89.

Petitioner does not dispute that the patient was severely compromised, nor that the prognosis was grave. Instead, Petitioner asserts that the patient had no chance for recovery without surgery, while with surgery, she might have had a 10 percent chance of recovery. Tr. II/296-97. Petitioner's expert, Dr. Hassenbusch, similarly testified that, in his opinion, there

was a 99 percent likelihood that the patient would have died without surgery, whereas with surgery, he estimated her chances for survival at 3 to 10 percent. Tr. III/28-29. Dr. Arico, a board certified neurosurgeon who prepared a report at Petitioner's request, stated: "Certainly, had some aggressive treatment program not been undertaken, [the patient] would have gone on to demise. Dr. Hussain's effort to decompress her was aggressive, but held out the only chance that this patient would have had for survival whatsoever." P. Ex. 1/2.

Even the summaries prepared by the neurologist and neurosurgeon who reviewed the records for NJPRO are somewhat supportive of the course of treatment pursued by Petitioner. The neurologist stated:

> One certainly can't fault Dr. Hussain under the circumstances for trying to evacuate the hemorrhage. Although with signs of mid-brain compression and an increased intracranial pressure, i.e. decreased pupillary reaction, the chances that such a procedure would improve the patient's condition was very small indeed.

I.G. Ex. 4/8.

The neurosurgeon concluded that the surgery was unnecessary, and opined that this would be the conclusion of the majority of neurosurgeons, although he noted, "there are those that would differ." Id. Even Dr. Kasoff conceded that there are neurosurgeons who would consider surgery an appropriate alternative. Tr. I/161-62. Dr. Kasoff also testified that there were neurosurgeons who would proceed with surgery if there was the slightest chance that the surgical procedure could benefit the patient. Tr. III/206. Dr. Kasoff stated that, in his view, such surgery would be a "viable option." Id.

Based on the testimony of Dr. Kasoff and Dr. Hassenbusch, as well as the written reports of Dr. Arico and the NJPRO consultants, I conclude that a reasonable body of neurosurgical opinion would support surgery to remove the hematoma as an acceptable alternative as a last-ditch effort to save the patient's life. I view the statutory standard "professionally recognized standards of health care" to require a consensus of opinion. Where reasonable physicians differ as to the appropriate treatment in a given case, a physician does not violate his obligations by pursuing a course of treatment which has the support of a respectable body of physicians. There is no evidence from which I could quantify the percentage of neurosurgeons who would advocate surgery as opposed to those who would advocate medical management alone. However, all of the neurosurgeons in the present case recognized that there was a body of support for surgical intervention. For this reason, I conclude that Petitioner did not violate professionally recognized standards of

neurosurgical practice in performing surgery to evacuate the hematoma.

Petitioner testified that the primary purpose of performing the surgery was to evacuate the hematoma. Tr. II/300. Petitioner inserted an ICP monitor as a secondary procedure to monitor the patient's ICP post-surgery. Petitioner testified that it is normal neurosurgical procedure to insert an ICP monitor after surgery to remove a hematoma. Tr. II/301-02. Dr. Hassenbusch opined that placing the catheter was within accepted neurosurgical standards of care. Tr. III/25-27; P. Ex. 18/2. However, even were I to accept that ICPM was "irrelevant," as Dr. Kasoff concluded, I would nevertheless conclude that insertion of the monitor did not represent a gross and flagrant violation of Petitioner's section 1156 obligations. This is because the insertion of the ICP monitor did not pose any significant additional risk to the patient beyond that posed by the surgery to evacuate the hematoma. The only risk posed by the ICP monitor independent of the surgery to evacuate the hematoma is that of infection. Tr. I/71. The I.G. presented no evidence from which I can assess the magnitude of this risk. I must conclude, therefore, that the I.G. did not meet his burden of proving that the insertion of the ICP monitor placed the patient in imminent danger or in an unnecessarily high risk situation.

The I.G. points out that Petitioner himself testified that hemorrhages of the basal ganglia are not helped by surgical means. I.G. Br. 21; Tr. II/268. Petitioner testified that stroke patients who present a "fixed deficit" are not helped by surgical means. Tr. II/268. I take this to mean that patients who have suffered irreversible brain damage due to strokes of the basal ganglia are not helped by surgical means. As noted above, the radiologist's report of the CAT scan gave as the most likely diagnosis a hemorrhage of the basal ganglia. However, there is considerable dispute in the record as to whether this patient had suffered irreversible brain damage at the time Petitioner performed surgery. Therefore, I have no basis to conclude that Petitioner's operative procedures in this patient's case were unnecessary and contrary to his obligations under section 1156 of the Act.

c. Petitioner committed gross and flagrant violations of his section 1156 obligation in his treatment of Patient 854914 (Case # 3).

Patient 854914, an 80 year old male with prior strokes/transient ischemic attacks (TIAs) and myocardial infarctions (heart attacks), presented to the emergency room (ER) at Bridgeton Hospital on July 28, 1985, with complaints of nausea and vomiting. He was admitted after an abnormal EKG. A neurological examination revealed minimal weakness over the left side but no significant sensory or motor deficits. The initial impression of

Dr. Gladwyn Baptist, the attending physician, was gastroenteritis with mild dehydration. Dr. Baptist also noted that myocardial infarction should be ruled out. On July 29, 1985, his family reported that his speech had become slurred. By July 30, 1985, his speech had become markedly slurred, he had difficulty opening his eyes, and his respiratory process was depressed and required intubation. I.G. Ex. 12/3, 32-33.

A neurologist, Dr. Sharan Rampal, was consulted and his initial impression included a note to rule out the possibility of a cerebellar infarction. He ordered a CAT scan[12] which showed right parietal infarct encroaching on the occiput, an acute right cerebellar infarction, severe atrophy and moderate ventricular dilation. I.G. Ex. 12/3. By August 1, 1985, the patient's neurological condition continued to deteriorate -- he was showing signs of decerebration (reduction of brain stem function). Dr. Rampal's impression of that date indicated:

> Unresponsive to verbal commands. Decerebrate posturing to deep pain. Eyes deviated to the left. Some spontaneous [illegible] movement to the left. Pupils pinpoint. Imp. Decerebrate [secondary] to cerebellar infarct; prognosis grave.

I.G. Ex. 12/35; Tr. I/174-75, Tr. II/307.

Dr. Rampal ordered a steroid (Mannitol) to reduce intracranial pressure and a repeat CAT scan. I.G. 12/35. Apparently for technical reasons, a print of the scan was not obtainable. Dr. Rampal did offer the following description of the CAT scan on August 2, 1985:

> For technical reasons, radiologist unable to print CT yesterday, [illegible] measurement of ventricles. On reviewing films today there appears to be [increased symbol] ventricular dilatation suggesting obstructive hydrocephalus. [Therefore symbol] will request urgent neurosurgical eval. for possible shunt. Imp. cerebellar infarct with IV [four] ventricular obstruction.

I.G. Ex. 12/36, Tr. I/171-72.

Dr. Baptist indicated on August 2, 1985, that the patient's neurological status continued to deteriorate -- he showed

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[12] There were three CAT scans done on this patient. However, the record does not contain copies of the findings of the examinations. Determination of the findings of each examination is based on the physician notes of record.

"decerebrate posturing and unresponsiveness." He further indicated multiple CVAs with cerebral edema. I.G. Ex. 12/36.

Petitioner was consulted on August 2, 1985. On that day, he performed, with the patient under general anesthesia, a "right frontal craniotomy, decompression and ventriculostomy" and as part of the operative procedure he "hooked up for intracranial pressure monitoring and calibration."[13] I.G. Ex. 12/5, 37.

On August 3, 1985, Petitioner noted:

> [P]atient is comatose, decerebrating bilaterally. Has withdrawal response to deep painful stimuli. His symptoms are [illegible] post fossa swelling [and symbol] hydrocephalus. If no improvement - next 2-3 days will consider post fossa decompression.

I.G. Ex. 12/38.

On August 3 and 4, 1985, both Dr. Rampal and Petitioner indicated that the patient's neurological condition remained essentially the same and a repeat CAT scan would be done. I.G. Ex. 12/40. Again on August 6, 1985, Petitioner noted similar neurological findings as previously, and a need for electroencephalogram (EEG) results. I.G. Ex. 12/41-42. That date, Dr. Baptist indicated no clinical improvement, EEG to assess brain function and prognosis "very poor." I.G. Ex. 12/41. There was no change in the patient's neurological status as reflected in Petitioner's note of August 7, 1985. I.G. Ex. 12/43.

The EEG examination was performed on August 8, 1985, and showed pronounced cortical function on the left side. I.G. Ex. 12/45. Apparently based on the continued lack of neurological improvement, a CAT scan showing evidence of increased mass effect compression in the posterior fossa with compression of the brain stem and the indication of some brain stem function by the EEG examination, Petitioner performed under general anesthesia a posterior fossa craniotomy, posterior fossa decompression, and

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[13] There is some confusion in the record as to whether Petitioner performed a craniotomy or craniectomy. The operative note states craniotomy as the procedure done, but the text refers to "burr hole" and "direct craniectomy". I.G. Ex. 12/5 [the operative report is misdated as August 9 rather than August 2, 1985]. Petitioner argues that he did a craniectomy. P. Br. 54. Considering the numerous references in the hospital records, including Petitioner's own notes, which refer to craniotomy (I.G. Ex. 12/3. 37), I must conclude that weight of the evidence suggests that the procedure done on August 2 was the more complex craniotomy and not a craniectomy.

ventriculostomy on August 9, 1985.[14] I.G. Ex. 12/6, 45-46. Petitioner noted on August 13, 1985, that the ICP monitor showed the patient's pressure to be within normal limits and the monitor was removed. I.G. Ex. 12/49. There was no improvement in the patient's condition post surgery. I.G. Ex. 12/4, 47-54. In fact on August 14, 1985, it was noted that the patient "has received all the possible options that might result in improvement, and his failure to do so implies irreversible sequelae of cerebellar infarction with brain stem compression." I.G. Ex. 12/49. By August 16, 1985, with continued poor prognosis, the patient was extubated, and he died that day. I.G. Ex. 12/4.

The I.G. and the NJPRO argue that the following findings represent gross and flagrant violations of Petitioner's obligation to provide care that meets professionally recognized standards of health care: 1) the operative procedure (craniotomy and insertion of an intracranial pressure monitoring catheter) on August 2, 1985 was not necessary since the patient had an acute brain stem infarct; 2) a repeat CAT scan was needed to verify the diagnosis prior to determining the type of surgery to perform; 3) the posterior decompression surgery on August 9, 1985 should not have been performed; and 4) the patient was exposed to the unnecessary risk of general anesthesia on two occasions. I.G. Exs. 8/2, 9/2.

In assessing the need for the surgery performed by Petitioner on August 2, 1985, it is important to reflect on the patient's clinical signs and findings as of that date and determine whether Petitioner acted in a manner consistent with the existing standards of practice in neurosurgery. Considering that Petitioner was dealing with several CVAs, including a stroke involving the cerebellum of the brain, it was necessary for him to act promptly to avoid total compromise of the patient's brain stem function. As stated by Dr. Kasoff, this portion of the brain is an "extremely sensitive and vital structure of the brain." Tr. I/93. He further indicated that due to:

> the possibility of rapid deterioration in the face of a swollen cerebellar hemisphere, because of stroke, it is often necessary to decompress [the] cerebella with great rapidity before impact has had a chance to cause devastation to the brain stem, which would be irreversible.

Tr. I/93.

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[14] Although on August 4, 1985, Petitioner indicated a need for a repeat CAT scan, there is no reference to the findings of such examination until his operative note of August 9, 1985. See I.G. Ex. 12/6.

Moreover, considering the extent of neurological damage that had occurred by August 2, 1985 (the patient was decerebrate), Dr. Kasoff opined that while a posterior fossa decompression procedure was appropriate in the early stages of a cerebellar stroke, the patient's brain stem was irreversibly damaged and that even decompression would not result in the patient's recovery. Tr. I/99-100, 173, 175.

Dr. Kasoff opined that the procedure that Petitioner performed on August 2, 1985 -- a craniotomy in order to insert a ventricular drain -- was proper when done in connection with a posterior fossa decompression. Tr. I/99-100. But he further opined that the use of an ICPM catheter was "irrelevant," nor could he find any record that pressure was recorded. Tr. I/96. In fact the only reference Petitioner made to the patient's ICP was when he removed the monitor on August 13, 1985, after the second operation. I.G. Ex. 12/49. At that point, even though the patient's pressure was normal, his condition was "unsalvageable." Tr. I/99.

Since neither surgical procedure performed by Petitioner on this patient was necessary, based on the application of existing standards of neurological surgical practice, Dr. Kasoff opined that the general anesthesia used in the two operations placed the patient in a "considerable unnecessary risk." Tr. I/100-01. Considering that Dr. Kasoff has expressed his opinion that the patient was beyond hope of recovery when the two surgeries were performed, a question arises whether any risk from a general anesthesia would have any impact on this patient. What is evident, according to Dr. Kasoff, is that Petitioner's failure to perform the posterior fossa decompression surgery timely when it might have had a positive impact on the patient placed the patient in imminent danger and unnecessarily in a high risk situation. Moreover, assuming that on August 2, 1985, the patient's brain stem compression could be reversed, Petitioner's choice of a ventricular drain and ICPM placed the patient in imminent danger and unnecessarily in a high risk situation. His delay of the posterior fossa decompression until August 9, 1985, even with some indication of brain stem activity by EEG, eliminated any realistic hope that the patient had for recovery.

