

INITIAL DECISION

OAL DKT. NO. BDS 08959-12

IN THE MATTER OF THE SUSPENSION
OR REVOCATION OF THE LICENSE OF
RICHARD A. KAUL, M.D., TO PRACTICE
MEDICINE AND SURGERY IN NEW JERSEY.

Maureen Hafner, Deputy Attorney General, for complainant Attorney General of the State of New Jersey (John J. Hoffman, Acting Attorney General of New Jersey, attorney)

Charles Shaw, Esq., for respondent Richard A. Kaul, M.D. (Law Offices of Charles Shaw, Esq., attorneys)

Record Closed: October 31, 2013 Decided: December 13, 2013

BEFORE J. HOWARD SOLOMON, ALJ t/a:

STATEMENT OF THE CASE AND PROCEDURAL HISTORY

This is a disciplinary proceeding brought by the Attorney General of the State of New Jersey (petitioner) on its complaint filed with the State Board of Medical Examiners (Board) on April 2, 2012, seeking to impose sanctions against Richard A. Kaul, M.D., a board-certified anesthesiologist (respondent), including the suspension or revocation of his medical license. Respondent filed his answer with the Board on April 9, 2012,

denying the allegations. The Attorney General filed an amended verified complaint with the Board on June 13, 2012, which then referred the matter to the Office of Administrative Law (OAL), where it was received on June 29, 2012, for hearing as a contested case.

Thereafter, petitioner moved to further amend its complaint, which was granted by the undersigned on December 18, 2012.

The second amended complaint alleged that respondent committed multiple acts of gross neglect, gross malpractice, gross incompetence, in violation of N.J.S.A. 45:1-21(c); repeated acts of negligence, malpractice or incompetence, in violation of N.J.S.A. 45:1-21(d); professional misconduct, in violation of N.J.S.A. 45:1-21(e) and (h), including failure to maintain medical malpractice insurance and/or a letter of credit, in violation of N.J.S.A. 45:9-19.7 and/or N.J.A.C. 13:35-6.18(b) and (d); failure to maintain good moral character, in violation of N.J.S.A. 45:9-6; failure to obtain hospital privileges or alternative privileges, in violation of N.J.A.C. 13:35-4A.6; professional misconduct, in violation of N.J.S.A. 45:1-21(e) and violation of a Board regulation pursuant to N.J.S.A. 45:1-21(h), including the failure to maintain proper patient records, in violation of N.J.A.C. 13:35-6.5; and misrepresentation of his training and experience in the performance of spinal surgeries, and for his failure to properly bill for his services, both in violation of N.J.S.A. 45:1-21(b). Petitioner further alleged that the above conduct presented a clear and imminent danger to the public health, safety, and welfare, pursuant to N.J.S.A. 45:1-22.

Petitioner further alleged that the Board issued investigative subpoenas to respondent and the New Jersey Spine and Rehabilitation Center (NJSR),¹ a one-room outpatient surgical center owned and operated by respondent, for patient records, which was refused by respondent, in violation of N.J.S.A. 45:1-18, and for his failure to cooperate with the Board, in violation of N.J.A.C. 13:45C-1.2 and -1.3(a)(5).

¹ Reference will be made herein to another one-room outpatient surgical center known as North Jersey Spine and Rehabilitation Center (NJSR), where respondent worked prior to opening his own center. Any abbreviation of respondent's center, known as the New Jersey Spine and Rehabilitation Center (NJSR), will be underlined to avoid confusion.

Prior to the commencement of the hearing, the parties filed various discovery motions, which were heard and disposed of prior to hearing. In addition, petitioner filed on short notice a motion for summary decision on its allegations that respondent failed to obtain required hospital privileges and/or alternative privileges (discussed below) and that he failed to maintain required medical malpractice insurance or a letter of credit (also discussed below). The undersigned reserved on the motion pending the conclusion of this matter. After the hearing had commenced, respondent's counsel moved to be relieved as counsel, for reasons heard in camera; the motion was denied.

The hearing took place on several dates, commencing on April 9, 2013, and concluding on June 28, 2013. Post-hearing briefs and reply briefs were submitted, after extensions were granted to both sides. The last brief was due and received on October 31, 2013, on which date the record closed.

FACTUAL DISCUSSION

Most of the facts, other than that respondent is a physician licensed to practice medicine and surgery in the state of New Jersey and is the owner and operator of NJSR, were in dispute. In presenting its case, petitioner produced several expert and lay witnesses, starting with Gregory J. Przybylski, M.D.

Gregory J. Przybylski, M.D.

Gregory J. Przybylski, M.D., is a licensed physician in the state of New Jersey and a board-certified neurosurgeon. He has written extensively about the spine, and has hospital privileges at JFK Medical Center and Jersey Shore Medical Center. After graduating from medical school, he completed several years of training in spinal surgical techniques and has been appointed to faculty positions in neurosurgery. He has never had any negative actions against his license in his seventeen years as a neurosurgeon.

Dr. Przybylski has performed an extensive amount of spinal fusions, minimally invasive surgeries, including decompression or fusion or a combination of both, averaging approximately 120 to 150 spinal surgeries a year. Over the past several years, he has

devoted the majority of his practice to minimally invasive surgeries and percutaneous procedures, which he began around 2002.

When asked to describe the differences between percutaneous and open surgeries, he responded that percutaneous are needle-based procedures while open surgery exposes the area of the spine to be treated. For open surgery, the training for the physician is significantly different than that for percutaneous procedures. In describing the differences between open spinal and minimally invasive surgeries, he stated that in open surgery, the area to be treated is much more exposed than in minimally invasive surgeries, the latter of which involves the insertion of a tube to conduct the repair. In minimally invasive surgery, the physician's field of vision is limited since the procedure is done through a tube. The physician must decide whether to perform an open or a minimally invasive surgery, after obtaining a cogent medical history and reviewing diagnostic tests. Both such surgeries are done in a hospital setting.

During his preliminary testimony, Dr. Przybylski produced a model of the lumbar spine and discussed its physiology, including facet joints and discs. He also demonstrated various surgical techniques, including fusion, designed to limit motion of the spine to advance healing.

Then he explained the differences between fusion and fixation. During a fusion, the process is to unite two bones disrupting a joint and pack the area with bone material to limit or prevent mobility. With fixation, wire, screws or rods, or a combination thereof, are used to immobilize the bones to allow for a fusion to occur.

Most spinal surgeries involve degenerative disc disorder where the disc dehydrates and becomes less of a shock absorber, resulting in pain. Various diagnostic tests are available, such as CT scans, MRIs and discograms, which assist the surgeon in determining the type of surgery needed. The importance of obtaining a cogent medical history and the use of diagnostic testing were taught in medical school, and became

heightened during his residencies. He discussed various articles and publications concerning spinal surgeries that he had relied upon in rendering his report.²

He mentioned that pain-management physicians consist of multidisciplines, such as radiologists, anesthesiologists, and internists trained to do percutaneous procedures (those procedures which are needle-based). After his review of the curriculum vitae of respondent P-109(a), it was his opinion that respondent did not have the requisite training to perform spinal surgeries, either open or minimally invasive.

According to respondent's curriculum vitae, he was a surgical intern in 1989–1990 at Catholic Medical Center in New York. Dr. Przybylski opined that interns at such a hospital would have had very little responsibility to perform spinal procedures on their own. He also noted that in 1990–1991, respondent was a surgical intern at Nassau County Medical Center in New York, where, again, Dr. Przybylski opined that there was limited training given to interns in performing surgical procedures on their own. Dr. Przybylski noted that in 1991–1992, respondent moved to Booth Memorial Medical Center in New York, a different medical center, where he likely would have had limited surgical experiences because he was newly transferred to that hospital. Respondent did complete a residency in anesthesiology at Albert Einstein–Montefiore Medical Center in New York during 1992–1995, during which he would not have had any exposure to spinal surgeries. This residency likely included training in epidurals, discographies, and needle-based procedures.

He further noted that in 1995–1996, respondent had a pain fellowship at the Department of Anesthetics at Bristol Royal Infirmary in Bristol, England. Here respondent would have received training in percutaneous procedures, not open or minimally invasive spinal fusion surgery.

Respondent also listed in his curriculum vitae his membership in 2006 in the American Society of Interventional Pain Physicians. Dr. Przybylski examined the website for this association and noted that it was open to doctors of different disciplines who

² See attached appendix for references.

sought to do interventional pain management, which treatment would have been limited to needle or percutaneous spinal procedures. In his curriculum vitae, respondent also listed the completion of a two-week fellowship in minimally invasive spine surgery at the Wooridul Hospital in Seoul, Korea, in 2004. In an excerpt from respondent's testimony before the Board on February 3, 2010 (P-98), respondent confirmed that his training in Korea was only for two weeks, a time period, according to Dr. Przybylski, that was totally insufficient for proper surgical training.

Dr. Przybylski added that a typical fellowship for minimally invasive surgery is approximately six to twelve months, which would involve performing procedures and caring for patients under the supervision of a monitor, an experienced physician. During the residency, the physician is eventually weaned from supervision and gradually performs surgeries on his or her own, with the monitor in attendance. Respondent also listed his membership in 2004 in the American Academy of Minimally Invasive Spinal Medicine and Surgery, which Dr. Przybylski mentioned is not recognized by the American Board of Medical Specialties. Membership in this organization is open to various physician disciplines, but membership by itself did not provide expertise in spinal surgery.

Respondent also mentioned that he is a diplomate of the American Board of Interventional Pain Management. Dr. Przybylski stated that this membership also involves physicians from various disciplines, such as physiatrists, neurologists and anesthesiologists, which leads to becoming a diplomate in percutaneous procedures, not minimally invasive ones.

He further commented that the continuing medical education (CME) courses taken by respondent did not qualify him to perform open or minimally invasive surgeries. Attendance at these courses did not lead to surgical competence, but only satisfied CME requirements for licensure.

As to respondent's certificate from the North American Spine Association, Dr. Przybylski commented that this association included a broad spectrum of physicians. Even a non-physician who took the appropriate course or courses offered could obtain a certificate, which only certified attendance. The amount of time and breadth of study

necessary to train for open or minimally invasive surgeries is much greater than merely attending CME courses.

He further opined that given respondent's lack of training, he would not have been granted hospital privileges for either open or minimally invasive surgeries, particularly at JFK Hospital, where Dr. Przybylski sits on a credentialing subcommittee. He would, however, have been given privileges as an anesthesiologist to perform percutaneous procedures.

Based upon his review of respondent's curriculum vitae, which illustrated his lack of training in either open or minimally invasive surgeries, Dr. Przybylski opined that respondent's performance of those surgeries constituted a gross deviation from medical standards.

Dr. Przybylski testified that there were also several risks associated with this deviation, citing, for example, a patient treated by respondent who underwent multilevel procedures that cannot not be corrected during the patient's life. Dr. Przybylski also noted atrophy in that patient and mentioned other maladies that were likely to develop.

Since complications could arise during open or minimally invasive surgeries, these surgeries should be done in a hospital setting or at least at the hospital's outpatient center. If a problem were to occur, the patient could be properly and immediately treated. Therefore, the surgeon must have hospital privileges. However, respondent did not have any hospital privileges. He further opined that since respondent was performing spinal surgeries, it was a gross deviation for him not to have hospital privileges. In the alternative, respondent could have worked with doctors who had hospital privileges, who could then take over the care of the patient, if needed. But no relationship with other doctors was noted in the materials he reviewed.

Dr. Przybylski was asked to give his opinion about respondent's treatment of patient **R.B.** In arriving at his opinion, Dr. Przybylski reviewed respondent's medical records, imaging reports, pre- and post-operative reports, and the consent for surgery. He opined that respondent deviated from the standards of care for treatment of this patient.

Respondent improperly performed a discogram, for which there should have been a control, or normal, disc. Since that was not done, he concluded that this was a gross deviation.

Upon his review of respondent's operative report, he noted that patient R.B. underwent a discectomy of L-3, L-4, and L-5 at the North Jersey Center for Surgery (NJCS) in Newton, New Jersey, an outpatient facility. A fusion was also performed using a mesh cage with allograft.

While the patient consented to a discectomy, the operative report showed that, in addition to a discectomy, fusions were performed, which were not contained in the consent. Dr. Przybylski explained that during surgery, other medical concerns might be discovered, which were unknown during the consent process. These new issues could be treated while the patient is under anesthesia, rather than subjecting the patient to a new surgery and further anesthesia. But nothing was noted in the operative report about encountering other problems necessitating expanding the surgery. He considered this to be a gross deviation.

Surgery was performed on April 11, 2005, where respondent performed a lumbar discogram at L4-5; lumbar discogram at L3-4; lumbar discectomy at L4-5; lumbar discectomy at L3-4; lumbar interbody fusion at L4-5 with mesh cage; and lumbar interbody fusion at L3-4 with mesh cage. A follow-up MRI on April 22, 2005, disclosed a large disc herniation at L4-5 with nerve impingement, which was the same area where respondent inserted the mesh cage.

On April 27, 2005, respondent performed another surgery for the removal of bone fragment using a percutaneous approach. On an MRI dated May 5, 2005, of the L4-5 surgery site, there was still a large disc herniation at that level. According to Dr. Przybylski, this meant that disc material that should have been removed by the prior surgeries was still present.

On May 9, 2005, respondent performed another surgery which consisted of a fragmentectomy of disc fragment in the L4-5 neural foraminal space on the left side where

two grams of fragment were removed. On June 6, 2005, the patient returned to respondent complaining of radiating pain in his left leg and of his inability to return to work.

On June 9, 2005, other MRIs were obtained, with and without contrast, of the lumbosacral spine. The imaging showed that at L4-5 there was still the presence of a large disc fragment, notwithstanding the prior surgeries. By then, the patient was reporting weakness and atrophy in his left leg.

Respondent planned another surgery to remove the fragment, which was his fourth surgery at the L4-5 disc. This surgery was performed on June 15, 2005. An MRI on August 25, 2005, revealed that a stable large disc fragment was present centered in the distal aspect of the left L4 neural foramen, impinging upon the left L4 nerve root, further indicating that a portion of the disc fragment extended into the proximal aspect of the neural foramen. On September 19, 2005, respondent performed a percutaneous procedure endoscopically, but another imaging obtained on October 4, 2005, showed there was no definite interval change from the prior imaging of August 25, 2005.

Respondent used mesh during surgery, which Dr. Przybylski stated was likely OptiMesh, adding that the use of OptiMesh was improper since it could not withstand the load from body weight as an interbody structural support. He cited the literature prepared by Spineology, the manufacturer of OptiMesh, which contained the following FDA notice in bold and bracketed print: "The safety and effectiveness of this device used for fusion of the interbody space has not been established." (P-13.) Dr. Przybylski stated that the proper material should have been Allograft or a PEEK (polyether ether ketone) cage, not mesh.

Dr. Przybylski opined the following gross deviations:

- 1. Performing a discography without a control level.
- 2. The inconsistency between the consent and the operative report.
- 3. The performance of multiple surgeries to the same area.

- 4. The use of mesh.
- 5. Respondent's lack of training in performing spinal surgery.

Dr. Przybylski noted that patient R.B. ended up with foot weakness and atrophy and developed a foot drop. In addition to the above deviations, the witness was also critical of respondent's repeated use of percutaneous techniques.

In all, he opined that respondent grossly deviated from the standards of care in his treatment of patient R.B.

Dr. Przybylski was then asked to render his opinion about respondent's treatment of patient G.H. An MRI on November 5, 2011, indicated there were degenerative disc changes at multiple levels with small focal disc herniations at L4-5 and L5-S1. On November 14, 2011, G.H. consulted with respondent. Respondent recommended a lumbar discogram at L2-L3, L3-L4, L4-L5 and L5-S1. On December 3, 2011, respondent performed a discogram, but not at L5-S1 as the operative report initially indicated. On the lumbar discography report of December 3, 2011, respondent reported that L5-S1 was not accessible. On an MRI taken December 3, 2011, grade-four annular tears of L2-L3 through the L5-S1 disc were noted. The patient then consulted with respondent on December 6, 2011, with ongoing complaints of pain in the low back and in both legs. Respondent recommended a lumbar decompression and interbody fusion at the L3-L4, L4-L5, and L5-S1 levels with the use of interbody cages, iliac-crest autograft, bone marrow harvest and GPS autograft. In his operative report dated December 9, 2011, respondent performed a lumbar decompression and interbody fusion with fusion cage at the L3-4, L4-5 and L5-S1 levels. Dr. Przybylski noted that the report described an incision over the iliac crest and a minimally invasive use of a retractor. He opined that this surgery involved an open procedure for Iliac-crest bone grafting, while the remainder consisted of minimally invasive surgery.

Dr. Przybylski noted that the consent for spinal surgery, which disclosed a lumbar decompression and interbody fusion at L3-L4, L4-L5, and L5-S1, with hardware and with iliac-crest bone harvest, did not contain any signature of either the patient or respondent.

According to the anesthesia record, the surgery lasted about six hours. (P-6 thru P-12, at G.H. 0347.) During surgery, respondent used mesh, which Dr. Przybylski concluded was likely OptiMesh. Again he discussed the FDA warning about the safety and effectiveness of this device for interbody structural support. (P-13.) Although a PEEK interbody cage was used at L3-4, respondent used mesh at other intervertebral spaces.

Dr. Przybylski opined that respondent deviated from the standards of care:

- 1. Performing three-level spinal fusions constituted a gross deviation. The guidelines only provide for one- or two-level, not three-level, fusions.
- 2. The use of OptiMesh at L4-5, L5-S1 constituted a gross deviation.
- 3. Discography was not necessary since it had already been established that there was pain at two levels. This constituted a deviation between moderate and gross.
- 4. The history and physical examination undertaken by respondent was without any neurological examination, which constituted a moderate deviation.
- 5. The consent forms did not have signatures to confirm if the patient had consented to the procedures.
- 6. Respondent's performance of an open procedure with his lack of training and qualifications constituted a gross deviation.
- 7. Respondent's lack of hospital privileges or alternative privileges was a gross deviation.

Dr. Przybylski also opined that the surgeries performed by respondent placed this patient at risk for neurological injury. A three-level spinal fusion could cause stiffness, require further surgeries, and cause the development of stenosis at the L2-3 level.

Dr. Przybylski saw this patient on July 24, 2012, and December 10, 2012. The patient reported that his leg pain had improved, but not his back pain. He had functional difficulties putting on shoes and socks. In his examination, Dr. Przybylski noted a long incision as well as an iliac-crest incision. Mesh cages were noted at L4-5 and L5-S1. On the follow-up CT scan, it was noted that the L4-5 and L5-S1 level end plates were eroding, which Dr. Przybylski opined was caused by bone destruction.

Dr. Przybylski was asked to give his opinion about respondent's treatment of <u>J.J.</u> In arriving at his opinion, Dr. Przybylski reviewed respondent's office records, operative reports and imaging studies. On an MRI performed on June 12, 2004, desiccation (dehydrated disks) was indicated at several levels. Respondent met with J.J. on September 9, 2005, where he planned to perform a discogram at L2-3, L3-4, L4-5 and L5-S1, which was performed on October 3, 2005.

According to respondent's records, he performed a surgery on October 11, 2005, at the Market Street Surgical Center in Saddle Brook, New Jersey. He performed a discogram at L4-5, L5-S1, discectomy at L4-5, discectomy at L5-S1, lumbar interbody fusion with mesh cage at L4-5, and lumbar interbody fusion with mesh cage at L5-S1, and he inserted a posterior pedicle screw placement at L4, L5, S1 bilaterally with posterior rod placement. (P-12 thru P-18, at J.J. 0216.)

According to the consent form of Market Street Surgical Center, the patient consented to a lumbar fusion at L5-S1, a single-level fusion. (<u>Id.</u> at J.J. 0215.) However, the operative report showed that a fusion was performed that exceeded the consent, namely, at L4-5 in addition to L5-S1. Dr. Przybylski could not find any reason in the operative report for the extra procedure. Furthermore, there was a receipt from Spineology for two OptiMesh devices. (<u>Id.</u> at J.J. 0321.)

When respondent saw J.J. in a follow-up consultation on November 7, 2005, respondent noted mild deficits over the L5 dermatomal distribution of the left lower extremity. (<u>Id.</u> at J.J. 0222.)

In a neurological examination performed by Comprehensive Neurological Services on November 30, 2005, J.J. complained of left-leg pain all the way down to the dorsum of the foot and the second and third digit of his left foot, which occurred daily with increased pain. The patient mentioned that he had never experienced this before. A follow-up consultation with respondent on December 2, 2005, indicated some mild weakness over the left-knee extensors. In another follow-up consultation, on December 16, 2005, respondent noted that the patient still complained of some left-sided leg pain, which respondent claimed in his notes was improving. (Id. at J.J. 0224.)

A CT scan obtained on December 22, 2005, disclosed that a left pedicle screw at L5 was medially located within the pedicle and might have breached the cortex of the lateral recess on the left. The radiologist noted "high density material within the disc space at L4-5 and extends adjacent subcutaneous tissues and compromises the left neural foramen," and that the left pedicle screw was "medially located within the pedicle and may breach the cortex of the lateral recess on the left." (Id. at J.J. 0225.)