In response to Dr. Kasoff and the NJPRO's assertions, Petitioner contends that, when he was consulted on August 2, 1985, his judgment as to the need to relieve the ventricular pressure was based on Dr. Rampal's belief that the patient's hydrocephalus required drainage. Tr. II/306. Petitioner acknowledged that the lack of a dispositive CAT scan as of August 2, 1985, complicated his choice of surgical procedures, since the extent of the cerebellar infarct was not known. I.G. Ex. 6/72. He explained his rationale for the first surgery as follows:

> My impression was, that likely, we're dealing with cerebellar infarct, but it could have been something associated with that, and the only objective evidence we saw, was obstructive hydrocephalus from the CAT scan. And based on his rapid deterioration from being awake to coma and responses, we did a ventriculostomy at this point, and monitored the pressure, and I continued to follow and review the films again.

I.G. Ex. 6/72.

The need for the subsequent posterior fossa decompression was explained as follows:

> [After the patient did not improve after the first surgery], at this point, it was, you know, obvious or clear after this, that we are dealing with cerebellar infarct, and maybe he may benefit by posterior fossa decompression.

I.G. Ex. 6/72-73.

Petitioner admitted that if the CAT scan or other studies showed that the obstructive hydrocephalus was caused by the cerebellar infarct then "the treatment o[f] choice at that time, is posterior fossa decompression and a ventriculostomy at the same time." I.G. Ex. 6/74, 80-81. It would appear that Dr. Kasoff and Petitioner and his experts all agree that the decompression surgery was needed. The apparent conflict is that Dr. Kasoff argues there was sufficient information to demonstrate its need by August 2, 1985. Petitioner argues differently.

Petitioner indicated that in the case of Patient 854914, as of August 2, 1985, the CAT scan showed only hydrocephalus. I.G. Ex. 6/80. He opined that in such situations:

> the simplest and easiest procedure was just ventriculostomy to put the drainage, shunting, to relieve the pressure, until you determine really what is going on, and at least give them a chance to recover some of his function.

I.G. Ex. 6/75.

In short, Petitioner explains his choice of surgery on August 2, 1985, on the inability of himself, Dr. Rampal, and the radiologist to be certain that the cause of the hydrocephalus was the cerebellar infarct and, therefore, it would have been incorrect to do a decompression because he was not sure of the cause of the pressure. I.G. Ex. 6/81-83. When the NJPRO pointed out to Petitioner that the CAT scans of July 30 and August 1, 1985, were reflective of a cerebellar stroke, and Dr. Rampal's

impression prior to the first surgery was cerebellar infarct, Petitioner indicated such evidence was uncertain. I.G. Ex. 6/84. When asked to identify the types of strokes that cause hydrocephalus, Petitioner admitted "any posterior fossa strokes" or "brain stem infarct . . ." I.G. Ex. 6/85. Although Petitioner admitted the August 1, 1985, CAT scan was "not the best quality," he considered it "reasonable" and he "was satisfied with the study." I.G. Ex. 6/85. He did not do a decompression on August 2, 1985, because he: 1) was not convinced that the patient had a brain stem infarct; 2) did not want to "put [the patient] through such a major procedure"; and 3) thought the cause of the hydrocephalus was possibly a "small tumor in the posterior fossa." I.G. Ex. 6/87-88.

This explanation is unsatisfactory. When Petitioner is consulted, as he was in this patient's case, his responsibility as a neurosurgeon is first to ensure that all diagnostic procedures have been performed which would reveal the cause and severity of the patient's condition. Dr. Kasoff expressed that such an obligation was reflective of professionally recognized standards of neurological practice. I.G. Ex. 6/96, 98. Moreover, Petitioner cannot defer responsibility for his own actions by pointing to others who were involved in the patient's treatment. He was the person who, by skill and training as a neurosurgeon, had to make the ultimate decision on the timing and type of surgery needed. By August 2, 1985, the patient's neurological condition was already severely compromised -- he was decerebrate and unresponsive. I.G. Ex. 12/36. CAT scans of July 30, 1985, and August 1, 1985, were indicative of a cerebellar infarct. I.G. Ex. 12/3, 36. Dr. Rampal's impression prior to the surgery was hydrocephalus secondary to a cerebellar infarct and the possible need of a shunt to relieve the cerebral pressure. I.G. Ex. 12/36. But Dr. Rampal sought a neurosurgical evaluation for guidance. Id. Petitioner's obligation at this point was independently to assess the patient's condition based on his signs and symptoms and available diagnostic studies. It is evident that the CAT scans were strongly suggestive of a cerebellar infarct. If Petitioner had doubts about the cause of the cerebral pressure, he should have repeated the CAT scan. He admits that a posterior fossa decompression is necessary when the brain stem is compressed. I.G. Ex. 6/72, 73.

Moreover, the record is clear that a significant delay in performing the decompression will eliminate any realistic possibility of the patient's recovery. Tr. I/93, 94. I agree with Dr. Kasoff that the hospital record reflecting the patient's neurological status supports that the decompression surgery was needed either on August 2, 1985, or earlier. Petitioner had sufficient information that the patient had suffered a cerebellar infarct. He may have not known the exact dimensions of that infarct based on the CAT scans available, but that could have

been remedied by a prompt repeat scan. I.G. Ex. 6/96.[15] Such a scan was not done until, at the earliest, August 8, 1985. Tr. III/34; I.G. Ex. 12/3; P. Ex. 20/31. He did not perform the posterior fossa decompression until August 9, 1985. I.G. Ex. 12/6, 46. Such a delay is inexcusable considering: 1) the serious, irreversible, and potentially devastating effect of continued brain stem compression; 2) the absence of improvement in the patient's neurological status after the first surgery; and 3) Petitioner's own note, on August 3, 1985, that such surgery would be performed in the next two or three days. Tr. I/93, 94; I.G. Ex. 12/38, 40. By August 9, 1985, the decompression surgery was essentially irrelevant, since the patient's brain stem was so severely compromised that reduction of the cerebral pressure would have no effect on his recovery. Tr. I/99-100, 173-75. In fact, subsequent to such surgery, the patient's cerebral pressure was normal and the ICPM device was removed. I.G. Ex. 12/49. There is no indication in the record that either the ventriculostomy performed on August 2, 1985, or the posterior fossa decompression performed on August 9, 1985, had any impact on the patient's neurological status or in any way improved his chances of recovery. It is evident that such surgeries were unnecessary, but considering that the patient was beyond any realistic hope of recovery, I am unable to conclude that Petitioner's use of general anesthesia on these two occasions placed the patient in imminent danger or unnecessarily in a high risk situation. His condition was such that any risk from surgery would have no impact on his outcome. I emphasize here that I am not condoning unnecessary surgery on unsalvageable patients. Section 1156(b)(1)(A) proscribes such a procedure when it occurs in a substantial number of cases without the need to show gross and flagrant conduct. The I.G. has not alleged such a violation in this case.[16]

Petitioner relies on Drs. Hassenbusch and Arico, as well as on Dr. Najum Kazmi, and Dr. Maurice Davidson, who are both neurosurgeons practicing in New Jersey, to support his actions. Dr. Kazmi is supportive of the first procedure because of the absence of clear evidence of the extent of the cerebellar infarct on the CAT scan. I.G. Ex. 6/103. I would agree except that, in this case, the remedy for a lack of complete information is a

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[15] I agree with Dr. Kasoff's opinion that Petitioner was obligated to determine quickly the cause of the patient's deteriorating neurological status and, if necessary, to obtain a repeat CAT scan. I.G. Ex. 6/96, 98.

[16] While such unnecessary surgery does not arise to a violation under section 1156 of the Act in this case, I am able to consider Petitioner's performance of such surgeries in my analysis of his trustworthiness to be a program provider and its impact on the reasonableness of the length of his exclusion.

repeat CAT scan. Delaying the decompression, especially as done here, seven days, is not acceptable, since brain stem compression is acknowledged to lead quickly to the patient's non-salvageability. Similarly, Dr. Hassenbusch's opinion is equally suspect. He bases his opinion of the need for the first surgery on the August 2, 1985, CAT scan results, and the second surgery on the patient's worsening condition and the August 8, 1985 CAT scan showing continuing brain stem pressure. Tr. III/34-37. But such opinion fails to consider that any significant delay in decompressing the brain stem will make recovery unlikely. Neither Dr. Hassenbusch nor Dr. Davidson provide a reasonable basis for Petitioner's delay of the decompression for seven days. Whatever chances the patient had for recovery, meager at best, were eliminated by the delay in performing surgery. Finally, Dr. Arico admits that the ventriculostomy was conservative and the decompression surgery is a recognized procedure to reduce brain stem pressure. P. Ex. 1/2. However, he fails to provide Petitioner with any basis to delay such surgery. In sum, Petitioner's experts do not justify Petitioner's actions in diagnosing and treating this patient in light of the information available to him or which could have been available with more aggressive diagnostic studies. While they have expressed their views that the decompression surgery was necessary to alleviate brain stem compression, an EEG showing minimal function does not support the need for surgery when the patient's brain stem has been compressed for over one week, and his neurological status was severely compromised and beyond any realistic hope of recovery.

Petitioner also presented an affidavit and report written by Dr. Rampal reflecting his opinion that both surgeries performed by Petitioner were necessary. P. Ex. 11. Here, again, Dr. Rampal fails to explain Petitioner's delay in performing the posterior fossa decompression -- the only surgery all experts agree could result in alleviation of brain stem compression. Moreover, Dr. Rampal's belated report, written in 1990, is suspect, due to his personal involvement in this patient's case and to the fact that Petitioner was the subject of a quality review by the hospital where the surgeries were performed.[17] Indirectly, Dr. Rampal's conduct was also placed in question by Petitioner's actions.

The record supports the following conclusions: 1) Petitioner failed to obtain a repeat CAT scan to verify the precise nature of the patient's condition prior to performing the surgery on August 2, 1985; 2) Petitioner's performance of a craniotomy and

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[17] I note that Dr. Rampal was the chairman of the quality review committee that cleared Petitioner of any wrongdoing. He clearly has personal involvement in this matter, and, therefore, his views are given no probative weight. See, Evelyn Reyes at 27.

insertion of ICPM device on August 2, 1985, was unnecessary; and 3) Petitioner's performance of a posterior fossa decompression on August 9, 1985, was also unnecessary. Since Petitioner did not obtain a repeat CAT scan and perform the decompression surgery timely, he placed the patient in imminent danger and unnecessarily in a high risk situation. These failures constitute gross and flagrant violations of Petitioner's obligation under section 1156 of the Act. However, I do not find that subjecting this patient, who had severe brain stem compression and was unsalvageable, to general anesthesia on two occasions placed this patient in imminent danger or unnecessarily in a high risk situation. Therefore, subjecting this patient to general anesthesia is not a gross and flagrant violation of Petitioner's obligation under section 1156 of the Act.

d. Petitioner's treatment of Patient 86-0935 (Case # 4) was a gross and flagrant violation of section 1156 of the Act.

This patient, an 83 year old female, was admitted to Elmer Community Hospital (ECH) on April 11, 1986. The patient had a history of organic brain syndrome, a condition equivalent to Alzheimer's disease. I.G. Ex. 13/4; Tr. I/102. She was admitted because she was unable to stand, had a 102 degree fever, and, according to her son, had become increasingly confused. The cause of the patient's fever was later found be a urinary tract infection. Dr. J. LaCavera was the physician who initially treated and admitted this patient to ECH. This patient had previously been admitted to ECH on two separate occasions. The first occasion, December 22, 1984, through January 3, 1985, she was admitted and treated for a subendocardial myocardial infarction, arteriosclerosis, and Alzheimer's disease. The patient was also admitted to ECH on a second occasion, January 7 through January 9, 1986, during which she was treated for angina pectoris, arteriosclerotic cardiovascular disease, and organic brain syndrome. I.G. Ex. 13/4.

A CAT scan was performed on this patient on April 15, 1986, four days after her admission. The CAT scan revealed a left intracerebral hematoma in the frontal region, with some edema but with no shift in the midline structures. Previous old multiple infarcts were noticed and remarked upon. Petitioner was consulted and became involved with the treatment of this patient on April 16, 1986. I.G. Ex. 13/6. There is no explanation as to why the CAT scan was not done at an earlier point in time, but I am convinced that the delay is not attributable in any way to Petitioner. Tr. I/104; Tr. II/317. On April 17, 1986, Petitioner performed a craniotomy on this patient to remove the intracerebral hematoma. Petitioner also inserted a ventricular drain and an ICPM device, which were removed on April 18, the day after the surgery. The patient was ultimately released from the hospital.

The NJPRO and the I.G. concluded that Petitioner grossly and flagrantly violated his obligations in this particular case, by failing to provide services of a quality that meets professionally recognized standards of health care, in that Petitioner: 1) inserted an ICPM device that was not indicated (NJPRO's conclusion was based on the fact that the device was removed twenty-four hours after the procedure; if consideration was given to the purpose of ICPM, the device would have remained, until maximum edema occurs -- three to five days after the operation); 2) performed a craniotomy with evacuation of a hematoma which is not justified in the record (NJPRO's conclusion was based in part on the nurse's notes of 4/11-4/29; according to NJPRO, the notes document no changes in the patient's mental status before the operation); and 3) subjected this patient to the hazards of general anesthesia and the risk of infection by the performance of the unnecessary cranial procedure. I.G. Exs. 8/4; 9/(sanction report).