Dr. Przybylski was then referred to a report of a neurosurgical evaluation conducted by Alfred A. Steinberger, M.D., on January 5, 2006. This physician noted a history of numbness and paresthesias in the left knee, which the patient described as something new, which was causing him to frequently fall. Dr. Steinberger performed surgery on January 31, 2006, which included a revision of left posterior segmental instrumentation at L4, L5 and S1. His operative notes reflected that the screw-rod construct on the left was not solid and that the nerve roots at the L4-5 foramen and the L5-S1 foramen were found to be severely compressed. This led to decompression at the L4-5 on the left. Dr. Steinberger also found that the nerve root at L4 was densely adherent to the scar. This was also true for the nerve at L5, as well as the nerve root at S1. He also corrected L4-5 by removing disc material and corrected extruding bony material which was previously placed and which compressed the nerve root. (Id. at J.J. 0632.)

Dr. Przybylski opined that respondent deviated from the following standards of care:

- 1. Performing a fusion constituted a gross deviation. Initial imaging revealed degenerative disc change and an MRI supported that no fusion was necessary.
- 2. Respondent's lack of proper training in performing a fusion constituted a gross deviation.
- 3. The L5-S1 cage extended beyond the disc-space footprint, placing the patient at risk of harm to nerves and blood vessels. This was a gross deviation.
- 4. The use of a mesh cage as an interbody support device constituted a gross deviation.

Dr. Przybylski further opined that risks to this patient included failure of fusion, which did occur, and injury to the nervous system.

He was asked to give his opinion about respondent's treatment of patient <u>F.K.</u> In forming his opinion, Dr. Przybylski again reviewed respondent's medical records, operative reports and imaging studies. According to respondent's records, on April 4, 2008, he recommended a lumbar discogram at L2-L3, L3-L4, L4-L5 and L5-S1. Based upon an MRI study of the lumbosacral spine on March 10, 2006, the patient had already undergone a discogram on April 7, 2006. An MRI study had been done on January 25, 2008, which indicated status post laminectomy at L3 and L4, fixation screws and stabilization rods from the L3 through L5 levels, and a worsening L2-L3 posterior disc herniation, among other findings. On April 19, 2008, respondent performed a provocative lumbar discogram at L2-3 and L3-4. Patient was seen on April 2, 2008, for a follow-up consultation, where respondent planned a lumbar interbody fusion at the L2-L3 and L3-L4 levels with the insertion of hardware for posterior stabilization. There were other follow-up consultations on May 14, 2008, and June 18, 2008, where respondent provided the same treatment plan.

According to respondent's operative report of July 28, 2008 (P-21 thru P-29, at F.K. 0021 to 0024), the following surgery was performed:

- 1. Removal of previous hardware from the L3, L4 and L5 levels;
- 2. Lumbar interbody fusion with mesh cage and allograft bone at the L2-L3 level:
- 3. Lumbar interbody fusion with interbody mesh cage and allograft bone at the L3-L4 level;
- 4. Lumbar interbody fusion with interbody mesh cage and allograft bone at the L4-L5 level; and
- 5. Insertion of pedicle screws at the L2, L3, and L4 pedicles on the right and at the L3, L4, and L5 pedicles on the left with insertion rods.

This surgery was performed at the Bergen/Passaic Ambulatory Surgery Center, an outpatient facility. According to the history taken by respondent on July 28, 2008, this patient was a smoker of one pack of cigarettes a day. Dr. Przybylski also noted some modification to the consent form, where it appeared that the location "L4-5" was inserted with a different ink and handwriting. Also noted was a receipt from Spineology for the delivery of three quantities of OptiMesh. From the records, Dr. Przybylski concluded that the surgery started at 13:45 and lasted until 20:25, six hours, forty minutes. (Id. at F.K. 0462.)

Dr. Przybylski opined the following deviations:

1. The patient already had a two-level fusion and the contemplation to perform another fusion was not supported by the guidelines. Since respondent was not sufficiently trained, it was a gross deviation to perform a surgical procedure in the first place.

- 2. A discography was not done with a control level, which constituted a gross deviation.
- 3. A three-level fusion was not within the training of respondent. Two levels—L3-4 and L4-5—had already been fused, and there was no indication to re-fuse, constituting a gross deviation.
- 4. The use of OptiMesh, which was not proper for an interbody space, constituted a gross deviation.
- 5. The screw fixation at the L2-3 level was not balanced on both sides. Accordingly, the lack of using screws bilaterally was a gross deviation.
- 6. Allograft, instead of autograft, was used even though this patient was a smoker, which constituted a gross deviation.
- 7. Respondent's lack of training in performing a three-level fusion for disc degeneration constituted a gross deviation. Only two levels were indicated within the guidelines.

Dr. Przybylski opined that the risk of exposing this patient to surgery, particularly where it was not indicated, was the development of a chronic condition known as reflex sympathetic dystrophy, which he described as swelling and pain to the touch and for which there is no known cure.

Dr. Przybylski was then asked to discuss respondent's treatment of patient <u>L.M.</u>, where he again opined that respondent deviated from medical standards. He reviewed respondent's records, operative reports and imaging studies.

At the initial consultation on May 3, 2011, the patient complained of lumbosacral pain, and numbness and tingling in the right arm and in the right leg. The patient also complained of weakness in the right arm and in the right leg and reported that the pain had been getting worse and was more severe on coughing, sneezing and going to the

bathroom. In the patient's past surgical history, respondent noted that the patient had undergone an anterior cervical discectomy and fusion at the C5-C6 and C6-C7 levels. (P-30 thru P-39 at L.M. 0138.)

Upon review of imaging studies, respondent's plan of treatment included a lumbar decompression and interbody fusion at the L4-L5 level with the use of allograft and autograft bone; the insertion of pedicle screws bilaterally at the L4 and L5 pedicles; and iliac-crest autograft, among other procedures. (Id. at L.M. 0140.) An MRI study on April 26, 2011, indicated end-plate changes. Dr. Przybylski noted that this patient had severe disc degeneration, for which it was uncommon to prescribe surgery. He said that there were other treatments available, such as physical therapy, exercise, weight loss and epidural injections. He also found, which he characterized as most unusual, a document entitled "Patient Mutual Binding Arbitration Agreement" dated May 3, 2011, as part of respondent's records.

Surgery was performed at the NJSR Center. According to respondent's operative report dated May 12, 2011, a midline incision was made and a tissue flap was created to the left using Bovie and Metzenbaum scissors. The soft tissues were sharply dissected down to the ilium. (Id. at L.M. 0146.) The report further stated that the ilium was opened with a chisel, which Dr. Przybylski opined was an open procedure.

The operative report further indicated that a scalpel was used to make a stab incision over the guide wire and blunt dilator, which Dr. Przybylski opined was minimally invasive surgery. An operative report of Sukdeb Datta, M.D., the co-surgeon, was signed on the same date of May 12, 2011, which Dr. Przybylski noted was identical to respondent's report. Both reports noted that once the mesh cage was inserted into the intervertebral space, allograft bone was then packed into the intervertebral space. Dr. Przybylski stated that PEEK, rather than a mesh cage, was the proper device for support.

According to the operative report of November 14, 2011, respondent performed a left-sided posterior cervical foraminotomy and decompression at the C3-4 and C4-5 levels. (<u>Id.</u> at L.M. 0188.)

In another operative report, dated January 14, 2012, (<u>Id.</u> at L.M. 0200 to 0202) respondent reported that he performed a provocative lumbar discogram at L2-3, L3-L4 and, what had already been fused, at L5. When Dr. Przybylski reviewed the discography, he noted that levels L2-3, L3-4, and L5-S1 were "asymptomatic." Therefore, the L2-3, L3-4, and L5-S1 levels were not the source of pain.

A discogram was performed on February 14, 2012. About a month later, the patient had a follow-up consult for neurophysiological testing of the lower extremities since there were ongoing complaints of pain in the lower back and legs. Respondent's treatment plan was for a series of three bilateral lumbar facet injections at the L3-L4, L4-L5 and L5-S1 levels. Respondent's findings, EMG and nerve conduction velocity (NCV), revealed no evidence of lumbar radiculopathy or peripheral neuropathy, which, according to Dr. Przybylski, was a normal study. He added that the testing performed by respondent should have indicated a paraspinal muscle abnormality since the patient had a prior surgery, but none was noted.

On March 6, 2012, the patient had a follow-up consultation with respondent where he had complaints of back and leg pain. Respondent's treatment plan was for a lumbar decompression and interbody fusion at the L3-L4 and L5-S1 levels with interbody cages, iliac-crest autograft, and a staged insertion and extension of pedicle screws bilaterally extending from L3 to S1 on the left and right.

According to the operative report of March 23, 2012 (<u>Id.</u> at L.M. 0223), respondent performed a lumbar decompression and interbody fusion with fusion cages at the L3-L4 level, use of the iliac-crest bone harvest, use of allograft bone, use of local autograft bone and use of bone-marrow harvest and reconstruction of the ilium using Vitoss (described as an artificial, ceramic-type material). Dr. Przybylski opined that an open procedure was done at the iliac crest. The balance of the surgery involved a minimally invasive procedure. Mesh cages were inserted. The surgery lasted a little less than two hours.

On March 30, 2012, respondent performed another surgery, which Dr. Przybylski stated was identical to the previous surgery. He noted that in the details of the procedure

an incision was made over the crest using Bovie and Metzenbaum scissors, with a dissection carried down to the iliac crest, which he opined was an open procedure. He also opined that the rest of the procedure was minimally invasive for screw fixation. He also found that the description of an L5-S1 fusion noted at the beginning of the operative report was not contained in the body of the report, and found this to be a discrepancy. From the anesthesia record, Dr. Przybylski noted this surgery lasted approximately four hours.

In a follow-up consultation on April 10, 2012, the patient reported no improvement in her ability to walk and in her ability to function. Respondent prescribed home rest and for the patient to return in four weeks. The patient was to obtain x-rays of the lumbosacral spine.

Rather than return to respondent, the patient consulted with Kenneth Rieger, M.D., an orthopedic surgeon. In his report of May 30, 2012, Dr. Rieger noted that radiographs of the lumbar spine demonstrated an L3-S1 posterior instrumented fusion with anterior interbody prosthesis at L3-L4, L4-L5 and L5-S1. He further indicated, "there does not appear to be any bone graft in the post-posterolateral gutters or anywhere for that matter." (Id. at L.M. 473.)

He ordered a CT scan of the lumbar spine, which was done on June 6, 2012, and which noted, among other things, that there were end-plate erosion changes at the L3-4 and L5-1 levels. Also foreign-body granuloma was another possibility, which Dr. Przybylski mentioned was an inflammatory process.

Dr. Przybylski opined the following deviations committed by respondent:

- 1. Respondent did not have the training for a fusion at the L4-5 level, which constituted a gross deviation.
- 2. In respondent's operative report, a PEEK cage was mentioned, but instead a mesh cage was used, which was improper for structural support. The use of a mesh cage as an interbody structural mechanism constituted a gross deviation.

- 3. Based upon respondent's lack of training, the performance of posterior C3-4, C4-5 decompressions constituted a gross deviation.
- 4. A lumbar fusion at L3-4 and L5-S1 was performed, although the discogram of January 14, 2012, and EMG study of February 14, 2012, showed normal findings. Since there were no clinical indications to proceed with fusion, the performance of surgery constituted a gross deviation.
- 5. Respondent was not qualified to perform an open iliac-crest harvest or a minimally invasive interbody fusion, which was a gross deviation.
- 6. The screw and mesh were improperly placed, which was a gross deviation in surgical technique. Consequently, a revision surgery was necessitated.
- 7. Respondent's lack of recognition of a foot drop was also a gross deviation.

Although a foot drop could happen as a result of the type of surgery this patient had undergone, the surgery itself was unnecessary. Therefore, the resulting foot drop, the use of mesh cage at the L3-4 and L5-S1 levels, and the performance of three fusions were all gross deviations.

Dr. Przybylski opined that the patient was at risk for nerve injury. He also noted that on March 23, 2012, and March 30, 2012, the patient underwent two separate surgeries, one week apart. He opined that there was no indication for either surgery, but performing two surgeries within a week subjected the patient to anesthesia twice and bone-graft harvesting, thus putting the patient at risk unnecessarily. He opined that this was also a gross deviation.

Dr. Przybylski was asked to render an opinion about respondent's treatment of patient **P.M.**

Respondent's initial consultation was on November 8, 2007, where a past surgical history of laminotomy at the L4-L5 level was noted. The patient was a smoker. His treatment plan was for a lumbar discogram at the L3-L4, L4-L5 and L5-S1 levels, which was done on January 21, 2006, at the Bergen Passaic Ambulatory Surgery Center. The procedure was performed by Shams Qureshi, M.D., who found concordant pain at L2-3 and at the L4-5 level. The patient was asymptomatic at the L3-L4 and L5-S1 levels. Repeat discograms were performed on March 10, 2007, and August 23, 2008, with the same results.

At a follow-up consultation on September 3, 2008, respondent rendered a treatment plan for a lumbar interbody fusion at the L2-3, L3-4 and L4-5 levels with an interbody mesh cage and allograft bone and insertion of posterior hardware.

On November 21, 2008, respondent performed a lumbar interbody fusion with mesh cage and allograft bone at the L2-L3 level, lumbar fusion with interbody mesh cage and lumbar interbody fusion and allograft bone at the L3-L4 level, lumbar interbody fusion with mesh cage and lumbar interbody fusion and allograft bone at the L4-L5 level, insertion of transfacet pedicular screws at the L3 pedicles bilaterally, insertion of transfacet pedicular screws at the L4 pedicles bilaterally, and insertion of transfacet pedicular screws at the L5 pedicles bilaterally, among other procedures. (P-40 thru 46 at M-0421.) Dr. Przybylski also noted from the operative report that "a guide wire was inserted through the needle and the needle was removed over the guide wire and incision was made and a set of dilators were advanced under fluoroscopic guidance to free the posterolateral margin at the disc." (Id. at P.M. 0423.) This was a minimally invasive technique, which included the insertion of pedicular screws at the L3, L4 and L5 pedicles bilaterally. Dr. Przybylski was then presented with photocopies of the imaging studies and commented that the screws were in the wrong trajectory, noting, for example, that the L5 screw was in an outward position.

In a radiology study on June 2, 2011, of the lumbar spine (patient had multiple studies done including the cervical and thoracic areas), the report noted, "there appears to be a loss in height and a possible partial fusion across a transitional and L5 vertebral body. There appear to be destructive changes seen along that end plate." (<u>Id.</u> at M 0441.)

Dr. Przybylski opined that respondent committed the following deviations:

- 1. Performing a three-level fusion constituted gross neglect, as it was not consistent with medical standards.
- 2. The technique used by the respondent constituted gross neglect since he was not adequately trained for minimally invasive surgical techniques.
- 3. The use of mesh cages constituted a gross deviation.
- 4. Since the patient was a smoker, the use of allograft presented a much higher risk of non-healing. The consequences for using allograft in a smoker needed to be documented, particularly informing the patient about the risk of non-healing with allograft, but was not. This constituted a gross deviation.
- 5. The transfacet pedicle screws were not in a proper plain and, therefore, could not achieve stability. This was a gross deviation.
- Dr. Przybylski was then asked about the treatment rendered by respondent to patient **K.S.** Among the documents he reviewed were the respondent's records, which included the operative reports, and imaging reports.

At the initial consultation on August 23, 2010, the patient was evaluated for pain in the head, neck, arms, lower back, left leg and left knee. Respondent's treatment plan consisted of a series of three cervical epidurals and a bilateral EMG/NCV of the lower extremities. The patient was a smoker. (P-47 thru P-52 at K.S. 0142 to 0144.)

In a follow-up visit on September 20, 2010, respondent performed neurophysiological testing which indicated the presence of left L5 radiculopathy. (<u>Id.</u> at K.S. 0561.) Dr. Przybylski, however, stated that the EMG report, also of September 20, 2010, was a better indicator for any L5 abnormality, which reported a normal result. The treatment plan consisted of three cervical epidurals, which were done on September 25,

2010, November 13, 2010, and January 7, 2011. In follow-up consultation on February 21, 2011, it was noted that the same symptoms appeared as in the prior consultations.

A two-level epidural injection was performed on March 18, 2011, April 8, 2011, and May 7, 2011. The follow-up consultation on June 21, 2011, revealed the same results. Respondent's plan of treatment was a lumbar discogram at L2-L3, L3-L4, L4-L5, and L5-S1. This was performed on July 16, 2011, where concordant lumbar discs at L4-5 and L5-S1 were noted. L2-3 and L3-4 were asymptomatic. A CT discogram of the lumbar spine was performed on July 16, 2011, which revealed a grade-three annular tear at the L2-L3 level, grade-two annular tear at the L3-L4 level, and grade-four annular tears at the L4-L5 and L5-S1 levels. (Id. at K.S. 0115.)

On September 23, 2011, respondent performed surgery, which included foraminoplasty (changing the shape of foramen) at the L4-5 and L5-S1 levels, thermal ablation of the annulus (which Dr. Przybylski explained was a laser application of heat), and autograft. (Id. at K.S. 0141.) Dr. Przybylski stated that this was a minimally invasive procedure, although done percutaneously. In a follow-up consultation on October 17, 2011, the patient still had the same complaints of pain in the head, neck and upper extremities as when previously seen by respondent on August 23, 2011. Respondent rendered a treatment plan consisting of a cervical discogram at C3-C4, C4-C5, C5-C6 and C6-C7. On December 3, 2011, a provocative cervical discogram at C3-4, C4-5, C5-6 and C6-7 was performed, with the conclusion that the patient had concordant discs at the C3-4, C4-5 and C5-6 levels. (Id. at K.S. 0153.)

On December 19, 2011, respondent performed a further operative procedure with a pre-operative diagnosis of cervical disc herniation and concordant cervical discogram at the C3-4, C4-5 and C5-6 levels. The operation consisted of an anterior cervical discectomy/fusion at the C4-5 and C5-6 levels with autograft bone, anterior plates, allograft and PEEK cages, iliac-crest bone graft, local autograft, bone-marrow aspirate, and reconstruction of the ilium using Vitoss. (Id. at K.S. 0539.) Dr. Przybylski described the procedure as an open operation for harvesting the iliac crest and for the use of Vitoss. In the report of December 19, 2011 (Id. at K.S. 0877), under the section "Neuro," no reasons were noted for the spinal surgery, only that the patient was alert and oriented.

According to the anesthesia record, the surgery lasted almost four hours. (Id. at K.S. 0905.)

Dr. Przybylski opined the following deviations:

- 1. A two-level microdiscectomy, a minimally invasive procedure for discmaterial removal, was performed on September 23, 2011, which was not the appropriate treatment for a painful disc. According to the EMG study, there was left L5 radiculopathy on one side and no reason for a two-level decompression of the nerve root. This constituted a gross deviation.
- 2. An open surgery was performed for the iliac bone graft, including discectomy/fusion for which respondent was not adequately trained. Based upon clinical history and examination, there was no indication for a three-level surgery. This constituted a gross deviation.
- 3. Respondent's failure to have hospital privileges, or at least a signed agreement with other doctors with hospital privileges, constituted a gross deviation since there existed risk of injury to the carotid artery, pharynx, esophagus and vertebral artery.

Dr. Przybylski was then asked about respondent's treatment of patient <u>H.S.</u> Among the documents reviewed were respondent's records, operative reports and imaging studies.

A prior MRI of the lumbar spine, performed on December 6, 2010, revealed left posterolateral herniation of the L4-L5 intervertebral disc impinging upon the medial aspect of the left neural foramen causing moderate stenosis and impinging upon the left L4 nerve root. There was also a posterior bulge of the L5-S1 intervertebral disc causing mild stenosis of the bilateral neural foramina. An MRI of the cervical spine was also performed that same day which indicated a posterior bulge of the C4-C5 intervertebral disc effacing the thecal sac. The impression also included an anterior bulge and right paracentral posterior herniation of the C5-C6 intervertebral disc impinging upon the thecal sac and the

underlying cervical spinal cord causing moderate stenosis of the spinal canal. Also, there was a posterior bulge of the C6-C7 intervertebral disc impinging upon the thecal sac causing mild stenosis of the spinal canal and causing moderate stenosis of the left neural foramen. (P-53 thru P-54 at H.S. 0001-0004.)

At the initial consultation with respondent on July 5, 2011, the patient reported being in an automobile accident on September 17, 2010. The patient had continuing complaints of significant pain in the head, neck, left arm, mid-back, lower back and right leg. The patient also complained of numbness and tingling in the left arm, numbness and tingling in the right leg, weakness in the left arm and weakness in the right leg. The patient also stated that he was asymptomatic before the accident, but following the accident had difficulty with sleep and daily activities and had difficulty getting from a sitting to a standing position. The sensory examination revealed C5 dermatome of the left upper extremity and L4 dermatome of the right lower extremity. Respondent's treatment plan was for three transforaminal epidural injections to be carried out with epidurograms under fluoroscopic control on the right side at the L4-L5 and L5-S1 levels, a bilateral EMG/NCV of the upper and lower extremities. On August 6, 2011, respondent performed transforaminal epidural at the L4-5 and L5-S1 at the NJSR Center. He performed an EMG on September 13, 2011, which indicated bilateral C5 and C6 radiculopathy. (Id. at H.S. 0006 to 0011.) The report concluded that there was no evidence of lumbar radiculopathy. (Id. at H.S. 0017.) Dr. Przybylski came to the same conclusion based upon the raw data for EMG testing.

Under respondent's treatment plan, the patient, on August 6, September 10, and September 24, 2011, received transforaminal epidural injections at the L4-5, L5-S1 foramens on the right side at the NJSR Center, even though, according to Dr. Przybylski, there was no evidence of radiculopathy at the L4-L5 level. (Id. at H.S. 0010 to 0028.)

On November 19, 2011, Nasar Shahid, M.D., also of the NJSR Center, performed provocative lumbar discograms at L2-3, L3-4, L4-L5 and L5-S1. The postoperative diagnosis was concordant lumbar discs at L3-4, L4-5 and L5-S1. (<u>Id.</u> at H.S. 0031.)

On the same date of November 19, 2011, a CT of the lumbar spine, post discogram, indicated an abnormal signal at the L2-3 level, which Dr. Przybylski did not confirm based upon respondent's handwritten notes for the EMG test previously done.

On December 21, 2011, the patient underwent surgery for lumbar decompression and interbody fusion of the left cage at the L4-5 level, discogram for tissue identification, iliac-crest bone graft, bone-marrow aspirate, insertion of segmental pedicle screws bilaterally at the L4 and L5 pedicles, and injection of a caudal epidural for postoperative pain relief. (Id. at H.S. 0044.)

According to Dr. Przybylski, respondent performed an open surgery for iliac-crest harvest, which he based upon respondent's note that a midline incision was made and a tissue flap was created to the left, using Bovie and Metzenbaum scissors, and that the ilium was opened with a chisel. He also referred to the insertion of a surgical endoscope through one of the portals, the insertion of working instruments through the other portal, and decompression for the remaining nucleus pulposus as a minimally invasive technique. Also included was the report's further description of an appropriate-sized rod placed into the screw-insertion sleeves and into the heads of the screws.³

According to the anesthesia record, the surgery lasted one hour, forty minutes. (<u>Id.</u> at H.S. 642.) In respondent's records there was a receipt from Spineology for the delivery of one OptiMesh. (<u>Id.</u> at H.S. 658.) Dr. Przybylski noted that the right-side L5 pedicle screw was not placed correctly.

Dr. Przybylski opined the following deviations:

1. The third epidural injection recommended by respondent was unnecessary. The imaging study showed no abnormality at the L4 root, L5 foramen, or L5 root at S1 foramen.

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³ He also noted that the December 21, 2011, operative reports of respondent and the co-surgeon, Nasir Shahid, M.D., were identical to each other, or at least exceedingly similar.

- 2. A three-level or more fusion was not indicated. This constituted a gross deviation.
- 3. Respondent performed a minimally invasive technique for lumbar fusion, for which he was not adequately trained, constituting a gross deviation.
- 4. The use of a mesh cage for interbody space support at the L4-L5 level constituted a gross deviation.
- 5. The malpositioning of the screw should have led respondent to seek further imaging at different angles. This was not done, which constituted a moderate deviation.
- 6. The third epidural and lumbar fusion were not indicated and, coupled with the risk of complications for the patient for performing this procedure when not necessary, constituted a gross deviation.
- Dr. Przybylski commented that the patient was put at risk for nerve-root injury, which could be permanent; nerve and blood vessel injury; and, with regard to the iliac crest, nerve damage and bowel disruption.
- Dr. Przybylski was then asked to render an opinion about respondent's treatment of patient **S.S.** Among the documents he reviewed were respondent's records, operative reports, and imaging studies.

At the initial consultation on August 1, 2007, the patient complained of neck, left arm, lower-back and right-leg pain. He was a fifty-three-year-old male who had a history of fifteen-year pain in his lower back and right leg. He now had complaints of pain, numbness and tingling in the right leg with some difficulty walking, exacerbated by coughing and sneezing. The patient also complained of headaches and some pain in the neck going into the left shoulder. He had received epidurals in the past and was a smoker. (P-57 thru P-70 at S.S. 0001.)

Respondent ordered MRIs of the lumbosacral and cervical spines followed by a treatment plan, which consisted of a series of three caudal epidurals and bilateral SI sacroiliac-joint injections. The last of the injections was performed on April 9, 2008. (<u>Id.</u> at S.S. 0039.)

In a follow-up consultation on July 9, 2008, the patient reported that relief from the injections had worn off and that pain in his low back and leg had returned. Respondent's treatment plan consisted of three intradiscal injections at the L5-S1 level. (<u>Id.</u> at S.S. 0043.)

In a follow-up consultation on October 1, 2008, the patient still complained of pain in the lower back. Subsequent electrophysiological evidence indicated bilateral L5-S1 radiculopathy. (<u>Id.</u> at S.S. 0055.)

On February 7, 2009, at the Bergen Passaic Ambulatory Surgery Center, respondent performed a provocative lumbar discogram at L2-3, L3-4, L4-5, and L5-S1. His post-operative diagnosis was concordant disc L5-S1. The other levels were asymptomatic. On CT of the lumbar spine on February 7, 2009, the conclusion was "a thin regenerative herniation at L5-S1 extending laterally to the right side, with some mild L5 nerve root encroachment." (Id. at S.S. 0064.)

On April 17, 2009, while at the Bergen Passaic Ambulatory Surgery Center in Clifton, New Jersey, respondent performed a lumbar laminectomy, microdiscectomy and interbody fusion at the L5-S1 level with an interbody mesh cage with allograft bone, and insertion of transfacet pedicular screws into the L5 pedicles bilaterally, among other procedures. In the operative report under "Details of Procedure," respondent wrote, "A minimally invasive approach was used to access the posterior elements of the spine and carry out the subsequent decompression and fusion." (Id. at S.S. 0079.) He then added, "Atavi minimally invasive retractor system was then advanced down onto the posterior bony elements of the spinal column." (Ibid.) The report further stated, "Approximately four tubes of allograft bone were tapped into the space and the mesh cage was disconnected from the driver," "transfacet pedicular screws were then inserted into the pedicles at the L5

level," and "Kirschner wire was used to drill through the facet into the pedicle." (<u>Id.</u> at S.S. 0080, 0081.) Dr. Przybylski opined that this was a minimally invasive fusion technique.

On August 5, 2009, respondent performed an EMG/NCV, which indicated normal limits and no evidence of a lumbar radiculopathy on the left or right. Dr. Przybylski confirmed this normal finding on the EMG report. But on August 31, 2009, an MRI of the lumbar spine, with contrast, found post-operative changes at L5-S1, no evidence for a recurrent or residual disc herniation at this level, and some enhancing epidural fibrosis (scar tissue). (Id. at S.S. 0101.)

On October 31, 2009, respondent, at the Bergen/Passaic Ambulatory Surgery Center, performed a selective transforaminal nerve root block at the L5-S1 level on the right side, and neurogram of the nerve-root sheath, L5-S1, on the right side. (<u>Id.</u> at S.S. 0111.) Again, on November 21, 2009, and December 5, 2009, also at the Bergen/Passaic Ambulatory Surgery Center, respondent repeated the same procedure.

According to Dr. Przybylski, if there were no improvement after the first procedure, it would have been appropriate for respondent to try a different injection and also to inject a different area.

According to a CT of the lumbar spine on May 5, 2010, status post L5-S1 fusion with pedicular screws at L5-S1, there was the appearance of resorption of the interbody bone graft at L5-S1 towards the right side, and fusion towards the left side was not seen at L5-S1. (Id. at S.S. 0125.) Dr. Przybylski explained that this meant that the bone material placed was disappearing and that there was no longer evidence of the fusion performed on April 17, 2009.

On December 9, 2011, respondent, while at the NJSR Center in Pompton Lakes, New Jersey, performed a lumbar decompression and fusion revision at the L5-S1 level; iliac-crest bone graft; local autograft; allograft bone; bone-marrow aspirate; reconstruction of ilium using Vitoss; removal of facet screws at the L5 pedicles, and insertion of pedicle screws and rods bilaterally at the L5 and S1 pedicles. (Id. at S.S. 0182–0183.) Dr. Przybylski stated that exposure of the iliac crest with the use of Bovie and Metzenbaum

scissors was an open procedure. Removal of the lumbar facet screws, insertion of an interbody mesh graft into the intervertebral space packed with allograft bone, use of a Jamshidi K-wire guided system, and insertion of screws on the left and right sides was a minimally invasive technique. There was a receipt from Spineology dated December 9, 2011, for one OptiMesh (<u>Id.</u> at S.S. 1468), which Dr. Przybylski found to be consistent with the mesh cage mentioned in the operative report.

On December 13, 2011, respondent again performed a procedure, also at the NJSR Center, four days after the December 9, 2011, surgery, consisting of a transforaminal epidural at the L5-S1 foramens on the right side and a caudal epidural. Respondent indicated ongoing symptomatology in the mid-lower back and right-lower extremity. (Id. at S.S. 0191.)

A report of a CT scan on December 14, 2011, at L5-S1 indicated:

there is a mild disc osteophyte complex, worse in the right foraminal region. Facet joint degeneration changes are noted. There is mild left foraminal stenosis. There is moderate right foraminal stenosis with impingement of the right exiting L5 nerve root. There is no significant spinal stenosis given the posterior laminectomy at this level. There were a few small pockets of air (which Dr. Przybylski stated was evidence of recent surgery) seen lateral to the right L5 vertebral body and anterior to the sacrum on the right. There is posterior dependent subcutaneous soft tissue edema with . . . fluid collection within the subcutaneous soft tissue at the level of L5.

[ld. at S.S. 0194.]

Dr. Przybylski noted that this was the area where respondent performed surgery.

Upon reviewing this CT scan, Dr. Przybylski noted that there were two surgeries at the L5-S1 level, one on April 17, 2009, and the other on December 9, 2011. Decompressions were done, and yet there was still nerve-root impingement. He noted that the CT scan did not mention screw fixation.

On December 19, 2011, respondent performed another surgery with a preoperative diagnosis of malpositioned right S1 pedicle screw. (<u>Id.</u> at S.S. 0196.) The surgical procedure consisted of the removal of pedicle screws on the right side at the L5 and S1 pedicles and injection of GPS autograft. (<u>Ibid.</u>) Respondent used Bovie and Metzenbaum scissors and carried out a dissection down to the screws on the right-hand side. The screw had breached the pedicle and the hardware on the right side was removed. (<u>Id.</u> at S.S. 0196 to S.S. 0197.) Dr. Przybylski opined that this was an open operation for the L5 and S1 pedicle screws.⁴

Dr. Przybylski opined the following deviations:

- 1. The patient underwent a number of percutaneous procedures, some of which were unnecessary. Further, treatment involved an open bone-graft harvest with a minimally invasive procedure with instrumented screws and mesh cage for interbody at L5-S1 space. This was a gross deviation.
- 2. Respondent failed to document that the patient, who was a smoker, understood the risks of using allograft bone. This was a gross deviation.
- 3. Although the revision surgery was not unreasonable, respondent was not adequately trained to perform either the original or the revision surgery. This constituted a gross deviation.
- 4. The use of the mesh cage and the removal of the L5 and S1 screws through an open approach were gross deviations.

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⁴ He also noted that the operative report of the co-surgeon, Nasir Shahid, M.D., was identical to, or extremely similar to, the report rendered by respondent of the same date. Since he could not determine who copied the other's report, he offered no opinion except to state that this was irregular, since each physician had to write a separate report based upon his or her own independent findings.

Dr. Przybylski explained that three operations increased the risk of scarring (epidural fibrosis), hence increased symptoms to the nerves, including numbness, weakness and/or pain.

Dr. Przybylski was then asked to render an opinion about respondent's treatment of patient **J.Z.**

On November 24, 2010, J.Z. consulted respondent for pain associated with severe chronic angina. There was a past medical history of severe coronary artery disease. After three rounds of thoracic epidural injections at the T3-4 level were ineffective (patient reported that he had no improvement after the second), respondent's treatment plan consisted of the insertion of a trial spinal-cord stimulator. (P-71 thru P-73 at J.Z. 0104.)

Dr. Przybylski stated that an epidural injection was commonly used for radicular pain, but here, with many areas of pain, he felt that an epidural would not have been effective. Although a first injection would have been appropriate, if the first were ineffective, subsequent injections were not necessary since they put the patient at risk of spinal-cord injury. He opined that this was a gross deviation, particularly at the thoracic area, where the spinal canal is at its narrowest compared with other areas of the spine.

On May 6, 2011, the patient returned to the NJSR Center for the insertion of a "temporal" (according to Dr. Przybylski, this was a typographical error in the record, which should have read "temporary") dorsal-column-stimulating trial lead in the patient's epidural space at the T7 level. (Id. at J.Z. 0137.)

In follow-up consultation on May 10, 2011, respondent noted that the patient had an 80 to 90 percent improvement in his pain level subsequent to the insertion of the trial spinal-cord stimulator and that the patient wanted to proceed with the insertion of a permanent stimulator. Respondent's treatment plan was for the insertion of two eight-electrode permanent dorsal-column-stimulation leads. (Id. at J.Z. 0130.)

On May 23, 2011, at the NJSR Center, respondent inserted two permanent spinal-cord stimulator leads into the epidural space at the T5 level. (<u>Id.</u> at J.Z. 0144.)

In a follow-up consultation on May 31, 2011, the patient reported that coverage from the stimulator was not adequate and that there was pain in the low back and legs. (Id. at J.Z. 0135.) An x-ray indicated that the lead on the right-hand side had dislodged and moved from the T5 level down to the T9 level. Respondent's notes further indicated that the patient was advised of the dislodgement of the lead and the need to reposition or remove this lead and to reinsert a new lead to obtain coverage up to the T5 level. (Id. at J.Z. 0136.)

On June 8, 2011, respondent removed the displaced right dorsal-column-stimulating lead and inserted a new lead. In his report, respondent mentioned that the "displaced lead was found to have retracted into the space and the anchoring device seemed to have migrated inferiorly." (Id. at J.Z. 0148.) He inserted a new eight-electrode lead through a needle, which was advanced under fluoroscopic guidance up to the T5-T6 level on the right side.⁵ (Ibid.)

At a follow-up consultation on June 14, 2011, respondent noted that there was good coverage both over the back and down both legs, since the patient was not complaining of leg pain. (<u>Id.</u> at J.Z. 0139.)

Then, on July 16, 2011, the patient was admitted to Chilton Memorial Hospital with chest pain. While there, a discharge was noted at the stimulator site. (<u>Id.</u> at J.Z. 0161.) A diagnosis of "methicillin-sensitive staphylococcus aureus" (which Dr. Przybylski described as a wound infection at the site of the stimulator implant) was made. (<u>Id.</u> at J.Z. 0163.) In the records of Chilton Memorial Hospital, it was noted that since respondent inserted the stimulator, he was called and updated about the patient's condition. The patient was discharged on July 19, 2011. Dr. Przybylski cautioned that, with this type of infection, respondent should have removed the device the day he was notified or first thing the next morning, since paralysis could have resulted. However, it was not until July 21, 2011,

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⁵ Dr. Przybylski noted that the report of co-surgeon, Michael McKee, M.D., was identical to the report of respondent.

when respondent saw the patient, that a plan was made for the removal of the leads and stimulator. Dr. Przybylski did not find any records to confirm removal.

Dr. Przybylski opined the following deviations:

- 1. The performance of two further epidural injections was not indicated. This was a gross deviation, putting the patient unnecessarily at risk for spinal-cord injury.
- 2. Since the patient was admitted to a hospital a month after the surgery, with infection at the site of the stimulator and leads, respondent's failure to take immediate action to remove them constituted a gross deviation.

Dr. Przybylski was asked to render an opinion about respondent's treatment of patient **T.Z.** He reviewed respondent's records, imaging studies, and operative reports.

At the initial consultation on January 21, 2010, T.Z., a thirty-six-year-old female, reported that she was involved in an automobile accident on December 21, 2009. Immediately following, she began to experience pain in the head, neck, left arm, lower back and right leg, with numbness and tingling in the left arm and right leg. She also complained of weakness in the left shoulder, left wrist and right hip, and dizziness and headaches. She also had some episodes of nausea and vomiting, and further stated that coughing, sneezing and going to the bathroom made the pain worse. Prior to the accident, she had been asymptomatic. The initial consultation report noted that the patient was a smoker and had previously undergone a surgery in 2007 for total disc replacement at the L4-5 level. Otherwise, her past medical history was non-significant. (P-74 thru P-88 at T.Z. 0188.)

Respondent ordered an MRI of the cervical and lumbar spine, a bilateral EMG/NCV of the upper and lower extremities, vestibular-function testing to address the dizziness and headaches, and physical therapy three times a week for the next four weeks. (<u>Id.</u> at T.Z. 0188 to 0190.)

On an MRI of the lumbar spine on February 24, 2010, the radiologist noted an artifact at the L5-S1 level (<u>Id.</u> at T.Z. 0191), presumably related to a prosthesis, although Dr. Przybylski found that respondent's notes indicated a total disc replacement at the L4-L5 level instead. The radiologist noted desiccation at L4-5.

In a follow-up consultation on March 25, 2010, respondent's treatment plan consisted of three caudal epidurals for bilateral C5-C6 radiculopathy and bilateral L5-S1 radiculopathy. In the EMG report, also of March 25, 2010, Dr. Przybylski noted that the raw data indicated a normal result at the L4-5 and L5-S1 levels. (<u>Id.</u> at T.Z. 0195 to 0202.)

On May 7, 2010, the patient received a lumbar caudal epidural injection in the lumbar spine, which was repeated on May 21, 2010, and August 6, 2010. (<u>Id.</u> at T.Z. 0196.) Although the patient indicated a decrease in pain by approximately 10 percent after the second injection, respondent proceeded with a third injection. (<u>Id.</u> at T.Z. 0211.)

In a follow-up consultation on September 9, 2010, the patient reported limited reduction of pain in her legs. Respondent's motor examination indicated "some weakness over the right hip flexors at 4/5 and over the left shoulder adductors at 4/5." (Id. at T.Z. 0214.) His treatment plan was for a series of three bilateral lumbar facet injections at the L4-L5 and L5-S1 levels. (Id. at T.Z. 0215.)

On October 8 and November 13, 2010, respondent performed bilateral lumbar facet injection at L3-L4, L4-L5 and L5-S, and lumbar facet arthrogram at L3-L4, L4-L5, and L5-S1. (Id. at T.Z. 0216 to 0221.)

On January 8, 2011, in follow-up consultation, respondent noted that the patient had no decrease in pain from the second treatment.

On July 20, 2011, a provocative lumbar discogram at the L1-2, L2-3, L3-L4, and L4-5 foramens was performed, with a post-operative diagnosis of concordant lumbar discs at L3-4 and L4-5. (Id. at T.Z. 0237.)

On August 9, 2011, in follow-up consultation, respondent's treatment plan was for a lumbar decompression and interbody fusion at the L3-L4 and L4-L5 levels with the use of an iliac-crest bone-marrow harvest, GPS autograft, and bilateral pedicle screws from L3 down to S1. (Id. at T.Z. 0245.)

On September 19, 2011, at the NJSR Center, respondent performed a lumbar decompression and interbody fusion at the L3-4 level using a PEEK cage, iliac-crest bone-marrow harvest and autograft, GPS autograft, bilateral pedicle screws from L3 down to S1 on the right side and L3 to L4 on the left side, caudal epidural injection with epidurogram for post-operative relief, and reconstruction of the iliac crest using Vitoss, among other procedures. (Id. at T.Z. 0253.)

In the operative report, respondent noted that he made a small incision over the posterior superior iliac spine on the left-hand side and dissection was carried down to the bone using Bovie and Metzenbaum scissors, identifying the posterior superior iliac spine. A bone-marrow aspirate was also obtained. (<u>Id.</u> at T.Z. 0254.) Dr. Przybylski opined that this was an open exposure with reconstruction of the iliac-crest site.

Respondent's operative report indicated that access was obtained to the intervertebral disc using a biportal technique with the initial introduction of an eighteen-gauge, ten-inch needle, and that over guide wire a set of serial dilators were advanced into the intervertebral disc space. An expandable PEEK cage was inserted with the use of a midline incision. Pedicle screws were inserted on the right side at the L3, L4, and S1 levels with the insertion of a rod. Pedicle screws were inserted on the left side at the L3 and L4 levels. (Id. at T.Z. 0255.) According to Dr. Przybylski, this was a minimally invasive procedure.

Respondent further noted that pedicle screws could not be safely inserted at the L5 or S1 levels and the construct on the right-hand side extended from L3 to S1. Again, Dr. Przybylski opined that respondent should not have been using screws, based upon his lack of adequate training. According to the anesthesia record, the surgery lasted almost four hours. (<u>Id.</u> at T.Z. 0924.)

On November 2, 2011, the patient met in consultation with Nasar Shahid, M.D. She stated that a few days after respondent's surgery, she had to be hospitalized because of her inability to walk. Her CPK count (which Dr. Przybylski described as an enzyme emitted due to muscle injury) was more than 2,000, which Dr. Przybylski explained was exceedingly high. T.Z. also had complaints of knee pain since the surgery and a tingling sensation on the inner side and front of the left thigh. She also reported walking with the use of a cane and brace.