Petitioner testified that he was not consulted by the admitting physician until April 16, 1986. On April 16, 1986, Petitioner examined the CAT scan and remarked that the CAT scan showed a high density area with surrounding edema in the left frontal region thought to represent an acute hematoma. He further remarked that the right frontal region also shows a considerable low density, as does the left, probably reflecting a previous infarct. Petitioner noted an infarct over the right convexity. Tr. II/317. Petitioner stated that he reviewed the patient's history prior to operating on her and had noted the patient's level of consciousness had decreased. Tr. II/317; I.G. Ex. 13/10. On April 16, Petitioner examined the patient and noted: "On examination, patient is stuporous at times, awake, not following verbal commands. Tone is equal, symmetrical, except decrease on the right side and right side hemiparesis." Tr. II/318; I.G. Ex. 13/6.

On April 17, 1986, Petitioner operated on the patient. Petitioner used general anesthesia in performing the operation. I.G. Ex. 13/7. Petitioner performed a frontal craniotomy, evacuated the hematoma, and inserted an ICP monitor. I.G. Ex. 13/7,10. Petitioner's stated purpose in performing surgery was to relieve the pressure by removing the clot, which, if successful, would allow the patient to recover her impaired functions. Tr. II/319-20. Petitioner testified that deterioration, along with the weakness exhibited by the patient, was a consideration for performing the surgery. Tr. II/319.

Petitioner removed the ICPM device on April 18, 1986, the day after surgery. Petitioner admitted that he had recorded no pressure values on the patient's chart. Tr. II/379-80. Petitioner testified that, by inserting the ICP monitor, he was not adding any extra insult to the patient because the patient already was having surgery for the hematoma. Tr. II/379-80.

When questioned why he removed the ICPM device on April 18, Petitioner stated: "Because she had improved . . . to a point that her paralyzed side was also moving, which is an improvement. Her mental status was improved. Pressure was normal. All was going along with the same thing that she was doing better. We decided at that point to take it out." Tr. II/320. Petitioner stated that the patient had right hemiparesis before surgery and that this condition was improved after the surgery. Id.

Dr. Kasoff, the neurosurgeon appearing on behalf of the I.G., examined the CAT scan used by Petitioner. He testified that the lack of shift in midline structures is indicative that the hematoma in this patient was of small size and was not posing a significant threat to the brain. He stated that such a hematoma would not pose a significant threat for clinical deterioration, and the lack of midline shift in this patient's brain indicates that if there were increases in intracranial pressure, they would be very small. Tr. I/103. Dr. Kasoff further testified that the CAT scan given to this patient showed multiple old infarcts of the brain, which can produce an picture very much like Alzheimer's disease, as appears in this CAT scan. He further testified that when a mass effect from hematoma occurs in a patient with previous multiple infarcts, that patient may be better able to tolerate those effects, because the previous infarcts have reduced the mass of brain tissue, and this would allow the brain to better accommodate a new mass effect. Tr. I/103.

Dr. Kasoff concluded:

> Based on the CAT scan findings, and based upon the hospital course and the condition of the patient, the appropriate treatment would have been strictly conservative, certainly supporting the patient medically, probably, the institution of decadron, that is a steroid medication that has the capacity of stabilizing a brain edema, and that is probably is the basis of the treatment for this patient.

Tr. I/104.

Dr. Kasoff also concluded that there was no basis for surgical intervention in this case stating:

> A hematoma of this size and under this circumstance, will resolve on its own. I am convinced, without any neurological sequela beyond what has already been in this patient's background, simply with time and the use of steroids, one of which being decadron. I think there are certainly cases of intracerebral hemorrhages that need to be evacuated. Those that are relatively superficial and those that have the potential to cause neurological deterioration.

> This was neither a large enough hemorrhage to consider removing, nor did it cause any neurological deterioration. Furthermore, the date at which the operation was performed was on the seventh hospital day. Presumably, this hemorrhage had already been there for at least a week and was well tolerated by the patient. This patient would have survived this without surgery and done as well as the patient did with the surgery. Without the risks of surgery.

Tr. I/105.

Dr. Kasoff, while acknowledging that Petitioner was not consulted until April 16, stated that performing surgery on the seventh day after this patient was admitted to the hospital was not appropriate:

> When intracerebral hemorrhages of this nature, when they are compelling, or when they require surgery, it is usually acute, and it is much earlier in the course of the process, . . . we would declare itself within the first two or three days. Surgery would be most appropriate either acutely on day one or following neurological deterioration, within the first two or three days. In a patient with a hemorrhage of this nature, it would be highly unusual for such a patient to have survived this hemorrhage for six or seven days, to then develop neurological deterioration. It would be almost unheard of.

Tr. I/106-7.

Dr. Kasoff agreed with Petitioner that this patient had a hematoma, and that assuming the attending physicians correctly concluded there was a deterioration in the patient's neurological condition, surgery was appropriate. Tr. I/181. However, the NJPRO and the I.G. dispute Petitioner's contention that there was any deterioration in the condition of this patient. Petitioner points to the attending physician's notes on April 14, 1986, to support his argument that the patient was deteriorating. The note states "[p]atient is confused, doesn't wish to be examined. Definite change for the worse." During the course of these proceedings, Dr. Kasoff was asked about the notes and responded:

> We know the lady was confused, she has a dementia syndrome that is chronic. I would expect this patient to be confused. The fact that she doesn't want to be examined indicates to me that she has the presence of mind and the physical abilities to push someone away or tell people that she didn't want to be examined.

Tr. I/177.

Dr. Kasoff's conclusion was that the patient's condition was not deteriorating, but that she was merely exhibiting symptoms consistent with her organic mental disorder.

Petitioner states that he was aware of this patient's history of Alzheimer's. Tr. II/375. Petitioner acknowledged that the admitting physician's report showed the patient's reflexes to be equal. Tr. II/376. However, he states that he examined this patient and concluded she was deteriorating. Petitioner's notes on April 16 state that the patient's level of consciousness had decreased and that the son had been informed of all of the risks of the surgery and consented to the surgery for his mother. I.G. Ex. 13/10. Petitioner's notes on the patient's chart, also dated April 16, state that the patient was stuporous at times and was not following verbal commands, and note that her tone is equal except for a slight right side hemiparesis. I.G. Ex. 13/6. He concluded on April 16 that the patient's level of consciousness had decreased and performed surgery the following day. I.G. Ex. 13/10. Petitioner testified that this patient's deterioration and weakness were considerations for performing the surgery. Tr. I/319. He testified further that her condition indicated that the hematoma was causing significant pressure to the brain. Id.

I do not find Petitioner's position on this issue persuasive in light of contradictory evidence. The admitting physician's notes do not support Petitioner's assertion that the patient had deteriorated. Specifically, on April 11, 1986, the day of admission, this patient was unable to answer any questions and was disoriented as to time, place, and date. I.G. Ex. 13/8. On April 12, 1986, the admitting physician describes the patient as "confused and refuses to eat," and notes the patient was lethargic. Id. There is also a mention that he would obtain a CAT scan for the patient. Id. His notes of April 13, 1986, list the patient as "[c]onfused as ever today, but less lethargic." I.G. Ex. 13/9. On April 14, 1986, he indicates that the patient was refusing to eat, was confused, and did not want to be examined. Additionally, he notes a definite change for worse in her personality, and mentions cortical infarct as a possible cause. Id. On April 15, he notes that the patient was confused. On April 16, he notes "confusion same." Id.

While the admitting physician does note a change for the worse in her personality, he does not note any change in either her level of consciousness or her confusion or disorientation. Similarly, the nurse's notes on April 15 indicate that the patient's appetite was good and that she was fed 65 percent of her lunch. I.G. Ex. 13/52. Also, the notes show that the patient's appetite was good and that she ate 70 percent of her breakfast on the morning of April 16. I.G. Ex. 13/53; Tr. II/377-78. The notes also indicate that the patient got out of bed and walked to a chair with assistance. I.G. Ex. 13/53; Tr. II/378. The note for lunch on April 16 says appetite fair, for lunch ate 50 percent,

returned to bed with assistance. Tr. II/378. The nurse's notes of April 16 indicate that, at 7:00 a.m., the patient was aroused by verbal stimuli and was lethargic, confused, and disoriented. I.G. Ex. 13/53. There is nothing in the nurse's notes that indicated this patient was in any way deteriorating. Indeed, that the patient's appetite remained good and that she got out of bed, albeit with assistance, do not support Petitioner's assertion that this patient was deteriorating. Moreover, that the patient was aroused by verbal stimuli on April 16 is a clear indication that she was not stuporous.

I find Dr. Kasoff's testimony regarding this patient particularly persuasive. Dr. Kasoff disagrees with Petitioner's assertion that this patient was deteriorating. Tr. I/182. Dr. Kasoff testified that a combination of two specific findings in this case would support surgical intervention. The first is a compromise in the level of consciousness, and the second is disordered motor function. Tr. III/165. In evaluating the motor function, the factors to look for are hemiplegia or hemiparesis, weakness, and unilateral weakness. In the area of cerebral function, higher cerebral function or level of consciousness, the factors to look for are obtundation and increasing somnolence. Dr. Kasoff discounted Petitioner's conclusion that the patient was confused. He stated that, due to her condition (Alzheimer's), the patient was probably confused most of the time. Tr. III/165. Dr. Kasoff testified that the patient had moments of regular lucidity and other, less lucid, moments. His conclusion was that "perhaps at some time the patient is a bit more oriented than at other times, but I think she fades in and out as her base line. And I don't believe that this lady veered very far from her baseline at any point in her hospitalization." Tr. III/165.

I am not persuaded that this patient's condition was deteriorating in such a way that this surgery was necessary or clinically indicated. There is undisputed testimony, from Petitioner and experts on both sides of this case, that in the instance of a small cerebral hematoma, with no shift in the midline structures, the best approach is a conservative one, that is, to treat it medically using steroids, such as Decadron, and to let the body reabsorb it. Petitioner specifically stated that his decision to operate on this patient was based on her deterioration. However, the record does not support Petitioner's contention that the patient was deteriorating. Petitioner merely makes assertions, unsupported by any tests, data, notes, or specific recollections, that this patient deteriorated. Petitioner noted on the progress records that the patient's level of consciousness had deteriorated and that surgery was discussed with the patient's son. I.G. Ex. 13/10. However, Petitioner's own notations in his consultation report, written the day before surgery, make no mention that the patient had deteriorated or that surgery was a possible option. I.G. Ex. 13/6. Lastly, the

progress note of April 29, written by Petitioner just before the patient's release, indicates that the patient was basically unchanged neurologically and that she still exhibited poor communication. I.G. Ex. 13/16.

Petitioner intervened in this case fully five days after the patient was admitted. I realize the late intervention was not the fault of the Petitioner, as it does not appear that Petitioner was consulted until April 15. However, I find Dr. Kasoff's testimony persuasive that surgery is not indicated in the case of a hematoma that the patient has tolerated well for several days. Even Dr. Hassenbusch, the expert who testified on behalf of Petitioner, stated that the preferred treatment for small hemorrhages, as in this case, is medical management as opposed to surgery. Tr. III/110. Petitioner's expert also agreed with Dr. Kasoff that neurologic decline is not an automatic signal to perform neurosurgical procedure. Tr. III/86. Petitioner's expert conceded that the CAT scan showed no shift in midline structures, and that is consistent with a small hemorrhage. Tr. III/109. Petitioner's expert also conceded that the patient's behavior patterns of confusion and not wanting to be examined is consistent with Alzheimer's disease. Tr. III/117.

In light of this testimony, I do not find that Petitioner's documentation of the patient's condition and supposed deterioration and his rationale for performing surgery on this patient were adequate. I also do not find Dr. Hassenbusch's testimony regarding this patient to be credible, since his assertion that this surgery was appropriate is in direct conflict with his statement that medical treatment is the preferred method of treatment for small hemorrhages, the type present in this case.

NJPRO and the I.G. also contend that Petitioner's insertion of an ICPM device was inappropriate in this instance. Dr. Kasoff testified throughout this hearing that he believed that ICPM was not a medically indicated procedure in stroke patients, because there is not generally an increase in the ICP of these patients. Moreover, in this particular instance, Dr. Hussain admitted removing the ventricular drain the day after surgery. Surgery was performed on April 17 and the ventricular was removed on April 18, one day after surgery. I.G. Exhibit 13/65. No pressure values were recorded in the patient's chart between April 17 and 18. The I.G. argues that this demonstrates a lack of consistency on the part of Petitioner.

Dr. Kasoff testified: "If the pressure monitor were put in to identify any increases in intracranial pressure, it should have then been left in for the period of time where we anticipate possible increases in intracranial pressure following the surgical procedure, which would have been a minimum of three days or so." Tr. I/111.

Dr. Hassenbusch directly contradicted Dr. Kasoff when he testified that the use of the catheter and monitor were within professionally recognized standards of health. Dr. Hassenbusch stated:

> Removal of the catheter one day after the surgery was reasonable. The catheter was placed essentially for immediate postoperative management to rule out any massive swelling on the first day after the operation. With low pressures being found in this catheter, it served I think little benefit in continuing it after that period.

Tr. III/44.

I find that Dr. Kasoff's testimony on this issue persuasive. If, indeed, Petitioner was concerned with ICP in this patient, he should have left the monitor on for the entire time during which he could have reasonably expected such increased pressures. That Petitioner removed the monitor, without waiting the entire three day period, undermines his contention that the insertion of the ICPM device was performed because the patient was at risk from ICP. Also, Petitioner conceded that there were no pressure readings recorded on the patient's chart. I find it unlikely that, if Petitioner had been concerned with ICP in this patient, he would not have recorded the pressure readings himself or directed someone to record them.