Dr. Shahid recommended an x-ray of the lumbar spine, and EMG and nerve-conduction studies of both lower extremities "to rule out femoral nerve involvement or root pathology." (<u>Id.</u> at T.Z. 0259.) On October 14, 2011, T.Z. underwent an electrodiagnostic examination to evaluate for lumbosacral radiculopathy. The impression was right S1 and acute bilateral L2 and/or L3 radiculopathy. (<u>Id</u> at T.Z. 0168.)

Dr. Przybylski found that, according to the raw data of this test, there was radiculopathy at L2-L4 bilaterally and on the right side of S1-2. (<u>Id.</u> at T.Z. 0169.) This was evidence of nerve compression, dysfunction or damage not previously seen.

On November 17, 2011, T.Z. consulted with George S. Naseef III, M.D., an orthopedic spine surgeon. A CT scan of the lumbar spine on December 8, 2011, indicated that there were two different intervertebral disc spacers, one at the L3-L4 level and the second at L4-5. There was also a rudimentary disc at L5-S1, which Dr. Przybylski explained was a non-fully formed or functional disc. The CT scan further indicated that a portion of the intervertebral disc plug at the L3-L4 level extended beyond the lateral margin of the vertebral body cortex into the medial aspect of the neural foramen at L3-L4, which Dr. Przybylski explained meant that the fusion material extended beyond the footprint of the vertebral body. (Id. at T.Z. 0155 to 0156.)

Further findings indicated that a portion of the left L-3 pedicle screw traversed the left lateral canal along the superior aspect of L-3 on the left, which Dr. Przybylski explained meant that the L-3 screw was inside the spinal canal, hence the L-3 nerve was affected. Further findings indicated that the left L-4 pedicle screw traversed the left lateral margin of the canal, which Dr. Przybylski explained meant that the L-4 nerve was affected. The

report further found that the right S-1 screw extended into the right canal and neural foramen and extended into the lateral recess, where it likely impinged on the S1 nerve root, which Dr. Przybylski opined was consistent with the EMG and the raw data for the EMG. (<u>Ibid.</u>)

Also, on the same date of December 8, 2011, an MRI of the lumbar spine was performed which revealed "some ankylosis on the left at the left L5-S1 facet joint with possible partial ankylosis on the right with generalized degenerative changes of facets at multiples levels." (Id. at T.Z. 0157.) Dr. Przybylski noted that ankylosis, a natural fusion of the facet joints, indicated that L5-S1 was never functional. The report further found that the right-sided S-1 screw extended through the right-sided spinal canal into the sacrum and likely into the lateral recess of the S-1 nerve root on the right. There was also mention of a portion of a screw traversing the lateral aspect of the canal at L-3 along the superior aspect. The radiologist advised that a personal evaluation be done. (Id. at T.Z. 0157.) The patient refused to return to respondent.

On January 30, 2012, Dr. Naseef performed surgery at Morristown Memorial Hospital with a preoperative diagnosis of malposition of hardware, painful hardware, lumbar stenosis, bilateral lower-extremity radiculopathy and pseudoarthrosis (lack of fusion). (Id. at T.Z. 0127.) The surgical procedure included "Exploration of fusion; removal of instrumentation, L3-S1; revision posterior instrumented fusion, L3-L5; L3-L5 laminectomy; bilateral laminal foraminotomies, L3-L4, L4-L5; use of local bone graft with Infuse," the latter of which Dr. Przybylski explained was genetically made material that stimulates bone production. (Id. at T.Z. 0127.) Dr. Naseef further noted in his operative report that "it became evident that the left L3 and L4 screws were directly in the canal. The right L3 nerve root with the screws were obtained in the canal and the right S1 screws directly in the canal. These were all removed." (Id. at T.Z. 0129.)

Dr. Przybylski opined the following deviations:

1. Performing percutaneous procedures involving a third epidural injection and a lumbar facet injection when there was no improvement after the second injection

was a gross deviation since there was no need to proceed with a third injection, placing the patient at risk for injury to the nerve roots.

- 2. Respondent's performance of an open harvest of the iliac bone graft was a gross deviation since he was not sufficiently trained. The patient was at significant risk for injury to the bowel, nerve root and blood vessels. The patient did, in fact, experience nerve injury.
- 3. The improper screw positions, and screws needing to be removed surgically, constituted a gross deviation. The patient sustained an injury in a procedure that was not necessary.
- 4. Resultant muscle damage, as indicated by the severely high CPK reading, constituted a gross deviation.
- 5. Respondent's lack of training in performing these procedures constituted a gross deviation.
- Dr. Przybylski further commented on risks for this patient resulting from fixation, such as stiffening of the lower portion of the spine, which could lead to L-2, L-3 stenosis and instability in this thirty-nine-year-old patient, whose life expectancy was for several more decades. He further opined that there was a high likelihood that she will need further treatment in her lifetime.

In summary, Dr. Przybylski's opinions were based upon his review of the medical records of respondent, imaging reports, respondent's curriculum vitae, the websites of associations in which respondent was a member, CME courses taken by respondent, respondent's lack of residency training in orthopedics or neurosurgery, and the internships noted by respondent, since they would not have provided training for minimally invasive surgery or open surgery. With regard to the one-year pain fellowship in 1995–1996 in England listed by respondent in his curriculum vitae, Dr. Przybylski was unable to tell what the fellowship consisted of, but mentioned that a one-year fellowship in the United States would not have been sufficient to train for surgery with instrumentation. Dr. Przybylski also

relied upon his own education, training and experience, as well as the guidelines contained in the medical literature produced, with which he was extremely familiar.

On cross-examination, Dr. Przybylski mentioned that the clinical guidelines, coupled with his training and experience, led him to his conclusions regarding respondent's deviations. While he acknowledged that the term "guideline" has a different ordinary English meaning than the term "standard," he added that, in the medical profession, "guideline" offers a significant basis for assisting physicians and a much higher significance than a simple English translation of the term.

He acknowledged that "off-label" use, which he defined as the use of a product differently from the way the FDA had approved it, was not unusual. While OptiMesh is considered "off label," he has used "off-label" products in his own practice. Due to the extensive time needed for FDA approval, "off-label" devices were sometimes used. Even pedicle screws used in spinal procedures could be "off label." Dr. Przybylski added that the use of an "off-label" product was in the discretion of the physician.

He was asked about his past experience as an expert witness. He mentioned that his involvement consists of approximately two cases per month. Over the past ten years, about 60 percent of his retainers were for plaintiffs/petitioners and 40 percent for the defense. However, in the past five years, it has evened to 50-50. When asked about spinal fusions, he acknowledged that there remains some controversy among physicians about when to perform a spinal fusion, even among members of the North American Spine Society.

While Dr. Przybylski was critical of respondent's use of discography, he acknowledged that discography is one of several tests available to determine the source of pain, which also includes CT scans with and without contrast, MRIs, and patient response to facet blocks, as well as nerve-root blocks.

When asked about credentialing, Dr. Przybylski acknowledged that there could be differences among hospitals in credentialing, but added that when he sought privileges at

JFK Medical Center, he was monitored by a thoracic surgeon on one or more cases to ensure his competence.

He mentioned that there has been a significant change in minimally invasive surgery since 2005. As a result, CME classes have become more essential. However, he reiterated that mere attendance at a CME course does not lead to a certification for the performance of minimally invasive surgery; it satisfies licensure requirements. He was also aware that certifications were available in spine surgeries outside the American Board of Medical Specialties.

Andrew Kaufman, M.D.

The next witness produced by petitioner was Andrew Kaufman, M.D., a board-certified anesthesiologist, with a sub-certification in pain medicine. Dr. Kaufman graduated from the University of Virginia medical school in May 1988, served an internship at Cabrini Medical Center in New York, and then did a residency in anesthesiology at Columbia-Presbyterian Medical Center. This was followed by a fellowship in pain management at Harvard University. He has hospital privileges at several hospitals, including University Hospital in Newark, where he has been serving as the divisional director of the Comprehensive Pain Center since January 2004. He has been co-medical director of the Pain Management Center at Overlook Medical Center from September 2006 to the present. Prior to that, he had hospital privileges at other hospitals in New Jersey, New York and Pennsylvania. He is certified by the American Board of Anesthesiology as well as the American Board of Anesthesiology-Pain Management. He has received numerous awards and honors, has published, and has been a presenter at several seminars. He has never had any adverse action taken against his medical license or his hospital privileges.

For the past twenty years, he has been specializing in interventional pain management, consisting of several modalities, such as spinal-cord-stimulator trials, minimally invasive lumbar decompression, radio-frequency ablations usually for facet joints, cervical and lumbar epidural injections, as well as administering discographies. On average he has performed thirty spine-related procedures a week over the past ten years.

The procedures he uses are predominantly percutaneous, the use of needles through the skin, performed under fluoroscopic guidance. In distinguishing the difference between open spinal surgery and minimally invasive fusion, he stated that in open spinal fusion, a scalpel is used to open the site to visualize the structures. In minimally invasive spinal fusion, the procedure is usually done through a tube to visualize the involved area.

After reviewing respondent's curriculum vitae, Dr. Kaufman opined that respondent was not competent to perform open or minimally invasive spinal surgeries, based upon respondent's lack of training, the continuing medical education courses he had taken and his patient records. He also reviewed a transcript of the proceedings before the Board of Medical Examiners on February 3, 2010. Nowhere in respondent's curriculum vitae did it indicate that he was trained as a fellow in spine surgery, particularly for open or minimally invasive surgeries.

He commented that CME credits, although required for licensure, do not qualify the attending physician to perform spinal surgeries. In order to be qualified, the physician must undergo extensive training, which is monitored by another physician, expert in that area of medicine. It was Dr. Kaufman's opinion that with respondent's training and background, he would not be given privileges at a hospital for either open or minimally invasive surgeries. For privileges, the physician must be clinically competent, which is only attained after proctoring by an expert in the given field. Respondent's curriculum vitae failed to present any such clinical experience.

Dr. Kaufman opined that respondent deviated from the standards of medical care in performing open spinal and minimally invasive spinal surgeries since he was not properly trained, nor had he taken any board examinations to demonstrate any competency.

Dr. Kaufman was then asked about respondent's care of patient J.Z. This patient was referred to Dr. Kaufman by a neurosurgeon for chronic pain in his chest and upper back. At first, Dr. Kaufman prescribed pain medication. When that did not work, the referring neurosurgeon (Dr. Campella) inserted a pump in the patient's spine at the direction of Dr. Kaufman to release pain medication.

Dr. Kaufman opined that the cause of the patient's back pain was nerve damage since J.Z., who had non-cardiac angina, was without back pain when he first saw respondent. Since then, the patient had been suffering from chronic regional pain syndrome (CRPS), which he opined was caused by an infection from the spinal-cord-stimulator lead inserted by respondent, which was not removed immediately when infection was noted. Dr. Kaufman emphasized that once infection was diagnosed, the immediate removal of the implant was critical.

On cross-examination, Dr. Kaufman stated that as a licensed physician he was allowed to perform any medical procedure, including surgery. However, in order for a physician to have hospital privileges, he or she must prove competency.

He further stated that spinal surgery was not included in the specialty of anesthesiology. Therefore, if an anesthesiologist sought to perform minimally invasive spinal surgery, a fellowship was necessary for extensive training under supervision. Even before the fellowship, that physician must have had prior training in spine surgery.

He mentioned that he has performed percutaneous discectomies over the past twelve years, which he qualified as minimally invasive surgery. In those procedures, a needle was inserted to remove material from the spine to relieve pressure. No sutures were involved. He also performed vertebroplasty as a percutaneous procedure.

Again referencing respondent's curriculum vitae, he stated that a two-week course in Seoul, Korea, such as that taken by respondent, would not qualify him to perform surgery, including the insertion of PEEK cages or pedicle screws.

He was asked about minimally invasive lumbar decompression. In performing this procedure, a punch incision is made for the insertion of a needle. Afterwards a steri-strip is used to close the wound. Usually, no stitches are required. The procedure is done under x-ray or fluoroscopic guidance with sedation, not general anesthesia. In performing this procedure, there is no direct visualization of the spine.

With regard to J.Z., he reiterated that when the site of an implant in the spinal area becomes infected, as it did with this patient, it is imperative to have the implant immediately removed, and the wound area washed. He acknowledged that he was unsure when respondent learned of the infection and the date it was ultimately removed.

Dr. Kaufman noted that respondent's curriculum vitae stated that he had returned to England and completed a pain-management fellowship at Bristol Royal Infirmary in 1995–1996. However, he mentioned that the Accreditation Council of Graduate Medical Education (ACGME) did not recognize this training. He also noted that respondent became a diplomate of the American Board of Anesthesiology in 1996, which he felt made respondent a competent anesthesiologist. However, respondent's curriculum vitae did not indicate any training for minimally invasive spinal surgery, including total discectomy with the placement of cages/spacers or the placement of pedicle screws. He further stated that these techniques would ordinarily be part of the training for an orthopedic surgeon or a neurosurgeon, both having specific fellowship programs after the completion of their residencies.

He opined that respondent's performance of total discectomies and fusions with the use of pedicle screws in both the lumbar and cervical spines exceeded the limits of interventional pain management and put patients at great risk, thereby constituting a gross deviation from accepted medical standards.

Patient J.Z.

Petitioner called patient J.Z. to testify. J.Z. was referred to respondent for pain management concerning cardiac angina, which he described as a squeezing, crushing feeling across his chest. His initial consultation was on November 24, 2010. At that consultation, respondent told him that he had privileges at Chilton Hospital and mentioned how well trained he was in the area of pain management.

Respondent suggested an epidural, at first, which was done, but did not work. Then respondent suggested the insertion of a spinal-cord stimulator. A trial lead was put in place on May 6, 2011, and a permanent one was inserted on May 23, 2011.

Subsequently, the lead became displaced. Respondent removed the lead and placed it on the right side of his spine.

Following this surgery, J.Z. noted fluids emitting from his rectum. His wife drove him to Chilton Hospital because that was the hospital where respondent stated he had privileges. The patient was admitted on July 16, 2011, with a diagnosis of a severe infection. He was treated by an infectious-disease doctor who wanted the stimulator removed immediately because infection could cause extensive damage. No one at the hospital agreed to remove the stimulator. J.Z. was discharged on July 19, 2011 (P-71; P-72 at J.Z. 0163), and met with respondent on July 21, 2011, at which time respondent agreed to remove the stimulator. J.Z. stated that it was removed within a week of July 21, 2011.

The patient stated that once the stimulator was removed, he began experiencing a burning pain all over his back and side, which was increasing. He was then diagnosed with neuropathy of the feet and now has complex regional pain syndrome (CRPS). He stated that the CRPS has been so severe that it has surpassed the pain for which he initially saw respondent. He remains under the care of Dr. Kaufman, who had a pain pump inserted, which emits opiates and other pain medication.

On cross-examination, J.Z. acknowledged that he had sent various e-mails to respondent, between April 13, 2011, and June 2, 2011, praising respondent for the chance to have his life changed, as respondent had promised. He was appreciative that respondent had inserted the stimulator without cost and had kept assuring J.Z. that it would change his life. However, J.Z. explained that all of these e-mails predated the onset of infection. (R-1.) He added that his life has changed, as promised by respondent, but for the worse.

It was noted by the undersigned that this patient ambulated very gingerly to and from the witness stand.

Patient L.M.

Petitioner then called patient L.M. to testify. L.M. had been experiencing pain in her low back and searched the Internet for a doctor. She found respondent's website, where he represented that he was board certified for a minimally invasive technique and as a spine specialist. (P-108.)

L.M. initially saw respondent on May 3, 2011, with complaint of low-back pain at L4-5. She brought the results of a prior MRI of the neck to this consultation. Respondent ordered new MRIs of both the neck and back. Respondent told her that he had privileges at Chilton Hospital. L.M. had a prior surgery in 2003 for surgical dissection and fusion with titanium plate and screws at the C5-6 and C6-7 levels.

L.M. said she trusted respondent. On April 12, 2011, she underwent surgery for an L4-L5 fusion with bilateral insertion of L3 pedicle screws. On May 14, 2011, respondent performed another surgery, this one at C3, C4, and C4-C5, which involved cervical decompression. On March 23, 2012, he performed a lumbar decompression fusion at L3-L4, and on March 30, 2012, he performed a lumbar decompression and fusion at L5-S1 with bilateral placement of pedicle screws at L4, and L5-S1. In all, the patient underwent four spinal surgeries.

She stated that respondent recommended performing the last two surgeries in two phases, claiming that it would result in a better outcome. The patient stated that she was under general anesthesia for about six hours each time. She did not recall respondent ever discussing risks of surgery with her, but risks were shown to her on a laptop computer.

The patient was asked to display the scar at the incision site. It measured approximately five inches vertically at the midline. After the March 2012 surgeries, the patient remained in pain and need to apply ice three hours a day for six months for relief, which she did not have to do prior to these surgeries.

L.M. ultimately stopped treating with respondent and consulted with Kenneth Rieger, M.D., a spine surgeon. She complained of pain, which was not subsiding. It was her belief that the pedicle screw was driven into the nerve root. She also felt restriction caused by the cages inserted by respondent.

On September 27, 2012, Dr. Rieger surgically removed the cages and pedicle screws inserted by respondent. A temporary bone stimulator was inserted to stimulate bone growth. The incision was made over the same incision left by respondent.

Patient S.S.

Petitioner then called patient S.S. to testify. He had been experiencing back pain and learned of respondent through the Internet. Respondent's website represented that he resolved low-back problems. On August 1, 2007, S.S. had his first consultation with respondent, complaining of low-back pain and numbness in both legs. Respondent ordered an MRI and x-rays of the back. S.S. felt very comfortable with respondent, who he said projected a feeling of trustworthiness. Respondent recommended epidural injections. Patient said that after several were done, his pain had not resolved. Respondent then recommended surgery to repair what the patient referred to as the "sack," which was giving him problems.

S.S. recalled that the surgery was on April 12, 2009, (the surgical record showed that surgery was performed on April 17, 2009) at the Bergen Passaic Ambulatory Surgery Center. The patient stated that respondent told him that he was going to inject a substance into his disc to relieve the pain, which left the patient with the distinct impression that, other than the injection, surgery was not involved. In addition, respondent told him that he might be out of work about a week. At the time, the patient was a police detective lieutenant, which required him to be on his feet during much of his work. He did not want to lose more than a week from work.

While at the Bergen Passaic Ambulatory Surgery Center, and after an IV had been put in place, an unidentified male, who was carrying several types of medical instruments, approached the patient. Upon seeing the various devices, the patient questioned this

individual since he thought he had the wrong patient. The individual assured S.S. that he was the correct patient. He then informed S.S. that he was having surgery and that he would be out of work for several months. S.S. became irate since that was not his understanding. He lifted the IV bag off of its stand and left the premises. He was met outside by the two police officers who had transported him to this facility. While he was explaining what had happened, respondent came outside and approached him. Respondent assured him that everything would be fine, put his arm around the patient, and walked him back into the facility. S.S. stated that he then must have been given a sedative through the IV because he immediately became calm.

Respondent then performed surgery, which consisted of a lumbar interbody fusion at L5-S1 with the use of an interbody mesh cage.

Although S.S. smoked over a pack of cigarettes a day, respondent never told him about the surgical risks associated with smoking.

Following surgery, S.S. felt no relief and remained out of work for about five months. Respondent later recommended a second lumbar surgery. S.S. decided to wait until after his retirement as a police officer. Then on December 9, 2011, after he retired, S.S. underwent a second surgery. His complaints were pain in the low back and numbness in both legs. Respondent performed a lumbar decompression and revision fusion at the L5-S1 level, which was the same level as the first surgery. S.S. was still smoking cigarettes at the time of the second surgery.

S.S. stated that following the second surgery, his pain was much worse. He could barely move or get comfortable and returned to respondent for consultation on December 13, 2011. Respondent ordered an x-ray and an MRI. On December 19, 2011, S.S. underwent another surgery to repair a screw, which the patient said had "popped out" and was pressing against a nerve. This last surgery took place at the NJSR Center. Following the third surgery, the pain had not subsided. S.S. had follow-up visits with respondent on December 27, 2011, and January 24, 2012, still complaining of pain. At the last consultation, respondent told S.S. that he would remove the screw.

About a week later, S.S. returned to the NJSR Center for surgery. After he was hooked up with an IV, he was kept waiting for a significant period of time. Then respondent approached him and told him that he did not have the tool to remove the screw, that he needed to order it, and that it should arrive in a few days. S.S. left the center and terminated his relationship with respondent. He explained that he only kept returning to respondent because he trusted him and thought he was his friend.

On May 24, 2012, S.S. consulted Erash Emami, M.D., a neurosurgeon. S.S. could no longer stand for more than twenty-five minutes at a time following his second surgery with respondent, and continued to experience low-back pain. Dr. Emami told him that his back problems were caused by instability.

On July 9, 2012, Dr. Emami operated on S.S. at St. Joseph's Medical Center in Paterson.

Following this surgery, his back pain has improved, but he continues to experience nerve pain in both legs, which extends into half of his right foot. He is no longer able to do his usual activities, which included mowing the lawn or standing for more than twenty-five minutes. He has numbness on a constant basis on the entire right side of his right foot. Before he ever saw respondent, he was going to the gym five days a week, but is no longer able.

S.S. was asked to display the surgical scar. It measured approximately two and one-half to three inches vertically at the midline towards the bottom. He also had a singular scar measuring three-quarters of an inch to one inch at the right of midline.

Patient J.J.

The next to testify for petitioner was J.J. He had been a patient of the Sussex County Total Health Center under the care of a chiropractor. He had complaints of back pain on his right side and the chiropractor recommended that he see respondent, who was also part of the same pain-management facility.

He met with respondent, with a complaint of pain limited to the right side of his back. He said respondent recommended minimally invasive surgery, which involved two small incisions on each side of his lower back and an incision in the middle of his back. The middle incision would be about one inch in length and the two smaller incisions would be minimal.

On October 11, 2005, the patient underwent a lumbar interbody fusion with the insertion of a mesh cage at L4-5, L5-1. The patient had no recollection of ever being told about the mesh cage.

While in the recovery area, J.J. began to feel extreme pain on his left side, which he had not experienced before. He said that it felt as if his left leg and foot were on fire. The pain on the right side had subsided.

At follow-up consultations, he told respondent of his left-side pain. At the last consultation on December 26, 2005, respondent ordered an MRI with contrast, which was done on the same date. After the MRI was completed, the patient returned to respondent's facility to review the images with him. When he entered the facility, he was met by a physical therapist who had already received the results of the MRI. She told him that the screws inserted by respondent were not positioned correctly. The patient then left the facility and never returned again to respondent.

On January 5, 2006, the patient consulted Albert Steinberger, M.D., a neurosurgeon. By this time, his left foot was dropping, which he noticed about three weeks following respondent's October 11, 2005, surgery. The patient's complaints were pain on his left side and loss of feeling on the inside of his left foot.

On January 31, 2006, after undergoing diagnostic tests, surgery was performed by Dr. Steinberger for revision of the entire fusion. Dr. Steinberger told him that the screws had been improperly inserted, and had to be removed and reinserted properly. Immediately following surgery, the patient's pain on the left side became less intense, although it still remained. He now wears fentanyl transdermal system patches, which he had not worn prior to respondent's surgeries.

The patient was a superintendent at a demolition company, but had lost more time from work because of respondent's treatment than he had at any time over his forty-year work history. As a result of the pain caused by respondent's surgeries, he lost his job, which was paying him a six-figure income, because he could not renew his commercial driver's license since the transdermal patches contain an opiate. He no longer is able to participate in boating and camping, his favorite activities, causing him to sell his boat. He added that his life, which used to be active, has changed dramatically.

The patient sued respondent for medical malpractice and was awarded damages of over one million dollars. However, he has been unable to collect on the judgment since respondent is not self-insured, nor did his medical malpractice insurance cover spinal surgeries. J.J. is using up his savings, is sixty-one years old, and stated that he is now unemployable.

When asked about the consent form, he stated that it only referred to a fusion of L4-L5, not a fusion of L5-S1, which was also done.

Because the patient was still experiencing pain, he returned to Dr. Steinberger on April 11, 2011, and Dr. Steinberger removed all of the hardware he inserted because a fusion had occurred. Removed were five screws and two bars. One screw, according to the patient, had to remain because of the overgrowth of bone.

The undersigned noted that when the patient approached and left the witness stand, he walked with a noticeable limp.

Patient G.O.

Patient G.O. testified on behalf of petitioner. In October 2011, the patient suffered a back injury while doing housework. He consulted a physician, who took x-rays.

He learned of respondent through the Internet since he was looking for a physician who performed minimally invasive surgery. The respondent's website represented that he

was a board-certified minimally invasive specialist. Since the patient had started a new job, he wanted a short recuperative period. For those reasons, he met with respondent on November 14, 2011. He brought his prior x-ray film with him. The patient had pain at L5-S1 where he had a previous laminectomy.

He described respondent as charismatic and appearing to be trustworthy. Respondent recommended a minimally invasive technique, and on December 9, 2011, the patient underwent a three-level fusion at L3-L4, L4-L5, and L5-S1 with insertion of cages and pedicle screws. The patient said that respondent never mentioned the word "fusion," and he only learned that he was having one fifteen minutes before surgery when a nurse told him.

During these proceedings the patient was asked to display the scar, which measured approximately four and one-half inches vertically at the midline of the low back. The patient stated that after surgery, the pain subsided, but, nevertheless, still exists. However, the bottom of his left foot is now numb on the outside, which feels cold and wet. This condition was not present before respondent's surgery.

The patient had follow-up visits with respondent on December 12, 2011, and January 17, 2012, where he told respondent of his back pain and numbness in his left foot. Respondent recommended an EMG, which was done.

On March 26, 2012, the patient again consulted with respondent and told him of his left-foot numbness. Respondent assured him that it would subside over time, but it never has.

The patient was referred to Dr. Przybylski for a second opinion, and saw him in consultation on November 10, 2012, and July 24, 2012. He told Dr. Przybylski that he returned to work and was functioning satisfactorily. He also mentioned that the pain was subsiding and the numbness to his left foot showed some improvement, although he still has numbness. He stated that before he saw respondent his pain level was at nine out of ten, and now his pain level is a four.

When asked about what he thought a minimally invasive surgery entailed, the patient analogized it to the scoping procedure previously done to his knee. It was his understanding that there would be minimal scarring, a quick recovery and less post-operative pain.

Patient T.Z.

The next patient called by petitioner was T.Z., a forty-year-old woman. In the latter part of 2009, she began experiencing pain in her neck and back following an automobile accident. A neighbor, who had been a patient of respondent, recommended him. T.Z. then checked respondent's website, where he represented that he was a board-certified minimally invasive spine specialist. T.Z. was under the clear impression that if she decided to treat with him, any surgery, if one were required, would be minimal, and nothing more.

At her initial consultation on January 21, 2010, respondent recommended nerve testing. She mentioned that he had a pleasant demeanor, which gained her trust, which led her to believe that he was qualified to perform minimally invasive surgery. She was directed for a CT scan of the neck and an MRI or other testing (she could not recall specifically) of her back. After these tests, respondent recommended three epidural injections, which were done, but were ineffective in relieving her pain.

When she saw respondent about her continuing pain, he told her that surgery would relieve it. He told her that he was going to insert two screws and scrape a disc that appeared to be bulging, that the surgery would last approximately forty-five minutes, and would only involve a small incision, about one inch in length. The patient stated that it was her clear understanding was that this was going to be a minor procedure, nothing more, and that she would be discharged the same day, followed by a minimal recovery period of about a week or so. The patient stated that she made it very clear to respondent that she would not agree to anything more significant. Although she smoked a pack of cigarettes a day, she stated that respondent never mentioned anything about smoking or its risks associated with surgery.

On September 19, 2011, respondent performed a fusion at L3-L4 with the insertion of five screws. The surgery took place at the NJSR Center. When T.Z. awakened from surgery, she was in excruciating pain. She was in so much pain that she could not get out of bed to get dressed when she was told that she was being discharged. Her husband, who was in the waiting room elsewhere in the facility, was notified by a nurse to bring pain medication she kept in her purse. Even that did not help. This was a pain she had never experienced before. In addition, she could not feel her right leg. She said that she had never had such a level of pain before this. Two nurses had to assist her in dressing. There were no discharge instructions and she was only given a telephone number to call if she had any problems.

On the date of the surgery, she and her husband arrived at the surgical center early in the morning for what was thought to be a forty-five-minute procedure. Instead, she left the surgery center around 5:00 or 6:00 p.m. Her husband told her that she was in surgery for about six to seven hours. The ride home was excruciating—she was in extreme pain and felt nauseous. Her husband had to stop several times. Upon arriving home, she could not walk because the pain was so intense. Her husband called his father and together they placed her in a plastic chair and lifted her up the ten to twelve steps into her home. Once she was inside, she was placed in a recliner.

T.Z. called the telephone number given to her by the surgical center several times a day, for three or four days, but never received a response from respondent. Then, about two weeks later, she received a telephone call from the surgical center scheduling a follow-up visit. However, she never wanted to see respondent again.

On December 24, 2011, T.Z. was taken to Pocono Hospital, where she was admitted, because she had severe difficulty walking. The pain and numbness to the inside of her legs and buttocks was worsening. An x-ray was taken and a blood test administered. She was also given pain medication. She said that a problem with her blood had developed, which, in turn, caused her legs to cramp.

When she first saw respondent, she was under the impression that he was going to reduce a bulging disc. However, while at Pocono Hospital, she was informed that the

entire disc had been removed. She also learned that five screws, instead of two, had been inserted.

From Pocono Hospital, she was transferred by ambulance to Lehigh Valley Hospital, where again blood tests were administered. Attempts were made to call respondent. T.Z. was kept at Lehigh Valley Hospital for about three or four days to treat the blood disorder. Upon discharge, she was told to follow up with respondent, but she wanted nothing more to do with him. It was then that she learned that respondent was not an orthopedist, as she had initially thought, but an anesthesiologist.

On October 14, 2011, after noticing oozing from one of the incisions left by respondent, she consulted Brian Morse, D.O., who performed nerve testing on her legs. They did not respond. He recommended that she see George Naseef, M.D., an orthopedic surgeon. She saw Dr. Naseef on November 17, 2011, complaining of difficulty in walking, leg numbness, her right ankle giving out (going off to the side), and loss of balance, particularly on non-flat surfaces. She brought with her the films of her CT scan taken at Pocono Hospital. Dr. Naseef told her that two screws had penetrated the nerve in her spine and that she needed surgery. He also mentioned that the oozing at the incision site signified infection, which needed to be resolved before he could operate. The patient then underwent a week or two of treatment to clear the infection.

On January 30, 2012, Dr. Naseef performed a revision surgery at Morristown Memorial Hospital.

During these proceedings, T.Z. was asked to display the scars left by respondent. One scar was vertical at the midline of the low back, and measured approximately eight inches. There was also a horizontal scar to the left of the eight-inch scar, which measured about two inches. The smaller scar was the site of the infection.

In her past medical history, T.Z. had lower back surgery in 2002 or 2004 (she could not recall the specific year), during which an artificial disc was inserted through her abdomen.

As the result of respondent's surgery, she had to use a walker for about six months for balance, which she began using immediately following the surgery. After six months, she used a cane daily, also for balance. For months, her husband had to escort her to the bathroom, where she used a specially raised toilet seat. This lasted for several months. In addition, her feet have become positioned outward. The inner sides of her legs remain numb and she continues to have back pain. She stated that no day is a good day. Her pain starts upon awakening and worsens as the day progresses.

It was noted by the undersigned that when she approached and left the witness stand, she used a cane and ambulated very slowly. She also brought a pillow to sit on and was sobbing throughout most of her testimony.

Her husband, M.Z., also testified. He accompanied T.Z. to her initial consultation with respondent. He specifically recalled respondent telling them that the procedure would last about forty-five minutes and would involve a three-quarter-inch incision.

On the date of surgery, he and his wife arrived at the surgery center around 6:30 or 7:00 a.m. After an IV was inserted, respondent spoke to both of them, confirming that recovery would be minimal, about three or four days. M.Z. stated that his wife went into surgery at approximately 8:00 a.m. and came out around 4:55 p.m.

When his wife came out of surgery, M.Z. was summoned to the recovery area, located on a different floor of the facility. As soon as he arrived on the floor, he could hear his wife screaming in pain. The surgical center would not give her any more pain medication, and discharged her. When they left the facility, T.Z. was in a wheelchair. M.Z. had to lift her out of the chair and place her into the car. The ride home was agonizing. His wife cried and screamed.

He stated that T.Z. is now essentially confined to a recliner. She does not even sleep in bed. He also confirmed the length of the eight-inch and the two-inch scars left by respondent, mentioning that prior to treating with respondent, T.Z. had no scars on her back. A prior spinal procedure was performed through her abdomen.

George S. Naseef III, M.D.

Petitioner called George S. Naseef III, M.D., a board-certified orthopedic surgeon, to testify. Dr. Naseef, who has hospital privileges at several hospitals, including Morristown Memorial Hospital, Overlook Medical Center, and St. Barnabas Medical Center, performed corrective surgery on T.Z.

His initial consultation with her was on November 17, 2011. She was in a great deal of pain following a prior surgery and had lost her S-1 reflex, had tingling and numbing and could not put her foot down. She brought prior CT scan films with her and he recommended an MRI. (P-74 thru P-88 at T.Z. 0116 and 0117.)

T.Z. returned to Dr. Naseef on December 1, 2011, continuing to have severe right S-1 radiculopathy and weakness. She also complained about drainage from the iliac-crest wound site, which she described as greenish in color. Upon examining the images (<u>Id.</u> at T.Z. 0155), Dr. Naseef determined that the L-3 screws were not in proper line and the right S-1 screw was in the S-1 nerve root, not in the pedicle. Both L-3 screws and the right S-1 screw had perforated the bone and were in the nerve canal. He rendered a diagnosis of malpositioning of hardware, but before performing corrective surgery, the infection had to be eliminated.

During surgery on January 30, 2012, Dr. Naseef noted that the right and left L-3 screws were in the canal, and the right S-1 screw was grossly malpositioned and in the canal. (<u>Id.</u> at T.Z. 0135 to 0138.) Once the right S-1 screw was removed, nerve function immediately returned to the patient's leg. His post-operative diagnosis included malposition of hardware and painful hardware, and bilateral lower extremity radiculopathy. (<u>Id.</u> at T.Z. 0135.) He stated that of the five screws inserted, only one was positioned correctly.

Alfred A. Steinberger, M.D.

Petitioner produced Alfred A. Steinberger, M.D., a board-certified neurosurgeon. Dr. Steinberger, who is licensed in New Jersey, graduated from Columbia University

Medical School, where he completed a neurosurgical residency. He has hospital privileges at Englewood Hospital, Hackensack University Medical Center, and Mt. Sinai Hospital in New York City. He has never had any negative actions taken against his license or hospital privileges. His medical practice is devoted exclusively to spinal surgeries.

On January 4, 2006, he had a neurosurgical consultation with patient J.J., who had a complaint of radiating left-leg pain. The patient stated that after he underwent surgery with respondent, he had developed numbness, pain and weakness in his left leg, with a left=foot drop and profound weakness in the foot, which he did not experience prior to the surgery. His pain was in the low back, radiating down the left buttock and hip region to the left thigh, into the shin and calf, and into the foot and toes. The patient produced a CT scan that was done on December 22, 2005, after his surgery with respondent, which showed instrumentation at L4 to S1. Dr. Steinberger thought the left L5 screw could have been medially placed. There also appeared high-density material at the interspace at L4-5 compatible with an allograft, which extended into the left neural foramen. (P-20 at J.J. 0610 to 0612.)

Upon further imaging studies, including a lumbar myelogram/CT scan, Dr. Steinberger noted that the pedicle wall had been breached with a screw. He recommended surgery to remove the material that had exuded into the foramen and to replace the screws, which had been improperly inserted by respondent. In addition, there was compression of the nerves on the left side of the spine, also caused by respondent's surgery on October 11, 2005.

During surgery on January 31, 2006, Dr. Steinberger found an unstable construct. He noted that the screws were not in proper position since they were inserted medially rather than straight. He removed the previous instrumentation at L4, L5 and S1 and drilled new holes at L5 and S1 for replacement screws. During the surgery he found that the nerve roots at the L4-5 foramen and the L5-S1 foramen had been severely compressed. He mentioned that if he had not done a decompression, there could have been a resultant paralysis. (Id. at J.J. 0632 and 0633.)

On March 22, 2011, Dr. Steinberger performed another surgery since the patient still complained of pain. Subsequently, finding that a fusion had successfully occurred for his revision surgery, he removed all of the hardware he had inserted. (<u>Id.</u> at J.J. 0603 and 0604.)

He further added that, based upon the CT scan in 2005, respondent should have been aware that there were medially placed screws and material compressing L4-5, and that surgery should have been done within twenty-four hours of the onset of the patient's foot drop. According to the patient's history, he had no difficulties with his left foot prior to treating with respondent, but afterwards was left with a left-foot drop. Dr. Steinberger stated that by the time he saw the patient, the left-foot drop had become a permanent condition, which should have been resolved early on.

Kenneth J. Reiger, M.D.

Petitioner called Kenneth J. Reiger, M.D., a board-certified orthopedic surgeon, who testified by telephone. Dr. Reiger graduated from Columbia University Medical School, where he did a residency in orthopedic surgery. This was followed by a fellowship in orthopedic surgery at the University of Louisville. He became certified as an orthopedic surgeon in 2009 or 2010 (he was not certain which year). He has hospital privileges at Morristown Memorial Hospital, Overlook Medical Center and St. Barnabas Medical Center for surgeries of the spine. He stated that his medical practice is exclusively devoted to surgery of the spine, performing on average 220 spinal surgeries a year.

His initial consultation with patient L.M. was on May 25, 2012. The patient was in extreme discomfort, with back and leg pain and searing pain down her legs. She also had a right-foot drop. (P-39 at L.M. 1472 and 1473.)

On his examination of the patient, Dr. Reiger noticed a single midline incision of approximately six inches. X-rays were taken of the cervical and lumbar spine. He noted a prior cervical fusion, satisfactorily performed in 2003. In the low back, however, he discovered that hardware, placed over four vertebrae, did not seem to be properly

positioned and that fusion had not occurred. He ordered a CT scan of the lumbar spine. The patient told him that in March 2012 she underwent a six-hour L3-S1 instrumented fusion and was told to return a week later for a further surgery. The second surgery also lasted approximately six hours. The patient reported that she had been in severe debilitating pain since these surgeries. (<u>Ibid.</u>)

On June 13, 2012, he and the patient reviewed the CT results, which showed that the right S1 screw was placed improperly and was impinging on the nerve and that there was no evidence of fusion from L-3 to S-1. (<u>Id.</u> at L.M. 1469 and 1470.)

At consultation on June 13, 2012, Dr. Reiger advised the patient of the need for corrective surgery. She still had a right-foot drop, which based upon the patient's history, occurred immediately after the prior surgery with respondent. Since the patient had undergone spinal surgeries previously, she deferred surgery to allow for a possible fusion, which never happened.

On September 27, 2012 Dr. Reiger performed surgery to remove hardware at L-3 to S-1 and performed a fusion at L-3 to S-1. He noted that there was no fusion at all from the prior surgery. He also performed a revision laminectomy at L-3 to S-1 to provide room for the nerve and inserted a bone stimulator. During the surgery, he noted that screws were improperly placed, removed them and inserted new ones. (Id. at L.M. 1397 to 1399.)

He commented that respondent's surgery on March 23, 2012, followed by another on March 30, 2012, was inappropriate. Not only was it too soon after the first surgery, which lasted some six hours, but there was no recovery in an ICU unit. Rather, the patient was discharged to heal at home. When Dr. Reiger performed his surgery on September 27, 2012, he made an incision over the same incision left by respondent. During surgery, he noted that the systems inserted by respondent were all different. In of his medical experience, he had never seen this before, explaining that the same system should have been used for interlocking purposes.

On cross-examination, he acknowledged that he did not know the patient's condition before she saw respondent.

Arash Emami, M.D.

Arash Emami, M.D., a board-certified orthopedic surgeon, testified on behalf of petitioner via telephone. He is a graduate of the University of Chicago School of Medicine, where he completed a residency in orthopedic surgery, followed by a spine fellowship of one year at the University of California, San Francisco. He became board certified as an orthopedic surgeon in 2002 and was recertified in 2012. He has privileges at St. Joseph's Hospital and the Hospital for Joint Diseases in New York City. His medical practice is dedicated to spinal surgeries, which includes open spinal fusions and minimally invasive surgeries. He performs about eight spinal surgeries a week and sees over 100 patients a week.

On May 24, 2012, Dr. Emami initially saw patient S.S., who had undergone a posterior spinal fusion at the L5-S1 level by respondent about six months earlier. Since then the patient had severe lumbosacral pain and severe radiculopathy. The patient also reported difficulty in standing and walking and the quality of his life had changed dramatically. The patient brought x-rays, which revealed a pedicle screw placement at the L5-S1 level. The patient reported that he had an interbody fusion at the L5-S1 level performed by respondent. The x-ray revealed pseudarthrosis (non-fusion) at that level. Dr. Emami's impression was pseudarthrosis and implant failure. Dr. Emami's treatment plan was to perform revision surgery to achieve a solid fusion. (P-57 thru P-70 at S.S. 1890 to 1892.)

Further imaging studies indicated implant failure and impingement of the S1 nerve root. Dr. Emami shared these findings with the patient at a subsequent follow-up visit.

On July 9, 2012, Dr. Emami performed a compartmentalized revision surgery. First he performed an anterior fusion since there was scar tissue already on the back. He felt that an anterior surgery was better suited. During surgery, the entire disc was

removed and disc material was extracted and a cage inserted. He then performed a posterior surgery for the insertion of screws and a rod. (Id. at S.S. 1901 and 1902.)

Dr. Emami found that the patient had no structural cage in the disc space at L5-S1, and, therefore, the fusion was incomplete, causing instability of the spine. Since there is a lot of stress across this segment of the spine, respondent's use of a one-sided pedicle screw with no cage was the cause of a pseudoarthrosis (fusion failure).