I conclude that, in performing a craniotomy and insertion of an ICPM device in this patient, Petitioner violated his obligation under the Act to provide health care in accordance with generally accepted professional standards. This stroke patient, with a small intercerebral hematoma, exhibited no shift in the midline structures of her brain and had been tolerating the stroke for over five days before Petitioner decided to operate on her. Both Petitioner and his expert conceded that the accepted method of treatment of small intercerebral hemorrhages was medical management. Petitioner deviated from that standard, and from generally accepted medical procedure, by performing surgery on this patient, who had a small intercerebral hemorrhage. The craniotomy and insertion of an ICPM device were not medically supportable, given that this patient's condition had not deteriorated.

There is evidence in the record to support that this patient exhibited symptoms similar, if not identical, to Alzheimer's disease. But there is no evidence from which I could reasonably conclude that the patient deteriorated neurologically. Indeed, the nurse's and attending physician's notes seem to indicate specifically that the patient was not deteriorating. Petitioner's notes mention the patient's deterioration in only one place and do not even mention deterioration in the consulting report dated April 16, the day before the patient was taken into

surgery. Further persuasive evidence to support my conclusion was provided when Dr. Kasoff testified that this patient was merely exhibiting her baseline behavior and was not deteriorating.

I also conclude that, as to this patient, Petitioner violated his obligations under the Act by insertion of an ICPM device in this patient and in removing it the day after surgery. Petitioner's insertion of an ICPM device in this case is not in accordance with professionally recognized medical standards. Dr. Kasoff testified that there is generally no indication of increased ICP in stroke patients. Both Dr. Kasoff and Dr. Hassenbusch testified that, based on their review of the CAT scan, there was no shift in the midline structures. This patient exhibited no symptoms of increased ICP, and no indications existed that would warrant the insertion of an ICPM device.

Even if I were to agree with Petitioner's contention that the insertion of an ICPM device was indicated in this case, I cannot agree that its removal on the day after surgery was in compliance with generally accepted medical practice. On this issue, there was conflicting expert testimony from Dr. Hassenbusch and Dr. Kasoff. Dr. Hassenbusch stated that the removal of the catheter and ICPM device one day after surgery was reasonable and appropriate, whereas Dr. Kasoff stated that the removal of the ICPM was medically inappropriate. I am more persuaded by Dr. Kasoff's testimony on this issue. It is logically inconsistent for Petitioner to insert an ICPM device in this patient and then remove it before three days, the period of time the patient was at risk from increased ICP due to swelling.

Neurosurgery is obviously a very complicated and delicate procedure. It should be performed only when clinically indicated. I conclude that, in this case, Petitioner violated professionally recognized standards when he performed surgery on this patient. This patient had a small hematoma, had been tolerating it well for five days with no shift in midline structures, had a greater ability to tolerate mass effect due to a history of previous infarcts, and showed no signs of neurologic or clinical deterioration. I further conclude that, in this case, performing a craniotomy and evacuating a hematoma on this patient violates recognized medical standards and is a gross and flagrant violation of Petitioner's obligation under the Act. In this instance, Petitioner subjected an otherwise healthy patient to the risks associated with surgery, general anesthesia, and infection from surgery that was not clinically indicated. Therefore, Petitioner placed this patient unnecessarily in a high risk situation. I realize that the testimony at the hearing was that there was a serious risk of one percent emanating from such a procedure. However, I hold that even a one percent risk of death or serious injury is unnecessarily high where, as here, the surgery is not clinically indicated, the patient is not

neurologically deteriorating, and the patient is likely to recover absent the surgical intervention.

I further conclude that there was no indication, given the previous infarcts, the lack of shift in the midline, and the small size of the hematoma, for Petitioner to insert an ICPM device. As there was no clinical indication that this patient had increased ICP, it was a violation of Petitioner's obligations under the Act to insert a device to monitor ICP. The removal of the ICPM device in this patient, after only one day, and before any risk of swelling and increased ICP subsided was also a violation of Petitioner's obligations under the Act. As there was no clinical indication for the insertion of an ICPM device or for its removal merely one day after surgery, Petitioner violated his obligation under the Act to provide medical care in accordance with professionally recognized standards. However, in making these findings with regard to the ICPM device, I cannot conclude that the insertion and removal of the ICPM device subjected the patient unnecessarily to a high risk situation. The reason I am not able to reach that conclusion is because the I.G. has not introduced any evidence that the insertion and removal of the ICPM device subjected the patient to additional risk over and above the risks of general anesthesia and infection incurred in the craniotomy and removal of the hematoma. Therefore, while I find that Petitioner, in inserting the ICPM device and removing it after only one day, violated his obligation under the Act to provide medical care in accordance with professionally recognized standards, I cannot conclude that, in inserting and removing the ICPM device, he committed a gross and flagrant violation of his obligation under the Act

e. Petitioner's treatment of Patient 277259 (Case # 5) did not violate section 1156 of the Act as contended by the I.G.

This patient was a 74 year old female who was admitted to Newcomb Medical Center on April 7, 1986, complaining of weakness in her left leg, difficulty walking, and a facial droop on the left side. I.G. Ex. 14/2. Additionally, the patient's daughter reported some changes in the patient's mentation and personality over the preceding two weeks. Id. Dr. Ruggieri, the attending physician, noted that his initial examination revealed a left central facial weakness associated with weakness of the left arm and left leg. Dr. Ruggieri's impression at that time was of stroke in progress with left hemiparesis. Id.

Dr. Skinner, a neurologist, saw the patient as a consultant on the day of her admission, April 7. His impression was that the patient had a frontoparietal lesion, most likely a CVA, with a tumor to be ruled out. Id.; see also I.G. Ex. 14/6. A CAT scan was performed on April 8, 1986, and revealed a tumor in the right frontal lobe, with edema surrounding the tumor, and shift of the

midline structures, and measuring 5 1/2 cm x 4 cm x 4 cm. I.G. Ex. 14/16.

Petitioner was called in for consultation on April 8, 1986. I.G. Ex. 14/7. His consultation report states that the patient was lethargic, not following verbal commands very well, and notes that the patient had vomited. Id. The consultation concludes: "As pt is deteriorating from awake to lethargic in 1-2 hours will be wise to monitor ICP and stabilise and then consider surgery for removal [of] lesion." Id.

Petitioner discussed his recommendation with the patient's family, and noted that the family was indecisive about giving their consent to surgery. I.G. Ex. 14/11. In the morning of April 9, 1986, after further discussion of the risks of delay, Petitioner noted that the patient's husband and daughter decided to proceed with treatment. Id. Later that day, Petitioner performed surgery to insert a ventricular catheter for decompression and monitoring of ICP. I.G. Ex. 14/3, 12, 26. Petitioner's post-operative orders include the medication Decadron, and if ICP readings exceeded 25 mm/Hg, Mannitol. I.G. Ex. 14/20. During the next two days, the patient's ICP ranged from 8 to 20 mm/Hg, with several readings of 15 or above. I.G. Ex. 14/24-6.

Petitioner tentatively scheduled the patient for surgery to remove the tumor on April 11, 1986. I.G. Ex. 14/14, 24. However, the patient's daughter, who was a nurse at St. Luke's Hospital in New York City, contacted a neurosurgeon there, and arranged to have the patient transferred to St. Luke's. I.G. 14/3, 14. The patient was transferred on April 11, 1986.

The I.G. and NJPRO concluded that Petitioner grossly and flagrantly violated his obligation to this patient in the following regard: 1) subjecting this patient with a brain tumor to an inappropriate intracranial operative procedure, i.e., the insertion of an ICPM catheter; and 2) failure to consider removal of the brain tumor rather than the insertion of an ICPM catheter. I.G. Ex.9; FFCL 25.

As an initial matter, I reject the allegation that Petitioner violated his obligation by failing to consider removal of the tumor, because that allegation is completely unsupported in the record. From Petitioner's first consultation, his notes indicate that he considered and, in fact, recommended removal of the tumor. Petitioner had scheduled the patient for surgery to remove the tumor on April 11, and the only reason that appears in the record for his failure to perform the surgery on that date was that the patient's family insisted that the patient be transferred to St. Luke's Hospital in New York to have the

surgery there. Certainly, Petitioner could not have performed the surgery without the family's consent.

I also conclude that the I.G. failed to prove that Petitioner violated his obligation to provide care in accordance with recognized standards of neurosurgery by inserting an ICPM catheter in this patient. In this regard, I am particularly persuaded by the discussion found in the treatise, Advances and Technical Standards in Neurosurgery, an excerpt of which is in evidence as P. Ex. 24. Dr. Kasoff indicated that this reference is considered authoritative. Tr. I/190. According to the author of the cited portion of the treatise, ICPM is used in tumor cases:

> In tumor cases the following routine is usually employed: The recording is started one or two days before a planned operation. Urgency sometimes necessitates the immediate drainage of fluid; otherwise the pressure is recorded for at least two hours to obtain information on the intracranial dynamics. In some patients it may be appropriate to keep the pressure at a low level for some days before operation e.g. in order to relieve the brain stem or optic nerves from stress.

P. Ex. 24/2.

I recognize that this article was written in the mid 1970's. Tr. I/192; I.G. Ex. 6/156. However, the treatment plan contained in the treatise was also endorsed by Dr. Davidson, one of Petitioner's experts, who stated in his written report, dated February 20, 1990:

> [A] very reasonable treatment for meningiomas is to lower the brain pressure for several days first, prior to removing the tumor. In a meningioma, the general thought is that the better the patient is going in, the better the patient is when surgery is finished. Thus, it is well worth a course of steroids for several days prior to removing a large meningioma. This would be enhanced by using an Intracranial Pressure Monitor.

P. Ex. 15.

Dr. Hassenbusch stated that in his practice he does not routinely insert an ICPM device in patients with brain tumors two days before a planned operation to remove the tumor, "except in a situation where there's severe swelling and in those situations, a pressure monitor as well as appropriate anti-swelling measures would be indicated." Tr. III/123. Moreover, the article Intracranial Pressure Monitoring, supra, at 44, cites tumors as among the indications for ICPM. P. Ex. 23/4-5.

Dr. Kasoff testified that he was unaware of any neurosurgeon in the United States who used ICPM before removing a brain tumor, except for research purposes. Tr. I/192. However, the I.G. did not introduce any medical literature or treatises to support the view expressed by Dr. Kasoff, namely that ICPM of patients with brain tumors has been discredited in the neurosurgical community. For this reason, I conclude that the authoritative medical literature introduced by Petitioner, combined with the testimony of two practicing neurosurgeons, demonstrates that ICPM of patients with certain types of brain tumors is within professionally accepted standards of neurosurgery. This conclusion is further reinforced by Petitioner's testimony that the neurosurgeon in New York to whose care the patient was transferred concurred with the plan of treatment.[18] Tr. II/330-331. Of course, this physician's agreement is not a justification for Petitioner's decision to insert the ICPM device. However, it does indicate that another practicing neurosurgeon at a large urban medical center apparently considered ICPM to be within professionally recognized standards of neurosurgical treatment for a patient with this type of brain tumor.

Petitioner based his decision to insert the ICPM device on his assessment that the patient was deteriorating in her level of consciousness and that she had vomiting and had increasing left hemiparesis. I.G. 14/11. In his view, these symptoms, when combined with the CAT scan showing a large tumor with massive edema, or swelling, indicated that increased ICP was a likely cause of the patient's symptoms. Id. This assessment would accord with Dr. Hassenbusch's view that ICPM would be appropriate in cases of severe swelling. I note that Petitioner did order anti-swelling medications for the patient. I.G. Ex. 14/19, 20.

The nurse's notes do not appear to document a clear deterioration of the patient's level of consciousness prior to the insertion of the ICPM device. For example, a nursing note on the evening of April 8 indicates that the patient had a Glasgow Coma Scale score of 15, which indicates a patient who is fully conscious and aware of her surroundings. I.G. Ex. 14/27; see Tr. I/112-113; Tr. II/382-83; Tr. III/119-20. However, the nursing notes do indicate "severe" left side weakness on April 8, which suggests a deterioration from the admission note which describes "some" left sided weakness. I.G. Ex. 14/28. The notes also confirm an episode of vomiting, which Dr. Hassenbusch testified is an important clinical sign for markedly increasing ICP. I.G. Ex.

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[18] I note that no record of Petitioner's conversation with the neurosurgeon at St. Luke's appears in the hospital records for this patient. This is another example of Petitioner's inadequate documentation, an occurrence which I observed throughout the hospital records.

14/27; see Tr. III/50. Finally, the nursing notes after insertion of the ICPM device reflect several readings above 15 mm/Hg, which would indicate increased ICP.

The nursing notes also repeatedly refer to a "neuro check sheet" for a detailed description of the patient's neurological condition. See, e.g., I.G. Ex. 14/26, 27. These "neuro check sheets" were not part of the exhibit introduced by the I.G., however. Dr. Hassenbusch testified that these sheets would be "critical" to a full understanding of the patient's condition. Tr. III/131.

As is true of most of the hospital records in this case, the documents which are in evidence do not appear to be complete. Moreover, as I have noted, the documentation by Petitioner which is present is often inadequate. Nevertheless, I conclude that the records before me as to this patient sufficiently support Petitioner's identification of clinical signs of increased ICP to demonstrate that he did not violate his obligations to provide care that met professionally recognized standards of neurosurgery. Accordingly, there is no issue of gross and flagrant conduct regarding this patient.

f. Petitioner's treatment of Patient 8617854M (Case # 6) did not violate section 1156 of the Act as contended by the I.G.