He further added that he had never seen a pedicle screw without a cage before, which was extremely unconventional. He had seen a unilateral pedicle screw with a cage and a bilateral pedicle screw without a cage, but not, as was the case with this patient, a pedicle screw fixation without a cage. He further commented that using a pedicle screw on one side without a cage was not a part of his medical training. He further commented that although a failure of fusion could occur even under ordinary circumstances, failures only accounted for 3 or 4 percent of the cases.

Susan M. Sugalski

Petitioner then called Susan M. Sugalski, who has been an investigator at the Division of Consumer Affairs, Enforcement Bureau for the Professional Boards, since 1991. On June 4, 2012, she ran a "Google search" for the New Jersey Spine and from Rehabilitation Center, which she obtained the web address www.njsrlaserspine.com, which she then visited. In reviewing this website, she went to various tabs, which included information on herniated discs, treatment, testimonials about respondent, a video tab and an articles tab. She downloaded portions of the website, which she printed and attached to her certification. (P-119.) His website mentioned that he is a minimally invasive spine specialist (P-119 at NJSR001) and that he has been a pioneer in minimally invasive and percutaneous spinal surgeries (ld. at NJSR003). His website also represented that a small incision was made at the surgical point (Id. at NJSR003 and NJSR005), and, as contained in an article, that his medical training was "as extensive as it is impressive" (Id. at NJSR0036).

Petitioner then rested its case, subject to the production of documentation relative to the disciplinary phase of these proceedings, as well as any rebuttal testimony.

Joan Balducci

Respondent's first witness was Joan Balducci, a self-employed consultant for ambulatory surgery centers, whose main task was to ensure compliance with the regulations. She was retained by respondent in the construction of his one-room surgery center, which was to be known as the New Jersey Surgical and Rehabilitation Center (NJSR) located in Pompton Plains. As with all one-room surgery centers, NJSR was regulated by the Board.

In order for <u>NJSR</u> to receive accreditation for Medicare approval, Balducci submitted an application to the Accreditation Association for Ambulatory Healthcare (AAAHC), which described all aspects of the physician's practice, such as the number of operating rooms, malpractice insurance, the number of physicians on staff, and so on. In 2011, <u>NJSR</u> received AAAHC accreditation.

Since respondent did not have hospital privileges, Balducci inquired about the need for alternative privileges. Since the application for alternative privileges as prepared by the Board did not include spinal surgeries on its list of practices requiring alternative privileges, it was her position that alternative privileges were not required.

On cross-examination, she acknowledged that a lumbar puncture, with anesthesia, required alternative privileges. However, she steadfastly maintained that since spinal surgery was not listed, alternative privileges were not required. She, nevertheless, called the Board on several occasions for confirmation, but never received a response. She never wrote to the Board for clarification.

Jeffrey Randolph, Esq.

Respondent then called Jeffrey Randolph, a New Jersey attorney, who specializes in healthcare law and general litigation. He represents ambulatory surgery centers and other medical facilities.

He provided legal services for respondent, including the need for alternative privileges. As did Balducci, he concluded that the practice of minimally invasive spine surgery did not require alternative privileges since it was not listed on the table of specialties provided by the Board requiring such privileges. Nevertheless, he called the Board on two occasions and sent an e-mail on one occasion to confirm his understanding. He said that all of his communications went unanswered.

On cross-examination, he was asked about the various definitions under the regulations, including "surgery," "anesthesia" and others where alternative privileges were required in the event that conscious sedation or regional or general anesthesia was administered by the surgery center.

Robert G. McGann

Respondent then called Robert G. McGann, the senior territory manager for Spineology, Inc., the manufacturer of OptiMesh. He has been with the company for more than eight years. Spineology also develops other medical instruments and implantable surgical devices. He said his client base consists primarily of neurosurgeons and orthopedic surgeons and sells about sixty to seventy OptiMesh devices a month. His sales territory includes Washington, D.C., to upstate New York and New England.

In January 2005 he heard about respondent while attending a North American Spine Surgery meeting. After that, he met with respondent. McGann commented that the surgery center where respondent worked at the time purchased its first OptiMesh in 2005. He estimated that over the course of time, the surgery center purchased

OptiMesh for about 100 patient cases. At times, he attended the surgeries to provide support, if needed, and witnessed respondent use OptiMesh on about eighty occasions.

He acknowledged that the FDA had not approved OptiMesh for interbody support, but mentioned that respondent used the product for such purpose, having been the first to order OptiMesh for interbody support.

He estimated that about fifty physicians in his customer base use OptiMesh on a regular basis, of which 85 percent use it for fusion. He further commented that OptiMesh is also used in Europe, and that approximately 25,000 such devices have been sold for various kinds of spinal surgeries.

He discussed his training, which consisted of one week at the home office, where he inserted the device into a cadaver. He acknowledged that the black-box warning from the FDA related to the use of OptiMesh for interbody fusions, and he was aware that OptiMesh did not provide structural support, as confirmed by the company's literature. Consequently, OptiMesh has become an "off-label" product, but added that "off-label" use of a product is a very common practice in the industry.

Kevin Earle

Kevin Earle testified by telephone on behalf of respondent. He was a former executive director of the Board from 1994 through 1998. From February 2005 through July 2005 he was employed as chief operating officer at the North Jersey Center for Surgery in Newton, New Jersey, which lasted about six months. He described the facility as a one-room surgery facility, which was AAAHC accredited.

Earle tried to obtain alternative privileges for respondent. In the process, he contacted Judith Gleason, who succeeded him as executive director of the Board, exchanging various e-mails with her. In her e-mail dated February 14, 2005, in response to his inquiry about respondent's need for alternative privileges, she wrote:

Kevin.

If these procedures are performed with the use of anesthesia services (conscious sedation, regional or general anesthesia) the physician in the office setting must have hospital privileges or alternative privileges to perform the procedure and also must have hospital or alternative privileges to administer or supervise the administration of anesthesia services. If an anesthesiologist is used for anesthesia, then the physician doing the procedure does not need privileges with respect to the provision of anesthesia.

Judy

[R-4(a) at K000000121.]

Although Earle knew that respondent did not have hospital privileges, he acknowledged that respondent, who was performing discectomies and fusions with the use of general anesthesia, was required to have either hospital or alternative privileges. He was familiar with the regulations since he was one of the drafters.

Judith I. Gleason

The next witness called by respondent was Judith I. Gleason, executive director for the Board from 1998 to 2001. She testified that she was involved in the development of the alternative-privilege regulations, adding that alternative privileges were extended to qualified applicants performing procedures in a one-room surgery center.

She was referred to the table of specialties downloaded from the website of the Board concerning alternative privileges. She stated that if anesthesia were to be used, alternative privileges were required for a one-room surgery setting, unless the physician had hospital privileges. Although the types of surgery performed by respondent were not listed on the table of specialties, she stated that if conscious sedation or regional or general anesthesia was used in his procedures, hospital or alternative privileges were required. She also commented that there was space on the application under "other" for any additional statements of the applicant.

Patient Ta.Z.

Ta.Z. (different from T.Z. produced by petitioner), testified on behalf of respondent.

On July 18, 2010, she was involved in an automobile accident and began to experience pain in her legs and spine, accompanied by tingling and numbness. At first she received physical therapy, but was then referred to respondent.

She saw respondent in July 2011, and respondent recommended knee and spinal injections. When the spinal injections did not relieve her pain, she underwent a lumbar fusion in two stages: stage one on August 5, 2011, and stage two on August 12, 2011. Prior to each surgery, respondent explained the nature of the surgery, her recovery period and the risks involved. She was required to fill out paperwork, including a consent form, which mentioned the risks of surgery. Both procedures were performed at the Surgery Center in Pompton Lakes, about two weeks apart, and involved the insertion of screws and rods. The first surgery lasted about one and one-half to two hours, during which she was under anesthesia. Following surgery, a nurse came to the recovery area to check on her. She was given instructions and left the center.

She returned for the second phase of the lumbar surgery and was again presented with paperwork, including a consent form. After her second surgery, a nurse and respondent came to the recovery area to check on her. While at home, she received a follow-up call from the surgery center to see how she was.

About every two weeks she takes Tylenol for minor pain, but no longer experiences significant pain in her back. Overall, she was very satisfied with the treatment she received from respondent.

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⁶ Through the assistance of a Spanish interpreter; whenever she met with respondent, she had an interpreter with her.

She displayed the scars from the surgeries. One measured about one and onehalf inches horizontally, while the other was vertical at the midline of the back measuring at least six inches.

Patient K.D.

Respondent then called K.D., a sixty-two-year-old male patient of respondent, to testify in his behalf. K.D. was referred by an orthopedist to respondent in 2002 for cervical-pain and neck-pain management.

He stated that he has had back pain since 1978, which became so severe that he was "pensioned off" as a police officer in 1979. Since then, back pain has always been a problem.

Respondent administered epidural injections, which gave some relief for about eighteen months. When the pain returned, respondent recommended a discectomy. He explained the risk associated with this procedure and answered all of K.D.'s questions. The patient underwent a discectomy in 2004, which he stated relieved his pain. He was contacted by the surgery center following the surgery and had follow-up visits with respondent. He has gone from a pain level of nine or ten to a three or four, with ten being the most pain.

In 2007, his lower-back pain returned. Respondent performed a two-stage fusion, the first stage on January 25, 2008, and the second on February 8, 2008, both involving the use of general anesthesia. Two titanium bars and six screws were inserted. Prior to each surgery, respondent explained the risks associated and answered all of the patient's questions.

Both surgical procedures lasted about five hours. After each, he was able to get up and walk. He stated that the fusion has changed his life and he no longer experiences the pain he had for the past thirty years.

His cervical problems returned, and he saw respondent, who told him that he was a candidate for a cervical fusion. Since respondent was in the midst of legal proceedings, the patient was referred to another physician.

He estimated that the scar in the midline of his back measured about four inches. When he met with respondent, respondent told him that he had received training in minimally invasive procedures in South Korea and taught minimally invasive surgeries to other physicians.

Patient D.H.

In the fall of 2004, D.H. was involved in a motor-vehicle accident and, thereafter, consulted with a chiropractor, who in turn referred the patient to respondent. D.H. stated that he was in constant pain and could not work or perform even household chores. Respondent administered epidural injections in both the neck and back, but his pain returned about a year later. Respondent recommended a discectomy to his neck, which was done on March 26, 2012. D.H. stated that the procedure and its risks were fully explained to him, including the length of the surgery and the recovery period. He was also advised that he would be placed under anesthesia.

The patient stated that prior to surgery he had a pain level of nine, which after surgery was reduced to a four. He was called by the surgery center after the surgery and he stated that the quality of his life had improved. When asked about his present complaints, he mentioned pain in his neck, shoulder and lower back depending on the day, which varies between a three and a seven on a pain scale of ten as the most pain.

Solomon Kamson, M.D., and Kent B. Remley, M.D.

Respondent produced Solomon Kamson, M.D., an anesthesiologist from the state of Washington, and Kent B. Remley, M.D., an interventional neuroradiologist licensed in the state of Indiana. Both testified that they practice interventional pain management, using percutaneous and minimally invasive procedures. Both physicians testified that they reviewed the records of respondent, his operative reports, and

imaging studies for the various patients set forth in the Second Amended Complaint filed by the Attorney General. Each praised the work of respondent, finding no deviations from the standards of care. Of interest is that both doctors have or had a business relationship with respondent in an African project where they had hoped to teach physicians minimally invasive surgeries. Also, neither of these witnesses had known about, or at least did not comment on, the several revision surgeries that took place to correct respondent's surgeries. Dr. Remley candidly stated that had he known about them, it might have changed his opinion about deviations.

Dr. Kamson's medical license issued by the State of Washington was suspended in November 2006 for his performance of minimally invasive surgical techniques, on the allegation of negligence. There was also an allegation that he misrepresented to a patient that he was the only physician qualified to perform minimally invasive surgery. These proceedings also alleged that he was not qualified for minimally invasive surgery. On January 16, 2007, Dr. Kamson entered into a consent order with the State of Washington whereby his license was placed on probationary status from January 2007 to July 2012, for unprofessional conduct in causing injury to a patient. He was required to have supervision, during this period, for his surgeries. These conditions were ultimately lifted in 2012.

However, on February 21, 2013, his medical license in Washington was again placed on probation because he allegedly failed to properly monitor a patient. He acknowledged that in the state of Montana his medical license was also placed on probationary status, which he claimed was the result of the Washington action. He confirmed that in Montana he was barred from performing certain minimally invasive surgical techniques. He also confirmed that his medical license in Alaska is suspended and that his medical license in California is on a probationary basis, which he again claimed was the result of the Washington matter. He acknowledged that his medical licenses issued in various states, as of the time of the hearing, were either suspended or on probationary status.

Victor Katz, M.D.

Respondent produced Victor Katz, M.D., a licensed physician in the states of New Jersey and New York. Dr. Katz is a board-certified orthopedic spine surgeon, who performs both minimally invasive and open spine surgeries.

The bulk of his practice consists of cervical fusions, performing over fifty to sixty a year. Also included are lumbar fusions and, on occasion, discectomies. During 2005 or 2006, he was told about respondent's use of OptiMesh for interbody fusions, and decided to observe respondent in its use. He watched more than seventy-five procedures and eventually participated in some. He said that on each Thursday over a nine-month period, he came to the surgery center, where he became involved in minimally invasive techniques, which he has since used in his own practice

He confirmed that he could not recall the names of the patients, that he did not participate in their aftercare, and that he was not involved in patient selection.

Richard A. Kaul, M.D.

Respondent testified in his own behalf. He graduated from medical school in London in 1988, which was then followed by a surgical internship in England from August 1988 to February 1989. It was there that he began to gain experience in the use of Bovie and Metzenbaum scissors, which was overseen by a registrar (according to respondent, the equivalent of a proctor). He then had a second internship from February 1989 to August 1989, which predominantly involved treatment of the liver. He was involved in diagnostic testing, such as EKG and others. His "hands-on" experience included the placement of catheters and other such devices, and during this time he reported to a registrar. His third internship occurred at Catholic Hospital in Jamaica, Queens, New York, in November 1989 for four months in surgery. He admitted patients, made incisions, and, ultimately, under the guidance of the surgeon, had "hands-on" training, including the removal of an appendix. He became familiar with tubular insertions through the abdomen, again using Bovie and Metzenbaum scissors to

explore the area of injury, and was allowed to repair and then close the abdominal wall. This fellowship ended in April 1990.

He said that he had a fourth internship, a surgical internship, at the Nassau University Medical Center, a trauma center. As part of his duties, he admitted patients and rendered diagnoses, particularly as they related to blunt-trauma injuries. He inserted drains and tubes and made two- to three-inch incisions. One incision was sixteen inches for an abdominal procedure, done under the guidance of the surgeon. This was a one-year internship.

Respondent followed his internships with a residency at Booth Memorial Hospital, which started in July 1991 and ended in April 1992. There, he was involved with admitting patients and was responsible for the oversight of interns. This was an active vascular-service facility where he assisted in procedures, which included incisions and dissections in the neck under the supervision of the responsible surgeon.

Respondent then decided to leave surgery and entered into a three-year residency in anesthesia at the Albert Einstein College of Medicine, which lasted from 1992 through 1995. In the third year of his residency, he became involved in interventional pain procedures with the use of fluoroscopic guidance, which was then becoming available. During this part of his training, he was learning about fluoroscopy and the use of inserting needles in the cervical, thoracic and lumbar areas of the spine.

In September 1995 he began a fellowship in England in interventional pain management, which he completed in September 1996. During the initial months of this fellowship he was an observer, but then he began to consult with patients, some of whom had spinal pain, reporting to a superior in the pain-management department.

His first employment was at a hospital in England, where he administered epidural and facet injections and occasionally referred patients for a discogram, which he himself performed. He was at this hospital for about three or four months. Then he relocated to London, where he worked at various clinics in private practice from 1996 to

2001, administering anesthesia and rendering interventional pain services, including injection and discogram.

Respondent then came to the United States, where he became employed at Hackensack University Medical Center as an anesthesiologist. He then became employed at Columbus Hospital in Bloomfield, New Jersey, from February 2002 through August 2002 in the pain clinic administering injections and performing discographies. His next employment was at Saint Clare's Hospital, from November 2002 to September 2003, working in the pain clinic.

In June 2004 respondent began working at outpatient surgical centers, including Pompton Plains, the Market Street Surgical Center and North Jersey Spine and Rehabilitation Center. While at Pompton Plains and the Market Street Surgical Center, he performed epidural and facet injections, discographies, selective nerve-root blocks, insertion of spinal stimulators, discectomies, lumbar interbody decompression and fusions with insertion of pedicle screws, all under fluoroscopic guidance. He also worked at a surgical center in Wyckoff for about six months administering injections, inserting stimulators and performing discographies.

From March 2007 until September 2010 he rendered services at the Bergen/Passaic Ambulatory Surgery Center, which included epidural and facet injections, discograms, sacroiliac joint injections, lumbar decompressions, cervical endoscopic discectomies, lumbar interbody fusions using OptiMesh and PEEK cages, and pedicle screws inserted percutaneously. All of the above procedures were done under fluoroscopic guidance.

Respondent stated that he is a diplomate of the American Board of Anesthesiology, becoming certified as an anesthesiologist in 1996. He also said that in 2004 the American Board of Interventional Pain Management granted him certification after he took a comprehensive written and oral examination. In addition, he has been a member of several medical societies.

In 2004 he took a two-week fellowship at the Wooridul Spinal Hospital in Seoul, Korea. Respondent stated that the hospital handles about 16,000 cases annually with minimally invasive techniques, adding that doctors from all over the world train there. He said that while he was there, he learned decompression and fusion techniques. The program commenced at 8:00 a.m. and lasted until 8:00 p.m. each day, consisting of lectures in the morning followed by the surgery room in the afternoon, where he would assist in procedures, which included the placement of hardware in the cervical and lumbar spines.

Respondent was asked about the CME courses listed in his curriculum vitae. These courses involved lectures, and some offered "hands-on" experience, but only on cadavers.

Respondent, who does not have hospital privileges, was then asked about his efforts to obtain alternative privileges. Since the Board's list of medical practices requiring alternative privileges did not include minimally invasive surgeries, and his consultation with an attorney on this issue did not result in different advice, he felt that alternative privileges were not required. Therefore, it was his belief that he could perform these procedures without such privileges. He also claimed that he consulted with Kevin Earle, who testified previously, who told him that he did not require alternative privileges for discectomies and fusions.

In 2007, respondent revisited the issue of alternative privileges because he had purchased a building in Pompton Lakes, which he was going to convert into a one-room AAAHC-accredited facility, to be known as the New Jersey Spine and Rehabilitation Center. He again consulted with an attorney, and was advised that minimally invasive surgery did not require such privileges. This facility was operational from March 2011 until April 2012. During this time, he performed, under fluoroscopic guidance, epidural and facet injections, radiofrequency ablations, discograms, minimally invasive surgeries, including discectomies in the cervical, thoracic and lumbar regions of the spine, fusions in the cervical and lumbar areas, grafting with OptiMesh and PEEK, and employing the use of K-wire.

He then was asked about the general procedures employed in his practice. At the initial consultation, the patient was provided with an intake package for insurance information, the patient's medical history and present medical issues. He then verified the information with the patient and conducted neurological and musculoskeletal examinations. He reviewed imaging studies if brought by the patient, and if not, ordered them. He then formulated a treatment plan, which could include further diagnostic tests, such as a repeat MRI, EMG/NCV, or interventional pain procedures. Using a model of the spine, he would then discuss his diagnostic findings with the patient, followed by a detailed discussion of what the procedure involved. He would also go over the risks and benefits of the procedure with the patient.

On the date of a procedure, he would again talk with the patient about what he was planning to do, as well as the risks involved, and answer any questions. Then the patient would sign a consent form in the pre-operative holding area. The anesthesiologist would then discuss the risks of anesthesia. An IV would be inserted, and the patient, who was dressed in a gown, would then transported by the anesthesiologist and a nurse into the operating room. Monitors, such as EKG, blood pressure and pulse, were put in place. The patient would lie on his or her stomach on the operating table, where the intravenous administration of anesthesia would begin. His procedures were performed under fluoroscopic guidance, which involved a technician moving the fluoroscope, at his direction. Even before the procedure started, he would view the bone structure through the fluoroscope. After the surgery was completed, the patient would be given aftercare instructions and a telephone number to call, if needed. A nurse would usually call the patient the following day to check on the patient's status and to reiterate the discharge instructions. At the time of discharge, a date would be scheduled for a follow-up examination.

On cross-examination, respondent acknowledged that in all of his internships and fellowships, he had no training in the performance of spinal surgeries, or in the insertion of screws, rods or OptiMesh. During his residency at Booth Memorial Medical Center, he had no spinal-surgery training, nor did he insert screws, rods or OptiMesh.

After completing his three-year anesthesiology training, he returned to England for a pain fellowship. However, the fellowship did not include spinal-fusion surgery or the insertion of screws, rods or OptiMesh.

Following his return to the United States, his hospital privileges at Hackensack University Medical Center were suspended because of his criminal conviction in England for the death of a patient during a dental surgery where he was the anesthesiologist (more fully discussed below). (P-98 at 14, lines 8 to 10.) His New Jersey medical license was then suspended for two years, with an active suspension from December 2003 to June 2004 for not disclosing his prior conviction.