This patient, a 70 year old male, with a diagnosis of a CVA involving the right hemisphere with left sided manifestations and arteriosclerotic cardiovascular disease, was admitted to Millville Hospital on June 21, 1986, by Dr. Dominic A. Diorio, the attending physician, following weakness and paralysis of the left upper and lower extremity. I.G. Ex. 15/3-4, 15. Other than the left sided involvement and lethargy, the patient was noted in no acute distress and responsive. I.G. Ex. 15/3, 15. In order to evaluate the severity and extent of the CVA, a CAT scan and EEG were ordered that day. I.G. Ex. 15/6. As of June 23, 1986, he improved somewhat but his paralysis remained the same. I.G. Ex. 15/15. The CAT scan was performed on June 23, 1986, and showed a "large acute infarction in the right parietal and temporal lobes . . . with a shift of the lateral ventricles towards the left." I.G. Ex. 15/15, 33. The EEG performed the same day showed an abnormal disturbance of the right hemisphere. I.G. Ex. 15/29. On June 24, 1986, he developed respiratory complications and was transferred to ICU where he was intubated. I.G. Ex. 15/15, 25. That day Dr. Dirk E. Skinner completed a neurological consultation. I.G. Ex. 15/21. He recommended, among other things, supportive care. Id. By June 26, 1986, Dr. Skinner noted that the patient had increased "stupor." I.G. Ex. 15/16. The patient's respiratory situation became acute on June 27, 1986, and Dr. Diorio noted the need for a neurosurgical consultation for measurement of ICP. I.G. Ex. 15/16, 23.

Petitioner examined the patient on that day and found him comatose and decerebrate to pain. I.G. Exs. 6/163, 15/22. His impression was brain edema with closed right ventricle, mass effect, and increased intracranial pressure. I.G. Exs. 6/164, 15/22. He recommended ventriculostomy and ICPM. Id. Prior to surgery, an anesthesiology note reflects that there was uncertainty whether a general anesthetic or local would be used with intravenous (IV) sedation. I.G. Ex. 15/17.[19] Petitioner performed a right frontal craniotomy and ventriculostomy to drain fluid and to monitor ICP.[20] I.G. Ex. 15/17-18, 28. Petitioner noted that the patient's brain was "edematous with increased pressure." I.G. Ex. 15/28.

There is a suggestion in the expiration summary prepared by Dr. Diorio that at the time of surgery the patient "had begun to herniate his brain stem and lost all signs of cerebral activity" from an intravascular hemorrhage. I.G. Ex. 15/26. However, as indicated above, other medical records prepared before or on the day of surgery do not support such brain devastation.

On the day after the surgery, the patient, upon examination, showed the absence of brain function. I.G. Ex. 15/18. This was confirmed by EEG on June 30 and July 1, 1986. I.G. Ex. 15/19-20, 30-31. After consultation with the Ethics Committee, the patient was removed from life support systems on July 1, 1986, and died. I.G. Ex. 15/20, 24-25.

At a hearing before the NJPRO, Petitioner explained his rationale for performing surgery as follows: "basically [due to the] massive brain swelling with edema, rapid deterioration . . . [I] suggested [that] monitoring of the pressure [might] improve the [patient's] status." I.G. Ex. 6/164. He also indicated because the patient was comatose at the time of surgery, no general anesthesia was used and the only thing the patient required was oxygen. I.G. Ex. 6/166.

The NJPRO and the I.G. assert that Petitioner grossly and flagrantly violated his quality of care obligation toward this patient by subjecting him, when he was experiencing an acute CVA, to an unnecessary operative procedure, i.e., ICPM catheter insertion. I.G. Ex. 9/3.

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[19] It also apparent from this note that the anesthesiologist was uncertain as to the type of procedure -- craniectomy or craniotomy, Petitioner was to perform.

[20] In the operative report, Petitioner refers to a craniectomy, but the procedure that he performed reflects he opened the small flap of skull, which would be indicative of a craniectomy. Also, other physicians who referred to this surgery indicated it was a craniectomy. See, I.G. Ex. 15/24-25.

Dr. Kasoff, as stated in other cases, opined that ICPM was unnecessary in this case. Tr. I/123-124, 126; I/169-170, 180. He based his opinion on the fact that, when Petitioner inserted the ICPM device, the possibility for ICP was remote, since ICP would rise within the first three days of the stroke, and by the seventh day there would be little or no risk of increased pressure. Tr. I/124. The absence of the recording of abnormal ICP values subsequent to the surgery confirmed his opinion. Tr. I/124-125. Moreover, Dr. Kasoff asserted that, to the extent that such pressure should be monitored, it should be done under local anesthesia to avoid the risks associated with general anesthesia. Tr. II/123. Again, he offered his opinion that general anesthesia places stroke victims at risk and, in the case of Patient 8617854M, it could convert this patient's stable, bland infarct to a hemorrhage infarct, having more mass effect and pressure than the original stroke. Tr. I/123. In contrast to Petitioner's surgical intervention, Dr. Kasoff indicated his suggestive course would have been limited to only supportive care. Tr. I/125. Lastly, Dr Kasoff was insistent that even evidence of neurological deterioration does not justify surgical intervention. Tr. I/200-201.

This patient suffered a large infarct in the right parietal and temporal lobes causing a mass effect which shifted the midline portion of the brain to the left. I.G. Ex. 15/33. Conservative treatment measures were initiated but they did not impact on his condition, and he continued to slowly deteriorate neurologically, with increased somnolence, difficulty with respiration, and eventually became comatose and decerebrate to pain. I.G. Ex. 15/8, 15, 16. It was at this point, approximately one week after the patient suffered the infarct that Petitioner was consulted. I.G. Exs. 6/163, 15/18, 22.

It is evident that the patient was severely compromised and very close to brain death at the time Petitioner chose to intervene surgically. Even Petitioner conceded that his surgical procedures, at best, increased the patient's chances of survival by only 5 percent to 10 percent. Tr. II/346. Dr. Kasoff, without seeing the actual CAT scan film, could not predict that the patient would die from the stroke. Tr. I/125-126. However, he did indicate that any attempt to reduce ICP from the infarct should be within the first few days after its occurrence. Tr. I/124. As in other cases, Dr. Kasoff's opinion seems focused on Petitioner's use of an ICPM device and does not give adequate credence to the possible ameliorating effect that the ventriculostomy may have had in reducing the damaging impact of the stroke. While he may not favor use of ICPM in his practice, its use has been accepted by at least a significant minority of neurosurgeons and advocated as a treatment option in many of the most prestigious teaching hospitals. Tr. III/47-48. Moreover, the monitoring was a secondary procedure done for the purpose of determining whether the draining of ventricular fluid would lead

to reduced ICP. Credible evidence from Petitioner's experts, Drs. Arico, Davidson, and Hassenbusch, demonstrated that the surgical procedures presented the patient's only hope for survival. P. Exs. 1/3, 16/2; Tr. III/59-61.

While this is a close case, especially considering the expiration summary of Dr. Diorio, I find performance of the ventriculostomy and ICPM was arguably reasonable as a last resort for a patient who had no other possibility of recovery. Unlike the earlier case of Patient 854914, there is no suggestion that another operative procedure was indicated. Nor is there any suggestion that Petitioner failed to obtain clarifying diagnostic tests or inappropriately delayed a needed surgical procedure. Here the I.G. and NJPRO rely on their argument that ICPM is unnecessary in stroke cases. As I have previously found, use of the ventricular catheter for monitoring after a ventriculostomy is not per se a violation of Petitioner's obligations under section 1156 of the Act. See, supra at 47.

Moreover, even assuming I agreed with Dr. Kasoff that use of these surgical procedures in this case was violative of Petitioner's obligation, there is no evidence that performance of such procedures in this patient's case was "gross or flagrant." The I.G. has not established that the patient was placed in "imminent danger" or under "unnecessarily high risk." First, the I.G. has failed to prove that a potentially harmful anesthetic agent was employed when the patient was prepared for surgery. Petitioner stated none were used. I.G. Ex. 6/166. This is understandable, considering that the patient was comatose and in need of no agent to put him to sleep or to prevent him from feeling pain. Therefore, absent such an agent, the damaging consequences suggested by Dr. Kasoff, such as complications from further hemorrhaging or swelling of the brain, would not occur. Second, even assuming such consequences, they increase morbidity by only one percent. Such a percentage is meaningless in this case. Here the patient was close to death, with, at best, a five to ten percent chance of recovery, and the surgical procedures were a last desperate act to save him. I do not find, in such circumstances, that employing surgical procedures that imposed a one percent risk was a gross and flagrant violation of Petitioner's obligation under section 1156.

g. Petitioner's treatment of Patient 632365 (Case # 7) was a gross and flagrant violation of section 1156 of the Act.

This patient was an 84 year old woman who was transported to the ER of the Millville Hospital on August 5, 1989, after being found on the floor and unresponsive in her home. It was reported by her daughter that the prior day the patient felt lightheaded, with generalized weakness, and complained of a cold and headache. A physical examination was uneventful except for a slight right facial asymmetry and a diminution of the withdrawal of the right arm to pain as compared to her left arm. Petitioner, who was the attending physician, made an admitting diagnosis of left CVA, rule out intracranial hemorrhage. I.G. Ex. 16/4-5.

A number of diagnostic procedures were performed on the patient in the ER to assist in assessing her medical problems. A portable x-ray of the patient's chest showed the patient's heart as enlarged and pulmonary venous congestion present.[21] The radiologist's impression was congestive heart failure (CHF).[22] I.G. Ex. 16/28. An electrocardiogram (EKG) was interpreted as negative. I.G. Ex. 16/33-34; Tr. II/352.

Several blood chemistry profiles were also performed. The results relevant to this case are as follows: her serum sodium level was 122 milliequivalents per liter, which is below the normal range of approximately 136-146 milliequivalents per liter; her creatine phosphokinase (CPK) levels were reported as 525 and 61 and her MB isoenzyme (MB) levels were reported as 20 and 0, (normal level for CPK is approximately 60-270 units per liter (U/L) and for MB is below 15 U/L). I.G. Exs. 16/57-58, 19/10. The serum sodium levels were tested again on August 9 and August 24, 1989, which indicated these respective results: 127 milliequivalents per liter and 117 milliequivalents per liter. I.G. Ex. 16/57.

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[21] The radiologist's report of the examination erroneously indicates the date as August 4, 1989. I.G. Ex. 16/28. However, a subsequent examination refers to the original examination as being done on August 5, 1989. I.G. Ex. 16/31.

[22] CHF is a clinical syndrome in which the heart fails to pump blood normally, resulting in congestion in the pulmonary and/or systemic circulation and diminished blood flow to the tissues because of reduced cardiac output. Due to this condition's severity, the cause of CHF should be determined, correctable conditions searched for, and contributing factors eliminated. The Merck Manual, 413-428 (14th ed. 1982); accord, Dorland's Illustrated Medical Dictionary, 237 (27th ed. 1988).

The MB level is significant in assessing cardiac function. Whenever that level is reported to be approximately four percent of the total CPK level or greater, there is an expectation of cardiac damage. A decreased serum sodium level can be reflective of an increase in the patient's total body water, which can be a complication if the patient suffers from CHF. The increased body water content can alter the patient's mental status and give an erroneous reflection of neurological deterioration. I.G. Ex. 19/10-11.

The patient was placed in intensive care initially, but then was transferred to neurological service. I.G. Ex. 7/14. By August 7, 1985, Petitioner noted that the patient was more "awake" and "verbalizing." I.G. Ex. 16/17. A CAT scan done that day showed a normal head without evidence of intracerebral hematoma. I.G. 16/37. This test result placed in question Petitioner's admitting diagnosis of left CVA and intracranial hemorrhage. For the next several days, Petitioner noted that the patient was weak, shaky, and dizzy. I.G. Ex. 16/17. An x-ray of the patient's cervical spine revealed marked degenerative changes with encroachment on the neural foramina. I.G. Ex. 16/29. Apparently, based on this examination finding and the patient's complaints of neck pain, Petitioner began her on a course of physical therapy on or about August 14, 1989. I.G. Ex. 7/15, 16/19. Petitioner noted no neurological deficits as of August 15, 1989. I.G. Ex. 16/19. A repeat cervical x-ray on August 16, 1989, confirmed the existence of degenerative joint disease of the cervical spine. I.G. Ex. 16/30. Petitioner's notes for the period of August 16-23, 1989, indicate that the patient's symptoms of pain and weakness continued, but she appeared at times confused. I.G. Ex. 16/20-22. On August 23, 1989, Petitioner recommended that she undergo a myelogram to rule out compression of the spinal cord. I.G. Ex. 16/22. Suddenly on August 24, 1989, the patient suffered a cardiopulmonary arrest, went into an irreversible coma, was transferred to intensive care, and died on August 30, 1989. I.G. Exs. 7/16-17, 16/22-26.

The I.G. and the NJPRO argue that Petitioner grossly and flagrantly violated his quality of care obligation toward this patient by: 1) failing to follow-up the abnormal CPK and MB fractions to rule out a myocardial infarction; 2) failing to address and treat the patient's low serum level with more frequent laboratory studies to determine if improvement in the overall serum sodium was occurring; and 3) failing to appreciate the patient's overall cardiac and electrolyte abnormalities by treating personally or by obtaining a cardiac or internal medicine consultation. I.G. Exs. 8/3, 9/3.

Dr. Joseph C. Spagnuolo, the Associate Medical Director of the NJPRO and board certified in internal medicine, gave the following rationale for the NJPRO's findings of gross and flagrant conduct by Petitioner. Petitioner's admitting diagnosis

of cerebral stroke was not borne out by a subsequent CAT scan which showed no evidence of an intracerebral hematoma. Petitioner was placed on notice of the patient's potential serious cardiac problems, based on the chest x-ray evidence of CHF and the abnormal/conflicting blood chemistry results. Dr. Spagnuolo noted the below normal serum sodium levels[23] and indicated that they were unrelated to an intracerebral hemorrhage. More importantly, a decreased sodium level is oftentimes a manifestation of an increase in the patient's total body water content. Such an increase can place a great strain on the patient's heart, especially when CHF is compromising the patient's heart. Moreover, an effect of decreased sodium levels can be an alteration of the patient's mental state which may resemble neurological deterioration. There are measures that can be taken to reduce the patient's water content, but since there may be several causes for this condition, the problem should be isolated by having the patient undergo diagnostic tests. The normal practice is to repeat the test for serum sodium levels at least every 24 hours until the level is within normal limits. In this case, Petitioner did not order additional tests nor attempt to treat this medical problem. When presented with conflicting CPK and MB levels, Dr. Spagnuolo indicated the proper standard of medical practice would be to measure promptly these levels again to confirm or deny any cardiac disease.[24] Petitioner was faulted for failing to recognize this clinical sign and consult with an internist or cardiologist to address the patient's cardiac status. In sum, Dr. Spagnuolo indicated that the NJPRO determined that Petitioner had grossly and flagrantly violated his obligation to adhere to acceptable standards of medical practice by: 1) failing to consider the patient's abnormal chest x-ray, serum sodium, and CPK levels; and 2) failing to treat these metabolic and cardiorespiratory problems. I.G. Ex. 19/9-11.

In explaining his treatment of this patient, Petitioner stated that the patient presented with an "acute cerebral vascular stroke" and had "no cardiac symptoms." I.G. Ex. 7/18. Since her initial EKG was normal, Petitioner claimed he "kept on thinking o[f] the neurological aspect. Never thought about the cardiac

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[23] Low serum sodium levels is known as hyponatremia and occurs when the kidney retains water and dilutes the serum sodium.

[24] Dr. Spagnuolo explained the significance of these fractions. CPK is an enzyme present in skeletal and cardiac muscle as well as in the brain. Whenever there is some injury to a muscle, CPK level will rise. Also, whenever the MB isoenzyme is reported to be approximate four percent of the total CPK level or greater, this signals the existence of cardiac damage. I.G. Ex. 19/9-11.

part of it." I.G. Ex. 7/18. He indicated that there were no "symptoms suggestive of cardiac problem[s]," but he speculated that possibly an internal or cardiac consult would have impacted on his assessment. I.G. Ex. 7/19.

With regard to the patient's CPK and MB levels, Petitioner indicated that they were reported as normal levels. I.G. Ex. 7/18. He asserted that he could not recall when the abnormal test results came or whether he saw them, but that if he had been aware of them, he would "repeat it or if I had a concern, I would ask some of the internists to look at it and maybe manage the patient." Tr.II/353, 387-89; I.G. Ex. 7/25, 29.

Regarding the patient's serum sodium levels, Petitioner indicated that, after the initial recording of 122, the patient was started on "I.V. fluids" and when she was showing a level of 127, five days later, her "neurological status was completely intact," and while he recognized that her serum sodium level was "relatively low" he did not consider it as requiring "acute correction." I.G. Ex. 7/17. He further admitted that when she went into cardiac arrest on August 24, 1989, her serum sodium level fell to 117, but at this point she "had no brain stem function" and was "brain dead." I.G. Ex. 7/17. He acknowledged that no effort was made to correct the serum sodium level at this point, due to the irreversibility of her clinical condition. I.G. Ex. 7/17.

Petitioner was questioned by the NJPRO physicians concerning his failure to follow-up on the serum sodium level of 127 that was done on August 9, 1989. While acknowledging that this was a "low" level, and that a repeat test could have been done, Petitioner blamed his lack of follow-up action on the patient's absence of symptoms. I.G. Ex. 7/24. He did admit that, considering the patient's serum sodium level, he "should have done [a repeat test] sooner [than he did on August 24, 1989]." I.G. Ex. 7/24. In response to the question whether Petitioner, knowing the patient has low serum sodium, he would treat the patient himself, Petitioner acknowledged that "[s]ometimes [he does it him]self, but if [he] suspect[s] that there's some other medical problem, [he] always get[s] the internist or cardiologist, depending on what problem it is to co-manage the patient." I.G. Ex. 7/28.

Petitioner was also questioned regarding the chest x-ray of August 5, 1989, where the radiologist reported a finding of CHF and the absence of any follow-up treatment for that condition. He claimed that the radiologist reported to him orally that the x-ray failed to show "anything acute in the chest." I.G. Ex. 7/26. However, Petitioner did acknowledge that, several days later, he received a written report which indicated that the patient had CHF. I.G. Ex. 7/26. When asked why he did not review the x-ray film again or speak with the radiologist, Petitioner could not provide an explanation other than admitting

that he "should have gone for another chest x-ray and clear[ed] up that point once and for all." I.G. Ex. 7/27, 35. Petitioner explained his not documenting in the patient's record the findings from the physical examinations regarding her cardiac condition by stating that he only notes "positive finding[s]." I.G. Ex. 7/35. It is evident that existing medical documentation in the patient's record indicative of a serious cardiac condition was not recognized by Petitioner since he admitted that if he "had at any time, any concern about it, [he] would have got a cardiologist or internist" to assist him in addressing the condition. I.G. Ex. 7/53.

To rebut the NJPRO findings concerning the abnormal/conflicting CPK and MB blood chemistry results, Petitioner relies on Dr. Hassenbusch, a neurosurgeon, for the proposition that the first abnormal test on August 5, 1989, triggered a more definitive study by electrophoresis which proved to be negative, and this second test resolved any conflict. Tr. II/67-68; P. Br. 67. The I.G. argues that such opinion is at best hypothetical and apparently not shared by the two board certified internal medicine physicians, one of whom is a hematologist, who reviewed this patient for the NJPRO and reached no such conclusion. I.G. Br. 47-48. However, the lab reports themselves tend to support Petitioner's contention. The lab result listing the abnormal CPK and MB readings states on its face that it was not performed by the electrophoresis method and, thus, may be less reliable. I.G. Ex. 16/57. The lab report which shows normal CPK and MB readings states on its face that it was obtained using the electrophoresis method. I.G. Ex. 16/56. The report which shows normal CPK and MB readings also states that it was read by a pathologist, who interpreted it as normal. Id. Thus, it would be reasonable for Petitioner to place greater weight on the test result that was done by electrophoresis and read by a pathologist. Petitioner also relies on the normal EKG test done in the ER as a basis for not pursuing the conflicting test results. P. Br. 68.

However, the normal EKG and the arguably normal CPK result are not sufficient justification for Petitioner's failure to order further diagnostic studies to clarify the patient's cardiac status. The x-ray showing CHF and abnormal serum sodium levels were sufficient indicators, by themselves, of possible cardiac problems to justify further diagnostic procedures. Petitioner concedes that he should have repeated the chest x-ray. Even if Petitioner believed that the initial CPK test was normal, further CPK results may have been helpful in evaluating the patient's condition. Again, when confronted by NJPRO, Petitioner agreed that he should have repeated these tests as well.

With regard to the low serum sodium levels, Petitioner offers no acceptable explanation other than he did not believe that the patient showed signs of any cardiac problems and therefore did not give these abnormal test results much significance. This

rationale is equally weak. Even accepting Petitioner's assertion that the radiologist orally told him the patient's chest x-ray was normal, the written report showing CHF should have alerted him to the need for further diagnostic tests, including more timely and repeated serum sodium evaluations. His assertion that the values were improving and in the low normal range is inconsistent with the assessment of the NJPRO physicians and the recognized normal values for such blood chemistry fractions. I.G. Exs. 5/6-7; 7/18, 24; 16/57, 58; 19/9-11.

In assessing Petitioner's care and treatment of this patient, I note that he was the admitting and attending physician. I.G. Ex. 16/4, 5. In such a role, Petitioner was in sole charge of the management of the patient while she was in the hospital. Whatever her medical problems, whether within Petitioner's specialty or not, they were subject to his diagnosis and treatment. Unlike the usual situation where Petitioner is called in as a consultant, and his role is limited to neurosurgery, here, he was responsible for the care of the patient for all medical problems. Therefore, his obligation to meet the recognized standards of medical care goes beyond the care and treatment of neurosurgical problems. The NJPRO and the I.G. can properly assess him under such standards.

The record of Petitioner's treatment of this patient is that he initially treated her for a stroke, which assessment was subsequently proven incorrect by a CAT scan showing no intracranial hemorrhage. I.G. Ex. 16/37. At the approximate time of admission or shortly thereafter, Petitioner was advised that this patient's chest x-ray showed CHF and her blood chemistry indicated abnormal serum sodium, CPK, and MB levels. I.G. Exs. 16/28, 57, 58; 19/10. In such circumstances, standard medical protocol calls for diagnostic studies to evaluate the cause and severity of the CHF, as well as repeat blood chemistry to confirm or deny cardiac damage. I.G. Ex. 19/9-11.

Here, Petitioner failed to recognize the significance of the findings from the chest x-ray and the blood tests. Such findings warranted further action by Petitioner, even though the patient had a negative EKG. He ordered no repeat x-ray to assess the patient's CHF. I.G. Ex. 7/27, 35. Nor did he perform or order repeat blood chemistry tests to obtain comparative CPK and MB results. He delayed obtaining repeat serum sodium levels and did not follow the customary practice of repeating the tests on a daily basis until normal values were shown. I.G. Exs. 7/24; 19/10. Despite the presence of signs of a compromised cardiac system, Petitioner made no effort to evaluate and treat this condition, limiting his treatment exclusively to the patient's neurological complaints. I.G. Ex. 7/18, 19, 53. In fact, it is possible that some of the patient's neurological complaints, such as confusion, were the product of her untreated low serum sodium level. I.G. Ex. 19/11. His suggestion that he was attentive and

saw the patient regularly is of no merit since he failed to ascertain in such visits the potential seriousness of the patient's cardiac condition. See P. Br. 67-68. If anything, it reaffirms his lack of understanding of cardiac problems, their diagnosis and treatment.

His explanation for failing to treat this patient's cardiac signs was that she had no apparent overt cardiac symptoms when he examined her.[25] But such an explanation is inadequate and demonstrates Petitioner's lack of knowledge and understanding of the significance of abnormal blood chemistry results and their relationship to possible cardiac disease. Particularly with regard to this patient, such lack of understanding and recognition of abnormal blood chemistry symptoms, combined with a x-ray finding of CHF, makes Petitioner's failure to assess and treat these cardiac signs especially egregious.[26] At the very least, Petitioner should have realized that they warranted obtaining a cardiac or internal medicine consultation. He was responsible for the patient's care and treatment and should have been aware that her possible cardiac problems were beyond his area of expertise. It is customary in such circumstances for physicians to consult other specialists who regularly treat such conditions. Petitioner did not do so in this case.

Cardiac disease can be life threatening. Failure to diagnose, assess, and treat signs of such a condition, such as congestive heart failure and abnormal blood chemistry studies, have an obvious implication on the patient's health and welfare. Here, Petitioner did not follow customary medical practice in repeating blood tests which showed potential cardiac electrolytic abnormalities. Nor did Petitioner follow accepted medical practice when he failed to repeat the chest x-ray. This is true, despite Petitioner's explanation that the written report was

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[25] Petitioner's admission that he only records "positive findings" in his examinations is troubling. Such an incomplete recording of his findings are likely to create problems in patient care, since other physicians who may be consulted will not have a full and accurate understanding of the patient's clinical condition. The absence of such historical data may compromise the future treatment of the patient.

[26] The I.G. argues that Petitioner's conduct concerning the care and treatment of this patient "led to the patient's death." I.G. R. Br. 28. While the record shows that his actions did not comport with proper standards of medical care and placed her in imminent danger or unnecessarily high risk, there is no proof that the patient's cardiac arrest and death occurred as a result of treatment failures by Petitioner. Nor do I need to make such a finding to conclude that his conduct was violative of section 1156 of the Act.

inconsistent with the radiologist's oral assessment, showing CHF. Petitioner obviously did not possess the necessary skill or acumen to realize the importance of these adverse cardiac findings and their relationship to the potential of severe cardiac compromise. Not only did Petitioner not know enough to begin assessment of the patient's cardiac status, and treatment if necessary, he failed to recognize that a medical consultation was needed. Such failures clearly placed this patient in imminent danger and placed her in an unnecessary high-risk situation. Consequently, Petitioner's conduct was a gross and flagrant violation of his obligation under section 1156 of the Act.

3. The I.G. has demonstrated that Petitioner is unable substantially to comply with his obligations under section 1156 of the Act.

Section 1156 authorizes an exclusion where the Secretary, or his lawful delegate, the I.G., agrees with the PRO's findings that Petitioner has violated his obligation under the Act and determines that Petitioner has demonstrated an unwillingness or a lack of ability substantially to comply with such obligation. Section 1156(b)(1) of the Act.[27] The I.G. does not contend, nor is there any evidence, that Petitioner is unwilling to comply with his obligation under the Act to provide medical care in accordance with professionally recognized standards. Indeed, from the outset of the NJPRO proceeding and throughout this hearing, Petitioner has indicated a willingness to comply with his obligations. See Tr. II/359-362.

It is the I.G.'s contention that Petitioner has demonstrated an inability to comply with his obligations. I.G. Br. 49. The I.G.