He acknowledged that the American Board of Medical Specialties does not recognize the certification he was issued by the American Board of Interventional Pain Management, and further acknowledged that while at the program in Seoul, Korea, he was only an observer, with some minimal participation in about twenty-five procedures. Furthermore, he acknowledged that he had never been granted hospital privileges for fusions or minimally invasive surgeries, although he tried to obtain such privileges from Meadowlands Hospital, but never received a response.

He also acknowledged that the only course he took where he dealt with live patients was the one in Seoul, Korea, and a two-day course in Germany where he was only an observer. He acknowledged that the CME courses sponsored by the North American Spine Society were open to anyone, even a non-physician, but only as to the lectures. Non-physicians could not attend cadaver training.

He was then presented with the itinerary of a three-day seminar he attended in Utah from March 26 to March 28, 2004. The itinerary provided for workshops from 8:00 to 10:00 a.m., and then from 10:00 a.m. to 4:00 p.m. on Saturday and Sunday there was open time for skiing, followed by après-ski.

Respondent was then asked about his medical-malpractice coverage. He was shown a declarations page for his medical-malpractice policy for the period June 10, 2004, to June 10, 2005. (P-111.) He confirmed that there was an endorsement to the

policy excluding coverage for spinal-surgery procedures, thereby conceding that between June 10, 2004, and June 10, 2005, he did not have insurance coverage for spinal surgeries.

He was then shown the declarations page of his medical-malpractice insurance policy for the period of June 10, 2005, to June 10, 2006. Again the policy contained an endorsement excluding coverage for spinal-surgery procedures. Respondent admitted that he had no insurance coverage for spinal surgeries during this time period. (P-113.)

Respondent was then shown a declarations page for his medical-malpractice insurance policy for the period of June 10, 2006, to June 10, 2007, and again acknowledged that the policy contained an endorsement excluding spinal surgeries. Respondent admitted that he had no insurance coverage for spinal-surgery procedures during this time period.

During a proceeding before the Preliminary Evaluation Committee of the Board on February 3, 2010, where respondent was placed under oath, he represented that the incisions he made were usually one-half inch to one inch. (P-98 at 59, lines 12 and 13.) He also mentioned that, at times, he used one or two stitches to close the wound involved. (Id. at lines 16 and 17.) He acknowledged that he never told the Board that his incisions could have been as long as six or more inches.

Respondent confirmed that the first time he inserted a pedicle screw in a live patient was at a surgery center, in the absence of any proctor. He had never performed this procedure on a live patient before, although he felt that with his experience in the insertion of needles gained in his anesthesiology training, he was able to perform this procedure. He also admitted that his entire experience in the insertion of rods consisted of one occasion when he inserted one rod at the seminar in Seoul, Korea.

He added that in 2003, while at the Market Street Surgical Center, he was monitored by an orthopedic surgeon in his performance of a lumbar endoscopic discectomy, which was a minimally invasive procedure for decompression.

He acknowledged that he often told his patients to view his website. He also acknowledged that he was sued by patient J.J. for medical malpractice in performing a minimally invasive surgery, for which J.J. was awarded a judgment in the amount of \$1.2 million.

Credibility

When facts are contested, the trier of fact must assess and weigh the credibility of the witnesses for purposes of making factual findings. Credibility is the value that a finder of fact gives to a witness's testimony. It requires an overall assessment of the witness's story in light of its rationality, its internal consistency, and the manner in which it "hangs together" with the other evidence. Carbo v. United States, 314 F.2d 718, 749 (9th Cir. 1963). There is no mechanical formula for determining the truth, to the extent it can be discerned, and many factors may be considered and weighed. These include the demeanor of the witnesses and the manner of testifying, the interest a witness may have in the outcome, and the reasonableness and coherence of the testimony. Dawson v. R.W. Vogel, Inc., CRT 4501-00, Initial Decision (Apr. 25, 2002), adopted as modified, Dir., Div. on Civil Rights (Aug. 28, 2002), https://njlaw.rutgers.edu/collections/oal/.

The testimony of each and every witness produced by petitioner, both fact and expert, was deemed extremely credible and compelling. Each presented a straightforward and clear picture of respondent's treatment. This included the credible testimony not only from petitioner's expert witnesses about respondent's lack of training and competency in performing spinal surgeries, but also from those physicians who had to perform revision surgeries in an effort to relieve patient suffering. There was also credible testimony produced by petitioner from several of respondent's former patients, who described how they have suffered because of the surgeries he performed.

Conversely, the testimony of Drs. Kamson and Remley, the two expert witnesses produced by respondent, was deemed lacking in credibility. Neither knew of, or at least failed to mention, the several revision surgeries that were necessary. Dr. Remley candidly admitted that had he been aware of the revision surgeries, his opinion about respondent's lack of any deviation might have been different.

Furthermore, Drs. Kamson and Remley had a past relationship with respondent in a project to instruct physicians in the Democratic Republic of the Congo, Africa, on minimally invasive techniques. Therefore, the continuation of respondent's medical license would have been important for their venture, thereby raising the issue of bias.

In addition, the suspensions/probations of Dr. Kamson's several medical licenses had a significant impact on his credibility.

The testimony of the patients who testified in behalf of respondent, although seemingly credible, was not considered. This is not a case about those procedures that may have been safely performed, but those that harmed others.

The testimony of respondent's witnesses Earle and Gleason was also deemed credible, each expressing the need for hospital or alternative privileges for respondent's one-room operating facility as required under the regulations since anesthesia was used (discussed below). Conversely, the testimony offered by respondent's other witnesses on the subject of alternative privileges was given little, if any, weight since they did not discuss the relevant regulations, but focused primarily on the language contained in or omitted from the alternative-privilege application.

The testimony of McGann, a non-physician, was also given little, if any, weight, since he acknowledged that OptiMesh did not provide structural support as was noted in the literature of Spineology, the manufacturer of OptiMesh. Dr. Katz was simply an observer who later had "hands-on" experience in minimally invasive techniques while operating on patients at respondent's facility, but was not involved in the decision-making process for determining which patients required such procedures, nor was he involved in their aftercare. Accordingly, little, if any, weight was given to his testimony.

The testimony offered by respondent confirmed his lack of education and training in the performance of spinal surgery. He reiterated the same internships, residencies, CME courses, and medical organizations to which he belonged that had been described by petitioner's experts. Nothing in his testimony advanced his training and skills over

the compelling testimony offered by petitioner's experts to the contrary. Consequently, little, if any, weight was given to his testimony.

FINDINGS OF FACT

Based upon consideration of the testimonial and documentary evidence presented at the hearing, and having had the opportunity to observe the demeanor of the witnesses and assess their credibility, I **FIND** as **FACT** the testimony of petitioner's witnesses, both fact and expert. Accordingly, I **FIND** that:

- 1. Respondent is a board-certified anesthesiologist.
- 2. His education, training, internships, residencies and fellowships were insufficient to prepare him for surgeries of the spine, whether minimally invasive or open.
- 3. The CME courses he took were insufficient to provide such education and training. If hands-on training were offered, it was, in most instances, done on cadavers. In others, he was primarily an observer.
- 4. In addition to his lack of sufficient education and training in spinal surgeries, he did not receive sufficient monitoring by a trained overseer. For instance, he was on his own the first time he inserted a pedicle screw in a live patient, without the presence of any trained monitor.
- 5. Respondent's treatment included, but was not limited to, inserting pedicle screws into the spinal canal; failing to immediately remove a stimulator after the onset of infection, thereby risking paralysis; using OptiMesh as an interbody structural device; and performing a staged fusion, as well as other acts as discussed above.
- 6. Some of the patient consents presented were unsigned.

- 7. He failed to carry medical malpractice insurance from June 10, 2004, to June 10, 2007 that covered spinal surgeries.
- 8. He did not have hospital or alternative privileges.
- 9. He used allograft bone in patients who were smokers.
- 10. He failed to advise patients who were smokers of the risks associated with smoking and allograft bone.
- 11. He misrepresented his qualifications, not only on his website, but also in discussions with his patients.
- 12. None of his certifications were recognized by the American Board of Medical Specialties, with the exception of his board-certification in anesthesiology. Non-recognition included his certification by the American Board of Interventional Pain Management.

LEGAL ANALYSIS AND CONCLUSION

Pursuant to the Medical Practices Act, N.J.S.A. 45:9-1 to -19, the Board possesses broad authority to regulate the practice of medicine in the state of New Jersey. In re License Issued to Zahl, 186 N.J. 341 (2006). Its supervision of the medical field is critical to the State's fulfillment of its "paramount obligation to protect the general health of the public." Id. at 352 (citation omitted). Companion legislation, entitled the Uniform Enforcement Act, N.J.S.A. 45:1-14 to -27, creates uniform standards "for license revocation, suspension and other disciplinary proceedings" by "professional and occupational boards." N.J.S.A. 45:1-14.

In addition to safeguarding the public from harmful medical practices, the Board upholds the reputation of the profession by punishing those whose conduct "lowers the standing of the medical profession in the public's eyes." <u>In re Fanelli License Revocation</u>, 174 N.J. 165, 179 (2002) (citation omitted).

Recognizing the specialized expertise of the Board, the Legislature has not defined with particularity what acts would constitute unprofessional conduct. In re Polk License Revocation, 90 N.J. 550, 574 (1982). Rather, substantial deference must be afforded to the Board's expert knowledge of what misconduct should constitute unfitness to practice medicine. Cf. Zahl, supra, 186 N.J. at 353 (citation omitted) ("Deference is appropriate because of the 'expertise and superior knowledge' of agencies in their specialized fields").

The right to an administrative hearing before any action can be taken that adversely affects a physician's medical license has "long been imbedded in our jurisprudence," <u>Fanelli</u>, <u>supra</u>, 174 <u>N.J.</u> at 173 (citation omitted), and is expressly guaranteed under the Administrative Procedure Act, <u>N.J.S.A.</u> 52:14B-11. At such hearing, the Attorney General must prove the elements of the case by a preponderance of the substantial credible evidence, which means that more likely than not, the charges are true. Polk, supra, 90 N.J. 550.

N.J.S.A. 45:1-21, which authorizes the Board to suspend or revoke a physician's license, provides, in part:

A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

- a. Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception, or misrepresentation;
- b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;
- c. Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

- d. Has engaged in repeated acts of negligence, malpractice or incompetence;
- e. Has engaged in professional or occupational misconduct as may be determined by the board;

Gross negligence, gross malpractice, or gross incompetence, as those terms are used in the licensing act, require something much greater than ordinary negligence, malpractice or incompetence in a civil suit for personal injury.

In a civil suit for medical malpractice, the injured party must demonstrate that the doctor deviated from an accepted practice standard and that such deviation caused harm to the party. Germann v. Matriss, 55 N.J. 193 (1970). However, malpractice alone is not a basis for the Board to interfere with a physician's license to practice. Accordingly, an administrative sanction for the suspension or revocation of the license must be brought within a statutory basis. State Bd. of Med. Exam'rs v. Weiner, 68 N.J. Super. 468, 483 (App. Div. 1961).

Such statutory bases are gross negligence, malpractice, and incompetence, which require a showing of misconduct so "egregious" or "flagrant" as to implicate a much higher magnitude of wrongdoing. Polk, supra, 90 N.J. at 565. "Gross neglect" has also been equated with "wanton or reckless disregard of the safety of others" or willful misconduct amounting to "heedlessness or reckless[ness]." In re Kerlin License Suspension or Revocation, 151 N.J. Super. 179, 185–86 (App. Div. 1977) (citations omitted). Therefore, to prove professional misconduct, the Attorney General must prove that a physician's act was so egregious as to constitute misconduct in the magnitude of gross malpractice. Polk, supra, 90 N.J. at 565; see In re Rodriguera, 93 N.J.A.R.2d (BDS) 33, where a medical doctor exposed patients to numerous unnecessary procedures, maintained misleading records, and committed forty-two violations of the Medical Practices Act. In Rodriguera, the Board appropriately ordered the revocation of the doctor's license, together with the payment of penalties and costs.

It is difficult to precisely define "gross negligence" because of the absence of guidelines to assist "in marking out the division between ordinary and gross negligence on the scale of ascending or descending degrees of care." Kerlin, supra, 151 N.J. Super. at 186 (citation omitted). It is not enough to show a simple deviation from accepted medical standards, even if it produced a significant untoward result. Ultimately, the term refers to conduct beyond ordinary neglect or malpractice, "how far beyond [being] left to the judgment of the Board, subject, of course, to judicial review." <a href="https://doi.org/10.1001/judgment-

A person who violates laws governing the practice of medicine and/or surgery in New Jersey may be sanctioned, assessed a civil penalty "of not more than \$10,000 for the first violation and not more than \$20,000 for the second and each subsequent violation," N.J.S.A. 45:1-25(a); may be submitted to supervision, monitoring or limitation on his or her practice as the Board may determine is necessary, N.J.S.A. 45:1-22(h); and may be ordered to pay costs incurred by the State, such as costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs, N.J.S.A. 45:1-25(d).

Based upon the facts adduced and the legal principles cited above, respondent performed spinal surgeries for which he was not adequately educated and trained. His surgeries were done posteriorly through incision, implanting hardware, such as screws, rods, and purported structural support devices. This was far beyond his training as an anesthesiologist, who was allowed to perform needle-based procedures for pain management, such as epidural and facet injections for the alleviation of pain or discograms for the purpose of diagnostic testing. There was nothing in his education or training that provided him with the experience necessary to perform spinal surgeries, either minimally invasive or open. In fact, the first time he ever inserted a pedicle screw on a live patient was at a surgery center when he was on his own. There was no one to monitor the surgery or assess his skill level. Nor had he previously performed fusions under the critical eye of a monitor. Clearly none of his CME courses provided the experience he needed, most of which, if "hands-on" training were provided, was done on cadavers, not live patients.

One such example, and most certainly not by way of limitation, of his gross negligence and incompetence was his treatment of patient T.Z., a forty-year-old woman

who was so traumatized by his surgery that she has been essentially relegated to a recliner. In her instance, respondent improperly inserted pedicle screws directly into her spinal canal, which not only caused her extreme pain and other maladies from which she still suffers, but also necessitated a revision surgery by an orthopedic surgeon to undo his neglect. The surgeon found that the right and left L-3 screws were in the canal and that the right S-1 screw was grossly malpositioned and in the canal. When he removed the right S-1 screw, nerve function immediately returned to the patient's leg. The revisionist surgeon's post-operative diagnosis included the malposition of hardware and painful hardware, and bilateral lower extremity radiculopathy. Of the five screws respondent inserted, only one was positioned correctly. This speaks volumes about respondent's incompetency and lack of training.

Respondent's negligence far exceeded ordinary negligence. His lack of education and training precluded him from even attempting spinal surgery in any form, whether it is called minimally invasive or open. This was not the case of a trained and certified spinal surgeon who may have been careless in a given instance, giving rise to ordinary negligence. This was about a doctor who operated on patients without sufficient training, skills and competence. I, therefore, **CONCLUDE** that respondent engaged in gross negligence, gross malpractice and gross incompetence, which damaged or endangered the life, health, welfare, safety or property of his patients, in violation of N.J.S.A. 45:1-21(c).

Respondent argued that there were no standards in place governing minimally invasive surgery and, therefore, he could not have deviated from such standards. This argument is without merit. At a fundamental level, all physicians, including respondent, are required to exercise "the degree of care, knowledge and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in his field." Schueler v. Strelinger, 43 N.J. 330, 344 (1964). Dr. Przybylski opined as to the standard of care applicable to the practice of minimally invasive spinal surgery and respondent's deviation from that standard, relying upon the set of guidelines contained in the compendium of articles and his own professional training and experience. The combination of his expert testimony and the documentary evidence is sufficient to identify the standard of care applicable to the treatment rendered by respondent.

Petitioner's specific allegations included respondent's deviation from the standard of care by improperly placing screws during spinal fusions, placing allograph bone in patients who smoked, performing multi-level fusions in a patient with degenerative disease, performing a staged fusion, improperly diagnosing various patients, improperly using and placing OptiMesh, and failing to obtain proper patient consent. The standard of care for each of these allegations can be broadly articulated as "the degree of care, knowledge and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in his field." Ibid. Accordingly, the argument that no standard governs the practice of minimally invasive spinal surgery is rejected. Instead, Dr. Przybylski's testimony on the standard of care applicable to these allegations must be considered in its entirety and weighed against any contrary testimony from respondent or his experts (their testimony, as discussed above, was given little, if any, weight) to determine what degree of care, knowledge and skill is ordinarily possessed and exercised by the average member of the profession performing these procedures.

For the same reasons, I **CONCLUDE** that respondent engaged in repeated acts of negligence, malpractice or incompetence, in violation of <u>N.J.S.A.</u> 45:1-21(d). Several of the patients who testified told of their experiences following respondent's surgeries. Many had to undergo a revision surgery to relieve their suffering and to correct, if possible, the damage caused by respondent.

I also **CONCLUDE** that respondent engaged in dishonesty, fraud, deception, misrepresentation, false promise or false pretense, in violation of <u>N.J.S.A.</u> 45:1-21, which provides, in part:

A board may refuse to admit a person to an examination or may refuse to issue or may suspend or revoke any certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

. . . .

b. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense.

On his website, respondent claimed that he was a minimally invasive spine specialist (P-119 at NJSR001), clearly implying that he had the necessary skills and training to perform minimally invasive spinal surgeries. His website also represented that a small incision was made at the surgical point (Id. at NJSR003 and NJSR005), and that his medical training was "as extensive as it is impressive" (Id. at NJSR0036). He also reiterated his skills when he personally met with patients. For the reasons expressed above, these representations proved to be false. Not only did he misrepresent his skill level, but when he met with some of his patients, T.Z. for example and others, he also misrepresented the extent and breadth of the surgery. example, he told T.Z. that he was going to insert two screws (which he was unqualified to do), and that the surgery itself would be of a short duration. Instead, he inserted five screws during a surgery that lasted several hours, leaving her with a scar that measured about eight inches. He also told her that her recuperative period would be short, only a few days, which would have complied with the express statements made by T.Z. prior to surgery where she expected a minimal procedure followed by a short recuperative period, and nothing more. Instead, the surgery far exceeded her expectations, her understanding and the limitations she expressly stated.

I also **CONCLUDE** that respondent failed to maintain medical malpractice insurance insuring spinal surgeries and/or a letter of credit, in violation of <u>N.J.S.A.</u> 45:9-19.7 and/or <u>N.J.A.C.</u> 13:35-6.18(b) and (d). <u>N.J.S.A.</u> 45:9-19.7(a) specifically requires a physician to list on the license renewal form, among other information, the name and address of the practitioner's medical malpractice insurer. In addition, <u>N.J.A.C.</u> 13:35-6.18(b) specifically provides that

[a]II physicians and podiatrists licensed to practice in this State who maintain a professional practice and have responsibility for patient care shall be covered by medical malpractice insurance or, if medical malpractice insurance is not available, shall secure and maintain a letter of credit at least in the sum of \$500,000 or more.

Furthermore, N.J.A.C. 13:35-6.18(d) requires that physicians "who are not covered by medical malpractice insurance shall present to the Board a true copy of the letter of credit required pursuant to (b) above." A "letter of credit" is a

a non-assignable, non-transferable, unexpired, continuous irrevocable obligation, liability bond or other instrument issued by a bank or saving association authorized to do business in this State, payable to the physician or podiatrist as the beneficiary within 30 days after a demand for payment and the presentation of a final judgment or settlement in a medical malpractice action.

[N.J.A.C. 13:35-6.18(a).]

At no time during these proceedings did respondent ever present a letter of credit that had been presented to and approved by the Board. His mere assertion that he maintained such letter of credit, without corroborative proof, was not considered.

In addition, his failure to maintain liability insurance coverage or a letter of credit in accordance with the above statutes and regulations constituted professional misconduct within the meaning of N.J.S.A. 45:1-21(e). N.J.A.C. 13:35-6.18(e).

I also **CONCLUDE** that respondent failed to obtain hospital privileges or alternative privileges, in violation of <u>N.J.A.C.</u> 13:35-4A.6, which provides in part:

- (a) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall be privileged to perform that surgery or special procedure by a hospital. If a practitioner is not privileged but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.
- (b) Before any practitioner may perform surgery (other than minor surgery), or special procedures, the practitioner shall have:
 - 1. A written transfer agreement with a licensed hospital with acute care capabilities which can be reached within 20 minutes during all hours in which

surgery or special procedures are performed in the office, if the hospital where the practitioner is privileged is not reachable within 20 minutes or if the practitioner is privileged by the Board; and

2. A written policy for handling emergency transport to a hospital at which the practitioner is privileged through 9-1-1 call or a written transfer agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital which the practitioner has established a transfer agreement. The written transfer agreement shall be posted in the office and all health care personnel in the office shall specifically be informed of the procedure to be followed.

In order to determine whether respondent was required to have hospital privileges or Board-approved privileges, it is necessary to define certain terms contained in the above regulation. Firstly, the term "surgery" is defined as a

manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering. Surgery includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture or extraction of tissue from the uterus.

[N.J.A.C. 13:35-4A.3.]

It was clear from the proofs presented that respondent engaged in the use of manual or operative procedures upon the body in the performance of minimally invasive surgeries, which included incisions (ranging up to eight inches in size).

Next, the term "special procedure," as contained in <u>N.J.A.C.</u> 13:35-4A.6, is defined as "patient care which requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile, for a diagnostic or therapeutic procedure. Examples of special procedures include . . . utilizing conscious sedation or general anesthesia." <u>N.J.A.C.</u> 13:35-4A.3. "Anesthesia services" are the " . . . administration of any anesthetic agent with the

purpose of creating conscious sedation, regional anesthesia or general anesthesia." lbid.

Therefore, it was clear from the proofs presented that respondent, through another anesthesiologist, utilized anesthesia in the performance of minimally invasive techniques for which he was required to have either hospital privileges or Board-approved privileges. He had neither. While he and his witnesses claimed that the application for privileges on the Board's website was somewhat confusing, the regulations were clear in requiring privileges for what respondent intended to perform at his one-room surgical center. He failed to present any proofs that he had such privileges. I, therefore, **CONCLUDE** that respondent failed to obtain hospital privileges or Board-approved privileges, in violation of N.J.A.C. 13:35-4A.6.

For all of the above reasons, I also **CONCLUDE** that respondent committed professional misconduct, in violation of <u>N.J.S.A.</u> 45:1-21(e) and (h), which states that a board may suspend or revoke a

certificate, registration or license issued by the board upon proof that the applicant or holder of such certificate, registration or license:

. . . .

e. Has engaged in professional or occupational misconduct as may be determined by the board;

. . . .

h. Has violated or failed to comply with the provisions of any act or regulation administered by the board.

Respondent was also charged with the failure to maintain good moral character, in violation of N.J.S.A. 45:9-6. Good moral character has been the "historic unquestioned prerequisite of fitness." In re Application of Matthews for Admission to the Bar of New Jersey, 94 N.J. 59, 76 (1983) (citation omitted). It includes an individual's penchant for honesty, fairness, and respect for the rights of others and for the laws of the state and nation. It also underscores the critical importance of integrity, truthfulness

and candor. Ibid.

According to the Final Decision and Order (the Order) of the Board filed on May 14, 2003, (P-114) respondent became licensed in New Jersey in 1996 after completing his residency at the Albert Einstein College of Medicine, Montefiore Medical Center, in anesthesiology, for which he acquired board certification. Thereafter, he returned to England. On March 9, 1999, a patient I.B. went to a dental office in London for the purpose of having a tooth extracted and other dental work. Respondent was the anesthesiologist. Shortly after the dental procedures were performed, the patient went into cardiac arrest. After her transfer to a hospital, she died on March 15, 1999, never having regained consciousness. The police began an inquiry into the circumstances of her death, and on October 15, 1999, arrested respondent and charged him with gross negligence/manslaughter. Thereafter, the Interim Orders Committee (Committee) of the General Medical Council (the GMC is equivalent to the Board) imposed restrictions on respondent's registration in the practice of anesthesiology. The criminal trial lasted fourteen days, resulting in his conviction of manslaughter on February 22, 2001. On March 1, 2001, the GMC entered an order of interim suspension.

Thereafter, on April 8, 2001, respondent submitted an application for privileges to Hackensack University Medical Center. A question on the application asked if respondent was ever convicted of any criminal offense, which he answered in the negative. The application also asked if his license to practice medicine in any jurisdiction had been voluntarily or involuntarily suspended, revoked or subject to restrictions. Respondent, once again, answered in the negative, when, in fact, at the time of his answer, his license had been suspended in England and had already been subject to restrictions for almost a year.

On September 9, 2000, respondent submitted a biennial renewal form to the Board. On the form, respondent was asked if there were any criminal charges pending against him, which he again answered in the negative.

On May 30, 2002, the Committee in England "erased" respondent's registration and prohibited any reapplication for a period of five years.

In light of these circumstances, the Board, on May 14, 2003, after a hearing, entered and filed an Order suspending respondent's license for a period of two years, with the first six months as an active suspension. The balance consisted of a probationary period. In arriving at its decision, the Board took into consideration: his conviction of manslaughter; the erasure of his license; his multiple misrepresentations; and the underlying gross malpractice in the death of I.B., which the GMC determined was a hypoxic brain injury and cardiac arrest caused by respondent in his failure to adequately monitor her blood oxygen level, which had fallen during treatment. (P-114 at 16.)

In its Order, the Board stated:

The Board has eschewed a more stringent penalty with the hope and expectation that respondent will resolve to practice with the vigilance that he has promised. He must also resolve to deal forthrightly and honestly with this Board, his employers and hospital and insurers. Future transgressions will not be deserving of leniency. Our expectations for the strictest of compliance with standard of care and the ethical tenets of the profession will be at the highest level.

[ld. at 39-40.]

In light of the foregoing, I **CONCLUDE** that respondent failed to maintain good moral character.

Petitioner also charged respondent with his failure to maintain proper patient records, in violation of N.J.A.C. 13:35-6.5. The proofs offered by petitioner revealed that certain patient consent forms were unsigned. These documents were necessary to ensure the patient's understanding of the risks associated with the procedures planned. Accordingly, I **CONCLUDE** that he violated N.J.A.C. 13:35-6.5.

Petitioner also charged respondent with the failure to properly bill for his services, in violation of N.J.S.A. 45:1-21(b). No proofs were offered, and, accordingly, this charge is dismissed.

Similarly, petitioner charged respondent with failure to comply with subpoenas for patient records, in violation of N.J.S.A. 45:1-18, and for failure to cooperate with the Board, in violation of N.J.A.C. 13:45C-1.2 and -1.3(a)(5). No proofs were offered, and, accordingly, these charges are dismissed.

Based upon the facts adduced and the legal principles cited above, it has been proven, well beyond a preponderance of the credible evidence, that respondent not only poses a danger to the public, but has violated several statutes and regulations governing the practice of medicine and surgery in this state.

He never should have performed any spinal surgeries, whether they were called minimally invasive or open, given his lack of education and training. The fact that he performed such surgeries, without the requisite education and training, and in disregard for the safety of several of the patients who testified on behalf of petitioner, his disregard of the above statutes and regulations governing the practice of medicine and surgery in this state, and his prior involvement with the Board, warrant nothing less than the revocation of his medical license.

ORDER

Based upon the foregoing, it is **ORDERED** that the license issued to respondent to practice medicine and surgery in the state of New Jersey be and is hereby **REVOKED**. It is **FURTHER ORDERED** that, pursuant to <u>N.J.S.A.</u> 45:1-25, respondent reimburse petitioner all costs incurred in this matter, including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript costs.

I hereby **FILE** my initial decision with the **BOARD OF MEDICAL EXAMINERS** for consideration.

This recommended decision may be adopted, modified or rejected by the **BOARD OF MEDICAL EXAMINERS**, which by law is authorized to make a final

decision in this matter. If the Board of Medical Examiners does not adopt, modify or reject this decision within forty-five days and unless such time limit is otherwise extended, this recommended decision shall become a final decision in accordance with N.J.S.A. 52:14B-10.

Within thirteen days from the date on which this recommended decision was mailed to the parties, any party may file written exceptions with the **EXECUTIVE DIRECTOR OF THE BOARD OF MEDICAL EXAMINERS, 140 East Front Street, 2nd Floor, Trenton, New Jersey 08608**, marked "Attention: Exceptions." A copy of any exceptions must be sent to the judge and to the other parties.

M 1.0

December 13, 2013	A fact falanin
DATE	J. HOWARD SOLOMON, ALJ t/a
Date Received at Agency:	
Date Mailed to Parties:	

APPENDIX

WITNESSES

For Petitioner:

Gregory J. Przybylski, M.D.

Andrew Kaufman, M.D.

Patient J.Z.

Patient L.M.

Patient S.S.

Patient J.J.

Patient G.O.

Patient T.Z.

M.Z. (husband of T.Z.)

George S. Naseef III, M.D.

Alfred A. Steinberger, M.D.

Kenneth J. Reiger, M.D.

Arash Emami, M.D.

Susan M. Sugalski

For Respondent:

Joan Balducci

Jeffrey Randolph, Esq.

Robert G. McGann

Kevin Earle

Judith I. Gleason

Patient Ta.Z.

Patient K.D.

Patient D.H.

Solomon Kamson, M.D.

Kent B. Remley, M.D.

Victor Katz, M.D.

Respondent, Richard A. Kaul, M.D.

EXHIBITS IN EVIDENCE

For Petitioner:

P-1	Dr. Kaul's Patient Record for R.B. (RB0001-RB0288)
P-2	Surgical Records from North Jersey Center for Surgery for R.B. (RB0307-RB0550)
P-3 P-4 (CD)	Records and CD from the ImageCare Center for R.B. Reports (RB0289-RB0306)
P-5 (CD)	CD (RB0551 & RB0552) 11/13/02: Right Foot 06/23/03: L-Spine 03/14/05: L-Spine 04/21/05: L-Spine 05/05/05: L-Spine 06/09/05: L-Spine 08/25/05: L-Spine 10/04/05: L-Spine 03/27/09: Brain 04/14/09: Brain
P-6	Dr. Kaul's Patient Record for G.H. (GH0001-GH0238)
P-7	NJSR Surgical Record for G.H. (GH0239-GH0383)
P-8	Patient Record for Dr. Gregory Przybylski for G.H.

	(GH0387-GH0391)
P-9	Records and CD from University Radiology for G.H.
P-10 (CD)	Reports (GH0385-GH0386) CD (GH0392) 03/06/12: L-Spine 11/05/11: L-Spine
P-11	Records and CD from Ridgefield Imaging Center, Inc., for G.H.
P-12 (CD)	Reports (GH0384) CD (GH0393) 12/03/11: L-Spine
P-13	Dr. Kaul's Patient Record for J.J. (JJ0201-JJ0410)
P-14	Market Street Surgical Center Records for J.J. (JJ0482-JJ0589)
P-15	Sussex County Total Health Records for J.J. (JJ0411-JJ0475)
P-16	Records and CD from The ImageCare Center for J.J.
P-17 (CD)	Reports (JJ0476-JJ0480) CD (JJ0483) 06/12/04: MRI 10/03/05: L-Spine
P-18 P-19 (CD)	Records and CD from Advanced Imaging Associates for J.J. Reports (JJ0481) CD (JJ0482) 12/22/05: L-Spine
P-20	Patient Record of Dr. Steinberger for J.J. (JJ0590-JJ0641)
P-21	Dr. Kaul's Patient Record for F.K. (0001-0076)
P-23 P-24 (CD)	Records and CD from Rochelle Park Imaging for F.K. Reports (1037-1040) CD (1041) 03/10/06:L-Spine & C-Spine
P-25 (CD)	CD from American Imaging Center for F.K. CD (1042) 04/07/06: Spine

P-26 (CD) CD from St. Joseph's Regional Medical Center for F.K. CD (1043) 01/31/07: Chest 02/14/07: L-Spine 03/12/10: Head 03/12/10: Neck Carotids 03/12/10: Brain/Head 04/28/10: Chest P-27 (CD) CD from the Valley Hospital for FK CD (1044) 04/25/08: L-Spine (X-ray & CT) P-28 Reports and CD from Morristown Medical Center P-29 (CD) for F.K. Reports (1045-1049) CD (1050) 12/23/08: FLX Myelogram L-Spine & CT L-Spine P-30 Dr. Kaul's Patient Record for L.M. (LM0001-LM0944) P-31 NJSR Surgical Record for L.M. (LM0945-LM1296) P-32 Reports and CD from The ImageCare Center (Newton) for L.M. P-33 (CD) Reports (LM1302-LM1336) CD (LM1512) 04/26/11: L-Spine 05/26/11: L-Spine 05/28/11: C-Spine 10/11/11: T-Spine& L-Spine 10/13/11: C-Spine 04/30/12: L-Spine P-34 Reports and CD from The ImageCare Center (Sparta) for L.M. P-35 (CD) Reports (LM1298-LM1299) CD (LM1513) 06/06/12: L-Spine P-36 Reports from Newton Medical Center for L.M. (LM1300-LM1301) 07/25/12: C-Spine P-37 Report and CD from Ridgefield Imaging Center for

P-38 (CD) L.M. Report (LM1297) CD (LM1514) 01/14/12: L-Spine P-39 Patient Record of Dr. Kenneth Rieger for L.M. (LM1337-LM1511) P-40 Dr. Kaul's Patient Record for P.M. (M0414-M0429) P-42 Reports and CD from The Radiology Center for P-43 (CD) P.M. Reports (M0430-0433) CD (M0434) 12/14/05:L-Spine & C-Spine P-44 Reports and CD from Hackettstown Regional P-45 (CD) Medical Center for P.M. Reports (M0439-0422) (M0438) CD 06/02/11: Sacrum/Coccyx L-Spine T-Spine C-Spine Hip-Bilateral Hand P-46 (CD) CD from Hackensack Medical and Molecular Imaging for P.M. (M0436) 01/21/06: L-Spine 03/05/07: L-Spine 03/10/07: L-Spine 08/23/08: L-Spine P-47 Dr. Kaul's Patient Record for K.S. (KS0001-KS0575) P-48 NJSR Surgical Records for K.S. (KS0576-KS0932) P-49 Reports and CD from Ridgefield Imaging Center for K.S. Reports (KS0933-KS0936) P-50 (CD) P-51 (CD) CDs (KS0937-KS0939) 03/01/12: C-Spine P-52 (CD) 12/03/11: C-Spine 07/16/11: L-Spine P-53 Dr. Kaul's Patient Record for H.S. (HS0001-HS0449)

P-54 NJSR Surgical Records for H.S. (HS0450-HS0669) P-55 Reports and CD from Ridgefield Imaging Center for H.S. P-55a(CD) Reports (HS0670-HS0671) CD (HS0677) 11/19/11: L-Spine P-56 Reports and CD from AP Diagnostic Imaging Inc. for P-56(a) H.S. (CD) Reports (HS0672-HS0676) CD (HS0678) 12/01/10: C-Spine L-Spine Right Knee P-57 Dr. Kaul's Patient Records for S.S. (SS0001-SS1372) P-58 NJSR Surgical Records for S.S. (SS1373-SS1698) P-59 Surgical Records from Bergen Passaic Ambulatory Surgical Center for S.S. (SS1704-SS1888) (SS1907-SS1983) P-60 Patient Record of Dr. Arash Emami for S.S. (SS1889-SS1902) P-61 Reports and CD from Chilton Hospital for S.S. P-62 (CD) Reports (SS1699-SS1703) CD (SS1984) 08/30/07: C-Spine 06/03/09: L-Spine 10/26/09: Brain P-63 Reports and CD from St. Joseph's Health Care System for S.S. P-64 (CD) Report (SS1907a-SS1908a) CD (SS1985) 02/07/09: L-Spine 04/16/12: L-Spine 07/02/12: Chest 07/12/12: Abdomen P-65 Reports and CD from University Imaging/St. Joseph's Healthcare System for S.S. P-66 (CD) Report (SS1903-SS1906) P-67 (CD)

CDs (SS1986-SS1987)

	05/05/10: Right Knee L-Spine
P-68 P-69 (CD) P-70 (CD)	Reports and CDs from Medical Park Imaging for S.S. Reports (SS1988-SS1991) CDs (SS1992-SS1993) 12/14/11: L-Spine

P-71 Dr. Kaul's Patient Record for J.Z. (JZ0101-JZ0422)

P-72 NJSR Surgical Records for J.Z. (JZ0423-JZ0622)

P-73 Patient Record for Dr. Andrew Kaufman for J.Z.

(JZ0623-JZ0717)

05/22/12: L-Spine

P-74 Dr. Kaul's Patient Record for T.Z. (TZ0181-TZ0814)

P-75 NJSR Surgical Records for T.Z. (TZ0879-TZ1002)

P-76 Patient Record for Dr. George Naseef for T.Z.

(TZ0110-TZ0180)

P-77 Medical Records from Lehigh Valley Hospital for T.Z.

(TZ1003-TZ1112)

P-78 Reports and CD from Open MRI of Phillipsburg for T.Z.

P-79 (CD) Reports (TZ0826-TZ0837)

CD (TZ1113)

05/03/03: Abdomen 07/18/03: Left Knee 07/22/03: Left Knee 07/31/03: Left Knee 05/18/04: Left Knee 02/04/05: L-Spine 07/11/05: Pelvis 09/16/05: L-Spine 01/05/10: C-Spine 02/24/10: L-Spine 02/24/10: C-Spine

P-80 Reports and CD from The ImageCare Centers for T.Z.

P-81 (CD) Reports (TZ0838-TZ0878) P-82 (CD) CDs (TZ1114-TZ1116)

P-83 (CD) 05/18/12: L-Spine

05/17/12: L-Spine 05/16/12: L-Spine 03/29/12: L-Spine 02/16/12: L-Spine 11/17/11: L-Spine

	12/09/10: Breast 12/09/10: Pelvic 04/20/10: Left Rib 05/28/09: Pelvis 05/28/09: L-Spine 04/03/09: Abdomen & Pelvis
P-84 P-85 (CD) P-86 (CD)	Reports and CDs from Morristown Medical Center for T.Z. Reports (TZ0815-TZ0823) CDs (TZ1117-TZ1118) 12/08/11: L-Spine 12/08/11: PICC Line 12/08/11: L-Spine 01/31/12: OR XR L-Spine 02/01/12: L-Spine
P-87 P-88 (CD)	Reports and CD from Ridgefield Imaging Center for T.Z. Reports (TZ0824-TZ0825) CD (TZ1119) 07/20/11: CT Discogram
P-89	Curriculum Vitae of Gregory J. Przybylski, M.D.
P-90	Expert Report of Gregory J. Przybylski, M.D., dated March 26, 2012
P-91	Expert Report of Gregory J. Przybylski, M.D., dated January 28, 2013
P-92	Articles and Medical Treatises relied upon by Gregory J. Przybylski, M.D.
P-93	List of Documents sent to Expert Witness Gregory J. Przybylski, M.D.
P-94	Curriculum Vitae of Andrew G. Kaufman, M.D., dated March 25, 2012
P-95	Expert Report of Andrew G. Kaufman, M.D., dated March 25, 2012
P-96	Expert Report of Andrew G. Kaufman, M.D., dated April 2, 2012
P-98	Testimony of Richard A. Kaul, M.D., before a Preliminary Evaluation Committee of the Board of Medical Examiners dated February 3, 2010

P-99	Hearing Testimony of Richard A. Kaul, M.D., dated April 9, 2003 (pages 23 to 26 only)
P-100	Testimony of Richard A. Kaul, M.D., in the matter of Jarrell v. Kaul Deposition dated October 23, 2008
P-101	Testimony of Richard A. Kaul, M.D., in the matter of Jarrell v. Kaul Deposition dated January 26, 2010
P-102	Testimony of Richard A. Kaul, M.D., in the matter of Jarrell v. Kaul (as to no letter of credit) Deposition dated August 25, 2010
P-104	Testimony of Richard A. Kaul, M.D. in the matter of Jarrell v. Kaul Transcript of Trial Testimony dated January 23, 2012
P-105	Testimony of Richard A. Kaul, M.D., in the matter of Jarrell v. Kaul Transcript of Trial Testimony dated January 24, 2012
P-107	Testimony of Richard A. Kaul, M.D., in the matter of Maze v. Kaul Deposition dated December 4, 2012
P-109	Richard A. Kaul's Curriculum Vitae with attached certifications dated through February 3, 2010 (0077-0141)
P-110	Updated Curriculum Vitae with attached certification dated through March 28, 2012 (1037-1127)
P-111	Copy of Medical Malpractice Insurance Policy from June 10, 2004, to June 10, 2005
P-112	Copy of Medical Malpractice Insurance Policy from June 10, 2005, to June 10, 2006
P-113	Copy of Medical Malpractice Insurance Policy from June 10, 2006, to June 10, 2007
P-114	Final Order of the Board dated May 14, 2003
P-115	Model of lumbar spine

P-116	Pedicle screws
P-117	Picture of minimally invasive surgery scars and open spinal scar
P-119	Certification of Susan Sugalski
P-121	FDA Warning letter dated 8/15/07
P-122	Anesthesiology application for alternative privileges

For Respondent:

R-1	Emails to respondent from patient J.Z.
R-2	No exhibit
R-3	Documents offered by Balducci
R-4(a)	Cover letter of J. Randolph, Esq., with attachments and emails from Earle to Gleason
R-5	Blank application for alternative privileges
R-6	Table of specialties from the website of the Board
R-7	Alternative privilege procedure
R-8	Curriculum vitae of Solomon Kamson, M.D.
R-9	Report of Solomon Kamson, M.D.
R-10	No exhibit
R-11	Pages 348 to 350 of <u>The Practice of Minimally Invasive Spinal</u> <u>Technique</u>
R-12	Report of Victor Katz, M.D.
R-13	Curriculum vitae of Kent B. Remley, M.D.
R-14	Report of Kent B. Remley, M.D.
R-15	Application for New Jersey Alternative Privileging Program
R-16	Deposition transcript of Dr. Robert F. Heary, dated May 29, 2013

Also included in respondent's exhibits is the deposition transcript of respondent, dated August 25, 2010 (petitioner's Exhibit P-102).

Also included in respondent's documents is a chart prepared and submitted on behalf of respondent entitled "Chart of Purported Patient Deviations and Rebuttal of Respondent's Experts."