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[27] The I.G. correctly points out that this section of the Act was amended in 1990 to clarify that the period of time in which to evaluate Petitioner's willingness or inability to substantially comply with his obligation under section 1156 is the time period prior to the PRO's submission of its report and recommendations to the I.G. I.G. R. Br. 11-12. See Pub. L. No. 101-508, § 4205, 104 Stat. 1388, 1388-112 to 113. The I.G. further points out that this amendment to the Act occurred after Petitioner was excluded from the programs. Id. The I.G. does not suggest that this amendment be applied retroactively. For this reason, I have considered evidence as to Petitioner's willingness and ability to comply with his obligation both prior to the NJPRO proceedings and afterward. However, I note that application of the amended standard would not alter my conclusions on this issue, since Petitioner's position before the NJPRO and at the hearing were consistent. Also, there is no indication that Petitioner took any corrective action after the NJPRO issued its report and recommendations.

cites the seven cases as evidence of a "consistent pattern of gross and flagrant violations." I.G. Br. 50. The I.G. contends that Petitioner's consistent use of ICPM, despite its lack of usefulness in the treatment of patients, indicates his inability to comply with his statutory obligations. I.G. Br. 53. The I.G. asserts that, with regard to Patient 63235 (Case # 7), Petitioner's failure to correctly diagnose, treat, and consult, also reflects Petitioner's inability to comply with his obligations. According to the I.G., Petitioner's consistent failure to comply with accepted standards of neurosurgery and medicine is strong evidence of Petitioner's inability to comply with his obligations.

Petitioner contends that he is both willing and able to comply with his obligations. To support his claim, Petitioner offered letters into evidence from eight neurosurgeons who attest to his ability. Petitioner states that he has modified his practice concerning ICPM; he now confers with another neurosurgeon when a question arises, and he is more careful in documentation. P. Br. 72. Petitioner also points to the testimony of Dr. Hassenbusch as evidence of his ability to comply with professionally recognized standards as a neurosurgeon. P. Br. 73.

I conclude that, while Petitioner has demonstrated a general willingness, he has also demonstrated an inability to comply with his obligations under the Act.[28] Petitioner's inability to comply with his obligation is established by his pattern of gross and flagrant violations, along with his pattern of errors in judgment and lack of documentation. Evidence of these deficiencies is shown in the three cases where I found Petitioner engaged in gross and flagrant violations of his obligation to follow professionally recognized standards of neurosurgery and medicine as required by section 1156 of the Act.

In the case of Patient 854914 (Case # 3), Petitioner failed to timely perform a posterior fossa decompression. Petitioner also did not correctly diagnose the patient's condition, despite the fact that the CAT scans of July 30, 1985, and August 1, 1985, were indicative of a cerebellar infarct. Instead of proceeding with the medically indicated post fossa decompression at that point, Petitioner demonstrated a lack of understanding of fundamental neurological concepts when he operated on this patient for hydrocephalus, instead of cerebellar infarct. Petitioner should have recognized that this patient's brain stem

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[28] Petitioner has expressed his willingness to comply with his obligation under section 1156, but as yet he has not demonstrated that he has taken corrective actions to cure the deficiencies noted in his obligations under the Act. This may be due more to his failure to recognize his deficiencies than to an unwillingness to correct them.

was compromised and that there was a need for an immediate post fossa decompression. The fact that Petitioner failed promptly to perform a post fossa decompression after having sufficient information that the patient had a cerebellar infarct, evidences a lack of understanding of basic neurological principles. It also evidences a lack of the skills of diagnosis and analysis that are so critical in the field of neurosurgery. By waiting seven days to perform this critical operative procedure, Petitioner ignored his own, but belated, assessment that a decompression was necessary three days earlier and essentially eliminated any slim hope that this patient had for recovery. The I.G.'s contention that Petitioner is unable to comply with his obligations is well supported in this instance. The treatment of Patient 854914 demonstrates that Petitioner lacks critical skills needed for analyzing a patient's condition and determining the medically proper course of action. His willingness to correct his actions is insufficient where Petitioner is lacking in some of the basic skills that are needed to perform neurosurgery in accordance with medically recognized standards.

In the case of Patient 860935 (Case # 4), Petitioner performed a surgical craniotomy and evacuation of a hematoma when these procedures were not medically indicated. Petitioner admitted that the treatment of this type of hematoma was usually medical, but attempted to support his decision to perform surgery on the basis that the patient was deteriorating. However, the evidence in the record does not support Petitioner's contention. In this case, although Petitioner espoused that he was aware of the standard treatment for this type of condition and when it was indicated, his application of that knowledge was shown to be lacking. Petitioner did not take into account that this patient had endured previous infarcts, which reflects an ability of the patient to tolerate better a hematoma with conservative treatment only. Petitioner overlooked that there was no shift in midline structures. Petitioner did not seem to have a proper concept as to what constitutes neurologic deterioration, as he often confuses "stuporous" -- a classic sign of neurologic deterioration -- with "confused." Petitioner improperly failed to consider that the patient had been tolerating the stroke for seven days and had a chronic neurological condition, Alzheimer's, which would affect her mental status independent of the stroke. In this instance, Petitioner's inability to assess properly all relevant information regarding this patient, make an appropriate diagnosis, or decide on a proper course of action, leads me to conclude that he is unable to comply with his obligations under the Act. This case points to a defect in basic skills of analysis and information assessment that are critical to doctors in general, and especially to neurosurgeons.

In case of Patient 632365 (Case # 7), Petitioner failed to properly diagnose and assess clear indicators that the patient had a serious cardiac condition. Petitioner failed to consult

with a specialist and failed to take proper action when confronted with a trifecta of symptoms, low serum sodium level, abnormal CPK and MB isoenzyme levels, and an abnormal chest x-ray. Admittedly, Petitioner is not a cardiologist. However, it was incumbent upon Petitioner, as the admitting and attending physician, properly to assess and treat this patient's medical conditions, and, if any condition is outside his area of expertise, to consult with the appropriate specialist who could properly assess and treat her. Instead of assessing and treating this patient for her cardiac condition, Petitioner focused his entire treatment on her neurological complaints. This conduct was particularly inappropriate, considering that some of the patient's confusion may have emanated from her cardiac condition rather than her neurological problems. Petitioner should have been aware that such symptoms oftentimes readily mimic neurological signs. Petitioner did not possess the necessary skill or acumen to realize the importance of these adverse cardiac findings and the potential threat these symptoms posed to his patient. Petitioner's failure to recognize relatively common medical signs of cardiac disease, to order additional diagnostic procedures to assess her cardiac status, and to provide treatment for any cardiac problems found, demonstrates that he lacks the ability to comply with his obligations under the Act. His lack of knowledge of basic cardiac signs, symptoms, and findings was so deficient that he failed to realize that a specialist should be consulted. Here, again, a willingness to conform to his obligations under section 1156 of the Act cannot make up for his basic inadequacies in medical knowledge of cardiac disease, diagnosis, and treatment.

Although Petitioner has frequently asserted that he is willing to do whatever is necessary to comply with his obligations under section 1156 of the Act, such willingness is inadequate protection for program beneficiaries and recipients when he lacks the basic medical knowledge to comply with his obligations under the Act. This point is graphically demonstrated in Petitioner's treatment of Patient 632365, where Petitioner demonstrated that he lacks the basic medical knowledge properly to diagnose and treat cardiac conditions, such as CHF. Petitioner's lack of understanding of signs and symptoms of this disease was so significant that he did not think to consult with another physician who had expertise in cardiac disorders. When asked what he had learned from this case at the NJPRO hearing, Petitioner provided the following:

> Because these questions have arisen, so maybe to correct it, maybe I've learned something, I don't know. I'm just -- at least if C.H.F. maybe would have been a concern, we might have repeated a chest x-ray, which I didn't do, I'm really not sure what it would have done in this patient. It might help me at least just to <u>cover me up</u>.

I.G. Ex. 8/42 (emphasis added).

My understanding of Petitioner's comment is that he still does not accept that he may have misdiagnosed this patient's cardiac condition. A repeat x-ray and additional blood tests would have provided Petitioner with information that could have led to a proper assessment of the patient's cardiac disease and, if necessary, to additional treatment measures. Rather than recognizing his deficiencies in medical knowledge and need for consultations in the future to assist in determining the existence and severity of cardiac conditions that his patients might present, Petitioner seems to be more concerned about his potential future liability than properly diagnosing, analyzing, and understanding the patient's underlying condition and providing proper patient care.

For the above reasons, I find that Petitioner is unable to comply with his obligations under the Act. Petitioner exhibited a consistent pattern of serious errors in the diagnosis and assessment of patients, which, in turn, indicates a lack of important, fundamental knowledge that is essential in meeting his obligations under the Act. An exclusion in this case is proper, as it will allow Petitioner time to sharpen his diagnostic skills, perhaps with the help of additional supervision or training. Petitioner has demonstrated a willingness to cooperate and learn, and hopefully will take the steps necessary to ensure he gains the experience and skills needed to become a provider who is able to fulfill his obligations under the Act.

4. <u>The five year exclusion imposed and directed against Petitioner is extreme and excessive; a three year exclusion is reasonable and comports with the remedial purposes of the Act.</u>

The I.G. adopted the recommendation of the NJPRO and imposed a five year exclusion against Petitioner. Authorization for this exclusion was based on section 1156 of the Act. Essentially, the following factors must be established to provide the I.G. with the authority to impose an exclusion under this section of the Act. There must be proof that 1) Petitioner committed gross and flagrant violations of his obligation to provide care which meets professionally recognized standards of health care, and 2) Petitioner is unwilling or has an inability substantially to comply with such obligation. I have found that the I.G. proved by a preponderance of the evidence that he has the requisite authority to exclude Petitioner. However, the record demonstrates that the five year exclusion warrants modification, and for the reasons set forth below, I am reducing the exclusion imposed against Petitioner to three years.

Petitioner has a right pursuant to section 1156(b)(4) of the Act to a hearing under section 205(b)(1) of the Act for the purpose of reviewing the Secretary's decision (or in this case, the I.G.

as his delegatee) to exclude him. Section 205(b)(1) provides for a de novo hearing and, based on the record established at the hearing, I have the authority to affirm, reverse, or modify the I.G.'s action against Petitioner. In this case, I have concluded that the remedy imposed against Petitioner is unreasonable. Based on my responsibilities in reviewing the I.G.'s determination, I am obliged to modify the length of the exclusion to comport with the minimum time period needed for Petitioner to demonstrate that he can be trusted to provide medical care to program beneficiaries and recipients in a manner consistent with his obligation to meet professionally recognized standards of health care. An exclusion of three years will be sufficient for Petitioner to satisfy his trustworthiness to be a program provider and comports with the remedial purposes of the Act. This time period will give Petitioner the opportunity to rectify the deficiencies, as established by the record, in his medical knowledge of the management, including the need for surgical intervention, of cerebral infarcts and hemorrhages and of the diagnosis and treatment of cardiac problems. At the end of this time period, Petitioner can seek reinstatement into the program pursuant to 42 C.F.R. § 1004.120, 57 Fed. Reg. 3350 (January 29, 1992).

In addition to ensuring that Petitioner can be trusted to be a program provider and that the conduct which led to his exclusion will not be repeated, his exclusion may have an ancillary benefit of deterring other providers of items or services from engaging in the same or similar misconduct. Reyes at 37. However, deterrence cannot be a primary purpose for imposing this exclusion. If deterrence becomes the primary purpose for this exclusion, then punishment becomes the objective, which is inconsistent with the remedial objectives of the Act. Hanlester Network, DAB 1275 at 51-52 (1991). Therefore, where an exclusion under section 1156 of the Act, a civil remedies statute, is essentially for deterrence purposes rather than remedial, the exclusion becomes punitive and is unconstitutional. Cf. United States v. Halper, 490 U.S. 435 (1989).

Evidence which is relevant to the reasonableness of an exclusion is admissible whether or not that evidence was available to the I.G. at the time the I.G. made his exclusion determination. Evidence which relates to a provider's trustworthiness or to the remedial objectives of the exclusion law is admissible at an exclusion hearing even if that evidence is of conduct other than that which establishes statutory authority to exclude a provider. However, I do not substitute my judgment for that of the I.G. An exclusion determination will be held to be reasonable where, given the evidence in the case, it is shown to fairly comport with legislative intent. "The word 'reasonable' conveys the meaning that . . . [the I.G.] is required at the hearing only to show that the length of the [exclusion] determined . . . was not

extreme or excessive." (Emphasis added.) 48 Fed. Reg. 3744 (1983).

The evidence of record establishes that some period of exclusion is warranted. However, the five year exclusion imposed by the I.G. must be modified. A major component of the I.G.'s case has not been sustained. The I.G. failed to prove by a preponderance of the evidence that Petitioner engaged in a pattern of misuse of ICPM in CVA and tumor cases. The I.G. also failed to prove by a preponderance of the evidence that Petitioner violated his obligation to provide care that met professionally recognized standards in the treatment of four of the seven patients cited.

Nevertheless, there is credible evidence that Petitioner failed in his obligation to meet professionally recognized standards of health care in three separate patient transactions in which his conduct placed the patients in imminent danger or unnecessarily in high risk situations. By regulatory definition, a single violation of this type constitutes a gross and flagrant violation which would justify Petitioner's exclusion. 42 C.F.R. § 1004(b). Here there were multiple instances of gross and flagrant violations. Moreover, while Petitioner has repeatedly expressed a willingness to comply with his requisite obligations, I have concluded that the record further establishes that he lacks an ability substantially to comply with them. Petitioner's multiple violations demonstrate that he cannot presently be trusted to provide care to program beneficiaries and recipients.

I have determined that a three year exclusion will adequately protect the Medicare and Medicaid programs and their beneficiaries and recipients. In reaching this conclusion, I have considered the risks to which Petitioner exposed three of his Medicare patients, and the likelihood that he would continue to pose a risk to program beneficiaries and recipients until his deficiencies in knowledge and judgment are corrected. I have also considered Petitioner's failure adequately to document in the medical records his clinical observations and rationale for choosing a particular course of treatment. Petitioner's poor documentation impacts on his trustworthiness as a program provider because it may impede the peer review process, which is intended to insure that beneficiaries and recipients receive competent, medically necessary care.

Petitioner's treatment of Patient 854914 (Case # 3) departed significantly from professionally recognized standards of neurosurgical practice and demonstrates a lack of knowledge and judgment that could continue to place program beneficiaries and recipients at risk if not corrected. He failed to order clarifying diagnostic tests when an existing CAT scan did not define with proper clarity the extent and location of the patient's cerebral infarct. Considering the clinical presentation, accepted neurosurgical practice required a prompt

posterior fossa decompression to eliminate pressure that was compromising the patient's brain stem which, if not alleviated, would lead to the patient's death. As a practicing neurosurgeon, Petitioner is rightfully expected to possess the necessary skill and experience to independently evaluate the patient's condition, and to employ existing diagnostic studies to determine the proper surgical intervention and the time frame in which it should be performed. Where the clinical picture is unclear, Petitioner is expected to know what additional tests are necessary to determine the proper course of treatment. Upon completion of such studies, he is to undertake a proper and medically correct surgical procedure which will provide the best chance for patient recovery. In this case, Petitioner undertook a preliminary surgical procedure of a ventriculostomy, with ICPM, and delayed performance of the urgently needed posterior fossa decompression. By the time Petitioner did the correct procedure, which was several days after his own specified time frame, he eliminated the acknowledged slim chance this patient had for recovery. Moreover, had Petitioner obtained a clarifying CAT scan on the day he first operated, he may have been able to avoid the performance of the initial, arguably unnecessary, surgical procedures. The inappropriate decisions he made were within his area of expertise and demonstrate a serious deficiency in his knowledge of accepted neurosurgical principles. It is obvious that continuation of such action by Petitioner would pose a significant risk to the Medicare and Medicaid programs.

As was true of the treatment of Patient 854914, Petitioner's treatment of Patient 86-0935 (Case # 4) deviated in significant aspects from professionally recognized standards of neurosurgery. Petitioner's treatment of Patient 86-0935 also demonstrates failures of knowledge and judgment that could expose beneficiaries and recipients to a continuing risk of unnecessary surgery. This patient's medical record also demonstrates Petitioner's failure adequately to document his clinical findings and treatment decisions. In this case, Petitioner performed a surgical craniotomy and insertion of an ICPM device in a patient who had been tolerating a small intracerebral hemorrhage well for seven days. Petitioner performed a surgical craniotomy and evacuated a hematoma under general anesthesia despite the fact that the patient exhibited no mass effect, no shift in the midline structures of her brain, and no neurologic deterioration. An additional factor weighing against surgery was this patient's increased ability to tolerate a small stroke, given her history of previous infarcts. Accepted medical practice is to treat small strokes conservatively, i.e., with drugs, instead of surgery, unless the patient exhibits deterioration. Petitioner deviated from accepted medical practice and subjected this patient to risks from general anesthesia and infection by operating. This is especially true because the patient was tolerating the stroke well for seven days and exhibited no signs of neurologic deterioration. Moreover, Petitioner failed in his

diagnosis sufficiently to take into account the fact that this patient had Alzheimer's disease. Petitioner, in his notes, makes repeated references that the patient was confused. Petitioner was unable to articulate a clear and logically supportable reason, either in his notes or in testimony at the hearing, as to why he believed this patient was suffering any neurologic deterioration. In making a decision to operate, Petitioner failed to give sufficient weight to the fact that this patient's baseline behavior was one which contained periods of haziness and confusion. Petitioner's stated rationale for performing surgery is not supported by the notes of the attending physician, nor is it supported by the nurses' notes. Petitioner's stated rationale is not supported even by his own sparse notes, which provide only conclusions and little supporting rationale. Petitioner disregarded the medically accepted and recognized treatment for small intracerebral hemorrhages, based on his mistaken assumption that the patient was deteriorating.

Petitioner also inserted an ICPM device into this patient when there was no indication of increased ICP. But, more importantly, he then removed the monitor one day after the surgery, when the patient was at risk from increased ICP from swelling for three days. Removal of the monitor in this instance is in direct conflict with Petitioner's stated purposes for inserting it in the first place and is a violation of Petitioner's obligation under the Act. In short, there were no logical and supportable clinical reasons for Petitioner to perform surgery on this patient or to remove the ICP monitor after only one day. These inappropriate decisions were within Petitioner's area of expertise and demonstrate a serious deficiency in Petitioner's knowledge of accepted neurosurgical and medical principles. Perhaps more importantly, these decisions demonstrate Petitioner's inability in this instance to correctly analyze and assess the medical needs of this patient and to proceed with the proper course of treatment. As a result, this patient was subjected unnecessarily to the risks of surgery under general anesthesia and the accompanying risk of infection. Continuation of such practices and actions by Petitioner would pose a significant risk to the Medicare and Medicaid programs.

The record of Petitioner's involvement in the management of the care and treatment of Patient 632365 (Case # 7), also reveals serious deficiencies in recognized standards of health care. As with the cases of Patient 854914 and Patient 86-0935, Petitioner's treatment of this patient also reveals serious gaps in Petitioner's knowledge which could place program beneficiaries and recipients at considerable risk. Here, Petitioner failed to recognize clear indicators of potential cardiac problems evidenced by low serum sodium levels, inconsistent CPK and MB isoenzyme test results, and radiological imagining showing CHF. His narrow focus on the patient's neurological impairments, despite strong indications of possible heart disease and the

obvious life threatening impact of such condition, is disturbing. It suggests that Petitioner is lacking in the knowledge of basic medical coronary diagnostic criteria. Even more disturbing is Petitioner's failure to recognize the need to seek consultation for a cardiac or internal medicine specialist. His expressions that he would utilize such consultive services in the future is not very reassuring, especially when he apparently lacks the basic knowledge of cardiac signs that would warrant such involvement of other medical specialties. Until Petitioner has the opportunity to refresh his knowledge of cardiac diseases and their care and treatment, he places program beneficiaries and recipients at risk. The three year period of exclusion will be an adequate time frame for Petitioner to demonstrate that the programs are no longer at risk from this past conduct.

While Petitioner, in appropriate cases, should solicit input from other attending or consultative physicians, the decision for surgical intervention, the type of surgery to be performed, and its timing has to made independently by him based on professionally recognized standards of health care. Petitioner, in a number of cases, asked me to review other physicians' opinions and tried to justify his actions based on the fact it was a joint decision of the doctors attending the patient. Such reliance on others does not excuse Petitioner where he did not follow professionally recognized standards of neurosurgical care. He cannot justify his surgical procedures on the fact that other physicians recommended them. He is being consulted for his neurosurgical skills and experience and should make an independent assessment of the correct course of action, especially when consulted by physicians who do not possess his level of neurosurgical expertise. I am disturbed that too often Petitioner showed a pattern of following others and not exercising his own independent assessment and judgment. Again, the period of exclusion that I am imposing will allow Petitioner time to demonstrate that this behavior no longer poses a risk to program beneficiaries and recipients.

In addition to the need for Petitioner to improve his medical knowledge and judgment, a three year exclusion will also allow Petitioner sufficient time to demonstrate that he understands his responsibility to adequately document the patient's hospital record so that the rationale and basis for his determination of the need for, and type and timing of, surgery can be assessed. Quality review is an accepted part of the medical community's efforts to reduce medical costs by eliminating unnecessary procedures and weeding out incompetent medical practices. Petitioner must be aware of this. Here, among the other concerns I have regarding Petitioner, I am disturbed about the absence of comprehensive consultative notes explaining the rationale for his actions. A number of the cases reviewed by the NJPRO were complicated by the absence of any rationale in the hospital record for Petitioner's surgical procedures. Considering the

complexity, importance, and cost of such procedures, such lack of documentation is indicative of an unacceptable level of sloppiness and carelessness. Even acknowledging that in most of these cases, Petitioner was involved in an emergent situation, he still must take the time to complete a reasonably comprehensive rationale for his actions. In a number of instances, Petitioner's notations were so poorly worded that it was unclear whether the surgical procedure he performed was a craniotomy or a craniectomy. He should leave no doubt as to the type of surgery he performed. Also of concern was the frequent absence of a clear indication by Petitioner as to the precise reason why a certain surgical procedure was undertaken and what Petitioner was attempting to achieve by its application in the patient's case.

There seemed to be a consensus among experts that the patient files in issue were poorly documented. I.G. Ex. 6/179; Tr. III/161-62. Petitioner concedes this point and avers to change his documentation practices in the future. However, considering the consistency of this documentary lapse and the length of its duration from 1985 through 1989, it is apparent that an exclusionary period is warranted to protect program beneficiaries and recipients from a repetition of this activity in the future.

The I.G. argues for retention of the five year exclusion. The principal basis for this period of exclusion is the I.G.'s conclusion that Petitioner grossly and flagrantly violated his statutory obligation and demonstrated an inability to comply with that obligation in the care of seven patients over a five year period. I.G. Br. 49-57; I.G. R. Br. 13-14. As I have held, in four of the patient cases, the I.G. has failed to meet his burden of proof to establish violations under section 1156 of the Act. A major component of the I.G.'s case was Petitioner's alleged misuse of ICPM on a regular basis to monitor and treat cerebral infarcts, hemorrhages, and tumors. Contrary to the I.G.'s position, the record demonstrates that Petitioner used this procedure in exceptional cases only. Apparently, the NJPRO and the I.G. concluded that Petitioner was too aggressive in his use of ICPM when a more conservative and less dangerous approach was needed. In fact, for the period of 1985 through 1986, Petitioner treated approximately 100 patients with CVAs, strokes, tumors, or hematomas and, of these patients, in only seven or eight instances did he insert an ICPM device.

Nor does the record support the I.G.'s assertion that a general anesthetic was used to insert the monitoring device in every patient's case. In at least one patient's case, the record supports that no agent was used to anesthetize the comatose patient. In all but one of the other patients, the patients were either unsalvageable and beyond any realistic hope of recovery or so severely compromised that the only hope of recovery emanated from Petitioner's surgical procedure. In such cases, a one percent risk from the general anesthesia does not meet the

definition of gross and flagrant conduct. I did find that, in the case of Patient 86-0935, the one percent risk of general anesthesia was significant, since the surgery was unnecessary and the patient would have recovered with the use of conservative measures. In this case, the patient was tolerating the stroke well, and surgery was not clinically indicated. For Petitioner to subject the patient to a one percent risk of serious injury or death, in that case, is a gross and flagrant violation.

Moreover, the neurological literature does not support the I.G.'s assertion that ICPM is universally contraindicated. The I.G's assertion that you only find ICPM in nationally recognized teaching institutions is, on its face, without merit. There is no basis for a conclusion that such monitoring is done only for academic reasons as suggested by Dr. Kasoff. Its use in prestigious teaching hospitals, such as the Mayo Clinic and Johns Hopkins, suggests that an influential segment of the neurosurgical community still recognizes the need for such monitoring.

While it appears that, since the mid 1980's, practicing neurosurgeons have begun to question the efficacy of such monitoring based on studies reflecting that ICPM is not helpful in the treatment of strokes and tumors, a significant minority of neurosurgeons still advocate its use in such cases. Here, the record shows Petitioner used such monitoring in specialized cases and only in conjunction with another procedure, such as a ventriculostomy or an evacuation of a hematoma, and was, for the most part, based on legitimate medical need. Furthermore, the I.G. failed to prove that use of such monitoring in any of the patient cases was a gross and flagrant violation of Petitioner's obligations to comply with professionally recognized standards of health care.

The I.G. failed to prove his case with regard to four of the seven patients. The I.G.'s case also suffered because a major component of his case -- misuse of ICPM -- was shown to be invalid in all but one patient. Thus, a five year exclusion of Petitioner is unwarranted. Such a lengthy period of time far exceeds the time needed to establish Petitioner's trustworthiness based on the conduct that I have detailed above. I am influenced by Petitioner's recognition and apparent willingness in the future to: 1) obtain second opinions of neurosurgeons in close cases; 2) improve the quality of his documentation in hospital records of patients under his care; and 3) acquire increased medical knowledge in areas where he may be deficient. The three year period of exclusion will allow Petitioner time to improve his medical knowledge and should be sufficient time to make unlikely the repetition of the serious deficiencies. Also in Petitioner's favor is that, even after he was placed under intensive scrutiny by the NJPRO, only one additional issue arose, and this was unrelated to the quality of his care in the field of

neurosurgery. Lastly, I note that neither the NJPRO nor the I.G. ever challenged Petitioner's surgical skills. The areas of Petitioner's behavior placed into disrepute by these cases are all subject to remedial action by him. Consequently, in light of the above analysis, any period of exclusion beyond three years is extreme or excessive and fails to comport with the remedial purposes of the Act.

CONCLUSION

Based on the applicable law and the evidence, I conclude that Petitioner, in the cases of three patients, grossly and flagrantly violated his obligation under section 1156 of the Act to provide health care services of a quality that met professionally recognized standards of health care and demonstrated a lack of ability substantially to comply with his obligation. I also conclude that Petitioner, in the cases of four other patients, did not grossly and flagrantly violate his obligation under section 1156 of the Act. I conclude that the I.G. had the authority to impose and direct an exclusion against Petitioner from participating in the Medicare and Medicaid programs. Lastly, I conclude that the five year exclusion imposed and directed by the I.G. against Petitioner is not reasonable, but that a three year exclusion will fully serve the remedial purposes of the Act.

/s/

Edward D. Steinman
Administrative Law Judge